Session CLE 403 | Can Your Client (Anti)Trust You? How to Hatch Your Plan for a Procompetitive Settlement Agreement

Session Description:

For the past few years, the pharmaceutical industry has come under bipartisan scrutiny. “Pharma Bro” Martin Shkreli’s company Vyera was not the first to be called out for anticompetitive behavior, and given the shifting nature of Pharmaceutical Antitrust Law, it certainly will not be the last. Under FTC Chairperson Lina Khan, the landscape in which pharmaceutical companies and their attorneys operate is starting to shift even more quickly. Shkreli’s case was an extreme example, but the FTC and antitrust plaintiffs have brought cases over much more nuanced conduct. Even though this industry’s landmark case, FTC v. Actavis, was decided back in 2013, the flood of litigation following Actavis is still in the process of defining the contours of what constitutes permissible vs anticompetitive behavior.

Expert attorneys, who have litigated some of the most well-known cases in the field, will guide you through: (1) what Pharmaceutical Antitrust entails; (2) what exactly Hatch-Waxman litigation and settlements are; (3) a short background on Actavis, which set the bar for Hatch Waxman settlement agreements; (4) an examination, through case studies, of conduct by both brands and generics that could raise red flags for the FTC and potential class action plaintiffs; and (5) how to balance an efficient settlement for your client against potential antitrust risks.

Moderator:
Aakruti G. Vakharia, Associate, Haug Partners LLP

Speakers:
Rohit K. Singla, Partner, Munger, Tolles & Olson LLP
Esther Oh, Attorney, Joseph Saveri Law Firm
Luna Barrington, Partner, Weil, Gotshal & Manges LLP
Anna Aryankalayil, Attorney Advisor to FTC Commissioner Phillips, Federal Trade Commission
Can Your Client (Anti)Trust You?

How to “Hatch” a Procompetitive Settlement Plan

CLE 403
"PHARMA BRO" MARTIN SHKRELI ORDERED TO RETURN $64 MILLION, BANNED FROM PHARMA INDUSTRY
Moderator

- Aakruti G. Vakharia
  Attorney, Haug Partners LLP

Speakers

- Rohit K. Singla
  Partner, Munger Tolles & Olson
- Luna Barrington
  Partner, Weil Gotshal & Manges
- Anna Aryankalayil
  (title) (employer)
- Esther Oh
  Attorney, Joseph Saveri Law Firm
What Brings You Here?

A. This Relates To My Practice Area
B. I’m Interested In This Topic
C. TBH I’m just here for the free Liquid IV
D. Several of the above
E. None of the above
What is Antitrust?

• Regulates Free Markets/Competition
• Protects Competition, Not Competitors
• Sherman Antitrust Act
• Clayton Act
• FTC Act
Pharmaceuticals/Hatch Waxman

- Innovator Drugs
  - Patents
  - FDA Approval
  - Exclusivity is critical

- Generic Entry/Brand Erosion

- Hatch Waxman Creates a Shortcut
FTC v. Actavis

• What is a Reverse Payment?
• Patent Term Split / Scope of the Patent Test
• Circuit Split
How did the Supreme Court Rule?

A. Patent Term Splits are OK
B. Patent Term Splits are Sometimes OK
C. Patent Term Splits are Never OK
FTC v. Actavis

• Scope-of-Patent Test Rejected
• Competition Harmed When Generics Stay Off Market
• Rule of Reason Analysis
• What is a “Payment” under Actavis?
• What does “Unexplained/Unjustified” mean?
Major Cases That Shaped Landscape

- In re Nexium
- Impax v. FTC
- FTC v. Viropharma
- In re Thalomid/Revlimid
- In re Generics
- In re Namenda
- In re Epipen
Other Forms of Abuse

- Orange Book Abuse
- Product Disparagement
- The List is Open-Ended and Growing!
How is the Government Enforcing?

- Pharma/Life Sciences is FTC Enforcement Priority
- FTC’s June 2022 Pharmaceutical Task Force Workshop
- FTC’s Annual MMA Report
- FTC’s Post-Actavis Advocacy in Private Patent Settlement Litigation
- State Enforcement Potentially Diverges From FTC
Have you ever been involved in Pharmaceutical Antitrust Litigation?

A. Yes, as a practitioner.

B. Yes, as a client.

C. No, but what’s it like?

D. What’s with all the questions? I’m just here for the Liquid IV.
Civil Pharma Antitrust Litigation

- Large and Complex
- Massive Discovery
- Treble Damages
- Best Practices
  - Follow the Cases
  - Scrutinize the Settlements
  - Run Settlements by the Antitrust Team
Contact Info

- Aakruti G. Vakharia – avakharia@haugpartners.com
- Luna Barrington – luna.barrington@weil.com
- Rohit K. Singla – rohit.singla@mto.com
- Esther Oh – eoh@saverilawfirm.com
- Anna Aryankalayil – [email]
QUESTIONS?
Contact Info

• Aakruti G. Vakharia – avakharia@haugpartners.com
• Luna Barrington – luna.barrington@weil.com
• Rohit K. Singla – rohit.singla@mto.com
• Esther Oh – eoh@saverilawfirm.com
• Anna Aryankalayil – [email]
March 9, 2022

**A Tale of Two Orphans: The Potential Ramifications of an Orphan Drug “Cutting in Line”**

Joshua Barlow, Aakruti G. Vakharia, Andrew Wasson

Haug Partners LLP

### INTRODUCTION:

Orphan drugs are the pharmaceutical industry’s way of helping those who suffer from rare conditions. Thanks to the Orphan Drug Act, such patients can get the medications they need, and pharmaceutical companies can be duly incentivized to invest the time and resources required to research and develop these drugs. But what happens when competing rival drug companies are successful in undermining those incentives? The results could have broad, and perhaps unintended, effects throughout the industry.

### ORPHAN DRUG PROCESS:

An orphan drug is one produced to treat a rare medical condition. Under the Orphan Drug Act, drug companies are offered several incentives to create drugs to treat these rare diseases that command smaller, and thus “less profitable,” markets for their treatment. First, a company may request an FDA “orphan drug” designation for a qualifying drug being researched. Upon receiving an orphan drug designation, the pharmaceutical company developing this drug will receive financial benefits such as tax credits during the period for which it conducts safety and efficacy testing. Following receipt of an orphan drug designation, the developer must then file an New Drug Application (NDA) with the Food and Drug Administration (FDA) in order to obtain permission to market the drug. Once the FDA approves the orphan drug’s NDA, then it is permitted to benefit from seven years of marketing exclusivity.

### FACTUAL BACKGROUND:

Firdapse (amifampidine phosphate) was developed by Catalyst Pharmaceuticals Inc. to treat a rare condition known as Lambert-Eaton Myasthenic Syndrome (LEMS). In November 2009, the FDA designated Firdapse as an orphan drug. Catalyst then filed its first NDA in 2015, which the FDA rejected on the grounds that Catalyst’s Firdapse application was “not complete to permit a substantive review.” Catalyst re-filed its Firdapse NDA in March 2018. In November 2018, the
FDA approved Firdapse to treat LEMS “in adults,” triggering market exclusivity until November 2025.

Meanwhile, Jacobus Pharmaceutical Co. Inc. had developed its own amifampridine drug to treat LEMS nineteen years prior to Catalyst’s Firdapse. Jacobus’s drug Ruzurgi received its orphan drug designation from the FDA in 1990. Jacobus continued developing it for more than two decades, delaying its submission of an NDA for Ruzurgi until August 2017, two years after Catalyst’s first NDA for Firdapse was submitted. Ruzurgi’s NDA was rejected. Catalyst’s NDA was approved in November 2018. Jacobus re-filed its NDA in 2018, including information about the treatment of LEMS in patients between the ages of six and sixteen. However, the drug’s label would mention that Ruzurgi may also be used to treat adults. Upon comparison with Catalyst’s approved NDA, the FDA found that Firdapse only covered the treatment of LEMS in adults. Consequently, the FDA construed this to mean that Firdapse only had exclusivity for treating adult patients, and not children. Thus, the FDA took it upon themselves to create an “administrative[] divide” between the treatment of LEMS in adults vs in children. As the FDA later acknowledged, this was the first time it ever “approved an application for a drug with an indication to treat pediatric patients for a certain disease while another sponsor has obtained orphan drug exclusivity for a drug application for the same drug with only an indication to treat adult patients for that disease.”

JOURNEY THROUGH THE COURTS:

Following the FDA’s Ruzurgi approval, Catalyst filed a complaint against the FDA in the Southern District of Florida alleging violations of the Administrative Procedures Act (APA) in approving Jacobus’s NDA. Jacobus intervened as a co-defendant. In its suit, Catalyst sought, among other relief, an order to revoke the FDA’s Ruzurgi approval. Catalyst’s lawsuit was based on two premises: First, the plain language of the Orphan Drug Act prevented the FDA from approving an NDA for the “same drug” that is used to treat “the same condition,” where Firdapse was approved first and Ruzurgi, the same drug (amifampidine), used to treat the same condition (LEMS), was approved only two years into Firdapse’s 7-year exclusivity. Second, in violation of the Food, Drug and Cosmetics Act (FDCA), Ruzurgi had “false or misleading” labeling suggesting that the drug could also be used for adult patients, even though Ruzurgi was only approved to treat children.

At the summary judgment phase of the case, it was undisputed that Firdapse and Ruzurgi are the “same drug,” and that LEMS, which both drugs treat, is a “single disease.” The Magistrate Judge, interpreting the doctrine of Chevron deference, determined that the phrase “same disease or condition” in the Orphan Drug Act is ambiguous, that the FDA was reasonable in its
interpretation, and that Ruzurgi’s label was not in violation of the FDCA. The District Court adopted the Magistrate’s recommendation and ruled in favor of the FDA and Jacobus.

Catalyst appealed to the 11th Circuit, which reversed the Southern District of Florida’s decision. The 11th Circuit held that the phrase “same disease and condition” was unambiguous, adding that “a statute is not ambiguous merely because it contains a term without a statutory definition.” The 11th Circuit went on to explain that “Congress is not required to define each and every word in a piece of legislation in order to express clearly its will.” As such, the Circuit Court determined that the Southern District erred in granting summary judgment in favor of the FDA and Jacobus. Jacobus’s subsequent motion for reconsideration was denied.

INDUSTRY WIDE IMPLICATIONS:

Even though this case primarily focuses on statutory interpretation, a victory for Jacobus and the FDA would have completely shifted the way medications enter the market.

When a brand company files an NDA for a new drug, and the NDA is approved, the drug may get at least one of several types of exclusivity. For example, orphan drugs get a 7-year exclusivity, “New Chemical Entities” or “NCEs” (a classification for small-molecule drugs) get a 5-year exclusivity, and NDAs entitled to new clinical investigation exclusivity get 3 years. This exclusivity begins when the FDA approves an NDA. Drug companies may obtain a 6-month extension, known as pediatric exclusivity, if they test the NDA-holding drug for use on children. Upon expiry of a drug’s exclusivity, competing generics may enter the market.

Under this system, the original NDA filer gets two main benefits if their application is approved: First, the NDA filer gets the exclusive right to market the drug for a set period of time. This is an incentive for drug companies to invest the time, money and effort to create innovative drugs because it provides these innovator companies the opportunity to recoup their investment by profiting from a period during which barriers to competitive entrants are erected by statute. Second, the NDA filer gets the option to extend its exclusivity to pediatric use.

Here, had the FDA been allowed to approve a second NDA for the same drug being used to treat the same disease, it would have completely disrupted the system by which orphan drugs enter the market. It would have created precedent allowing drugs to enter under the guise of a new pediatric exception to an orphan drug NDA, but still would have permitted such secondary entrants to create labels suggesting that use in adults is approved. This would have driven down the profit incentive for initial orphan drug NDA filers and undermine the economic incentive for drug companies to commit the considerable resources it takes to research, develop, and market new drugs for rare indications.
LESSONS:

The situation in this case can serve as a cautionary tale to orphan drug developers. Jacobus was the first company to develop amifampidine to treat LEMS, and Jacobus was the first company to receive the orphan drug designation for Ruzurgi. It was also already giving the drug out for free at research institutions like the Mayo Clinic for years before Catalyst filed its NDA for Firdapse. In the case of orphan drugs, perhaps companies like Jacobus could use this example to push for changes to ensure that companies who first develop an orphan drug do not get foreclosed from marketing it due to the delay between receiving an orphan drug designation and the filing of an NDA.

Perhaps FDA’s decision was intended to permit Jacobus to enjoy a slice of the profits for a drug it did develop first. But giving this credit should not come at the expense of inadvertently setting precedent that can potentially upset a much larger, and much more active part of the pharmaceutical industry. As such, orphan drug companies should take steps to protect their innovations by following through on the entire process – from filing patents to submitting the NDA to requesting their pediatric exclusivity – to mitigate the risk that a later filer is able to secure exclusivity on a first filer’s drug.

1 21 U.S.C.S. § 360
2 LEMS is a rare autoimmune disease in which one’s immune system attacks the body’s own tissue. There are only about 400 known cases of LEMS in the US. Lambert Eaton Myasthenic Syndrome, NATIONAL ORGANIZATION FOR RARE DISEASES, 2019 https://rarediseases.org/rare-diseases/lambert-eaton-myasthenic-syndrome/#:~:text=Affected%20Populations,LEMS%20in%20the%20United%20States”
3 Catalyst Pharms., Inc. v. Becerra, 14 F.4th 1299 (11th Cir. 2021).
4 Id.
5 21 U.S.C. § 9
7 Catalyst Pharms., Inc. v. Becerra, 14 F.4th at 1307 (citing United States v. Sepulveda, 115 F.3d 882, 886 n.9 (11th Cir. 1997))
8 Id.
9 The NCE approval is “granted to a drug that contains no active moiety that has been approved by the FDA under section 505(b).” FDA Patents and Exclusivity, FOOD AND DRUG ADMINISTRATION, May 19, 2015 https://www.fda.gov/media/92548/download; see 21 U.S.C.S. § 355.
10 FDA exclusivities are different than patent exclusivities, and can run concurrently depending on
the date a patent was issued versus the date an NDA was approved. 21 U.S.C.S. § 355 applies to all new small-molecule drugs.
Synopsis
Cigarette manufacturer brought antitrust action against competitor, alleging violation of Robinson-Patman Act. Following verdict in favor of manufacturer, the United States District Court for the Middle District of North Carolina, Frank W. Bullock, Jr., Chief Judge, granted competitor's motion for judgment notwithstanding the verdict, 748 F.Supp. 344, and manufacturer appealed. The Court of Appeals affirmed, 964 F.2d 335, and certiorari was granted. The Supreme Court, Justice Kennedy, held that: (1) there is no per se rule of nonliability under Robinson-Patman Act for predatory price discrimination when recoupment is alleged to take place through supracompetitive oligopoly pricing, but (2) competitor's alleged below-cost sales of generic cigarettes through discriminatory volume rebates did not create competitive injury in violation of Robinson-Patman Act.

Affirmed.

Justice Stevens filed dissenting opinion in which Justices White and Blackmun joined.

**2580 Syllabus**

*209* Cigarette manufacturing is a concentrated industry dominated by only six firms, including the two parties here. In 1980, petitioner (hereinafter Liggett) pioneered the economy segment of the market by developing a line of generic cigarettes offered at a list price roughly 30% lower than that of branded cigarettes. By 1984, generics had captured 4% of the market, at the expense of branded cigarettes, and respondent Brown & Williamson entered the economy segment, beating Liggett's net price. Liggett responded in kind, precipitating a price war, which ended, according to Liggett, with Brown & Williamson selling its generics at a loss. Liggett filed this suit, alleging, *inter alia*, that volume rebates by Brown & Williamson to wholesalers amounted to price discrimination that had a reasonable possibility of injuring competition in violation of § 2(a) of the Clayton Act, as amended by the Robinson–Patman Act. Liggett claimed that the rebates were integral to a predatory pricing scheme, in which Brown & Williamson set below-cost prices to pressure Liggett to raise list prices on its generics, thus restraining the economy segment's growth and preserving Brown & Williamson's supracompetitive profits on branded cigarettes. After a jury returned a verdict in favor of Liggett, the District Court held that Brown & Williamson was entitled to judgment as a matter of law. Among other
things, it found a lack of injury to competition because there had been no slowing of the generics' growth rate and no tacit coordination of prices in the economy segment by the various manufacturers. In affirming, the Court of Appeals held that the dynamic of conscious parallelism among oligopolists could not produce competitive injury in a predatory pricing setting.

**Held:** Brown & Williamson is entitled to judgment as a matter of law. Pp. 2586–2598.

(a) The Robinson–Patman Act, by its terms, condemns price discrimination only to the extent that it threatens to injure competition. A claim of primary-line competitive injury under the Act, the type alleged here, is of the same general character as a predatory pricing claim under § 2 of the Sherman Act: A business rival has priced its products in an unfair manner with an object to eliminate or retard competition and thereby gain and exercise control over prices in the relevant market. Accordingly, two prerequisites to recovery are also the same. A plaintiff must prove (1) that the prices complained of are below an appropriate measure of its rival's costs and (2) that the competitor had a reasonable prospect of recouping its investment in below-cost prices. Without recoupment, even if predatory pricing causes the target painful losses, it produces lower aggregate prices in the market, and consumer welfare is enhanced. For recoupment to occur, the pricing must be capable, as a threshold matter, of producing the intended effects on the firm's rivals. This requires an understanding of the extent and duration of the alleged predation, the relative financial strength of the predator and its intended victim, and their respective incentives and will. The inquiry is whether, given the aggregate losses caused by the below-cost pricing, the intended target would likely succumb. If so, then there is the further question whether the below-cost pricing would likely injure competition in the relevant market. The plaintiff must demonstrate that there is a likelihood that the scheme alleged would cause a rise in prices above a competitive level sufficient to compensate for the amounts expended on the predation, including the time value of the money invested in it. Evidence of below-cost pricing is not alone sufficient to permit an inference of probable recoupment and injury to competition. The determination requires an estimate of the alleged predation's cost and a close analysis of both the scheme alleged and the relevant market's structure and conditions. Although not easy to establish, these prerequisites are essential components of real market injury. Pp. 2586–2590.

(b) An oligopoly's interdependent pricing may provide a means for achieving recoupment and thus may form the basis of a primary-line injury claim. Predatory pricing schemes, in general, are implausible, see *Matsushita Electric Industrial Co. v. Zenith Radio Corp.*, 475 U.S. 574, 588–590, 106 S.Ct. 1348, 1356–1358, 89 L.Ed.2d 538 and are even more improbable when they require coordinated action among several firms, *id.*, at 590, 106 S.Ct., at 1358. They are least likely to occur where, as alleged here, the cooperation among firms is tacit, since effective tacit coordination is difficult to achieve; since there is a high likelihood that any attempt by one oligopolist to discipline a rival by cutting prices will produce an outbreak of competition; and since a predator's present losses fall on it alone, while the later supracompetitive profits must be shared with every other oligopolist in proportion to its market share, including the intended victim. Nonetheless, the Robinson–Patman Act suggests no exclusion from coverage when primary-line injury occurs in an oligopoly setting, and this Court declines to create a *per se* rule of nonliability. In order for all of the Act's words to carry adequate meaning, competitive injury under the Act must extend beyond the monopoly setting. Pp. 2590–2592.

**c)** The record in this case demonstrates that the scheme Liggett alleged, when judged against the market's realities, does not provide an adequate basis for a finding of liability. While a reasonable jury could conclude that Brown & Williamson envisioned or intended an anticompetitive course of events and that the price of its generics was below its costs for 18 months, the evidence is inadequate to show that in pursuing this scheme, it had a reasonable prospect of recovering its losses from below-cost pricing through slowing the growth of generics. No inference of recoupment is sustainable on this record, because no evidence suggests that Brown & Williamson was likely to obtain the power to raise the prices for generic cigarettes above a competitive level, which is an indispensable aspect of Liggett's own proffered theory. The output and price information does not indicate that oligopolistic price coordination in fact produced supracompetitive prices in the generic segment. Nor does
the evidence about the market and Brown & Williamson's conduct indicate that the alleged scheme was likely to have brought about tacit coordination and oligopoly pricing in that segment. Pp. 2591–2598.

964 F.2d 335 (CA 4 1992) affirmed.

KENNEDY, J., delivered the opinion of the Court, in which REHNQUIST, C.J., and O'CONNOR, SCALIA, SOUTER, and THOMAS, JJ., joined. STEVENS, J., filed a dissenting opinion, in which WHITE and BLACKMUN, JJ., joined, post, p. ––––.

Attorneys and Law Firms

Phillip Areeda, Cambridge, MA, for petitioner.

Robert H. Bork, Washington, DC, for respondent.

Opinion

*212 Justice KENNEDY delivered the opinion of the Court.

This case stems from a market struggle that erupted in the domestic cigarette industry in the mid–1980's. Petitioner Brook Group, Ltd., whom we, like the parties to the case, refer to as Liggett because of its former corporate name, charges that to counter its innovative development of generic cigarettes, respondent Brown & Williamson Tobacco Corporation introduced its own line of generic cigarettes in an unlawful effort to stifle price competition in the economy segment of the national cigarette market. Liggett contends that Brown & Williamson cut prices on generic cigarettes below cost and offered discriminatory volume rebates to wholesalers to force Liggett to raise its own generic cigarette prices and introduce oligopoly pricing in the economy segment. We hold that Brown & Williamson is entitled to judgment as a matter of law.

I

In 1980, Liggett pioneered the development of the economy segment of the national cigarette market by introducing a line of “black and white” generic cigarettes. The economy segment of the market, sometimes called the generic segment, is characterized by its bargain prices and comprises a variety of different products: black and whites, which are true generics sold in plain white packages with simple black lettering describing their contents; private label generics, which carry the trade dress of a specific purchaser, usually a retail chain; branded generics, which carry a brand name but which, like black and whites and private label generics, are sold at a deep discount and with little or no advertising; and “Value–25s,” packages of 25 cigarettes that are sold to the consumer some 12.5% below the cost of a normal 20–cigarette pack. By 1984, when Brown & Williamson entered the generic segment and set in motion the series of events giving rise to this suit, Liggett's black and whites represented 97% of the generic segment, which in turn accounted for a little more than 4% of domestic cigarette sales. Prior to Liggett's introduction of black and whites in 1980, sales of generic cigarettes amounted to less than 1% of the domestic cigarette market.

Because of the procedural posture of this case, we view the evidence in the light most favorable to Liggett. The parties are in basic agreement, however, regarding the central, historical facts. Cigarette manufacturing has long been one of America's most concentrated industries, see F. Scherer & D. Ross, Industrial Market Structure and Economic Performance 250 (3d ed. 1990) (hereinafter Scherer & Ross); App. 495–498, and for decades, production has been dominated by six firms: R.J. Reynolds, Philip Morris, American Brands, Lorillard, and the two litigants involved here, Liggett and Brown & Williamson. R.J. Reynolds and Philip Morris, the two industry leaders, enjoyed respective market shares of about 28% and 40% at the time of trial. Brown
113 S.Ct. 2578, 125 L.Ed.2d 168, 61 USLW 4699, 1993-1 Trade Cases P 70,277

& Williamson ran a **2583 distant third, its market share never exceeding 12% at any time relevant to this dispute. Liggett's share of the market was even less, from a low of just over 2% in 1980 to a high of just over 5% in 1984.

The cigarette industry also has long been one of America's most profitable, in part because for many years there was no significant price competition among the rival firms. See Scherer & Ross 250–251; R. Tennant, American Cigarette Industry 86–87 (1950); App. 128, 500–509, 531. List prices for cigarettes increased in lockstep, twice a year, for a number of years, irrespective of the rate of inflation, changes in the costs of production, or shifts in consumer demand. Substantial evidence suggests that in recent decades, the industry reaped the benefits of prices above a competitive level, though not through unlawful conduct of the type that once characterized the industry. See Tennant, supra, at 275, 342; App. 389–392, 514–519, 658–659; cf. American Tobacco Co. v. United States, 328 U.S. 781, 66 S.Ct. 1125, 90 L.Ed. 1575 (1946); *214 United States v. American Tobacco Co., 221 U.S. 106, 31 S.Ct. 632, 55 L.Ed. 663 (1911); Scherer & Ross 451.

By 1980, however, broad market trends were working against the industry. Overall demand for cigarettes in the United States was declining, and no immediate prospect of recovery existed. As industry volume shrank, all firms developed substantial excess capacity. This decline in demand, coupled with the effects of nonprice competition, had a severe negative impact on Liggett. Once a major force in the industry, with market shares in excess of 20%, Liggett's market share had declined by 1980 to a little over 2%. With this meager share of the market, Liggett was on the verge of going out of business.

At the urging of a distributor, Liggett took an unusual step to revive its prospects: It developed a line of black and white generic cigarettes. When introduced in 1980, black and whites were offered to consumers at a list price roughly 30% lower than the list price of full-priced, branded cigarettes. They were also promoted at the wholesale level by means of rebates that increased with the volume of cigarettes ordered. Black and white cigarettes thus represented a new marketing category. The category's principal competitive characteristic was low price. Liggett's black and whites were an immediate and considerable success, growing from a fraction of a percent of the market at their introduction to over 4% of the total cigarette market by early 1984.

As the market for Liggett's generic cigarettes expanded, the other cigarette companies found themselves unable to ignore the economy segment. In general, the growth of generics came at the expense of the other firms' profitable sales of branded cigarettes. Brown & Williamson was hardest hit, because many of Brown & Williamson's brands were favored by consumers who were sensitive to changes in cigarette prices. Although Brown & Williamson sold only 11.4% of the market's branded cigarettes, 20% of the converts to *215 Liggett's black and whites had switched from a Brown & Williamson brand. Losing volume and profits in its branded products, Brown & Williamson determined to enter the generic segment of the cigarette market. In July 1983, Brown & Williamson had begun selling Value–25s, and in the spring of 1984, it introduced its own black and white cigarette.

Brown & Williamson was neither the first nor the only cigarette company to recognize the threat posed by Liggett's black and whites and to respond in the economy segment. R.J. Reynolds had also introduced a Value–25 in 1983. And before Brown & Williamson introduced its own black and whites, R.J. Reynolds had repriced its “Doral” branded cigarette at generic levels. To compete with Liggett's black and whites, R.J. Reynolds dropped its list price on Doral about 30% and used volume rebates to wholesalers as an incentive to spur orders. Doral was the first competition at Liggett's price level.

**2584 Brown & Williamson's entry was an even graver threat to Liggett's dominance of the generic category. Unlike R.J. Reynolds' Doral, Brown & Williamson's product was also a black and white and so would be in direct competition with Liggett's product at the wholesale level and on the retail shelf. Because Liggett's and Brown & Williamson's black and whites were more or less fungible, wholesalers had little incentive to carry more than one line. And unlike R.J. Reynolds, Brown & Williamson not only matched Liggett's prices but beat them. At the retail level, the suggested list price of Brown & Williamson's black and whites was the same as Liggett's, but Brown & Williamson's volume discounts to wholesalers were larger. Brown & Williamson's rebate structure also encompassed a greater number of volume categories than Liggett's, with the highest categories carrying
special rebates for orders of very substantial size. Brown & Williamson marketed its black and whites to Liggett's existing distributors as well as to its own full list of *216 buyers, which included a thousand wholesalers who had not yet carried any generic products.

Liggett responded to Brown & Williamson's introduction of black and whites in two ways. First, Liggett increased its own wholesale rebates. This precipitated a price war at the wholesale level, in which Liggett five times attempted to beat the rebates offered by Brown & Williamson. At the end of each round, Brown & Williamson maintained a real advantage over Liggett's prices. Although it is undisputed that Brown & Williamson's original net price for its black and whites was above its costs, Liggett contends that by the end of the rebate war, Brown & Williamson was selling its black and whites at a loss. This rebate war occurred before Brown & Williamson had sold a single black and white cigarette.

Liggett's second response was to file a lawsuit. Two weeks after Brown & Williamson announced its entry into the generic segment, again before Brown & Williamson had sold any generic cigarettes, Liggett filed a complaint in the United States District Court for the Middle District of North Carolina alleging trademark infringement and unfair competition. Liggett later amended its complaint to add an antitrust claim under § 2(a) of the Clayton Act, as amended by the Robinson–Patman Act, 49 Stat. 1526, 15 U.S.C. § 13(a), which alleged illegal price discrimination between Brown & Williamson's full-priced branded cigarettes and its low-priced generics. See Liggett Group, Inc. v. Brown & Williamson Tobacco Corp., 1989–1 Trade Cas. (CCH) ¶ 68,583, p. 61,099, 1988 WL 161235 (MDNC 1988). These claims were either dismissed on summary judgment, see ibid., or rejected by the jury. They were not appealed.

Liggett also amended its complaint to add a second Robinson–Patman Act claim, which is the subject of the present controversy. Liggett alleged that Brown & Williamson's volume rebates to wholesalers amounted to price discrimination that had a reasonable possibility of injuring competition, *217 in violation of § 2(a). Liggett claimed that Brown & Williamson's discriminatory volume rebates were integral to a scheme of predatory pricing, in which Brown & Williamson reduced its net prices for generic cigarettes below average variable costs. According to Liggett, these below-cost prices were not promotional but were intended to pressure it to raise its list prices on generic cigarettes, so that the percentage price difference between generic and branded cigarettes would narrow. Liggett explained that it would have been unable to reduce its wholesale rebates without losing substantial market share to Brown & Williamson; its only choice, if it wished to avoid prolonged losses on its principal product line, was to raise retail prices. The resulting reduction in the list price gap, it was said, would restrain the growth of the economy segment and preserve Brown & Williamson's supracompetitive profits on its branded cigarettes.

**2585 The trial began in the fall of 1989. By that time, all six cigarette companies had entered the economy segment. The economy segment was the fastest growing segment of the cigarette market, having increased from about 4% of the market in 1984, when the rebate war in generics began, to about 15% in 1989. Black and white generics had declined as a force in the economy segment as consumer interest shifted toward branded generics, but Liggett's overall volume had increased steadily to 9 billion generic cigarettes sold. Overall, the 2.8 billion generic cigarettes sold in 1981 had become 80 billion by 1989.

The consumer price of generics had increased along with output. For a year, the list prices for generic cigarettes established at the end of the rebate war remained stable. But in June of 1985, Liggett raised its list price, and the other firms followed several months later. The precise effect of the list price increase is difficult to assess, because all of the cigarette firms offered a variety of discounts, coupons, and other promotions directly to consumers on both generic and *218 branded cigarettes. Nonetheless, at least some portion of the list price increase was reflected in a higher net price to the consumer.

In December 1985, Brown & Williamson attempted to increase its list prices, but retracted the announced increase when the other firms adhered to their existing prices. Thus, after Liggett's June 1985 increase, list prices on generics did not change again until the summer of 1986, when a pattern of twice yearly increases in tandem with the full-priced branded cigarettes was established. The dollar amount of these increases was the same for generic and full-priced cigarettes, which resulted in a
greater percentage price increase in the less expensive generic cigarettes and a narrowing of the percentage gap between the list price of branded and black and white cigarettes, from approximately 38% at the time Brown & Williamson entered the segment to approximately 27% at the time of trial. Also by the time of trial, five of the six manufacturers, including Liggett, had introduced so-called “subgenerics,” a category of branded generic cigarette that sold at a discount of 50% or more off the list price of full-priced branded cigarettes.

After a 115–day trial involving almost 3,000 exhibits and over a score of witnesses, the jury returned a verdict in favor of Liggett, finding on the special verdict form that Brown & Williamson had engaged in price discrimination that had a reasonable possibility of injuring competition in the domestic cigarette market as a whole. The jury awarded Liggett $49.6 million in damages, which the District Court trebled to $148.8 million. After reviewing the record, however, the District Court held that Brown & Williamson was entitled to judgment as a matter of law on three separate grounds: lack of injury to competition, lack of antitrust injury to Liggett, and lack of a causal link between the discriminatory rebates and Liggett's alleged injury. Liggett Group, Inc. v. Brown & Williamson Tobacco Corp., 748 F.Supp. 344 (MDNC 1990). With respect to the first issue, which is the *219 only one before us, the District Court found that no slowing of the growth rate of generics, and thus no injury to competition, was possible unless there had been tacit coordination of prices in the economy segment of the cigarette market by the various manufacturers. Id., at 354–355. The District Court held that a reasonable jury could come to but one conclusion about the existence of such coordination among the firms contending for shares of the economy segment: it did not exist, and Brown & Williamson therefore had no reasonable possibility of limiting the growth of the segment. Id., at 356–358.

The United States Court of Appeals for the Fourth Circuit affirmed. Liggett Group, Inc. v. Brown & Williamson Tobacco Corp., 964 F.2d 335 (1992). The Court of Appeals held that the dynamic of conscious parallelism among oligopolists could not produce competitive injury in a predatory pricing setting, which necessarily involves a price cut by one of the oligopolists. Id., at 342. In the **2586 Court of Appeals' view, “[t]o rely on the characteristics of an oligopoly to assure recoupment of losses from a predatory pricing scheme after one oligopolist has made a competitive move is ... economically irrational.” Ibid.

We granted certiorari, 506 U.S. 984, 113 S.Ct. 490, 121 L.Ed.2d 428 (1992), and now affirm.

II

A

Price discrimination is made unlawful by § 2(a) of the Clayton Act, 38 Stat. 730, as amended by the Robinson–Patman Act, which provides:

“It shall be unlawful for any person engaged in commerce, in the course of such commerce, either directly or indirectly, to discriminate in price between different purchasers of commodities of like grade and quality ... where the effect of such discrimination may be substantially to lessen competition or tend to create a monopoly in any line of commerce, or to injure, destroy, or prevent *220 competition with any person who either grants or knowingly receives the benefit of such discrimination, or with customers of either of them.” 15 U.S.C. § 13(a).

Although we have reiterated that “‘a price discrimination within the meaning of [this] provision is merely a price difference,’ ” Texaco Inc. v. Hasbrouck, 496 U.S. 543, 558, 110 S.Ct. 2535, 2544, 110 L.Ed.2d 492 (1990) (quoting FTC v. Anheuser–Busch, Inc., 363 U.S. 536, 549, 80 S.Ct. 1267, 1274, 4 L.Ed.2d 1385 (1960)), the statute as a practical matter could not, and does not, ban all price differences charged to “different purchasers of commodities of like grade and quality.” Instead, the statute contains a number of important limitations, one of which is central to evaluating Liggett's claim: By its terms, the Robinson–

113 S.Ct. 2578, 125 L.Ed.2d 168, 61 USLW 4699, 1993-1 Trade Cases P 70,277

Patman Act condemns price discrimination only to the extent that it threatens to injure competition. The availability of statutory defenses permitting price discrimination when it is based on differences in costs, § 13(a), “changing conditions affecting the market for or the marketability of the goods concerned,” ibid., or conduct undertaken “in good faith to meet an equally low price of a competitor,” § 13(b); Standard Oil Co. v. FTC, 340 U.S. 231, 250, 71 S.Ct. 240, 250, 95 L.Ed. 239 (1951), confirms that Congress did not intend to outlaw price differences that result from or further the forces of competition. Thus, “the Robinson–Patman Act should be construed consistently with broader policies of the antitrust laws.” Great Atlantic & Pacific Tea Co. v. FTC, 440 U.S. 69, 80, n. 13, 99 S.Ct. 925, 933, n. 13, 59 L.Ed.2d 153 (1979). See also Automatic Canteen Co. of America v. FTC, 346 U.S. 61, 63, 74, 73 S.Ct. 1017, 1019, 1025, 97 L.Ed. 1454 (1953).

Liggett contends that Brown & Williamson's discriminatory volume rebates to wholesalers threatened substantial competitive injury by furthering a predatory pricing scheme designed to purge competition from the economy segment of the cigarette market. This type of injury, which harms direct competitors of the discriminating seller, is known as primary-line injury. See FTC v. Anheuser–Busch, Inc., supra, 363 U.S., at 538, 80 S.Ct., at 1268–1269. We last addressed primary-line injury over 25 years ago, in *221 Utah Pie Co. v. Continental Baking Co., 386 U.S. 685, 87 S.Ct. 1326, 18 L.Ed.2d 406 (1967). In Utah Pie, we reviewed the sufficiency of the evidence supporting jury verdicts against three national pie companies that had engaged in a variety of predatory practices in the market for frozen pies in Salt Lake City, with the intent to drive a local pie manufacturer out of business. We reversed the Court of Appeals and held that the evidence presented was adequate to permit a jury to find a likelihood of injury to competition. Id., at 703, 87 S.Ct., at 1336.

Utah Pie has often been interpreted to permit liability for primary-line price discrimination on a mere showing that the defendant intended to harm competition or produced a declining price structure. The case **2587 has been criticized on the grounds that such low standards of competitive injury are at odds with the antitrust laws' traditional concern for consumer welfare and price competition. See Bowman, Restraint of Trade by the Supreme Court: The Utah Pie Case, 77 Yale L.J. 70 (1967); R. Posner, Antitrust Law: An Economic Perspective 193–194 (1976); L. Sullivan, Antitrust 687 (1977); 3 P. Areeda & D. Turner, Antitrust Law ¶ 720c (1978) (hereinafter Areeda & Turner); R. Bork, The Antitrust Paradox 386–387 (1978); H. Hovenkamp, Economics and Federal Antitrust Law 188–189 (1985). We do not regard the Utah Pie case itself as having the full significance attributed to it by its detractors. Utah Pie was an early judicial inquiry in this area and did not purport to set forth explicit, general standards for establishing a violation of the Robinson–Patman Act. As the law has been explored since Utah Pie, it has become evident that primary-line competitive injury under the Robinson–Patman Act is of the same general character as the injury inflicted by predatory pricing schemes actionable under § 2 of the Sherman Act. See, e.g., Henry v. Chloride, Inc., 809 F.2d 1334, 1345 (CA8 1987); D.E. Rogers Associates, Inc. v. Gardner–Denver Co., 718 F.2d 1431, 1439 (CA6 1983), cert. denied, 467 U.S. 1242, 104 S.Ct. 3513, 82 L.Ed.2d 822 (1984); William Inglis & Sons Baking Co. v. ITT Continental Baking Co., 668 F.2d 1014, 1041 (CA9 1981), cert. denied, 459 U.S. 825, 103 S.Ct. 57, 58, 74 L.Ed.2d 61 (1982); *222 Malcolm v. Marathon Oil Co., 642 F.2d 845, 853, n. 16 (CA5), cert. denied, 454 U.S. 1125, 102 S.Ct. 975, 71 L.Ed.2d 113 (1981); Pacific Engineering & Production Co. of Nevada v. Kerr–McGee Corp., 551 F.2d 790, 798 (CA10), cert. denied, 434 U.S. 879, 98 S.Ct. 234, 54 L.Ed.2d 160 (1977); International Telephone & Telegraph Corp., 104 F.T.C. 280, 401–402 (1984); Hovenkamp, supra, at 189; 3 Areeda & Turner ¶ 720c; P. Areeda & H. Hovenkamp, Antitrust Law ¶ 720c (Supp.1992) (hereinafter Areeda & Hovenkamp). There are, to be sure, differences between the two statutes. For example, we interpret § 2 of the Sherman Act to condemn predatory pricing when it poses “a dangerous probability of actual monopolization,” Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 455, 113 S.Ct. 884, 890, 122 L.Ed.2d 247 (1993), whereas the Robinson–Patman Act requires only that there be “a reasonable possibility” of substantial injury to competition before its protections are triggered, Falls City Industries, Inc. v. Vanceo Beverage, Inc., 460 U.S. 428, 434, 103 S.Ct. 1282, 1288, 75 L.Ed.2d 174 (1983). But whatever additional flexibility the Robinson–Patman Act standard may imply, the essence of the claim under either statute is the same: A business rival has priced its products in an unfair manner with an object to eliminate or retard competition and thereby gain and exercise control over prices in the relevant market.

Accordingly, whether the claim alleges predatory pricing under § 2 of the Sherman Act or primary-line price discrimination under the Robinson–Patman Act, two prerequisites to recovery remain the same. First, a plaintiff seeking to establish competitive injury resulting from a rival's low prices must prove that the prices complained of are below an appropriate measure of its rival's
costs. See, e.g., Cargill, Inc. v. Monfort of Colorado, Inc., 479 U.S. 104, 117, 107 S.Ct. 484, 493, 93 L.Ed.2d 427 (1986); Matsushita Elec. Industrial Co. v. Zenith Radio Corp., 475 U.S. 574, 585, n. 8, 106 S.Ct. 1348, 1355, n. 8, 89 L.Ed.2d 538 (1986); Utah Pie, 386 U.S., at 698, 701, 702–703, n. 14, 87 S.Ct., at 1333, 1335, 1335–1336, n. 14; In re E.I. Du Pont de Nemours & Co., 96 F.T.C. 653, 749 (1980). Cf. United States v. National Dairy Products Corp., 372 U.S. 29, 83 S.Ct. 594, 9 L.Ed.2d 561 (1963) (holding that below-cost prices may constitute “unreasonably low” prices for purposes of § 3 of the Robinson–Patman Act, 15 U.S.C. § 13a). Although Cargill and Matsushita reserved as a formal matter the question “whether recovery should ever be available ... when the pricing in question is above some measure of incremental cost,” Cargill, supra, 479 U.S., at 117–118, n. 12, 107 S.Ct., at 493, n. 12 (quoting Matsushita, supra, 475 U.S., at 585, n. 9, 106 S.Ct., at 1355, n. 9), the reasoning in both opinions suggests that only below-cost prices should suffice, and we have rejected elsewhere the notion that above-cost prices that are below general market levels or the costs of a firm's competitors inflict injury to competition cognizable under the antitrust laws. See Atlantic Richfield Co. v. USA Petroleum Co., 495 U.S. 328, 340, 110 S.Ct. 1884, 1892, 109 L.Ed.2d 333 (1990). “Low prices benefit consumers regardless of how those prices are set, and so long as they are above predatory levels, they do not threaten competition.... We have adhered to this principle regardless of the type of antitrust claim involved.” Ibid. As a general rule, the exclusionary effect of prices above a relevant measure of cost either reflects the lower cost structure of the alleged predator, and so represents competition on the merits, or is beyond the practical ability of a judicial tribunal to control withoutcourting intolerable risks of chilling legitimate price-cutting. See Areeda & Hovenkamp ¶¶ 714.2, 714.3. “To hold that the antitrust laws protect competitors from the loss of profits due to such price competition would, in effect, render illegal any decision by a firm to cut prices in order to increase market share. The antitrust laws require no such perverse result.” Cargill, supra, 479 U.S., at 116, 107 S.Ct., at 492.

Even in an oligopolistic market, when a firm drops its prices to a competitive level to demonstrate to a maverick the unprofitability of straying from the group, it would be illogical to condemn the price cut: The antitrust laws then would be an obstacle to the chain of events most conducive to a breakdown of oligopoly pricing and the onset of competition. Even if the ultimate effect of the cut is to induce or reestablish supracompetitive pricing, discouraging a price cut and forcing firms to maintain supracompetitive prices, thus depriving consumers of the benefits of lower prices in the interim, does not constitute sound antitrust policy. Cf. Areeda & Hovenkamp ¶¶ 714.2d, 714.2f; Areeda & Turner, Predatory Pricing and Related Practices under Section 2 of the Sherman Act, 88 Harv.L.Rev. 697, 708–709 (1975); Posner, Antitrust Law: An Economic Perspective, at 195, n. 39.

The second prerequisite to holding a competitor liable under the antitrust laws for charging low prices is a demonstration that the competitor had a reasonable prospect, or, under § 2 of the Sherman Act, a dangerous probability, of recouping its investment in below-cost prices. See Matsushita, supra, 475 U.S., at 589, 106 S.Ct., at 1357; Cargill, supra, 479 U.S., at 119, n. 15, 107 S.Ct., at 494, n. 15. “For the investment to be rational, the [predator] must have a reasonable expectation of recovering, in the form of later monopoly profits, more than the losses suffered.” Matsushita, supra, 475 U.S., at 588–589, 106 S.Ct., at 1356–1357. Recoupment is the ultimate object of an unlawful predatory pricing scheme; it is the means by which a predator profits from predation. Without it, predatory pricing produces lower aggregate prices in the market, and consumer welfare is enhanced. Although unsuccessful predatory pricing may encourage some inefficient substitution toward the product being sold at less than its cost, unsuccessful predation is in general a boon to consumers.

That below-cost pricing may impose painful losses on its target is of no moment to the antitrust laws if competition is not injured: It is axiomatic that the antitrust laws were passed for “the protection of competition, not competitors.” Brown Shoe Co. v. United States, 370 U.S. 294, 320, 82 S.Ct. 1502, 1521, 8 L.Ed.2d 510 (1962). Earlier this Term, we held in the Sherman Act § 2 context that it was not enough to inquire “whether the defendant has engaged in ‘unfair’ or ‘predatory’ tactics”; rather, we insisted that the plaintiff prove “a dangerous probability that [the defendant] would monopolize a particular market.” Spectrum Sports, 506 U.S., at 459, 113 S.Ct., at 892. Even an act of pure malice by one business competitor against another does not, without more, state a claim under the federal antitrust laws; those laws do not create a federal law of unfair
113 S.Ct. 2578, 125 L.Ed.2d 168, 61 USLW 4699, 1993-1 Trade Cases P 70,277

competition or “purport to afford remedies for all torts committed by or against persons engaged in interstate commerce.” Hunt v. Crumboch, 325 U.S. 821, 826, 65 S.Ct. 1545, 1548, 89 L.Ed. 1954 (1945).

For recoupment to occur, below-cost pricing must be capable, as a threshold matter, of producing the intended effects on the firm's rivals, whether driving them from the market, or, as was alleged to be the goal here, causing them to raise their prices to supracompetitive levels within a disciplined oligopoly. This requires an understanding of the extent and duration of the alleged predation, the relative financial strength of the predator and its intended victim, and their respective incentives and will. See 3 Areeda & Turner ¶ 711b. The inquiry is whether, given the aggregate losses caused by the below-cost pricing, the intended target would likely succumb.

If circumstances indicate that below-cost pricing could likely produce its intended effect on the target, there is still the further question whether it would likely injure competition in the relevant market. The plaintiff must demonstrate that there is a likelihood that the predatory scheme alleged would cause a rise in prices above a competitive level that would be sufficient to compensate for the amounts expended on the predation, including the time value of the money invested in it. As we have observed on a prior occasion, “[i]n order to recoup their losses, [predators] must obtain enough market power to set higher than competitive prices, and then must sustain those prices long enough to earn in excess *226 profits what they earlier gave up in below-cost prices.” Matsushita, 475 U.S., at 590–591, 106 S.Ct., at 1358.

Evidence of below-cost pricing is not alone sufficient to permit an inference of probable recoupment and injury to competition. Determining whether recoupment of predatory losses is likely requires an estimate of the cost of the alleged predation and a close analysis of both the scheme alleged by the plaintiff and the structure and conditions of the relevant market. Cf., e.g., Elzinga & Mills, Testing for Predation: Is Recoupment Feasible?, 34 Antitrust Bull. 869 (1989) (constructing one possible model for evaluating recoupment). If market circumstances or deficiencies in policy would prevent a reasonable jury from finding that the scheme alleged would likely result in sustained supracompetitive pricing, the plaintiff's case has failed. In certain situations—for example, where the market is highly diffuse and competitive, or where new entry is easy, or the defendant lacks adequate excess capacity to absorb the market shares of his rivals and cannot quickly create or purchase new capacity—summary disposition of the case is appropriate. See, e.g., Cargill, 479 U.S., at 119–120, n. 15, 107 S.Ct., at 494, n. 15.

These prerequisites to recovery are not easy to establish, but they are not artificial obstacles to recovery; rather, they are essential components of real market injury. As we have said in the Sherman Act context, “predatory pricing schemes are rarely tried, and even more rarely successful,” Matsushita, supra, 475 U.S., at 589, 106 S.Ct., at 1357, and the costs of an erroneous finding of liability are high. “[T]he mechanism by which a firm engages in predatory pricing—lowering prices—is the same mechanism by which a firm stimulates competition; because ‘cutting prices in order to increase business often is the very essence of competition ...[,] mistaken inferences ... are especially costly, **2590 because they chill the very conduct the antitrust laws are designed to protect.’ ” Cargill, supra, 479 U.S., at 122, n. 17, 107 S.Ct., at 495, n. 17 (quoting Matsushita, supra, 475 U.S., at 594, 106 S.Ct., at 1360). It would be ironic indeed if the standards for predatory pricing liability *227 were so low that antitrust suits themselves became a tool for keeping prices high.

B

Liggett does not allege that Brown & Williamson sought to drive it from the market but that Brown & Williamson sought to preserve supracompetitive profits on branded cigarettes by pressuring Liggett to raise its generic cigarette prices through a process of tacit collusion with the other cigarette companies. Tacit collusion, sometimes called oligopolistic price coordination or conscious parallelism, describes the process, not in itself unlawful, by which firms in a concentrated market might in effect share monopoly power, setting their prices at a profit-maximizing, supracompetitive level by recognizing their shared economic

113 S.Ct. 2578, 125 L.Ed.2d 168, 61 USLW 4699, 1993-1 Trade Cases P 70,277

interests and their interdependence with respect to price and output decisions. See 2 Areeda & Turner ¶ 404; Scherer & Ross 199–208.

In *Matsushita*, we remarked upon the general implausibility of predatory pricing. See 475 U.S., at 588–590, 106 S.Ct., at 1356–1358. *Matsushita* observed that such schemes are even more improbable when they require coordinated action among several firms.  Id., at 590, 106 S.Ct., at 1358. *Matsushita* involved an allegation of an express conspiracy to engage in predatory pricing. The Court noted that in addition to the usual difficulties that face a single firm attempting to recoup predatory losses, other problems render a conspiracy “incalculably more difficult to execute.”  Ibid. In order to succeed, the conspirators must agree on how to allocate present losses and future gains among the firms involved, and each firm must resist powerful incentives to cheat on whatever agreement is reached.  *Ibid.*

However unlikely predatory pricing by multiple firms may be when they conspire, it is even less likely when, as here, there is no express coordination. Firms that seek to recoup predatory losses through the conscious parallelism of oligopoly must rely on uncertain and ambiguous signals to achieve concerted action. The signals are subject to misinterpretation and are a blunt and imprecise means of ensuring smooth *228* cooperation, especially in the context of changing or unprecedented market circumstances. This anticompetitive minuet is most difficult to compose and to perform, even for a disciplined oligopoly.

From one standpoint, recoupment through oligopolistic price coordination could be thought more feasible than recoupment through monopoly: In the oligopoly setting, the victim itself has an economic incentive to acquiesce in the scheme. If forced to choose between cutting prices and sustaining losses, maintaining prices and losing market share, or raising prices and enjoying a share of supracompetitive profits, a firm may yield to the last alternative. Yet on the whole, tacit cooperation among oligopolists must be considered the least likely means of recouping predatory losses. In addition to the difficulty of achieving effective tacit coordination and the high likelihood that any attempt to discipline will produce an outbreak of competition, the predator's present losses in a case like this fall on it alone, while the later supracompetitive profits must be shared with every other oligopolist in proportion to its market share, including the intended victim. In this case, for example, Brown & Williamson, with its 11–12% share of the cigarette market, would have had to generate around $9 in supracompetitive profits for each $1 invested in predation; the remaining $8 would belong to its competitors, who had taken no risk.

Liggett suggests that these considerations led the Court of Appeals to rule out its theory of recovery as a matter of law. Although **2591** the proper interpretation of the Court of Appeals' opinion is not free from doubt, there is some indication that it held as a matter of law that the Robinson–Patman Act does not reach a primary-line injury claim in which tacit coordination among oligopolists provides the alleged basis for recoupment. The Court of Appeals' opinion does not contain the traditional apparatus of fact review; rather, it focuses on theoretical and legal arguments. The final paragraph appears to state the holding: Brown & Williamson *229* may not be held liable because oligopoly pricing does not “ ‘provide an economically rational basis’ ” for recouping predatory losses. 964 F.2d, at 342.

To the extent that the Court of Appeals may have held that the interdependent pricing of an oligopoly may never provide a means for achieving recoupment and so may not form the basis of a primary-line injury claim, we disagree. A predatory pricing scheme designed to preserve or create a stable oligopoly, if successful, can injure consumers in the same way, and to the same extent, as one designed to bring about a monopoly. However unlikely that possibility may be as a general matter, when the realities of the market and the record facts indicate that it has occurred and was likely to have succeeded, theory will not stand in the way of liability. See *Eastman Kodak Co. v. Image Technical Services, Inc.*, 504 U.S. 451, 466, 467, 112 S.Ct. 2072, ———, 119 L.Ed.2d 265 (1992).

The Robinson–Patman Act, which amended § 2 of the original Clayton Act, suggests no exclusion from coverage when primary-line injury occurs in an oligopoly setting. Unlike the provisions of the Sherman Act, which speak only of various forms of express agreement and monopoly, see 15 U.S.C. §§ 1–2, the Robinson–Patman Act is phrased in broader, disjunctive terms,
prohibiting price discrimination "where the effect of such discrimination may be substantially to lessen competition or tend to create a monopoly," 15 U.S.C. § 13(a). For all the words of the Act to carry adequate meaning, competitive injury under the Act must extend beyond the monopoly setting. Cf. Reiter v. Sonotone Corp., 442 U.S. 330, 99 S.Ct. 2326, 60 L.Ed.2d 931 (1979) ("Canons of construction ordinarily suggest that terms connected by a disjunctive be given separate meanings, unless the context dictates otherwise"). The language referring to a substantial lessening of competition was part of the original Clayton Act § 2, see Act of Oct. 15, 1914, ch. 323, 38 Stat. 730, and the same phrasing appears in § 7 of that Act. In the § 7 context, it has long been settled that excessive concentration, and the oligopolistic price coordination *230 it portends, may be the injury to competition the Act prohibits. See, e.g., United States v. Philadelphia Nat. Bank, 374 U.S. 321, 83 S.Ct. 1715, 10 L.Ed.2d 915 (1963). We adhere to "the normal rule of statutory construction that identical words used in different parts of the same act are intended to have the same meaning." Sullivan v. Stroop, 496 U.S. 478, 484, 110 S.Ct. 2499, 110 L.Ed.2d 438 (1990) (internal quotation marks omitted). See also J. Truett Payne Co. v. Chrysler Motors Corp., 451 U.S. 557, 562, 101 S.Ct. 1923, 101 S.Ct. 1927, 68 L.Ed.2d 442 (1981) (evaluating the competitive injury requirement of Robinson–Patman Act § 2(a) in light of analogous interpretations of Clayton Act § 7). We decline to create a *per se* rule of nonliability for predatory price discrimination when recoupment is alleged to take place through supracompetitive oligopoly pricing. Cf. Cargill, 479 U.S., at 121, 107 S.Ct., at 495.

III

Although Liggett's theory of liability, as an abstract matter, is within the reach of the statute, we agree with the Court of Appeals and the District Court that Liggett was not entitled to submit its case to the jury. It is not customary for this Court to review the sufficiency of the evidence, but we will do so when the issue is properly before us and the benefits of providing guidance **2592 concerning the proper application of a legal standard and avoiding the systemic costs associated with further proceedings justify the required expenditure of judicial resources. See, e.g., Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585, 605–611, 105 S.Ct. 2847, 2859–2861, 86 L.Ed.2d 467 (1985); Monsanto Co. v. Spray–Rite Service Corp., 465 U.S. 752, 765–768, 104 S.Ct. 1464, 1471–1472, 79 L.Ed.2d 775 (1984); United States v. Pabst Brewing Co., 384 U.S. 546, 550–552, 86 S.Ct. 1665, 1668–1669, 16 L.Ed.2d 765 (1966). The record in this case demonstrates that the anticompetitive scheme Liggett alleged, when judged against the realities of the market, does not provide an adequate basis for a finding of liability.

A

Liggett's theory of competitive injury through oligopolistic price coordination depends upon a complex chain of cause *231 and effect: Brown & Williamson would enter the generic segment with list prices matching Liggett's but with massive, discriminatory volume rebates directed at Liggett's biggest wholesalers; as a result, the net price of Brown & Williamson's generics would be below its costs; Liggett would suffer losses trying to defend its market share and wholesale customer base by matching Brown & Williamson's rebates; to avoid further losses, Liggett would raise its list prices on generics or acquiesce in price leadership by Brown & Williamson; higher list prices to consumers would shrink the percentage gap in retail price between generic and branded cigarettes; and this narrowing of the gap would make generics less appealing to the consumer, thus slowing the growth of the economy segment and reducing cannibalization of branded sales and their associated supracompetitive profits.

Although Brown & Williamson's entry into the generic segment could be regarded as procompetitive in intent as well as effect, the record contains sufficient evidence from which a reasonable jury could conclude that Brown & Williamson envisioned or intended this anticompetitive course of events. See, e.g., App. 57–58, 67–69, 89–91, 99, 112–114, 200, 241, 253, 257, 262–263, 279–280, 469–470, 664–666. There is also sufficient evidence in the record from which a reasonable jury could conclude that for a period of approximately 18 months, Brown & Williamson's prices on its generic cigarettes were below its costs,
id., at 338–339, 651, 740, and that this below-cost pricing imposed losses on Liggett that Liggett was unwilling to sustain, given its corporate parent's effort to locate a buyer for the company, see id., at 74, 92, 200, 253, 596–597. Liggett has failed to demonstrate competitive injury as a matter of law, however, because its proof is flawed in a critical respect: The evidence is inadequate to show that in pursuing this scheme, Brown & Williamson had a reasonable prospect of recovering its losses from below-cost pricing through slowing the growth of generics. As we have noted, “[t]he success of any predatory scheme depends on maintaining monopoly power for long enough both to recoup the predator's losses and to harvest some additional gain.” Matsushita, 475 U.S., at 589, 106 S.Ct., at 1357 (emphasis omitted).

No inference of recoupment is sustainable on this record, because no evidence suggests that Brown & Williamson—whatever its intent in introducing black and whites may have been—was likely to obtain the power to raise the prices for generic cigarettes above a competitive level. Recoupment through supracompetitive pricing in the economy segment of the cigarette market is an indispensable aspect of Liggett's own proffered theory, because a slowing of growth in the economy segment, even if it results from an increase in generic prices, is not itself anticompetitive. Only if those higher prices are a product of nonmarket forces has competition suffered. If prices rise in response to an excess of demand over supply, or segment growth slows as patterns of consumer preference become stable, the market is functioning in a competitive manner. Consumers are not injured from the perspective of the antitrust laws by the price increases; they are in fact causing them. Thus, the linchpin of the predatory scheme alleged by Liggett is Brown & Williamson's ability, with the other oligopolists, to raise prices above a competitive level in the generic segment of the market. Because relying on tacit coordination among oligopolists as a means of recouping losses from predatory pricing is “highly speculative,” Areeda & Hovenkamp ¶ 711.2c, at 647, competent evidence is necessary to allow a reasonable inference that it poses an authentic threat to competition. The evidence in this case is insufficient to demonstrate the danger of Brown & Williamson's alleged scheme.

Based on Liggett's theory of the case and the record it created, there are two means by which one might infer that Brown & Williamson had a reasonable prospect of producing sustained supracompetitive pricing in the generic segment adequate to recoup its predatory losses: first, if generic output or price information indicates that oligopolistic price coordination in fact produced supracompetitive prices in the generic segment; or second, if evidence about the market and Brown & Williamson's conduct indicate that the alleged scheme was likely to have brought about tacit coordination and oligopoly pricing in the generic segment, even if it did not actually do so.

In this case, the price and output data do not support a reasonable inference that Brown & Williamson and the other cigarette companies elevated prices above a competitive level for generic cigarettes. Supracompetitive pricing entails a restriction in output. See National Collegiate Athletic Assn. v. Board of Regents of Univ. of Okla., 468 U.S. 85, 104–108, 104 S.Ct. 2948, 2962–2963, 82 L.Ed.2d 70 (1984); Broadcast Music, Inc. v. Columbia Broadcasting System, Inc., 441 U.S. 1, 19–20, 99 S.Ct. 1551, 1562, 60 L.Ed.2d 1 (1979); P. Samuelson & W. Nordhaus, Economics 516 (12th ed. 1985); Sullivan, Antitrust, at 32; Bork, The Antitrust Paradox, at 178–179; 2 Areeda & Turner ¶ 403a; Easterbrook, The Limits of Antitrust, 63 Texas L.Rev. 1, 20, 31 (1984). In the present setting, in which output expanded at a rapid rate following Brown & Williamson's alleged predation, output in the generic segment can only have been restricted in the sense that it expanded at a slower rate than it would have absent Brown & Williamson's intervention. Such a counterfactual proposition is difficult to prove in the best of circumstances; here, the record evidence does not permit a reasonable inference that output would have been greater without Brown & Williamson's entry into the generic segment.
Following Brown & Williamson's entry, the rate at which generic cigarettes were capturing market share did not slow; indeed, the average rate of growth doubled. During the four years from 1980 to 1984 in which Liggett was alone in the generic segment, the segment gained market share at an average rate of 1% of the overall market per year, from 0.4% in 1980 to slightly more than 4% of the cigarette market in 1984. In the next five years, following the alleged predation, the generic segment expanded from 4% to more than 15% of the domestic cigarette market, or greater than 2% per year.

While this evidence tends to show that Brown & Williamson's participation in the economy segment did not restrict output, it is not dispositive. One could speculate, for example, that the rate of segment growth would have tripled, instead of doubled, without Brown & Williamson's alleged predation. But there is no concrete evidence of this. Indeed, the only industry projection in the record estimating what the segment's growth would have been without Brown & Williamson's entry supports the opposite inference. In 1984, Brown & Williamson forecast in an important planning document that the economy segment would account for 10% of the total cigarette market by 1988 if it did not enter the segment. App. 133, 135. In fact, in 1988, after what Liggett alleges was a sustained and dangerous anticompetitive campaign by Brown & Williamson, the generic segment accounted for over 12% of the total market. Id., at 354–356. Thus the segment's output expanded more robustly than Brown & Williamson had estimated it would had Brown & Williamson never entered.

Brown & Williamson did note in 1985, a year after introducing its black and whites, that its presence within the generic segment “appears to have resulted in ... a slowing in the segment's growth rate.” Id., at 257. But this statement was made in early 1985, when Liggett itself contends the below-cost pricing was still in effect and before any anticompetitive contraction in output is alleged to have occurred. Whatever it may mean, this statement has little value in evaluating the competitive implications of Brown & Williamson's later conduct, which was alleged to provide the basis for recouping predatory losses.

In arguing that Brown & Williamson was able to exert market power and raise generic prices above a competitive level in the generic category through tacit price coordination with the other cigarette manufacturers, Liggett places its principal reliance on direct evidence of price behavior. This evidence demonstrates that the list prices on all cigarettes, generic and branded alike, rose to a significant degree during the late 1980's. Id., at 325. From 1986 to 1989, list prices on both generic and branded cigarettes increased twice a year by similar amounts. Liggett's economic expert testified that these price increases outpaced increases in costs, taxes, and promotional expenditures. Id., at 525. The list prices of generics, moreover, rose at a faster rate than the prices of branded cigarettes, thus narrowing the list price differential between branded and generic products. Id., at 325. Liggett argues that this would permit a reasonable jury to find that Brown & Williamson succeeded in bringing about oligopolistic price coordination and supracompetitive prices in the generic category sufficient to slow its growth, thereby preserving supracompetitive branded profits and recouping its predatory losses.

A reasonable jury, however, could not have drawn the inferences Liggett proposes. All of Liggett's data are based upon the list prices of various categories of cigarettes. Yet the jury had before it undisputed evidence that during the period in question, list prices were not the actual prices paid by consumers. 100 Tr. 227–229. As the market became unsettled in the mid–1980's, the cigarette companies invested substantial sums in promotional schemes, including coupons, stickers, and giveaways, that reduced the actual cost of cigarettes to consumers below list prices. 33 Tr. 206–209, 51 Tr. 130. This promotional activity accelerated as the decade progressed. App. 509, 672. Many wholesalers also passed portions of their volume rebates on to the consumer, which had the effect of further undermining the significance of the retail list prices. Id., at 672, 687–692, 761–763. Especially in an oligopoly setting, in which price competition is most likely to take place through less observable and less regulable means than list prices, it would be unreasonable to draw conclusions about the existence of tacit coordination or supracompetitive pricing from data that reflect only list prices.
Even on its own terms, the list price data relied upon by Liggett to demonstrate a narrowing of the price differential between
generic and full-priced branded cigarettes could not support the conclusion that supracompetitive pricing had been introduced
into the generic segment. Liggett's gap data ignore the effect of "subgeneric" cigarettes, which were priced at discounts
of 50% or more from the list prices of normal branded cigarettes. See, e.g., id., at 682–686. Liggett itself, while supposedly
under the sway of oligopoly power, pioneered this development in 1988 with the introduction of its "Pyramid" brand. Id., at 326. By the time of trial, five of the six major manufacturers offered a cigarette in this category at a discount from the full list
price of at least 50%. Id., at 685–686; 147 Tr. 107. Thus, the price difference between the highest priced branded cigarette and
the lowest price cigarettes in the economy segment, instead of narrowing over the course of the period of alleged predation as
Liggett would argue, grew to a substantial extent. In June 1984, before Brown & Williamson entered the generic segment, a
consumer could obtain a carton of black and white generic cigarettes from Liggett at a 38% discount from the list price of a
leading brand; after the conduct Liggett complains of, consumers could obtain a branded generic from Liggett for 52%
off the list price of a leading brand. See App. 325–326, 685.

It may be that a reasonable jury could conclude that the cumulative discounts attributable to subgenerics and the various
consumer promotions did not cancel out the full effect of the increases in list prices, see id., at 508–509, and that actual prices to
the consumer did indeed rise, but rising prices do not themselves permit an inference of a collusive market dynamic. Even in a
concentrated market, the occurrence of a price increase does not in itself permit a rational inference of conscious parallelism or
supracompetitive pricing. Where, as here, output is expanding at the same time prices are increasing, rising prices are equally
consistent with growing product demand. Under these conditions, a jury may not infer competitive injury from price and output
data absent some evidence that tends to prove that output was restricted or prices were above a competitive level. Cf. Monsanto,
465 U.S., at 763, 104 S.Ct., at 1470.

Quite apart from the absence of any evidence of that sort, an inference of supracompetitive pricing would be particularly
anomalous in this case, as the very party alleged to have been coerced into pricing through oligopolistic coordination denied
that such coordination existed: Liggett's own officers and directors consistently denied that they or other firms in the industry
priced their cigarettes through tacit collusion or reaped supracompetitive profits. App. 394–399, 623–631; 11 Tr. 170–174, 64
Tr. 51–56. Liggett seeks to explain away this testimony by arguing that its officers and directors are businessmen who do not
ascribe the same meaning to words like "competitive" and "collusion" that an economist would. This explanation is entitled
to little, if any, weight. As the District Court found:

"This argument was considered at the summary judgment stage since these executives gave basically the same testimony at
their depositions. The court allowed the case to go to trial in part because the Liggett executives were not economists
and in part because of affidavits from the Liggett executives stating that they were confused by the questions asked by B
rown & W[illiamson] lawyers and did not mean to contradict the testimony of [their economic expert] Burnett. However, at
trial, despite having consulted extensively with Burnett and having had adequate time to familiarize themselves with concepts
such as tacit collusion, oligopoly, and monopoly profits, these Liggett executives again contradicted Burnett's theory." 748
F.Supp., at 356.
oligopoly pricing in the face of these unusual competitive pressures is through tacit price coordination with the other cigarette firms.

Yet the situation facing the cigarette companies in the 1980's would have made such tacit coordination unmanageable. Tacit coordination is facilitated by a stable market environment, fungible products, and a small number of variables upon which the firms seeking to coordinate their pricing may focus. See generally Scherer & Ross 215–315; 6 P. Areeda, supra, ¶¶ 1428–1430. Uncertainty is an oligopoly's greatest enemy. By 1984, however, the cigarette market was in an obvious state of flux. The introduction of generic cigarettes in 1980 represented the first serious price competition *239 in the cigarette market since the 1930's. See Scherer & Ross 250–251; App. 128. This development was bound to unsettle previous expectations and patterns of market conduct and to reduce the cigarette firms' ability to predict each other's behavior.

The larger number of product types and pricing variables also decreased the probability of effective parallel pricing. When Brown & Williamson entered the economy segment in 1984, the segment included Value–25s, black and whites, and branded generics. With respect to each product, the net price in the market was determined not only by list prices, but also by a wide variety of discounts and promotions to consumers and by rebates to wholesalers. In order to coordinate in an effective manner and eliminate price competition, the cigarette companies would have been required, without communicating, to establish parallel practices with respect to each of these variables, many of which, like consumer stickers or coupons, were difficult to monitor. Liggett has not even alleged parallel behavior with respect to these other variables, and the inherent limitations of tacit collusion suggest that such multivariable coordination is improbable. See R. Dorfman, The Price System 99–100, and n. 10 (1964); Scherer & Ross 279.

In addition, R.J. Reynolds had incentives that, in some respects, ran counter to those of the other cigarette companies. It is implausible that without a shared interest in retarding the growth of the economy segment, Brown & Williamson and its fellow oligopolists could have engaged in parallel pricing and raised generic prices above a competitive level. “[C]oordination will not be possible when any significant firm chooses, for any reason, to 'go it alone.' ” 2 Areeda & Turner ¶ 404b2, at 276. It is undisputed—indeed it was conceded by Liggett's expert—that R.J. Reynolds acted without regard to the supposed benefits of oligopolistic coordination when it repriced Doral at generic levels in the spring of 1984 and that the natural and probable consequence *240 of its entry into the generic segment was procompetitive. 55 Tr. 15–16; 51 Tr. 128. Indeed, Reynolds' apparent objective in entering the segment was to capture a significant amount of volume in order to regain its number one sales position in the cigarette industry from Philip Morris. App. 75, 130, 209–211. There is no evidence that R.J. Reynolds accomplished this goal during the period relevant to this case, or that its commitment to achieving that goal changed. Indeed, R.J. Reynolds refused to follow Brown & Williamson's attempt to raise generic prices in June 1985. The jury thus had before it undisputed evidence that contradicts the suggestion that the major cigarette companies shared a goal of limiting the growth of the economy segment; one of the industry's two major players concededly entered the segment to expand volume and compete.

Even if all the cigarette companies were willing to participate in a scheme to restrain the growth of the generic segment, they **2597 would not have been able to coordinate their actions and raise prices above a competitive level unless they understood that Brown & Williamson's entry into the segment was not a genuine effort to compete with Liggett. If even one other firm misinterpreted Brown & Williamson's entry as an effort to expand share, a chain reaction of competitive responses would almost certainly have resulted, and oligopoly discipline would have broken down, perhaps irretrievably. “[O]nce the trust among rivals breaks down, it is as hard to put back together again as was Humpty-Dumpty, and non-collusive behavior is likely to take over.” Samuelson & Nordhaus, Economics, at 534.

Liggett argues that the means by which Brown & Williamson signaled its anticompetitive intent to its rivals was through its pricing structure. According to Liggett, maintaining existing list prices while offering substantial rebates to wholesalers was a signal to the other cigarette firms that Brown & Williamson did not intend to attract additional smokers to the generic segment by its entry. But a reasonable *241 jury could not conclude that this pricing structure eliminated or rendered insignificant

113 S.Ct. 2578, 125 L.Ed.2d 168, 61 USLW 4699, 1993-1 Trade Cases P 70,277

the risk that the other firms might misunderstand Brown & Williamson's entry as a competitive move. The likelihood that Brown & Williamson's rivals would have regarded its pricing structure as an important signal is low, given that Liggett itself, the purported target of the predation, was already using similar rebates, as was R.J. Reynolds in marketing its Doral branded generic. A Reynolds executive responsible for Doral testified that given its and Liggett's use of wholesaler rebates, Brown & Williamson could not have competed effectively without them. App. 756. And despite extensive discovery of the corporate records of R.J. Reynolds and Philip Morris, no documents appeared that indicated any awareness of Brown & Williamson's supposed signal by its principal rivals. Without effective signaling, it is difficult to see how the alleged predation could have had a reasonable chance of success through oligopoly pricing.

Finally, although some of Brown & Williamson's corporate planning documents speak of a desire to slow the growth of the segment, no objective evidence of its conduct permits a reasonable inference that it had any real prospect of doing so through anticompetitive means. It is undisputed that when Brown & Williamson introduced its generic cigarettes, it offered them to a thousand wholesalers who had never before purchased generic cigarettes. Record, Plaintiff's Exh. No. 4079; 87 Tr. 191; 88 Tr. 143–147. The inevitable effect of this marketing effort was to expand the segment, as the new wholesalers recruited retail outlets to carry generic cigarettes. Even with respect to wholesalers already carrying generics, Brown & Williamson's unprecedented volume rebates had a similar expansionary effect. Unlike many branded cigarettes, generics came with no sales guarantee to the wholesaler; any unsold stock represented pure loss to the wholesaler. By providing substantial incentives for wholesalers to place large orders, Brown & Williamson created *242 strong pressure for them to sell more generic cigarettes. In addition, as we have already observed, see supra, at 25, many wholesalers passed portions of the rebates about which Liggett complains on to consumers, thus dropping the retail price of generics and further stimulating demand. Brown & Williamson provided a further, direct stimulus, through some $10 million it spent during the period of alleged predation placing discount stickers on its generic cartons to reduce prices to the ultimate consumer. 70 Tr. 246. In light of these uncontested facts about Brown & Williamson's conduct, it is not reasonable to conclude that Brown & Williamson threatened in a serious way to restrict output, raise prices above a competitive level, and artificially slow the growth of the economy segment of the national cigarette market.

To be sure, Liggett's economic expert explained Liggett's theory of predatory **2598 price discrimination and testified that he believed it created a reasonable possibility that Brown & Williamson could injure competition in the United States cigarette market as a whole. App. 600–614. But this does not alter our analysis. When an expert opinion is not supported by sufficient facts to validate it in the eyes of the law, or when indisputable record facts contradict or otherwise render the opinion unreasonable, it cannot support a jury's verdict. Cf. J. Truett Payne Co., Inc., 451 U.S., at 564–565, 101 S.Ct., at 1928–1929 (referring to expert economic testimony not based on "documentary evidence as to the effect of the discrimination on retail prices" as "weak" at best). Expert testimony is useful as a guide to interpreting market facts, but it is not a substitute for them. As we observed in Matsushita, "expert opinion evidence ... has little probative value in comparison with the economic factors" that may dictate a particular conclusion. 475 U.S., at 594, n. 19, 106 S.Ct., at 1360, n. 19. Here, Liggett's expert based his opinion that Brown & Williamson had a reasonable prospect of recouping its predatory losses on three factors: Brown & Williamson's black and white pricing structure, corporate *243 documents showing an intent to shrink the price differential between generic and branded cigarettes, and evidence of below-cost pricing. App. 601–602. Because, as we have explained, this evidence is insufficient as a matter of law to support a finding of primary-line injury under the Robinson–Patman Act, the expert testimony cannot sustain the jury's verdict.

IV

We understand that the chain of reasoning by which we have concluded that Brown & Williamson is entitled to judgment as a matter of law is demanding. But a reasonable jury is presumed to know and understand the law, the facts of the case, and the realities of the market. We hold that the evidence cannot support a finding that Brown & Williamson's alleged scheme was
likely to result in oligopolistic price coordination and sustained supra-competitive pricing in the generic segment of the national cigarette market. Without this, Brown & Williamson had no reasonable prospect of recouping its predatory losses and could not inflict the injury to competition the antitrust laws prohibit. The judgment of the Court of Appeals is

Affirmed.

Justice STEVENS, with whom Justice WHITE and Justice BLACKMUN join, dissenting.

For a period of 18 months in 1984 and 1985, respondent Brown & Williamson Tobacco Corporation (B & W) waged a price war against petitioner, known then as Liggett & Myers (Liggett). Liggett filed suit claiming that B & W's pricing practices violated the Robinson–Patman Act. After a 115–day trial, *244 the jury agreed, and awarded Liggett substantial damages. The Court of Appeals, however, found that Liggett could not succeed on its claim, because B & W, as an independent actor controlling only 12% of the national cigarette market, could not injure competition. Liggett Group, Inc. v. Brown & Williamson Tobacco Corp., 964 F.2d 335, 340–342 (CA4 1992).

Today, the Court properly rejects that holding. See ante, at 2590–2592. Instead of remanding the case to the Court of Appeals to resolve the other issues raised by the parties, however, the Court goes on to review portions of the voluminous trial record, and comes to the conclusion that the evidence does not support the jury's finding that B & W's price discrimination “had a reasonable possibility of injuring competition.” In my opinion the evidence is plainly sufficient to support that finding.

*245

The fact that a price war may not have accomplished its purpose as quickly or as completely as originally intended does not immunize conduct that was illegal when it occurred. A proper understanding of this case therefore requires a brief description of the situation before the war began in July 1984; the events that occurred during the period between July 1984 and the end of 1985; and, finally, the facts bearing on the predictability of competitive harm during or at the end of that period.

Background

B & W is the third largest firm in a highly concentrated industry. Ante, at 2583. For decades, the industry has been marked by the same kind of supra-competitive pricing that is characteristic of the textbook monopoly. Without the necessity of actual agreement among the six major manufacturers, “prices for cigarettes increased in lockstep, twice a year, for a number of years, irrespective of the rate of inflation, changes in the costs of production, or shifts in consumer demand.” Ante, at 2583. Notwithstanding the controversy over the health effects of smoking and the increase in the federal excise tax, profit margins improved “handsomely” during the period between 1972 and 1983.

*246 The early 1980's brought two new developments to the cigarette market. First, in 1980, when its share of the market had declined to 2.3%, Liggett introduced a new line of generic cigarettes in plain black and white packages, offered at an effective price of approximately 30% less than branded cigarettes. Ante, at 2583. A B & W memorandum described this action as “the first time that a [cigarette] manufacturer has used pricing as a strategic marketing weapon in the U.S. since the depression era.” App. 128. This novel tactic proved successful; by 1984, Liggett's black and whites represented about 4% of the total market and generated substantial profits. The next development came in 1984, when R.J. Reynolds (RJR), the second
B & W executives prepared a number of internal memoranda planning responses to these two market developments. See App. 120, 127, 157, 166. With respect to RJR, B & W decided to “follo[w] precisely the pathway” of that company, id., at 121, reasoning that “introduction of a branded generic by B & W now appears to be feasible as RJR has the clout and sales force coverage to maintain the price on branded generics,” id., at 145. Accordingly, B & W planned to introduce a new “branded generic” of its own, known as Hallmark, to be sold at the same prices as RJR’s Doral. Id., at 124, 142–144.

*B247  B & W took a more aggressive approach to Liggett’s black and whites. It decided to launch its own line of black and white cigarettes with the “[s]ame style array” and list price as Liggett’s, but with “[s]uperior discounts/allowances.” Id., at 124. B & W estimated that its own black and whites would generate a “trading profit” of $5.1 million for the second half of 1984 and $43.6 million for 1985. Id., at 125. At the same time, however, B & W, anticipating “competitive counterattacks,” was “prepared to redistribute this entire amount in the form of additional trade allowances.” Ibid. B & W's competitive stance was confined to Liggett; the memorandum outlining B & W's plans made no reference to the possibility of countermoves by RJR, or to the use of B & W's trading profits to increase allowances on any product other than black and whites.

This “dual approach” was designed to “provide B & W more influence to manage up the prices of branded generics to improve profitability,” id., at 123, and also the opportunity to participate in the economy market, with a view toward “manag[ing] down generic volume,” id., at 109. Notwithstanding its ultimate aim to “limit generic segment growth,” id., at 113, B & W estimated an aggregate potential trading profit on black and whites of $342 million for 1984 to 1988, id., at 146. Though B & W recognized that it might be required to use “some or all of this potential trading profit” to maintain its market position, it also believed that it would recoup its losses as the segment became “more profitable, particularly as it approaches maturity.” Ibid.

B & W began to implement its plan even before it made its first shipment of black and whites in July 1984, with a series of price announcements in June of that year. When B & W announced its first volume discount schedule for distributors, Liggett responded by increasing its own discounts. Though Liggett's discounts remained lower than B & W's, B & W responded in turn by increasing its rebates still further. After four or five moves and countermoves, the dust settled *B248 with B & W's net prices to distributors lower than Liggett's. 6 B & W's deep discounts not only forfeited all of its $48.7 million in projected trading profits for the next 18 months, but actually resulted in sales below B & W's average variable cost. Id., at 338–339.

**B2601 Assessing the pre-July 1984 evidence tending to prove that B & W was motivated by anticompetitive intent, the District Court observed that the documentary evidence was “more voluminous and detailed than any other reported case. This evidence not only indicates B & W wanted to injure Liggett, it also details an extensive plan to slow the growth of the generic cigarette segment.” Liggett Group, Inc. v. Brown & Williamson Tobacco Corp., 748 F.Supp. 344, 354 (MDNC 1990).

The 18–Month Price War

The volume rebates offered by B & W to its wholesalers during the 18–month period from July 1984 to December 1985 unquestionably constituted price discrimination covered by § 2(a) of the Clayton Act, 38 Stat. 730, as amended by the Robinson–Patman Act, 49 Stat. 1526, 15 U.S.C. § 13(a). 7 Nor were the discounts justified by any statutory or affirmative defense: They were not cost justified, 8 App. 525, were *B249 not good-faith efforts to meet the equally low price of a competitor, 9 and were not mere introductory or promotional discounts, 91 Tr. 42.
113 S.Ct. 2578, 125 L.Ed.2d 168, 61 USLW 4699, 1993-1 Trade Cases P 70,277

The rebate program was intended to harm Liggett and in fact caused it serious injury. The jury found that Liggett had suffered actual damages of $49.6 million, App. 28, an amount close to, but slightly larger than, the $48.7 million trading profit B & W had indicated it would forgo in order to discipline Liggett. See supra, at 4. To inflict this injury, B & W sustained a substantial loss. During the full 18-month period, B & W’s revenues ran consistently below its total variable costs, with an average deficiency of approximately $0.30 per carton and a total loss on B & W black and whites of almost $15 million. App. 338–339. That B & W executives were willing to accept losses of this magnitude during the entire 18 months is powerful evidence of their belief that prices ultimately could be “managed up” to a level that would allow B & W to recoup its investment.

The Aftermath

At the end of 1985, the list price of branded cigarettes was $33.15 per carton, and the list price of black and whites, $19.75 per carton. App. 325. Over the next four years, the list price on both branded and black and white cigarettes increased twice a year, by identical amounts. The June 1989 increases brought the price of branded cigarettes to $46.15 per carton, and the price of black and whites to $33.75—an amount even higher than the price for branded cigarettes when the war ended in December 1985. Ibid. Because the rate of increase was higher on black and whites than on brandeds, the price differential between the two types of cigarettes narrowed, ibid., from roughly 40% in 1985 to 27% in 1989. See 964 F.2d, at 338.

The expert economist employed by Liggett testified that the post–1985 price increases were unwarranted by increases in manufacturing or other costs, taxes, or promotional expenditures. App. 525. To be sure, some portion of the volume rebates granted distributors was passed on to consumers in the form of promotional activity, so that consumers did not feel the full brunt of the price increases. Nevertheless, the record amply supports the conclusion that the post–1985 price increases in list prices produced higher consumer prices, as well as higher profits for the manufacturers.

The legal question presented by this evidence is whether the facts as they existed during and at the close of the 18–month period, and all reasonable inferences to be drawn from those facts, see n. 3, supra, justified the finding by the jury that B & W’s discriminatory pricing campaign “had a reasonable possibility of injuring competition,” see supra, at 2599, and n. 2.

II

The Sherman Act, 26 Stat. 209, enacted in 1890, the Clayton Act, 38 Stat. 730, enacted in 1914, and the Robinson–Patman Act, which amended the Clayton Act in 1936, all serve the purpose of protecting competition. Because they have a common goal, the statutes are similar in many respects. All three prohibit the predatory practice of deliberately selling below cost to discipline a competitor, either to drive the competitor out of business or to raise prices to a level that will enable the predator to recover its losses and, in the long run, earn additional profits. Sales below cost and anticompetitive intent are elements of the violation of all three statutes. Neither of those elements, however, is at issue in this case. See ante, at 2592 (record contains sufficient evidence of anticompetitive intent and below-cost pricing).

The statutes do differ significantly with respect to one element of the violation, the competitive consequences of predatory conduct. Even here, however, the three statutes have one thing in common: Not one of them requires proof that a predatory plan has actually succeeded in accomplishing its objective. Section 1 of the Sherman Act requires proof of a conspiracy. It is the joint plan to restrain trade, however, and not its success, that is prohibited by § 1. Nash v. United States, 229 U.S. 373, 378, 33 S.Ct. 780, 782, 57 L.Ed. 1232 (1913). Section 2 of the Sherman Act applies to independent conduct, and may be violated when there is a “dangerous probability” that an attempt to achieve monopoly power will succeed. Swift & Co. v. United States, 196 U.S. 375, 396, 25 S.Ct. 276, 279, 49 L.Ed. 518 (1905). The Clayton Act goes beyond the “dangerous probability” standard to
113 S.Ct. 2578, 125 L.Ed.2d 168, 61 USLW 4699, 1993-1 Trade Cases P 70,277

cover price discrimination “where the effect of such discrimination may be to substantially lessen competition or tend to create
a monopoly in any line of commerce.” § 2, 38 Stat. 730.

*252 The element of competitive injury as defined in the Robinson–Patman Act is broader still. 13 See S.Rep. No. 1502, 74th
was designed to reach discriminations “in their incipiency, before the harm to competition is effected. It is enough that they
‘may’ have the prescribed effect.” Corn Products Refining Co. v. FTC, 324 U.S. 726, 738, 65 S.Ct. 961, 967, 89 L.Ed. 1320
(1945) (internal quotation marks omitted). Or, as the Report of the Senate Judiciary Committee on the proposed Act explained,
“to catch the weed in the seed will keep it from coming to flower.” S.Rep. No. 1502, at 4.

Accordingly, our leading case concerning discriminatory volume rebates described the scope of the Act as follows:

*253 “There are specific findings that such injuries had resulted from respondent's discounts, although the statute does
not require the Commission to find that injury has actually resulted. The statute requires no more than that the effect of the
prohibited price discriminations ‘may be substantially to lessen competition ... or to injure, destroy, or prevent competition.’
After a careful consideration of this provision of the Robinson–Patman Act, we have said that ‘the statute does not require
that the discrimination must in fact have harmed competition, but only that there is a reasonable possibility that they “may”
have such an effect.’ Corn Products Co. v. Federal Trade Comm'n, 324 U.S. 726, 742 [65 S.Ct. 961, 969, 89 L.Ed. 1320].”

See also Falls City Industries, Inc. v. Vanco Beverage, Inc., 460 U.S. 428, 435, 103 S.Ct. 1282, 1288, 75 L.Ed.2d 174 (1983)
(“In keeping with the Robinson–Patman Act's prophylactic purpose, § 2(a) does not require that the discriminations must in
fact have harmed competition” (internal quotation marks omitted)).

In this case, then, Liggett need not show any actual harm to competition, but only the reasonable possibility that such harm
would flow from B & W's conduct. The evidence presented supports the conclusion that B & W's price war was intended to
discipline Liggett for its unprecedented use of price competition in an industry that had enjoyed handsome supracompetitive
profits for about half a century. The evidence also demonstrates that B & W executives were confident enough in the feasibility
of their plan that they were willing to invest millions of company dollars in its outcome. And all of this, of course, must be
viewed against a background of supracompetitive, parallel pricing, in which “prices for cigarettes increased in lockstep, twice
a year ... irrespective of the rate of inflation, changes in the cost of production, or shifts in consumer demand,” ante, at 2583,
bringing with them dramatic increases in profit margins, see n. 5, supra. In this context, it is surely fair to infer that B & W's
disciplinary *254 program had a reasonable prospect of persuading Liggett to forgo its maverick price reductions and return
to parallel **2604 pricing policies, and thus to restore the same kind of supracompetitive pricing that had characterized the
industry in the past. When the facts are viewed in the light most favorable to Liggett, I think it clear that there is sufficient
evidence in the record that the “reasonable possibility” of competitive injury required by the statute actually existed.

III

After 115 days of trial, during which it considered 2,884 exhibits, 85 deposition excerpts, and testimony from 23 live witnesses,
the jury deliberated for nine days and then returned a verdict finding that B & W engaged in price discrimination with a
“reasonable possibility of injuring competition.” 748 F.Supp., at 348, n. 4; n. 2, supra. The Court's contrary conclusion rests
on a hodgepodge of legal, factual, and economic propositions that are insufficient, alone or together, to overcome the jury's
assessment of the evidence.
First, as a matter of law, the Court reminds us that the Robinson–Patman Act is concerned with consumer welfare and competition, as opposed to protecting individual competitors from harm; “the antitrust laws were passed for the protection of competition, not competitors.” See ante, at 2588 (internal quotations marks and emphasis omitted). For that reason, predatory price cutting is not unlawful unless the predator has a reasonable prospect of recouping his investment from supracompetitive profits. Ante, at 2589. The jury, of course, was so instructed, see n. 2, supra, and no one questions that proposition here.

As a matter of fact, the Court emphasizes the growth in the generic segment following B & W's entry. As the Court notes, generics' expansion to over 12% of the total market by 1988 exceeds B & W's own forecast that the segment would grow to only about 10%, assuming no entry by B & W. Ante, at 2594. What these figures do not do, however, is answer the relevant question: whether the prices of generic cigarettes during the late 1980's were competitive or supracompetitive.

On this point, there is ample, uncontradicted evidence that the list prices on generic cigarettes, as well as the prices on branded cigarettes, rose regularly and significantly during the late 1980's, in a fashion remarkably similar to the price change patterns that characterized the industry in the 1970's when supracompetitive, oligopolistic pricing admittedly prevailed. See supra, at 2599; ante, at 2583. Given its knowledge of the industry's history of parallel pricing, I think the jury plainly was entitled to draw an inference that these increased prices were supracompetitive.

The Court responds to this evidence dismissively, suggesting that list prices have no bearing on the question because promotional activities of the cigarette manufacturers may have offset such price increases. Ante, at 2594. That response is insufficient for three reasons. First, the promotions to which the majority refers related primarily to branded cigarettes; accordingly, while they narrowed the differential between branded prices and black and white prices, they did not reduce the consumer price of black and whites. See 33 Tr. 208–210. Second, the Court's speculation is inconsistent with record evidence that the semiannual list price increases were not offset by consumer promotions. See n. 12, supra. See also ante, at 2585 (“at least some portion of the list price increase was reflected in a higher net price to the consumer”). Finally, to the extent there is a dispute regarding the effect of promotional activities on consumer prices for generics, the jury presumably resolved that dispute in Liggett's favor, and the Court's contrary speculation is an insufficient basis for setting aside that verdict. 15

**2605 256 As a matter of economics, the Court reminds us that price cutting is generally pro-competitive, and hence a “boon to consumers.” Ante, at 2588. This is true, however, only so long as reduced prices do not fall below cost, as the cases cited by the majority make clear. 16 When a predator deliberately engages in below-cost pricing targeted at a particular competitor over a sustained period of time, then price cutting raises a credible inference that harm to competition *257 is likely to ensue. 17 None of our cases disputes that proposition.

Also as a matter of economics, the Court insists that a predatory pricing program in an oligopoly is unlikely to succeed absent actual conspiracy. Though it has rejected a somewhat stronger version of this proposition as a rule of decision, see ante, at 2590–2592, the Court comes back to the same economic theory, relying on the supposition that an “anticompetitive minuet is most difficult to compose and to perform, even for a disciplined oligopoly,” ante, at 2590. See ante, at 2595–2597 (implausibility of tacit coordination among cigarette oligopolists in 1980's). I would suppose, however, that the professional performers who had danced the minuet for 40 to 50 years would be better able to predict whether their favorite partners would follow them in the future than would an outsider, who might not know the difference between Haydn and Mozart. 18 In any event, the jury was *258 surely entitled to **2606 infer that at the time of the price war itself, B & W reasonably believed that it could signal its intentions to its fellow oligopolists, see App. 61, assuring their continued cooperation.

Perhaps the Court's most significant error is the assumption that seems to pervade much of the final sections of its opinion: that Liggett had the burden of proving either the actuality of supracompetitive pricing, or the actuality of tacit collusion. See ante, at 2593–2595 (finding absence of actual supracompetitive pricing), 2596–2597 (finding absence of evidence suggesting actual

113 S.Ct. 2578, 125 L.Ed.2d 168, 61 USLW 4699, 1993-1 Trade Cases P 70,277

coordination). In my opinion, the jury was entitled to infer from the succession of price increases after 1985—when the prices for branded and generic cigarettes increased every six months from $33.15 and $19.75, respectively, to $46.15 and $33.75—that B & W's below-cost pricing actually produced supracompetitive prices, with the help of tacit collusion among the players. See supra, at 2604. But even if that were not so clear, the jury would surely be entitled to infer that B & W's predatory plan, in which it invested millions of dollars for the purpose of achieving an admittedly anticompetitive result, carried a “reasonable possibility” of injuring competition.

Accordingly, I respectfully dissent.

All Citations

509 U.S. 209, 113 S.Ct. 2578, 125 L.Ed.2d 168, 61 USLW 4699, 1993-1 Trade Cases P 70,277

Footnotes

*p The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See United States v. Detroit Lumber Co., 200 U.S. 321, 337, 26 S.Ct. 282, 287, 50 L.Ed. 499.

1 Because the parties in this case agree that the relevant measure of cost is average variable cost, however, we again decline to resolve the conflict among the lower courts over the appropriate measure of cost. See Cargill, Inc. v. Montfort of Colorado, Inc., 479 U.S. 104, 117–118, n. 12, 107 S.Ct. 484, 493, n. 12, 93 L.Ed.2d 427 (1986); Matsushita Elec. Industrial Co. v. Zenith Radio Corp., 475 U.S. 574, 585, n. 8, 106 S.Ct. 1348, 1355, n. 8, 89 L.Ed.2d 538 (1986).

2 This statement could well have referred to the rate at which the segment was growing relative to prior years' generic volume; this “internal” rate of growth would inevitably slow as the base volume against which it was measured grew.

1 “It shall be unlawful for any person engaged in commerce, in the course of such commerce, either directly or indirectly, to discriminate in price between different purchasers of commodities of like grade and quality ... where the effect of such discrimination may be substantially to lessen competition or tend to create a monopoly in any line of commerce, or to injure, destroy, or prevent competition with any person who either grants or knowingly receives the benefit of such discrimination, or with customers of either of them....” 15 U.S.C. § 13(a).

2 The jury gave an affirmative answer to the following special issue:

“1. Did Brown & Williamson engage in price discrimination that had a reasonable possibility of injuring competition in the cigarette market as a whole in the United States?” App. 27.

The jury made its finding after being instructed that “injury to competition” means “the injury to consumer welfare which results when a competitor is able to raise and to maintain prices in a market or well-defined submarket above competitive levels. In order to injure competition in the cigarette market as a whole, Brown & Williamson must be able to create a real possibility of both driving out rivals by loss-creating price cutting and then holding on to that advantage to recoup losses by raising and maintaining prices at higher than competitive levels.

“You must remember that the Robinson–Patman Act was designed to protect competition rather than just competitors and, therefore, injury to competition does not mean injury to a competitor. Liggett & Myers can not satisfy this element simply by showing that they were injured by Brown & Williamson's conduct. To satisfy this element, Liggett & Myers
must show, by a preponderance of the evidence, that Brown & Williamson's conduct had a reasonable possibility of injuring competition in the cigarette market and not just a reasonable possibility of injuring a competitor in the cigarette market.”  \textit{Id.}, at 829–830.

As the majority notes, the procedural posture of this case requires that we view the evidence in the light most favorable to Liggett.  \textit{Ante}, at 2582. On review of a judgment notwithstanding the verdict, the party against whom the judgment is entered “must be given the benefit of every legitimate inference that can be drawn from the evidence.”  See C. Wright & A. Miller, \textit{Federal Practice and Procedure} § 2528, pp. 563–564 (1971).

When the Court states that “[s]ubstantial evidence suggests that in recent decades, the industry reaped the benefits of prices above a competitive level,” \textit{ante}, at 2583, I assume it accepts the proposition that a reasonable jury could find abnormally high prices characteristic of this industry.

An internal B & W memorandum, dated May 15, 1984, states in part:

“Manufacturer's price increases generally were below the rate of inflation but margins improved handsomely due to favorable leaf prices and cost reductions associated with automation. For example, Brown & Williamson's variable margin increased from $2.91/M in 1972 to $8.78/M in 1981, an increase of over 200%. In 1982, the industry became much more aggressive on the pricing front, fueled by a 100% increase in the Federal Excise Tax. Brown & Williamson's variable margin increased from $10.78/M in 1982 and \textit{[sic]} to $12.61/M in 1983.

“The impact of these pricing activities on the smoking public was dramatic. The weighted average retail price of a pack of cigarettes increased 56% between 1980 and 1983 (from $.63 to $.98).” App. 127.

On June 4, 1984, B & W announced a maximum rebate of $0.30 per carton for purchases of over 8,000 cases per quarter; a week later, Liggett announced a rebate of $0.20 on comparable volumes. On June 21, B & W increased its rebate to $0.50, and a day later, Liggett went to $0.43. After three more increases, B & W settled at $0.80 per carton, while Liggett remained at $0.73. See App. 327, 420–421.

That quantity discounts are covered by the Act, and prohibited when they have the requisite effect on competition, has been firmly established since our decision in \textit{FTC v. Morton Salt Co.}, 334 U.S. 37, 42–44, 68 S.Ct. 822, 826–827, 92 L.Ed. 1196 (1948).

“\textit{Provided}, That nothing herein contained shall prevent differentials which make only due allowance for differences in the cost of manufacture, sale, or delivery resulting from the differing methods or quantities in which such commodities are to such purchasers sold or delivered.”  § 13(a).

“\textit{Provided, however}, That nothing herein contained shall prevent a seller rebutting the prima-facie case thus made by showing that his lower price or the furnishing of services or facilities to any purchaser or purchasers was made in good faith to meet an equally low price of a competitor, or the services or facilities furnished by a competitor.”  § 13(b).

The jury gave a negative answer to the following special issue:

“3. Did Brown & Williamson engage in price discrimination in good faith with the intention to meet, but not beat, the equally low net prices of Liggett Group, Inc.?” App. 27–28.

By offering its largest discounts to Liggett's 14 largest customers, App. 168–169, 174, B & W not only put its “money where the volume is,” \textit{id.}, at 402, but also applied maximum pressure to Liggett at a lesser cost to itself than would have resulted from a nondiscriminatory price cut.
It is also true that these same years, other major manufacturers entered the generic market and expanded their generic sales. Ante, at 2585. Their entry is entirely consistent with the possibility that lockstep increases in the price of generics brought them to a level that was supracompetitive, though lower than that charged on branded cigarettes.

"Q Does this mean that the price increases, which you testified are happening twice a year, are used up in these consumer promotions?

"A Not by any stretch of the imagination. Although there has been an increase in the use of this type of promotional activity over the last four or five years, the increase in that promotional activity has been far outstripped by the list price increases. The prices go up by a lot; the promotional activity, indeed, does go up. But the promotional activity has not gone up by anywhere near the magnitude of the list price increases. Further, those price increases are not warranted by increasing costs, since the manufacturing costs of making cigarettes have remained roughly constant over the last five years.” App. 509.

See text of statute, n. 1, supra.

One of the purposes of broadening the Clayton Act's competitive injury language in the Robinson–Patman Act was to provide more effective protection against predatory price-cutting. As the Attorney General's National Committee to Study the Antitrust Laws explained in its 1955 report:

“In some circumstances, to be sure, injury to even a single competitor should bring the Act into play. Predatory price cutting designed to eliminate a smaller business rival, for example, is a practice which inevitably frustrates competition by excluding competitors from the market or deliberately impairing their competitive strength. The invalidation of such deliberate price slashes for the purpose of destroying even a single competitor, moreover, accords distinct recognition to the narrower tests of ‘injury’ added to the price discrimination provisions of the Clayton Act through the 1936 Robinson–Patman amendments. The discrimination provisions in the original Clayton Act were feared by the legislators as inadequate to check the victimization of individual businessmen by predatory price cuts that nevertheless created no general impairment of competitive conditions in a wider market. To reach such destructive price cuts endangering the survival of smaller rivals of a powerful seller was an express objective of the liberalizing amendments in the ‘injury’ clause of the Robinson–Patman Act.” Report of the Attorney General's National Committee to Study the Antitrust Laws 165–166 (1955) (footnotes omitted).

In finding an absence of actual supracompetitive pricing, the Court also relies on the testimony of Liggett executives, who stated that industry prices were fair. Illustrative is the following exchange:

“Q I want to know—yes or no—sir, whether or not you say that the price you charged for branded cigarettes, which is the same price you say everybody else charged, was a fair and equitable price for that product to the American consumer.

“AA It's what the industry set, and based on that it's a fair price.” App. 396.

The problem with this testimony, and testimony like it, is that it relates to the period before the price war, as well as after, see id., at 392, when there is no real dispute but that prices were supracompetitive. (“[T]he profits in the cigarette industry are the best of any industry I've been associated with, very much so.” Ibid.) Some of the testimony cited by the Court, for instance, is that of an outside director who served only from 1977 or 1978 until 1980, see 64 Tr. 51–56, cited ante, at 2595; his belief in the competitiveness of his industry must be viewed against the “[s]ubstantial evidence suggesting that in recent decades, the industry reaped the benefits of prices above a competitive level” to which the majority itself refers, ante, at 2583.
The jury was, of course, entitled to discount the probative force of testimony from executives to the effect that there was no collusion among tobacco manufacturers, App. 397–398, and that they had appeared before a congressional committee to vouch for the competitive nature of their industry, id., at 623–631. The jury was also free to give greater weight to the documentary evidence presented, the inferences to be drawn therefrom, and the testimony of experts who agreed with the textbook characterization of the industry. See App. 640–645; R. Tennant, American Cigarette Industry 342 (1950).

In *Atlantic Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 339–340, 110 S.Ct. 1884, 1890–1891, 109 L.Ed.2d 333 (1990), for example, we noted that low prices benefit consumers “so long as they are above predatory levels.” In *Cargill, Inc. v. Monfort of Colorado, Inc.*, 479 U.S. 104, 118, 107 S.Ct. 484, 493, 93 L.Ed.2d 427 (1986), we recognized that price cutting of a predatory nature is “inimical” to competition, and limited our approving comments to pricing that is “above some measure of incremental costs.” *Id.* at 117–118, and n. 12, 107 S.Ct., at 493, n. 12 (internal quotation marks omitted).


Judge Easterbrook has made the same point:

“Wisdom lags far behind the market

“[L]awyers know less about the business than the people they represent.... The judge knows even less about the business than the lawyers.” Easterbrook, *The Limits of Antitrust*, 63 Texas L.Rev. 1, 5 (1984).
SPECTRUM SPORTS, INC., et al., Petitioners

v.

Shirley McQUILLAN, et vir, dba Sorboturf Enterprises.

No. 91–10.


Synopsis
Former distributors brought action against manufacturer and other distributors to recover for violations of the Sherman Act. The District Court entered judgment and jury verdict in favor of former distributor, and defendants appealed. The Court of Appeals for the Ninth Circuit affirmed, 907 F.2d 154. On certiorari, the Supreme Court, Justice White held that: (1) intent to monopolize is not, alone, sufficient to justify dangerous probability of success, and (2) there must be showing of relevant product in geographic markets and the defendant's economic power in that market.

Reversed and remanded.

Procedural Posture(s): On Appeal.

**885  *447 Syllabus *

Shortly after the manufacturer of sorbothane—a patented elastic polymer with shock-absorbing characteristics— informed respondents, distributors of medical, athletic, and equestrian products made with sorbothane, that it would no longer sell them the polymer, petitioner Spectrum Sports, Inc., became the national distributor of sorbothane athletic products. Respondents' business failed, and they filed suit in the District Court against petitioners and others, seeking damages for alleged violations of, inter alia, § 2 of the Sherman Act, which makes it an offense for any person to “monopolize, or attempt to monopolize, or combine or conspire ... to monopolize any part of the trade or commerce among the several States.” A jury found that the defendants violated § 2 by, in the words of the verdict sheet, “monopolizing, attempting to monopolize, and/or conspiring to monopolize.” The Court of Appeals affirmed, noting that, although the jury had not specified which of the three possible § 2 violations had occurred, the verdict stood because the evidence established a case of attempted monopolization. Relying on its earlier rulings in Lessig v. Tidewater Oil Co., 327 F.2d 459, and its progeny, the court held that the jury could have inferred two of the elements of that offense—a specific intent to achieve monopoly power and a dangerous probability of monopolization of a relevant market—from evidence showing the defendants' unfair or predatory conduct, without any proof of relevant market or the defendants' market power, and that the jury was properly instructed that it could make such inferences.

Held: Petitioners may not be liable for attempted monopolization under § 2 absent proof of a dangerous probability that they would monopolize a relevant market and specific intent to monopolize. The conduct of a single firm, governed by § 2, is unlawful “only when it threatens actual monopolization.” Copperweld Corp. v. Independence Tube Corp., 467 U.S. 752, 767, 104 S.Ct. 2731, 2739, 81 L.Ed.2d 628. Consistent with this approach, Courts of Appeals other than the court below have generally required a plaintiff in an attempted monopolization case to prove that (1) the defendant has engaged in predatory or...
anticompetitive conduct with (2) a specific intent to monopolize and (3) a dangerous probability of achieving monopoly power. Unfair or predatory conduct may be sufficient to prove the necessary intent for \( \text{*448} \) monopolize. However, intent alone is insufficient to establish the dangerous probability of success, *Swift & Co. v. United States, 196 U.S. 375, 402, 25 S.Ct. 276, 282, 49 L.Ed. 518* which requires inquiry into the relevant product and geographic market and the defendant's economic power in that market. There is little if any support in the statute or case law for Lessig's contrary interpretation of § 2. Moreover, Lessig and its progeny are inconsistent with the Sherman Act's purpose of protecting the public from the failure of the market. The law directs itself only against conduct that unfairly tends to destroy competition, and, thus, courts have been careful to avoid constructions of § 2 which might chill competition rather than foster it. The concern that § 2 might be applied so as to further anticompetitive ends is plainly not met by inquiring only whether the defendant has engaged in “unfair” or “predatory” tactics. Since the jury's instructions and the Court of Appeals' affirmance both misconstrued § 2, and since the jury's verdict did not negate the possibility that it rested on the attempt to monopolize ground alone, the case is remanded for further proceedings. Pp. 889–892.

907 F.2d 154 (CA 9 1990), reversed and remanded.

WHITE, J., delivered the opinion for a unanimous Court.

Attorneys and Law Firms

James D. Vail, Cleveland, OH, for petitioner.

Robert A. Long, Jr., DC, for U.S. as amicus curiae supporting the petitioners.

Jeffrey M. Shohet, San Diego, CA, for respondents.

Opinion

Justice WHITE delivered the opinion of the Court.

Section 2 of the Sherman Act, 26 Stat. 209, as amended, 15 U.S.C. § 2, makes it an offense for any person to “monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States....” The **887** jury in this case returned a verdict finding that petitioners had monopolized, attempted to monopolize, and/or conspired to monopolize. The District Court entered a judgment ruling \( \text{*449} \) that petitioners had violated § 2, and the Court of Appeals affirmed on the ground that petitioners had attempted to monopolize. The issue we have before us is whether the District Court and the Court of Appeals correctly defined the elements of that offense.

I

Sorbothane is a patented elastic polymer whose shock-absorbing characteristics make it useful in a variety of medical, athletic, and equestrian products. BTR, Inc. (BTR), owns the patent rights to sorbothane, and its wholly owned subsidiaries manufacture the product in the United States and Britain. Hamilton–Kent Manufacturing Company (Hamilton–Kent) and Sorbothane, Inc. (S.I.), were at all relevant times owned by BTR. S.I. was formed in 1982 to take over Hamilton–Kent's sorbothane business. \(^1\) App. to Pet. for Cert. A3. Respondents Shirley and Larry McQuillan, doing business as Sorboturf Enterprises, were regional distributors of sorbothane products from 1981 to 1983. Petitioner Spectrum Sports, Inc. (Spectrum), was also a distributor of sorbothane products. Petitioner Kenneth B. Leighton, Jr., is a co-owner of Spectrum. *Ibid.* Kenneth Leighton, Jr., is the son of Kenneth Leighton, Sr., the president of Hamilton–Kent and S.I. at all relevant times.
In 1980, respondents Shirley and Larry McQuillan signed a letter of intent with Hamilton–Kent, which then owned all manufacturing and distribution rights to sorbothane. The letter of intent granted the McQuillans exclusive rights to purchase sorbothane for use in equestrian products. Respondents were designing a horseshoe pad using sorbothane.

In 1981, Hamilton–Kent decided to establish five regional distributorships for sorbothane. Respondents were selected to be distributors of all sorbothane products, including medical products and shoe inserts, in the Southwest. Spectrum was selected as distributor for another region. Id., at A4–A5.

In January 1982, Hamilton–Kent shifted responsibility for selling medical products from five regional distributors to a single national distributor. In April 1982, Hamilton–Kent told respondents that it wanted them to relinquish their athletic shoe distributorship as a condition for retaining the right to develop and distribute equestrian products. As of May 1982, BTR had moved the sorbothane business from Hamilton–Kent to S.I. Id., at A6. In May, the marketing manager of S.I. again made clear that respondents had to sell their athletic distributorship to keep their equestrian distribution rights. At a meeting scheduled to discuss the sale of respondents' athletic distributorship to petitioner Leighton, Jr., Leighton, Jr., informed Shirley McQuillan that if she did not come to agreement with him she would be “‘looking for work.’ ” Id., at A6. Respondents refused to sell and continued to distribute athletic shoe inserts.

In the fall of 1982, Leighton, Sr., informed respondents that another concern had been appointed as the national equestrian distributor, and that they were “no longer involved in equestrian products.” Id., at A7. In January 1983, S.I. began marketing through a national distributor a sorbothane horseshoe pad allegedly indistinguishable from the one designed by respondents. Ibid. In August 1983, S.I. informed respondents that it would no longer accept their orders. Ibid. Spectrum Therapont became national distributor of sorbothane athletic shoe inserts. Pet. for Cert. 6. Respondents sought to obtain sorbothane from the BTR's British subsidiary, but were informed by that subsidiary that it would not sell sorbothane in the United States. Respondents' business failed. App. to Pet. for Cert. A8.


The case was tried to a jury, which returned a verdict against one or more of the defendants on each of the 11 alleged violations on which it was to return a verdict. All of the defendants were found to have violated § 2 by, in the words of the verdict sheet, “monopolizing, attempting to monopolize, and/or conspiring to monopolize.” App. 410. Petitioners were also found to have violated civil RICO and the California unfair practices law, but not § 1 of the Sherman Act. The jury awarded $1,743,000 in compensatory damages on each of the violations found to have occurred. This amount was trebled under § 4 of the Clayton Act. The District Court also awarded nearly $1 million in attorney's fees and denied motions for judgment notwithstanding the verdict and for a new trial.

The Court of Appeals for the Ninth Circuit affirmed the judgment in an unpublished opinion. Judgt. order reported at 907 F.2d 154 (1990). The court expressly ruled that the trial court had properly instructed the jury on the Sherman Act claims and found that the evidence supported the liability verdicts as well as the damages awards on these claims. The court then affirmed the judgment of the District Court, finding it unnecessary to rule on challenges to other violations found by the jury. App. to Pet. for Cert. A28. On the § 2 issue that petitioners present here, the Court of Appeals, noting that the jury had found that petitioners had violated § 2 without specifying whether they had monopolized, attempted to monopolize, or conspired to monopolize, held that the verdict would stand if the evidence supported any one of the three possible violations of § 2. Id., at A15. The court went on to conclude that a case of attempted monopolization had been established. The court rejected petitioners' argument

113 S.Ct. 884, 122 L.Ed.2d 247, 61 USLW 4123, 1993-1 Trade Cases P 70,096

that attempted monopolization had not been established because respondents had failed to prove that petitioners had a specific intent to monopolize **889** a relevant market. The court also held that in order to show that respondents’ **453** attempt to monopolize was likely to succeed it was not necessary to present evidence of the relevant market or of the defendants’ market power. In so doing, the Ninth Circuit relied on Lessig v. Tidewater Oil Co., 327 F.2d 459 (CA9), cert. denied, 377 U.S. 993, 84 S.Ct. 1920, 12 L.Ed.2d 1046 (1964), and its progeny. App. to Pet. for Cert. A18–A19. The Court of Appeals noted that these cases, in dealing with attempt to monopolize claims, had ruled that “if evidence of unfair or predatory conduct is presented, it may satisfy both the specific intent and dangerous probability elements of the offense, without any proof of relevant market or the defendant's market power [sic].” Id., at A19. If, however, there is insufficient evidence of unfair or predatory conduct, there must be a showing of “relevant market or the defendant's market power [sic].” Ibid. The court went on to find:

“There is sufficient evidence from which the jury could conclude that the S.I. Group and Spectrum Group engaged in unfair or predatory conduct and thus inferred that they had the specific intent and the dangerous probability of success and, therefore, McQuillan did not have to prove relevant market or the defendant’s marketing power.” Id., at A21.

The decision below, and the Lessig line of decisions on which it relies, conflicts with holdings of courts in other Circuits. Every other Court of Appeals has indicated that proving an attempt to monopolize requires proof of a dangerous probability of monopolization of a relevant market. We **454** granted certiorari, 503 U.S. 958, 112 S.Ct. 1557, 118 L.Ed.2d 206 (1992), to resolve this conflict among the Circuits. We reverse.

II

While § 1 of the Sherman Act forbids contracts or conspiracies in restraint of trade or commerce, § 2 addresses the actions of single firms that monopolize or attempt to monopolize, as well as conspiracies and combinations to monopolize. Section 2 does not define the elements of the offense of attempted monopolization. Nor is there much guidance to be had in the scant legislative history of that provision, which was added late in the legislative process. See 1 E. Kintner, Legislative History of the Federal Antitrust Laws and Related Statutes 23–25 (1978); 3 P. Areeda & D. Turner, Antitrust Law ¶ 617, pp. 39–41 (1978). The legislative history does indicate that much of the interpretation of the necessarily broad principles of the Act was to be left for the courts in particular cases. See, e.g., 21 Cong.Rec. 2460 (1890) (statement of Sen. Sherman). See also 1 **890** Kintner, supra, at 19; 3 Areeda & Turner, supra, ¶ 617, at 40.

This Court first addressed the meaning of attempt to monopolize under § 2 in Swift & Co. v. United States, 196 U.S. 375, 25 S.Ct. 276, 49 L.Ed. 518 (1905). The Court's opinion, written by Justice Holmes, contained the following passage:

**455** “Where acts are not sufficient in themselves to produce a result which the law seeks to prevent—for instance, the monopoly—but require further acts in addition to the mere forces of nature to bring that result to pass, an intent to bring it to pass is necessary in order to produce a dangerous probability that it will happen, Commonwealth v. Peaslee, 177 Massachusetts 267, 272 [59 N.E. 55, 56 (1901)]. But when that intent and the consequent dangerous probability exist, this statute, like many others and like the common law in some cases, directs itself against that dangerous probability as well as against the completed result.” Id., at 396, 25 S.Ct., at 279.

The Court went on to explain, however, that not every act done with intent to produce an unlawful result constitutes an attempt. “It is a question of proximity and degree.” Id., at 402, 25 S.Ct., at 281. Swift thus indicated that intent is necessary, but alone is not sufficient, to establish the dangerous probability of success that is the object of § 2’s prohibition of attempts. **7**

The Court's decisions since Swift have reflected the view that the plaintiff charging attempted monopolization must prove a dangerous probability of actual monopolization, which has generally required a definition of the relevant market and

113 S.Ct. 884, 122 L.Ed.2d 247, 61 USLW 4123, 1993-1 Trade Cases P 70,096

examination of market power. In Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp., 382 U.S. 172, 177, 86 S.Ct. 347, 350, 15 L.Ed.2d 247 (1965), we found that enforcement of a fraudulently obtained patent claim could violate the Sherman Act. We stated that, to establish monopolization or attempt to monopolize under § 2 of the Sherman Act, it would be necessary to appraise the exclusionary power of the illegal patent claim in terms of the relevant market for the product involved. *456 Ibid. The reason was that “[w]ithout a definition of that market there is no way to measure [the defendant's] ability to lessen or destroy competition.” Ibid.

Similarly, this Court reaffirmed in Copperweld Corp. v. Independence Tube Corp., 467 U.S. 752, 104 S.Ct. 2731, 81 L.Ed.2d 628 (1984), that “Congress authorized Sherman Act scrutiny of single firms only when they pose a danger of monopolization. Judging unilateral conduct in this manner reduces the risk that the antitrust laws will dampen the competitive zeal of a single aggressive entrepreneur.” Id., at 768, 104 S.Ct., at 2740. Thus, the conduct of a single firm, governed by § 2, “is unlawful only when it threatens actual monopolization.” Id., at 767, 104 S.Ct., at 2739. See also Lorain Journal Co. v. United States, 342 U.S. 143, 154, 72 S.Ct. 181, 187, 96 L.Ed. 162 (1951); United States v. Griffith, 334 U.S. 100, 105–106, 68 S.Ct. 941, 945, 92 L.Ed. 1236 (1948); American Tobacco Co. v. United States, 328 U.S. 781, 785, 66 S.Ct. 1125, 1127, 90 L.Ed. 1575 (1946).

The Courts of Appeals other than the Ninth Circuit have followed this approach. Consistent with our cases, it is generally required that to demonstrate attempted monopolization a plaintiff must prove (1) that the defendant has engaged in predatory or anticompetitive conduct with (2) a specific intent to monopolize and (3) a dangerous probability of achieving monopoly power. See 3 Areeda & Turner, supra, ¶ 820, at 312. In order to determine whether there is a dangerous probability of monopolization, courts have found it necessary to consider the relevant market and the defendant's ability to lessen or destroy competition in that market. *891

*457 Notwithstanding the array of authority contrary to Lessig, the Court of Appeals in this case reaffirmed its prior holdings; indeed, it did not mention either this Court's decisions discussed above or the many decisions of other Courts of Appeals reaching contrary results. Respondents urge us to affirm the decision below. We are not at all inclined, however, to embrace Lessig's interpretation of § 2, for there is little, if any, support for it in the statute or the case law, and the notion that proof of unfair or predatory conduct alone is sufficient to make out the offense of attempted monopolization is contrary to the purpose and policy of the Sherman Act.

The Lessig opinion claimed support from the language of § 2, which prohibits attempts to monopolize “any part” of commerce, and therefore forbids attempts to monopolize any appreciable segment of interstate sales of the relevant product. See United States v. Yellow Cab Co., 332 U.S. 218, 226, 67 S.Ct. 1560, 1564–1565, 91 L.Ed. 2010 (1947). The “any part” clause, however, applies to charges of monopolization as well as to attempts to monopolize, and it is beyond doubt that the former requires proof of market power in a relevant market. United States v. Grinnell Corp., 384 U.S. 563, 570–571, 86 S.Ct. 1698, 1704, 16 L.Ed.2d 778 (1966); United States v. E.I. du Pont de Nemours & Co., 351 U.S. 377, 404, 76 S.Ct. 994, 1012, 100 L.Ed. 1264 (1956). *891

In support of its determination that an inference of dangerous probability was permissible from a showing of intent, the Lessig opinion cited, and added emphasis to, this Court's reference in its opinion in Swift to “'intent and the consequent dangerous probability.'” 327 F.2d, at 474, n. 46, quoting 196 U.S., at 396, 25 S.Ct., at 279. But any question whether dangerous probability of success requires proof of more than intent alone should have been removed by the subsequent passage in Swift which stated that “not every act that may be done with intent to produce an unlawful result ... constitutes an attempt. It is a question of proximity and degree.” Id., at 402, 25 S.Ct., at 281.

The Lessig court also relied on a footnote in du Pont & Co., supra, 351 U.S., at 395, n. 23, 76 S.Ct., at 1008, n. 23, for the proposition that when the charge is attempt to monopolize, the relevant market is “not in issue.” That footnote, which appeared in analysis of the relevant market issue in du Pont, rejected the Government's reliance on several cases, noting that “the scope
of the market was not in issue” in *Story Parchment Co. v. Paterson Parchment Paper Co.*, 282 U.S. 555, 51 S.Ct. 248, 75 L.Ed. 544 (1931). That reference merely reflected the fact that, in *Story Parchment*, which was not an attempt to monopolize case, the parties did not challenge the definition of the market adopted by the lower courts. Nor was *du Pont* itself concerned with the issue in this case.

It is also our view that *Lessig* and later Ninth Circuit decisions refining and applying it are inconsistent with the policy of the Sherman Act. The purpose of the Act is **892** not to protect businesses from the working of the market; it is to protect the public from the failure of the market. The law directs itself not against conduct which is competitive, even severely so, but against conduct which unfairly tends to destroy competition itself. It does so not out of solicitude for private concerns but out of concern for the public interest. See, e.g., *Brunswick Corp. v. Pueblo Bowl–O–Mat, Inc.*, 429 U.S. 477, 488, 97 S.Ct. 690, 697, 50 L.Ed.2d 701 (1977); *Cargill, Inc. v. Monfort of Colorado, Inc.*, 479 U.S. 104, 116–117, 107 S.Ct. 484, 492–493, 93 L.Ed.2d 427 (1986); *Brown Shoe Co. v. United States*, 370 U.S. 294, 320, 82 S.Ct. 1502, 1521, 8 L.Ed.2d 510 (1962).

Thus, this Court and other courts have been careful to avoid constructions of § 2 which might chill competition, rather than foster it. It is sometimes difficult *459* to distinguish robust competition from conduct with long-term anticompetitive effects; moreover, single-firm activity is unlike concerted activity covered by § 1, which “inherently is fraught with anticompetitive risk.” *Copperweld*, 467 U.S., at 767–769, 104 S.Ct., at 2739–2740. For these reasons, § 2 makes the conduct of a single firm unlawful only when it actually monopolizes or dangerously threatens to do so. *Id.*, at 767, 104 S.Ct., at 2739. The concern that § 2 might be applied so as to further anticompetitive ends is plainly not met by inquiring only whether the defendant has engaged in “unfair” or “predatory” tactics. Such conduct may be sufficient to prove the necessary intent to monopolize, which is something more than an intent to compete vigorously, but demonstrating the dangerous probability of monopolization in an attempt case also requires inquiry into the relevant product and geographic market and the defendant's economic power in that market.

III

We hold that petitioners may not be liable for attempted monopolization under § 2 of the Sherman Act absent proof of a dangerous probability that they would monopolize a particular market and specific intent to monopolize. In this case, the trial instructions allowed the jury to infer specific intent and dangerous probability of success from the defendants' predatory conduct, without any proof of the relevant market or of a realistic probability that the defendants could achieve monopoly power in that market. In this respect, the instructions misconstrued § 2, as did the Court of Appeals in affirming the judgment of the District Court. Since the affirmance of the § 2 judgment against petitioners rested solely on the legally erroneous conclusion that petitioners had attempted to monopolize in violation of § 2 and since the jury's verdict did not negate the possibility that the § 2 verdict rested on the attempt to monopolize ground alone, the judgment *460* of the Court of Appeals is reversed, *Sunkist Growers, Inc. v. Winckler & Smith Citrus Products Co.*, 370 U.S. 19, 29–30, 82 S.Ct. 1130, 1136, 8 L.Ed.2d 305 (1962), and the case is remanded for further proceedings consistent with this opinion. 10

So ordered.

All Citations

506 U.S. 447, 113 S.Ct. 884, 122 L.Ed.2d 247, 61 USLW 4123, 1993-1 Trade Cases P 70,096
Footnotes

* The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See United States v. Detroit Lumber Co., 200 U.S. 321, 337, 26 S.Ct. 282, 287, 50 L.Ed. 499.

1 Sorbothane, Inc., was formerly called Sorbo, Inc. App. 67.

2 Two violations of § 1 were alleged, resale price maintenance and division of territories. Attempted monopolization, monopolization, and conspiracy to monopolize were charged under § 2. All in all, four alleged violations of federal law and seven alleged violations of state law were sent to the jury.

3 The special verdict form advised the jury as follows:

“The following pages identify the name of each defendant and the claims for which plaintiffs contend that the defendant is liable. If you find that any of the defendants are liable on any of the claims, you may award damages to the plaintiffs against those defendants. Should you decide to award damages, please assess damages for each defendant and each claim separately and without regard to whether you have already awarded the same damages on another claim or against another defendant. The court will insure that there is no double recovery. The verdict will not be totaled.” App. 416.

4 The District Court's jury instructions were transcribed as follows:

“In order to win on the claim of attempted monopoly, the Plaintiff must prove each of the following elements by a preponderance of the evidence: first, that the Defendants had a specific intent to achieve monopoly power in the relevant market; second, that the Defendants engaged in exclusionary or restrictive conduct in furtherance of its specific intent; third, that there was a dangerous probability that Defendants could sooner or later achieve [their] goal of monopoly power in the relevant market; fourth, that the Defendants' conduct occurred in or affected interstate commerce; and, fifth, that the Plaintiff was injured in the business or property by the Defendants' exclusionary or restrictive conduct.

.. . . .

“If the Plaintiff has shown that the Defendant engaged in predatory conduct, you may infer from that evidence the specific intent and the dangerous probability element of the offense without any proof of the relevant market or the Defendants' marketing [sic] power.” Id., at 251–252. See also App. to Pet. for Cert. A16, A20.

Our grant of certiorari was limited to the first question presented in the petition: “Whether a manufacturer's distributor expressly absolved of violating Section 1 of the Sherman Act can, without any evidence of market power or specific intent, be found liable for attempting to monopolize solely by virtue of a unique Ninth Circuit rule?” Pet. for Cert. i.

Justice Holmes confirmed that this was his interpretation of Swift in Hyde v. United States, 225 U.S. 347, 32 S.Ct. 793, 56 L.Ed. 1114 (1912). In dissenting in that case on other grounds, the Justice, citing Swift, stated that an attempt may be found where the danger of harm is very great; however, “combination, intention and overt act may all be present without amounting to a criminal attempt... There must be dangerous proximity to success.” 225 U.S., at 387–388, 32 S.Ct., at 810.


Lessig cited United States v. Yellow Cab Co., 332 U.S., at 226, 67 S.Ct., at 1564–1565, in support of its interpretation, but Yellow Cab relied on the “any part” language to support the proposition that it is immaterial how large an amount of interstate trade is affected, or how important that part of commerce is in relation to the entire amount of that type of commerce in the Nation.

Respondents conceded in their brief that the case should be remanded to the Court of Appeals if we found error in the instruction on attempt to monopolize. Brief for Respondents 45–46.

917 F.3d 147
United States Court of Appeals, Third Circuit.

FEDERAL TRADE COMMISSION, Appellant
v.
SHIRE VIROPHARMA, INC.

No. 18-1807

| Argued December 11, 2018
| (Filed: February 25, 2019)

Synopsis

Background: Federal Trade Commission (FTC) alleging that pharmaceutical manufacturer's petitioning of Food and Drug Administration (FDA) to delay approval of generic equivalents to its drug was unfair method of competition prohibited by FTC Act. The United States District Court for the District of Delaware, No. 1-17-cv-00131, Richard G. Andrews, J., 2018 WL 1401329, dismissed complaint, and FTC appealed.

Holdings: The Court of Appeals, Smith, Chief Judge, held that:

FTC Act provision permitting FTC to bring action to enjoin any entity that “is violating, or is about to violate” any provision of law it enforced was nonjurisdictional, and

FTC was not entitled to injunction barring manufacturer from engaging in allegedly unfair method of competition.

Affirmed.

Procedural Posture(s): On Appeal; Motion to Dismiss for Failure to State a Claim.

*149 On Appeal from the United States District Court for the District of Delaware, District Court No. 1-17-cv-00131, District Judge: The Honorable Richard G. Andrews

Attorneys and Law Firms

Bradley S. Albert, Meredyth Andrus, Thomas J. Dillickrath, Matthew M. Hoffman [ARGUED], June Im, Nicholas Leefer, Joel R. Marcus, Joseph Mathias, James H. Weingarten, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, DC 20580, Counsel for Appellant

J. Clayton Everett, Jr., Scott A. Stempel, Morgan Lewis & Bockius, 1111 Pennsylvania Avenue, N.W., Suite 800 North, Washington, DC 20004, Noah J. Kaufman, Morgan Lewis & Bockius, One Federal Street, Boston, MA 02110, Steven A. Reed [ARGUED], Jessica J. Taticchi, Morgan Lewis & Bockius, 1701 Market Street, Philadelphia, PA 19103, Counsel for Appellee

George P. Slover, Consumers Union, 1101 17th Street, N.W., Suite 500, Washington, DC 20036, Counsel for Amicus Appellant
Shire ViroPharma, Inc. (“Shire”), 1 manufactured and marketed the lucrative drug Vancocin, which is indicated to treat a life-threatening gastrointestinal infection. After Shire got wind that manufacturers were considering making generic equivalents to Vancocin, it inundated the United States Food and Drug Administration (“FDA”) with allegedly meritless filings to delay approval of those generics. The FDA eventually rejected Shire's filings and approved generic equivalents to Vancocin, but the filings nonetheless resulted in a high cost to consumers—Shire had delayed generic entry for years and reaped hundreds of millions of dollars in profits.

Nearly five years later—and after Shire had divested itself of Vancocin—the Federal Trade Commission (“FTC”) filed suit against Shire in the United States District Court for the District of Delaware under Section 13(b) of the Federal Trade Commission Act, 15 U.S.C. § 53(b). The FTC sought a permanent injunction and restitution, *150 alleging that Shire's petitioning was an unfair method of competition prohibited by the Act. Shire moved to dismiss, arguing that the FTC's allegations of long-past petitioning activity failed to satisfy Section 13(b)'s requirement that Shire “is violating” or “is about to violate” the law. The District Court agreed and dismissed the case.

On appeal, the FTC urges us to adopt a more expansive view of Section 13(b). According to the FTC, the phrase “is violating, or is about to violate” in Section 13(b) is satisfied by showing a past violation and a reasonable likelihood of recurrent future conduct. We reject the FTC's invitation to stretch Section 13(b) beyond its clear text. The FTC admits that Shire is not currently violating the law. And the complaint fails to allege that Shire is about to violate the law. We will therefore affirm the District Court's judgment.

I. 2

A.

A company that wishes to manufacture and market a new drug in the United States must submit to the FDA a New Drug Application (“NDA”) demonstrating the safety and efficacy of the product. 3 Usually, the NDA filer demonstrates safety and efficacy by using expensive in vivo clinical endpoint studies, where researchers provide sick patients with either the proposed drug or a placebo to compare the safety and efficacy of the drug with the placebo. See Fed. Trade Comm'n v. Actavis, Inc., 570 U.S. 136, 142, 133 S.Ct. 2223, 186 L.Ed.2d 343 (2013) (describing the “long, comprehensive, and costly testing process” underlying an NDA). After FDA approval, the manufacturer must seek approval through a supplemental NDA if it wishes to change the drug or its label.

A generic drug manufacturer need not file an NDA because it is essentially copying the approved branded drug. The generic manufacturer must instead file an Abbreviated New Drug Application (“ANDA”), which relies on the approved drug's profile.
for safety and efficacy. See id. (“The Hatch-Waxman process, by allowing the generic to piggy-back on the pioneer's approval efforts, speeds the introduction of low-cost generic drugs to market, thereby furthering drug competition.” (internal alteration, quotation marks, and citation omitted)). The generic manufacturer must demonstrate, inter alia, that the proposed generic drug is bioequivalent to the referenced branded drug. See 21 C.F.R. § 314.3(b) (defining bioequivalence as “the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalences or pharmaceutical alternatives becomes available at the site of drug action....”).

*151 B.

Shire develops, manufactures, and markets branded drugs. Until Shire divested itself of the product in 2014, this included Vancocin capsules. Vancocin capsules are an oral antibiotic used to treat Clostridium-difficile associated diarrhea, which is a serious, potentially life-threatening gastrointestinal infection. When Vancocin capsules were developed, the NDA did not include in vivo clinical endpoint studies because the capsules were an alternative delivery system to Vancocin oral solution, which the FDA already knew to be safe and effective. Instead, the NDA included in vitro dissolution data (which measures how quickly the capsules dissolve) and in vivo pharmacokinetic data (which compares the absorption of the drug in capsule form versus oral solution form).

In April 1986, the FDA approved Vancocin capsules. Shire acquired Vancocin capsules in November 2004. From then until 2011, Vancocin capsules were Shire's largest revenue-generating product. Vancocin capsules accounted for all of Shire's net revenue until 2009 and up to 53% of its net revenue in 2011. United States sales for Vancocin capsules grew from $40 million in 2003 to almost $300 million in 2011.

Generic manufacturers, attracted by Vancocin's financial success, wanted to enter the market. Vancocin was vulnerable to generic competition because it lacked both patent protection and regulatory exclusivity. One primary barrier to generic entry remained—the FDA's recommendation that generic manufacturers seeking to demonstrate bioequivalence conduct in vivo clinical endpoint studies. Ironically, these tests were more expensive and onerous than the in vitro dissolution testing and in vivo pharmacokinetic studies that had been used to gain approval of Vancocin capsules in the first place. The FDA apparently realized this inconsistency; in October 2004 it convened a public meeting of the Advisory Committee for Pharmaceutical Science (the “Advisory Committee”) to reassess bioequivalence testing for locally-acting gastrointestinal drugs like Vancocin.

Shire became increasingly concerned that the FDA might allow generic manufacturers to demonstrate bioequivalence using in vitro data. Shire thus hired a bioequivalence consultant to advise it on the FDA's likely course of action. In November 2005, the consultant confirmed Shire's suspicions, advising Shire that the FDA would likely allow generic manufacturers to submit in vitro dissolution data to establish bioequivalence to Vancocin capsules. The consultant counseled Shire to submit a citizen petition “sooner than later” but warned that without supporting clinical data, Shire “could not convince the FDA of its position against use of in vitro dissolution testing.” Compl. ¶ 45.

Shire's fear came to pass: the FDA indeed changed its position on bioequivalence testing for Vancocin capsules. In February 2006, the FDA advised a generic manufacturer that bioequivalence for Vancocin capsules could be demonstrated by in vitro dissolution testing. The FDA also shared this guidance with other generic manufacturers that inquired. In March 2007, the first generic manufacturer submitted its ANDA for Vancocin capsules. Two other generic manufacturers followed suit later that year.
C.

Not surprisingly, Shire wanted to protect its monopoly on the Vancocin market. Among its options was a citizen petition. The First Amendment guarantees individuals the right to petition the government. U.S. Const. amend. I. Consistent with that right, the Administrative Procedure Act permits any “interested person” to petition a federal agency “for the issuance, amendment, or repeal of a rule.” 5 U.S.C. § 553(e); see also 21 C.F.R. § 10.30 (FDA regulation governing citizen petitions).

The filing of a citizen petition can substantially delay approval of a generic drug. During the time period at issue here, the FDA automatically suspended ANDA approval if a branded manufacturer filed a citizen petition. The FDA is obligated to respond to every citizen petition within 180 days. Id. § 10.30(e)(5); see also 21 U.S.C. § 355(q)(1)(F). But the FDA's response need not dispose of the entire petition within that time. The FDA may deny the petition, approve it in whole or in part, provide a tentative response, or delay a decision by modifying or postponing any suggested action. See 21 C.F.R. § 10.30(e)(2)(i)–(iv).

From March 2006 to April 2012, Shire submitted a total of forty-three filings to the FDA and instituted three federal court proceedings—all allegedly to delay the approval of generic Vancocin capsules by convincing the FDA to require ANDA applicants to conduct in vivo clinical endpoint studies. Shire's filings ranged from a citizen petition and amendments thereto to public comments on other manufacturers' ANDAs. Many of these filings were around the same time Shire suspected the FDA was nearing approval of generic equivalents to Vancocin.

On April 9, 2012, the FDA rejected Shire's citizen petition. The FDA concluded that Shire's scientific challenges to the bioequivalence recommendation “lack[ed] merit” and “were unsupported.” Compl. ¶ 104 (internal quotation marks omitted); App. 77–95. On that same day the FDA approved three ANDAs for generic Vancocin capsules. Shire lost almost 70% of its unit sales for Vancocin capsules within three months.

D.

Nearly five years later, on February 7, 2017, the FTC sued Shire, seeking a permanent injunction and equitable monetary relief under Section 13(b) of the FTC Act. The FTC claimed that Shire's conduct—submitting serial, meritless filings—had harmed consumers and competition because it enabled Shire to maintain and extend its monopoly by delaying the FDA's approval of generic alternatives to Vancocin capsules. See 15 U.S.C. § 45(a).

*153 The FTC alleged that, absent an injunction, “there is a cognizable danger” that Shire will “engage in similar conduct causing future harm to competition and consumers.” Compl. ¶ 150. It based this assertion on Shire's (1) knowledge that its petitioning campaign would enrich it at the expense of consumers; (2) incentive to engage in similar conduct in the future; and (3) opportunity to engage in similar conduct in the future. As to the third point, the FTC specifically alleged that Shire “marketed and developed drug products,” namely Cinryze, “for commercial sale in the United States, and it could do so in the future.” Id. ¶¶ 8, 151.

Shire moved to dismiss the complaint, arguing that the FTC had failed to plead sufficient facts to invoke its authority under Section 13(b). Shire also contended that its petitioning activity was immune from antitrust challenge pursuant to the Noerr-Pennington doctrine. See E. R.R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 136, 81 S.Ct. 523, 5 L.Ed.2d 464 (1961); United Mine Workers of Am. v. Pennington, 381 U.S. 657, 670, 85 S.Ct. 1585, 14 L.Ed.2d 626 (1965). The FTC responded that Section 13(b) authorized its lawsuit and that Shire had engaged in sham petitioning, which is not protected by Noerr-Pennington.
The District Court granted Shire’s motion to dismiss, ruling that the FTC had failed to plead sufficient facts to show that Shire “is violating, or is about to violate” the law. The Court flatly rejected the FTC’s contention that Shire was about to violate the law merely because it had the incentive and opportunity to engage in similar conduct in the future.

The FTC filed this timely appeal.

II.

We begin by addressing whether Section 13(b)'s requirements are jurisdictional. The FTC contends that Section 13(b) is not jurisdictional while Shire argues the opposite. The District Court appears to have assumed—without expressly analyzing the issue—that Section 13(b) does not impose a jurisdictional requirement.

The Supreme Court of the United States has instructed us to assume that statutory limitations are nonjurisdictional unless Congress provides otherwise. In Arbaugh v. Y&H Corp., the Court addressed whether Title VII's definition of “employer” (which only includes those having fifteen or more employees) “affects federal-court subject-matter jurisdiction or, instead, delineates a substantive ingredient of a Title VII claim for relief.” 546 U.S. 500, 503, 126 S.Ct. 1235, 163 L.Ed.2d 1097 (2006). The Court held that it was the latter, cautioning courts against “drive-by jurisdictional rulings” that fail to actually assess “whether the federal court had authority to adjudicate the claim in suit.” Id. at 511, 126 S.Ct. 1235 (citation omitted).

The Supreme Court reiterated that a plaintiff obtains the “basic statutory *grant[ ]*” of subject matter jurisdiction in 28 U.S.C. § 1331 by pleading a colorable claim that arises under the Constitution or the laws of the United States. Id. at 513, 126 S.Ct. 1235. The plaintiff in Arbaugh had invoked federal question jurisdiction by pleading a claim under Title VII. Id. The Court held that the fifteen-employee threshold went to the merits of the Title VII claim, explaining that Congress had not clearly delineated it as a jurisdictional requirement. Id. at 514–16, 126 S.Ct. 1235. The Supreme Court created a “readily administrable bright line”—“when Congress does not rank a statutory limitation on coverage as jurisdictional, courts should treat the restriction as nonjurisdictional in character.” Id. at 516, 126 S.Ct. 1235.

Under the standard announced in Arbaugh, Section 13(b)'s “is” or “is about to violate” requirement is nonjurisdictional. Section 13(b) provides, in relevant part:

Whenever the [FTC] has reason to believe—

(1) that any person, partnership, or corporation *is violating, or is about to violate*, any provision of law enforced by the [FTC,] and

(2) that the enjoining thereof pending the issuance of a complaint by the [FTC] and until such complaint is dismissed by the [FTC] or set aside by the court on review, or until the order of the [FTC] made thereon has become final, would be in the interest of the public—

the [FTC] ... may bring suit in a district court of the United States to enjoin any such act or practice.


The FTC's claim arises under a law of the United States—15 U.S.C. § 53(b). It thus falls within the general grant of jurisdiction in § 1331. The District Court also had jurisdiction under 28 U.S.C. §§ 1337(a) and 1345.
Section 13(b) includes no indicia that Congress intended to “rank a statutory limitation ... as jurisdictional”; as such, we must follow the Supreme Court’s “readily administrable bright line” rule and treat the statutory language as nonjurisdictional. *Arbaugh*, 546 U.S. at 516, 126 S.Ct. 1235. Whether a person “is violating, or is about to violate” the law relates to the merits of a Section 13(b) claim, and does not indicate that Congress intended to strip district courts of their authority to resolve the FTC’s claim. Because “nothing in [Section 13(b)] displays any intent to withdraw federal jurisdiction ... we will not presume that the statute means what it neither says nor fairly implies.” *Verizon Md. Inc. v. Pub. Serv. Comm’n of Md.*, 535 U.S. 635, 644, 122 S.Ct. 1753, 152 L.Ed.2d 871 (2002).

We conclude that the District Court had jurisdiction pursuant to 28 U.S.C. §§ 1331, 1337(a), and 1345.

III. 12

A.

The FTC Act declares “[u]nfair methods of competition in or affecting commerce” to be unlawful, 15 U.S.C. § 45(a)(1), and directs the FTC to prevent violations of the Act, *id.* § 45(a)(2). The FTC has multiple instruments in its toolbox to combat unfair methods of competition; among these are administrative proceedings and lawsuits in federal court. *See id.* § 45(b), 53(b).

Section 5(b), the FTC’s administrative remedy, is its traditional enforcement tool. *See id.* § 45(b). Since its inception, the FTC Act has provided for administrative proceedings to remedy unfair methods of competition. Federal Trade Commission Act § 5, 38 Stat. 719 (1914) (current version at 15 U.S.C. § 45(b) (2018)). If the FTC has “reason to believe” that a person, partnership, or corporation “has been or is using” unfair methods of competition, the FTC can issue an administrative complaint “stating its charges in that respect.” 15 U.S.C. § 45(b). If after receiving the FTC’s complaint the respondent contests the charges, the parties adjudicate in a trial-type proceeding in front of an administrative law judge (“ALJ”). Either party may appeal the ALJ’s decision. If the FTC believes the respondent is violating the law, it issues a written report and serves a cease and desist order upon the respondent. *Id.* The respondent has sixty days to seek review “in the appropriate court of appeals.” *Id.*

In addition to cease and desist orders, Section 5 provides for limited monetary remedies. If a respondent violates a cease and desist order, the FTC may seek a civil penalty of no more than $ 10,000 per violation. *Id.* § 45(l). The civil penalty is recoverable in a “civil action brought by the Attorney General.” *Id.* The FTC may also file a civil action to recover a penalty for knowing violations of rules “respecting unfair or deceptive acts or practices.” *Id.* § 45(m)(1)(A). In these actions the District Court is permitted “to grant mandatory injunctions and such other and further equitable relief” as appropriate to enforce the FTC’s final order. *Id.* § 45(l).

Section 13 authorizes the FTC—in certain circumstances—to file suit in federal district court. Unlike Section 5, Section 13 was not part of the original FTC Act. Rather, Section 13(b) was added later in an effort to solve one of the main problems of the FTC’s relatively slow-moving administrative regime—the need to quickly enjoin ongoing or imminent illegal conduct. In Section 5 proceedings, the FTC must prevail to obtain a cease and desist order. *See id.* § 45(b). Even if the FTC issues a cease and desist order, it must seek a court’s aid in enforcing the order. *Id.* § 45(l) To remedy this shortcoming and allow a quicker response, Congress amended the FTC Act in 1973 to allow the FTC to obtain a temporary restraining order or preliminary injunction in federal court whenever it “has reason to believe” that violations of the FTC Act are occurring or are about to occur. *Id.* § 53(b). Section 13(b) thus empowers the FTC to speedily address ongoing or impending illegal conduct, rather than wait for an administrative proceeding to conclude. *See id.*
B.

The crux of the FTC’s claim is that it is entitled to pursue immediate relief in the District Court under Section 13(b), rather than via the administrative remedy set forth in Section 5. We begin with the text of the FTC Act. See *156 Murphy v. Millennium Radio Grp. LLC, 650 F.3d 295, 302 (3d Cir. 2011) (“When the statute's language is plain, the sole function of the courts—at least where the disposition required by the [text] is not absurd—is to enforce it according to its terms.”) (internal quotation marks omitted). Section 13(b) provides, in relevant part,

Whenever the [FTC] has reason to believe—

(1) that any person, partnership, or corporation is violating, or is about to violate, any provision of law enforced by [the FTC], and

(2) that the enjoining thereof pending the issuance of a complaint by the [FTC] and until such complaint is dismissed by the [FTC] or set aside by the court on review, or until the order of the [FTC] made thereon has become final, would be in the interest of the public—

the [FTC] by any of its attorneys designated by it for such purpose may bring suit in a district court of the United States to enjoin any such act or practice. Upon a proper showing that, weighing the equities and considering the [FTC]’s likelihood of ultimate success, such action would be in the public interest, and after notice to the defendant, a temporary restraining order or a preliminary injunction may be granted without bond: Provided, however, That if a complaint is not filed within such period (not exceeding 20 days) as may be specified by the court after issuance of the temporary restraining order or preliminary injunction, the order or injunction shall be dissolved by the court and be of no further force and effect: Provided further, That in proper cases the [FTC] may seek, and after proper proof, the court may issue, a permanent injunction.


Section 13(b) requires that the FTC have reason to believe a wrongdoer “is violating” or “is about to violate” the law. Id. § 53(b)(1). We conclude that this language is unambiguous; it prohibits existing or impending conduct. Simply put, Section 13(b) does not permit the FTC to bring a claim based on long-past conduct without some evidence that the defendant “is” committing or “is about to” commit another violation.

The plain language of Section 13(b) is reinforced by its history. “Generally, where the text of a statute is unambiguous, the statute should be enforced as written and only the most extraordinary showing of contrary intentions in the legislative history will justify a departure from that language.” Millennium Radio Grp. LLC, 650 F.3d at 302 (internal quotation marks omitted). When Congress added Section 13(b), the provision was expected to be used for obtaining injunctions against illegal conduct pending completion of FTC administrative hearings. See S. Rep. No. 93-151, at 30 (1973) (“The purpose of [Section 13(b)] is to permit the [FTC] to bring an immediate halt to unfair or deceptive acts or practices when ... [a]t the present time such practices might continue for several years until agency action is completed.”). The provision was not designed to address hypothetical conduct or the mere suspicion that such conduct may yet occur. Cf. id. (explaining that Section 13(b) is meant to “bring an immediate halt to unfair or deceptive acts or practices...”). Nor was it meant to duplicate Section 5, which already prohibits past conduct.

C.
The FTC's arguments to the contrary are unconvincing. The FTC contends that relief under Section 13(b) is appropriate when it shows a reasonable likelihood that past violations will recur. In other words, "when a defendant has already violated the law but the illegal conduct has ceased, injunctive relief should be granted if 'there exists some cognizable danger of recurrent violation.' " Br. of Appellant 21 (quoting United States v. W.T. Grant Co., 345 U.S. 629, 633, 73 S.Ct. 894, 97 L.Ed. 1303 (1953)).

The FTC borrows its "likelihood of recurrence" standard from the common law standard for an award of injunctive relief. A party can generally obtain injunctive relief for past conduct that is likely to recur; the wrongdoer cannot avoid an injunction by voluntarily ceasing its illegal conduct. W.T. Grant Co., 345 U.S. at 632, 73 S.Ct. 894. Although injunctive relief can survive discontinuance of the illegal conduct, "the moving party must satisfy the court that relief is needed. The necessary determination is that there exists some cognizable danger of recurrent violation, something more than the mere possibility which serves to keep the case alive." Id. at 633, 73 S.Ct. 894.

The FTC insists that other courts have "consistently" applied the likelihood of recurrence standard in Section 13(b) cases. Br. of Appellant 21–22. This is true, and unsurprising, given that Section 13(b) explicitly authorizes the FTC to obtain injunctions. But none of the cases cited by the FTC considers the issue presented here—the meaning of Section 13(b)'s threshold requirement that a party "is" violating or "is about to" violate the law.

The FTC next protests that our interpretation of "is about to violate" would make it harder to get in the courthouse door than to win injunctive relief. 15 The FTC contends that the likelihood of recurrence standard—which applies when a court is considering whether to grant or deny injunctive relief—must be the sole standard to plead a Section 13(b) claim. But the FTC cannot overcome Congress's plain language in Section 13(b), which requires the FTC to plead a Section 13(b) claim. The FTC also places much weight on cases interpreting the Securities Act of 1933 and the Securities Exchange Act of 1934. These Acts permit the Securities Exchange Commission to seek injunctive relief in federal court when a defendant "is engaged" or is "about to engage" in a violation of securities laws. 15 U.S.C. §§ 77t(b) and 78u(d)(1). We reject the FTC's invitation to import the interpretation of "is" or "is about to" contained in cases interpreting the securities laws. We "look to other statutes pertaining to the same subject matter which contain similar terms" only if "the ordinary meaning of a statute and the statute's legislative history fail to provide sufficient guidance to a term's meaning." Liberty Lincoln-Mercury, Inc. v. Ford Motor Co., 171 F.3d 818, 823 (3d Cir. 1999). Here, the plain language of Section 13(b) answers the question for us—"is about to violate"
means something more than a past violation and a likelihood of recurrence. If we were in doubt, the structure and history of the
FTC Act support our interpretation. Moreover, the statutory scheme—the addition of Section 13(b) to cure a shortcoming
of Section 5(b)—is not similar to the securities laws, which have always permitted suits for injunctions. See also Amicus Br. of
Washington Legal Foundation 9 (“While several other statutes include language similar to the FTC’s ‘about to violate’ language,
none of those statutes include agency-litigating authority that even remotely resembles the overall structure and history of
the FTC Act.”).

Finally, the FTC trots out the old adage that a remedial statute like the FTC Act should be construed broadly. Because Section
13(b)'s “is” or “is about to” requirement allegedly conflicts with the remedial purpose of the FTC Act, the FTC says we should
disregard the plain meaning of that language. Of course, none of the authority the FTC cites stands for the broad proposition
that we can ignore clear statutory language if it does not promote a remedial interpretation. See Touche Ross & Co. v. Redington,
442 U.S. 560, 578, 99 S.Ct. 2479, 61 L.Ed.2d 82 (1979) (explaining that “generalized references” to “remedial purposes” of a
statute will “not justify reading a provision more broadly than its language and the statutory scheme reasonably permit” (internal
quotation marks omitted)).

The FTC points to a parade of horribles that it predicts will result if we uphold the District Court's decision. See, e.g., Br. of
*159 Appellant 35 (“Limiting the FTC's Section 13(b) authority to cases of ongoing or imminent violation would make it easy
for wrongdoers to evade Congress' purposes in creating the regime. As soon as a potential defendant got wind that the FTC was
investigating its activities, it could simply stop those activities and render itself immune from suit in federal court unless the
FTC could allege and prove an imminent re-violation.”). But there is no reason to believe that our decision today unnecessarily
restricts the FTC's ability to address wrongdoing. Section 5 authorizes administrative proceedings based on past violations.
And, of course, if the FTC believes that a wrongdoer is “about to violate” the law during the pendency of an administrative
proceeding, it could then come to court and obtain an injunction under Section 13(b).

The FTC's understandable preference for litigating under Section 13(b), rather than in an administrative proceeding, does not
justify its expansion of the statutory language. If the FTC wants to recover for a past violation—where an entity “has been”
violating the law—it must use Section 5(b). 15 U.S.C. § 45(b). If the FTC instead chooses to use Section 13(b), it must plead
that a violation of the law “is” occurring or “is about to” occur. Id. § 53(b). Here, the FTC wants to use the most advantageous
aspects of each statutory provision—to punish Shire for a past violation using the less onerous enforcement mechanism. But
the FTC's attempt to squeeze Shire's conduct into the “about to violate” category distorts Section 13(b) beyond its intended
purpose. Section 13(b) cannot accommodate the FTC's interpretation—that “about to violate” means only that a violation could
recur at some future point.

In short, we reject the FTC's contention that Section 13(b)'s “is violating” or “is about to violate” language can be satisfied by
showing a violation in the distant past and a vague and generalized likelihood of recurrent conduct. Instead, “is” or “is about
to violate” means what it says—the FTC must make a showing that a defendant is violating or is about to violate the law.

D.

Here, the FTC never initiated Section 5 proceedings against Shire. Instead, the FTC waited until five years after Shire had
stopped its allegedly illegal conduct before seeking an injunction under Section 13(b). Viewed under the correct standard, the
FTC's complaint fails to allege that Shire “is violating” or “is about to violate” the law. The FTC does not contest that
Shire is not currently violating the law. Indeed, Shire divested itself of Vancocin in 2014, two years after generic competition
entered the market.
Instead, the FTC relies on Section 13(b)'s “is about to violate” language. The few factual allegations in the FTC's forty-five page complaint that suggest Shire “is about to violate” the law are woefully inadequate to state a claim under Section 13(b). The FTC alleges generally that Shire “is engaged in the business of, among other things, developing, manufacturing, and marketing branded drug products, including inter alia, Cinryze.” Compl. ¶ 8. As to the likelihood that Shire will engage in illegal behavior, the FTC alleges, “[a]bsent an injunction, there is a cognizable danger that [Shire] will engage in similar conduct causing future harm to competition and consumers. [Shire] knowingly carried out its anticompetitive and meritless petitioning campaign to preserve its monopoly profits. It did so conscious of the fact that this conduct would greatly enrich it at the expense of consumers.” Id. ¶ 150. Without mentioning Cinryze by name, the FTC alleges that Shire “has the incentive and opportunity to continue to engage in similar conduct in the future. At all relevant times, [Shire] marketed and developed drug products for commercial sale in the United States, and it could do so in the future. Consequently, [Shire] has the incentive to obstruct or delay competition to these or other products.” Id. ¶ 151.

The District Court concluded that these vague allegations failed to “plausibly suggest [Shire] is ‘about to violate’ any law enforced by the FTC, particularly when the alleged misconduct ceased almost five years before filing of the complaint.” Op. 158. We agree. Taking the factual allegations in the complaint as true, Shire stopped its sham petitioning campaign in 2012 when the FDA approved generic equivalents to Vancocin. The complaint contains no allegations that Shire engaged in sham petitioning in the five-year gap between the 2012 cessation in petitioning and the 2017 lawsuit. The complaint also lacks specific allegations that Shire is “about to violate” the law by petitioning as to Cinryze, the only other drug mentioned.

At oral argument in the District Court, the FTC provided more support for its argument that Shire “is about to violate” the law. The FTC explained that Shire is “perfectly positioned” to commit violations in the future because it is already marketing a “blockbuster drug” that is in the pipeline. Id. at 11. That drug, Cinryze, is not ripe for generic entry but has “the same type of significance as Vancocin....” Id. We need not consider whether these allegations might satisfy the pleading standard. None of these facts—other than that Shire markets Cinryze—are pleaded in the complaint, which the FTC chose not to amend. Based upon the pleading before us, we conclude that the FTC has failed to plead that Shire is “about to violate” any law.

In this case, given the paucity of allegations in the complaint, the FTC fails to state a claim under any reasonable definition of “about to violate.” Whatever the outer reach of “about to violate” may be, the facts in this case do not approach it. We therefore leave for another day the exact confines of Section 13(b)'s “about to violate” language.

*161 IV.

Under Section 13(b) of the FTC Act, the FTC must plead that Shire “is” violating or “is about to” violate the law. But Shire indisputably is not currently violating the law, nor is it alleged to be poised to do so anytime in the foreseeable future. The FTC thus fails to state a claim upon which relief can be granted. We will affirm the District Court's judgment.

The FTC's improper use of Section 13(b) to pursue long-past petitioning has the potential to discourage lawful petitioning activity by interested citizens—activity that is protected by the First Amendment. Because we affirm the District Court's judgment dismissing the complaint, we need not address the issue further but suggest that the FTC be mindful of such First Amendment concerns.

All Citations

917 F.3d 147, 2019-1 Trade Cases P 80,681
Footnotes

1 Shire ViroPharma, Inc. is the corporate successor to ViroPharma, which it acquired in 2014—after the petitioning activity at issue in this case ceased.

2 We derive the facts of this case from the FTC’s complaint. In our review of the grant of the motion to dismiss, we take the allegations to be true and construe them in the light most favorable to the FTC. *In re: Tower Air, Inc.*, 416 F.3d 229, 232 n.1 (3d Cir. 2005).


4 The FDA has flexibility in determining how a manufacturer must establish bioequivalence. See, e.g., 21 C.F.R. § 320.24(a) (providing that the FDA may require either *in vivo* or *in vitro* studies to demonstrate bioequivalence).


6 The Advisory Committee is a body of sixteen independent experts from academia, non-profits, and hospitals. These experts are “knowledgeable in the fields of pharmaceutical sciences, clinical pharmacology, and gastrointestinal diseases.” Compl. ¶ 85.

7 Although inapplicable to Shire’s citizen petition, Congress passed the Food and Drug Administration Amendments Act of 2007 to assuage the FDA’s fear that many brand manufacturers’ citizen petitions were meritless attempts to delay generic competition. See 21 U.S.C. § 355(q). Post-2007, the FDA cannot delay ANDA approval due to a citizen petition unless “a delay is necessary to protect the public health.” *Id.* § 355(q)(1)(A)(ii). Under the amendment, the FDA may also deny a citizen petition filed “with the primary purpose of delaying” ANDA approval that “does not on its face raise valid scientific or regulatory issues.” *Id.* § 355(q)(1)(E).

8 This time period has since been shortened to 150 days. 21 C.F.R. § 10.30(e)(5).

9 Shire did not prevail in any of its lawsuits, which were either dismissed or withdrawn.

10 Despite the District Court’s grant of Shire’s motion to dismiss—which was couched in jurisdictional terms—the Court also reached Shire’s *Noerr-Pennington* defense. The Court declined to dismiss the case on these grounds, explaining that the allegations in the complaint were sufficient to invoke the sham petitioning exception—at least at the pleading stage. Because we affirm the District Court’s dismissal, Shire’s *Noerr-Pennington* defense is not before us on appeal.

11 The District Court’s opinion was murky on this point, citing both Rule 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure. At several points the District Court couched its inquiry as jurisdictional, yet still addressed the merits of Shire’s *Noerr-Pennington* defense. Regardless of the District Court’s conclusion, our review is plenary.
We exercise jurisdiction under 28 U.S.C. § 1291. Because Section 13(b)'s requirements are nonjurisdictional, we consider the dismissal to be under Rule 12(b)(6) of the Federal Rules of Civil Procedure. We exercise plenary review over the District Court's order granting a motion to dismiss for failure to state a claim. Mariotti v. Mariotti Bldg. Prods., Inc., 714 F.3d 761, 765 (3d Cir. 2013). We accept “all well-pleaded allegations in the complaint as true and view[ ] them in the light most favorable to the plaintiff.” Id. The movant can obtain relief only if the complaint's allegations, “however true, could not raise a claim of entitlement to relief.” Id. (alteration and internal quotation marks omitted).

The appropriate court of appeals is “any circuit where the method of competition ... was used or where [the respondent] resides or carries on business.” 15 U.S.C. § 45(c).

Although the result in Evans Products Co. cuts against the FTC, the Commission tries to rely on portions of the Ninth Circuit's reasoning. The Ninth Circuit, however, did not interpret “about to violate.” See Fed. Trade Comm'n v. Evans Prods. Co., 775 F.2d 1084, 1086 (9th Cir. 1985). Instead, it gave Chevron deference to the FTC's interpretation of a different part of Section 13(b)—the so-called permanent injunction proviso. See id. The FTC claimed that the permanent injunction proviso was a standalone cause of action that authorized it to obtain a permanent injunction against violations of any provision of law it enforced. See id. Here, however, the FTC has expressly disclaimed reliance on the permanent injunction proviso, see Br. of Appellant 23 n.8, making the FTC's arguments relying on Evans Products Co. at best inapposite and at worst misleading.

The FTC argues that the District Court erred by imposing a “higher” pleading threshold of “imminent recurrence.” Br. of Appellant 22. The FTC is wrong. The District Court never imposed an imminence requirement. In fact, it didn't even use the word “imminent” in its opinion. The Court held that the factual allegations in the FTC's complaint failed to “plausibly suggest [Shire] is ‘about to violate’ any law enforced by the FTC, particularly when the alleged misconduct ceased almost five years before filing of the complaint.” Op. 160.

The FTC also claims that the District Court's interpretation could interfere with other statutes that contain similar language. Given the unique history and structure of the FTC Act, we consider this fear unfounded.

The FTC also asserts that Section 13(b)'s “reason to believe” language confers upon it unreviewable discretion to file suit. See 15 U.S.C. § 53(b) (“Whenever the Commission has reason to believe—(1) that any person, partnership, or corporation is violating, or is about to violate, any provision of law ... [the FTC] may bring suit in a district court of the United States to enjoin any such act or practice.”) (emphasis added)). We decline to consider this argument because the FTC failed to raise it in the District Court. Garza v. Citigroup Inc., 881 F.3d 277, 284 (3d Cir. 2018) (“It is well established that arguments not raised before the District Court are waived on appeal.” (internal citation omitted)). Even if this argument were not waived, we would find it unpersuasive. Here, there is no evidence to support the FTC's “reason to believe” Shire is violating or is about to violate the law.

At oral argument in the District Court, the FTC explained that it “generally” pursues administrative proceedings and a preliminary injunction simultaneously. App. 381. It is unclear why the FTC did not use that strategy here, particularly when Shire's allegedly illegal conduct ceased long before the FTC filed suit.

We also reject the FTC's standalone claim for equitable monetary relief. Assuming that such relief is available under Section 13(b), the FTC must still meet the “is” or “is about to” requirement.
Synopsis

Labor union sued contractor's association, with which it had entered into bargaining agreement, and association members and others charged with conspiracy to restrain union's business activities in violation of the Sherman Act. The United States District Court for the Northern District of California, Robert F. Peckham, J., 404 F.Supp. 1067, dismissed for failure to state a claim. The Court of Appeals for the Ninth Circuit, 648 F.2d 527, affirmed in part and reversed in part. Certiorari was granted. The Supreme Court, Justice Stevens, held that complaint alleging that defendants coerced certain third parties and some of the association's members to enter into business relationships with nonunion contractors and subcontractors, thereby adversely affecting trade of certain unionized firms and restraining unions' business activities did not sufficiently allege that the union was "injured in [its] business or property" by reason of anything forbidden in the antitrust laws.

Judgment of Court of Appeals reversed.

Justice Marshall filed dissenting opinion.

Procedural Posture(s): Motion to Dismiss for Failure to State a Claim.

**898 Syllabus**

Petitioner multiemployer association and respondents (collectively the Union) are **899 parties to collective-bargaining agreements governing the terms and conditions of employment in construction-related industries in California. The Union filed suit in Federal District Court, alleging that petitioner and its members, in violation of the antitrust laws, coerced certain third parties and some of petitioner's members to enter into business relationships with nonunion contractors and subcontractors, and thus adversely affected the trade of certain unionized firms, thereby restraining the Union's business activities. Treble damages were sought under § 4 of the Clayton Act, which authorizes recovery of such damages by "any person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws." The District Court dismissed the complaint as insufficient to allege a cause of action for treble damages under § 4. The Court of Appeals reversed.

*Held:* Based on the allegations of the complaint, the Union was not a person injured by reason of a violation of the antitrust laws within the meaning of § 4 of the Clayton Act. Pp. 902–913.
(a) Even though coercion allegedly directed by petitioner at third parties in order to restrain the trade of “certain” contractors and subcontractors may have been unlawful, it does not necessarily follow that the Union is a person injured by reason of a violation of the antitrust laws within the meaning of § 4. Pp. 902–904.

(b) The question whether the Union may recover for the alleged injury cannot be answered by literal reference to § 4’s broad language. Instead, as was required in common-law damages litigation in 1890 when § 4’s predecessor was enacted as § 7 of the Sherman Act, the question requires an evaluation of the Union's harm, the petitioner's alleged wrongdoing, and the relationship between them. Pp. 904–907.

(c) The Union's allegations of consequential harm resulting from a violation of the antitrust laws, although buttressed by an allegation of intent to harm the Union, are insufficient as a matter of law. Other relevant factors—the nature of the alleged injury to the Union, which is neither a consumer nor a competitor in the market in which trade was allegedly restrained, the tenuous and speculative character of the causal relationship between the Union's alleged injury and the alleged restraint, the potential for duplicative recovery or complex apportionment of damages, and the existence of more direct victims of the alleged conspiracy—weigh heavily against judicial enforcement of the Union's antitrust claim. Pp. 907–913.

648 F.2d 527 (9th Cir.1983), reversed.

Attorneys and Law Firms

*520 James P. Watson argued the cause for petitioner. With him on the briefs was George M. Cox.

Victor J. Van Bourg argued the cause and filed a brief for respondents.*

* Briefs of amici curiae urging reversal were filed by Solicitor General Lee, Assistant Attorney General Baxter, Deputy Solicitor General Wallace, Elinor Hadley Stillman, Robert B. Nicholson, and Robert J. Wiggers for the United States; by Peter G. Nash for the Associated General Contractors of America, Inc.; and by Edward B. Miller and Stephen A. Bokat for the Chamber of Commerce of the United States.

J. Albert Woll, Laurence Gold, and George Kaufmann filed briefs for the American Federation of Labor and Congress of Industrial Organization as amici curiae urging affirmance.

Kenneth E. Ristau, Jr., and David A. Cathcart filed a brief for the Pacific Maritime Association as amici curiae.

Opinion

Justice STEVENS delivered the opinion of the Court.

This case arises out of a dispute between parties to a multiemployer collective bargaining agreement. The plaintiff unions allege that, in violation of the antitrust laws, the multiemployer association and its members coerced certain third parties, as well as some of the association's members, to enter into business relationships with nonunion firms. This coercion, according to the complaint, adversely affected the trade of certain unionized firms and thereby restrained the business activities of the unions. The question presented is whether the complaint sufficiently alleges that the unions have been “injured in [their] business or property by reason of anything forbidden in the antitrust laws” and may therefore recover treble damages under § 4 of the Clayton Act. 15 U.S.C. § 15. Unlike the majority of the Court of Appeals for the Ninth Circuit, we agree with the District Court's conclusion that the complaint is insufficient.
I

The two named plaintiffs (the “Union”)—the California State Council of Carpenters and the Carpenters 46 Northern Counties **900 Conference Board—are affiliated with the United Brotherhood of Carpenters and Joiners of America, AFL–CIO. The plaintiffs represent more than 50,000 individuals employed by the defendants in the carpentry, drywall, pile driving, and related industries throughout the state of California. The Union's complaint is filed as a class action on behalf of numerous affiliated local unions and district councils. The defendants are Associated General Contractors of California, Inc. ("Associated"), a membership corporation composed of various building and construction contractors, approximately 250 members of Associated who are identified by name in an exhibit attached to the complaint, and 1,000 unidentified co-conspirators.

The Union and Associated, and their respective predecessors, have been parties to collective bargaining agreements governing the terms and conditions of employment in construction-related industries in California for over 25 years. The wages and other benefits paid pursuant to these agreements amount to more than $750,000,000 per year. In addition, approximately 3,000 contractors who are not members of Associated have entered into separate “memorandum agreements” with the Union, which bind them to the terms of the master collective bargaining agreements between the Union and Associated. The amended complaint does not *522 state the number of nonsignatory employers or the number of nonunion employees who are active in the relevant market.

In paragraphs 23 and 24 of the amended complaint, the Union alleges the factual basis for five different damages claims. Paragraph 23 alleges generally that the defendants conspired to abrogate and weaken the collective bargaining relationship between the Union and the signatory employers. In seven subsections, paragraph 24 sets forth activities allegedly committed pursuant to the conspiracy. The most specific allegations relate to the labor relations between the parties. **901 Paragraph 25 describes the alleged “purpose and effect” of these activities: first, “to weaken, destroy, and restrain the trade of certain contractors,” who were either members of Associated or memorandum contractors who had signed agreements with the Union; and second, to restrain “the free exercise of the business activities of plaintiffs and each of them.” **901 Plaintiffs claim that these alleged antitrust violations *524 caused them $25,000,000 in damages. *524 The complaint does not identify any specific component of this damage claim.

After hearing “lengthy oral argument” and after receiving two sets of written briefs, one filed before and the second filed after this Court's decision in Connell Construction Co. v. Plumbers & Steamfitters, 421 U.S. 616, 95 S.Ct. 1830, 44 L.Ed.2d 418 (1975), the District Court dismissed the complaint, including the federal antitrust claim. 404 F.Supp. 1067 (ND Cal.1975).
The court observed that the complaint alleged “a rather vague, general conspiracy,” and that the allegations “appear typical of disputes a union might have with an employer,” which in the normal course are resolved by grievance and arbitration or by the NLRB. *Id.*, at 1069. Without seeking to clarify or further amend the first amended complaint, the Union filed its notice of appeal on October 9, 1975.

Over five years later, on November 20, 1980, the Court of Appeals reversed the District Court's dismissal of the Union's federal antitrust claim. 648 F.2d 527 (CA9 1980). The majority *525 of the Court of Appeals disagreed with the District Court's characterization of the antitrust claim; it adopted a construction of the amended complaint which is somewhat broader than the allegations in the pleading itself. *526 The Court of **902 Appeals held (1) that a Sherman Act violation—a group boycott—had been alleged, *ibid.*; (2) that the defendants' conduct was not within the antitrust exemption for labor activities, *id.*, at 532–536; and (3) that the plaintiffs had standing to recover damages for the injury to their own business activities occasioned by the defendants' “industry-wide boycott against all subcontractors with whom the Unions had signed agreements, ...” *Id.*, at 537. In support of the Union's standing, the majority reasoned that the Union was within the area of the economy endangered by a breakdown of competitive conditions, not only because injury to the Union was a foreseeable consequence of the antitrust violation, but also because that injury was specifically intended by the defendants. The court noted that its conclusion was consistent with other cases holding that union organizational *526* and representational activities constitute a form of business protected by the antitrust laws. *528

II

As the case comes to us, we must assume that the Union can prove the facts alleged in its amended complaint. It is not, however, proper to assume that the Union can prove facts that it has not alleged or that the defendants have violated the antitrust laws in ways that have not been alleged.

We first note that the Union's most specific claims of injury involve matters that are not subject to review under the antitrust laws. The amended complaint alleges that the defendants have breached their collective bargaining agreements in various ways, and that they have manipulated their corporate names and corporate status in order to divert business to nonunion divisions or firms that they actually control. Such deceptive diversion of business to the nonunion portion of a so-called “double-breasted” operation might constitute a breach of contract, an unfair labor practice, or perhaps even a *527 common-law fraud or deceit, but in the context of the bargaining relationship between the parties to this litigation, such activities are plainly not subject to review under the federal antitrust laws. *528 Similarly, the charge that the defendants “advocated, encouraged, induced, and aided nonmembers ... to refuse **903 to enter into collective bargaining relationships” with the Union (¶ 23(3)) does not describe an antitrust violation.

The Union's antitrust claims arise from alleged restraints caused by defendants in the market for construction contracting and subcontracting. *528 The complaint alleges that defendants “coerced” *528 two classes of persons: (1) landowners and others who let construction contracts, *i.e.*, the defendants' customers and potential customers; and (2) general contractors, *i.e.*, defendants' competitors and defendants themselves. Coercion against the members of both classes was designed to induce them to give some of their business—but not necessarily all of it—to nonunion firms. Although the pleading does not allege that the coercive conduct increased the aggregate share of nonunion firms in the market, it does allege that defendants' activities weakened and restrained the trade “of certain contractors.” See n. 4, *supra*. Thus, particular victims of coercion may have diverted particular contracts to nonunion firms and thereby caused certain unionized subcontractors to lose some business.
We think the Court of Appeals properly assumed that such coercion might violate the antitrust laws.17 An agreement to restrain trade may be unlawful even though it does not entirely exclude its victims from the market. See Associated Press v. United States, 326 U.S. 1, 17, 65 S.Ct. 1416, 1423, 89 L.Ed.2d 2013 (1945). Coercive activity that prevents its victims from making free choices between market alternatives is inherently destructive of competitive conditions and may be condemned even without proof of its actual market effect. Cf. Klors, Inc. v. Broadway-Hale Stores, Inc., 359 U.S. 207, 210–214, 79 S.Ct. 705, 708–10, 3 L.Ed.2d 741 (1959).18

*529 Even though coercion directed by defendants at third parties in order to restrain the trade of “certain” contractors and subcontractors may have been unlawful, it does **904 not, of course, necessarily follow that still another party—the Union—is a person injured by reason of a violation of the antitrust laws within the meaning of § 4 of the Clayton Act.

III

We first consider the language in the controlling statute. See Consumer Product Safety Comm’n v. GTE Sylvania, Inc., 447 U.S. 102, 108, 100 S.Ct. 2051, 2056, 64 L.Ed.2d 766 (1980). The class of persons who may maintain a private damage action under the antitrust laws is broadly defined in § 4 of the Clayton Act. 15 U.S.C. § 15. That section provides:

“Any person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws may sue therefor in any district court of the United States in the district in which the defendant resides or is found or has an agent, without respect to the amount in controversy, and shall recover threefold the damages by him sustained, and the cost of suit, including a reasonable attorney's fee.”

A literal reading of the statute is broad enough to encompass every harm that can be attributed directly or indirectly to the consequences of an antitrust violation. Some of our prior cases have paraphrased the statute in an equally expansive way.19 But before we hold that the statute is as broad as its *530 words suggest, we must consider whether Congress intended such an open-ended meaning.

The critical statutory language was originally enacted in 1890 as § 7 of the Sherman Act. 26 Stat. 210. The legislative history of the section shows that Congress was primarily interested in creating an effective remedy for consumers who were forced to pay excessive prices by the giant trusts and combinations that dominated certain interstate markets.20 That history supports a broad construction of this remedial provision. A proper interpretation of the section cannot, however, ignore the larger context in which the entire statute was debated.

*531 The repeated references to the common law in the debates that preceded the enactment of the Sherman Act make it clear that Congress intended the Act to be **905 construed in the light of its common-law background.21 Senator Sherman stated that the bill “does not announce a new principle of law, but applies old and well recognized principles of the common law to the complicated jurisdiction of our State and Federal Government.”22 Thus our comments on the need for judicial interpretation of § 1 are equally applicable to § 7:
“One problem presented by the language of § 1 of the Sherman Act is that it cannot mean what it says. The statute says that ‘every’ contract that restrains trade is unlawful. But, as Mr. Justice Brandeis perceptively noted, restraint is the very essence of every contract; read literally, § 1 would outlaw the entire body of private contract law.... Congress, however, did not intend the text of the Sherman Act to delineate the full meaning of the statute or its application in concrete situations. The legislative history makes it perfectly clear that it expected the courts to give shape to the statute's broad mandate by drawing on common-law tradition.” National Society of Professional Engineers v. United States, 435 U.S. 679, 687–688, 98 S.Ct. 1355, 1363–64, 55 L.Ed.2d 637 (1978) (footnotes omitted).

Just as the substantive content of the Sherman Act draws meaning from its common-law antecedents, so must we consider the contemporary legal context in which Congress acted when we try to ascertain the intended scope of the private remedy created by § 7.

In 1890, notwithstanding general language in many state constitutions providing in substance that “every wrong shall have a remedy,” a number of judge-made rules circumscribed the availability of damages recoveries in both tort and contract litigation—doctrines such as foreseeability and proximate cause, directness of injury, certainty of damages, and privity of contract. Although particular common-law limitations were not debated in Congress, the frequent references to common-law principles imply that Congress simply assumed that antitrust damages litigation would be subject to constraints comparable to well-accepted common-law rules applied in comparable litigation.

The federal judges who first confronted the task of giving meaning to § 7 so understood the congressional intent. Thus in 1910 the Court of Appeals for the Third Circuit held as a matter of law that neither a creditor nor a stockholder of a corporation that was injured by a violation of the antitrust laws could recover treble damages under § 7. The court explained that the plaintiff's injury as a stockholder was “indirect, remote, and consequential.” Loeb v. Eastman Kodak Co., 183 F. 704, 709 (CCA3 1910). This holding was consistent with Justice Holmes' explanation of a similar construction of the remedial provision of the Interstate Commerce Act a few years later: “The general tendency of the law, in regard to damages at least, is not to go beyond the first step.” Southern Pacific Co. v. Darnell-Taenzer Lumber Co., 245 U.S. 531, 533, 38 S.Ct. 186, 62 L.Ed. 451 (1918).

When Congress enacted § 4 of the Clayton Act in 1914, and when it reenacted that section in 1955, 69 Stat. 282, it adopted the language of § 7 and presumably also the judicial gloss that avoided a simple literal interpretation.

As this Court has observed, the lower federal courts have been “virtually unanimous in concluding that Congress did not intend the antitrust laws to provide a remedy in damages for all injuries that might conceivably be traced to an antitrust violation.” Blue Shield of Virginia, Inc. v. McCready, ––– U.S. ––––, 102 S.Ct. 2540, 2547, 73 L.Ed.2d 149 (1982).

An antitrust violation may be expected to cause ripples of harm to flow through the Nation's economy; but ‘despite the broad wording of § 4 there is a point beyond which the wrongdoer should not be held liable.’ Id., [Illinois Brick Co. v. Illinois, 431 U.S. 720] at 760 [97 S.Ct. 2061 at 2082, 52 L.Ed.2d 707] (BRENNAN, J., dissenting) [citing Illinois Brick v. Illinois, 431 U.S. 720, 97 S.Ct. 2061, 52 L.Ed.2d 707 (1977)]. It is reasonable to assume that Congress did not intend to allow every person tangentially affected by an antitrust violation to maintain an action to recover threefold damages for the injury to his business or property.” Blue Shield of Virginia, Inc. v. McCready, — U.S. ——, ——, 102 S.Ct. 2540, 2547, 73 L.Ed.2d 149 (1982).

It is plain, therefore, that the question whether the Union may recover for the injury it allegedly suffered by reason of the defendants' coercion against certain third parties cannot be answered simply by reference to the broad language of § 4. Instead, as was required in common-law damages litigation in 1890, the question requires us to evaluate the plaintiff's harm, the alleged wrongdoing by the defendants, and the relationship between them.
IV

There is a similarity between the struggle of common-law judges to articulate a precise definition of the concept of “proximate cause,” and the struggle of federal judges to articulate a precise test to determine whether a party injured by an antitrust violation may recover treble damages. It is common ground that the judicial remedy cannot encompass every conceivable harm that can be traced to alleged wrongdoing. In both situations the infinite variety of claims that may arise make it virtually impossible to announce a black-letter rule that will dictate the result in every case. Instead, previously decided cases identify factors that circumscribe and guide the exercise of judgment in deciding whether the law affords a remedy in specific circumstances.

The factors that favor judicial recognition of the Union's antitrust claim are easily stated. The complaint does allege a causal connection between an antitrust violation and harm to the Union and further alleges that the defendants intended to cause that harm. As we have indicated, however, the mere fact that the claim is literally encompassed by the Clayton Act does not end the inquiry. We are also satisfied that an allegation of improper motive, although it may support a plaintiff's damages claim under § 4, is not a panacea that will enable any complaint to withstand a motion to dismiss. Indeed, in McCready, we specifically held: “The availability of the § 4 remedy to some person who claims its benefit is not a question of the specific intent of the conspirators.” 457 U.S., at ––––, 102 S.Ct., at 2548.

A number of other factors may be controlling. In this case it is appropriate to focus on the nature of the plaintiff's alleged injury. As the legislative history shows, the Sherman Act was enacted to assure customers the benefits of price competition, and our prior cases have emphasized the central interest in protecting the economic freedom of participants in the relevant market. Last Term in Blue Shield of Virginia v. McCready, supra, we identified the relevance of this central policy to a determination of the plaintiff's right to maintain an action under § 4. McCready alleged that she was a consumer of psychotherapeutic services and that she had been injured by the defendants' conspiracy to restrain competition in the market for such services. The Court stressed the fact that “McCready's injury was of a type that Congress sought to redress in providing a private remedy for violations of the antitrust laws.” 457 U.S., at ––––, 102 S.Ct., at 2550, citing Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 487–489, 97 S.Ct. 690, 697, 50 L.Ed.2d 701 (1977). After noting that her injury “was inextricably intertwined with the injury the conspirators sought to inflict on psychologists and the psychotherapy market,” McCready, 457 U.S., at ––––, 102 S.Ct., at 2555, the Court concluded that such an injury “falls squarely within the area of congressional concern.” Id., at ––––, 102 S.Ct., at 2551.

In this case, however, the Union was neither a consumer nor a competitor in the market in which trade was restrained. It is not clear whether the Union's interests would be served or disserved by enhanced competition in the market. As a general matter, a union's primary goal is to enhance the earnings and improve the working conditions of its membership; that goal is not necessarily served, and indeed may actually be harmed, by uninhibited competition among employers striving to reduce costs in order to obtain a competitive advantage over their rivals. At common law—as well as in the early days of administration of the federal antitrust laws—the collective activities of labor unions were regarded as a form of conspiracy in restraint of trade. Federal policy has since developed not only a broad labor exemption from the antitrust laws, but also a separate body of labor law specifically designed to protect and encourage the organizational and representational activities of labor unions. Set against this background, a union, in its capacity as bargaining representative, will frequently not be part of the class the Sherman Act was designed to protect, especially in disputes with employers with whom it bargains. In each case its alleged injury must be analyzed to determine whether it is of the type that the antitrust statute was intended to forestall.
in light of the longstanding collective bargaining relationship between the parties, the Union's labor-market interests seem to predominate, and the Brunswick test is not satisfied.

An additional factor is the directness or indirectness of the asserted injury. In this case, the chain of causation between the Union's injury and the alleged restraint in the market for construction subcontracts **910 contains several somewhat vaguely defined links. According to the complaint, defendants applied coercion against certain landowners and other contracting parties in order to cause them to divert business from certain union contractors to nonunion contractors. 44 As a result, *541 the Union's complaint alleges, the Union suffered unspecified injuries in its “business activities.” 45 It is obvious that any such injuries were only an indirect result of whatever harm may have been suffered by “certain” construction contractors and subcontractors. 46

If either these firms, or the immediate victims of coercion by defendants, have been injured by an antitrust violation, their injuries would be direct and, as we held in McCready, supra, they would have a right to maintain their own treble damages actions against the defendants. An action on their behalf would encounter none of the conceptual difficulties that *542 encumber the Union's claim. 47 The existence of an identifiable class of persons whose self-interest would normally motivate them to vindicate the public interest in antitrust enforcement diminishes the justification for allowing a **911 more remote party such as the Union to perform the office of a private attorney general. 48 Denying the Union a remedy on the basis of its allegations in this case is not likely to leave a significant antitrust violation undetected or unremedied.

Partly because it is indirect, and partly because the alleged effects on the Union may have been produced by independent factors, the Union's damages claim is also highly speculative. There is, for example, no allegation that any collective bargaining agreement was terminated as a result of the coercion, no allegation that the aggregate share of the contracting market controlled by union firms has diminished, no allegation that the number of employed union members has declined, and no allegation that the Union's revenues in the form of dues or initiation fees have decreased. Moreover, although coercion against certain firms is alleged, there is no assertion that any such firm was prevented from doing business with any union firms or that any firm or group of firms was subjected to a complete boycott. See nn. 9, 15 and 16, supra. *543 Other than the alleged injuries flowing from breaches of the collective bargaining agreements—injuries that would be remediable under other laws—nothing but speculation informs the Union's claim of injury by reason of the alleged unlawful coercion. Yet, as we have recently reiterated, it is appropriate for § 4 purposes “to consider whether a claim rests at bottom on some abstract conception or speculative measure of harm.” Blue Shield of Virginia v. McCready, supra, 457 U.S., at ––––, n. 11, 102 S.Ct., at 2547, n. 11; citing Hawaii v. Standard Oil, supra, 405 U.S., at 262–263 n. 14, 92 S.Ct., at 891 n. 14. 49

The indirectness of the alleged injury also implicates the strong interest, identified in our prior cases, in keeping the scope of complex antitrust trials within judicially manageable limits. 50 These cases have stressed the importance of avoiding *544 either the risk of duplicate recoveries on the one hand, or the danger of complex apportionment of damages on the other. Thus, in Hanover Shoe, Inc. v. United Shoe Machinery Corp., 392 U.S. 481, 88 S.Ct. 2224, 20 L.Ed.2d 1231 (1968), we refused to allow the defendants to discount the plaintiffs' damages claim to the extent that overcharges had been passed on to the plaintiffs' customers. We noted that any attempt to ascertain damages with such precision “would often require additional long and complicated proceedings involving massive evidence and complicated theories.” **912 Id., at 493, 88 S.Ct., at 2231. In Illinois Brick Co. v. Illinois, 431 U.S. 720, 97 S.Ct. 2061, 52 L.Ed.2d 707 (1977), we held that treble damages could not be recovered by indirect purchasers of concrete blocks who had paid an enhanced price because their suppliers had been victimized by a price-fixing conspiracy. We observed that potential plaintiffs at each level in the distribution chain would be in a position to assert conflicting claims to a common fund, the amount of the alleged overcharge, thereby creating the danger of multiple liability for the fund and prejudice to absent plaintiffs.
“Permitting the use of pass-on theories under § 4 essentially would transform treble-damages actions into massive efforts to apportion the recovery among all potential plaintiffs that could have absorbed part of the overcharge—from direct purchasers to middlemen to ultimate consumers. However appealing this attempt to allocate the overcharge might seem in theory, it would add whole new dimensions of complexity to treble-damages suits and seriously undermine their effectiveness.” *Id.*, at 737–738, 97 S.Ct., at 2070.

The same concerns should guide us in determining whether the Union is a proper plaintiff under § 4 of the Clayton Act. As the Court wrote in *Illinois Brick*, massive and complex damages litigation not only burdens the courts, but also undermines the effectiveness of treble-damages suits. *Id.*, at 745, 97 S.Ct., at 2074. In this case, if the Union's complaint asserts a claim for damages under § 4, the District Court would face problems of identifying damages and apportioning them among directly victimized contractors and subcontractors and indirectly affected employees and union entities. It would be necessary to determine to what extent the coerced firms diverted business away from union subcontractors, and then to what extent those subcontractors absorbed the damage to their businesses or passed it on to employees by reducing the workforce or cutting hours or wages. In turn it would be necessary to ascertain the extent to which the affected employees absorbed their losses and continued to pay union dues.

We conclude, therefore, that the Union's allegations of consequential harm resulting from a violation of the antitrust laws, although buttressed by an allegation of intent to harm the Union, are insufficient as a matter of law. Other relevant factors—the nature of the Union's injury, the tenuous and speculative character of the relationship between the alleged antitrust violation and the Union's alleged injury, the potential for duplicative recovery or complex apportionment of damages, and the existence of more direct victims of the alleged conspiracy—weigh heavily against judicial enforcement of the Union's antitrust claim. Accordingly, we hold that, based on the allegations of this complaint, the District Court was correct in concluding that the Union is not a person injured by reason of a violation of the antitrust laws within the meaning of § 4 of the Clayton Act. The judgment of the Court of Appeals is reversed.

It is so ordered.

Justice MARSHALL, dissenting.

Section 4 of the Clayton Act provides that a damage action may be brought under the antitrust laws by “*any person who [has been] injured in his business or **property by reason of anything forbidden in the antitrust laws.*” 15 U.S.C. § 15 (emphasis added). Despite the absence of an “articulable consideration of statutory policy” supporting the denial of standing, *Blue Shield of Virginia v. McCready*, — U.S. —, —, 102 S.Ct. 2540, 2541, 73 L.Ed.2d 149 (1982), the Court today holds that the intended victim of a restraint of trade does not constitute a “person who [has been] injured in his business or property by reason of anything forbidden in the antitrust laws.” Because I believe that this decision imposes an unwarranted judge-made limitation on the antitrust laws, I respectfully dissent.

Congress' adoption of the broad language of § 4 was not accidental. As this Court observed in *Pfizer Inc. v. India*, 434 U.S. 308, 312, 98 S.Ct. 384, 587, 54 L.Ed.2d 563 (1978), “Congress used the phrase ‘any person’ intending it to have its naturally broad and inclusive meaning. There was no mention in the floor debates of any more restrictive definition.” Only last Term we emphasized that the all-encompassing language of § 4 “reflects Congress' expansive remedial purpose’ in enacting § 4: Congress sought to create a private enforcement mechanism that would deter violators and deprive them of the fruits of their illegal actions, and would provide ample compensation to the victims of antitrust violations.” *Blue Shield of Virginia v. McCready*, supra, 457 U.S. at —, 102 S.Ct., at 2541, quoting *Pfizer Inc. v. India*, supra, 434 U.S. at 313–314, 98 S.Ct., at 587–88.
In keeping with the inclusive language and remedial purposes of § 4, this Court has “refused to engraft artificial limitations on the § 4 remedy.” Blue Shield of Virginia v. McCreedy, supra, 457 U.S. at ——, 102 S.Ct., at 2545 (footnote omitted). Thus, for example, in Pfizer Inc. v. India, the Court held that the statutory phrase “any person” is broad enough to encompass a foreign sovereign. In Reiter v. Sonotone, 442 U.S. 330, 99 S.Ct. 2326, 60 L.Ed.2d 931 (1979), the Court likewise adopted an expansive reading of the statutory term “property,” ruling that a consumer who pays a higher price as a result of a price-fixing conspiracy has sustained an injury to his “property” and therefore has standing to sue under § 4.

The plaintiff unions fit comfortably within the language of § 4. The complaint alleges that plaintiffs suffered injury as a result of a restraint of trade that was “designed to weaken and destroy plaintiffs and each of them.” Complaint, ¶ 26. The Court does not suggest that a union is not a “person” within the meaning of § 4, or that plaintiffs cannot prove injury to their “business or property.” Moreover, it would require a strained reading of § 4 to conclude that a party that an antitrust violation was aimed at cannot prove that it suffered injury “by reason of” an antitrust violation.

Far from supporting the Court's conclusion, ante, at 11–14, the common-law background of the antitrust laws highlights the anomaly of denying a remedy to the intended victim of unlawful conduct. Since antitrust violations are essentially “tortious acts,” Bigelow v. RKO Radio Pictures, 327 U.S. 251, 264, 66 S.Ct. 574, 579, 90 L.Ed. 652 (1946), the most apt analogy is to the common law of torts. Although many legal battles have been fought over the extent of tort liability for remote consequences, conduct, it has always been assumed that the victim of an intentional tort can recover from the tortfeasor if he proves that the tortious conduct was a cause-in-fact of his injuries. An inquiry into proximate cause has traditionally been deemed unnecessary in suits against intentional tortfeasors. For example, if one party makes false representations to another, intending them to be communicated to a third party and acted upon to his detriment, the third party can bring an action for misrepresentation against the originator of the false information if he suffers injury as a result. Indeed, in many situations the common law holds an intentional tortfeasor liable even for the unforeseeable consequences of his conduct. I am not aware of any cases exonerating an intentional tortfeasor from responsibility for the intended consequences of his actions merely because he inflicted harm upon his victim indirectly rather than directly.

This case does not implicate the sort of “articulable consideration of statutory policy” which we have deemed necessary to deny standing to a party encompassed by the language of § 4. Blue Shield of Virginia v. McCreedy, supra, 457 U.S. at ——, 102 S.Ct., at 2541. In Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 97 S.Ct. 690, 50 L.Ed.2d 701 (1979), we denied standing to parties that suffered injury because an illegal acquisition prevented them from reaping profits that they would have reaped had the acquired firms been permitted to fail. We reasoned that permitting recovery for “the profits [plaintiffs] would have realized had competition been reduced” would be “inimical” to the purposes of the antitrust laws, id., at 488, 97 S.Ct., at 697, since plaintiffs' injuries did not “reflect the anticompetitive effect either of the violation or of anticompetitive acts made possible by the violation,” id., at 489, 97 S.Ct., at 697. This consideration of statutory policy is not applicable here, for plaintiffs allege that they suffered injury as a result of the defendants' efforts to coerce and induce letters of construction contracts and others to deal with nonunion carpentry firms solely because of their nonunion status. If plaintiffs prove their allegations, they will prove that they suffered harm attributable to the anticompetitive consequences of the defendants' restraint of trade.

Nor does the present case implicate the consideration of statutory policy underlying this Court's decisions in Illinois Brick Co. v. Illinois, 431 U.S. 720, 97 S.Ct. 2061, 52 L.Ed.2d 707 (1977), and Hawaii v. Standard Oil Co., 405 U.S. 251, 92 S.Ct. 885, 31 L.Ed.2d 184 (1972). Critical to the denial of standing in those cases was the risk of duplicative recovery that would have been created by affording the plaintiffs standing. In Illinois Brick the Court held that an indirect purchaser has no standing to sue a seller on the theory that overcharges paid to the seller by a direct purchaser were passed on to the indirect purchaser. Supra, 431 U.S. at 730–731, 97 S.Ct., at 2066–67. If the Court had held in Illinois Brick that the indirect purchaser has standing, sellers would have faced the prospect of two treble damage actions based on the same overcharges.
Shoe, Inc. v. United Shoe Machinery Corp., 392 U.S. 481, 88 S.Ct. 2224, 20 L.Ed.2d 1231 (1968), had established that a direct purchaser can sue a seller for the entire amount of the seller's overcharges, and that the seller cannot assert as a defense that the direct purchaser passed the overcharges through to its customers (the indirect purchasers). Similarly, in Hawaii v. Standard Oil Co., where the State of Hawaii sought to recover for financial harm allegedly suffered by the general economy of the State, the Court denied standing because “[a] large and ultimately indeterminable part of the injury to the ‘general economy,’ as it is measured by economists, is no more than a reflection of injuries to the ‘business or property’ of consumers, for which they may recover themselves under § 4.” Supra, 405 U.S. at 264, 92 S.Ct., at 892. 7

There is no risk of double recovery here. The plaintiff unions seek recovery for injuries distinct from those that other parties may have suffered. One such distinct injury *551 plaintiffs may have suffered is a decrease in union dues resulting from a reduction in work available to union members. In addition to regular dues, it is not uncommon for employees to pay periodic dues representing a percentage of their wages. See R. Gorman, Basic Text on Labor Law 650 (1976). 8 If union members lost work as a result of the alleged restraint of trade, their wages and thus the dues collected by the plaintiff unions may have been reduced.

Any recovery of lost dues by the plaintiff unions would not duplicate recoveries that might be obtained by either unionized carpentry firms or employees of those firms. A recovery of lost dues by a union would not duplicate a recovery for lost profits that might be obtained by a firm for which union members worked, for union dues are not an element of a firm's profits. Nor would a recovery of lost dues by a union duplicate recoveries of lost wages that employees might obtain. Although periodic union dues are based on a percentage of wages, there would be no double recovery because union dues would be subtracted from lost wages in calculating the employees' damages. The Hanover Shoe rule barring the assertion of a “pass-through” defense would not prevent subtraction of union dues from wages in determining the employees' damages. The Hanover Shoe rule was designed to avoid the “additional long and complicated proceedings involving massive evidence and complicated theories” that would be required to determine the extent to which price overcharges were passed through to an indirect purchaser. **916 Supra, 392 U.S. at 493, 88 S.Ct., at 2231. In sharp contrast, where union dues are a percentage of wages, there is no difficulty in determining the amount of dues that a union lost as a result of a reduction in the wages earned by union members.

*552 I recognize that it may not be easy to ascertain to what extent any reduction in union dues was attributable to the defendants' conduct. But our cases make it clear that “[i]f there is sufficient evidence in the record to support an inference of causation, the ultimate conclusion as to what the evidence proves is for the jury.” Perkins v. Standard Oil Co., 395 U.S. 642, 648, 89 S.Ct. 1871, 1874, 23 L.Ed.2d 599 (1969) (reinstating jury verdict based on injury indirectly caused by price discrimination in violation of the Robinson-Patman Act). Insofar as the amount of damages is concerned, an antitrust plaintiff need only provide a reasonable estimate of the damages stemming from an antitrust violation. See Bigelow v. RKO Pictures, supra, 327 U.S. at 266, 66 S.Ct., at 580. “ ‘Difficulty of ascertainment is no longer confused with right of recovery,’ ” id., at 265, 66 S.Ct., at 580, quoting Story Parchment Co. v. Paterson Co., 282 U.S. 555, 566, 51 S.Ct. 248, 251, 75 L.Ed. 544 (1931), and “[t]he most elementary conceptions of justice and public policy require that the wrongdoer shall bear the risk of the uncertainty which his own wrong has created,” 327 U.S., at 265, 66 S.Ct., at 580.

Any concern the Court may have that the plaintiffs cannot prove their case does not justify throwing them out of court solely on the basis of the pleadings. If, during discovery, it becomes apparent that plaintiffs cannot establish a reasonable inference of causation or cannot provide evidence supporting a rational estimate of damages, they will be vulnerable to a motion for summary judgment. Dismissal for failure to state a claim is too crude a procedural device to be used to vindicate the “interest ... in keeping the scope of antitrust trials within judicially manageable limits.” Ante, at 911.

All Citations

Footnotes

* The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See United States v. Detroit Lumber Co., 200 U.S. 321, 337, 26 S.Ct. 282, 287, 50 L.Ed. 499.

1 The facts set forth in paragraphs 23 and 24, initially alleged in support of the Union’s federal antitrust claim, are realleged in each of the other claims for relief: breach of collective bargaining agreements (¶ ¶ 29–31); intentional interference with contractual relations (¶¶ 32–35); intentional interference with business relationships (¶¶ 36–39); and violation of the California antitrust statute (¶¶ 40–43).

2 For example, it is alleged that defendants breached their collective bargaining agreements “by failing to pay agreed-upon wages, by failing to use the hiring hall, by failing to pay Trust Fund contributions, by failing to observe other terms and conditions of employment, and by generally weakening the good faith requirement of the collective bargaining agreements;” that defendants improperly changed their names and corporate status and made use of so-called “double breasted operations;” and that they encouraged nonmembers of Associated to refuse to enter into collective bargaining agreements with the Union.

3 The word “coerced” did not appear in the complaint as originally filed. Even as amended after the filing of motions to dismiss, the complaint does not allege that the defendants used any coercion to persuade nonmembers of Associated to refuse to enter into collective bargaining agreements with the Union (¶ 24(3)). The complaint alleges neither the identity nor the number of landowners, general contractors, or others who were coerced into making contracts with nonunion firms.

4 Paragraph 25, which describes the effect of the conspiracy, reads in full as follows:

“The purpose and effect of the above described activities, plan and conspiracy are oppressive, unreasonable, and illegal, and are in restraint of trade and an unlawful interference and restraint of the free exercise of the business activities of plaintiffs and each of them, all in violation of 15 U.S.C. Section 1. The purpose and effect of the above described activities, plan and conspiracy, in addition, are to weaken, destroy, and restrain the trade of certain contractors, both members of the Associated General Contractors of California, Inc. and non-members, who are ‘memorandum contractors,’ who have faithfully performed the terms and conditions set out in the master collective bargaining agreements described above. The effect of this restraint on trade is to further weaken and destroy plaintiffs in this matter. These activities are in restraint of the free exercise of plaintiffs' trade and an interference therein, all in violation of 15 U.S.C. Section 1.” App. E 20–21.

5 Plaintiffs do not seek injunctive relief under Section 16 of the Clayton Act, 15 U.S.C. § 26, and they do not ask us to consider whether they have standing to request such relief.

6 An order dismissing the federal antitrust claim and the state-law claims was filed on August 4, 1975, and an amended order dismissing the entire complaint was entered on September 10, 1975. The District Court had initially stayed the breach of contract claim for 120 days pending grievance and arbitration procedures. On reconsideration it also dismissed the breach of contract claim, deciding that the suit had been prematurely filed.

7 Addressing the federal antitrust claim, the District Court concluded:
The essence of plaintiffs' claim seems to be that defendants violated the antitrust laws insofar as they declined to enter into agreements with plaintiffs to deal only with subcontractors which were signatories to contracts with plaintiffs, precisely the type of agreement which subjected the union in *Connell* to antitrust liability. *Id.*, at 1070.

The District Court reasoned that the employers' refusal to enter into such an agreement could not provide the basis for an antitrust claim.

8 The Court of Appeals affirmed the dismissal of all other claims.

9 The Court of Appeals majority read subparagraph (4) of paragraph 24, quoted *supra*, at 900, as though it alleged that the defendants had coerced landowners and other persons who let construction contracts “to hire only construction firms, primarily subcontractors, who had not signed with the Unions.” *Id.*, at 532; see also *id.*, at 544 (denying petition for rehearing) (emphasis added). The word “only” does not appear in the amended complaint, and it implies that the defendants' activities gave rise to a broader restraint than was actually alleged.

The majority read subparagraph (5) of paragraph 24 to charge that defendants had “coerced and aided each other to subcontract only with subcontractors who had not signed with the Union.” *Id.*, at 531 (emphasis added). Again using the word “only,” which does not appear in the complaint itself, the majority characterized the defendants' alleged activities as “very similar to a concerted refusal to deal, or a group boycott.” *Ibid.* It concluded that the allegations “present virtually the obverse of the situation described in *Connell*”: the conspiracy, if successful, “would effectively lock union-signatory subcontractors out of a portion of the market for carpentry work.” *Id.*, at 532.


Circuit Judge Sneed dissented. He first rejected the majority's characterization of the complaint, agreeing instead with the District Court. Second, assuming that the complaint alleged a boycott of certain employers, he concluded that neither the employees of a victim of the boycott nor their collective bargaining representative had standing to assert the antitrust claim. Finally, he concluded that an injury that affected only the Union's organizational and representational activity was remediable under the labor laws rather than the antitrust laws.

The Court of Appeals denied the petition for rehearing and rehearing en banc on May 22, 1981. Accompanying the order was a statement by the majority rebutting the petitioners' assertion that the opinion rendered multiemployer bargaining units unlawful, and a dissent by Circuit Judge Sneed. 648 F.2d, at 543, 545.

11 The Union had an adequate opportunity to amend its pleading to add factual allegations demonstrating that the District Court's decision to dismiss the complaint was based on a misunderstanding of its antitrust claim.

12 In analyzing the antitrust allegations in the amended complaint, we therefore construe the references to “contractors and subcontractors who are not signatories to collective bargaining agreements” as referring to completely independent nonunion firms rather than to operations covertly controlled by one or more defendants.

13 The Court of Appeals did not reverse the District Court's dismissal of the complaint with regard to these allegations. 648 F.2d, at 531–532, 537, 540.

14 See Brief of Respondents 37. There is no allegation of wrongful conduct directed at nonunion subcontracting firms. We therefore assume that, if any nonunion firms refused to bargain with the Union because of the conspiracy, they did so because they were rewarded with business they would not otherwise have obtained. Thus, nonunion firms could not be
considered victims of the conspiracy; rather, they appear to have been its indirect beneficiaries. None are named either as defendants or as coconspirators.

The amended complaint also does not allege any restraint on competition in the market for labor union services. Unlike the two cases involving union plaintiffs cited by the Court of Appeals, see n. 10, supra, in this case there is no claim that competition between rival unions has been injured or even that any rival unions exist.

The complaint does not specify the nature of the “coercion.” It does not, for example, allege that the defendants refused to deal with all members of either of the two classes of persons against whom coercion was applied. Indeed, it is highly improbable that the defendants—all of whom are signatories to union contracts—would refuse to deal with all of their customers and potential customers in an attempt to divert all of their business to nonunion firms.

There is no allegation that any person subjected to coercion was required to deal exclusively with nonunion firms.

Had the District Court required the Union to describe the nature of the alleged coercion with particularity before ruling on the motion to dismiss, it might well have been evident that no violation of law had been alleged. In making the contrary assumption for purposes of our decision, we are perhaps stretching the rule of Conley v. Gibson, 355 U.S. 41, 47–48, 78 S.Ct. 99, 102–03, 2 L.Ed.2d 80 (1957), too far. Certainly in a case of this magnitude, a district court must retain the power to insist upon some specificity in pleading before allowing a potentially massive factual controversy to proceed.

Although we do not know what kind of coercion defendants allegedly employed, we assume for purposes of decision that it had a predatory “nature or character,” Klors, Inc. v. Broadway-Hale Stores, Inc., 359 U.S. 207, 211, 79 S.Ct. 705, 709, 3 L.Ed.2d 741 (1959), and that it would “cripple the freedom of traders and thereby restrain their ability to sell in accordance with their own judgment.” Kiefer-Stewart Co. v. Seagram & Sons, 340 U.S. 211, 213, 71 S.Ct. 259, 260, 95 L.Ed. 219 (1951).

In Mandeville Farms v. Sugar Co., 334 U.S. 219, 68 S.Ct. 996, 92 L.Ed. 1328 (1948), the Court held that growers of sugar beets could maintain a treble-damages action against refiners who had allegedly conspired to fix the price that they would pay for the beets. Although previous price-fixing cases had involved agreements among sellers to fix sales prices, the Court readily concluded that the act applied equally to an agreement among competing buyers to fix purchase prices. The Court stated:

“The statute does not confine its protection to consumers, or to purchasers, or to competitors, or to sellers. Nor does it immunize the outlawed acts because they are done by any of these. Cf. United States v. Socony-Vacuum Oil Co., 310 U.S. 150, 60 S.Ct. 811, 84 L.Ed. 1129; American Tobacco Co. v. United States, 328 U.S. 781, 66 S.Ct. 1125, 90 L.Ed. 1575. The Act is comprehensive in its terms and coverage, protecting all who are made victims of the forbidden practices by whomever they may be perpetrated.” 334 U.S., at 236, 68 S.Ct., at 1006.

Similarly broad language was used in later cases holding that actions could be maintained by consumers, Reiter v. Sonotone Corp., 442 U.S. 330, 337–338, 99 S.Ct. 2326, 2330, 60 L.Ed.2d 931 (1979), by a foreign government, Pfizer Inc. v. India, 434 U.S. 308, 313–314, 98 S.Ct. 584, 588, 54 L.Ed.2d 563 (1978), and by the direct victim of a boycott. Blue Shield of Virginia v. McCready, —— U.S. ——, ——, 102 S.Ct. 2540, 2550–51, 73 L.Ed.2d 149 (1982). In each of those cases, however, the actual plaintiff was directly harmed by the defendants' unlawful conduct. The paraphrasing of the language of § 4 in those opinions added nothing to the even broader language that the statute itself contains.

See 21 Cong.Rec. 1767–1768, 2455–2456, 2459, 2615, 3147–3148 (1890). The original proposal, which merely allowed recovery of the amount of actual enhancement in price, was successively amended to authorize double damages and then treble-damages recoveries, in order to provide otherwise remedyless small consumers with an adequate incentive to bring suit. Id., at 1765, 2455, 3145. The same purpose was served by the special venue provisions, the provision
for the recovery of attorneys' fees, and the elimination of any requirement that the amount in controversy exceed the jurisdictional threshold applicable in other federal litigation. See, e.g., id., at 2612, 3149. Moreover, changes in the description of the remedy extended the section's coverage beyond price-fixing.

See, e.g., id., at 2456, 2459, 3151–3152.

Id., at 2456. Senator Sherman added, “The purpose of this bill is to enable the courts of the United States to apply the same remedies against combinations which injuriously affect the interests of the United States that have been applied in the several states to protect local interests.” Id.; see also id., at 2459, 3149, 3151–3152. Although members of Congress referred particularly to common-law definitions of “monopoly” and “restraint of trade,” they appear to have been generally aware that the statute would be construed by common-law courts in accordance with traditional canons. For example, at the beginning of the debate on the Sherman Act, one Senator cautioned his colleagues,

“A careful analysis of the terms of the bill is essential. We must know what it means, what its legal effect is, if we give force to it as it is written.... We must adopt, therefore, the known methods of the courts in determining what the bill means.” Id., at 1765.

For example, the state constitution of Illinois, adopted in 1870, provided: “Every person ought to find a certain remedy in the laws for all injuries and wrongs which he may receive in his person, property or reputation ....” § 19. Comparable provisions were found in the state constitutions of Arkansas, Connecticut, Delaware, Indiana, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Minnesota, Mississippi, New Hampshire, Ohio, and Vermont. See generally F.B. Hough, American Constitutions (1871).

One treatise stated, “Natural, proximate, and legal results are all that damages can be recovered for, even under a statute entitling one ‘to recover any damage.’ ” 3 J. Lawson, Rights, Remedies, and Practice 1740 (1890). Another leading treatise explained,

“The chief and sufficient reason for this rule is to be found in the impossibility of tracing consequences through successive steps to the remote cause, and the necessity of pausing in the investigation of the chain of events at the point beyond which experience and observation convince us we cannot press our inquiries with safety.”


In torts, a leading treatise on damages set forth the general principle that, “[w]here the plaintiff sustains injury from the defendant's conduct to a third person, it is too remote, if the plaintiff sustains no other than a contract relation to such a third person, or is under contract obligation on his account, and the injury consists only in impairing the ability or inclination of such person to perform his part, or in increasing the plaintiff's expense or labor of fulfilling such contract, unless the wrongful act is willful for that purpose.” Thus, A, who had agreed with a town to support all the town paupers for a specific period, in return for a fixed sum, had no cause of action against S for assaulting and beating one of the paupers, thereby putting A to increased expense. Similarly, a purchaser under an output contract with a manufacturer had no right of recovery against a trespasser who stopped the company's machinery, and a creditor could not recover against a person who had forged a note, causing diminution in the dividends from an estate. 1 J. Sutherland, A Treatise on the Law of Damages 55–56 (1882) (emphasis in original).
Similarly, in contract, the common-law courts drew a distinction between direct and consequential damages; the latter had to be specifically included in the contract to be recoverable. See id., at 74–93; 1 T. Sedgwick, A Treatise on the Measure of Damages 203–244 (1891) (discussing the rule of Hadley v. Baxendale, 9 Ex. 341, 156 Eng.Rep. 145 (1854)).

The common law required the plaintiff to prove, with certainty, both the existence of damages and the causal connection between the wrong and the injury. No damages could be recovered for uncertain, conjectural, or speculative losses. See generally cases cited in F. Bohlen, Cases on the Law of Torts 292–312 (2d ed. 1925) (cases alleging emotional harm to plaintiff). Even if the injury was easily provable, there would be no recovery if the plaintiff could not sufficiently establish the causal connection. See 1 J. Sutherland, supra n. 25, at 94–126; 1 T. Sedgwick, supra n. 25, at 245–294.


See n. 22, supra. The common law, of course, is an evolving body of law. We do not mean to intimate that the limitations on damages recoveries found in common-law actions in 1890 were intended to serve permanently as limits on Sherman Act recoveries. But legislators familiar with these limits could hardly have intended the language of § 7 to be taken literally.

See also Ames v. American Telephone & Telegraph Co., 166 F. 820 (CC D Mass.1909). Applying “ordinary principles of law” to the general language of the statute, the court held that a stockholder had no legally cognizable antitrust claim against defendants for illegally acquiring the corporation, thereby rendering plaintiff's stock worthless. Plaintiff's claim was not distinguishable from any injury sustained by the company itself. Therefore, the court stated, a contrary result would “subject the defendant not merely to treble damages, but to sextuple damages, for the same unlawful act.” Id., at 823.

The Court held in that case that the plaintiff shippers could recover damages from the defendant railroad for charging an excessive freight rate, even though they had been able to pass on the damage to their purchasers. Justice Holmes wrote that the law holds the defendant “liable if proximately the plaintiff has suffered a loss,” but “does not attribute remote consequences to a defendant.” Southern Pacific Co. v. Darnell-Taenzer Lumber Co., 245 U.S. 531, 533–534, 38 S.Ct. 186, 62 L.Ed. 451 (1918).

The label “antitrust standing” has traditionally been applied to some of the elements of this inquiry. As commentators have observed, the focus of the doctrine of “antitrust standing” is somewhat different from that of standing as a constitutional doctrine. Harm to the antitrust plaintiff is sufficient to satisfy the constitutional standing requirement of injury in fact, but the court must make a further determination whether the plaintiff is a proper party to bring a private antitrust action. See Berger & Bernstein, An Analytical Framework for Antitrust Standing, 86 Yale L.J. 809, 813 n. 11 (1977); Pollock, Standing to Sue, Remoteness of Injury, and the Passing-On Doctrine, 32 Antitrust L.J. 5, 6–7 (1966).

In his comment, Mahoney v. Beatman: A Study in Proximate Cause, 39 Yale L.J. 532, 533 (1930), Leon Green noted: “Legal theory is too rich in content not to afford alternative ways, and frequently several of them, for stating an acceptable judgment.” Earlier, in his Rationale of Proximate Cause 135–136 (1927) (footnotes omitted), Green had written:

“ ‘Cause,’ although irreducible in its concept, could not escape the ruffles and decorations so generously bestowed: remote, proximate, direct, immediate, adequate, efficient, operative, inducing, moving, active, real, effective, decisive, supervening, primary, original, contributory, ultimate, concurrent, causa causans, legal, responsible, dominating, natural, probable, and others. The
difficulty now is in getting any one to believe that so simple a creature could have been so extravagantly garbed.”

Some courts have focused on the directness of the injury, e.g., *Loeb v. Eastman Kodak Co.*, 183 F. 704, 709 (CCA3 1910); *Productive Inventions, Inc. v. Trico Prods. Corp.*, 224 F.2d 678, 679 (CA2 1955), cert. denied, 350 U.S. 936, 76 S.Ct. 301, 100 L.Ed. 818 (1956); *Volasco Products Co. v. Lloyd A. Fry Roofing Co.*, 308 F.2d 383, 394–395 (CA6 1962), cert. denied, 372 U.S. 907, 83 S.Ct. 721, 9 L.Ed.2d 717 (1963). Others have applied the requirement that the plaintiff must be in the “target area” of the antitrust conspiracy, that is, the area of the economy which is endangered by a breakdown of competitive conditions in a particular industry. E.g., *Pan-Islamic Trade Corp. v. Exxon Corp.*, 632 F.2d 539, 546–547 (CA5 1980); *Engine Specialties, Inc. v. Bombardier Ltd.*, 605 F.2d 1, 17–18 (CA1 1979); *Calderone Enterprises Corp. v. United Artists Theater Circuit, Inc.*, 454 F.2d 1292–1295 (CA2 1971). Another court of appeals has asked whether the injury is “arguably within the zone of interests protected by the antitrust laws.” *Malamud v. Sinclair Oil Corp.*, 521 F.2d 1142, 1151–1152 (CA6 1975). See generally Berger & Bernstein, supra n. 31.

As a number of commentators have observed, these labels may lead to contradictory and inconsistent results. See Berger & Bernstein, supra n. 31, at 835, 843; Handler, *The Shift From Substantive to Procedural Innovations in Antitrust Suits*, 71 Colum.L.Rev. 1, 27–31 (1971); Sherman, *Antitrust Standing: From Loeb to Malamud*, 51 N.Y.U.L.Rev. 374, 407 (1976) (“it is simply not possible to fashion an across-the-board and easily applied standing rule which can serve as a tool of decision for every case”). In our view, courts should analyze each situation in light of the factors set forth in the text infra.

Cf. *Blue Shield of Virginia v. McCready*, supra, 457 U.S., at ———, n. 13, 102 S.Ct., at 2548 n. 13 (discussing elusiveness of test of proximate cause); *Palsgraf v. Long Island R.R. Co.*, 248 N.Y. 339, 162 N.E. 99 (1928); id., at 351–352, 162 N.E., at 103 (Andrews, J., dissenting) (“What is a cause in a legal sense, still more what is a proximate cause, depend in each case upon many considerations .... What we do mean by the word ‘proximate’ is, that because of convenience, of public policy, of a rough sense of justice, the law arbitrarily declines to trace a series of events beyond a certain point.”).

It is well settled that a defendant's specific intent may sometimes be relevant to the question whether a violation of law has been alleged. See *United States v. Columbia Steel Co.*, 334 U.S. 495, 522, 68 S.Ct. 1107, 1121, 92 L.Ed. 1533 (1948). Moreover, there no doubt are cases in which such an allegation would adequately support a plaintiff's claim under § 4. Cf. Handler, supra n. 33, at 30 (specific intent of defendant to cause injury to a particular class of persons should “ordinarily be dispositive” in creating standing to sue); Lytle & Perdue, *Antitrust Target Area Under Section 4 of the Clayton Act: Determination of Standing in Light of the Alleged Antitrust Violation*, 25 Am.U.L.Rev. 795, 814–816 (1976) (suggesting that standing in a group boycott situation should be based on the purpose of the boycott).


In *McCready* we rejected the contention that, because there was no specific intent to harm the plaintiff, her injury was thereby rendered remote. This case presents a different question, but in neither case is the motive allegation of controlling importance.

See *United States v. Topco Associates, Inc.*, 405 U.S. 596, 610, 92 S.Ct. 1126, 1134, 31 L.Ed.2d 515 (1972) (“Antitrust laws in general, and the Sherman Act in particular, are the Magna Carta of free enterprise. They are as important to the preservation of economic freedom and our free-enterprise system as the Bill of Rights is to the protection of our fundamental personal freedoms. And the freedom guaranteed each and every business, no matter how small, is
McCreary, a Blue Shield subscriber, alleged that Blue Shield and the Neuropsychiatric Society of Virginia, Inc. had unlawfully conspired to restrain competition in the market for psychotherapeutic services by providing insurance coverage only for consumers who patronized psychiatrists, not psychologists. McCready obtained services from a psychologist and was denied reimbursement.

Moreover, it has not even alleged any marketwide restraint of trade. The allegedly unlawful conduct involves predatory behavior directed at “certain” parties, rather than a claim that output has been curtailed or prices enhanced throughout an entire competitive market.

In Mine Workers v. Pennington, 381 U.S. 657, 85 S.Ct. 1585, 14 L.Ed.2d 626 (1965), the Court recognized that wages lie at the heart of the subjects of mandatory collective bargaining, and that “the elimination of competition based on wages among the employers in the bargaining unit,” which directly benefits the union, also has an effect on competition in the product market. See generally Leslie, Principles of Labor Antitrust, 66 Va.L.Rev. 1183, 1185–1188 (1980); Winter, Collective Bargaining and Competition: The Application of Antitrust Standards to Union Activities, 73 Yale L.J. 14, 17–20, 28–30 (1963).


There is a parallel between these allegations and the claim in Connell Construction Co. v. Plumbers & Steamfitters, 421 U.S. 616, 95 S.Ct. 1830, 44 L.Ed.2d 418 (1975). The plaintiff in that case, a general building contractor, was coerced by the defendant union into signing an agreement not to deal with nonunion subcontractors. Similarly, in the McCready case, supra, the plaintiff was the direct victim of unlawful coercion. As the Court noted, “McCready did not yield to Blue Shield's coercive pressure, and bore Blue Shield's sanction in the form of an increase in the net cost of her psychologist's services.” 457 U.S., at ——, 102 S.Ct., at 2551. Her status was thus comparable to that of a contracting or subcontracting firm that refused to yield to the defendants' coercive practices and therefore suffered whatever sanction that coercion imposed. Like McCready, and like Connell Construction Co., such a firm could maintain an action against the defendants. In contrast, the Union is neither a participant in the market for construction contracts or subcontracts nor a direct victim of the defendants' coercive practices. We therefore need not decide whether the direct victim of a boycott, who suffers a type of injury unrelated to antitrust policy, may recover damages when the ultimate purpose of the boycott is to restrain competition in the relevant economic market.

Its brief merely echoes the Court of Appeals' description of its allegations: “the Unions have been injured in their business, i.e., organizing carpentry industry employees, negotiating and policing collective bargaining agreements, and securing jobs for their members.” Brief of Respondents 25–26.
Because of the absence of specific allegations, we can only speculate about the specific components of the Union's claim. If the Union asserts that its attempts to organize previously nonunion firms have been frustrated because nonunion firms wish to continue to obtain business from those subjected to coercion by the defendants, its harm stems most directly from the conduct of persons who are not victims of the conspiracy. See n. 14, supra. If the Union claims that dues payments were adversely affected because employees had less incentive to join the Union in light of expanding nonunion job opportunities, its damage is more remote than the harm allegedly suffered by unionized subcontractors. The same is true if the Union contends that revenues from dues payments declined because its members lost jobs or wages because their unionized employers lost business. That harm, moreover, is even more indirect than the already indirect injury to its members, yet a number of decisions have denied standing to employees with merely derivative injuries. See, e.g., *Pitchford v. PEPI, Inc.*, 531 F.2d 92, 97 (CA3), cert. denied, 426 U.S. 935, 96 S.Ct. 2649, 49 L.Ed.2d 387 (1976); *Contreras v. Grower Shipper Vegetable Assn.*, 484 F.2d 1346 (CA9 1973), cert. denied, 415 U.S. 932, 94 S.Ct. 1445, 39 L.Ed.2d 490 (1974); *Reibert v. Atlantic Richfield Co.*, 471 F.2d 727 (CA10), cert. denied, 411 U.S. 938, 93 S.Ct. 1900, 36 L.Ed.2d 399 (1973). But see *Nichols v. Spencer Int'l Press, Inc.*, 371 F.2d 334 (CA7 1967).

Indeed, if there is substance to the Union's claim, it is difficult to understand why these direct victims of the conspiracy have not asserted any claim in their own right. The Union's suggested explanations of this fact tend to shed doubt on the proposition that these “victims” were actually harmed at all.

“Many unionized firms will respond to the alleged boycott ... by setting up double-breasted operations or shifting more of their resources to the non-unionized part of their operations when double-breasted operations already exist. In this manner, unionized subcontractors can avoid losing any business and, as a result, these subcontractors will not ‘possess the classic economic incentive to file suit.’ Alternatively, unionized subcontractors may simply not renew the collective bargaining agreement when it expires.” Brief of Respondents 49.


We expressly noted in *McCready* that:

“... our cautious approach to speculative, abstract, or impractical damages theories has no application to McCready's suit. The nature of her injury is easily stated: As the result of an unlawful boycott, Blue Shield failed to pay the cost she incurred for the services of a psychologist. Her damages were fixed by the plan contract and, as the Court of Appeals observed, they could be ‘ascertained to the penny.’ ” 457 U.S., at ——, n. 11, 102 S.Ct., at 2547, n. 11.

This interest was also identified in the legislative debates preceding the enactment of the Sherman Act. Speaking in opposition to a proposed amendment that might have complicated the procedures in private actions, Senator Edmunds said:

“Therefore I say as to the suggested amendment of my friend from Mississippi—and I repeat it in all earnestness—that if I were a lobbyist and wanted to entangle this business, I should provide that everybody might sue everybody else in one common suit and have a regular pot-pourri of the affair, as his amendment proposes, and leave it to the lawyers of the trust to have an interminable litigation in respect of the proper parties, whether their interests were common or diverse or how they were affected, and take twenty years in order to get a result as to a single one of them. The Judiciary Committee did not think it wise to do that sort of thing, because we were in earnest about the business, as I know my friend is.” 21 Cong.Rec. 3148 (1890).
We pointed out in *McCready, supra*, 457 U.S., at ——, n. 11, 102 S.Ct., at 2547, n. 11:

“If there is a subordinate theme to our opinions in *Hawaii* and *Illinois Brick*, it is that the feasibility and consequences of implementing particular damages theories may, in certain limited circumstances, be considered in determining who is entitled to prosecute an action brought under § 4.... Thus we recognized that the task of disentangling overlapping damages claims is not lightly to be imposed upon potential antitrust litigants, or upon the judicial system.”

Although the policy against duplicative recoveries may not apply to the other type of harm asserted in the Union's brief—reduction in its ability to persuade nonunion contractors to enter into union agreements—the remote and obviously speculative character of that harm is plainly sufficient to place it beyond the reach of § 4. See n. 46, *supra*.

Cf. *Radovich v. National Football League*, 352 U.S. 445, 454, 77 S.Ct. 390, 395, 1 L.Ed.2d 456 (1957) (given Congress' determination that the activities prohibited by the antitrust laws are “injurious to the public” and its creation of “sanctions allowing private enforcement of the antitrust laws by an aggrieved party,” “this Court should not add requirements to burden the private litigant beyond what is specifically set forth by Congress in those laws”).

See *Karseal Corp. v. Richfield Oil Corp.*, 221 F.2d 358, 363 (CA9 1955) (antitrust action is basically a suit to recover “for a tort”).

See Restatement of Torts § 279 (1934) (“If the actor's conduct is intended by him to bring about bodily harm to another which the actor is not privileged to inflict, it is the legal cause of any bodily harm of the type intended by him which it is a substantial factor in bringing about.”); *id.*, at Comment c (“There are no rules which relieve the actor from liability because of the manner in which his conduct has resulted in the injury such as there are where the liability of a negligent actor is in question. Therefore, the fact that the actor's conduct becomes effective in harm only through the intervention of new and independent forces for which the actor is not responsible is of no importance.”) (citations omitted); *id.*, at § 280 (same rule applies to conduct intended to cause harm other than bodily harm); *Seidel v. Greenberg*, 108 N.J.Sup. 248, 261–269, 260 A.2d 863, 871–876 (1969); *Derossier v. New England Tel. & Tel. Co.*, 81 N.H. 451, 464, 130 A. 145, 152 (1925) (“For an intended injury the law is astute to discover even very remote causation.”).

The Court's reliance on Sutherland's treatise on damages is misplaced. *Ante*, at n. 25. Although Sutherland stated as a general proposition that a defendant is not liable to a plaintiff for injuries suffered as a result of the defendant's conduct with respect to a third party, he distinguished cases in which “the wrongful act is willful for that purpose,” by which he presumably meant cases in which the defendant intended to injure the plaintiff. 1 J. Sutherland, A Treatise on the Law of Damages 55 (1882). In the examples given by Sutherland and cited by the Court, there is no suggestion that the defendants intended to inflict injury upon the plaintiffs.


See Blue Shield of Virginia v. McCready, supra, 457 U.S., at ———, 102 S.Ct., at 2546 (noting that Illinois Brick and Hawaii v. Standard Oil Co. “focused on the risk of duplicative recovery engendered by allowing every person along a chain of distribution to claim damages arising from a single transaction that violated the antitrust laws”).

Significantly, the risk of duplicative recovery that the Court relied on in both Illinois Brick and Hawaii v. Standard Oil Co. is not simply a judicially invented reason for restricting the broad scope of § 4. Permitting two recoveries based on the very same injuries would be contrary to the basic statutory scheme governing damage actions, for the result would be to subject antitrust defendants to sextuple-damage awards rather than the treble-damage awards that Congress contemplated. See II P. Areeda & D. Turner, Antitrust Law § 337d (1978).

Since we have only the pleadings before us, we do not know how the plaintiff unions collect their dues. However, plaintiffs are entitled to survive a motion to dismiss under Fed.R.Civ.Proc. 12(b)(6) if there is any set of facts that, if proven at trial, would entitle them to recover.
Synopsis

Antitrust treble-damages action was brought by State of Illinois and local government entities alleging that concrete block manufacturers had engaged in price-fixing conspiracy. The United States District Court for the Northern District of Illinois, Eastern Division, 67 F.R.D. 461, granted defendants’ motion for partial summary judgment, and plaintiffs appealed. The Court of Appeals, 536 F.2d 1163, reversed, and certiorari was granted. The Supreme Court, Mr. Justice White, held that (1) whatever rule is to be adopted regarding pass-on theories in antitrust actions, it must apply equally to plaintiffs and defendants and (2) only overcharged direct purchaser, and not others in chain of manufacture or distribution, is party “injured in his business or property” within meaning of the Clayton Act.

Judgment of Court of Appeals reversed and remanded.

Mr. Justice Brennan filed dissenting opinion in which Mr. Justice Marshall and Mr. Justice Blackmun joined.

Mr. Justice Blackmun filed dissenting opinion.

Procedural Posture(s): On Appeal; Motion for Summary Judgment.

**2062** Syllabus*

*720 Respondents, the State of Illinois and 700 local governmental entities, brought this antitrust treble-damages action under s 4 of the Clayton Act alleging that petitioners, concrete block manufacturers (which sell to masonry contractors, which in turn sell to general contractors, from which respondents purchase the block in the form of masonry structures) had engaged in a price-fixing conspiracy in violation of s 1 of the Sherman Act. Petitioners, relying on Hanover Shoe, Inc. v. United Shoe Machinery Corp., 392 U.S. 481, 88 S.Ct. 2224, 20 L.Ed.2d 1231, moved for partial summary judgment against all plaintiffs that were indirect purchasers of block from petitioners, contending that only direct purchasers could sue for the alleged overcharge. The District Court granted the motion, but the Court of Appeals reversed, holding that indirect purchasers such as respondents could recover treble damages for an illegal overcharge if they could prove that the overcharge was passed on to them through the intermediate distribution channels. Hanover Shoe held that generally the illegally overcharged direct purchaser suing for
97 S.Ct. 2061, 52 L.Ed.2d 707, 1977-1 Trade Cases P 61,460

Treble damages, and not others in the chain of manufacture or distribution, is the party "injured in his business or property" within the meaning of s 4. Held:

1. If a pass-on theory may not be used defensively by an antitrust violator (defendant) against a direct purchaser (plaintiff) that theory may not be used offensively by an indirect purchaser (plaintiff) against an alleged violator (defendant). Therefore, unless Hanover Shoe is to be overruled or limited, it bars respondents' pass-on theory. Pp. 2066-2070.

(a) Allowing offensive but not defensive use of pass-on would create a serious risk of multiple liability for defendants, since even though an indirect purchaser had **2063 already recovered for all or part of an overcharge passed on to him, the direct purchaser would still automatically recover the full amount of the overcharge that the indirect purchaser had shown to be passed on, and, similarly, following an automatic recovery of the full overcharge by the direct purchaser, the indirect purchaser could sue to recover the same amount. Overlapping recoveries would certainly result from the two lawsuits unless the indirect purchaser is unable to establish any pass-on whatsoever. Pp. 2067-2068.

*721 (b) The Court's perception in Hanover Shoe of the uncertainties and difficulties in analyzing price and output decisions "in the real economic world rather than an economist's hypothetical model," applies with equal force to the assertion of pass-on theories by plaintiffs as it does to such assertion by defendants. P. 2068.

(c) Because Hanover Shoe would bar petitioners from using respondents' pass-on theory as a defense to a treble-damages suit by the direct purchasers (the masonry contractors), Hanover Shoe must be overruled (or narrowly limited), or it must be applied to bar respondents' attempt to use this pass-on theory offensively. Pp. 2069-2070.

2. Hanover Shoe was correctly decided and its construction of s 4 is adhered to. Pp. 2070-2076.

(a) Considerations of stare decisis weigh heavily in the area of statutory construction, where Congress is free to change this Court's interpretation of its legislation. P. 2070.

(b) Whole new dimensions of complexity would be added to treble-damages suits, undermining their effectiveness, if the use of pass-on theories under s 4 were allowed. Even under the optimistic assumption that joinder of potential plaintiffs would deal satisfactorily with problems of multiple litigation and liability, s 4 actions would be transformed into massive multiparty litigations involving many distribution levels and including large classes of ultimate consumers remote from the defendant. The Court's concern in Hanover Shoe with the problems of "massive evidence and complicated theories" involved in attempting to establish a pass-on defense against a direct purchaser applies a fortiori to the attempt to trace the effect of the overcharge through each step in the distribution chain from the direct purchasers to the ultimate consumer. Pp. 2070-2074.

(c) Attempts to carve out exceptions to Hanover Shoe for particular types of markets would entail the very problems that Hanover Shoe sought to avoid. Pp. 2074-2075.

(d) The legislative purpose in creating a group of "private attorneys general" to enforce the antitrust laws under s 4, Hawaii v. Standard Oil Co. of California, 405 U.S. 251, 262, 92 S.Ct. 885, 891, 31 L.Ed.2d 184, is better served by holding direct purchasers to be injured to the full extent of the overcharge paid by them than by attempting to apportion the overcharge among all that may have absorbed a part of it. Pp. 2074-2076.

536 F.2d 1163, reversed and remanded.
97 S.Ct. 2061, 52 L.Ed.2d 707, 1977-1 Trade Cases P 61,460

Attorneys and Law Firms


Lee A. Freeman, Jr., Chicago, Ill., for respondents.

Donald I. Baker, Washington, D.C., for the United States, as amicus curiae, by special leave of Court.

Opinion

*723 Mr. Justice WHITE delivered the opinion of the Court.

Hanover Shoe, Inc. v. United Shoe Machinery Corp., 392 U.S. 481, 88 S.Ct. 2224, 20 L.Ed.2d 1231 (1968), involved an antitrust treble-damages action *724 brought under s 4 of the Clayton Act 1 against a manufacturer of **2064 shoe machinery by one of its customers, a manufacturer of shoes. In defense, the shoe machinery manufacturer sought to show that the plaintiff had not been injured in its business as required by s 4 because it had passed on the claimed illegal overcharge to those who bought shoes from it. Under the defendant's theory, the illegal overcharge was absorbed by the plaintiff's customers indirect purchasers of the defendant's shoe machinery who were the persons actually injured by the antitrust violation.

In this case we once again confront the question whether the overcharged direct purchaser should be deemed for purposes of s 4 to have suffered the full injury from the overcharge; but the issue is presented in the context of a suit in which the plaintiff, an indirect purchaser, seeks to show its injury by establishing pass-on by the direct purchaser and in which the antitrust defendants rely on Hanover Shoe's rejection of the pass-on theory. Having decided that in general a pass-on theory may not be used defensively by an antitrust violator against a direct purchaser plaintiff, we must now decide whether that theory may be used offensively by an indirect purchaser plaintiff against an alleged violator.

I

Petitioners manufacture and distribute concrete block in the Greater Chicago area. They sell the block primarily to masonry contractors, who submit bids to general contractors for the masonry portions of construction projects. The general contractors in turn submit bids for these projects to customers such as the respondents in this case, the State of Illinois and 700 local governmental entities in the Greater Chicago area, including counties, municipalities, housing authorities, and school districts. See 67 F.R.D. 461, 463 (ND Ill.1975); App. 16-48. Respondents are thus indirect purchasers of concrete block, which passes through two separate levels in the chain of distribution before reaching respondents. The block is purchased directly from

responders by masonry contractors and used by them to build masonry structures; those structures are incorporated into entire buildings by general contractors and sold to respondents.

Respondent State of Illinois, on behalf of itself and respondent local governmental entities, brought this antitrust treble-damages action under s 4 of the Clayton Act, alleging that petitioners had engaged in a combination and conspiracy to fix the prices of concrete block in violation of s 1 of the Sherman Act. The complaint alleged that the amounts paid by respondents for concrete block were more than $3 million higher by reason of this price-fixing conspiracy. The only way in which the antitrust violation alleged could have injured respondents is if all or part of the overcharge was passed on by the masonry and general contractors to respondents, rather than being absorbed at the first two levels of distribution. See Illinois v. Ampress Brick Co., 536 F.2d 1163, 1164 (CA7 1976).

(1) Petitioner manufacturers moved for partial summary judgment against all plaintiffs that were indirect purchasers of concrete block from petitioners, contending that as a matter of law only direct purchasers could sue for the alleged overcharge. The District Court granted petitioners' motion, but the Court of Appeals reversed, holding that indirect purchasers such as respondents in this case can recover treble damages for an illegal overcharge if they can prove that the overcharge was passed on to them through intervening links in the distribution chain.

**2066 We granted certiorari, 429 U.S. 938, 97 S.Ct. 352, 50 L.Ed.2d 307 (1976), to resolve a conflict among the Courts of Appeals on the question whether the offensive use of pass-on authorized by the decision below is consistent with Hanover Shoe's restrictions on the defensive use of pass-on. We hold that it is not, and we reverse. We reach this result in two steps. First, we conclude that whatever rule is to be adopted regarding pass-on in antitrust damages actions, it must apply equally to plaintiffs and defendants. Because Hanover Shoe would bar petitioners from using respondents' pass-on theory as a defense to a treble-damages suit by the direct purchasers (the masonry contractors), we are faced with the choice of overruling (or narrowly limiting) Hanover Shoe or of applying it to bar respondents' attempt to use this pass-on theory offensively. Second, we decline to abandon the construction given s 4 in Hanover Shoe that the overcharged direct purchaser, and not others in the chain of manufacture or distribution, is the party "injured in his business or property" within the meaning of the section in the absence of a convincing demonstration that the Court was wrong in Hanover Shoe to think that the effectiveness of the antitrust treble-damages action would be substantially reduced by adopting a rule that any party in the chain may sue to recover the fraction of the overcharge allegedly absorbed by it.

II

(2) The parties in this case agree that however s 4 is construed with respect to the pass-on issue, the rule should apply equally to plaintiffs and defendants that an indirect purchaser should not be allowed to use a pass-on theory to recover damages from a defendant unless the defendant would be allowed to use a pass-on defense in a suit by a direct purchaser. Respondents, in arguing that they should be allowed to recover by showing pass-on in this case, have conceded that petitioners should be allowed to assert a pass-on defense against direct purchasers of concrete block, Tr. of Oral Arg. 33, 48; they ask this Court to limit Hanover Shoe's bar on pass-on defenses to its "particular factual context" of overcharges for capital goods used to manufacture new products. Id., at 41; see id., at 36, 47-48.

Before turning to this request to limit Hanover Shoe, we consider the substantially contrary position, adopted by our dissenting Brethren, by the United States as amicus curiae, and by lower courts that have allowed offensive use of pass-on, that the unavailability of a pass-on theory to a defendant should not necessarily preclude its use by plaintiffs seeking treble damages against that defendant. Under this view, Hanover Shoe's rejection of pass-on would continue to apply to defendants...
allowing offensive but not defensive use of pass-on would create a serious risk of multiple liability for defendants. Even though an indirect purchaser had already recovered for all or part of an overcharge passed on to it, the direct purchaser would still recover automatically the full amount of the overcharge that the indirect purchaser had shown to be passed on; similarly, following an automatic recovery of the full overcharge by the direct purchaser, the indirect purchaser could sue to recover the same amount. The risk of duplicative recoveries created by unequal application of the Hanover Shoe rule is much more substantial than in the more usual situation where the defendant is sued in two different lawsuits by plaintiffs asserting conflicting claims to the same fund. A one-sided application of Hanover Shoe substantially increases the possibility of inconsistent adjudications and therefore of unwarranted multiple liability for the defendant by presuming that one plaintiff (the direct purchaser) is entitled to full recovery while preventing the defendant from using that presumption against the other plaintiff; overlapping recoveries are certain to result from the two lawsuits unless the indirect purchaser is unable to establish any pass-on whatsoever. As in Hawaii v. Standard Oil Co. of Cal., 405 U.S. 251, 264, 92 S.Ct. 885, 892, 31 L.Ed.2d 184 (1972), we are unwilling to “open the door to duplicative recoveries” under $4.\footnote{731}

Second, the reasoning of Hanover Shoe cannot justify unequal treatment of plaintiffs and defendants with respect to the permissibility of pass-on arguments. The principal basis for the decision in Hanover Shoe was the Court's perception of the uncertainties and difficulties in analyzing price and output changes "in the real economic world rather than an economist's hypothetical model," 392 U.S., at 493, 88 S.Ct., at 2231 and of the costs to the judicial system and the efficient enforcement of the antitrust laws of attempting to reconstruct those decisions in the courtroom.\footnote{732} This perception that the attempt to trace the complex economic adjustments to a change in the cost of a particular factor of production would greatly complicate and reduce the effectiveness of already protracted treble-damages proceedings applies with no less force to the assertion of pass-on theories by plaintiffs than it does to the assertion by defendants. However “long and complicated” the proceedings would be when defendants sought to prove pass-on, ibid., they would be equally so when the same evidence was introduced by plaintiffs. Indeed, the evidentiary complexities and uncertainties involved in the defensive use of pass-on against a direct purchaser are multiplied in the offensive use of pass-on by a plaintiff several steps removed from the defendant in the chain of distribution. The demonstration of how much of the overcharge was passed on by the first purchaser must be repeated at each point at which the price-fixed goods changed hands before they reached the plaintiff.\footnote{733} (3) It is argued, however, that Hanover Shoe rests on a policy of ensuring that a treble-damages plaintiff is available to deprive antitrust violators of “the fruits of their illegality,” id., at 494, 88 S.Ct., at 2232, a policy that would be furthered by allowing plaintiffs but not defendants to use pass-on theories. See, e.g., In re Western Liquid Asphalt Cases, 487 F.2d 191, 197 (CA9 1973), cert. denied, sub nom. Standard Oil Co. of Cal. v. Alaska, 415 U.S. 919, 94 S.Ct. 1419, 39 L.Ed.2d 474 (1974); Brief for United States as Amicus Curiae 4-6, 12-13, 17-19.\footnote{734} We do not read the Court's concern in Hanover Shoe for the effectiveness of the treble-damages remedy as countenancing unequal application of the Court's pass-on rule. Rather, we understand Hanover Shoe as resting on the judgment that the antitrust laws will be more effectively enforced by concentrating the full recovery for the overcharge in the direct purchasers rather than by allowing every plaintiff potentially affected by the overcharge to sue only for the amount it could show was absorbed by it.\footnote{735}

(4) We thus decline to construe s 4 to permit offensive use of a pass-on theory against an alleged violator that could not use the same theory as a defense in an action by direct purchasers. In this case, respondents seek to demonstrate that masonry contractors, who incorporated petitioners' block into walls and other masonry structures, passed on the alleged overcharge on the block to general contractors, who incorporated the masonry structures into entire buildings, and that the general contractors in turn passed on the overcharge to respondents in the bids submitted for those buildings. We think it clear that under a fair reading of Hanover Shoe petitioners would be barred from asserting this theory in a suit by the masonry contractors.
In Hanover Shoe this Court did not endorse the broad exception that had been recognized in that case by the courts below permitting the pass-on defense against middlemen who did not alter the goods they purchased before reselling them. The masonry contractors here could not be included under this exception in any event, because they transform the concrete block purchased from defendants into the masonry portions of buildings. But this Court in Hanover Shoe indicated the narrow scope it intended for any exception to its rule barring pass-on defenses by citing, as the only example of a situation where the defense might be permitted, a pre-existing cost-plus contract. In such a situation, the purchaser is insulated from any decrease in its sales as a result of attempting to pass on the overcharge, because its customer is committed to buying a fixed quantity regardless of price. The effect of the overcharge is essentially determined in advance, without reference to the interaction of supply and demand that complicates the determination in the general case. The competitive bidding process by which the concrete block involved in this case was incorporated into masonry structures and then into entire buildings can hardly be said to circumvent complex market interactions as would a cost-plus contract.

We are left, then, with two alternatives: either we must overrule Hanover Shoe (or at least narrowly confine it to its facts), or we must preclude respondents from seeking to recover on their pass-on theory. We choose the latter course.

III

(5) In considering whether to cut back or abandon the Hanover Shoe, rule, we must bear in mind that considerations of stare decisis weigh heavily in the area of statutory construction, where Congress is free to change this Court's interpretation of its legislation. See Edelman v. Jordan, 415 U.S. 651, 671, 94 S.Ct. 1347, 1359, 39 L.Ed.2d 662 (1974); Burnet v. Coronado Oil & Gas Co., 285 U.S. 393, 406-408, 52 S.Ct. 443, 447-448, 76 L.Ed. 815 (1932) (Brandeis, J., dissenting). This presumption of adherence to our prior decisions construing legislative enactments would support our reaffirmance of the Hanover Shoe construction of s 4, joined by eight Justices without dissent only a few years ago, even if the Court were persuaded that the use of pass-on theories by plaintiffs and defendants in treble-damages actions is more consistent with the policies underlying the treble-damages action than is the Hanover Shoe rule. But we are not so persuaded.

(6) Permitting the use of pass-on theories under s 4 essentially would transform treble-damages actions into massive efforts to apportion the recovery among all potential plaintiffs that could have absorbed part of the overcharge from direct purchasers to middlemen to ultimate consumers. However appealing this attempt to allocate the overcharge might seem in theory, it would add whole new dimensions of complexity to treble-damages suits and seriously undermine their effectiveness.

As we have indicated, potential plaintiffs at each level in the distribution chain are in a position to assert conflicting claims to a common fund the amount of the alleged overcharge by contending that the entire overcharge was absorbed at that particular level in the chain. A treble-damages action brought by one of these potential plaintiffs (or one class of potential plaintiffs) to recover the overcharge implicates all three of the interests that have traditionally been thought to support compulsory joinder of absent and potentially adverse claimants: the interest of the defendant in avoiding multiple liability for the fund; the interest of the absent potential plaintiffs in protecting their right to recover for the portion of the fund allocable to them; and the social interest in the efficient administration of justice and the avoidance of multiple litigation. Reed, Compulsory Joinder of Parties ** in Civil Actions, 55 Mich.L.Rev. 327, 330 (1957). See Provident Tradesmens Bank & Trust Co. v. Patterson, 390 U.S. 102, 110-111, 88 S.Ct. 733, 738-739, 19 L.Ed.2d 936 (1968); 7 C. Wright & A. Miller, Federal Practice and Procedure s 1602 (1972).

Opponents of the Hanover Shoe rule have recognized this need for compulsory joinder in suggesting that the defendant could interplead potential claimants under 28 U.S.C. s 1335. But if the defendant, for any of a variety of reasons, does not
choose to interplead the absent potential claimants, there would be a strong argument for joining them as “persons needed for just adjudication” under Fed.Rule Civ.Proc. 19(a). 21 See *739 Comment, Standing to Sue in Antitrust Cases: The Offensive Use of Passing-On, 123 U.Pa.L.Rev. 976, 998 (1975). These absent potential claimants would seem to fit the classic definition of “necessary parties,” for purposes of compulsory joinder, given in Shields v. Barrow, 17 How. 130, 139, 15 L.Ed. 158 (1855): “Persons having an interest in the controversy, and who ought to be made parties, in order that the court may act on that rule which requires it to decide on, and finally determine the entire controversy, and do complete justice, by adjusting all the rights involved in it.”

See Notes of Advisory Committee on 1966 Amendment to Rule 19, 28 U.S.C. App., p. 7760; 7 C. Wright & A. Miller, supra, ss 1604, 1618; 3A J. Moore, Federal Practice P 19.08 (1974). The plaintiff bringing the treble-damages action would be required, under Fed.Rule Civ.Proc. 19(c), to “state the names, if known,” of these absent potential claimants; they should also be notified by some means that the action was pending. 22 Where, as would often be the case, the potential claimants at a particular level of distribution are so numerous that joinder of all is impracticable, a representative presumably would have to be found to bring them into the action as a class. See Fed.Rule Civ.Proc. 19(d); 3A J. Moore, supra P 19.21.

It is unlikely, of course, that all potential plaintiffs could or would be joined. Some may not wish to assert claims to the *740 overcharge; others may be unmanageable as a class; and still others may be beyond the personal jurisdiction of the court. We can assume that ordinarily the action would still proceed, the absent parties not being deemed “indispensable” under Fed.Rule Civ.Proc. 19(b). See Provident Tradesmens Bank & Trust Co. v. Patterson, supra. But allowing indirect purchasers to recover using pass-on theories, even under the optimistic **2072 assumption that joinder of potential plaintiffs will deal satisfactorily with problems of multiple litigation and liability, would transform treble-damages actions into massive multiparty litigations involving many levels of distribution and including large classes of ultimate consumers remote from the defendant. In treble-damages actions by ultimate consumers, the overcharge would have to be apportioned among the relevant wholesalers, retailers, and other middlemen, whose representatives presumably should be joined. 23 And in suits *741 by direct purchasers or middlemen, the interests of ultimate consumers are similarly implicated. 24

There is thus a strong possibility that indirect purchasers remote from the defendant would be parties to virtually every treble-damages action (apart from those brought against defendants at the retail level). The Court's concern in Hanover Shoe to avoid weighing down treble-damages actions with the “massive evidence and complicated theories,” 392 U.S., at 493, 88 S.Ct., at 2231, involved in attempting to establish a pass-on defense against a direct purchaser applies a fortiori to the attempt to trace the effect of the overcharge through each step in the distribution chain from the direct purchaser to the ultimate consumer. We are no more inclined than we were in Hanover Shoe to ignore the burdens that such an attempt would impose on the effective enforcement of the antitrust laws.

(7) Under an array of simplifying assumptions, economic theory provides a precise formula for calculating how the overcharge is distributed between the overcharged party (passer) and its customers (passees). If the market for the passer's product is perfectly competitive; if the overcharge is imposed equally on all of the passer's competitors; and if the passer maximizes its profits, then the ratio of the shares of the overcharge borne by passees and passer will equal the ratio of the elasticities of supply and demand in the market for the passer's product. 25 *742 Even if these **2073 assumptions are accepted, there remains a serious problem of measuring the relevant elasticities the percentage change in the quantities of the passer's product demanded and supplied in response to a one percent change in price. In view of the difficulties that have been encountered, even in informal adversary proceedings, with the statistical techniques used to estimate these concepts, see Finkelstein, Regression Models in Administrative Proceedings, 86 Harv.L.Rev. 1442, 1444 (1973), it is unrealistic to think that elasticity studies introduced by expert witnesses will resolve the pass-on issue. We need look no further than our own difficulties with sophisticated statistical methodology that were evident last Term in Gregg v. Georgia, 428 U.S. 153, 96 S.Ct. 2909, 49 L.Ed.2d 859 (1976), and its companion cases. See id., at 184-185, 96 S.Ct., at 2930-2931 (joint opinion of Stewart, Powell, and Stevens, JJ.); 428 U.S. 227,

97 S.Ct. 2061, 52 L.Ed.2d 707, 1977-1 Trade Cases P 61,460


More important, as the Hanover Shoe Court observed, 392 U.S., at 493, 88 S.Ct., at 2231, “in the real economic world rather than an economist's hypothetical model,” the latter's drastic simplifications generally must be abandoned. Overcharged direct purchasers often sell in imperfectly competitive markets. They often compete with other sellers that have not been subject to the overcharge; and their pricing policies often cannot be explained solely by the convenient assumption of profit maximization. 26 As we concluded in *743 Hanover Shoe, 392 U.S., at 492, 88 S.Ct., at 2231, attention to “sound laws of economics” can only heighten the awareness of the difficulties and uncertainties involved in determining how the relevant market variables would have behaved had there been no overcharge. 27

It is quite true that these difficulties and uncertainties will be less substantial in some contexts than in others. There have been many proposals to allow pass-on theories in some of these contexts while preserving the Hanover Shoe rule in others. Respondents here argue, not without support from some lower courts, 28 that pass-on theories should be permitted for middlemen that resell goods without altering them and for contractors that add a fixed percentage markup to the cost of their materials in submitting bids. Brief for Respondents 9-30; Tr. of Oral Arg. 36-48. Exceptions to the Hanover Shoe rule have also been urged for other situations in which most of the overcharge is purportedly passed on for example, where a price-fixed good is a small but vital input into a *744 much larger product, making the demand for the price-fixed good highly inelastic. Compare **2074 Philadelphia Housing Auth. v. American Radiator & Standard Sanitary Corp., 50 F.R.D. 13 (ED Pa.1970), aff'd sub nom. Mangano v. American Radiator & Standard Sanitary Corp., 438 F.2d 1187 (CA3 1971), with In re Master Key Antitrust Litigation, 1973-2 Trade Cas. P 74,680 (Conn.). See Schaefer, supra, n. 25, at 918-925.

We reject these attempts to carve out exceptions to the Hanover Shoe rule for particular types of markets. 29 An exception allowing evidence of pass-on by middlemen that resell the goods they purchase of course would be of no avail to respondents, because the contractors that allegedly passed on the overcharge on the block incorporated it into buildings. See supra, at 2069. An exception for the contractors here on the ground that they purport to charge a fixed percentage above their costs would substantially erode the Hanover Shoe rule without justification. Firms in many sectors of the economy rely to an extent on cost-based rules of thumb in setting prices. See F. Scherer, Industrial Market Structure and Economic Performance 173-179 (1970). These rules are not adhered to rigidly, however; the extent of the markup (or the allocation of costs) is varied to reflect demand conditions. Id., at 176-177. The intricacies of tracing the effect of an overcharge on the purchaser's prices, costs, sales, and profits thus are not spared the litigants.

More generally, the process of classifying various market situations according to the amount of pass-on likely to be *745 involved and its susceptibility of proof in a judicial forum would entail the very problems that the Hanover Shoe rule was meant to avoid. The litigation over where the line should be drawn in a particular class of cases would inject the same “massive evidence and complicated theories” into treble-damages proceedings, albeit at a somewhat higher level of generality. As we have noted, supra, at 2069-2070, Hanover Shoe itself implicitly discouraged the creation of exceptions to its rule barring pass-on defenses, and we adhere to the narrow scope of exemption indicated by our decision there.

The concern in Hanover Shoe for the complexity that would be introduced into treble-damages suits if pass-on theories were permitted was closely related to the Court's concern for the reduction in the effectiveness of those suits if brought by indirect purchasers with a smaller stake in the outcome than that of direct purchasers suing for the full amount of the overcharge. The apportionment of the recovery throughout the distribution chain would increase the overall costs of recovery by injecting extremely complex issues into the case; at the same time such an apportionment would reduce the benefits to each plaintiff by dividing the potential recovery among a much larger group. Added to the uncertainty of how much of an overcharge could be established at trial would be the uncertainty of how that overcharge would be apportioned among the various plaintiffs. This
additional uncertainty would further reduce the incentive to sue. The combination of increasing the costs and diffusing the benefits of bringing a treble-damages action could seriously impair this important weapon of antitrust enforcement.

(8) We think the longstanding policy of encouraging vigorous private enforcement of the antitrust laws, see, e.g., Perma Life Mufflers, Inc. v. International Parts Corp., 392 U.S. 134, 139, 88 S.Ct. 1981, 1984, 20 L.Ed.2d 982 (1968), supports our adherence to the Hanover Shoe rule, under which direct purchasers are not only spared the burden of litigating the intricacies of pass-on but also are permitted to recover the full amount of the overcharge. We recognize that direct purchasers sometimes may refrain from bringing a treble-damages suit for fear of disrupting relations with their suppliers. But on balance, and until there are clear directions from Congress to the contrary, we conclude that the legislative purpose in creating a group of “private attorneys general” to enforce the antitrust laws under s 4, Hawaii v. Standard Oil Co. of Cal., 405 U.S., at 262, 92 S.Ct., at 891, is better served by holding direct purchasers to be injured to the full extent of the overcharge paid by them than by attempting to apportion the overcharge among all that may have absorbed a part of it.

(9) It is true that, in elevating direct purchasers to a preferred position as private attorneys general, the Hanover Shoe rule denies recovery to those indirect purchasers who may have been actually injured by antitrust violations. Of course, as Mr. Justice BRENNAN points out in dissent, “from the deterrence standpoint, it is irrelevant to whom damages are paid, so long as some one redresses the violation.” Post, at 2082. But s 4 has another purpose in addition to deterring violators and depriving them of “the fruits of their illegality,” Hanover Shoe, 392 U.S., at 494, 88 S.Ct., at 2232; it is also designed to compensate victims of antitrust violations for their injuries. E.g., Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 485-486, 97 S.Ct. 690, 695-696, 50 L.Ed.2d 701 (1977). Hanover Shoe does further the goal of compensation to the extent that the direct purchaser absorbs at least some and often most of the overcharge. In view of the considerations supporting the Hanover Shoe rule, we are unwilling to carry the compensation principle to its logical extreme by attempting to allocate damages among all “those within the defendant's chain of distribution,” post, at 2082, especially because we question the extent to which such an attempt would make individual victims whole for actual injuries suffered rather than simply depleting the overall recovery in litigation over pass-on issues. Many of the indirect purchasers barred from asserting pass-on claims under the Hanover Shoe rule have such a small stake in the lawsuit that even if they were to recover as part of a class, only a small fraction would be likely to come forward to collect their damages. And given the difficulty of ascertaining the amount absorbed by any particular indirect purchaser, there is little basis for believing that the amount of the recovery would reflect the actual injury suffered.

For the reasons stated, the judgment is reversed, and the case is remanded for further proceedings consistent with this opinion.

So ordered.

Mr. Justice BRENNAN, with whom Mr. Justice MARSHALL and Mr. Justice BLACKMUN join, dissenting.

Respondent State of Illinois brought this treble-damages civil antitrust action under s 4 of the Clayton Act on behalf of itself and various local governmental entities in the Greater Chicago area alleging that an overcharge in the price of concrete block used in the construction of public buildings was made by the petitioners, manufacturers and sellers of concrete block, pursuant to a price-fixing conspiracy in violation of s 1 of the Sherman Act, 15 U.S.C. s 1. Section 4 of the Clayton Act, 38 Stat. 731, 15 U.S.C. s 15, broadly provides: “(A) person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws may sue therefor . . . and shall recover threefold the damages by him sustained . . . .”

Decisions of the Court defining the reach of s 4 have been consistent with its broad objectives: to compensate victims of antitrust violations and to deter future violations. The Court has stated that s 4 “does not confine its protection to consumers, or to purchasers, or to competitors, or to sellers . . . (but) is comprehensive in its terms and coverage, protecting all who are made victims of the forbidden practices by whomever they may be perpetrated.” Mandeville Island Farms, Inc. v. American Crystal

Today's decision that s 4 affords a remedy only to persons who purchase directly from an antitrust offender is a regrettable retreat from that line of cases. Section 4 was clearly intended to operate to protect individual consumers who purchase through middlemen. Indeed, Congress acted on the premise that s 4 gave a cause of action to indirect as well as direct purchasers when it recently enacted the Hart-Scott-Rodino Antitrust Improvements Act of 1976, 90 Stat. 1394-1396, 15 U.S.C. s 15c et seq. (1976 ed.), and authorized state attorneys general to sue as parens patriae to recover damages on behalf of citizens of their various States.

Today's decision flouts Congress' purpose and severely undermines the effectiveness of the private treble-damages action as an instrument of antitrust enforcement. For in many instances, the brunt of antitrust injuries is borne by indirect purchasers, often ultimate consumers of a product, as increased costs are passed along the chain of distribution. In these instances, the Court's decision frustrates both the compensation and deterrence objectives of the treble-damages action. Injured consumers are precluded from recovering damages from manufacturers, and direct purchasers who act as middlemen have little incentive to sue suppliers so long as they may pass on the bulk of the illegal overcharges to the ultimate consumers. This frustration of the congressional scheme is in no way mandated by Hanover Shoe, Inc. v. United Shoe Machinery Corp., 392 U.S. 481, 88 S.Ct. 2224, 20 L.Ed.2d 1231 (1968). To the contrary, the same considerations that Hanover Shoe held required rejection of the defendant's argument there, that because plaintiff had passed on cost increases to consumers in the form of higher prices defendant should be relieved of liability especially the consideration that it is essential to the public interest to preserve the effectiveness of the private treble-damages action require affirmance of the decision below construing s 4 to authorize respondents' suit.

I

In Hanover Shoe, supra, the Court held that a defendant in a treble-damages action could not escape liability, except in very limited circumstances, by proof that the plaintiff had passed on illegal overcharges to others farther along in the chain of distribution. The defendant in Hanover Shoe, United Shoe, argued that Hanover was not entitled to recover damages because the increased price it had paid for United's equipment had in turn been reflected in the increased price at which Hanover had sold its shoes to the consuming public. The Court held that several reasons supported its conclusion that this defense was not available to United despite “the argument that sound laws of economics require” its recognition, 392 U.S., at 492, 88 S.Ct., at 2231. First, the Court followed earlier cases holding that the “victim of an overcharge is (immediately) damaged within the meaning of s 4 to the extent of that overcharge.” Id., at 491, 88 S.Ct., at 2230. The particularly apt precedent supporting this proposition was Southern Pacific Co. v. Darnell-Taenzer Lumber Co., 245 U.S. 531, 38 S.Ct. 186, 62 L.Ed. 451 (1918), where a pass-on defense had been rejected because of “(t)he general tendency of the law in regard to damages at least, . . . not to go beyond the first step,” and the Court's belief that “(t)he carrier ought not to be allowed to retain his illegal profit, and the only one who can take it from him is the one that alone was in relation with him, and from whom the carrier took the sum. . . .” Id., at 533-534, 38 S.Ct., at 186. In other words, the requirement of privity between plaintiff and defendant was a reason to deny defendant the pass-on defense, since otherwise the defendant would be able to profit by his own wrong. Hanover Shoe cannot be read, however, as limiting actions to parties in privity with one another. That was made clear in Perkins v. Standard Oil Co., 395 U.S. 642, 648, 89 S.Ct. 1871, 1874, 23 L.Ed.2d 599 (1969), decided the next Term, a price discrimination case in which the Court traced an illegal overcharge through several levels in the chain of distribution, ultimately holding that a plaintiff seeking to recover damages need show only a “causal connection between the price discrimination in violation of the (antitrust laws) and the injury suffered. . . . If there is sufficient evidence in the record to support an inference of causation, the ultimate conclusion as to what that evidence proves is for the jury.” Darnell-Taenzer does, however, support Hanover Shoe's denial of the pass-on defense for the other reasons relied upon in Hanover Shoe: the difficulty of proving and quantifying a pass-on, and the role of the treble-damages action as the most effective means of antitrust enforcement. 392 U.S., at 492-494, 88 S.Ct., at 2231-2232.
The Court correctly discerned that the difficulty of reconstructing hypothetical pricing decisions, would aggravate the already complex nature of antitrust litigation since pass-on defenses would become commonplace whenever the chain of distribution extended beyond the plaintiff. This would lessen the effectiveness of the treble-damages action, since ultimate consumers individually often suffer only minor damages and therefore have little incentive to bring suit. Limiting defendants' liability to the loss of profits suffered by direct purchasers would thus allow the antitrust offender to avoid having to pay the full social cost of his illegal conduct in many cases in which indirect purchasers failed to bring suit. Consequently, “those who violate the antitrust laws by price fixing or monopolizing would retain the fruits of their illegality because no one was available who would bring suit against them. Treble damage actions, the importance of which the Court has many times emphasized, would be substantially reduced in effectiveness.” Id., at 494, 88 S.Ct., at 2232.

Hanover Shoe thus confronted the Court with the choice, as had been true in Darnell-Taenzer, of interpreting s 4 in a way that might overcompensate the plaintiff, who had certainly suffered some injury, or of defining it in a way that under-deters the violator by allowing him to retain a portion of his ill-gotten overcharges. The Court chose to interpret s 4 so as to allow the plaintiff to recover for the entire overcharge. This choice was consistent with recognition of the importance of the treble-damages action in deterring antitrust violations. But Hanover Shoe certainly did not imply that an indirect purchaser would not also have a cause of action under s 4 when the illegal overcharges were passed on to him.

Despite the superficial appeal of the argument that Hanover Shoe should be applied “consistently,” thus precluding plaintiffs and defendants alike from proving that increased costs were passed along the chain of distribution, there are sound reasons for treating offensive and defensive passing-on cases differently. The interests at stake in “offensive” passing-on cases, where the indirect purchasers sue for damages for their injuries, are simply not the same as the interests at stake in the Hanover Shoe, or “defensive” passing-on situation. There is no danger in this case, for example, as there was in Hanover Shoe, that the defendant will escape liability and frustrate the objectives of the treble-damages action. Rather, the same policies of insuring the continued effectiveness of the treble-damages action and preventing wrongdoers from retaining the spoils of their misdeeds favor allowing indirect purchasers to prove that overcharges were passed on to them. Hanover Shoe thus can and should be limited to cases of offensive assertion of the passing-on defense to antitrust liability, where direct and indirect purchasers are not parties in the same action. I fully agree with the observation: “The attempt to transform a rejection of a defense because it unduly hampers antitrust enforcement into a reason for a complete refusal to entertain the claims of a certain class of plaintiffs seems an ingenious attempt to turn the decision (in Hanover Shoe ) and its underlying rationale on its head.” In re Master Key Antitrust Litigation, 1973-2 Trade Cas. P 74,680, pp. 94,978-94,979 (Conn.).

II

A

Today's decision goes far to frustrate Congress' objectives in creating the treble-damages action. Treble-damages actions were first authorized under s 7 of the Sherman Act, 26 Stat. 210. The legislative history of this section shows that it was conceived primarily as a remedy for “(t)he people of the United States as individuals,” especially for consumers. See, e. g., 21 Cong.Rec. 1767-1768 (1890) (remarks of Sen. George); see also id., at 2612 (Sens. Teller and Reagan), 2615 (Sen. Coke), 2640 (Sen. Spooner). In the Clayton Act of 1914, Congress extended the s 7 remedy to persons injured by “any violation of the antitrust laws.” See Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 486 n. 10, 97 S.Ct. 690, 696 n. 10, 50 L.Ed.2d 701 (1977), citing H.R.Rep.No.627, 63d Cong., 2d Sess., 14 (1914). These actions were conceived primarily as “opening(ing) the door of justice to every man, whenever he may be injured by those who violate the antitrust laws, and giv(ing) the injured party

The Court has interpreted s 4 broadly, this in recognition of the plainly stated congressional objective, Northern Pacific R. Co. v. United States, 356 U.S. 1, 4, 78 S.Ct. 514, 517, 2 L.Ed.2d 545 (1958), that the private treble-damages action play a paramount role in the enforcement of the fundamental economic policy of the Nation, Zenith Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100, 130-131, 89 S.Ct. 1562, 1580, 23 L.Ed.2d 129 (1969); Minnesota Mining & Mfg. Co. v. New Jersey Wood Finishing Co., 381 U.S. 311, 318, 85 S.Ct. 1473, 1477, 14 L.Ed.2d 405 (1965), and has **2080 concluded that “the purposes of the antitrust laws are best served by insuring that the private action will be an ever-present threat to deter anyone contemplating business behavior in violation of the antitrust laws.” Perma Life Mufflers, Inc. v. International Parts Corp., 392 U.S. 134, 139, 88 S.Ct. 1981, 1984, 20 L.Ed.2d 982 (1968). The federal courts have accordingly been cautioned “not (to) *756 add requirements to burden the private litigant beyond what is specifically set forth by Congress in (the antitrust) laws,” Radovich v. National Football League, 352 U.S. 445, 454, 77 S.Ct. 390, 395, 1 L.Ed.2d 456 (1957), and express approval has been given the “tendency of the courts . . . to find some way in which damages can be awarded where a wrong has been done. Difficulty of ascertainment is no longer confused with right of recovery” for a proven invasion of the plaintiff's rights.” Bigelow v. RKO Radio Pictures, 327 U.S. 251, 265-266, 66 S.Ct. 574, 580, 90 L.Ed. 652 (1946). See also Zenith Radio Corp. v. Hazeltine Research, Inc., supra, 395 U.S., at 130-131, 89 S.Ct., at 1580; Perma Life Mufflers, Inc. v. International Parts Corp., supra; Hanover Shoe, Inc. v. United Shoe Machinery Corp., 392 U.S., at 494, 88 S.Ct., at 2232. And Radiant Burners, Inc. v. Peoples Gas, Light & Coke Co., 364 U.S. 656, 660, 81 S.Ct. 365, 367, 5 L.Ed.2d 358 (1961), emphasized that to plead a cause of action under s 4 “allegations adequate to show a violation and . . . that plaintiff was damaged thereby are all the law requires.”

B

The recently enacted Hart-Scott-Rodino Antitrust Improvements Act of 1976 was expressly adopted to create “an effective mechanism to permit consumers to recover damages for conduct which is prohibited by the Sherman Act, by giving State attorneys general a cause of action (to sue as parens patriae on behalf of the States' citizens) against antitrust violators.” S.Rep.No.94-803, p. 6 (1976). Title III of the new Act responded to the holding of Hawaii v. Standard Oil Co. of Cal., 405 U.S. 251, 92 S.Ct. 885, 31 L.Ed.2d 184 (1972), that the Clayton Act does not authorize a State to sue for damages for an injury to its general economy allegedly attributable to a violation of the antitrust laws. The Senate Report accompanying the new Act expressly found that “(t)he economic burden of most antitrust violations is borne by the consumer in the form of higher prices for goods and services,” S.Rep.No.94-803, supra, at 39, and it is clear that the new Act is intended to provide a remedy *757 for injured consumers whether or not they purchased directly from the violator. The Senate Report states, id., at 42:

“A direct cause of action is granted the States to avoid the inequities and inconsistencies of restrictive judicial interpretations. . . . Section 4C is intended to assure that consumers are not precluded from the opportunity of proving the amount of their damage and to avoid problems with respect to manageability (of class actions), standing, privity, target area, remoteness, and the like.” 13 (Emphasis supplied.)

Representative Rodino, a sponsor, stated during the House debates:

“(A)ssuming the State attorney general proves a violation, and proves that an overcharge was ‘passed on’ to the consumers, injuring them ‘in their property’; that is, their pocketbooks recoveries are authorized by the compromise bill whether **2081 or not the consumers purchased directly from the price fixer, or indirectly, from intermediaries, retailers, or middlemen. The technical and procedural argument that consumers have no ‘standing’ whenever they are not ‘in privity’ with the price fixer, and have not purchased directly from him, is rejected by the compromise bill. Opinions relying on this procedural *758 technicality . . . are squarely rejected by the compromise bill.” 122 Cong.Rec. H10295 (daily ed. Sept. 16, 1976).
It is difficult to see how Congress could have expressed itself more clearly. Even if the question whether indirect purchasers could recover for damages passed on to them was open before passage of the 1976 Act, and I do not believe that it was, Congress' interpretation of s 4 in enacting the parens patriae provision should resolve it in favor of their authority to sue. Indeed, the House Report accompanying the bill actually referred to the opinion of the District Court in this case as an example of the correct answer. N. 13, supra. The Court's tortuous efforts to impose a "consistency" upon this area of the law that Congress has so clearly rejected is a return to the "legal somersaults and twistings and turnings" of the Court's earlier opinions that ultimately led to the passage of the Clayton Act in 1914 to salvage the ailing Sherman Act. See 51 Cong.Rec. 9086 (1914) (remarks of Rep. Kelly).

Hanover Shoe correctly observed that the necessity of tracing a cost increase through several levels of a chain of distribution "would often require additional long and complicated proceedings involving massive evidence and complicated theories." 392 U.S., at 493, 88 S.Ct., at 2231. But this may be said of almost all antitrust cases. Hanover Shoe itself highlights this unavoidable complication, in that it requires the plaintiff to prove a probable course of events which would have occurred but for the violation. In essence, estimating the amount of damages passed on to an indirect purchaser is no different from and no more complicated than estimating what the middleman's selling price would have been, absent the violation. In re Western Liquid Asphalt Cases, 487 F.2d 191 (CA9 1973), cert. denied sub nom. Standard Oil of Cal. v. Alaska, 415 U.S. 919, 94 S.Ct. 2219, 39 L.Ed.2d 474 (1974). Admittedly, there will be many cases in which the plaintiff will be unable to prove that the overcharge was passed on. In others, the portion of the overcharge passed on may be only approximately determinable. But again, this problem hardly distinguishes this case from other antitrust cases. Reasoned estimation is required in all antitrust cases, but "while the damages (in such cases) may not be determined by mere speculation or guess, it will be enough if the evidence show the extent of the damages as a matter of just and reasonable inference, although the result be only approximate." Story Parchment Co. v. Paterson Paper Co., 282 U.S. 555, 563, 51 S.Ct. 248, 250, 75 L.Ed. 544 (1931). See also Bigelow v. RKO Radio Pictures, 327 U.S., at 366, 66 S.Ct., at 580; Eastman Kodak Co. v. Southern Photo Materials Co., 273 U.S. 395, 379, 47 S.Ct. 400, 405, 71 L.Ed. 684 (1927). Lack of precision in apportioning damages between direct and indirect purchasers is thus plainly not a convincing reason for denying indirect purchasers an opportunity to prove their injuries and damages. Moreover, from the deterrent standpoint, it is irrelevant to whom damages are paid, so long as someone redresses the violation. Antitrust violators are equally deterred whether the judgments against them are in favor of direct or indirect purchasers. Hanover Shoe said as much. The Court's decision recognized that some plaintiffs would recover more than their due, but concluded that the necessity of assuring that someone recover and thus deter future violations and prevent the antitrust offender from profiting by his illegal overcharge outweighed any resulting injustice.

I concede that despite the broad wording of s 4 there is a point beyond which the wrongdoer should not be held liable. See, e. g., Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 97 S.Ct. 690, 50 L.Ed.2d 701 (1977); Hawaii v. Standard Oil Co. of Cal., 405 U.S. 251, 92 S.Ct. 885, 31 L.Ed.2d 184 (1972). Courts have therefore developed various tests of antitrust "standing," not unlike the concept of proximate cause in tort law, to define that point. The definition has been variously articulated, usually in terms of two tests. The most restrictive test focuses on the directness of the injury; the more liberal, and more widely accepted, on whether the plaintiff is within the "target area" of the defendant's violation. But if the broad language of s

97 S.Ct. 2061, 52 L.Ed.2d 707, 1977-1 Trade Cases P 61,460

4 means anything, surely it must render the defendant liable to those within the defendant's chain of distribution. It would indeed be “paradoxical to deny recover to the ultimate consumer while permitting the middlemen a windfall recovery.” P. Areeda, Antitrust Analysis: Problems, Text, Cases 75 (2d ed. 1974).

IV

I acknowledge some abstract merit in the argument that to allow indirect purchasers to sue, while, at the same time, precluding defendants from asserting pass-on defenses in suits by direct purchasers, subjects antitrust defendants to the risk of multiple liability. But as a practical matter, existing procedural mechanisms can eliminate this danger in most instances. Even though, as the Court says, no procedure currently exists which can eliminate the possibility entirely, ante, at 2067, n. 11, the hypothetical possibility that a few defendants might be subjected to the danger of multiple liability does not, in my view, justify erecting a bar against all recoveries by indirect purchasers without regard to whether the particular case presents a significant danger of double recovery. The “double recovery” specter was argued in **2083 the Congress that passed the Hart-Scott-Rodino Act, and was rejected. The Senate Report recorded the Act’s purpose to codify the holding of the Court of Appeals for the Ninth Circuit in In re Western Liquid Asphalt Cases, supra:

“We therefore see no problem of double recovery, and we believe that if this difficulty should arise in some other connection, the district court will be able to fashion relief accordingly. In addition to the court’s control over its decree, numerous devices exist. We note that the consolidation of cases, which has already occurred, is one means of averting duplicitous awards. The short, four-year statute of limitations is another; later suits, after *762 final judgment herein, are unlikely. 15 U.S.C. s 15b. In other cases, it may be that statutory interpleader, 28 U.S.C. s 1335, could be used by antitrust defendants to avoid double liability. If necessary, special masters may be appointed to handle complex cases. Finally, there are the doctrines of res judicata and collateral estoppel and procedures for compulsory joinder. The day is long past when courts, particularly federal courts, will deny relief to a deserving plaintiff merely because of procedural difficulties or problems of apportioning damages.”

Moreover, the possibility of multiple recovery arises in only two situations: (1) where suits by direct and indirect purchasers are pending at the same time but in different courts; and (2) where additional suits are filed after an award of damages based on the same violation in a prior suit. 19 In the first situation, the United States, Brief as Amicus Curiae 25, cogently points out that district courts may make use of the alternatives suggested by the Manual for Complex Litigation, 1 (pt. 2) J. Moore, Federal Practice (1976): district courts may use the intradistrict transfer power created by 28 U.S.C. s 1404(b), coordinate pretrial proceedings of cases pending in *763 different districts, or transfer cases to a single district pursuant to s 1404(a). In addition, the Judicial Panel on Multidistrict Litigation is empowered by 28 U.S.C. s 1407 to transfer cases involving common questions of fact to any district for coordinated pretrial proceedings upon its determination that the transfer “will be for the convenience of parties and witnesses and will promote the just and efficient conduct of such actions.” After pretrial transfers under this section, cases can be consolidated and transferred to the same district for trial pursuant to the transfer power under s 1404(a). 20 A further device mentioned in Western Liquid Asphalt is statutory interpleader under 28 U.S.C. s 1335, by which the defendant can bring all potential plaintiffs into the same court and require them to litigate inter se to determine their appropriate shares of the total recovery. 21

True, there is a greater hypothetical danger of multiple recovery where suits are **2084 independently instituted after an earlier suit based on the same violation has proceeded to judgment. 22 But even here the likelihood that defendants *764 will
be subjected to multiple liability is, as a practical matter, remote. The extended nature of antitrust actions, often involving years of discovery, combines with the short four-year statute of limitations to make it impractical for potential plaintiffs to sit on their rights until after entry of judgment in the earlier suit.

The Court today regrettably weakens the effectiveness of the private treble-damages action as a deterrent to antitrust violations by, in most cases, precluding consumers from recovering for antitrust injuries. For in many instances, consumers, although indirect purchasers, bear the brunt of antitrust violations. To deny them an opportunity for recovery is particularly indefensible when direct purchasers, acting as middlemen, and ordinarily reluctant to sue their suppliers pass on the bulk of their increased costs to consumers farther along the chain of distribution. Congress has given us a clear signal that § 4 is not to be read to have the restrictive scope ascribed to it by the Court today. I would follow the congressional understanding and therefore would affirm.

Mr. Justice BLACKMUN, dissenting.

I regard Mr. Justice BRENNAN'S dissenting opinion as persuasive and convincing, and I join it without hesitation.

**2085 I add these few sentences only to say that I think the plaintiffs-respondents in this case, which they now have lost, are the victims of an unhappy chronology. If Hanover Shoe, Inc. v. United Shoe Machinery Corp., 392 U.S. 481, 88 S.Ct. 2224, 20 L.Ed.2d 1231 (1968), had not preceded this case, and were it not “on the books,” I am positive that the Court today would be affirming, perhaps unanimously, the judgment of the Court of Appeals. The policy behind the Antitrust Acts and all the signs point in that direction, and a conclusion in favor of indirect purchasers who could demonstrate injury would almost be compelled.

But Hanover Shoe is on the books, and the Court feels that it must be “consistent” in its application of pass-on. That, *766 for me, is a wooden approach, and it is entirely inadequate when considered in the light of the objectives of the Sherman and Clayton Acts. The Hart-Scott-Rodino Antitrust Improvements Act of 1976 tells us all that is needed as to Congress' present understanding of the Acts. Nevertheless, we must now await still another statute which, as the Court acknowledges, ante, at 2068-2069, n. 14, the Congress may adopt. One regrets that it takes so long and so much repetitious effort to achieve, and have this Court recognize, the obvious congressional aim.

All Citations

431 U.S. 720, 97 S.Ct. 2061, 52 L.Ed.2d 707, 1977-1 Trade Cases P 61,460

Footnotes

* The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See United States v. Detroit Timber & Lumber Co., 200 U.S. 321, 337, 26 S.Ct. 282, 287, 50 L.Ed. 499.

1 Section 4 of the Clayton Act, 38 Stat. 731, 15 U.S.C. s 15, provides:

“Any person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws may sue therefor in any district court of the United States in the district in which the defendant resides or is found or has an agent, without respect to the amount in controversy, and shall recover threefold the damages by him sustained, and the cost of suit, including a reasonable attorney's fee.”
The Court cited, as an example of when a pass-on defense might be permitted, the situation where “an overcharged buyer has a pre-existing ‘cost-plus’ contract, thus making it easy to prove that he has not been damaged . . . .” 392 U.S., at 494, 88 S.Ct., at 2232. See infra, at 2069-2070.

The Court explained the economic uncertainties and complexities involved in proving pass-on as follows:

“A wide range of factors influence a company's pricing policies. Normally the impact of a single change in the relevant conditions cannot be measured after the fact; indeed a businessman may be unable to state whether, had one fact been different (a single supply less expensive, general economic conditions more buoyant, or the labor market tighter, for example), he would have chosen a different price. Equally difficult to determine, in the real economic world rather than an economist's hypothetical model, is what effect a change in a company's price will have on its total sales. Finally, costs per unit for a different volume of total sales are hard to estimate. Even if it could be shown that the buyer raised his price in response to, and in the amount of, the overcharge and that his margin of profit and total sales had not thereafter declined, there would remain the nearly insuperable difficulty of demonstrating that the particular plaintiff could not or would not have raised his prices absent the overcharge or maintained the higher price had the overcharge been discontinued. Since establishing the applicability of the passing-on defense would require a convincing showing of each of these virtually unascertainable figures, the task would normally prove insurmountable. On the other hand, it is not unlikely that if the existence of the defense is generally confirmed, antitrust defendants will frequently seek to establish its applicability. Treble-damage actions would often require additional long and complicated proceedings involving massive evidence and complicated theories.” 392 U.S., at 492-493, 88 S.Ct., at 2231. (Footnote omitted.)

Section 1 of the Sherman Act, c. 647, 26 Stat. 209, as amended, 15 U.S.C. s 1, provides in relevant part:

“Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is hereby declared to be illegal . . . .”

Private treble-damages actions brought by masonry contractors, general contractors, and private builders were settled, without prejudice to this suit. 536 F.2d, at 1164.

The responses to petitioners' interrogatories indicated that only four of the plaintiffs represented by the State purchased concrete block directly from one of the petitioners. 67 F.R.D. 461, 463 (N.D.Ill.1975). Only 7% of the 700 public entities named as plaintiffs were apparently able to state the cost of the concrete block used in their building projects. Brief for Petitioners 5 n. **. In the only example cited to us by the parties, the cost of the concrete block was reported as less than one-half of one percent of the total cost of the project. Id., at 21 n. *.

The District Court based its grant of summary judgment against the indirect purchaser plaintiffs not on the ground that this Court's construction of s 4 in Hanover Shoe barred their attempt to show that the masonry and general contractors passed on the overcharge to them, but rather on the ground that these indirect purchasers lacked standing to sue for an overcharge on one product concrete block that was incorporated by the masonry and general contractors into an entirely new and different product a building. 67 F.R.D., at 467-468. Although the Court of Appeals held that these indirect purchasers did have standing to sue for damages under s 4, it agreed with the District Court's reading of Hanover Shoe. 536 F.2d, at 1164-1167. Because we find Hanover Shoe dispositive here, we do not address the standing issue, except to note, as did the Court of Appeals below, 536 F.2d, at 1166, that the question of which persons have been injured by an illegal overcharge for purposes of s 4 is analytically distinct from the question of which persons have sustained injuries too remote to give them standing to sue for damages under s 4. See Handler & Blechman, Antitrust and the Consumer Interest: The Fallacy of Parens Patriae and A Suggested New Approach, 85 Yale L.J. 626, 644-645 (1976).


97 S.Ct. 2061, 52 L.Ed.2d 707, 1977-1 Trade Cases P 61,460


See infra, at 2069-2070.

In recognition of the need to avoid duplicative recoveries, courts adopting the view that pass-on theories should not be equally available to plaintiffs and defendants have agreed that defendants should be allowed to assert a pass-on defense against a direct purchaser if an indirect purchaser is also attempting to recover on a pass-on theory in the same lawsuit. E. g., In re Western Liquid Asphalt Cases, 487 F.2d, at 200-201; West Virginia v. Chas. Pfizer & Co., 440 F.2d, at 1086-1088; Boshes v. General Motors Corp., 59 F.R.D. 589, 592-598 (ND Ill.1973); In re Master Key Antitrust Litigation, 1973-2 Trade Cas. P 74,680, p. 94,978 (Conn.); Carnivale Bag Co. v. Slide-Rite Mfg. Corp., 395 F.Sup. 287, 290-291 (SDNY 1975). See also Brief for State of California as Amicus Curiae 6-12.

Moreover, even if ways could be found to bring all potential plaintiffs together in one huge action, the complexity thereby introduced into treble-damages proceedings argues strongly for retaining the Hanover Shoe rule. See Part III, infra.

That this rationale was more important in the decision to bar the pass-on defense than the second reason the concern that if pass-on defenses were permitted indirect purchasers would lack the incentive to sue and antitrust violators would retain their ill-gotten gains, see supra, at 2064-2065, is shown by the fact that the Court recognized an exception for pre-existing cost-plus contracts, which “mak(e) it easy to prove that (the direct purchaser) has not been damaged.” 392 U.S., at 494, 88 S.Ct., at 2232. (Emphasis added.) The amount of the stake that the customers of the direct purchaser have in a lawsuit against the overcharger is not likely to depend on whether they buy under a cost-plus contract or in a competitive market, but the Court allowed a pass-on defense in the former situation because the pre-existing cost-plus contract makes easy the normally complicated task of demonstrating that the overcharge has not been absorbed by the direct purchaser. See Note, The Effect of Hanover Shoe on the Offensive Use of the Passing-on Doctrine, 46 So.Cal.L.Rev. 98, 108 (1972).

Offensive use of pass-on by the last purchaser in the distribution chain is simpler in one respect than defensive use of pass-on against a direct purchaser that sells a product to other customers. In the latter case, even if the defendant shows that as a result of the overcharge the direct purchaser increased its price by the full amount of the overcharge, the direct purchaser may still claim injury from a reduction in the volume of its sales caused by its higher prices. This
additional element of injury from reduced volume is not present in the suit by the final purchaser of the overcharged goods, where the issue regarding injury will be whether the defendant's overcharge caused the plaintiff to pay a higher price for whatever it purchased. But the final purchaser still will have to trace the overcharge through each step in the distribution chain. In our view, the difficulty of reconstructing the pricing decisions of intermediate purchasers at each step in the chain beyond the direct purchaser generally will outweigh any gain in simplicity from not having to litigate the effects of the passed-on overcharge on the direct purchaser's volume.


Congress made clear, however, that this legislation did not alter the definition of which overcharged persons were injured within the meaning of s 4. It simply created a new procedural device parens patriae actions by States on behalf of their citizens to enforce existing rights of recovery under s 4. The House Report quoted above stated that the parens patriae provision “creates no new substantive liability”; the relevant language of the newly enacted s 4C(a) of the Clayton Act tracks that of existing s 4, showing that it was intended only as “an alternative means . . . for the vindication of existing substantive claims.” H.R.Rep. No. 94-499, supra, at 9, 1976 U.S.Code Cong. & Admin.News, p. 2578. “The establishment of an alternative remedy does not increase any defendant's liability.” Ibid. Representative Rodino himself acknowledged in the remarks cited above that this legislation did not create a right of recovery for consumers where one did not already exist.

We thus cannot agree with the dissenters that the legislative history of the 1976 Antitrust Improvements Act is dispositive as to the interpretation of s 4 of the Clayton Act, enacted in 1914, or the predecessor section of the Sherman Act, enacted in 1890. Post, at 2080-2081. The cases cited by Mr. Justice BRENNAN, post, at 2084-2085, n. 24, to support his reliance on this legislation all involved specific statutory language that was thought to clarify the meaning of an earlier statute. E. g., Red Lion Broadcasting Co. v. FCC, 395 U.S. 367, 380-381, 89 S.Ct. 1794, 1801, 23 L.Ed.2d 371 (1969) (language in 1959 amendment to s 315 of the Communications Act approved fairness doctrine adopted by FCC under the “public interest” standard of the original Act). Here, by contrast, Congress borrowed the language of s 4 in adding the parens patriae section. The views expressed by particular legislators as to the meaning of that language in s 4 “cannot serve to change the legislative intent of Congress . . . ‘since the statements were (made) after passage of the (Clayton) Act.’ ” Regional Rail Reorganization Act Cases, 419 U.S. 102, 132, 95 S.Ct. 335, 353, 42 L.Ed.2d 320 (1974), quoting National Woodwork Mfrs. Ass'n v. NLRB, 386 U.S. 612, 639 n. 34, 87 S.Ct. 1250, 1265, 18 L.Ed.2d 357 (1967).

While we do not lightly disagree with the reading of Hanover Shoe urged by these legislators, we think the construction of s 4 adopted in that decision cannot be applied for the exclusive benefit of plaintiffs. Should Congress disagree with this result, it may, of course, amend the section to change it. But it has not done so in the recent parens patriae legislation.

In a separate trial pursuant to Fed.Rule Civ.Proc. 42(b), the District Court held that the defendant shoe machinery manufacturer was not permitted to assert a pass-on defense against its customer. 185 F.Supp. 826 (MD Pa.), aff'd, 281 F.2d 481 (CA3), cert. denied, 364 U.S. 901, 81 S.Ct. 234, 5 L.Ed.2d 194 (1960). The District Court indicated that pass-on defenses were barred against “consumers” who use the defendant's product to make their own but not against “middlemen” who simply resell the defendant's product. 185 F.Supp., at 830-831. Both on interlocutory appeal and after

97 S.Ct. 2061, 52 L.Ed.2d 707, 1977-1 Trade Cases P 61,460

For Educational Use Only

Another situation in which market forces have been superseded and the pass-on defense might be permitted is where the direct purchaser is owned or controlled by its customer. Cf. Perkins v. Standard Oil Co., 395 U.S. 642, 648, 89 S.Ct. 1871, 1874, 23 L.Ed.2d 599 (1969); In re Western Liquid Asphalt Cases, 487 F.2d, at 197, 199.

The sole dissenting Justice in Hanover Shoe did not reach the pass-on question. 392 U.S., at 513, 88 S.Ct., at 2241.

In this Part, we assume that use of pass-on will be permitted symmetrically, if at all. This assumption, of course, reduces the substantial risk of multiple liability for defendants that is posed by allowing indirect purchasers to recover for the overcharge passed on to them while at the same time allowing direct purchasers automatically to collect the entire overcharge. See supra, at 2067-2068. But the possibility of inconsistent judgments obtained by conflicting claimants remains nonetheless. Even this residual possibility justifies bringing potential and actual claimants together in one action if possible.


For example, a condition precedent for invoking statutory interpleader is the posting of a bond for the amount in dispute, 28 U.S.C. s 1335(a)(2), see 3A J. Moore, supra, P 22.10, and a defendant may be unwilling to put up a bond for the huge amounts normally claimed in multiple-party treble-damages suits. For a discussion of other circumstances in which statutory interpleader may be “impractical,” see McGuire, The Passing-On Defense and the Right of Remote Purchasers to Recover Treble Damages under Hanover Shoe, 33 U.Pitt.L.Rev. 177, 197-198 (1971).

Rule 19(a) provides in part:

“A person who is subject to service of process and whose joinder will not deprive the court of jurisdiction over the subject matter of the action shall be joined as a party in the action if (1) in his absence complete relief cannot be accorded among those already parties, or (2) he claims an interest relating to the subject of the action and is so situated that the disposition of the action in his absence may (i) as a practical matter impair or impede his ability to protect that interest or (ii) leave any of the persons already parties subject to a substantial risk of incurring double, multiple, or otherwise inconsistent obligations by reason of his claimed interest.”

See the comment of the Advisory Committee on the 1966 Amendment to Rule 19: “In some situations it may be desirable to advise a person who has not been joined of the fact that the action is pending, and in particular cases the court in its discretion may itself convey this information by directing a letter or other informal notice to the absentee.” 28 U.S.C. App., p. 7760.

E. g., Philadelphia Housing Auth. v. American Radiator & Standard Sanitary Corp., 50 F.R.D. 13 (ED Pa.1970), aff'd sub nom. Mangano v. American Radiator & Standard Sanitary Corp., 438 F.2d 1187 (CA3 1971) (suit against manufacturers of plumbing fixtures on behalf of all homeowners in the United States). There often will be more levels of distribution or manufacture between the defendant and the ultimate consumers than the two levels (masonry and general contractors) in this case. For example, in Philadelphia Housing Auth., supra, the plaintiffs included homeowners who had bought used rather than new homes and who therefore had to show that each time their houses changed hands the sellers passed on part of the plumbing manufacturers' original overcharge. 50 F.R.D., at 19-20, 25-26. Treble-damages suits by ultimate consumers against any of the manufacturers of industrial raw materials or equipment that have been charged in recent Government price-fixing suits would involve not only several levels within a distribution chain, but also several separate
chains of distribution; for example, chromite sand is used to make ingots, ingots are used to make steel, and steel is used to make consumer products. Handler & Blechman, supra, n. 7, at 640 n. 77, and see id., at 636-637 (citing Justice Department price-fixing suits against defendants far removed from consumers).

24 E. g., Donson Stores, Inc. v. American Bakeries Co., 58 F.R.D. 481 (SDNY 1973) (motion to intervene by a putative class of 20 million consumers of bread in treble-damages action against bread manufacturers). Cf. Handler & Blechman, supra, n. 7, at 653 (arguing that the effect of legislation authorizing States to bring treble-damages actions on behalf of their citizens, see n. 14, supra, will be to interject claims on behalf of large classes of consumers into treble-damages suits brought by middlemen). Thus in this case the plaintiff housing authorities, App. 20, presumably have passed on part of the alleged overcharge to their tenants and subtenants, who would have to be brought into the suit before damages could be fairly apportioned.

25 An overcharge imposed by an antitrust violator or group of violators on their customers is analytically equivalent to an excise tax imposed on the violator's product in the amount of the overcharge. The effect of such an overcharge can be calculated using the economic theorems for the incidence of an excise tax. See Schaefer, Passing-On Theory in Antitrust Treble Damage Actions: An Economic and Legal Analysis, 16 Wm. & Mary L.Rev. 883, 887, 893 (1975), and sources cited in id., at 887 n. 21.

26 Thus, in the instant case respondents have offered to prove that general and masonry contractors calculate their bids by adding a percentage markup to the cost of their materials, Brief for Respondents 20-23, rather than by attempting to equate marginal cost and marginal revenue as required by an explicit profit-maximizing strategy.

27 Mr. Justice BRENNAN in dissent argues that estimating a passsee's damages requires nothing more than estimating what the passer's price would have been absent the violation, and suggests that apportioning the overcharge throughout the distribution chain is “no different from and no more complicated” than the initial task of estimating the amount of the overcharge itself. Post, at 2081-2082 and n. 14. But as the dissent recognizes, post, at 2076 n. 3, unless the indirect purchaser is at the end of the distribution chain it can claim damages not only from the portion of the overcharge it absorbs but also from the portion it passes on, which causes a reduction in sales volume under less than perfectly inelastic demand conditions. See n. 13, supra. The difficulties of the task urged upon us by the dissenters cannot be so easily brushed aside.

In any event, as we understand the dissenters' argument, it reduces to the proposition that because antitrust cases are already complicated there is little harm in making them more so. We disagree.


29 We note that supporters of the offensive use of pass-on, other than litigants in particular cases, generally have not contended for a halfway rejection of Hanover Shoe that would permit offensive use of pass-on in some types of market situations but not in others. See, e. g., Tr. of Oral Arg. 57 (United States as amicus curiae ); Note, The Defense of “Passing On” in Treble Damage Suits Under the Antitrust Laws, 70 Yale L.J. 469, 476, 478 (1961); commentators cited in n. 11, supra.


31 Commentators have noted that recoveries in treble-damages actions aggregating large numbers of small claims often have failed to compensate the individuals on behalf of whom the suits have been brought. E. g., Handler, The Shift from Substantive to Procedural Innovations in Antitrust Suits the Twenty-Third Annual Antitrust Review, 71 Colum.L.Rev.
The dissenting opinion of Mr. Justice BRENNAN appears to suggest that the 1976 parens patriae legislation, see n. 14, supra, provides an answer to this problem of compensating indirect purchasers for small injuries. Post, at 2084, n. 23. Quite to the contrary, the Act “recognizes that rarely, if ever, will all potential claimants actually come forward to secure their share of the recovery,” and that “the undistributed portion of the fund . . . will often be substantial.” H.R.Rep.No.94-499, p. 16 (1975); 1976 U.S.Code Cong. & Admin.News, p. 2585. The portion of the fund recovered in a parens patriae action that is not used to compensate the actual injuries of antitrust victims is to be used as “a civil penalty . . . deposited with the State as general revenues,” Clayton Act s 4E(2), 15 U.S.C. s 15e(2) (1976 ed.), enacted by the 1976 Act, or “for some public purposes benefiting, as closely as possible, the class of injured persons,” such as reducing the price of the overcharged goods in future sales. H.R.Rep.No.94-499, supra, at 16, 1976 U.S.Code Cong. & Admin.News, p. 2585. That Congress chose to provide such innovative methods of distributing damages awarded in a parens patriae action under newly enacted s 4C of the Clayton Act, 15 U.S.C. s 15c (1976 ed.), does not eliminate the obstacles to compensating indirect purchasers bringing traditional suits under s 4.

1 The block was sold to various general and special contractors who had successfully bid to construct public buildings. The State was thus an indirect purchaser of the block.

2 There is, of course, a point beyond which antitrust defendants should not be held responsible for the remote consequences of their actions. See the discussion in Part III, ante, at 2082-2083.

3 The portion of an illegal overcharge that a direct purchaser can pass on depends upon the elasticity of demand in the relevant product market. If the market is relatively inelastic, he may pass on a relatively large portion. If demand is relatively elastic, he may not be able to raise his price and will have to absorb the increase, making it up by decreasing other costs or increasing sales volume. It is extremely unlikely that a middleman could pass on the entire cost increase. But rarely would he have to absorb the entire increase. R. Posner, Antitrust Cases, Economic Notes, and Other Materials 147-149 (1974).

4 The opinion recognizes that “there might be situations for instance, when an overcharged buyer has a pre-existing 'cost-plus' contract, thus making it easy to prove that he has not been damaged where the considerations requiring that the passing-on defense not be permitted in this case would not be present.” 392 U.S., at 494, 88 S.Ct., at 2232.

5 Hanover Shoe, did not involve the consumers of the plaintiff's shoes, to whom the overcharge allegedly was passed. United's passing-on argument is referred to as “defensive” passing on. The State's position, seeking recovery of illegal overcharges allegedly passed on to it and its citizens, is referred to as “offensive” passing on.

6 Hanover alleged that United monopolized the shoe machinery industry in violation of s 2 of the Sherman Act by its practice of leasing but refusing to sell its shoemaking machinery.

7 In Darnell-Taenzer, shippers brought suit for reparations against a railroad claiming that the railroad had charged unreasonable rates. The railroad argued that the shippers had in turn passed on to their customers any excess over the reasonable rate.

8 “(T)he impact of a single change in the relevant conditions cannot be measured after the fact; indeed a businessman may be unable to state whether, had one fact been different . . . , he would have chosen a different price. . . .” 392 U.S., at 492-493, 88 S.Ct., at 2231. The Court further observed that it is equally difficult to ascertain “what effect a change in a company's price will have on its total sales”; and it is all but impossible to demonstrate that the particular plaintiff
The pass-on defense in Hanover Shoe was asserted by a defendant against whom a prima facie case of liability had already been made out. The Clayton Act provides: “A final judgment . . . rendered in any civil or criminal proceeding brought by or on behalf of the United States under the antitrust laws . . . shall be prima facie evidence against such defendant . . .” 15 U.S.C. s 16(a). The Government had secured a judgment against United in United States v. United Shoe Machinery Corp., 110 F.Supp. 295 (Mass.1953), summarily aff'd, 347 U.S. 521, 74 S.Ct. 699, 98 L.Ed. 910 (1954).

Commentators almost unanimously conclude that, despite Hanover Shoe, s 4 should be construed to authorize indirect purchasers to recover upon proof that increases were passed on to them. See, e. g., Comment, Standing to Sue in Antitrust Cases: The Offensive Use of Passing-On, 123 U.Pa.L.Rev. 976 (1975); Comment, Mangano and Ultimate-Consumer Standing: The Misuse of the Hanover Doctrine, 72 Colum.L.Rev. 394 (1972); Note, The Effect of Hanover Shoe on the Offensive Use of the Passing-on Doctrine, 46 So.Cal.L.Rev. 98 (1972). But see Handler & Blechman, Antitrust and the Consumer Interest: The Fallacy of Parens Patriae and A Suggested New Approach, 85 Yale L.J. 626, 638-655 (1976).

In addition, most courts have read Hanover Shoe as not preventing indirect purchasers from attempting to prove that they have been injured. See, e. g., Yoder Bros., Inc. v. California-Florida Plant Corp., 537 F.2d 1347 (CA5 1976); In re Western Liquid Asphalt Cases, 487 F.2d 191 (CA9 1973), cert. denied sub nom. Standard Oil Co. of Cal. v. Alaska, 415 U.S. 919, 94 S.Ct. 1419, 39 L.Ed.2d 474 (1974); Illinois v. Bristol-Myers Co., 152 U.S.App.D.C. 367, 470 F.2d 1276 (1972); West Virginia v. Chas. Pfizer & Co., 440 F.2d 1079 (CA2), cert. denied sub nom. Cotler Drugs, Inc. v. Chas. Pfizer & Co., 404 U.S. 871, 92 S.Ct. 81, 94 S.Ct. 1419, 30 L.Ed.2d 115 (1971); In re Master Key Antitrust Litigation, 1973-2 Trade Cas. P 74,680 (Conn.).

A further indication of Congress' desire to create a remedy for all persons, including consumers, even though their individual injuries might be comparatively slight, was the elimination of the jurisdictional-amount requirement for antitrust actions. See 21 Cong.Rec. 2612, 3148-3149 (1890) (remarks of Sens. Sherman and Edmunds).

The fact that damages are trebled both aids deterrence and provides the incentive of compensation, since it encourages suits for relatively minor injuries.

Congress rejected earlier Court of Appeals and District Court decisions erecting standing barriers to suits by indirect purchasers and chose instead to pattern the Act “after such innovative decisions as In re Western Liquid Asphalt Cases, 487 F.2d 191 (9th Cir. 1973); In re Master Key Litigation, 1973 Trade Cases P 74,680 and 1975 Trade Cases P 60,377 (DC Conn.); State of Illinois v. Ampress Brick Co., 1975 Trade Cases P 60,295 (DC Ill.) (this case below); Carnivale Bag Co. v. Slide Rite Mfg., 1975 Trade Cases P 60,370 (S.D.N.Y.); In re Antibiotics Antitrust Actions, 333 F.Supp. 278 (S.D.N.Y.1971); and West Virginia v. Charles Pfizer & Co., 440 F.2d 1079 (2d Cir. 1971).” Congress accepted these decisions as correctly stating the law. S.Rep.No. 94-803, pp. 42-43 (1976).

In Hanover Shoe, the measure of damages was the difference between the amount Hanover paid for the lease and the amount it would have paid had United agreed to sell the machinery. It has been suggested that the burden of demonstrating a pass-on may be no more difficult or speculative than the plaintiff's initial task of proving an overcharge in the first instance. See Pollock, Automatic Treble Damages and the Passing-on Defense: The Hanover Shoe Decision, 13 Antitrust Bull. 1183, 1210 (1968).

One commentator has suggested that, in deciding whether to permit recovery by indirect purchasers in a particular case, courts should consider the number of intervening hands the product has passed through and the extent of its change in the process. P. Areeda, Antitrust Analysis: Problems, Text, Cases 75 (2d Ed. 1974).
This holding is consistent with the Court's continuing concern for the effectiveness of the treble-damages action, which has been sustained even when the plaintiff was “no less morally reprehensible than the defendant” with whom he had conspired. Perma Life Mufflers, Inc. v. International Parts Corp., 392 U.S. 134, 139, 88 S.Ct. 1981, 1984, 20 L.Ed.2d 982 (1968).

Earlier this Term, Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., disallowed a treble-damages recovery, stating that in order to recover antitrust plaintiffs must prove “antitrust injury, which is to say injury of the type the antitrust laws were intended to prevent and that flows from that which makes (the) defendants' acts unlawful.” 429 U.S., at 489, 97 S.Ct., at 697. At least one Court of Appeals has rephrased the target-area test in terms of whether the injury to the plaintiff is a reasonably foreseeable consequence of the defendant's illegal conduct. Mulvey v. Samuel Goldwyn Productions, 433 F.2d 1073 (CA9 1970), cert. denied, 402 U.S. 923, 91 S.Ct. 1377, 28 L.Ed.2d 662 (1971).

If direct and indirect purchasers bring suit in the same court, the cases may be consolidated and damages allocated in accordance with Fed.Rule Civ.Proc. 42(a). See West Virginia v. Chas. Pfizer & Co., 440 F.2d 1079 (CA2 1971).


Petitioners suggest that interpleader may be an impractical alternative for some defendants, since it requires a defendant to complicate the suit by bringing in ultimate consumers and to post bond for the amount in controversy. See 28 U.S.C. s 1335(a)(2). Although s 1335 clearly places a burden upon defendants who elect to use it in order to avoid potential multiple liability, that burden is not unique to antitrust cases, and Congress has clearly indicated that it considers the burden justified. See S.Rep. No. 94-803, p. 44 (1976).

The problem of potential multiple recoveries is not present in this case. All suits against petitioners were filed in the Northern District of Illinois. Petitioners never sought consolidation under Fed.Rule Civ.Proc. 42(a) and stipulated in settlements with direct purchasers that the settlement would not affect the rights of indirect purchasers.

The opinion for the Court “recognize(s) that direct purchasers sometimes may refrain from bringing a treble-damages suit for fear of disrupting relations with their suppliers,” but concludes that “on balance, and until there are clear directions from Congress to the contrary, we conclude that the legislative purpose in creating a group of ‘private attorneys general’ to enforce the antitrust laws . . . is better served by holding direct purchasers to be injured to the full extent of the overcharge paid by them than by attempting to apportion the overcharge among all that may have absorbed a part of it.” Ante, at 2075. But the intent of Congress in enacting the parens patriae provision of the 1976 Act was clearly to provide a mechanism to permit recovery by consumers, and this purpose is not furthered by a rule that will keep most consumers out of court.


97 S.Ct. 2061, 52 L.Ed.2d 707, 1977-1 Trade Cases P 61,460

Although it is true, as the Court's opinion states, ante, at 2068-2069 n. 14, that the post-enactment statements of “particular legislators” who participated in the enactment of a statute cannot change its meaning, see Regional Rail Reorganization Act Cases, 419 U.S. 102, 132, 95 S.Ct. 335, 352, 42 L.Ed.2d 320 (1974), quoting National Woodwork Manufacturers Ass'n v. NLRB, 386 U.S. 612, 639 n. 34, 87 S.Ct. 1250, 1265, 18 L.Ed.2d 357 (1967), in this case, the House and Senate Reports accompanying the amendments to s 4 of the Clayton Act clearly reveal the 94th Congress' interpretation of that section as permitting the kind of consumer action which the Court now prohibits. Moreover, it is no answer to this to say that the new parens patriae provision will not in all cases directly compensate indirect purchasers, ante, at 2075-2076, n. 31, for it is clear that despite the difficulty of distributing benefits to such injured persons the new Act authorizes recovery by the State on their behalf.
§ 15. Suits by persons injured [Statutory Text & Notes of Decisions subdivisions I to V]

(a) Amount of recovery; prejudgment interest

Except as provided in subsection (b), any person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws may sue therefor in any district court of the United States in the district in which the defendant resides or is found or has an agent, without respect to the amount in controversy, and shall recover threefold the damages by him sustained, and the cost of suit, including a reasonable attorney's fee. The court may award under this section, pursuant to a motion by such person promptly made, simple interest on actual damages for the period beginning on the date of service of such person's pleading setting forth a claim under the antitrust laws and ending on the date of judgment, or for any shorter period therein, if the court finds that the award of such interest for such period is just in the circumstances. In determining whether an award of interest under this section for any period is just in the circumstances, the court shall consider only--

(1) whether such person or the opposing party, or either party's representative, made motions or asserted claims or defenses so lacking in merit as to show that such party or representative acted intentionally for delay, or otherwise acted in bad faith;

(2) whether, in the course of the action involved, such person or the opposing party, or either party's representative, violated any applicable rule, statute, or court order providing for sanctions for dilatory behavior or otherwise providing for expeditious proceedings; and

(3) whether such person or the opposing party, or either party's representative, engaged in conduct primarily for the purpose of delaying the litigation or increasing the cost thereof.

(b) Amount of damages payable to foreign states and instrumentalities of foreign states

(1) Except as provided in paragraph (2), any person who is a foreign state may not recover under subsection (a) an amount in excess of the actual damages sustained by it and the cost of suit, including a reasonable attorney's fee.

(2) Paragraph (1) shall not apply to a foreign state if--
§ 15. Suits by persons injured [Statutory Text & Notes of Decisions..., 15 USCA § 15

(A) such foreign state would be denied, under section 1605(a)(2) of Title 28, immunity in a case in which the action is based upon a commercial activity, or an act, that is the subject matter of its claim under this section;

(B) such foreign state waives all defenses based upon or arising out of its status as a foreign state, to any claims brought against it in the same action;

(C) such foreign state engages primarily in commercial activities; and

(D) such foreign state does not function, with respect to the commercial activity, or the act, that is the subject matter of its claim under this section as a procurement entity for itself or for another foreign state.

(c) Definitions

For purposes of this section--

(1) the term “commercial activity” shall have the meaning given it in section 1603(d) of Title 28, and

(2) the term “foreign state” shall have the meaning given it in section 1603(a) of Title 28.

CREDIT(S)


Current through P.L. 117-148. Some statute sections may be more current, see credits for details
In re Lidoderm Antitrust Litig.

United States District Court for the Northern District of California

August 9, 2016, Decided; August 9, 2016, Filed

Case No. 14-md-02521-WHO

Reporter
2016 U.S. Dist. LEXIS 105619 *; 2016 WL 4191612

IN RE LIDODERM ANTITRUST LITIGATION


For Plumbers & Pipefitters Local 178 Health & Welfare Trust Fund, Plaintiff: Lionel Z. Glancy, LEAD ATTORNEY, Glancy Prongay & Murray LLP, Los Angeles, CA; Daniel C. Girard, Girard Gibbs LLP, San Francisco, CA; David S. Nalven, Hagens Berman Sobol Shapiro LLP, Cambridge, MA.


For Roofers Local 96 Health and Welfare Fund, on their behalf and on behalf of all others similarly situated, Plaintiff: David Richard Woodward, LEAD ATTORNEY, Heins Mills and Olson, P.L.C., Minneapolis, MN; Jeffrey L. Kodroff, LEAD ATTORNEY, Spector Roseman & Kodroff & Willis,P.C., Philadelphia, PA; Renee Diane Steiner, LEAD ATTORNEY, Heins Mills & Olson, P.L.C., Minneapolis, MN; David S. Nalven, Hagens Berman Sobol Shapiro LLP, Cambridge, MA.


For Painters District Council No.30 Health & Welfare Fund, on behalf of itself and all others similarly situated, Plaintiff: William J. O’Brien, LEAD ATTORNEY, Attorney at Law, Los Angeles, CA; Daniel C. Girard, Girard Gibbs LLP, San Francisco, CA; David S. Nalven, Hagens Berman Sobol Shapiro LLP, Cambridge, MA.

For PHILADELPHIA FEDERATION OF TEACHERS HEALTH & WELFARE FUND, on behalf of itself and all others similarly situated, Plaintiff: STEWART L. COHEN, LEAD ATTORNEY, COHEN TAUBER SPIEVACK & WAGNER LLP, NEW YORK, NY; Daniel C. Girard, Girard Gibbs LLP, San Francisco, CA; David S. Nalven, Hagens Berman Sobol Shapiro LLP, Cambridge, MA; MICHAEL COREN, COHEN PLACITELLA & ROTH, PHILADELPHIA, PA; Michael D. Donovan, Donovan Searles, LLC, Philadelphia, PA; Noah I. Axler, Donovan Searles and Axler, Philadelphia, PA.

For INTERNATIONAL ASSOCIATION OF FIRE FIGHTERS LOCAL 22 HEALTH & WELFARE FUND, on behalf of itself and all others similarly situated, Plaintiff: Krishna Brian Narine, LEAD ATTORNEY, Meredith Narine, Philadelphia, PA; Daniel C. Girard, Girard Gibbs LLP, San Francisco, CA; David S. Nalven, Hagens Berman Sobol Shapiro LLP, Cambridge, MA.

For TEAMSTERS UNION LOCAL 115 HEALTH & WELFARE FUND, on behalf of itself and all others similarly situated, Plaintiff: MINDEE J. REUBEN, LEAD ATTORNEY, WEINSTEIN KITCHENOFF & ASHER LLC, PHILADELPHIA, PA; Robert Samuel Kitchenoff, LEAD ATTORNEY, Weinstein Kitchenoff and Asher LLC, Philadelphia, PA; Daniel C. Girard, Girard Gibbs LLP, San Francisco, CA; David S. Nalven, Hagens Berman Sobol Shapiro LLP, Cambridge, MA.


For American Sales Company, LLC, on behalf of itself and all others similarly situated, Plaintiff: David S. Nalven, LEAD ATTORNEY, Hagens Berman Sobol Shapiro LLP, Cambridge, MA; John Radice, LEAD ATTORNEY, Radice
Law Firm, Long Beach, NJ; Thomas M. Sobol, LEAD ATTORNEY, Hagens Berman Sobol Shapiro LLP, Cambridge, MA; Gregory T Arnold, Cambridge, MA; Peter Russell Kohn, Faruqi and Faruqi LLP, Jenkintown, PA.


For ALBERTSONS LLC, Plaintiff: Anna Theresa Neill, LEAD ATTORNEY, Kenny Nachwalter, P.A., Miami, FL; Scott Eliot Perwin, LEAD ATTORNEY, Kenny Nachwalter, P.A., Miami, FL.

For Rite Aid Corporation, Plaintiff: Anna Theresa Neill, LEAD ATTORNEY, Kenny Nachwalter, P.A., Miami, FL; Daniel Paul Thiel, Hangley Aronchick Segal Pudlin Schiller, Philadelphia, PA; Eric L Bloom, Hangley Aronchick Segal Pudlin Schiller, Harrisburg, PA; Monica L. Rebuck, Hangley Aronchick Segal & Pudlin, Harrisburg, PA.


For All Plaintiffs, Plaintiff: Peter Russell Kohn, LEAD ATTORNEY, Faruqi and Faruqi LLP, Jenkintown, PA; Christina H Sharp, LEAD ATTORNEY, Girard Gibbs LLP, San Francisco, CA; David S. Nalven, Hagens Berman Sobol Shapiro LLP, Cambridge, MA.


For Watson Pharmaceuticals, Inc., Defendant: James Patrick Schaefer, LEAD ATTORNEY, Skadden Arps Slate Meagher & Flom LLP, Palo Alto, [*33] CA; Daniel B. Asimow, Arnold & Porter LLP, San Francisco, CA; David S. Elkins, Squire Patton Boggs (US) LLP, Palo Alto, CA; Karen Hoffman Lent, PRO HAC VICE, Skadden Arps Slate Meagher Flom LLP, New York, NY; Sean M Tepe, PRO HAC VICE, Skadden, Arps, Slate, Meagher and Flom LLP,
Washington, DC; Steven C. Sunshine, PRO HAC VICE, Skadden Arps Slate Meagher and Flom LLP, Washington, DC.


For Actavis Plc., Defendant: James Patrick Schaefer, LEAD ATTORNEY, Skadden Arps Slate Meagher & Flom LLP, Palo Alto, CA; Daniel B. Asimow, Arnold & Porter LLP, San Francisco, CA; David S. Elkins, Squire Patton Boggs (US) LLP, Palo Alto, CA; Karen Hoffman Lent, PRO HAC VICE, Skadden Arps Slate Meagher Flom LLP, New York, NY; Sean M Tepe, PRO HAC VICE, Skadden, Arps, Slate, Meagher and Flom LLP, Washington, DC; Steven C. Sunshine, PRO HAC VICE, Skadden Arps Slate Meagher and Flom LLP, Washington, DC.

For Anda, Inc, Defendant: James Patrick Schaefer, LEAD ATTORNEY, Skadden Arps Slate Meagher & Flom LLP, Palo Alto, CA; Daniel B. Asimow, Arnold & Porter LLP, San Francisco, CA; David S. Elkins, Squire Patton Boggs (US) LLP, Palo Alto, CA; Karen Hoffman Lent, PRO HAC VICE, Skadden Arps Slate Meagher Flom LLP, New York, NY; Sean M Tepe, PRO HAC VICE, Skadden, Arps, Slate, Meagher and Flom LLP, Washington, DC; Steven C. Sunshine, PRO HAC VICE, Skadden Arps Slate Meagher and Flom LLP, Washington, DC.

For ANDA Pharmaceuticals, Inc., Defendant: James Patrick Schaefer, LEAD ATTORNEY, Skadden Arps Slate Meagher & Flom LLP, Palo Alto, CA; Daniel B. Asimow, Arnold & Porter LLP, San Francisco, CA; David S. Elkins, Squire Patton Boggs (US) LLP, Palo Alto, CA; Karen Hoffman Lent, PRO HAC VICE, Skadden Arps Slate Meagher Flom LLP, New York, NY; Sean M Tepe, PRO HAC VICE, Skadden, Arps, Slate, Meagher and Flom LLP, Washington, DC; Steven C. Sunshine, PRO HAC VICE, Skadden Arps Slate Meagher and Flom LLP, Washington, DC.

For Valmed Pharmaceuticals, Inc., Defendant: James Patrick Schaefer, LEAD ATTORNEY, Skadden Arps Slate Meagher & Flom LLP, Palo Alto, CA; Daniel B. Asimow, Arnold & Porter LLP, San Francisco, CA; David S. Elkins, Squire Patton Boggs (US) LLP, Palo Alto, CA; Karen Hoffman Lent, PRO HAC VICE, Skadden Arps Slate Meagher Flom LLP, New York, NY; Sean M Tepe, PRO HAC VICE, Skadden, Arps, Slate, Meagher and Flom LLP, Washington, DC; Steven C. Sunshine, PRO HAC VICE, Skadden Arps Slate Meagher and Flom LLP, Washington, DC.

For All Parties, Miscellaneous: Daniel C. Girard, LEAD ATTORNEY, Girard Gibbs LLP, San Francisco, CA; Christina H Sharp, LEAD ATTORNEY, Girard Gibbs LLP, San Francisco, CA; David S. Nalven, Hagens Berman Sobol Shapiro LLP, Cambridge, MA.

For OptiSource, LLC, Witness: Mark Aaron Cunningham, LEAD ATTORNEY, Jones Walker LLP, New Orleans, LA.

Judges: WILLIAM H. ORRICK, United States District Judge.

Opinion by: WILLIAM H. ORRICK

Opinion

ORDER ON MOTIONS FOR PRODUCTION OR PRECLUSION AND PRODUCTION OF ATTORNEY NOTES


Attorney-client privilege issues lie at the heart of litigation over a settlement alleged to be anticompetitive when a party's lawyers are the principal negotiators and advisors regarding the agreement. That party cannot testify to its
subjective beliefs about the reasons for entering into the settlement and preclude its adversaries from discovering
the content of the lawyers’ advice by simply asserting that the attorney-client advice was irrelevant to those
subjective beliefs. Instead, when the record shows that attorney-client advice played a significant role in formulating
a party’s subjective beliefs on central issues in the case, the adversaries are entitled to disclosure of the otherwise
privileged material to test the credibility of those subjective beliefs. But if a party relies solely on objective evidence,
or subjective beliefs derived exclusively from business judgment and experience, the attorney-client privilege should
be protected.

Currently before me are two motions: (i) plaintiffs’ renewed motion for production or preclusion, arguing that
defendants have put “at issue” subjective beliefs requiring defendants to either waive attorney-client privilege [*37]
for related information or be precluded from raising the beliefs on summary judgment or trial; and (ii) plaintiffs’
motion to compel Endo to produce the notes of former General Counsel Caroline Manogue regarding the
negotiations of the Watson settlement. Each motion raises multiple issues of privilege. On the record developed in
discovery, I GRANT in part and DENY in part each motion.

DISCUSSION

I. PLAINTIFFS’ RENEWED MOTION FOR PRODUCTION OR PRECLUSION

Last fall, plaintiffs argued that defendant Endo put “at issue” attorney-client communications by relying on subjective
beliefs informed by its counsel with respect to testimony Endo gave to the Federal Trade Commission. At that
juncture of the case, prior to the depositions of defendants and “in light of Endo’s express disclaimer of any intent to
rely on its subjective belief,” I declined to find “that Endo has broadly placed at issue unidentified documents and
communications that would normally be protected by the attorney-client or work product doctrines.” December 3,
2015 Order at 3. I invited plaintiffs, as the case progressed, to “reassert the waiver issue with respect to specifically
identified documents or communications so that [*38] I may rule on discrete waiver assertions.” Id.

Disputes precipitated by the breadth of defendants’ privilege assertions — unsurprising given the subject matter of
this case — and the unsettled question of what exact subjective beliefs defendants intend to rely on to defend the
Watson settlement have occurred since.¹ In order to provide finality and clarity on the issue, following the April 5,
2016 Case Management Conference I ordered defendants to identify all subjective beliefs that they intend to
introduce or rely on at trial on the following topics:

(a) Endo’s assessment of the strength of the relevant patents and its expectations concerning the outcome of
the patent litigations;
(b) Endo’s reasons, explanations and intentions for the Payments, and its beliefs about the impact the
Payments would have on competition;
(c) Endo’s beliefs about Watson’s final ANDA approval and an at-risk launch by Watson;
(d) Endo’s reasons or incentives, if any, for agreeing to a generic entry date before September 2013;² and
(e) Endo’s intention to launch an authorized generic version of Lidoderm.

¹ The basic provisions of the July 2012 Watson settlement included: (i) termination of the patent litigations; (ii) Endo providing
brand-name Lidoderm patches to Watson for Watson to sell; (iii) Endo allowing Watson to sell its generic version of Lidoderm
starting on a date certain (before Teikoku’s patents expired); and (iv) Endo giving Watson a period of exclusivity to market
Watson’s generic version of Lidoderm patches without competition from Endo’s generic [*40] patch.

² The defendants appropriately construed this topic as Endo’s reasons or incentives for not agreeing to a date before September 15,
2013 (Endo, Teikoku), or reasons or incentives for agreeing to the date of September 15, 2013 (Watson).
Defendants did so. Plaintiffs renewed their motion, arguing that defendants’ reliance on the identified subjective beliefs means they have placed "at issue" attorney-client privilege information that in fairness must either be disclosed or defendants should be precluded from relying on the particular subjective beliefs as this case goes forward. Plaintiffs support their motion by showing how, when defendants' major trial witnesses were deposed, those witnesses relied on assertions of attorney-client privilege to refuse to answer questions regarding topics disclosed under (a) through (e) above. Plaintiffs also rely on the descriptions included in defendants’ privilege logs to demonstrate that numerous documents have been withheld under the attorney-client privilege that expressly implicate the subjective beliefs defendants intend to rely on.

As discussed in more detail below, given the evidence plaintiffs have presented showing that defendants actually relied on attorney advice in reaching their subjective beliefs, I conclude that defendants will be precluded from relying on specific subjective beliefs unless they choose to waive the privilege as to communications and information regarding the same. This does not mean that defendants will be unable to rely on any evidence with respect to those topics or defenses. Defendants may rely on objective evidence from experts that does not cross into what defendants believed or why defendants were motivated to agree to certain terms in the Watson settlement.

A. Legal Standard

Plaintiffs argue that a topic becomes "at issue" and creates an implied waiver of the attorney-client privilege when "in fairness" the privileged information should be disclosed so the other side can refute a claim or defense. Defendants counter that at issue waiver only occurs when a party makes an affirmative choice to rely on attorney advice for a claim or defense. Plaintiffs' formulation is slightly overbroad and defendants' is too narrow.

"The privilege which protects attorney-client communications may not be used both as a sword and a shield. Where a party raises a claim which in fairness requires disclosure of the protected communication, the privilege may be implicitly waived." Chevron Corp. v. Pennzoil Co., 974 F.2d 1156, 1162 (9th Cir. 1992) (internal citation omitted); see also Kaiser Found. Health Plan, Inc. v. Abbott Labs., Inc., 552 F.3d 1033, 1042 (9th Cir. 2009). In Bittaker v. Woodford, 331 F.3d 715 (9th Cir. 2003), the Ninth Circuit explained "[i]n practical terms, this means that parties in litigation may not abuse the privilege by asserting claims the opposing party cannot adequately dispute unless it has access to the privileged materials. The party asserting the claim is said to have implicitly waived the privilege." Id. at 719. However, the "court imposing the waiver does not order disclosure of the materials categorically; rather, the court directs the party holding the privilege to produce the privileged materials if it wishes to go forward with its claims implicating them. The court thus gives the holder of the privilege a choice: If you want to litigate this claim, then you must waive your privilege to the extent necessary to give your opponent a fair opportunity to defend against it." Id. at 720.

In the Ninth Circuit, the standard for determining when an implied waiver of the attorney-client privilege occurs is set out in Hearn v. Rhay, 68 F.R.D. 574, 581 (E.D. Wash. 1975). See Home Indem. Co. v. Lane Powell Moss & Miller, 43 F.3d 1322, 1326 (9th Cir. 1995).

Under Hearn, an implied waiver of the attorney-client privilege occurs when (1) the party asserts the privilege as a result of some affirmative act, such as filing suit; (2) through this affirmative act, the asserting party puts

---

3 Teikoku and Watson appropriately rephrased some of the topics so that they disclosed their subjective beliefs as to the topics at issue. See Exs. B & C to Kohn Decl.

4 The Bittaker court noted that "three important implications flowed from this regime": first, the court must impose a waiver no broader than needed to ensure the fairness of the proceedings before it; second, the holder may preserve the confidentiality of the privileged communications by choosing to abandon the claim that gives rise to the waiver; and third, a court may impose contours and protections on the use of the privileged information. Id. at 721.
the privileged information at issue; and (3) allowing the privilege would deny the opposing party access to information vital to its defense.

Id. at 1326.

Plaintiffs rely heavily on United States v. Amlani, 169 F.3d 1189 (9th Cir. 1999). There, the [*43] district court found that defendant impliedly waived the attorney-client privilege with respect to communications involving him, his wife, his current counsel, and his former counsel by asserting a claim of attorney disparagement in the appeal of his conviction and sentence. Amlani's claim for disparagement was based on allegations that the government deprived him of his Sixth Amendment right to counsel when the prosecutor intentionally undermined his confidence in his chosen counsel by disparaging Amlani's counsel in front of him. Id. at 1191. The district court found that Amlani waived the privilege and allowed the government to investigate the claim by issuing subpoenas and seeking the testimony of defendant, his wife, and his counsel into the circumstances surrounding the substitution of new counsel.

The Ninth Circuit affirmed, applying the Hearn test. It concluded that Amlani put the circumstances at issue by claiming disparagement and prejudice from having to substitute in new counsel as a result, and that the government "demonstrated a real need for the evidence, especially in deciding the question of whether the allegedly disparaging statements caused Amlani to seek new counsel." Id. at 1195. The court recognized [*44] that privileged communications "do not become discoverable simply because they are related to issues raised in the litigation" and that when the sought-after evidence is only one of several forms of indirect evidence about an issue, the privilege has not been waived. Id. But it explained that "fairness" required the disclosure because to defend against defendant's claim, "the government must have access to" the communications at issue. Id.

As the court explained, other potential sources of evidence on the issue would be "of little, if any, value in evaluating whether the prosecutor's statements caused Amlani to retain other counsel. If the government has no access to the subpoenaed documents and other communications because of the privilege, it would be forced to rely almost exclusively on Amlani's and Katz's characterization of events." Id. at 1196. Therefore, "[i]n fairness, to defend against these charges, the government must have access to Amlani's communications with counsel to determine whether in fact the disparaging comments caused the substitution of counsel." Id.; see also Apple Inc. v. Samsung Elecs. Co., 306 F.R.D. 234, 243 (N.D. Cal. 2015) (when defendant attempted to defeat sanctions related to an inadvertent disclosure of confidential materials relying [*45] on and submitting for in camera review its own privileged documents, it went beyond "mere denials" and its "use placed the privileged information at issue while improperly limiting Apple and Nokia's ability to assess or challenge these assertions. This waived privilege."); Landmark Screens, LLC v. Morgan, Lewis & Bockius LLP, No. 08-02581 JF (HRL), 2009 U.S. Dist. LEXIS 102579, at *7-8 (N.D. Cal. Oct. 21, 2009) (where plaintiff put at issue fact of when it became aware of the alleged fraud by alleging tolling of the statute of limitations, "[i]nformation that shows when Landmark discovered the alleged fraud would therefore be vital to MLB’s defense, and the Hearn test is met."); Rambus Inc. v. Samsung Elecs. Co., No. C-05-02298 RMW, 2007 U.S. Dist. LEXIS 97619, at *13 (N.D. Cal. Nov. 13, 2007) (because defendant asserted tolling of statute of limitations to when it discovered former employee's fraud counterclaim, implied waiver was found as to relevant communications); cf. Chevron Corp. v. Donziger, 2013 U.S. Dist. LEXIS 168187, at *9, *11 (S.D.N.Y. Nov. 21, 2013) (following Hearn and considering whether it would "be unfair for a party asserting contentions to an adjudicating authority to then rely on its privileges to deprive its adversary of access to material that might disprove or undermine the party's contentions" and concluding "implied waiver may be found where a party puts a claim or defense at issue that in fairness requires [*46] disclosure of privileged material, whether or not the privileged material explicitly was relied upon in making the claim or defense.").

Contrary to defendants' position, the actual use of attorney client information in prosecuting or defending this case is not necessary to effect an implied waiver under Hearn. Cf. Bowne, Inc. v. AmBase Corp., 150 F.R.D. 465, 488 (S.D.N.Y. 1993) (concluding defendant waived privilege for communications by asserting it was not at fault for a missed proxy statement mailing; "][t]he implicit point was that even if a party does not attempt to make use of a privileged communication, he may waive the privilege if he asserts a factual claim the truth of which can only be assessed by examination of a privileged communication."); but see DR Distributors, LLC v. 21 Century Smoking,
That said, a simple showing of relevance to a case will not suffice. The information sought must be directly relevant and necessary to allow a party to fully challenge the claims or defenses of the party asserting the privilege, and the information cannot be secured through other sources. See, e.g., In re Geothermal Res. Int'l, Inc., 93 F.3d 648, 653 (9th Cir. 1996) (emphasizing that the privilege is waived only when "the client tenders an issue touching directly upon the substance or content of an attorney-client communication" and not when the testimony sought would be "only one of several forms of indirect evidence" about an issue); 1st Sec. Bank of Washington v. Eriksen, No. CV06-1004RSL, 2007 U.S. Dist. LEXIS 4449, 2007 WL 1888811, at *3 (W.D. Wash. Jan. 22, 2007) (information otherwise protected by privilege must be "vital" to party's claim; "[m]ere relevance to defendant's case is not sufficient."); see also Cervantes v. CEMEX, Inc., No. 1:12-CV-1932-LJO-JLT, 2014 U.S. Dist. LEXIS 115652, 2014 WL 4104200, at *9 (E.D. Cal. Aug. 18, 2014) (if "mere showing" that privileged information would be "helpful" to a party "was deemed sufficient, the privilege would be completely eviscerated and clients would no longer be permitted to seek advice of counsel in confidence").

Relatedly, defendants cannot avoid waiver by offering to [*48] rely at summary judgment or trial solely on non-legal justifications for certain subjective beliefs. There is no doubt — given the question at issue is whether anticompetitive goals motivated defendants' settlement — that business advice and non-legal facts were considered by settlement decision-makers. But if defendants inject their subjective beliefs on specific topics as part of their defense of the Watson settlement — like a subjective belief that patent litigation is inherently uncertain — where evidence establishes that the subjective belief was also informed by attorney advice, it would be unfair to not allow plaintiffs access to defendants' contemporaneous attorney-client information to test the veracity of the defendants' justifications in this litigation even though that belief is based in part on business judgment and executive experience.

B. Defendants' Subjective Beliefs

Endo has identified 29 subjective beliefs as to topics (b) - (e) on which it intends to rely at summary judgment and trial. See Exhibit A to the Declaration of Peter Kohn, Dkt. No. 463-2. Watson/Actavis has identified 28 subjective beliefs.

---

5 Many of defendants’ cases are inapposite because they cite to or rely on the Third Circuit’s analysis in Rhone-Poulenc Rorer which, contrary to Hearn, requires affirmative use of the privileged information to find implied waiver. See, e.g., Sorensen v. Black & Decker Corp., No. 06CV1572BTM(CAB), 2007 U.S. Dist. LEXIS 26335, 2007 WL 1976652, at *2 (S.D. Cal. Apr. 9, 2007) [*47] (relying on Rhone-Poulenc Rorer); Harter v. Univ. of Indianapolis, 5 F. Supp. 2d 657, 664 (S.D. Ind. 1998) (following Rhone-Poulenc Rorer).

6 Defendants rely on 1st Sec. Bank of Washington v. Eriksen, No. CV06-1004RSL, 2007 U.S. Dist. LEXIS 4449, 2007 WL 1888811, at *3 (W.D. Wash. Jan. 22, 2007) for the proposition that because their subjective beliefs can be supported by non-privileged information, there is no waiver. See, e.g., Watson Oppo. at 2. In that case, however, the privileged information at issue was not relevant to the question at the heart of the case (defendant's [*49] malpractice liability), and was at most relevant to damages (the reasonableness of the subsequent settlement). As the privileged information did not go to the central issue, there was no need to pierce the privilege and non-privileged facts sufficed for proof on the ancillary damages issue.

7 Because Endo understood that in my December 2015 Order I determined that any subjective belief regarding topic (a) would result in a waiver of the attorney-client privilege and attorney work product doctrines, Endo has elected not to present evidence of its subjective beliefs regarding "Endo's assessment of the strength of the relevant patents and its expectations concerning the outcome of the patent litigation." Plaintiffs nevertheless ask me to require Endo to produce privileged [*50] documents on this topic because: (i) Endo made false representations to the FTC and this Court about its beliefs on the patent litigation; and (ii) Endo has nonetheless put at issue this topic through its subjective beliefs about the September 2013 Watson entry date and its
beliefs on topics (a) - (e). Ex. B to the Kohn Declaration. Teikoku has identified 11 subjective beliefs on topics (a) - (c) and (e). Ex. C to the Kohn Declaration.

As described in more detail below, plaintiffs have demonstrated that many of the subjective statements identified by defendants rely in significant part on legal advice. The depositions of defense fact witnesses and the assertions of privilege in those depositions demonstrate that legal advice was provided and considered. The privilege logs likewise show that legal advice was provided on these topics and considered by senior management, and confirm that defendants' settlement negotiators and often primary decision-makers were the attorneys.

Some of the subjective beliefs under each category plausibly implicate only business decisions and could have been theoretically reached without attorney-client input. For example, under (b) — "Endo's Reasons, Explanations and Intentions for the Payments, and its Beliefs About the Impact the Payments Would Have on Competition" — Endo's Subjective Belief 1 is that: "All terms of the Agreement were part of a negotiated package that enabled the parties to resolve the patent litigation in a manner that permitted Watson to enter the market before the expiration of the patents Endo asserted against Watson." On its face, some components of that belief could plausibly be based solely on business judgment.

The problem is that in order to test the veracity of that belief — including whether other factors were involved and how much weight each factor had in motivating the parties to "resolve the patent litigation" and allow Watson "early" entry — other justifications that plaintiffs have shown relied on attorney-client advice are also directly implicated. As to many of the subjective beliefs [52] discussed below, defendants' position is essentially this: "Trust us. The justifications we are putting forward here are why we settled." But in order to test or rebut defendants' assertions, in fairness, plaintiffs should be given access to contemporaneous information regarding those topics that necessarily implicate attorney-client advice. Cf. Amlani, 169 F.3d at 1196 ("If the government has no access to the subpoenaed documents . . . it would be forced to rely almost exclusively" on defendants' characterization of events).

Given the importance of many of these beliefs to the merits of this case, if defendants choose to rely on a subjective belief identified below that the record shows directly implicate attorney-client advice, defendants will have effectuated an at-issue waiver for that belief and will be required to produce withheld privileged documents. At oral argument, defendants complained that requiring them to decide whether to waive attorney-client privilege or forego reliance on subjective beliefs to defend this case puts them in an untenable position and would "eviscerate" the attorney-client privilege. Defendants' sky-is-falling protest ignores the unique circumstances of this case. Defendants' position would put plaintiffs in a truly untenable posture — requiring them to challenge the subjective beliefs defendants assert to justify the Watson settlement post-hoc without access to the contemporaneous information and documents defendants actually relied on. Moreover, as explained below, many of the "beliefs" defendants wish to rely on at summary judgment or trial can be presented through objective evidence by experts without touching on defendants' subjective beliefs.

---

8 Indeed, the privilege disputes the parties have brought before me implicate many of these topics — for example Endo and Teikoku's discussion of the status of Watson's ANDA as well as the strategy for Endo's Citizen Petition — and demonstrate [51] that attorneys were inherently involved in helping the companies formulate their beliefs and strategies.

9 The Ninth Circuit in Home Indem. Co. v. Lane Powell Moss & Miller, 43 F.3d 1322, 1326 (9th Cir. 1995) concluded that it was not an abuse of discretion to deny defendants access to plaintiff's attorney-client privileged information, because that information was not critical to defendants' defense. Specifically, facts defendants admitted undermined their theory as to the relevance of the privileged documents. Id. at 1326-27 (plaintiffs' actions and intent); see also id. at 1327 (reasonableness of insurer's settlement, an ancillary issue, established by facts regarding existing judgment). The facts in Home Indemnity — the irrelevance of privileged documents to the central liability issue and that other admitted evidence fully established the ancillary damages issue — differentiate this case [53] from that one.
C. Topic [*54] (a) — Defendants' Assessment of the Strength of the Relevant Patents and Expectations Concerning the Outcome of the Patent Litigations

Endo, correctly understanding that I have already ruled that any attempt to rely on a subjective belief regarding the strength of the relevant patents and expectations concerning the outcome of the Watson patent litigation would create an at-issue waiver, has not identified any subjective beliefs under (a). Teikoku has identified one subjective belief:

Teikoku may introduce or rely on at trial evidence that at the time it entered into the Settlement Agreement, Teikoku believed that the outcome of the Watson litigation was uncertain.

Watson has identified two subjective beliefs:

1. There are risks inherent in patent litigation, including that District Courts, and Judge Robinson of the District of Delaware specifically, and the Federal Circuit routinely find patents valid, enforceable, and infringed, and as a consequence, there was a risk that the district court and/or the Federal Circuit would find the '529, '510, '333, and/or '334 Patents valid, enforceable, and infringed by Actavis.
2. An appeal of the district court decision in the '529 patent litigation would last at least a year from the date of decision.

Given that the subject matter here is the Watson patent litigation and the justifications for resolving that litigation, these subjective beliefs necessarily involve attorney-client advice. Xuedan Wang v. Hearst Corp., No. 12 CV 793 (HB), 2012 U.S. Dist. LEXIS 179609, at *8 (S.D.N.Y. Dec. 19, 2012) (“I find it difficult to imagine that a good faith defense . . . raised by a corporation as large and as sophisticated as Hearst would not involve the advice of its legal department.”).

Teikoku and Watson's argument — that these specific subjective beliefs can be based on business judgment and the general knowledge [*56] of pharmaceutical executives — is accurate to a point. But the privilege logs and deposition testimony demonstrate that the status of the Watson patent litigation and the risks involved to both sides were discussed between executives and counsel, which is to be expected. Kohn Decl., Ex. E, W1 — W3 (Watson CEO discussed strength of patents and status of patent litigation with counsel), W4-W7 (Watson in-house patent counsel invoked privilege as to discussions regarding Watson patent litigation), W8 (Watson in-house patent counsel knew what CEO's beliefs were as to merits of patent litigation, but could not reveal those beliefs because of attorney-client privilege), W14; see also Kohn Ex. F T1 (Teikoku CEO could not disclose his opinion about patent litigation without disclosing privileged information because “[e]verything involves opinions from counsel.”), T2-T3 (Teikoku's Director of Business Development and Manager of Corporate Development did not know anyone at Teikoku who had an opinion about the Watson litigation not based on legal advice), T5 (CEO asserting privilege

---

10 Endo did disclose — as Subjective Belief 26 — that the post-trial motions in patent cases take a few months to resolve and appeals in patent litigation take approximately a year to resolve. Ex. A at 5. While phrased in a general way, if this belief is introduced in evidence it would necessarily suggest a subjective belief as to the Watson patent litigation. It is therefore treated, along with Watson's Subjective Belief 2, as an expectation concerning the outcome of the patent litigation. See Kohn Decl., Ex. D E22 (Endo attorney [*55] and Senior VP of Intellectual Property asserted privilege in response to questions about likelihood of success in Watson litigation).

11 Watson relies on extensive deposition citations to testimony by its former CEO Paul Bisaro that he and similarly situated people in his industry were familiar with Paragraph IV patent litigation and the inherent risks involved. See, e.g., Hoffman Lent Decl. [Dkt. No. 477-1], Ex. B at W1-W8. However, Watson's own excerpts confirm that their executives' beliefs as to the outcome of the litigation at issue were informed by counsel. Id. at W4-W5.

12 See also Dkt. No. 434 at 3 (asserting privilege over comments Watson's CFO Todd Joyce made characterizing “Watson's beliefs regarding the strength or weakness of its position in the patent litigations” because those beliefs were based on legal advice Joyce received from counsel). Watson counsel also created analyses of the patent litigation, but it was unclear whether these analyses were provided to executives or settlement decision-makers [*58] at Watson, other than General Counsel David Buchen. See generally, Kohn Decl. Ex. H (Watson privilege log excerpts).
and lack of knowledge about rulings in Watson litigation).\textsuperscript{13} If business executives were allowed to testify concerning their subjective [*57] beliefs about the inherent uncertainties in patent litigation and timeframes for trial court and appellate decisions generally, the direct and unmistakable implication from that testimony is that those considerations weighed on the settlement of the Watson litigation as to which defendants have asserted privilege.\textsuperscript{14}

Relatedly, Watson argues that it should be allowed to rely on identified subjective beliefs where they are backed up by "public statements" made by Watson during the relevant timeframe. Watson Oppo. at 2-3; see also Hoffman Lent Decl., Ex. C W1-W7. However, those public statements do not disprove the evidence that attorney advice was provided on these subjective beliefs. Nor do the public statements show that attorney advice played no direct role in Watson's formation of the subjective beliefs. In essence, Watson is arguing that because it said something publicly at that time, no other motivations could have been at play, despite evidence that extensive attorney information about the [*59] patent litigation was provided to Watson executives. Cf. \textit{United States v. Amlani}, 169 F.3d at 1196 ("If the government has no access to the subpoenaed documents and other communications because of the privilege, it would be forced to rely almost exclusively on Amlani's and Katz's characterization of events.").

At summary judgment or trial, defendants' experts will be allowed to testify on these topics based on objective evidence (including the pleadings and transcripts from the Watson patent litigation). Those experts may also opine on the timing of the trial court decision, post-trial motions, and resolution of appeals to the Federal Circuit. Those experts, however, will not be allowed to discuss or suggest what the defendants' actual subjective beliefs may have been on these topics.

\section*{D. Topic (b) — Defendants' Reasons, Explanations and Intentions for the Payments, and Beliefs about the Impact the Payments Would Have on Competition}

On topic (b), Endo identifies the following subjective beliefs:

\begin{enumerate}
  \item All terms of the Agreement were part of a negotiated package that enabled the parties to resolve the patent litigation in a manner that permitted Watson to enter the market before the expiration of the patents Endo asserted against Watson [*60].
  \item The Agreement permitted Watson to enter the market before the expiration of the patents Endo asserted against Watson.
  \item The Agreement eliminated or reduced uncertainty concerning the latest date that Watson would be able to launch a generic form of Lidoderm\textsuperscript{\textregistered} if it obtained FDA approval.
  \item The Agreement created a second seller of branded Lidoderm\textsuperscript{\textregistered}, during a time when it was uncertain whether Watson would have a generic Lidoderm\textsuperscript{\textregistered} available to market.
  \item A generic Lidoderm\textsuperscript{\textregistered} product would not have been introduced to the market earlier in the absence of the Agreement.
  \item The Agreement reduced litigation expenses and the business distractions associated with litigation.
  \item Endo was unwilling to agree to a Start Date, as that term is defined in the Agreement, earlier than September 15, 2013.
  \item Endo agreed to the terms of the Agreement in order to resolve the costs, distractions, and uncertainties inherent in its patent litigation with Watson.
  \item Endo agreed to the terms of the Agreement in order to obtain certainty as to the date of entry of generic competition and thereby permit it to make more informed and rational decisions about the allocations of its resources and to facilitate [*61] its access to capital to grow its business, all of which enhanced competition.
\end{enumerate}

\textsuperscript{13} Documents listed on Teikoku's privilege log also confirm that communications with the "client" regarding the Watson patent litigation and trial outcome have also been withheld. Kohn Decl., Ex. I at 1-5.

\textsuperscript{14} Therefore, Watson Subjective Belief 5 (asserting that given the timeframe for an appeal in the underlying patent litigation, Watson's early entry was procompetitive) puts at issue attorney-client information.
10. The provision of branded Lidoderm pursuant to Section 3(b)-3(k) of the Agreement addressed Watson's concern that it might not obtain FDA approval of its ANDA.
11. The provision of branded Lidoderm pursuant to Section 3(b)-3(k) of the Agreement was not intended to delay the Start Date and was not in exchange for a later Start Date, as that term is defined in the Agreement.
12. The Agreement does not limit or impede Watson's wholesaler affiliate, Anda, Inc., from offering branded Lidoderm provided pursuant to Section 3(b)-3(k) to its customers at a price lower than what Endo charged or what other wholesalers charged for Lidoderm.
13. Section 3(e) of the Agreement ensured that entities with contracts with Endo for branded Lidoderm would get the benefit of those contracts even if they purchased branded Lidoderm® from Anda, Inc.
14. Any cost associated with the provision of Branded Lidoderm pursuant to Section 3(b)-3(k) of the Agreement was counterbalanced by Watson's agreement to pay Endo a royalty on its generic Lidoderm.
15. The partially exclusive licensing provisions in the Agreement, including Section 2(b), were not intended to delay the Start Date and were not in exchange for[*62] a later Start Date, as that term is defined in the Agreement.
16. There is no way to know whether the parties would have reached a settlement agreement had they been required to negotiate without all of the elements in the Agreement.

Teikoku identifies the following:
1. The branded Lidoderm provided pursuant to the Settlement Agreement would permit Watson (a) early entry to the market for prescription adhesive 5% lidocaine patches (the "market"), and (b) to compete against Endo on price.
2. The cost of Teikoku's contribution to the settlement — consisting of half-price discounts to Endo totaling $5 million — was small.
3. Teikoku believed that its contribution to the settlement would maintain good business relations with Endo and in turn benefit Teikoku in their ongoing business negotiations.
4. Teikoku believed that Endo had the contractual right to control the litigation and settlement with Watson pursuant to the Teikoku-Endo April 10, 2007 letter agreement.
5. Teikoku believed that resolution of the patent litigation against Watson would (a) help avoid the further costs, distractions and uncertainties inherent in such litigation, and (b) allow Watson to launch a generic version of Lidoderm [*63] before the expiration of the '529 patent.
6. Apart from maintaining good business relations and avoiding further costs, distractions and uncertainties, as set forth above, and without taking into consideration the potential outcomes of the litigation or regulatory proceedings in the FDA, Teikoku believed that the terms embodied in the May 28, 2012 Settlement and License Agreement would not necessarily benefit Teikoku.

Watson identifies the following:
3. All of the terms of the Agreement, including the partially-exclusive patent license, provision of branded Lidoderm product and royalty for generic sales, were part of a negotiated package that enabled the parties to reach a settlement that allowed Actavis to launch generic Lidoderm significantly in advance of the last patent expiration.
4. The terms of the Agreement were procompetitive, because they were part of a negotiated settlement that enabled Actavis to launch generic Lidoderm 25 months before the expiration of the last patent, which had 41 months remaining at the time of settlement.
5. Even if Actavis prevailed during the '529 patent trial, given the time an appeal would take regarding that litigation alone, the terms of the Agreement were procompetitive [*64] because they were part of a negotiated settlement that enabled Actavis to launch generic Lidoderm before patent litigation proceedings would have ended.
6. The terms of the Agreement were procompetitive, because they were part of a settlement that precluded Endo/Teikoku from submitting a new Citizen Petition, amending the pending Citizen Petition, and/or bringing suit against the FDA, thereby removing potential barriers to Actavis receiving FDA approval for generic Lidoderm.
7. Endo's provision of brand Lidoderm was procompetitive, because it added a competing supplier of brand Lidoderm during a time period when Actavis did not or was unlikely to have had generic Lidoderm available to market, and facilitated sales at a price lower than what Endo charged and/or what other wholesalers charged for Lidoderm.

8. The Agreement was procompetitive because it reduced litigation expenses and the business distractions associated with litigation.

9. Actavis agreed to the terms of the Agreement in order to obtain certainty as to the date of entry of generic competition and thereby permit it to make more informed and rational decisions about the allocations of its resources, all of which enhanced competition. [*65]

10. The provision of branded Lidoderm pursuant to Section 3(b)-3(k) of the Agreement was not intended to and did not delay the Entry Date, as that date is defined in the Agreement.

11. The provision of the partially exclusive licensing provisions in the Agreement, including Section 2(b), was not intended to and did not delay the Entry Date, as that date is defined in the Agreement.

As an initial matter I recognize that the first part of this topic — the reasons, explanations, and intentions for the "payment" of free product to Watson — would appear to necessarily implicate attorney-client advice because that payment was a key, if not the central, term of the Watson settlement negotiated by defendants' counsel. The second part of this topic — the "beliefs about the impact" on competition — by its nature falls more squarely into the provenance of business knowledge and industry experience (except where the testimony implicates whether and why Watson's generic entry was "early" or "uncertain," because those statements necessarily rely on defendants' attorney-client-informed beliefs about the strength of the Watson patent litigation and uncertainties regarding the FDA's actions). With that foundation, I group the [*66] beliefs identified by defendants to resolve whether the particular subjective beliefs put at issue privileged information.

1. Resolving Litigation to Allow Watson "Early Entry" Into Market on a Specific Date

Defendants argue that the fact that the Settlement allowed Watson to enter the market and sell its generic Lidoderm before the expiration of the patents can be shown by the agreed-to date of entry provided in settlement (September 15, 2013) and the patent expiration dates (one year later for the '510 patent and two years later for the '529 patent). That is true. That fact can be established through testimony about the Settlement Agreement and evidence on the face of the patents themselves. See Endo Subjective Belief 2, Watson Subjective Belief 4 (in part). Allowing subjective testimony as to that fact would not create an at issue waiver.

However, describing the entry as "early" and testimony concerning how or why Watson would seek early entry, why Endo/Teikoku would agree to early entry (the "reasons, explanations and intentions" for the payments), and why early entry was procompetitive, necessarily involves beliefs about the strength of the patents and the outcome of the patent litigation. See Endo Subjective Beliefs1,7; Teikoku Subjective Belief 1(a); Watson Subjective Beliefs 3 (in part) 4 (in part), 5. In deposition, Endo's witnesses would not explain why the entry date was agreed to other than it was part of a negotiated package, and rested on assertions of attorney-client privilege. Declaration of Daniel Asimow (Dkt. No 475-1), Ex. 2 (Dep. Tr. of Levin) at 302 (Endo CFR would not "speculate" on earlier date but it would have been "challenging"), Ex. 4 (Levin FTC testimony) at 125; see also Kohn Decl., Ex. D E8, E44 (General Counsel discussed September 2013 start date with Endo executives); E9 (Endo patent attorney and VP of Intellectual Property instructed not to answer question regarding entry date on grounds of privilege); see also Ex. E W17 (Watson in-house counsel asserted [*68] privilege when questioned whether entry date reflected assessment of strength of patent litigation); W20 (asserting privilege over reasons for September 2013 entry date); W44 (in-

---

15 See, e.g., Kohn Ex. D, E1 (Endo General Counsel discussed with Endo executives whether settlement would be possible without provision of free branded Lidoderm); Ex. E W23 (Watson counsel discussed provision of free product with CEO; refused to disclose contents of conversation based on privilege).

16 Obviously, objective expert testimony could establish this fact as well, [*67] based on authenticated documents.
house counsel asserting privilege as to best launch date scenario); W49 (General Counsel discussed the reasons for the September 15, 2013 launch date with CEO, including reasons based on legal advice).\(^{17}\) Allowing subjective testimony on these issues would create an at issue waiver.

2. Agreement was a Negotiated Package

Defendants' business executives\(^{18}\) may testify that they accepted the terms of the settlement as a package, and would not have settled unless all elements of the agreement were present. Endo Subjective Beliefs 1 and 16 (in part); Watson Subjective Belief 3 (in part). Defendants cannot, however, offer testimony as to their negotiation strategy or attempt to explain why each component was necessary to the settlement "package." \(^{[*69]}\) Plaintiffs have shown that defendants in-house counsel (and in the case of Teikoku, outside counsel) were the main negotiators and in most cases the actual decision-makers on the Settlement. See, e.g., Kohn Decl., Ex D E3 (Endo CEO Holveck relied on advice of General Counsel who "had the details" on settlement negotiations and ultimate agreement); Kohn Reply Decl., Ex J E69 (Endo General Counsel approved settlement of patent litigation). Testimony about what was negotiated, when it was negotiated, and why provisions were required to settle would necessarily put at issue attorney-client information.

3. Resolving "Uncertainty" of Date of Generic Launch

Beliefs about the date on which Watson would be able to launch their generic based solely on competitive intelligence (at Endo/Teikoku) or on business plans and status (at Watson) about Watson's capacity to launch (e.g., Watson's access to ingredients, manufacturing capacity), do not necessarily involve attorney-client advice and do not create \(^{[*70]}\) an at issue waiver. Similarly, testimony about the business benefits of knowing exactly when a generic might enter the market from Endo (Endo Subjective Belief 9 (in part)) or Watson (Watson Subjective Belief 9 (in part)) can also be based purely on business and industry experience.

However, as discussed above, beliefs about resolving the "uncertainty" surrounding the generic launch date and allowing Watson "early" entry, necessarily implicate beliefs as to the outcome of patent litigation. The same analysis applies to the approval of Watson's ANDA by the FDA and resolution of the related Endo Citizen Petition.\(^{19}\) Subjective beliefs that necessarily rely on what defendants have been told regarding the outcome of the patent litigation put attorney-client information at issue.

With respect to the FDA's approval of Watson's ANDA, any beliefs that touch on that subject will also put "at issue" attorney-client advice. See Endo Subjective Belief 10. Defendants argue that business executives have beliefs and understandings about the FDA's approval \(^{[*71]}\) of ANDAs not informed by attorney-client information (given their experience in the industry) and defendants' scientists likewise have beliefs not informed by attorney-client information about the FDA's requirements and activities with respect to ANDAs generally and the Watson ANDA in particular. That is undoubtedly true. But plaintiffs have established that each of the defendants' actual understanding of the status of Watson's ANDA and the implications of the FDA's actions on the ANDA were based in significant part on attorney-client advice. Kohn Decl., Ex. D E28, E29, E32 (Endo General Counsel advised client as to whether FDA might decide Watson ANDA by a particular date in light of FDA's actions and Citizen Petition, and asserting privilege over contents of communications); Ex. E W27 (Watson's CEO's view on ANDA approval

\(^{17}\) As noted above, defendants' business executives cannot discuss their subjective beliefs about the uncertainties inherent in patent litigation and appeals (as to the merits or timeframe) because that would put at issue attorney-client information. See, e.g., Watson Subjective Belief 5.

\(^{18}\) The use of the terms "business executives" or "business employees" in this Order is meant to distinguish between in-house counsel (including general counsel) and non-lawyer executives and employees.

\(^{19}\) Endo Subjective Beliefs 3, 5, 9 (in part); Teikoku Subjective Belief 5(b); Watson Subjective Belief 9 (to extent relies on resolution of uncertainty).
This conclusion is supported by my prior Order affirming Watson's assertions of privilege regarding the ANDA and the publicly filed briefing on the parties' privilege disputes. See, e.g., Dkt. No. 434 at 3 (Watson claiming privilege over Robert Stewart's (President of Global Operations) email [*73] disclosing his "take on the implications [of the ANDA] for the development and manufacturing of generic Lidoderm," which Stewart provided to Watson General Counsel Buchen in aid of Buchen's settlement negotiations); Dkt. No. 434-3 (Watson General Counsel Buchen's role was to provide advice about the Watson litigation and settlement, and as settlement discussions "intensified" in Spring 2012 Buchen required "updates of significance" on the status of Watson's ANDA to inform his legal advice and settlement negotiations); see also Minute Order, Dkt. No. 435.

The "uncertainty" regarding Watson's generic launch date also implicates the Citizen Petition then-pending with the FDA. See Watson Subjective Belief 6. As with the ANDA, plaintiffs have established that each of the defendants' actual understanding as to the purpose, content, status, and chance of success of the Citizen Petition depended in part on attorney-client advice. Kohn Decl., Ex. D E38, E39 (Endo relied on outside counsel in formulating position and advice on intertwined regulatory and legal issues with Citizen Petition); E40-41 (Endo CFO's knowledge about Citizen Petition came exclusively from Endo's lawyers); Ex. E W31 (Watson [*74] CEO had conversation with General Counsel about likely outcome of Citizen Petition; asserted privilege in refusing to disclose contents of those conversations); W32, W54 (Watson General Counsel provided legal advice to CEO and executive committee regarding likely outcome of Citizen Petition); W34 (General Counsel and outside counsel studied impact of potential outcomes with respect to Citizen Petition); Ex. F T20 (Teikoku CEO's opinion about likelihood of denial of Citizen Petition based on attorney-client advice), T24 (Teikoku outside counsel discussed status of Citizen Petition with Endo General Counsel).

The parties' privilege disputes confirm that defendants relied on attorney-client advice regarding the purpose, content, status, and chance of success of the Citizen Petition. See Dkt. No. 449 (Watson asserted privilege over information regarding status and potential outcomes of Citizen Petition); Dkt. No. 434 at 4 (Watson asserted privilege over a discussion of in-house counsel's "plans regarding Watson's potential response to Endo's Citizen Petition"); Dkt. No. 434-3 (Watson General Counsel Buchen provided legal advice about status of Citizen Petition); Dkt. No. 413 at 14 (upholding [*75] Endo's assertion of privilege regarding advice on Citizen Petition, especially with respect to Manogue and other Endo counsels' discussions of the Citizen Petition and its amendments "in context of Watson litigation settlement discussions"); Dkt. No. 386-1 (Endo's General Counsel provided analysis to Endo and Teikoku as to the contents, strengths, and implications of the Citizen Petition and its 2012 amendments, including supervising the work of outside consultants on the Citizen Petition); Dkt. Nos. 359, 367 (Teikoku asserted privilege over discussions of timing of Citizen Petition made in connection with settlement discussions with Watson); cf. Dkt. No. 413 (discussing broad assertions of privilege by Endo over a range of documents dealing with Citizen Petition and Amendments).

Defendants' views on these topics — the potential outcomes of the patent litigation, the FDA's actions with and potential resolution of the ANDA, and the FDA's actions with and potential resolution of the Endo Citizen Petition — were formed with attorney-client input. Critically, they are central to the merits of this case. As such, fairness dictates that defendants should not be able to offer subjective beliefs that necessarily [*76] hinge on the

---

20 In Opposition, Watson submits deposition excepts from its regulatory 30(b)(6) witness containing non-attorney-client information that also weighed on Watson's understanding of the likelihood of ANDA approval. Hoffman Lent Decl., Ex. 2 W16. The fact that Watson relied in part on non-legal advice is accepted. That does not, however, undermine that legal advice likewise played a significant role. In fairness, therefore, if this topic is put at issue by Watson, plaintiffs should have access to the attorney-client information so they can determine the significance of the various factors (legal, regulatory, and others) that motivated Watson's beliefs as to the strength and timing of the ANDA approval; a central question that goes directly to the heart of this case. See also id. W19 (non-attorney-client information about Watson's thoughts on Endo Citizen Petition).
potential outcome of the patent litigation, the ANDA, or the Citizen Petition without allowing plaintiffs access to contemporaneous attorney-client documents regarding those topics.\(^{21}\)

4. ANDA Approval and Resolution of the Citizen Petition by the FDA

As discussed above, the record in this case demonstrates that the contents, strategy, status, and likelihood of success of both Watson's ANDA and Endo's Citizen Petition were the subject of attorney-client advice and these topics were not merely discussed in the settlement negotiations, but were central to those negotiations and, thus, the merits of this case. Any attempt to rely on or introduce defendants’ subjective beliefs about these topics will put attorney-client information at issue.

5. Allowing Second Seller of Branded Lidoderm into Market [*77]

The fact that the Settlement Agreement allowed a second seller of branded Lidoderm into the market is obvious from the face of the Agreement and can be testified to by defendants' fact witnesses. Teikoku Subjective Belief 1(b).

However, any assertion concerning the timing of this entry or its procompetitive significance (e.g., because it allowed Watson to enter the market "early" or at a time when it was "uncertain" whether Watson would have a generic Lidoderm available to the market, see Endo Subjective Belief 4, Watson Subjective Belief 7) puts attorney-client information at issue. See also Kohn Decl., Ex. D E13, E14 (Endo General Counsel discussed with client "what role" provision of branded Lidoderm would play in settlement). Timing was uncertain because of uncertainty regarding the outcome of the patent litigation and the status of the ANDA and Citizen Petition — topics which put at issue attorney-client information.

6. No Intention to "Delay" Watson's Entry

Endo and Watson want to rely on subjective beliefs that portions of the Agreement (provision of branded Lidoderm to Watson and partially exclusive licensing) were not intended to delay the start date for Watson's generic. Endo [*78] Subjective Beliefs 11, 15; Watson Subjective Beliefs 10, 11. However, Endo and Watson do not explain what these provisions were intended for, presumably because that would touch directly on attorney-client advice. See e.g., Kohn Decl., Ex. D E13, E14 (Endo General Counsel discussed with client "what role" provision of branded Lidoderm would play in settlement); E15 (Endo in-house patent counsel asserting privilege in response to question about reason free product was provided). Endo and Watson cannot insert these subjective beliefs at summary judgment or trial, absent a proffer of a justification devoid of attorney-client input. Endo and Watson's actual justifications for these provisions in the Agreement, obviously, are central to the merits of this case.

7. Reduced Litigation Expenses and Business Distractions

This topic does not necessarily rely on attorney-client advice.\(^{22}\) Testimony can be based (as defendants assert) on the experience of business executives who have been involved in Paragraph IV patent litigation or who tracked the

\(^{21}\) Subjective beliefs about when non-Watson generics might enter the market is similarly permitted only to the extent it is based solely on competitive intelligence. Otherwise, these beliefs implicate on attorney-client advice. See e.g., Dkt No. 434 at 3-4 (Watson asserting privilege over in-house attorney's "fulsome patent litigation analysis" regarding non-Watson generic Lidoderm entry).

\(^{22}\) Endo Subjective Beliefs 6 and 8 (in part; no subjective testimony about "uncertainties" in patent litigation allowed without placing topic at issue); Teikoku's Subjective Belief 5(a) & 6 (in part; no subjective testimony about "uncertainties" inherent in patent litigation); Watson Subjective Belief 8.
expenses incurred from and any business distraction caused by the Watson litigation itself. The Supreme Court in *Actavis* acknowledged that avoiding litigation [*79]* expenses might constitute a "legitimate justification" for a reverse payment settlement. *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223, 2236, 186 L. Ed. 2d 343 (2013) ("The reverse payment, for example, may amount to no more than a rough approximation of the litigation expenses saved through the settlement."). Therefore, while testimony on this topic is central to the prosecution and defense of this case, because it can be shown exclusively through testimony of executives without implicating attorney-client privileged information, testimony on these subjective beliefs will not put at issue attorney-client advice.

8. Agreement’s Impact on Watson’s/Anda’s Ability to Offer Branded Lidoderm and Impact on Existing Endo Contracts

Endo’s Subjective Beliefs 12 and 13 and Watson’s Subjective Belief 7 (in part) — that the Agreement did not limit Watson or its wholesaler affiliate Anda from offering the branded Lidoderm at prices below what Endo or other wholesalers charged [*80]* and that the Agreement protects Endo’s existing contracts — are based on the face of the Agreement and do not necessarily implicate attorney-client information. These beliefs do not put attorney-client information at issue.

9. Costs Associated with Agreement and Control Over Settlement

Endo’s Subjective Belief 14, about how the costs of Agreement would be offset by royalty payments on Watson’s generic, does not necessarily implicate attorney-client information, can be established from the face of Agreement, and can be testified to based solely on testimony from business witnesses. This belief does not put attorney-client information at issue. 23

Teikoku’s Subjective Belief 2, that its contribution to the Agreement was small, similarly does not necessarily involve attorney-client information and can be established by testimony from business executives. Teikoku’s [*81]* Subjective Belief 3, that its settlement contribution was to "maintain good business relations" with Endo, does not necessarily involve attorney-client information and can be established by business executives. Teikoku’s Subjective Belief 4, about the terms of its agreements with Endo regarding control over Paragraph IV patent litigation, do not necessarily implicate attorney-client information and can be testified to by business executives. 24

Teikoku’s Subjective Belief 6 includes a number of discrete assertions--that apart from the benefits of maintaining a good business relationship with Endo (OK), avoiding costs and distractions (OK), avoiding uncertainties (places attorney-client information at issue), and without taking into consideration the potential litigation and regulatory outcomes, the Terms in the Agreement “would not necessarily benefit Teikoku.” The problem with this belief is that Teikoku does not explain the reasoning behind it. Therefore, I cannot determine [*82]* whether it implicates attorney-client information. Absent a proffer of a justification devoid of attorney-client input, Teikoku cannot insert this subjective belief at summary judgment or trial.

E. Topic (c) — Defendant’s Beliefs About Watson’s Final ANDA Approval and an At-Risk Launch by Watson

Endo’s subjective beliefs:

17. Watson was unlikely to have launched a generic Lidoderm product “at risk” (i.e., before resolution of the patent litigation, including appeals) because (i) Watson did not have an economic incentive to launch at risk

23 However, the testimony cannot extend to the role the royalty payment agreement played in the settlement, because that puts attorney-client information at issue. Kohn Decl., Ex. D E18 (Endo General Counsel discussed with CEO and CFO role royalty provision played in settlement, but refused to disclose what she told them based on privilege).

24 While Teikoku’s CEO testified that the interpretation of the details of the agreements between Endo and Teikoku required assistance of counsel, he was able to testify as to his general understanding. Kohn Decl., Ex. F T13.
under the circumstances; (ii) Watson likely would have enjoyed the same statutory exclusivities with respect to other generic competition had it deferred its launch until after final resolution of the patent litigation, including appeals; (iii) Watson experienced manufacturing difficulties that would have delayed its ability to launch an FDA-approved generic Lidoderm product; (iv) Watson would not have risked incurring substantial damages in launching at risk; and (v) Watson did not have a history of launching at risk under similar circumstances.

18. Whether FDA would approve Watson's ANDA for a generic Lidoderm product was uncertain as of the date of the [*83] Agreement.

19. Whether FDA would grant Endo's citizen petition regarding the bioequivalence standards for generic Lidoderm, and if so whether it would apply new bioequivalence standards to Watson's generic product, was uncertain as of the date of the Agreement.

20. Statements by Watson's executives about the prospect of launching a generic Lidoderm product at risk were mere bluster and a negotiating tactic.

21. Statements by Watson's executives about the prospect of launching a generic Lidoderm product at risk became more conservative over time and appeared to be conditioning investors to be unsurprised if Watson did not launch at risk.

22. Watson's executives were concerned about whether and when FDA would grant approval for Watson to launch its generic Lidoderm product.

23. The scientific position set forth in Endo's citizen petition and amendments concerning Lidoderm was meritorious.

24. Endo's agreement to forego any appeal of FDA's decision on Endo's citizen petition and amendments thereto, and other provisions in Section 5(a) of the Agreement, may have emboldened FDA to deny Endo's citizen petition or caused it to decide on the petition sooner than it otherwise would have decided absent the Agreement. [*84]

Teikoku's subjective beliefs:

1. Teikoku believed Watson faced substantial technological and manufacturing hurdles in launching its generic prescription adhesive 5% lidocaine patch product within the 30-month stay period and for some time afterward.
2. Teikoku believed that whether FDA would adopt bioequivalency standards for topical patches, potentially precluding approval of Watson's ANDA, was uncertain.
3. Teikoku believed that whether FDA would approve Watson's ANDA was uncertain.

Watson's subjective beliefs:

12. Actavis faced significant uncertainty about whether and when the FDA would approve its ANDA for generic Lidoderm:
   a. Actavis was concerned that the FDA was engaging in a perpetual review due to the content and timing of certain deficiency letters it received for its ANDA;
   b. Actavis was unsure as to when the FDA would issue its ruling on Endo's Citizen Petition; under the operative regulatory rules at the time, the FDA did not have a deadline by which it was required to issue its decision and Actavis's ANDA could not be approved until the FDA ruled on the Citizen Petition.

13. Endo's Citizen Petition was not objectively baseless.

14. Actavis was concerned that the FDA may require [*85] Actavis to conduct clinical endpoint studies in order to demonstrate bioequivalence for generic Lidoderm ANDAs, which could cause Actavis to lose its 180-day exclusivity as the first filer for generic Lidoderm.
   a. If the FDA required clinical endpoint studies for generic Lidoderm, the approval of Actavis's ANDA could have been substantially delayed, or even entirely precluded.

15. Actavis was concerned that Endo would sue the FDA if the FDA ruled against the Citizen Petition and seek a temporary restraining order that would delay approval of Actavis's ANDA.

16. Actavis was concerned that it would lose its 180-day exclusivity period because it did not receive tentative approval by May 13, 2012.

17. Actavis could not launch from a regulatory perspective until it successfully completed process validation at the 1,000 gallon scale-up level, which required the production of three successful, successive process validation lots.
18. Section 5 of the Agreement, in which Endo/Teikoku agreed to not submit a new Citizen Petition, amend the pending Citizen Petition, or bring suit against the FDA, removed potential barriers to resolution of the Citizen Petition, and consequently, final approval for [*86] Actavis's Lidoderm ANDA.

19. Actavis would not have launched generic Lidoderm unless and until it had a sufficient amount of manufactured product available to sell such that it would (i) satisfy fully the market's demand for generic product, (ii) have an appropriate level of inventory on hand, and (iii) maximize the value of its 180-day exclusivity.

   a. Actavis would not have been in a position to launch at-risk upon termination of the 30-month stay because it would not have had requisite launch quantities of the product.

   b. Actavis would not have launched generic Lidoderm until it resolved significant problems and requirements concerning its commercial manufacturing process, including (1) fixing problems with its equipment; (2) optimizing the manufacturing process; (3) successfully completing process validation at the 1,000 gallon scale; (4) improving batch yields and cycle times; and (5) manufacturing the requisite launch quantities commensurate with the forecasted demand.

   c. The Agreement provided the opportunity for Actavis's Salt Lake City facility to fix the issues with its equipment and optimize its manufacturing process to increase batch yields and cycle times; absent these improvements, [*87] Actavis believes it may have needed up to 2 years to build the requisite launch quantities.

20. Actavis would not have launched generic Lidoderm in advance of a judgment of the district court in the trial regarding the '529 patent.

21. Any evaluation of an "at risk" launch of generic Lidoderm would have considered the size of the product market, the degree to which Actavis could maximize the value of its first-to-file exclusivity, the likelihood of additional generic competitors, the content of a trial court decision, and the risk of an injunction and/or significant damages.

As discussed above, all subjective beliefs about the FDA's actions with respect to Watson's ANDA, including its potential approval, put at issue attorney-client advice because the record in this case shows that defendants' attorneys were extensively involved in advising whether and when the ANDA might be approved. While it is true that defendants' scientists and employees working on regulatory matters could testify as to how the FDA handles ANDAs generally and the timeframe for regulatory action on ANDAs in general, the direct and unmistakable implication of testimony from defendants' employees is that those considerations weighed [*88] on decisions made with respect to the Watson ANDA and, therefore, the settlement of the Watson litigation. Endo Subjective Belief 18; Teikoku Subjective Belief 3; Watson Subjective Belief 12a., 12.b., 16. Defendants can present testimony about the Watson ANDA and the FDA's actions on it, not as subjective beliefs but by objective expert testimony. 25

The regulatory matters — the ANDA and the Citizen Petition — were expressly related (i.e., the Citizen Petition asked the FDA to require ANDAs like Watson’s to meet specific bioequivalence standards). The record demonstrates that defendants’ counsel were intimately involved in crafting the content for the Citizen Petition and its amendments, monitoring its status, and advising their clients on the chance of success of the Citizen Petition. As a result, any subjective beliefs that discuss the content of, status of, or the FDA determination on Endo’s Citizen

25 Similarly, Watson Subjective Belief 15 (it was concerned Endo would sue the FDA if the FDA ruled against Endo’s Citizen Petition) and Subjective Belief 18 (that the Agreement’s provisions preventing Endo from submitting revisions or a new Citizen Petition or suing the FDA “removed potential barriers” to resolution of the Citizen Petition and helped lead to approval of the ANDA), by their nature implicate attorney-client advice, a conclusion supported by Watson’s own admissions that counsel were intimately involved in advising Watson about the status of the ANDA and Citizen Petition, and counsel used that information in his settlement negotiations. These subjective beliefs, therefore, put that attorney-client information at issue. See, e.g., Kohn Decl., Ex. E W22 (General Counsel advised Watson CEO about non-interference provisions of settlement); [*89] W28-30 (Watson FDA 30(b)(6) witness instructed not to answer question regarding whether FDA approved ANDA or denied Citizen Petition because of settlement). Watson’s citation to its executives’ non-attorney-client-based beliefs about the utility of the non-interference provisions does not prove that Watson did not also rely on legal advice about the same or otherwise undermine the importance of the legal advice on this issue. But see Hoffman Lent Decl., Ex. B W15.
Petition and its amendments also put attorney-client information at issue. See Endo Subjective Belief 19, 23, 24; Teikoku Subjective Belief 2; Watson Subjective Belief 12b, [*90] 13, 14.

With respect to "at risk" launch, that term is defined as launching a generic drug on the market before "a final court decision" in the underlying Paragraph IV patent litigation. See, e.g., AstraZeneca AB v. Apotex Corp., 782 F.3d 1324, 1330 (Fed. Cir. 2015). By its very definition, the concept requires reference to the status and strength of the patent litigation and necessarily implicates legal advice. See also Kohn Decl., Ex. D E20, E25 (Endo VP of Intellectual Property (a patent attorney) discussed Watson at risk launch with client); E23 (Endo General Counsel discussed likelihood of at risk launch with Endo executives); Ex. E W42, 48 (Watson CEO discussed at risk launch with counsel); W46 (Watson CEO and General Counsel discussed risk of treble damages); Ex. F T16 (Teikoku Director of Business Development testified that no one at Teikoku had an opinion as to at risk launch not based on attorney-client advice), T18 (Teikoku outside counsel recalls but rests on privilege to refuse to disclose opinion of Endo General Counsel as to likelihood of at risk launch), T19 (Teikoku outside counsel advised his client on likelihood of at risk launch). Accordingly, any subjective beliefs about whether Watson would launch (1) given Watson's economic incentives [*91] and risks, including treble damages (Endo Subjective Belief 17(i),(iv)), (2) given the timeframe for final court decisions (Endo Subjective Belief 17(ii)), Watson Subjective Belief 21 (in part)) (3) given the content of the trial court decision (Watson Subjective Belief 21 (in part)), and (4) before a final trial court or appellate court decision, would put attorney-client information as to the strength and status of the patent litigation at issue. Watson Subjective Belief 20.26

Defendants may present subjective testimony to show that Watson did not have capacity to launch before [*92] September 15, 2013, based on competitive intelligence (for Endo/Teikoku) or business hurdles (for Watson).27 When phrased without reference to being at risk but with reference to the date the Settlement Agreement allowed the launch, these subjective beliefs do not necessarily implicate attorney-client advice and logically were known to defendants' business executives and employees, independent of attorney advice. Endo Subjective Belief 17(iii); Teikoku Subjective Belief 1; Watson Subjective Beliefs 17, 19. Relatedly, if business executives formed a subjective belief as to Watson's history of launching when ongoing Paragraph IV litigation had not been resolved based solely on their experience in the industry or their view of Watson's public statements, they may testify as to those beliefs as well. Endo Subjective Beliefs 17(v), 20, 21.28

F. Topic (d) Endo's Reasons or Incentives, if Any, For Agreeing to a Generic Entry Date Before September 2013

Endo's subjective beliefs:

25. Endo had a commercial interest in retaining as much of the relevant patent life as possible and believed Watson was unlikely to have launched at risk. Ultimately, September 15, 2013 was the only date on which the parties could agree in the context of an overall settlement.

26. Subsequent to the entry of judgment, patent cases typically involve post-trial motions in the District Court taking a few months to resolve, and usually result in appeals in the Court of Appeals that typically take

26 We know that counsel for Watson advised and weighed in on the risks of an at risk launch. Kohn Decl., Ex. E W46-48. Therefore, while some of the factors in Watson Subjective Belief 21 ("evaluation of 'at risk' launch") might be based on business judgment, the weight given to these factors — including the "legal factors" which necessarily relied on attorney-client advice — is unknown and it would be unfair to allow Watson to testify as to some of these factors, while asserting privilege over contemporaneous information that would disclose exactly how the business and legal factors were actually weighed by Watson.


28 With respect to Endo Subjective Belief 22, regarding Watson executives' concerns about the FDA approval of the ANDA, if Endo's executives or employees formed this Subjective Belief solely based on comments Watson made publicly, then they can testify as to that Subjective Belief. If, however, Endo learned about [*93] these concerns through the settlement negotiations themselves, the statements would necessarily implicate attorney-client information and put that information at issue.
approximately a year to resolve. Based on these typical steps, appeals in the '529 litigation would not have been resolved any earlier than September 15, 2013.

Watson's subjective beliefs:

22. The Agreement, which contemplated a launch of generic Lidoderm on September 15, 2013 (subject to FDA approval of Actavis's then-pending ANDA), resolved uncertainty created by the patent litigation as to when Actavis[*94] would have been able to commence sales of generic Lidoderm free of potential liability.

23. The Agreement brought two patent litigations to a conclusion and thereby avoided further and significant litigation costs and distraction of Actavis personnel.

24. The date of entry of generic Lidoderm, together with other provisions of the Agreement, represent a negotiated outcome that enabled Actavis to launch generic Lidoderm (subject to FDA approval of Actavis's then-pending ANDA) more than two years before the expiration of the relevant patents and to sell generic Lidoderm in competition with Endo for approximately two-thirds of the remaining period of exclusivity under the '529 patent.

1. Endo's Subjective Beliefs 25, 26.

As to Endo's desire to retain as much commercial benefit for as long "as possible," that possibility is essentially the same as its belief as to the strength and outcome of the Paragraph IV litigation and necessarily puts at issue attorney-client information. As to at risk launch, that has been addressed above. The belief that September 15, 2013, was the "only date" the parties could agree to in settlement, as phrased, necessarily implicates attorney-client information on a key merits[*95] issue because it hinges on the settlement discussions (both between the parties and between defendants' executives and their own counsel). Kohn Decl., Ex. D E8. Rephrasing this belief to limit it to Endo's position that it refused to agree to an earlier date does not avoid the problem. As discussed above, without a proffer as to why Endo stuck to that date, it too likely puts at issue attorney-client information.

Finally, no subjective testimony concerning Endo's belief as to the Paragraph IV litigation timeframe (Endo Subjective Belief 26) is allowed. It can be provided by expert testimony based on objective evidence.

2. Watson's Subjective Beliefs 22 — 24

As discussed above, no subjective beliefs about or based on litigation uncertainty and related at risk launch risks will be allowed without putting at issue attorney-client information. Watson Subjective Belief 22. A subjective belief based on business executive testimony regarding costs and distractions of litigation (Watson Subjective Belief 23) is permissible without creating an at issue waiver. As to the many parts of Watson Subjective Belief 24, business executives can testify only as to the fact that the settlement was a negotiated[*96] package. Any subjective testimony regarding "early" entry of generic Lidoderm will put attorney-client information at issue.

G. Topic (e) Endo's Intention to Launch an Authorized Generic Version of Lidoderm

Endo's subjective beliefs:

27. At the time the Agreement was reached, Endo did not have a definite plan or an intention to launch an authorized generic when the first generic came to market.

28. A decision on whether to launch an authorized generic of Lidoderm would not have occurred until after observing the actual market reaction to the entry of a generic Lidoderm product and learning more about the potential launch of additional generic products.

29. In the event of a launch of a single generic Lidoderm product, Endo intended to employ strategies to compete against the generic on price with branded Lidoderm.

Teikoku's subjective beliefs:
Teikoku may introduce or rely on at trial evidence that at the time it entered into the Settlement Agreement, Teikoku believed that Endo would possibly not launch an authorized generic form of Lidoderm if and when Watson's generic product were approved for sale in the U.S.

Watson's subjective beliefs:

25. Rational companies, such as Endo, consider a host of factors in determining whether and when to launch authorized generics, and that each decision is, ultimately, case-specific.
26. Rational companies, such as Endo, do not always launch authorized generics after the first ANDA generic launches.
27. Rational companies, such as Endo, can intend to launch an authorized generic without intending to launch that authorized generic during the 180-day exclusivity period of a first-filing ANDA generic.
28. There are additional strategies that rational companies can employ in lieu of an authorized generic to maintain product profitability following ANDA generic entry.

Compared to the subjective beliefs discussed previously, there is only thin evidence that defendants discussed any aspect of Endo's intent to launch an authorized generic version of Lidoderm with their counsel. Kohn Decl., Ex. D E48-49; Ex. E W50. The limited discussions were logically related to the settlement provision giving Watson a period of generic exclusivity. See, e.g., Kohn Decl., Ex. D E1, E18, E48. Notwithstanding that the discussions occurred in the context of the Watson settlement negotiations, testimony about Endo's plans and ability to launch a generic Lidoderm does not necessarily or obviously implicate attorney-client advice but is more logically based on business judgment and experience. See Kohn Decl., Ex. D E26 (Endo President of Branded Pharmaceuticals testifying before FTC, without asserting privilege, about timing of Endo's authorized generic launch). Similarly, testimony regarding Endo's and other patent holders/exclusive licensees' history of launching authorized generics is more logically based on business judgment and experience devoid of attorney-client advice. That conclusion is supported by the record here, showing that Endo's subjective beliefs on these topics were based wholly on market research and other economic justifications. See Asimow Decl., Exs. 8-10. Defendants will not effect an at-issue waiver if they rely on these subjective beliefs at summary judgment or trial.

H. Endo's Selective Disclosure

Plaintiffs also argue that Endo effectuated a subject-matter waiver of privileged documents by selectively disclosing privileged information and allowing former General Counsel Manogue to testify as to communications regarding the likelihood of the FDA's approving Watson's ANDA and Endo's assessment of the merits of its Citizen Petition.

"[I]t has been widely held that voluntary disclosure of the content of a privileged attorney communication constitutes waiver of the privilege as to all other such communications on the same subject." Weil v. Investment/Indicators, Research & Management, 647 F.2d 18, 24 (9th Cir. 1981). As the Ninth Circuit explained, "[w]hen (the privilege holder's) conduct touches a certain point of disclosure, fairness requires that his privilege shall cease whether he intended that result or not. He cannot be allowed, after disclosing as much as he pleases, to withhold the remainder. He may elect to withhold or disclose, but after a certain point his election must remain final." Id. (quoting VIII J. Wigmore, Evidence § 2291, at 636 (McNaughton rev. 1961)). As to the scope of the waiver, "[d]isclosing a privileged communication or raising a claim that requires disclosure of a protected communication results in waiver as to all other communications on the same subject." Hernandez v. Tanninen, 604 F.3d 1095, 1100 (9th Cir. 2010); see also Fed. R. Evid. 502(a) (waiver of the privilege "extends to an undisclosed communication or information in a federal or state proceeding only if 1) the waiver is intentional; 2) the disclosed and undisclosed communications or information concern the same subject matter; and 3) they ought in fairness to be considered together.").

Plaintiffs argue that during her deposition Manogue disclosed portions of confidential communications that she had with officers of Endo, in particular, that she did not believe that the FDA would approve Watson's ANDA prior to September 15, 2013. Kohn Decl., Ex. D E28 (Manogue Dep. at 205:14-206:18). Manogue based that belief on Endo's "citizen petition and the trouble it appeared Watson had with their ANDA filing with the FDA." Id.
The parties dispute whether Manogue rested her disclosed belief on legal advice and analysis. Plaintiffs contend Manogue's disclosed opinion necessarily was based on legal advice and analysis because in her testimony to the FTC, Manogue explained that all conversations with Endo's then CEO Holveck, CFO Levin, and President of Branded Pharmaceuticals Lortie about the Watson ANDA were "for the purpose of providing legal advice," thus preventing the FTC from inquiring further into Manogue's communications with any of those officers. Ex. D W36 (FTC Tr. 247:12-23, 341:2-11). Plaintiffs also argue that Levin similarly testified that, "we believed . . . that there was good science and good arguments that were pending with regulators that put meaningful risk" on the approval of [*101] Watson's ANDA. Ex. D E42 (Levin Dep. at 174:12-175:20). This disclosure, according to plaintiffs, necessarily disclosed attorney-client information because Levin further testified that everything he knew with respect to the Citizen Petition, he "learned from Endo's lawyers" or people working for Endo's lawyers. Id. E40 (Dep. 204:8-22); see also E41 (Dep. 205:16-207:5 (Levin could not testify about what Endo believed regarding the Citizen Petition without revealing attorney-client communications)).

Endo counters that in her deposition in this case, Manogue explained that her opinions on the status of the ANDA were business opinions, based on her years of experience and her observations of the FDA's responses to the ANDA and the pendency of the Citizen Petition. Ex. D E28. However, she admitted that when she gave her advice to Holveck and Levin regarding the status of the ANDA, she was wearing her "general counsel" hat, although she based that opinion on experience, not legal analysis. Id. E30, E31.

Plaintiffs contend these "partial disclosures" by Manogue and Levin were for "tactical advantage" to support Endo's Subjective Beliefs 18, 19 (discussed above) about the uncertainties with [*102] respect to the FDA approval of the ANDA and status of the Citizen Petition. As discussed above, any attempt by Endo to rely on a subjective belief as to the likelihood of approval or timing on the ANDA puts at issue attorney-client information. That Manogue may have based her opinions in part on her industry experience (which was as counsel, not as a business executive) does not undermine the evidence that attorney-client advice on these topics played a direct and significant role in formulating Endo's beliefs as to the ANDA's likelihood of success, the related chance of success on Endo's Citizen Petition, and the FDA's timing on both.

In sum, I will not find that as of now Endo has made a subject matter waiver that entitles plaintiffs to all of Endo's contemporaneous attorney-client discussions/information regarding the Watson ANDA or Endo Citizen Petition. But, consistent with the rulings previously discussed, Endo cannot provide subjective testimony on these subject matters (contents, chances of success, and timing) without putting all related attorney-client information on those matters at issue.

II. MOTION TO COMPEL PRODUCTION OF NOTES

In the May 2, 2016 Case Management Conference, [*103] the parties discussed plaintiffs' request for the production of notes taken by former Endo General Counsel Manogue regarding "settlement-related conversations." Dkt. No. 453 at 5; Dkt. No. 459 at 1. The existence of these notes — which were not clearly identified in Endo's privilege log as notes of Manogue regarding the Watson settlement — came to light during Manogue's deposition. Dkt. No. 453 at 5. Following the parties' meet and confers on this issue, Endo identified privilege log entries by Bates numbers said to contain the notes. After further questions by plaintiffs, Endo re-reviewed the withheld notes and re-characterized the privilege log entries to note Manogue as the custodian and that the documents related to the Watson settlement. See Ex. L to Plaintiffs' Motion for Production (Dkt. No. 479-13). Endo also identified additional log entries as containing relevant Manogue notes. Id.

Plaintiffs move to compel production of all or part of these notes, arguing that because Manogue — who was the main Endo representative involved in the Watson settlement negotiations and the ultimate decision-maker — could not recall much if anything of substance about those negotiations at her [*104] deposition, any work product protection of the notes is overcome by plaintiffs’ need. Plaintiffs also argue that because Endo's original and amended privilege log entries were and are deficient, Endo has failed to meet its burden to show the documents at issue are protected and the notes should be disclosed.
Pursuant to my Order, defendants submitted for in camera review twelve sets of notes, annotated to show information they contend is protected work-product or attorney-client privileged.29

A. Legal Standard

Attorney notes are protected by the work product doctrine. SEC v. Roberts, 254 F.R.D. 371, 375 (N.D. Cal. 2008) ("There is no dispute that the interview notes in question here are classic attorney work product—they comprise handwritten notes that include the attorney's mental impressions, [*105] conclusions and opinions."). Typically, notes taken by an attorney are treated as opinion, as opposed to fact, work product. See, e.g., Tierno v. Rite Aid Corp., No. C 05-02520, 2008 U.S. Dist. LEXIS 112461, 2008 WL 2705089, at *4 (N.D. Cal. July 8, 2008) ("an attorney’s notes and memoranda of statements are protected as opinion work product because they reveal the attorney's mental processes and show what facts the attorney deems legally significant.").30

Opinion work product "receives greater protection than ordinary work product and is discoverable only upon a showing of rare and exceptional circumstances." Tennison v. City & County of San Francisco, 226 F.R.D. 615, 623 (N.D. Cal. 2005) (citation omitted); see also Holmgren v. State Farm Mut. Auto. Ins. Co., 976 F.2d 573, 577 (9th Cir. 1992) ("A party seeking opinion work product must make a showing beyond the substantial need/undue hardship test required under Rule 26(b)(3) for non-opinion work product.").31 However, even where opinion work product is concerned, if the facts being recorded by the attorney disclose "concerns a layman would have as well as a lawyer in these particular circumstances, and in no way reveal anything worthy of the description 'legal theory,',” disclosure may [*106] be warranted. In re John Doe Corp., 675 F.2d 482, 493 (2d Cir. 1982) (disclosing interviewing attorney notes); see also FTC v. Boehringer Ingelheim Pharms., Inc., 778 F.3d 142, 151, 414 U.S. App. D.C. 188 (D.C. Cir. 2015) (recognizing that "not every item which may reveal some inkling of a lawyer's mental impressions . . . is protected as opinion work product." . . . Opinion work product protection is warranted only if the selection or request reflects the attorney's focus in a meaningful way.").

For example, in a reverse-payment agreement case, the D.C. Circuit recognized that "[a] company may select an executive who is a lawyer to negotiate the business terms of a settlement; this does not mean that the lawyer's thoughts relating to financial and business decisions are opinion work product when she is simply parroting the thoughts of the business managers." FTC v. Boehringer Ingelheim Pharms., Inc., 778 F.3d 142, 151, 414 U.S. App. D.C. 188, 199 (2015). The court explained that "[w]here it appears that the focus or framework provided by counsel in requesting or collecting information is obvious or non-legal in nature, it is [*107] incumbent upon the party claiming opinion work product protection to explain specifically how disclosure would reveal the attorney's legal impressions and thought processes." Id;32

---

29 The parties have a side dispute on whether Endo should have: (i) produced for in camera review three sets of documents it previously identified as "notes" but on re-review determined were not "notes" and, therefore, fell outside the scope of the response; (ii) redacted irrelevant information from four sets of notes produced for in camera review. Dkt. Nos. 480, 485, 486. I find that Endo's redactions and its re-characterization of the notes were appropriate.

30 Rule 26 distinguishes between opinion work product, which reveals "the mental impressions, conclusions, opinions, or legal theories of a party's attorney or other representative concerning the litigation,” and fact work product, which does not. Fed. R. Civ. P. 26(b)(3)(B).

31 Under Fed. R. Civ. P. 26(b)(3), fact work product is discoverable if "the party shows that it has substantial need for the materials to prepare its case and cannot, without undue hardship, obtain their substantial equivalent by other means," so long as counsel's "impressions, conclusions, opinions, or legal theories" are not disclosed.

32 The cases relied on by Endo for the proposition that courts have refused to produce attorney notes of settlement discussions are inapposite. They either reject production of attorneys' notes of settlement discussions without analysis (Tate & Lyle Americas, LLC, v. Glatt Air Techniques, Inc., 2015 U.S. Dist. LEXIS 104265, 2015 WL 4647561, at *4 (C.D. Ill. July 31, 2015)), decline to produce notes because they "might" reveal litigation strategy (Wilson v. Dep't of Justice, 1991 U.S. Dist. LEXIS 12617,
B. Plaintiffs' Justification for Production

The central factual question in this case is whether Endo, Teikoku, and Watson settled the patent litigation for anti-competitive purposes on anti-competitive terms or whether the settlement was justified by pro-competitive concerns. As such, the facts regarding the negotiation of the settlement with Watson go directly to the heart of plaintiffs' claims and defendants' defenses. [*108] I conclude that plaintiffs have shown a compelling need for disclosure of portions of Manogue's notes.

First, General Counsel Manogue was the main person at Endo engaged in negotiations regarding the settlement both with Teikoku (as to terms of settlement that would be mutually acceptable) and with Watson. Second, although Manogue met with counsel in preparation for her deposition in this case over the course of three days, when asked in her deposition about specifics regarding the settlement negotiations, she repeatedly responded that she “could not recall.” For example:

Q Let me ask this question: You understand there was a point in time during the negotiations between Endo and Watson regarding Lidoderm that there was an agreement in principle reached?
A (No response).
Q Do you recall that?
MR. READE: Objection, lack of foundation, but go ahead.
THE WITNESS: I don't recall.
BY MR. SOBOL:
Q Okay. Do you remember there was a point in time where an understanding was reached, and that it needed to be memorialized into a settlement agreement?
A I don't recall.

Deposition of Caroline Manogue (478-6). Ex. A to Plaintiffs' Motion to Compel Production of Notes at 21:13 — 22:2.

Regarding discussions with [*109] General Counsel David Buchen from Watson:

Q Okay, so on the 25th of January, you had a conversation with Mr. Buchen. At least, that's what's attributed to having occurred by this chart, correct?
A That's what the chart says, yes.
Q You don't have any memory about it at all, right?
A I do not.

Id. at 33:12-19.

With respect to a call the following day with Teikoku CEO Paul Mori:

Q Just it's fair to infer that what you were probably doing on that day was providing them information about what had been discussed the previously day with Mr. Buchen in context?
A I don't know.

Id., 34:7-11. With respect to an in-person meeting with Buchen from Watson in January 2012, Manogue could recall nothing of substance, other than an exchange of niceties. Id. at 71:18 — 72:5. Even after being shown emails following that meeting and describing some proposed terms of settlement offered by Watson, Ms. Manogue's recollection was not refreshed and she could not recall any details about conversations with Buchen during that time frame or in the subsequent months. Id., 72-81; 104-107.

When asked about various updates Manogue gave to Teikoku officers about the settlement negotiations, Manogue similarly could not recall what information [*110] she provided about the status of the Watson negotiations, even

after plaintiffs attempted to refresh her recollection with contemporaneous documents. \textit{Id.} at 33-34, 87-89, 91-93, 98-99.

Even general questions elicited no substantive response about the settlement negotiation status or terms.

- Q Do you recall that you actually did participate in negotiating the settlement of the Lidoderm case?
  - A I did.
- Q What do you remember?
  - A Not very much. I don't recall.

\textit{Id.}, 101:13-18.

- Q And as you sit here today, please describe to the jury everything you can remember about what you said to Watson and Watson said to you before the settlement agreement with respect to Lidoderm was entered into.

MR. READE: Objection to the form. Go ahead.

THE WITNESS: I don't recall.

BY MR. SOBOL:

- Q Anything?
  - A I don't recall.

\textit{Id.}, 102:19 — 103:4; \textit{see also} 114 (could not recall starting positions); \textit{see also} 133 (could not recall anything about stage of negotiations in May 2012, at same time a press release about the potential settlement was being drafted), 136 (could not recall details of "breakthrough" in negotiations on May 9).

Apparently defense counsel made a strategic choice to not use Manogue's own notes — which were in their possession and logged (albeit incorrectly) [*111] in the privilege log — to refresh her recollection prior to her deposition. It also appears that, despite the significance of the Watson settlement to Endo, Manogue cannot recall any substantive details about the negotiations of that settlement. Contemporaneous information regarding this topic is central both to plaintiffs' burden at trial and Endo's defenses.

Third, as to other sources of information regarding the negotiations with Watson, plaintiffs show that there is little. Watson's CEO testified that he avoided taking notes. Deposition of Paul Bisaro, (Ex. B to Pls. Mot.) at 111:19-112:6. Watson's General Counsel testified that he discarded his notes. Deposition David Buchen, (Ex. C. to Pls. Mot) at 79:2-80:6. David Holveck, Endo's CEO, testified that the only thing he recalled from a settlement meeting he attended with Manogue and Watson's CEO, CFO and General Counsel was that he introduced himself. Deposition of David Holveck (Ex. D to Pls. Mot.) at 123:1-124:13. Plaintiffs assert that there were no written documents exchanged between Watson and Endo reflecting the negotiation of the settlement's terms. Pls. Mot. at n.1.

In Opposition, Endo does not dispute Manogue's central role [*112] in negotiating the Watson settlement. Nor do they argue that in her deposition Manogue provided sufficient testimony for plaintiffs' purposes. Instead, Endo argues — as supported by a declaration from Manogue — that the notes are properly withheld as opinion work product because they were not "verbatim" and that Manogue only wrote down the information she believed was of use or significant. Endo also asserts that documents produced by the parties and testimony of Manogue, Levin, Buchen, and Bisaro "reflect the progression of settlement negotiations."

In the portions of the Manogue deposition Endo relies on, Manogue is asked about the contents of two documents purporting to disclose some terms being negotiated, but those documents did not refresh her recollection. Manogue Dep. 78:5-79:2; 104:23. Endo also relies on nine lines of deposition testimony where Manogue discusses Watson wanting, at an unspecified time, Endo and Teikoku to agree not to sue the FDA in connection with the approval of any generic product and to withdraw their Citizen Petition. \textit{Id.} at 128:2-11. Endo cites to the FTC testimony of CFO Levin, regarding the potential agreement between Endo and Watson to "collaborate" [*113] on a urology product (but that collaboration was not agreed to for reasons Levin could not recall), as well as Levin's testimony about aspects of the final settlement agreement. Levin FTC Testimony (Ex. 2 to Asimow Decl.), at 113:11-114:13, 135:4-141:24. Endo points also to Levin's deposition testimony where he speaks generally to a belief that each party had to "take their own regulatory risk," but Levin does not disclose any specific terms that were negotiated on or around that point. Levin Dep. (Ex. 3 to Asimow Decl.) at 273:-277:24.
Endo cites to the deposition testimony of Watson General Counsel David Buchen, where documents were used in a generally unsuccessful attempt to refresh his recollection as to various negotiation points. Buchen Dep. (Ex. 4 to Asimow Decl.) at 67:21-69:17, 121:22-124:2, 127:8-135:8, 138:9-145:13, 173:2-176:8. Endo also relies on Buchen's comments about theoretical settlement strategies unrelated to the Endo discussions. Id., 103:13 — 105:19. Buchen does testify as to "general recollection" of Watson's desire to launch an authorized generic right away (that was rejected) and Buchen testified regarding the final terms of the agreement. Id., 108:16-111:7, 182:12-187:11. Finally, Endo relies on the deposition testimony of Paul Bisaro about one in-person settlement meeting where substantive settlement terms were not discussed. Bisaro Dep. (Ex. 5 to Asimow Decl.) at 176:7 — 178:13. Based on this weak evidentiary record in response, Endo asserts that plaintiffs have not made the extraordinarily rare showing of compelling need to overcome opinion work product protection. Endo also argues that some portions of the notes are protected by the attorney-client privilege and likewise should not be produced.

Endo has not shown that any of the participants in the settlement negotiations can provide — either through contemporaneous documents or through testimony — concrete information about the exact terms that were exchanged, much less when those terms were proposed, debated, agreed to, or rejected. The terms of the Watson settlement — both those rejected and those agreed-to — are key to plaintiffs' claims and defendants' defenses on the merits of this case. As a result, there is a compelling need to disclose Manogue's notes.

C. Review of the Notes Produced for In Camera Review

Endo "color coded" the Manogue notes for my in camera review. Red are notes of Manogue's conversations with Watson. Blue are notes of Manogue's conversations with Teikoku. Silver are notes of conversations between Manogue and Watson that touch upon antitrust liability and, therefore, Endo asserts are covered by the common-interest privilege. Green are notes of internal Endo conversations or talking points to be raised or raised with Watson.\[33\]

It appears that many of the Watson notes (coded red) as well as the "internal discussions" about the Watson negotiations (coded green) appear to be simply "verbatim" lists of terms exchanged or proposed for exchange. These notes also include references to phrases like "thanks for that" and "we believe" indicating the notes were either a script for her conversations with Watson's General Counsel Buchen or verbatim notes of what was actually said. Given the context of ongoing settlement discussions and the verbatim/script nature of at least these portions of the notes, the notes are more akin to fact work product than opinion work product. See, e.g., FTC v. Boehringer Ingelheim Pharms., Inc., 778 F.3d at 151. Plaintiffs have shown substantial need for the red notes and they should be produced. With respect to the green notes, the portions of those notes which reflect proposed or actual settlement terms exchanged with Watson, as well as any indication in the notes showing the date on which they were recorded, should be produced.\[34\] The remainder of the green notes — those portions which do not reflect proposed or actual settlement terms exchanged with Watson — are protected attorney-client information that absent being put at issue (as discussed above) may be withheld from production.

With respect to the blue notes — notes of Manogue's conversations with Teikoku — as with the green notes, Endo must produce the portions of those notes that reflect proposed or actual settlement terms exchanged with Watson (as well as any indications showing the time/date the notes were taken). Again, this information is key for plaintiffs' case and Endo has not shown that plaintiffs have access to this critical information through other

---

\[33\] While Manogue had virtually no recall of the settlement discussions (and their progression) during her deposition, her recollection was apparently sufficiently refreshed by reviewing these notes, allowing her to perform the color coding. I also note that Endo does not distinguish in its color coding between fact work product and opinion work product, as it contends that all of the notes are opinion work product.

\[34\] Even if the red notes and these portions of the green notes could be construed to be opinion work product (which I reject), they should still be produced. Based on the showing of materiality, Manogue's absolute lack of recall, the business executives' lack of recall, as well as plaintiffs' compelling and unique need (given the legal issues in this case focus on the terms of the settlement agreement) these notes should still be produced.
documents or testimony. The remainder of the blue notes are protected attorney-client information that may be withheld, assuming the contents of those notes are covered by the joint privilege (as discussed in my prior Orders) and the subject matters addressed by the notes are not put at issue.

The one remaining issue is the few silver coded notes from April and May 2012 that Endo claims are covered by a common interest privilege with Watson because the material reflects the sharing of antitrust legal advice between Endo and Watson related to potential terms of the parties' settlement. Oppo. at 5. My prior common interest privilege analysis did not address attorney communications between Endo and Watson, and was limited to addressing communications between Endo and Teikoku. Within five [*118] days of the date of this Order, Endo shall file a two page brief providing legal authority for asserting a common interest privilege for these notes (dated April 16, 2012, May 7, 2012 and May 8, 2012). Five days after that brief is filed, plaintiffs may file a two page response.

III. ADMINISTRATIVE MOTIONS TO SEAL

Plaintiffs’ Motion to Seal Kohn Declaration Exhibits D — I and Portions of Renewed Motion for Production or Preclusion. Dkt. No 462. The information at issue has been designated as confidential or highly confidential by defendants. Endo files a declaration in support, moving that identified portions of Ex. D remain sealed (E3, E26, E28, E30, E32, E38, E41, E43 and E49) asserting good cause exists to seal this confidential and competitively-sensitive information. Dkt. No 464. Endo also moves to seal Ex. G in full, as good cause exists to seal its privilege log. Finally, Endo moves to seal discrete portions of the plaintiffs' brief which discuss these materials, specifically: Page 8 footnote 7, Page 10 line 24, Page 11 lines 1-28, Page 12 lines 1-8, Page 12 lines 14-27, Page 13 lines 1-2, Page 16 lines 25-26, Page 17 lines 3-15, Page 23 lines 17-27, and Page 24 lines 1-17. Id. [*119]

Teikoku submits a declaration, arguing good cause exists to seal portions of Exhibit F (T8 — T12, T14, T19) and lines 6-20 on page 15 of plaintiffs' brief, because those disclose Teikoku's thoughts on confidential settlement negotiations, confidential business discussions, and confidential business strategies. Dkt. No. 465.

Plaintiffs' motion is GRANTED in part: Endo and Teikoku have shown good cause for continued sealing of the information identified above. Within 10 days of the date of this Order, plaintiffs shall e-file revised redacted versions of their motion and supporting exhibits consistent with this Order. The Clerk shall UNSEAL Ex. E (Dkt. No. 462-9), Ex. H (Dkt. No. 462-15), and Ex. I (Dkt. No. 462-17).

Endo's Motion to Seal Portions of its Opposition and Exhibits in Support . Dkt. No. 472. Endo seeks to seal Exhibits [*120] 1, 6 and 10 in their entirety and Page 14, lines 3-4 of Endo's Opposition, arguing good cause exists to seal this information regarding its competitive intelligence strategies, confidential strategies regarding settlements, and confidential business strategies for launching authorized generics. Dkt. No. 472-2. Endo's motion is GRANTED.

Teikoku’s Motion to Seal Portions of its Exhibits in Support of Opposition. Dkt. No. 473. Teikoku seeks to seal portions of Exhibit A, T8-T12, T14 and T19, consistent with the request to seal granted above (Dkt. No. 462). Teikoku's motion to seal is GRANTED.

Watson’s Motion to Seal Portions of Exhibits in Support of Opposition . Dkt. No. 476. Watson seeks to seal portions of Exhibit B, Rows 16, 27, 28, based on good cause because that information discloses Watson's business strategy on launching new generic products and its regulatory strategy with respect to the FDA. Watson's motion to seal is GRANTED.

35 Watson did not file a declaration in support of plaintiffs' motion regarding information Watson designated as confidential. That is consistent with Watson's own administrative motion to seal (Dkt. No. 476) discussed below, where Watson discusses testimony from the same witnesses discussed in plaintiffs' exhibit, but seeks to seal only testimony of two other employees.
Plaintiffs' Motion to Seal Portions of their Motion re Discoverability of Notes and Exhibits in Support. Dkt. No 478. The information at issue (Exhibits A-F and cites to that information in their motion), has been designated as confidential or highly [*121] confidential by Endo or Watson. Endo submits a declaration arguing good cause exists to seal the following: Ex. A, pages 97-99, 108-112, 166-167, 176-177, 179, 181-185, and 189-190, as those portions of Exhibit A disclose Endo's confidential settlement approach and negotiation strategies, strategies concerning FDA regulatory matters, and confidential accounting information; and Ex. F, excerpts from its privilege log, in full. Dkt. No. 481.

Watson filed a declaration arguing good cause exists to seal the following: lines 91:16, 20-21, 92:1-6, 11-16, 106:16-18, 22, 25, and 107:4-5 of Exhibit A, because that information discloses the terms of Actavis's licensing negotiations for a product that has not launched; and lines 117:18-23; 118:1-14; and 119:9-14, 17-18 of Exhibit E, because that information reveals proprietary formulation and composition details. Dkt. No. 482.

Plaintiffs' motion is GRANTED in part: Endo and Watson have shown good cause for continued sealing of the information identified above. Within 10 days of the date of this Order, plaintiffs shall e-file revised redacted versions of their motion and supporting exhibits consistent with this Order. The Clerk shall UNSEAL Ex. B [*122] (Dkt. No. 478-8), Ex. C (Dkt. No. 478-10), and Ex. D (Dkt. No. 478-12).

Plaintiffs' Motion to Seal Portions of the Reply Brief and Exhibits in Support. Dkt. No. 490. The information at issue (contained in Exhibits J-M and cited in portions of the reply brief) has been designated as confidential or highly confidential by defendants. Teikoku files a declaration in support, contending that good cause exists to file under seal Exhibit M in full as well as the following pages from the Reply: Page 8, Line 21-Page 9, Line 2; Page 28, Lines 22-26; Page 29, Lines 17-20; Page 32, Lines 6-7; Page 32, Lines 21-24; Page 33, Lines 3-5. The information at issue references highly confidential discussions designed to facilitate settlement negotiations. Dkt. No. 493.

Endo filed a declaration in support, arguing good cause exists for sealing the following: Exhibit J, E61; the entirety of Exhibit M; and Page 8 Lines 21-27, Page 9 Lines 1-2, Page 12 Lines 23-27, and Page 13 Lines 1-4 because that information discloses confidential discussions between Endo and its business partner Teikoku regarding allocations of costs in connection with a potential settlement and would reveal Endo's internal decision making [*123] processes regarding patent litigation settlements. Dkt. No. 495. Watson did not file a declaration.

Plaintiffs' motion is GRANTED in part: Endo and Teikoku have shown good cause for continued sealing of the information identified above. Within 10 days of the date of this Order, plaintiffs shall e-file revised redacted versions of their reply and exhibit J consistent with this Order. The Clerk shall UNSEAL Exhibits K (Dkt. No. 490-7) and L (Dkt. No. 490-8).

Endo's Motion to Seal Exhibits in Support of its Opposition. Dkt. No. 491. Endo seeks to file under seal Exhibits 3-5 submitted in support of its Opposition, but notes the materials in those exhibits were designated confidential by Teikoku or Watson. Watson filed a declaration in support, arguing that good cause exists to seal pages and lines 127:19-21; 128:7, 11, 17, 18; and 129:3 of Exhibit 4 because that information discloses the terms of Actavis's licensing negotiations, including potential royalty rates, for a product Actavis has not yet launched. Dkt. No. 496. Teikoku did not file a declaration.

Endo's motion is GRANTED in part: Watson has shown good cause for continued sealing of the information identified above. Within 10 days [*124] of the date of this Order, Endo shall e-file a revised redacted version of Exhibit 4 consistent with this Order. The Clerk shall UNSEAL Exhibits 3 (Dkt. No. 491-3) and 5 (Dkt. No. 491-5).

CONCLUSION

In light of this Order, Endo shall produce the redacted red, green, and blue Manogue notes as required by this Order on or before August 16, 2016. By that same date, defendants must file a final election on subjective beliefs disclosing whether they intend to rely on any subjective beliefs that, as identified in this Order, put at issue attorney-client information. The parties shall then meet and confer regarding reopening any discovery foreclosed by
defendants' assertions of privilege or otherwise necessitated by this Order. The Case Management Conference set for August 9, 2016 is continued until August 30, 2016; any joint status report or dispute regarding discovery shall be filed by August 26, 2016. The Case Management Conference set for September 6, 2016 is VACATED. The normal Case Management Schedule will resume for the October 4, 2016 Conference.

IT IS SO ORDERED.

Dated: August 9, 2016

/s/ William H. Orrick

WILLIAM H. ORRICK

United States District Judge

End of Document
In re Niaspan Antitrust Litig.

United States District Court for the Eastern District of Pennsylvania

May 23, 2018, Decided; May 24, 2018, Filed

MASTER FILE NO. 13-MD-2460

Report
2018 U.S. Dist. LEXIS 87150 *; 2018-1 Trade Cas. (CCH) P80,396; 2018 WL 2363577

IN RE: NIASPAN ANTITRUST LITIGATION; THIS DOCUMENT RELATES TO: ALL ACTIONS


Opinion by: Jan E. DuBois

Opinion

MEMORANDUM

I. INTRODUCTION

In this multidistrict antitrust litigation, plaintiffs seek to preclude defendants Barr Pharmaceuticals, LLC ("Barr") and Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries, Ltd., Teva Women's Health, Inc., and Teva Sales and Marketing, Inc. (together, "Teva"), from using certain deposition testimony on the ground that Barr and Teva improperly used the attorney-client privilege as a "sword" and a "shield" during the course of the deposition. Because plaintiffs have not shown that Barr and Teva took affirmative steps to place attorney advice at issue, their request is denied.

II. BACKGROUND

This multidistrict litigation concerns what has come to be known as a "reverse payment," or "pay-for-delay," settlement—a practice in which a brand-name drug manufacturer brings a patent-infringement action against a generic drug manufacturer and then compensates the generic drug manufacturer for its agreement to refrain from entering the market with a competing generic version of the brand-name drug until a specified date. In this case, two putative classes—the Direct-Purchaser Plaintiffs ("DPPs") and the End-Payor Plaintiffs ("EPPs")—allege [*2] that the brand-name manufacturer of Niaspan, Kos Pharmaceuticals, Inc. ("Kos"), entered into anticompetitive reverse-payment settlement agreements in March of 2005 with Barr, the generic manufacturer of that drug, in order to terminate patent-infringement litigation brought by Kos against Barr in the United States District Court for the Southern District of New York. Kos was later acquired by defendant AbbVie Inc. ("AbbVie"); Barr was later acquired by Teva.

On March 26, 2018, the parties deposed Paul Bisaro, the former President and Chief Operating Officer of Barr. During the deposition, counsel for plaintiffs asked Bisaro about outside counsel's "opinions in 2004 or 2005 regarding the invalidity, unenforceability or noninfringement of Kos' Niaspan patent." Counsel for Teva objected on the ground of attorney-client privilege and instructed Bisaro not to answer. Bisaro Dep. 35:4-1. Counsel for Teva
later asked Bisaro during redirect, "Absent a settlement, would Barr have launched generic Niaspan at risk," to which Bisaro responded, "No." Bisaro Dep. 174:10-20.

At the end of the deposition, counsel for DPPs asked Bisaro, "Is your testimony today that Barr would not have launched at [*3] risk based in any way on the patent merits?" Bisaro Dep. 192:3-5. Bisaro responded:

I don't know what you're trying to get me to say. Yes or no to what? I mean, if we decided to launch at risk, it would be a number of factors. One of those factors would have been the relative merits of the patent. But it also had to take into effect a lot of other factors including risk, including the potential for preliminary injunction, including potential treble damages, our ability to pay those potential damages if they happened. . . . It's based on enormous number of factors.

Bisaro Dep. 192:6-21. When counsel for DPPs asked, "What were the relative merits of the patents," counsel for Teva objected on the basis of attorney-client privilege and instructed Bisaro not to answer.

The DPPs, on behalf of all plaintiffs, now ask the Court to preclude defendants from using Bisaro's testimony that Barr would not have launched a generic version of Niaspan "at risk." Plaintiffs argue that defendants made an impermissible use of the attorney-client privilege as both a "sword" and a "shield" by "present[ing] arguments and factual assertions that implicate attorney advice, while simultaneously preventing Plaintiffs [*4] from exploring the basis behind those arguments and assertions." Letter-Brief for Plaintiffs at 4-5, In re Niaspan Antitrust Litigation, No. 13-md-2460 (Apr. 13, 2018) [hereinafter Pls. Brief], Doc. No. 529. In response, defendants Barr and Teva contend that the "so-called 'sword and shield' doctrine applies [only] where a party selectively waiv[es] its privilege for favorable advice while asserting its privilege on unfavorable advice." Letter-Brief for Defendants at 3, In re Niaspan Antitrust Litigation, No. 13-md-2460 (Apr. 16, 2018) [hereinafter Defs. Brief], Doc. No. 532. The Court heard oral argument on this issue in a telephone conference on May 14, 2018. Plaintiffs' request is ripe for decision.

III. APPLICABLE LAW

The attorney-client privilege "protects from disclosure confidential communications made between attorneys and clients for the purpose of obtaining or providing legal assistance to the client." In re Grand Jury Subpoena, 745 F.3d 681, 687 (3d Cir. 2014). However, a party may not use the attorney-client privilege as "both a sword and a shield" by selectively "waiv[ing] its privilege for favorable advice while asserting its privilege on unfavorable advice." In re EchoStar Commun. Corp., 448 F.3d 1294, 1301 (Fed. Cir. 2006). Consequently, a party may not "rely upon the legal advice [*5] it received . . . without permitting [the opposing party] the opportunity to probe the surrounding circumstances and substance of that advice." Berkley Inv. Grp., Ltd. v. Colkitt, 455 F.3d 195, 222 (3d Cir. 2006) (citing Livingstone v. North Belle Vernon Borough, 91 F.3d 515, 537 (3d Cir. 1996)).

A party is deemed to have waived the privilege where it "has made the decision and taken the affirmative step in the litigation to place the advice of the attorney in issue." Rhone-Poulenc Rorer v. Home Indem. Co., 32 F.3d 851, 863 (3d Cir. 1994). Attorney advice "is not in issue merely because it is relevant, and does not necessarily become in issue merely because the attorney's advice might affect the client's state of mind in a relevant manner." Id. at 863. Instead, the "advice of counsel is placed in issue where the client asserts a claim or defense, and attempts to prove that claim or defense by disclosing or describing an attorney client communication." Id.

IV. DISCUSSION

1 An "at risk" launches refers to the launch of a generic pharmaceutical after the expiration of the thirty-month stay imposed by the Hatch-Waxman Act, 21 U.S.C. § 355, but before the conclusion of any patent litigation filed by the brand-name manufacturer against the generic manufacturer, placing the generic manufacturer "at risk" of liability for patent infringement. See FTC v. Actavis, Inc., 570 U.S. 136, 143, 133 S. Ct. 2223, 186 L. Ed. 2d 343 (2013); Astrazeneca AB v. Apotex Corp., 782 F.3d 1324, 1330 (Fed. Cir. 2015).
Plaintiffs have failed to show that defendants have improperly used the attorney-client privilege as both a "sword" and a "shield": they have not shown that (1) Bisaro's testimony implicated attorney advice and (2) Bisaro's testimony was relevant to proving a claim or defense in this case.

**A. Bisaro's Testimony Does Not Implicate Attorney Advice**

First, and most importantly, plaintiffs have failed to show that Bisaro's testimony implicates attorney advice. In the record before the Court, the testimony elicited by defendants was that Barr would not have launched at risk—Bisaro did not mention either the advice of counsel or the merits of the underlying patent litigation. In contrast, plaintiffs, not defendants, elicited the testimony from Bisaro regarding those topics. When plaintiffs asked about outside counsel's opinion on the merits of the patent litigation, defendants objected on the basis of attorney-client privilege. This was a proper assertion of the privilege and did not amount to a waiver. Accord *Synygy, Inc. v. Zs Assocs.*, No. 07-3536, 2013 U.S. Dist. LEXIS 106109, at *6 (E.D. Pa. July 29, 2013) (finding no waiver where testimony elicited by opposing counsel "merely revealed the fact of a communication with counsel without revealing the substance of that communication").

Plaintiffs argue that Bisaro's testimony regarding an "at risk" launch necessarily implicates attorney advice. In their argument, plaintiffs rely on the decision *In re Lidoderm Antitrust Litig., No. 14-md-02521-WHO, 2016 U.S. Dist. LEXIS 105619 at *90 (N.D. Cal. Aug. 9, 2016)*, which concluded, "By its very definition, the concept [of an at risk launch] requires reference to the status and strength of the patent litigation and necessarily implicates legal advice." The *Lidoderm* court, however, relied on the broader [*7*] standard utilized by the Ninth Circuit in addressing issues of waiver of the attorney-client privilege, which requires only that the advice be "directly relevant and necessary to allow a party to fully challenge the claims or defenses of the party asserting the privilege" *id. at *46* (emphasis in original). Applying that standard, the *Lidoderm* court did not require plaintiffs to show that defendants made "affirmative use" of attorney advice in proving a claim or defense as required by the Third Circuit, and expressly distinguished decisions under the more demanding standard of the Third Circuit as "inapposite." *Id. at *46 n.5* (citing *Rhone-Poulenc Rorer, Inc., 32 F.3d at 863*). Because the *Lidoderm* court reached its decision employing the broader standard of the Ninth Circuit, it is inapplicable to this case.

This Court applies the Third Circuit rule in addressing issues related to waiver of the attorney client privilege in this case. Simply stated, that rule provides that the "advice of counsel is placed in issue where the client asserts a claim or defense, and attempts to prove that claim or defense by disclosing or describing an attorney client communication." *Rhone-Poulenc Rorer, 32 F.3d at 863*. As described above, any attorney advice in this case was merely relevant to the testimony [*8*] elicited by defendants, and plaintiffs have not shown that defendants attempted to prove a claim or defense by disclosing or describing a client communication.

Plaintiffs' reliance on the decision in *In re: Cardizem CD Antitrust Litig., Case No. 99-md-1278, 2002 U.S. Dist. LEXIS 29685 (E.D. Mich. Jan. 9, 2002)*, ECF No. 573, is also misplaced. In that case, the defendant generic manufacturer "repeatedly argued . . . that its fear of being subject to a treble-damage judgment for willful infringement . . . caused it to stay off the market," and its officers, including its general counsel, testified that the risk of patent liability was a "critical factor" and "[t]he biggest reason" it did not enter the market with a generic drug. *2002 U.S. Dist. LEXIS 29685, [slip op.] at 2, 2 n.1*. Based on those facts, the *Cardizem* court concluded that defendant had taken an "affirmative act" to put its fear of patent liability "at issue" as the "critical facts" in its defense, and thus had improperly used the attorney-client privilege as both a "sword" and "shield." *2002 U.S. Dist. LEXIS 29685, [slip op.] at 2, 5-6*.

Defendants in this case have not placed the advice of counsel in issue as a "critical fact" in their defense. As noted above, Bisaro testified only that Barr would not have launched at risk absent a settlement agreement, [*9*] and defendants did not inquire into the role that the advice of counsel or the merits of the underlying litigation played in Barr's decision. Those issues were raised by plaintiffs, and defendants blocked further inquiry on the basis of attorney-client privilege. The record before the Court thus shows that attorney advice is, at most, merely relevant to
Bisaro's testimony, and that defendants did not take an "affirmative step" to place attorney advice in issue to prove a claim or defense.

B. Bisaro's Testimony Is Not Relevant to a Claim or Defense

Plaintiffs have also failed to show how Bisaro's testimony is relevant to proving a claim or defense in the case, which the Third Circuit requires in order for attorney advice to be "in issue." Rhone-Poulenc Rorer, 32 F.3d at 863. On this issue, plaintiffs argue that defendants selectively waived the attorney-client privilege when Bisaro testified in response to plaintiffs' questioning that Barr's decision not to launch at risk depended, in part, on the "relative merits of the patent[s]" in the underlying litigation. Pls. Brief at 4.

The Supreme Court has made it clear that "a detailed exploration of the validity of the patent itself is not necessary to determine the anticompetitive [*10] effects of a reverse-payment settlement. FTC v. Actavis, Inc., 570 U.S. 136, 158, 133 S. Ct. 2223, 186 L. Ed. 2d 343 (2013). Instead, the anticompetitive effects of a reverse payment depend on "its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification." Id. at 159.

Although plaintiffs may establish the relevance of the merits of the patents in the underlying litigation to the anticompetitive effects of the reverse payment at the summary judgment stage or trial, they have failed to do so on the present state of the record. Plaintiffs have not shown that defendants "attempt[ed] to prove [a] claim or defense" through Bisaro's testimony, and consequently have failed to show that defendants thereby placed attorney advice at issue.

V. CONCLUSION

For the foregoing reasons, on the present state of the record, the Court denies plaintiffs' request to bar defendants' use of Bisaro's testimony that Barr would not have launched a generic version of Niaspan at risk. The Court's decision is without prejudice to plaintiffs' right to renew their request or file a motion in limine if warranted by the evidence presented in motions for summary [*11] judgment or at trial.

An appropriate order follows.

ORDER

AND NOW, this 23rd day of May, 2018, upon consideration of the letter brief filed by plaintiffs on April 13, 2018 (Document No. 530), requesting that the Court bar defendants from using certain testimony by Paul Bisaro, former President and Chief Operating Officer of defendant Barr Pharmaceuticals, LLC ("Barr"), regarding whether Barr would have launched a generic Niaspan "at risk," as an improper use of the attorney-client privilege as both a "sword" and a "shield," the letter brief filed by defendants Barr, Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries, Ltd., Teva Women's Health, Inc., and Teva Sales and Marketing, Inc. (together, "Teva"), on April 16, 2018 (Document No. 532), in opposition to plaintiffs' request, and the supplemental letter brief filed by plaintiffs on May 18, 2018 (Document No. 540), following a telephone conference with the parties, through counsel, on May 14, 2018, for the reasons set forth in the accompanying Memorandum dated May 23, 2018, IT IS ORDERED that plaintiffs' request that Paul Bisaro's testimony be barred IS DENIED WITHOUT PREJUDICE to plaintiffs' right to renew their request [*12] or file a motion in limine if warranted by the evidence presented in motions for summary judgment or at trial.

BY THE COURT:

/s/ Hon. Jan E. DuBois

DuBOIS, JAN E., J.
End of Document

209 L.Ed.2d 361, 2021-1 Trade Cases P 81,618, 21 Cal. Daily Op. Serv. 3590...

141 S.Ct. 1341
Supreme Court of the United States.

AMG CAPITAL MANAGEMENT, LLC, et al., Petitioners
v.
FEDERAL TRADE COMMISSION

No. 19-508

| Argued January 13, 2021
| Decided April 22, 2021

Synopsis
Background: Federal Trade Commission (FTC) brought action against payday lenders, their owner, and others, alleging, inter alia, that high-interest, short-term payday loans offered through various proprietary websites violated the Federal Trade Commission Act (FTC Act). Following bifurcation of proceedings into liability and relief phases, the parties filed cross-motions for summary judgment. Generally adopting report and recommendation of Cam Ferenbach, United States Magistrate Judge, the United States District Court for the District of Nevada, Gloria M. Navarro, Chief Judge, granted FTC's motion on the FTC Act claim, 29 F.Supp.3d 1338, as clarified, 2014 WL 12788195, and subsequently enjoined owner from engaging in consumer lending and ordered him to pay approximately $1.27 billion in equitable monetary relief to the Commission, 2016 WL 5791416. Defendants appealed. The Court of Appeals for the Ninth Circuit, O'Scannlain, Senior Circuit Judge, 910 F.3d 417, affirmed. Certiorari was granted.

The Supreme Court, Justice Breyer, held that the section of the FTC Act authorizing the Commission to obtain injunctive relief, including, in proper cases, a “permanent injunction” in federal court against those violating or about to violate a law that the Commission enforces, does not authorize the Commission to seek, and a court to award, equitable monetary relief such as restitution or disgorgement; abrogating FTC v. Commerce Planet, Inc., 815 F.3d 593.

Reversed and remanded.

Procedural Posture(s): Petition for Writ of Certiorari; On Appeal; Motion for Summary Judgment.

*1343 Syllabus*

The Federal Trade Commission filed a complaint against Scott Tucker and his companies alleging deceptive payday lending practices in violation of § 5(a) of the Federal Trade Commission Act. The District Court granted the Commission's request pursuant to § 13(b) of the Act for a permanent injunction to prevent Tucker from committing future violations of the Act, and relied on the same authority to direct Tucker to pay $1.27 billion in restitution and disgorgement. On appeal, the Ninth Circuit rejected Tucker's argument that § 13(b) does not authorize the award of equitable monetary relief.

Held: Section 13(b) does not authorize the Commission to seek, or a court to award, equitable monetary relief such as restitution or disgorgement. Pp. 1345–1352.
(a) Congress granted the Commission authority to enforce the Act's prohibitions on “unfair or deceptive acts or practices,” 15 U.S.C. §§ 45(a)(1)–(2), by commencing administrative proceedings pursuant to § 5 of the Act. Section 5(l) of the Act authorizes the Commission, following completion of the administrative process and the issuance of a final cease and desist order, to seek civil penalties, and permits district courts to “grant mandatory injunctions and such other and further equitable relief as they deem appropriate in the enforcement of such final orders of the Commission.” § 45(l). Section 19 of the Act further authorizes district courts (subject to various conditions and limitations) to grant “such relief as the court finds necessary to redress injury to consumers,” § 57b(b), in cases where someone has engaged in unfair or deceptive conduct with respect to which the Commission has issued a final cease and desist order applicable to that person, see § 57b(a)(2). Here, the Commission responded to Tucker's payday lending practices by seeking equitable monetary relief directly in district court under § 13(b)'s authorization to seek a “permanent injunction.” In doing so, the Commission acted in accordance with its increasing tendency to use § 13(b) to seek monetary awards without prior use of the Commission's traditional administrative proceedings. The desirability of the Commission's practice aside, the question is whether Congress, by enacting § 13(b) and using the words “permanent injunction,” granted the Commission authority to obtain monetary relief directly from courts and effectively bypass the requirements of the administrative process. Pp. 1345–1347.

(b) Section 13(b) does not explicitly authorize the Commission to obtain court-ordered monetary relief, and such relief is foreclosed by the structure and history of the Act. Section 13(b) provides that the “Commission may seek ... a permanent injunction.” § 53(b). By its terms, this provision concerns prospective injunctive relief, not retrospective monetary relief. Section 13(b) allows the Commission to go directly to district court when the Commission seeks injunctive relief pending administrative proceedings or when it seeks only a permanent injunction. Other statutory provisions, in particular the conditioned and limited monetary relief authorized in § 19, confirm this conclusion. It is highly unlikely that Congress, without mentioning the matter, would grant the Commission authority to circumvent its traditional § 5 administrative proceedings. Pp. 1347–1350.

(c) The Commission's contrary arguments are unavailing. First, Porter v. Warner Holding Co., 328 U.S. 395, 66 S.Ct. 1086, 90 L.Ed. 1332, and Mitchell v. Robert DeMario Jewelry, Inc., 361 U.S. 288, 80 S.Ct. 332, 4 L.Ed.2d 323, did not adopt a universal rule that statutory authority to grant an injunction automatically encompasses the power to grant equitable monetary remedies. Instead, the text and structure of the particular statutory scheme at issue can limit a court's jurisdiction in equity. Second, in enacting § 19 two years after § 13(b), Congress did not simply create an alternative enforcement path with similar remedies. The Court does not believe Congress would have enacted § 19's provisions expressly authorizing monetary relief if § 13(b) already implicitly allowed the Commission to obtain that same monetary relief without satisfying § 19's conditions and limitations. Third, § 19's saving clauses—preserving “any authority of the Commission under any other provision of law” and “any other remedy or right of action provided by State or Federal law,” § 57b(e)—do not help answer whether § 13(b) gave the Commission the authority to obtain equitable monetary relief directly in court in the first place. Fourth, the Act's 1994 and 2006 amendments, which did not modify the specific language at issue here, do not demonstrate congressional acquiescence to lower court rulings that favor the Commission's interpretation of § 13(b). Fifth, policy arguments that § 5 and § 19 are inadequate to provide redress to consumers should be addressed to Congress. Pp. 1349–1352.

910 F.3d 417, reversed and remanded.

BREYER, J., delivered the opinion for a unanimous Court.

Attorneys and Law Firms

Michael Pattillo, Washington, DC, for the petitioners.
Section 13(b) of the Federal Trade Commission Act authorizes the Commission to obtain, “in proper cases,” a “permanent injunction” in federal court against “any person, partnership, or corporation” that it believes “is violating, or is about to violate, any provision of law” that the Commission enforces. 87 Stat. 592, 15 U. S. C. § 53(b). The question presented is whether this statutory language authorizes the Commission to seek, and a court to award, equitable monetary relief such as restitution or disgorgement. We conclude that it does not.

Petitioner Scott Tucker controlled several companies that provided borrowers with short-term payday loans. The companies, operating online, would show a potential customer a loan's essential terms. When the companies explained those terms, they misled many customers. The companies’ written explanations seemed to say that customers could normally repay a loan by making a single payment. And that payment would cost a person who, for example, borrowed $300 an extra $90. (The customer would likely repay a total of $390.) But in fine print the explanations said that the loan would be automatically renewed unless the customer took affirmative steps to opt out. Thus, unless the customer who borrowed $300 was aware of the fine print and actively prevented the loan's automatic renewal, he or she could end up having to pay $975, not $390. Between 2008 and 2012, Tucker's businesses made more than 5 million payday loans, amounting to more than $1.3 billion in deceptive charges.

In 2012 the Federal Trade Commission filed suit and claimed that Tucker and his companies were engaging in “unfair or deceptive acts or practices in or affecting commerce,” in violation of § 5(a) of the Act. 15 U. S. C. § 45(a)(1). (We shall refer to all of the defendants collectively as Tucker.) In asserting that Tucker's practices were likely to mislead consumers, the Commission did not first use its own administrative proceedings. Rather, the Commission filed a complaint against Tucker directly in federal court. The Commission, relying upon § 13(b), asked the court to issue a permanent injunction to prevent Tucker from committing future violations of the Act. Relying on the same provision, the Commission also asked the court to order monetary relief, in particular, restitution and disgorgement. The Commission moved for summary judgment.

The District Court granted the Commission's summary judgment motion. The court also granted the Commission's request for an injunction and directed Tucker to pay $1.27 billion in restitution and disgorgement. The court ordered the Commission to use these funds first to provide “direct redress to consumers” and then to provide “other equitable relief ” reasonably related to Tucker's alleged business practices. Finally, the court ordered the Commission to deposit any remaining funds in the United States Treasury as disgorgement.

On appeal, Tucker argued that § 13(b) does not authorize the monetary relief the District Court had granted. The Ninth Circuit rejected Tucker's claim. 910 F.3d 417 (2018). It pointed to Circuit precedent that had interpreted § 13(b) as “empower[ing]
district courts to grant any ancillary relief necessary to accomplish complete justice, including restitution.” FTC v. Commerce Planet, Inc., 815 F.3d 593, 598 (2016); see also FTC v. H. N. Singer, Inc., 668 F.2d 1107, 1113 (C.A.9 1982). Two judges, while recognizing that precedent in many Circuits supported that use of § 13(b), expressed doubt as to the correctness of that precedent.

Tucker then sought certiorari in this Court. In light of recent differences that have emerged among the Circuits as to the scope of § 13(b), we granted his petition.

II

The Federal Trade Commission Act prohibits, and authorizes the Commission to prevent, “[u]nfair methods of competition” and “unfair or deceptive acts or practices.” 15 U. S. C. §§ 45(a)(1)–(2). The Act permits the Commission to use both its own administrative proceedings (set forth in § 5 of the Act) and court actions in exercising this authority. In construing § 13(b), it is helpful to understand how the Commission's authority (and its interpretation of that authority) has evolved over time.

Ever since the Commission's creation in 1914, it has been authorized to enforce the Act through its own administrative proceedings. Section 5 of the Act describes the relevant administrative proceedings in some detail. If the Commission has “reason to believe” that a party “has been or is using any unfair method of competition or unfair or deceptive act or practice,” it can file a complaint against the claimed violator and adjudicate its claim before an Administrative Law Judge. § 45(b). The ALJ then conducts a hearing and writes a report setting forth findings of fact and reaching a legal conclusion. Ibid. If the ALJ concludes that the conduct at issue was unfair or misleading, the ALJ will issue an order requiring the party to cease and desist from engaging in the unlawful conduct. Ibid. The party may then seek review before the Commission and eventually in a court of appeals, where the “findings of the Commission as to the facts” (if supported by the evidence) “shall be conclusive.” § 45(c). If judicial review favors the Commission (or if the time to seek judicial review expires), the Commission's order normally becomes final (and enforceable). § 45(g).

In the 1970s Congress authorized the Commission to seek additional remedies in court. In 1973 Congress added § 13(b), the provision at issue here. That provision permits the Commission to proceed directly to court (prior to issuing a cease and desist order) to obtain a “temporary restraining order or a preliminary injunction,” and also allows the Commission, “in proper cases,” to obtain a court-ordered “permanent injunction.” 15 U. S. C. § 53(b). In the same legislation, Congress also amended § 5(l) of the Act to authorize district courts to award civil penalties against respondents who violate final cease and desist orders, and to “grant mandatory injunctions and such other and further equitable relief as they deem appropriate in the enforcement of such final orders of the Commission.” § 45(l). Two years later, Congress enacted § 19 of the Act, which authorizes district courts to grant “such relief as the court finds necessary to redress injury to consumers,” including through the “refund of money or return of property.” § 57b(b). However, Congress specified that the consumer redress available under § 19 could be sought only (as relevant here, and subject to various conditions and limitations) against those who have “engage[d] in any unfair or deceptive act or practice ... with respect to which the Commission has issued a final cease and desist order which is applicable to such person.” § 57b(a)(2).

Beginning in the late 1970s, the Commission began to use § 13(b), and in particular the words “permanent injunction,” to obtain court orders for redress of various kinds in consumer protection cases—without prior use of the administrative proceedings in § 5. See, e.g., FTC v. Virginia Homes Mfg. Corp., 509 F.Supp. 51, 59 (D.Md. 1981) (relying on § 13(b) to order the defendant to notify past customers of their warranty rights); see also D. Fitzgerald, The Genesis of Consumer Protection Remedies Under Section 13(b) of the FTC Act 1–2, Paper at FTC 90th Anniversary Symposium, Sept. 23, 2004 (Fitzgerald); Beales & Muris, Striking the Proper Balance: Redress Under Section 13(b) of the FTC Act, 79 Antitrust L. J. 1, 3–4 (2013). The Commission used this authority to seek and win restitution and other forms of equitable monetary relief directly in court.
Similarly, in the late 1990s the Commission began to use § 13(b)’s “permanent injunction” authority in antitrust cases to seek monetary awards, such as restitution and disgorgement—again without prior use of traditional administrative proceedings. See Complaint in FTC v. Mylan Labs., Inc., No. 98–3114 (DC); Complaint in FTC v. The Hearst Trust, No. 01–734 (DC). In 2003 the Commission issued guidance that limited its use of § 13(b) to obtain monetary relief to “exceptional cases” involving a “[c]lear [v]iolation” of the antitrust laws. Policy Statement on Monetary Equitable Remedies in Competition Cases, 68 Fed. Reg. 45821 (emphasis deleted). But in 2012 the Commission withdrew its policy statement and the limitations it imposed. See Withdrawal of the Commission Policy Statement on Monetary Equitable Remedies in Competition Cases, 77 Fed. Reg. 47071.

The result is that the Commission presently uses § 13(b) to win equitable monetary relief directly in court with great frequency. The Commission tells us that “the agency [now] brings dozens of [§ 13(b)] cases every year seeking a permanent injunction and the return of illegally obtained funds.” Brief for Respondent 8; see also, e.g., Ohlhausen, Dollars, Doctrine, and Damage Control: How Disgorgement Affects the FTC’s Antitrust Mission 7, Speech at Dechert LLP, NY, Apr. 20, 2016 (Commission sought disgorgement in antitrust cases four times between 2012 and 2016, which is “as many times as the [Commission] pursued such relief in the prior twenty years”). With respect to consumer protection cases, the Commission adds that “there's no question that the agency brings far more cases in court than it does in the administrative process.” Tr. of Oral Arg. 49. In fiscal year 2019, for example, the Commission filed 49 complaints in federal court and obtained 81 permanent injunctions and orders, resulting in $723.2 million in consumer redress or disgorgement. See FTC, Fiscal Year 2021 Congressional Budget Justification 5 (Feb. 10, 2020), https://www.ftc.gov/system/files/documents/reports/fy-2021-congressional-budget-justification/fy_2021_cbj_final.pdf. In the same period, the Commission issued only 21 new administrative complaints and 21 final administrative orders.

Our task here is not to decide whether this substitution of § 13(b) for the administrative procedure contained in § 5 and the consumer redress available under § 19 is desirable. Rather, it is to answer a more purely legal question: Did Congress, by enacting § 13(b)’s words, “permanent injunction,” grant the Commission authority to obtain monetary relief directly from courts, thereby effectively bypassing the process set forth in § 5 and § 19?

III

Several considerations, taken together, convince us that § 13(b)’s “permanent injunction” language does not authorize the Commission directly to obtain court-ordered monetary relief. For one thing, the language refers only to injunctions. It says, “in proper cases the Commission may seek, and after proper proof, the court may issue, a permanent injunction.” 15 U. S. C. § 53(b) (emphasis added). An “injunction” is not the same as an award of equitable monetary relief. Compare, e.g., United States v. Oregon State Medical Soc., 343 U.S. 326, 333, 72 S.Ct. 690, 96 L.Ed. 978 (1952) (injunction typically offers prospective relief against ongoing or future harm), with, e.g., 1 D. Dobbs, Law of Remedies § 4.1(1) (2d ed. 1993) (restitution typically offers retrospective relief to redress past harm). We have, however, sometimes interpreted similar language as authorizing judges to order equitable monetary relief. See Porter v. Warner Holding Co., 328 U.S. 395, 66 S.Ct. 1086, 90 L.Ed. 1332 (1946); Mitchell v. Robert DeMario Jewelry, Inc., 361 U.S. 288, 80 S.Ct. 332, 4 L.Ed.2d 323 (1960).

But if this language alone is not enough, there is more. The language and structure of § 13(b), taken as a whole, indicate that the words “permanent injunction” have a limited purpose—a purpose that does not extend to the grant of monetary relief. Those words are buried in a lengthy provision that focuses upon purely injunctive, not monetary, relief. It says (in relevant part):

“Whenever the Commission has reason to believe—

“(1) that any person, partnership, or corporation is violating, or is about to violate, any provision of law enforced by the Federal Trade Commission, and
“(2) that the enjoining thereof pending the issuance of a complaint by the Commission and until such complaint is dismissed by the Commission or set aside by the court on review, or until the order of the Commission made thereon has become final, would be in the interest of the public—

“the Commission by any of its attorneys designated by it for such purpose may bring suit in a district court of the United States to enjoin any such act or practice. Upon a proper showing that, weighing the equities and considering the Commission's likelihood of ultimate success, such action would be in the public interest, and after notice to the defendant, a temporary restraining order or a preliminary injunction may be granted without bond: Provided, however, That if a complaint is not filed within such period (not exceeding 20 days) as may be specified by the court after issuance of the temporary restraining order or preliminary injunction, the order or injunction shall be dissolved by the court and be of no further force and effect: Provided further, That in proper cases the Commission may seek, and after proper proof, the court may issue, a permanent injunction.” 15 U. S. C. § 53(b) (final emphasis added).

Taken as a whole, the provision focuses upon relief that is prospective, not retrospective. Consider the words “is violating” and “is about to violate” (not “has violated”) setting forth when the Commission may request injunctive relief. Consider too the words “pending the issuance of a complaint,” “until such complaint is dismissed,” “temporary restraining order,” “preliminary injunction,” and so forth in the first half of the section. These words reflect that the provision addresses a specific problem, namely, that of stopping seemingly unfair practices from taking place while the Commission determines their lawfulness. Cf. § 53(a) (providing similar provisional relief where false advertising regarding food, drugs, devices, and cosmetics is at issue). And the appearance of the words “permanent injunction” (as a proviso) suggests that those words are directly related to a previously issued preliminary injunction. They might also be read, for example, as granting authority for the Commission to go one step beyond the provisional and (“in proper cases”) dispense with administrative proceedings to seek what the words literally say (namely, an injunction). But to read those words as allowing what they do not say, namely, as allowing the Commission to dispense with administrative proceedings to obtain monetary relief as well, is to read the words as going well beyond the provision's subject matter. In light of the historical importance of administrative proceedings, that reading would allow a small statutory tail to wag a very large dog.

Further, the structure of the Act beyond § 13(b) confirms this conclusion. Congress in § 5(l) and § 19 gave district courts the authority to impose limited monetary penalties and to award monetary relief in cases where the Commission has issued cease and desist orders, i.e., where the Commission has engaged in administrative proceedings. Since in these provisions Congress explicitly provided for “other and further equitable relief,” 15 U. S. C. § 45(l), and for the “refund of money or return of property,” § 57b(b), it likely did not intend for § 13(b)'s more cabined “permanent injunction” language to have similarly broad scope.

More than that, the latter provision (§ 19) comes with certain important limitations that are absent in § 13(b). As relevant here, § 19 applies only where the Commission begins its § 5 process within three years of the underlying violation and seeks monetary relief within one year of any resulting final cease and desist order. 15 U. S. C. § 57b(d). And it applies only where “a reasonable man would have known under the circumstances” that the conduct at issue was “dishonest or fraudulent.” § 57b(a)(2); see also § 45(m)(1)(B)(2) (providing court-ordered monetary penalties against anyone who engages in conduct previously identified as prohibited in a final cease and desist order, but only if the violator acted with “actual knowledge that such act or practice is unfair or deceptive”). In addition, Congress enacted these other, more limited, monetary relief provisions at the same time as, or a few years after, it enacted § 13(b) in 1973.

It is highly unlikely that Congress would have enacted provisions expressly authorizing conditioned and limited monetary relief if the Act, via § 13(b), had already implicitly allowed the Commission to obtain that same monetary relief and more without satisfying those conditions and limitations. Nor is it likely that Congress, without mentioning the matter, would have granted
the Commission authority so readily to circumvent its traditional § 5 administrative proceedings. See FitzGerald 1 (arguing that, in the mid-1970s, “no one imagined that Section 13(b) of the [FTC] Act would become an important part of the Commission's consumer protection program” (footnote omitted)).

At the same time, to read § 13(b) to mean what it says, as authorizing injunctive but not monetary relief, produces a coherent enforcement scheme: The Commission may obtain monetary relief by first invoking its administrative procedures and then § 19's redress provisions (which include limitations). And the Commission may use § 13(b) to obtain injunctive relief while administrative proceedings are foreseen or in progress, or when it seeks only injunctive relief. By contrast, the Commission's broad reading would allow it to use § 13(b) as a substitute for § 5 and § 19. For the reasons we have just stated, that could not have been Congress’ intent. Cf. *Whitman v. American Trucking Assns., Inc.*, 531 U.S. 457, 468, 121 S.Ct. 903, 149 L.Ed.2d 1 (2001) (“Congress ... does not ... hide elephants in mouseholes”).

IV

The Commission makes several arguments to the contrary. First, the Commission points to traditional equitable practice and to two previous cases where we interpreted provisions authorizing injunctive relief to authorize equitable monetary relief as well. See *Porter v. Warner Holding Co.*, 328 U.S. 395, 66 S.Ct. 1086, 90 L.Ed. 1332 (1946); *Mitchell v. Robert DeMario Jewelry, Inc.*, 361 U.S. 288, 80 S.Ct. 332, 4 L.Ed.2d 323 (1960). In *Porter* we said that “[n]othing is more clearly a part of the subject matter of a suit for an injunction than the recovery of that which has been illegally acquired and which has given rise to the necessity for injunctive relief.” 328 U.S., at 399, 66 S.Ct. 1086. In *Mitchell* we said that, “[w]hen Congress entrusts to an equity court the enforcement of prohibitions contained in a regulatory enactment, it must be taken to have acted cognizant of the historic power of equity to provide complete relief in light of the statutory purposes.” 361 U.S., at 291–292, 80 S.Ct. 332. The Commission argues that these cases consequently support the proposition that the traditional equitable “authority to grant an ‘injunction’ includes the power to grant restorative monetary remedies.” Brief for Respondent 21.

The problem for the Commission is that we did not in these two cases purport to set forth a universal rule of interpretation. And both cases involved different statutes. See *Porter*, 328 U.S., at 397, 66 S.Ct. 1086 (Emergency Price Control Act provision authorizing courts to issue “‘a permanent or temporary injunction, restraining order, or other order’ ”); *Mitchell*, 361 U.S., at 289, 80 S.Ct. 332 (Fair Labor Standards Act provision authorizing courts to “‘restrain violations’” of the Act's antiretaliation ban). In both cases, we recognized that the text and structure of the statutory scheme at issue can, “in so many words, or by a necessary and inescapable inference, restric[t] the court's jurisdiction in equity.” *Porter*, 328 U.S., at 398, 66 S.Ct. 1086; *Mitchell*, 361 U.S., at 291, 80 S.Ct. 332. Thus in *Porter* we examined “other provision[s] of the [Emergency Price Control] Act” to determine whether they “expressly or impliedly preclud[e] a court from ordering restitution in the exercise of its equity jurisdiction.” 328 U.S., at 403, 66 S.Ct. 1086. And in *Mitchell* we examined other provisions of the Fair Labor Standards Act before concluding that there was “no indication in the language” that the statute precluded equitable relief in the form of lost wages. 361 U.S., at 294, 80 S.Ct. 332.

Moreover, more recently, we have held, based on our reading of a statutory scheme as a whole, that a provision's grant of an “injunction” or other equitable powers does not automatically authorize a court to provide monetary relief. Rather, we have said, the scope of equitable relief that a provision authorizes “remains a question of interpretation in each case.” *Mertens v. Hewitt Associates*, 508 U.S. 248, 257, 113 S.Ct. 2063, 124 L.Ed.2d 161 (1993). Our decision in *Meghrig v. KFC Western, Inc.*, 516 U.S. 479, 116 S.Ct. 1251, 134 L.Ed.2d 121 (1996), is instructive. There, we considered a provision in the Resource Conservation and Recovery Act that authorizes district courts “to restrain any person who has contributed or who is contributing to the past or present handling, storage, treatment, transportation, or disposal of any solid or hazardous waste,” and “to order such person to take such other action as may be necessary, or both.” 98 Stat. 3268, 42 U. S. C. § 6972(a). The question was whether this


language permits courts to award restitution in the form of past cleanup costs. We concluded that, despite Porter, the provision's grant of equitable authority does not authorize past cleanup costs because the relevant statutory scheme (as here) contained other “elaborate enforcement provisions,” including (as here) provisions that explicitly provide for that form of relief. Meghrig, 516 U.S., at 487, 116 S.Ct. 1251. Here, the inference against § 13(b)’s authorization of monetary relief is strong and follows from the interpretive approach we took in Meghrig.

Second, the Commission argues that Congress simply created two enforcement avenues, one administrative and the other judicial, leaving the Commission the power to decide which of the two “separate, parallel enforcement paths” to take. Brief for Respondent 41. To the extent that § 19 authorizes “similar relief” as § 13(b), the Commission continues, that reflects only the fact that each pathway is an alternative route to “similar endpoints.” Id., at 41–42. This statement, however, does not overcome the interpretive difficulties we have set forth, for example permitting the Commission to avoid the conditions and limitations laid out in § 19. We cannot believe that Congress merely intended to enact a more onerous alternative to § 13(b) when it enacted § 19 two years later.

Third, the Commission points to saving clauses in § 19, which, it says, save its ability to use § 13(b) to obtain monetary relief. See id., at 42. Those clauses preserve “any authority of the Commission under any other provision of law” and preserve “any other remedy or right of action provided by State or Federal law.” 15 U. S. C. § 57b(e). Here, however, the question is not one of preserving pre-existing remedies given by other statutory provisions. The question is whether those other provisions (namely, § 13(b)) gave that remedy in the first place.

Fourth, the Commission points out that the courts of appeals have, until recently, consistently accepted its interpretation, and that Congress has in effect twice ratified that interpretation in subsequent amendments to the Act. See, e.g., Brief for Respondent 8, and n. 3 (citing the similar conclusions of eight Circuits). But see FTC v. Credit Bureau Center, LLC, 937 F.3d 764 (C.A.7 2019); FTC v. AbbVie Inc., 976 F.3d 327 (C.A.3 2020). We have held that Congress’ acquiescence to a settled judicial interpretation can suggest adoption of that interpretation. See, e.g., Monessen Southwestern R. Co. v. Morgan, 486 U.S. 330, 338, 108 S.Ct. 1837, 100 L.Ed.2d 349 (1988). We have also said, however, that when “Congress has not comprehensively revised a statutory scheme but has made only isolated amendments ... [i]t is impossible to assert with any degree of assurance that congressional failure to act represents affirmative congressional approval of [a court's] statutory interpretation.” Alexander v. Sandoval, 532 U.S. 275, 292, 121 S.Ct. 1511, 149 L.Ed.2d 517 (2001) (internal quotation marks omitted). We find this latter statement the more relevant here.

The two examples of acquiescence to which the Commission refers do not convince us that Congress acquiesced in the lower courts’ interpretation. The Commission first points to amendments that Congress made to the Act in 1994. See § 10, 108 Stat. 1695–1696. Those two amendments, however, simply revised § 13(b)’s venue, joinder, and service rules, not its remedial provisions. They tell us nothing about the words “permanent injunction” in § 13(b).

The Commission also points to amendments made to the Act in 2006. Those amendments modified the scope of § 5 so that, where certain conduct in foreign commerce is involved, § 5 authorizes “all remedies available to the Commission,” including “restitution.” See § 3, 120 Stat. 3372. We agree, however, that restitution is available, for example, when the Commission uses its administrative process. See, e.g., 15 U. S. C. § 57b(b). That being so, these amendments also tell us nothing about the scope of § 13(b).

Fifth, the Commission and its amici emphasize the policy-related importance of allowing the Commission to use § 13(b) to obtain monetary relief. They suggest that it is undesirable simply to enjoin those who violate the Act while leaving them with profits earned at the unjustified expense of consumers. See, e.g., Brief for Respondent 8–9; Brief for Truth in Advertising, Inc., as Amicus Curiae 7–13; Brief for American Antitrust Institute as Amicus Curiae 9–21; Brief for National Consumer Law Center et al. as Amici Curiae 10–20; Brief for Illinois et al. as Amici Curiae 5–11. They point to the billions of dollars that
Nothing we say today, however, prohibits the Commission from using its authority under § 5 and § 19 to obtain restitution on behalf of consumers. If the Commission believes that authority too cumbersome or otherwise inadequate, it is, of course, free to ask Congress to grant it further remedial authority. Indeed, the Commission has recently asked Congress for that very authority, see Hearing before the Senate Committee on Commerce, Science, and Transportation on Oversight of the Federal Trade Commission, Prepared Statement of the FTC, 116th Cong., 2d Sess., 3–5 (2020), and Congress has considered at least one bill that would do so, see S. 4626, 116th Cong., 2d Sess., § 403 (2020) (revising § 13 to expressly authorize restitution and disgorgement). We must conclude, however, that § 13(b) as currently written does not grant the Commission authority to obtain equitable monetary relief.

* * *

For these reasons, we reverse the Ninth Circuit's judgment, and we remand the case for further proceedings consistent with this opinion.

It is so ordered.

All Citations

Footnotes

* The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See United States v. Detroit Timber & Lumber Co., 200 U.S. 321, 337, 26 S.Ct. 282, 50 L.Ed. 499.
§ 45. Unfair methods of competition unlawful; prevention by Commission, 15 USCA § 45

(a) Declaration of unlawfulness; power to prohibit unfair practices; inapplicability to foreign trade

(1) Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful.

(2) The Commission is hereby empowered and directed to prevent persons, partnerships, or corporations, except banks, savings and loan institutions described in section 57a(f)(3) of this title, Federal credit unions described in section 57a(f)(4) of this title, common carriers subject to the Acts to regulate commerce, air carriers and foreign air carriers subject to part A of subtitle VII of Title 49, and persons, partnerships, or corporations insofar as they are subject to the Packers and Stockyards Act, 1921, as amended, except as provided in section 406(b) of said Act, from using unfair methods of competition in or affecting commerce and unfair or deceptive acts or practices in or affecting commerce.

(3) This subsection shall not apply to unfair methods of competition involving commerce with foreign nations (other than import commerce) unless--

(A) such methods of competition have a direct, substantial, and reasonably foreseeable effect--

(i) on commerce which is not commerce with foreign nations, or on import commerce with foreign nations; or

(ii) on export commerce with foreign nations, of a person engaged in such commerce in the United States; and

(B) such effect gives rise to a claim under the provisions of this subsection, other than this paragraph.

If this subsection applies to such methods of competition only because of the operation of subparagraph (A)(ii), this subsection shall apply to such conduct only for injury to export business in the United States.

(4)(A) For purposes of subsection (a), the term “unfair or deceptive acts or practices” includes such acts or practices involving foreign commerce that--
§ 45. Unfair methods of competition unlawful; prevention by Commission, 15 USCA § 45

(i) cause or are likely to cause reasonably foreseeable injury within the United States; or

(ii) involve material conduct occurring within the United States.

(B) All remedies available to the Commission with respect to unfair and deceptive acts or practices shall be available for acts and practices described in this paragraph, including restitution to domestic or foreign victims.

(b) Proceeding by Commission; modifying and setting aside orders

Whenever the Commission shall have reason to believe that any such person, partnership, or corporation has been or is using any unfair method of competition or unfair or deceptive act or practice in or affecting commerce, and if it shall appear to the Commission that a proceeding by it in respect thereof would be to the interest of the public, it shall issue and serve upon such person, partnership, or corporation a complaint stating its charges in that respect and containing a notice of a hearing upon a day and at a place therein fixed at least thirty days after the service of said complaint. The person, partnership, or corporation so complained of shall have the right to appear at the place and time so fixed and show cause why an order should not be entered by the Commission requiring such person, partnership, or corporation to cease and desist from the violation of the law so charged in said complaint. Any person, partnership, or corporation may make application, and upon good cause shown may be allowed by the Commission to intervene and appear in said proceeding by counsel or in person. The testimony in any such proceeding shall be reduced to writing and filed in the office of the Commission. If upon such hearing the Commission shall be of the opinion that the method of competition or the act or practice in question is prohibited by this subchapter, it shall make a report in writing in which it shall state its findings as to the facts and shall issue and cause to be served on such person, partnership, or corporation an order requiring such person, partnership, or corporation to cease and desist from using such method of competition or such act or practice. Until the expiration of the time allowed for filing a petition for review, if no such petition has been duly filed within such time, or, if a petition for review has been filed within such time then until the record in the proceeding has been filed in a court of appeals of the United States, as hereinafter provided, the Commission may at any time, upon such notice and in such manner as it shall deem proper, modify or set aside, in whole or in part, any report or any order made or issued by it under this section. After the expiration of the time allowed for filing a petition for review, if no such petition has been duly filed within such time, the Commission may at any time, after notice and opportunity for hearing, reopen and alter, modify, or set aside, in whole or in part, any report or order made or issued by it under this section, whenever in the opinion of the Commission conditions of fact or of law have so changed as to require such action or if the public interest shall so require, except that (1) the said person, partnership, or corporation may, within sixty days after service upon him or it of said report or order entered after such a reopening, obtain a review thereof in the appropriate court of appeals of the United States, in the manner provided in subsection (c) of this section; and (2) in the case of an order, the Commission shall reopen any such order to consider whether such order (including any affirmative relief provision contained in such order) should be altered, modified, or set aside, in whole or in part, if the person, partnership, or corporation involved files a request with the Commission which makes a satisfactory showing that changed conditions of law or fact require such order to be altered, modified, or set aside, in whole or in part. The Commission shall determine whether to alter, modify, or set aside any order of the Commission in response to a request made by a person, partnership, or corporation under paragraph 1 (2) not later than 120 days after the date of the filing of such request.

(c) Review of order; rehearing

Any person, partnership, or corporation required by an order of the Commission to cease and desist from using any method of competition or act or practice may obtain a review of such order in the court of appeals of the United States, within any circuit where the method of competition or the act or practice in question was used or where such person, partnership, or corporation
resides or carries on business, by filing in the court, within sixty days from the date of the service of such order, a written petition praying that the order of the Commission be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Commission, and thereupon the Commission shall file in the court the record in the proceeding, as provided in section 2112 of Title 28. Upon such filing of the petition the court shall have jurisdiction of the proceeding and of the question determined therein concurrently with the Commission until the filing of the record and shall have power to make and enter a decree affirming, modifying, or setting aside the order of the Commission, and enforcing the same to the extent that such order is affirmed and to issue such writs as are ancillary to its jurisdiction or are necessary in its judgement to prevent injury to the public or to competitors pendente lite. The findings of the Commission as to the facts, if supported by evidence, shall be conclusive. To the extent that the order of the Commission is affirmed, the court shall thereupon issue its own order commanding obedience to the terms of such order of the Commission. If either party shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Commission, the court may order such additional evidence to be taken before the Commission and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Commission may modify its findings as to the facts, or make new findings, by reason of the additional evidence so taken, and it shall file such modified or new findings, which, if supported by evidence, shall be conclusive, and its recommendation, if any, for the modification or setting aside of its original order, with the return of such additional evidence. The judgment and decree of the court shall be final, except that the same shall be subject to review by the Supreme Court upon certiorari, as provided in section 1254 of Title 28.

(d) Jurisdiction of court

Upon the filing of the record with it the jurisdiction of the court of appeals of the United States to affirm, enforce, modify, or set aside orders of the Commission shall be exclusive.

(e) Exemption from liability

No order of the Commission or judgement of court to enforce the same shall in anywise relieve or absolve any person, partnership, or corporation from any liability under the Antitrust Acts.

(f) Service of complaints, orders and other processes; return

Complaints, orders, and other processes of the Commission under this section may be served by anyone duly authorized by the Commission, either (a) by delivering a copy thereof to the person to be served, or to a member of the partnership to be served, or the president, secretary, or other executive officer or a director of the corporation to be served; or (b) by leaving a copy thereof at the residence or the principal office or place of business of such person, partnership, or corporation; or (c) by mailing a copy thereof by registered mail or by certified mail addressed to such person, partnership, or corporation at his or its residence or principal office or place of business. The verified return by the person so serving said complaint, order, or other process setting forth the manner of said service shall be proof of the same, and the return post office receipt for said complaint, order, or other process mailed by registered mail or by certified mail as aforesaid shall be proof of the service of the same.

(g) Finality of order

An order of the Commission to cease and desist shall become final--
(1) Upon the expiration of the time allowed for filing a petition for review, if no such petition has been duly filed within such time; but the Commission may thereafter modify or set aside its order to the extent provided in the last sentence of subsection (b).

(2) Except as to any order provision subject to paragraph (4), upon the sixtieth day after such order is served, if a petition for review has been duly filed; except that any such order may be stayed, in whole or in part and subject to such conditions as may be appropriate, by--

(A) the Commission;

(B) an appropriate court of appeals of the United States, if (i) a petition for review of such order is pending in such court, and (ii) an application for such a stay was previously submitted to the Commission and the Commission, within the 30-day period beginning on the date the application was received by the Commission, either denied the application or did not grant or deny the application; or

(C) the Supreme Court, if an applicable petition for certiorari is pending.

(3) For purposes of subsection (m)(1)(B) and of section 57b(a)(2) of this title, if a petition for review of the order of the Commission has been filed--

(A) upon the expiration of the time allowed for filing a petition for certiorari, if the order of the Commission has been affirmed or the petition for review has been dismissed by the court of appeals and no petition for certiorari has been duly filed;

(B) upon the denial of a petition for certiorari, if the order of the Commission has been affirmed or the petition for review has been dismissed by the court of appeals; or

(C) upon the expiration of 30 days from the date of issuance of a mandate of the Supreme Court directing that the order of the Commission be affirmed or the petition for review be dismissed.

(4) In the case of an order provision requiring a person, partnership, or corporation to divest itself of stock, other share capital, or assets, if a petition for review of such order of the Commission has been filed--

(A) upon the expiration of the time allowed for filing a petition for certiorari, if the order of the Commission has been affirmed or the petition for review has been dismissed by the court of appeals and no petition for certiorari has been duly filed;

(B) upon the denial of a petition for certiorari, if the order of the Commission has been affirmed or the petition for review has been dismissed by the court of appeals; or
(C) upon the expiration of 30 days from the date of issuance of a mandate of the Supreme Court directing that the order of the Commission be affirmed or the petition for review be dismissed.

(h) Modification or setting aside of order by Supreme Court

If the Supreme Court directs that the order of the Commission be modified or set aside, the order of the Commission rendered in accordance with the mandate of the Supreme Court shall become final upon the expiration of thirty days from the time it was rendered, unless within such thirty days either party has instituted proceedings to have such order corrected to accord with the mandate, in which event the order of the Commission shall become final when so corrected.

(i) Modification or setting aside of order by Court of Appeals

If the order of the Commission is modified or set aside by the court of appeals, and if (1) the time allowed for filing a petition for certiorari has expired and no such petition has been duly filed, or (2) the petition for certiorari has been denied, or (3) the decision of the court has been affirmed by the Supreme Court, then the order of the Commission rendered in accordance with the mandate of the court of appeals shall become final on the expiration of thirty days from the time such order of the Commission was rendered, unless within such thirty days either party has instituted proceedings to have such order corrected so that it will accord with the mandate, in which event the order of the Commission shall become final when so corrected.

(j) Rehearing upon order or remand

If the Supreme Court orders a rehearing; or if the case is remanded by the court of appeals to the Commission for a rehearing, and if (1) the time allowed for filing a petition for certiorari has expired, and no such petition has been duly filed, or (2) the petition for certiorari has been denied, or (3) the decision of the court has been affirmed by the Supreme Court, then the order of the Commission rendered upon such rehearing shall become final in the same manner as though no prior order of the Commission had been rendered.

(k) “Mandate” defined

As used in this section the term “mandate”, in case a mandate has been recalled prior to the expiration of thirty days from the date of issuance thereof, means the final mandate.

(l) Penalty for violation of order; injunctions and other appropriate equitable relief

Any person, partnership, or corporation who violates an order of the Commission after it has become final, and while such order is in effect, shall forfeit and pay to the United States a civil penalty of not more than $10,000 for each violation, which shall accrue to the United States and may be recovered in a civil action brought by the Attorney General of the United States. Each separate violation of such an order shall be a separate offense, except that in a case of a violation through continuing failure to obey or neglect to obey a final order of the Commission, each day of continuance of such failure or neglect shall be deemed a separate offense. In such actions, the United States district courts are empowered to grant mandatory injunctions and such other and further equitable relief as they deem appropriate in the enforcement of such final orders of the Commission.
(m) Civil actions for recovery of penalties for knowing violations of rules and cease and desist orders respecting unfair or deceptive acts or practices; jurisdiction; maximum amount of penalties; continuing violations; de novo determinations; compromise or settlement procedure

(1)(A) The Commission may commence a civil action to recover a civil penalty in a district court of the United States against any person, partnership, or corporation which violates any rule under this subchapter respecting unfair or deceptive acts or practices (other than an interpretive rule or a rule violation of which the Commission has provided is not an unfair or deceptive act or practice in violation of subsection (a)(1)) with actual knowledge or knowledge fairly implied on the basis of objective circumstances that such act is unfair or deceptive and is prohibited by such rule. In such action, such person, partnership, or corporation shall be liable for a civil penalty of not more than $10,000 for each violation.

(B) If the Commission determines in a proceeding under subsection (b) that any act or practice is unfair or deceptive, and issues a final cease and desist order, other than a consent order, with respect to such act or practice, then the Commission may commence a civil action to obtain a civil penalty in a district court of the United States against any person, partnership, or corporation which engages in such act or practice--

(1) after such cease and desist order becomes final (whether or not such person, partnership, or corporation was subject to such cease and desist order), and

(2) with actual knowledge that such act or practice is unfair or deceptive and is unlawful under subsection (a)(1) of this section.

In such action, such person, partnership, or corporation shall be liable for a civil penalty of not more than $10,000 for each violation.

(C) In the case of a violation through continuing failure to comply with a rule or with subsection (a)(1), each day of continuance of such failure shall be treated as a separate violation, for purposes of subparagraphs (A) and (B). In determining the amount of such a civil penalty, the court shall take into account the degree of culpability, any history of prior such conduct, ability to pay, effect on ability to continue to do business, and such other matters as justice may require.

(2) If the cease and desist order establishing that the act or practice is unfair or deceptive was not issued against the defendant in a civil penalty action under paragraph (1)(B) the issues of fact in such action against such defendant shall be tried de novo. Upon request of any party to such an action against such defendant, the court shall also review the determination of law made by the Commission in the proceeding under subsection (b) that the act or practice which was the subject of such proceeding constituted an unfair or deceptive act or practice in violation of subsection (a).

(3) The Commission may compromise or settle any action for a civil penalty if such compromise or settlement is accompanied by a public statement of its reasons and is approved by the court.

(n) Standard of proof; public policy considerations

The Commission shall have no authority under this section or section 57a of this title to declare unlawful an act or practice on the grounds that such act or practice is unfair unless the act or practice causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or
to competition. In determining whether an act or practice is unfair, the Commission may consider established public policies as evidence to be considered with all other evidence. Such public policy considerations may not serve as a primary basis for such determination.

CREDIT(S)


Footnotes

1 So in original. Probably should be “clause”.

15 U.S.C.A. § 45, 15 USCA § 45
Current through P.L. 117-148. Some statute sections may be more current, see credits for details

© 2022 Thomson Reuters. No claim to original U.S. Government Works.
Synopsis

Background: Direct purchasers of brand-name drug commenced putative class action against proprietary drug manufacturer and generic drug manufacturer, alleging that their settlement agreement violated the Sherman Act and Clayton Act as unjustified restraint on trade. The United States District Court for the District of New Jersey, William H. Walls, J., dismissed the action. Purchasers appealed.

Holdings: The Court of Appeals, Scirica, Circuit Judge, held that:

inference arose that settlement between manufacturers was payment to eliminate risk of competition, and

plaintiffs stated rule-of-reason claim.

Vacated and remanded.

Attorneys and Law Firms


Steve D. Shadowen, Esq., Hilliard & Shadowen, Mechanicsburg, PA, for Amicus Curiae 53 Law, Economics, and Business Professors, The American Antitrust Institute and Consumers Union.


In this appeal from the grant of a motion to dismiss for failure to state a rule-of-reason claim under Sections 1 and 2 of the Sherman Act under Federal Rule of Civil Procedure 12(b)(6), we are asked to determine whether FTC v. Actavis, --- U.S. ----, 133 S.Ct. 2223, 186 L.Ed.2d 343 (2013), covers, in addition to reverse cash payments, a settlement in which the patentee drug manufacturer agrees to relinquish its right to produce an “authorized generic” of the drug (“no-AG agreement”) to compete with a first-filing generic’s drug during the generic’s statutorily guaranteed 180 days of market exclusivity under the Hatch–Waxman Act as against the rest of the world.

In Actavis, the Supreme Court held that unexplained large payments from the holder of a patent on a drug to an alleged infringer to settle litigation of the validity or infringement of the patent (“reverse payment”) “can sometimes violate the antitrust laws.” Id. at 2227. The Court rejected the near-irrebuttable presumption, known as the “scope of the patent” test, that a patentee can make such reverse payments so long as it is paying potential competitors not to challenge its patent within the patent's lifetime.
Plaintiffs here, direct purchasers of the brand-name drug Lamictal, sued Lamictal's producer, Smithkline Beecham Corporation, d/b/a GlaxoSmithKline (“GSK”), and Teva Pharmaceutical Industries Ltd. (“Teva”), a manufacturer of generic Lamictal, for violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 & 2. In earlier litigation, Teva had challenged the validity and enforceability of GSK's patents on lamotrigine, Lamictal's active ingredient. Teva was also first to file an application with the FDA alleging patent invalidity or nonenforceability and seeking approval to produce generic lamotrigine tablets and chewable tablets for markets alleged to be annually worth $2 billion and $50 million, respectively. If the patent suit resulted in a judicial determination of invalidity or nonenforceability—or a settlement incorporating such terms—Teva would be statutorily entitled to a valuable 180–day period of market exclusivity, during which time only it and GSK could produce generic lamotrigine tablets. (The relevant statute permits the brand to produce an “authorized generic” during the exclusivity period. Mylan Pharm., Inc. v. FDA, 454 F.3d 270, 276–77 (4th Cir.2006); Teva Pharm. Indus. Ltd. v. Crawford, 410 F.3d 51, 55 (D.C.Cir.2005); see also Sanofi–Aventis v. Apotex Inc., 659 F.3d 1171, 1175 (Fed.Cir.2011).)

After the judge presiding over the patent litigation ruled the patent's main claim invalid, GSK and Teva settled. They agreed Teva would end its challenge to GSK's patent in exchange for early entry into the $50 million annual lamotrigine chewables market and GSK's commitment not to produce its own, “authorized generic” version of Lamictal tablets for the market alleged to be worth $2 billion annually. Plaintiffs contend that this “no-AG agreement” qualifies as a “reverse payment” under Actavis because, like the cash reverse payments the Court there warned could face antitrust scrutiny, GSK’s no-AG commitment was designed to induce Teva to abandon the patent fight and thereby agree to eliminate the risk of competition in the $2 billion lamotrigine tablet market for longer than the patent's strength would otherwise permit.

We believe this no-AG agreement falls under Actavis’s rule because it may represent an unusual, unexplained reverse transfer of considerable value from the patentee to the alleged infringer and may therefore give rise to the inference that it is a payment to eliminate the risk of competition. As the Court noted, these kinds of settlements are subject to the rule of reason.

I.

“A patent ... is an exception to the general rule against monopolies and to the right to access to a free and open market.” Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 177, 86 S.Ct. 347, 15 L.Ed.2d 247 (1965) (quoting Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 816, 65 S.Ct. 993, 89 L.Ed. 1381 (1945)). The Constitution’s “Patent Clause itself reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the ‘Progress of Science and useful Arts.’ ” Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 146, 109 S.Ct. 971, 103 L.Ed.2d 118 (1989) (quoting U.S. Const. art. I, § 8, cl. 8). In turn, “[f]rom their inception, the federal patent laws have embodied a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy.” Id.; see X Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 1780a (3d ed.2011) (“Patent law ... serves the interests of consumers by protecting invention against prompt imitation in order to encourage more innovation than would otherwise occur.”). A patent, consequently, “is a special privilege designed to serve the public purpose of promoting the ‘Progress of Science and useful Arts.’ ” Precision Instrument Mfg. Co., 324 U.S. at 816, 65 S.Ct. 993.

The resulting regulatory framework has the following four relevant features identified by the Supreme Court in *Actavis*, 133 S.Ct. at 2227–29.

First, a new drug—that is, a pioneer, “brand-name” drug—cannot be introduced until it is approved by the Food and Drug Administration ("FDA"). 21 U.S.C. § 355(a). A New Drug Application ("NDA") requires the applicant to submit, among other things, “full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use,” id. § 355(b)(1)(A), as well as comprehensive information about the drug, id. § 355(b)(1). This reporting requirement entails “a long, comprehensive, and costly testing process.” *Actavis*, 133 S.Ct. at 2228.

Second, the Hatch–Waxman Act facilitates the development of generic drugs by allowing an applicant to file, for new drugs shown to be “bioequivalent” to a drug previously approved by the FDA, 21 U.S.C. § 355(j)(2)(A)(iv), a less onerous and less costly “Abbreviated New Drug Application” ("ANDA") in lieu of an NDA. See id. § 355(j); *Actavis*, 133 S.Ct. at 2228. The ANDA process “allow[s] the generic to piggy-back on the pioneer's approval efforts ..., thereby furthering drug competition.” *Actavis*, 133 S.Ct. at 2228 (citing *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, — U.S. ——, 132 S.Ct. 1670, 1676, 182 L.Ed.2d 678 (2012)).

Third, Hatch–Waxman “sets forth special procedures for identifying, and resolving, related patent disputes.” *Id.* A new drug applicant must list information on any patents issued on the drug’s composition or methods of use. See 21 U.S.C. § 355(b)(1); *Caraco*, 132 S.Ct. at 1676. If the FDA approves the new drug, it publishes this information, without verification, in its *Orange Book*. 4 *Caraco*, 132 S.Ct. at 1676. In turn, any manufacturer filing an ANDA to produce a generic version of that pioneer drug must consult the *Orange Book* and “assure the FDA that [the] proposed generic drug will not infringe the brand's patents.” *Id.* As relevant here, the manufacturer may tender that assurance with a “paragraph IV” certification that the relevant listed patents are “invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug.” 21 U.S.C. § 355(j)(2)(A)(vii)(IV). But “[f]iling a paragraph IV certification means provoking litigation,” Caraco, 132 S.Ct. at 1677, because the patent statute treats paragraph IV certification as a per se act of infringement, see 35 U.S.C. § 271(e)(2)(A). 7 The patentee then has an incentive to sue within 45 days in order to trigger a 30–month stay of the FDA's potential approval of the generic “while the parties litigate patent validity (or infringement) in court. If the courts decide the matter within that period, the FDA follows that determination; if they do not, the FDA may go forward and give approval to market the generic product.” *Actavis*, 133 S.Ct. at 2228 (citing 21 U.S.C. § 355(j)(5)(B)(iii)). 8

“Fourth, Hatch–Waxman provides a special incentive for a generic to be the first to file an Abbreviated New Drug Application taking the paragraph IV route.” *Id.* at 2228–29. From when it first begins marketing its drug or when a court enters judgment finding the challenged patent invalid or unenforceable, the first-filing generic enjoys a 180–day period of exclusivity during which no other generic manufacturer can enter the market. See 21 U.S.C. § 355(j)(5)(B)(iii), (iv). 9 This exclusivity period belongs to first-filing ANDA applicants alone and is nontransferable. See *id.* § 355(j)(5)(D); *Actavis*, 133 S.Ct. at 2229. The period does not, however, prevent the brand-patentee from marketing its own “authorized generic.” *Mylan Pharm.*, 454 F.3d at 276–77; *Teva Pharm. Indus.*, 410 F.3d at 55; *see also Sanofi–Aventis*, 659 F.3d at 1175.

II.

A. 11
Plaintiffs, a putative class represented by King Drug Company of Florence, Inc., and Louisiana Wholesale Drug Co., Inc., are direct purchasers of Lamictal from Defendant GSK. GSK pioneered Lamictal, a brand-name drug used to treat epilepsy and bipolar disorder, and secured U.S. Patent No. 4,602,017 (“the ′017 patent”) on lamotrigine, Lamictal's active ingredient. The patent expired on July 22, 2008. GSK sells both Lamictal tablets and Lamictal chewable tablets, although most Lamictal prescriptions are for the nonchewable tablets \(^{397}\) (most relevant here). Lamictal tablet sales exceeded $2 billion between March 2007 and 2008, while chewable sales measured about $50 million over a yearlong span around 2005.

In April 2002, Defendant Teva filed the first paragraph IV ANDAs to market generic lamotrigine tablets and chewables. Teva certified that its proposed generics did not infringe the ′017 patent and/or that the ′017 patent was unenforceable. GSK soon sued in federal court, see Complaint, Smithkline Beecham Corp. v. Teva Pharm. USA, Inc., No. 02–3779 (D.N.J. Aug. 5, 2002) (ECF No. 1), staying the FDA's approval of Teva's ANDAs for 30 months. In late January 2005, the parties tried the patent case before Judge Bissell, who ruled that the patent's main claim, for the invention of lamotrigine, was invalid. Plaintiffs allege that “it was highly likely that Teva would prevail with respect to the remaining patent claims,” which “were extremely weak in view of Judge Bissell's ruling that claim 1 was invalid.”

In February 2005, the parties settled their dispute before Judge Bissell could rule on the validity of the ′017 patent's remaining claims. GSK agreed to allow Teva to market generic lamotrigine chewables by no later than June 1, 2005, or 37 months before the patent was to expire on July 22, 2008. \(^{12}\) GSK further agreed to permit Teva to sell generic lamotrigine tablets on July 21, 2008, if GSK received a “pediatric exclusivity” extension, \(^{13}\) or March 1, 2008, if GSK did not. (With a pediatric exclusivity extension, the patent would still have expired on July 22, 2008, but the FDA would have been foreclosed from approving ANDAs filed by competing generics until January 22, 2009. See generally AstraZeneca AB v. Apotex Corp., 782 F.3d 1324, 1341, 1343 (Fed.Cir.2015).)

Most relevant here, GSK also agreed not to market an authorized generic until January 2009, after Teva's 180–day market exclusivity period was to expire (the “no-AG agreement” component of the settlement). In fact, plaintiffs allege, Teva “had an interest in delaying a final court decision finding the ′ 017 patent invalid” because the FDA had not yet approved Teva's ANDAs, and Teva therefore wanted time to secure FDA approval so it could “take advantage of its valuable 180–day period,” which would have begun to run with a final judgment finding the patent invalid or noninfringed.

In exchange, Teva agreed to drop its litigation challenging GSK's patent and, plaintiffs allege, delay its entry into the lamotrigine tablet market. If not for the consideration it received, plaintiffs allege, Teva would have launched its generic lamotrigine tablet “at risk” after receiving FDA approval (which occurred later, in August 2006), even if Judge Bissell had not yet ruled the patent invalid (as, they allege, he was likely to do). Indeed, Teva was later to assert, in other litigation against GSK, that GSK's no-AG agreement was “an important component of the settlement between the parties and formed part of the inducement to Teva to relinquish the rights and defenses it was asserting against GSK in the Patent Litigation.” JA 76 (alteration and emphases omitted). \(^{14}\) Judge Bissell approved the parties' settlement and dismissed the case on April 4, 2005.
to dismiss, countering that, under our decision in In re K–Dur Antitrust Litigation, 686 F.3d 214 (3d Cir.2012), only cash payments constitute actionable “reverse payments.”

In K–Dur, we charted a course different from that set by several other courts of appeals by rejecting the “scope of the patent” test, under which “a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent,” Actavis, 133 S.Ct. at 2230 (citation omitted). We reasoned that the scope-of-the-patent test “is contrary to the policies underlying the Hatch–Waxman Act and a long line of Supreme Court precedent on patent litigation and competition.” K–Dur, 686 F.3d at 214. Patents, we noted, are simply legal conclusions of the Patent Office. They should not be irrebuttably presumed valid, we said, especially given “the public interest support[ing] judicial testing and elimination of weak patents,” id. at 215–16, and “[t]he line that Congress drew [in Hatch–Waxman specifically] between the competing objectives of promoting innovation and advancing the public interest, id. at 217. For these reasons, we held that rule of reason scrutiny is proper for reverse payment settlements. Id. at 218.

The District Court here focused on our limitation of K–Dur to the pharmaceutical context, see id. at 216–18, and statements approving “settlements based on a negotiated entry date for marketing of the generic drug,” id. at 217–18, to restrict K–Dur’s reach to “settlements when a generic manufacturer is paid off with money, which is not the case here,” In re Lamictal Direct Purchaser Antitrust Litig., No. 12–0995, 2012 WL 6725580, at *6 (D.N.J. Dec. 6, 2012). The court observed that Teva surely “received consideration,” or otherwise would have had “no incentive to settle,” but it viewed the parties’ settlement as “based on negotiated entry dates” rather than money. Id. Concluding the settlement was not subject to antitrust scrutiny under K–Dur, id., and that, “from a policy perspective, this settlement did introduce generic products onto the market sooner than what would have occurred had GSK’s patent not been challenged,” id. at *7, the court granted the defendants’ motion to dismiss for failure to state a claim.

Plaintiffs appealed and we stayed proceedings pending the Supreme Court's decision in Actavis. After the Court's decision, we remanded for further consideration in light of Actavis. In January 2014, the District Court “affirm[ed] its order of dismissal.” In re Lamictal Direct Purchaser Antitrust Litig., 18 F.Supp.3d 560, 561 (D.N.J.2014). Although conceding that “there is some very broad language in the [Actavis] opinion regarding patent settlements of all kinds,” id. at 566, the court read Actavis, as it had K–Dur before, as requiring antitrust scrutiny only of reverse payment patent settlements that “involve an exchange of money” rather than some other type of valuable consideration, id. at 568. In the alternative, the court stated, it “considered the settlement under the ‘five considerations’ ” of Actavis’s rule of reason and concluded that the settlement “would survive.” Id. at 570.

Plaintiffs contend that under Actavis antitrust scrutiny is not limited to reverse payments of cash. They assert the antitrust laws may be violated when a brand-name drug manufacturer induces a would-be generic competitor to delay market entry by agreeing not to launch an authorized generic to compete with the generic. Further, they argue, the District Court usurped the jury's role in purporting to conduct a rule of reason analysis by applying the five considerations the Actavis Court discussed to justify, not redefine, use of the already well-established rule of reason analysis. We will vacate and remand.

A.

As noted, in Actavis, the Supreme Court rejected the “scope of the patent” test, a categorical rule that reverse payment patent settlements in the Hatch–Waxman context were immune from antitrust scrutiny so long as the asserted anticompetitive effects fell within the scope of the patent. The Court held that “reverse payment settlements ... can sometimes violate the antitrust laws,”
Company A sues Company B for patent infringement. The two companies settle under terms that require (1) Company B, the claimed infringer, not to produce the patented product until the patent's term expires, and (2) Company A, the patentee, to pay B many millions of dollars. Because the settlement requires the patentee to pay the alleged infringer, rather than the other way around, this kind of settlement agreement is often called a “reverse payment” settlement agreement. And the basic question here is whether such an agreement can sometimes unreasonably diminish competition in violation of the antitrust laws. See, e.g., 15 U.S.C. § 1 (Sherman Act prohibition of “restraint[s] of trade or commerce”). Cf. Palmer v. BRG of Ga., Inc., 498 U.S. 46, 111 S.Ct. 401, 112 L.Ed.2d 349 (1990) (per curiam) (invalidating agreement not to compete).

Actavis, 133 S.Ct. at 2227.

The Court of Appeals for the Eleventh Circuit had applied its scope-of-the-patent test to the following facts. See id. at 2227; FTC v. Watson Pharm., Inc., 677 F.3d 1298 (11th Cir.2012), rev’d sub nom. Actavis, 133 S.Ct. 2223. Solvay Pharmaceuticals developed a brand-name drug called AndroGel in 1999 and obtained a relevant patent in 2003. Later in 2003, three would-be generic AndroGel manufacturers, Actavis first (soon followed by Paddock Laboratories and Par Pharmaceutical), filed ANDAs with paragraph IV certifications. Solvay sued. Thirty months into the litigation, the FDA approved Actavis's first-filed ANDA. Actavis, 133 S.Ct. at 2229.

The parties settled in 2006. Under the terms of the settlement,

Actavis agreed that it would not bring its generic to market until August 31, 2015, 65 months before Solvay's patent expired (unless someone else marketed a generic sooner). Actavis also agreed to promote AndroGel to urologists. The other generic manufacturers made roughly similar promises. And Solvay agreed to pay millions of dollars to each generic—$12 million in total to Paddock; $60 million in total to Par; and an estimated $19–$30 million annually, for nine years, to Actavis. The companies described these payments as compensation for other services the generics promised to perform, but the FTC contends the other services had little value.

Id. (citations omitted).

The FTC sued the settling manufacturers for violating the antitrust laws by agreeing to share Solvay's monopoly profits. Id. at 2229–30. The FTC contended Solvay's reverse payments to the generic manufacturers were compensation for the generics' agreements not to compete with AndroGel. Id. at 2229. The Court of Appeals for the Eleventh Circuit disagreed, and affirmed
the dismissal of the FTC's complaint, on the ground that, absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.” *Watson Pharm.*, 677 F.3d at 1312. In its view, “patent holder[s] had a lawful right to exclude others from the market.” *Id.* at 1307 (internal quotation marks omitted). Even though a patent might be found invalid if litigated, the court thought “the FTC's approach would put that burden back on the parties and the court, undo much of the benefit of settling patent litigation, and discourage settlements,” in derogation of the important public policy interests served by settlement. *Id.* at 1313–14.

The Supreme Court disagreed. It began with the premise that an asserted patent “may or may not be valid, and may or may not be infringed.” *Actavis*, 133 S.Ct. at 2231. Although a valid patent gives its holder the right to “‘exclude[ ] all ... from the use of the protected process or product’ ” and charge prices of its choosing, including supracompetitive prices, “an invalidated patent carries with it no such right. And even a valid patent confers no right to exclude products or processes that do not actually infringe.” *Id.* (emphasis in original) (quoting *United States v. Line Material Co.*, 333 U.S. 287, 308, 68 S.Ct. 550, 92 L.Ed. 701 (1948)). And from the time of their paragraph IV certification, the generics in *Actavis* had challenged both the validity and the scope of the *AndroGel* patent. *Id.* The Court observed that, as alleged by the FTC, Solvay had “agreed to pay the [generics] many millions of dollars to stay out of its market, even though the [generics] did not have any claim that [Solvay] was liable to them for damages.” *Id.* The Court was concerned that this “‘unusual’ ‘form of settlement’ could ‘have significant adverse effects on competition’” and thought, accordingly, “that patent and antitrust policies are both relevant in determining the ‘scope of the patent monopoly’—and consequently antitrust law immunity—that is conferred by a patent.” *Id.*

The Court cited several of its earlier cases for this proposition that courts must balance “the lawful restraint on trade of the patent monopoly and the illegal restraint prohibited broadly by the Sherman Act.” *Id.* (quoting *Line Material*, 333 U.S. at 310, 68 S.Ct. at 550); see also *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 390–91, 68 S.Ct. 525, 92 L.Ed. 746 (1948). The antitrust question, it reasoned, must be answered “by considering traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances, such as here those related to patents.” *Actavis*, 133 S.Ct. at 2231. Only then can a court conclude “whether a particular restraint lies ‘beyond the limits of the patent monopoly.’ ” *Id.* at 2231–32 (quoting *id.* at 2241–42 (Roberts, C.J., dissenting)). By contrast, Chief Justice Roberts, joined in dissent by Justices Scalia and Thomas, would have held that “the scope of the patent—i.e., the rights conferred by the patent—forms the zone within which the patent holder may operate without facing antitrust liability.” *Id.* at 2238 (Roberts, C.J., dissenting). In the dissenters' view, “a patent holder acting within the scope of its patent does not engage in any unlawful anticompetitive behavior; it is simply exercising the monopoly rights granted to it by the Government.” *Id.* at 2240. And, they maintained, the patent's scope “should be determined by reference to patent law.” *Id.* (emphasis in original).

As noted, the Court explained that its “precedents make clear that patent-related settlement agreements can sometimes violate the antitrust laws.” *Id.* at 2232 (majority opinion) (citing *United States v. Singer Mfg. Co.*, 374 U.S. 174, 83 S.Ct. 1773, 10 L.Ed.2d 823 (1963); *Line Material*, 333 U.S. at 310–11, 68 S.Ct. at 550; *United States v. New Wrinkle, Inc.*, 342 U.S. 371, 378–80, 72 S.Ct. 350, 96 L.Ed. 417 (1952)). The Court viewed these prior cases as “seek[ing] to accommodate patent and antitrust policies, finding challenged terms and conditions unlawful unless patent law policy offsets the antitrust law policy strongly favoring competition,” notwithstanding the possible validity or infringement of the patent in question. *Id.* at 2233; see *id.* at 2244 (Roberts, C.J., dissenting) (“The majority seems to think that even if the patent is valid, a patent holder violates the antitrust laws merely because the settlement took away some chance that his patent would be declared invalid by a court.” (emphasis in original)). Rejecting the dissent's view “that a patent holder may simply ‘pay a competitor to respect its patent’ and quit its patent invalidity ... or noninfringement claim without any antitrust scrutiny whatever,” *id.* at 2233 (majority opinion) (alteration in original) (quoting *id.* at 2239 (Roberts, C.J., dissenting)), the Court reasoned that “[t]he dissent does not identify any patent statute that it understands to grant such a right to a patentee, whether expressly or by fair implication.” *Id.* Such a right, the Court thought, “would be difficult to reconcile ... with the patent-related policy of eliminating unwarranted patent
grant so the public will not ‘continually be required to pay tribute to would-be monopolists without need or justification.’ ” Id. (quoting Lear, Inc. v. Adkins, 395 U.S. 653, 670, 89 S.Ct. 1902, 23 L.Ed.2d 610 (1969)).

The Court further explained that its holding should not be read to subject to antitrust scrutiny “commonplace forms” of settlement, such as tender by an infringer of less than the patentee's full demand. See id. But reverse payments, it said, are not such “familiar settlement forms.” Id. In a reverse payment settlement, the patentee “pays money ... purely so [the alleged infringer] will give up the patent fight.” Id. These payments are said to flow in “reverse” because “a party with no claim for damages (something that is usually true of a paragraph IV litigation defendant) walks away with money simply so it will stay away from the patentee's market. That,” the Court thought, “is something quite different,” and something that falls outside accepted “traditional examples” of settlement. Id.

Notwithstanding the potential concern “that antitrust scrutiny of a reverse payment agreement would require the parties to litigate the validity of the patent in order to demonstrate what would have happened to competition in the absence of the settlement,” the Court identified “five sets of considerations” militating in favor of permitting antitrust scrutiny. Id. at 2234. First, the Court saw in reverse payments the “potential for genuine adverse effects on competition.” Id. (quoting FTC v. Ind. Fed’n of Dentists, 476 U.S. 447, 460–61, 106 S.Ct. 2009, 90 L.Ed.2d 445 (1986)). The inference may be drawn from a reverse payment that the patent holder is paying the alleged infringer to defend “a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed by the generic product.” Id. Even though other settlement terms might allow a generic challenger to enter the market prior to patent expiration, and thus permit some competition benefiting consumers, a reverse payment inducing delay—i.e., a “payment in return for staying out of the market—simply keeps prices at patentee-set [supracompetitive] levels ... while dividing that return between the challenged patentee and the patent challenger.” Id. at 2234–35.

Second, the Court thought “these anticompetitive consequences will at least sometimes prove unjustified.” Id. at 2235–36. Although a payment may be justified *403 if, for example, it approximates litigation expenses saved by the settlement or is true “compensation for other services that the generic has promised to perform,” it may not be justified when used “to prevent the risk of competition” by eliminating “the risk of patent invalidation or a finding of noninfringement.” Id. at 2236; see also, e.g., id. (noting that the antitrust harm occurs when “the payment's objective is to maintain supracOMPETITIVE prices to be shared among the patentee and the challenger rather than face what might have been a competitive market—the very anticompetitive consequence that underlies the claim of antitrust unlawfulness”). At the same time, the Court did not rule out other justifications.

Third, the Court reasoned, in reverse payment situations “the patentee likely possesses the power to bring” about this anticompetitive harm. Id. Not only does a patent protect such market power, but the size of a reverse payment may serve as a proxy for this power because a firm without such power (and the supracompetitive profits that power enables) is unlikely to buy off potential competitors. Id.

Fourth, “the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself.” Id. at 2236–37. Instead, the anticompetitive harm from such a payment appears not to be that the patentee is reaping supracompetitive monopoly profits from a decidedly invalid or noninfringed patent, but rather that there is a risk that the patent-enabled monopoly is unwarranted, and foreclosing such a challenge harms consumers. See id. at 2236 (“[T]he payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm.”). 19

Fifth, parties may still find other ways to settle, such as “by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point.” Id. at 2237. The Court
emphasized, however, that “[i]f the basic reason [for the reverse payment] is a desire to maintain and to share patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement.” Id.

The Court concluded that, because of the fact-specific nature and the complexity of reverse payment agreements, courts should apply the traditional rule-of-reason analysis. See id. at 2237–38.

B.

We do not believe Actavis's holding can be limited to reverse payments of cash. For the following reasons, we think that a no-AG agreement, when it represents an unexplained large transfer of value from the patent holder to the alleged infringer, may be subject to antitrust scrutiny under the rule of reason. We find the allegations here sufficient to state such a claim under the Sherman Act. 20

I.

In the Actavis Court's view, reverse payments are problematic because of *404 their potential to negatively impact consumer welfare by preventing the risk of competition, which arises from expected litigation outcomes. See Actavis, 133 S.Ct. at 2236. The Court's reasoning was not that reverse payments per se violate the antitrust laws, or are per se anticompetitive. To the contrary, the Court declined to “abandon[ ] ... the ‘rule of reason’ in favor of presumptive rules (or a ‘quick-look’ approach),” which are “appropriate only where an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets.” Id. at 2237 (internal quotation marks omitted). Instead, the Court focused on whether a reverse payment could have an anticompetitive effect or, alternatively, whether it was reasonable compensation for litigation costs or the value of services. In other words, the Court reasoned that “even a small risk of invalidity” may not justify a “large payment” (presumably enabled by “patent-generated monopoly profits”) that “likely seeks to prevent the risk of competition.” Id. at 2236. And, the Court reiterated, it is the prevention of that risk of competition—eliminating “the risk of patent invalidation or a finding of noninfringement” by “paying the challenger to stay out” of the market (for longer than the patent's strength would otherwise allow)—that “constitutes the relevant anticompetitive harm,” which must then be analyzed under the rule of reason. Id. at 2236–37.

It seems to us that no-AG agreements are likely to present the same types of problems as reverse payments of cash. The no-AG agreement here may be of great monetary value to Teva as the first-filing generic. In Actavis, the Supreme Court recognized generally that the 180-day exclusivity period is “possibly ‘worth several hundred million dollars,’ ” and may be where the bulk of the first-filer's profits lie. Id. at 2229 (quoting C. Scott Hemphill, Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem, 81 N.Y.U. L.Rev. 1553, 1579 (2006)). 21 There are also plausible indicia that this pattern held true here: The Amici States point out that “[p]ublic records show that generic sales of Lamictal in 2008 were some 671 million dollars,” so the no-AG agreement “was clearly worth millions of dollars, if not hundreds of millions of dollars[,] to the generic.” Amici States' Br. 16. And the FTC suggests, using sales of the drug Paxil as a yardstick, that GSK's no-AG agreement would have been worth hundreds of millions of dollars to Teva. Appellants' Br. 24. 22

*405 At the same time, a brand's commitment not to produce an authorized generic means that it must give up the valuable right to capture profits in the new two-tiered market. The no-AG agreement transfers the profits the patentee would have made from its authorized generic to the settling generic—plus potentially more, in the form of higher prices, because there will now be a generic monopoly instead of a generic duopoly. Thus, “the source of the benefit to the claimed infringer is something costly to the patentee.” Aaron Edlin et al., Activating Actavis, Antitrust, Fall 2013, at 16, 22 n. 22. Absent a no-AG promise,
launching an authorized generic would seem to be economically rational for the brand. For this reason, the fact that the brand promises not to launch an authorized generic (thereby giving up considerable value to the settling generic) makes the settlement something more than just an agreed-upon early entry: it “may instead provide strong evidence that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market.” *Actavis*, 133 S.Ct. at 2235.

The anticompetitive consequences of this pay-for-delay may be as harmful as those resulting from reverse payments of cash. If the brand uses a no-AG agreement to induce the generic to abandon the patent fight, the chance of dissolving a questionable patent vanishes (and along with it, the prospects of a more competitive market). As with a reverse payment of cash, a brand agreeing not to produce an authorized generic may thereby have “avoid[ed] the risk of patent invalidation or a finding of noninfringement.” *Id.* at 2236. In addition, when the parties' settlement includes a no-AG agreement, the generic also presumably agrees to an early entry date that is later than it would have otherwise accepted. 23 And during this time, the brand's monopoly remains in force. Once the generic enters, moreover, it faces no competition with other generics at all.

Antitrust law is designed to protect consumers from arrangements that prevent competition in the marketplace. See, e.g., *Actavis*, 133 S.Ct. at 2234–35; *id.* at 2238 (Roberts, C.J., dissenting); accord XII Areeda & Hovenkamp, supra, ¶ 2046c (2014 Supp.). The District Court here held that “the Supreme Court considered a reverse payment to involve an exchange of money” because “when the Supreme Court said ‘payment’ it meant a payment of money.” *Lamictal*, 18 F.Supp.3d at 568. But, we think, a no-AG agreement could likewise “prevent the risk of competition.” *Actavis*, 133 S.Ct. at 2236; cf. XII Areeda & Hovenkamp, supra, ¶ 2046c1 (2014 Supp.) (explaining that under a “pay-for-delay settlement ... consumer welfare remains the same as it would be under continued monopoly production by a single firm”); FTC Amicus Br. 22 (“It is not the transfer of cash or the form of reverse payment that triggers antitrust concern; it is the impact of that payment on consumer welfare.”). We do not believe the Court intended to draw such a formal line. 24 Nor did the *Actavis* Court limit its reasoning or holding to cash payments only. 25

2.

Defendants contend that no-AG agreements are distinguishable from reverse payments because they are in essence “exclusive licenses” and patent law expressly contemplates exclusive licenses. 26 They argue the *Actavis* Court rejected the dissent's arguments in part because the dissent could “not identify any patent statute that it understands to grant such a right to a patentee, whether expressly or by fair implication.” *Actavis*, 133 S.Ct. at 2233; see GSK Br. 22–23, 34; Teva Br. 22–26. They suggest that if “the patent statute specifically gives a right to restrain competition in the manner challenged,” *Actavis*, 133 S.Ct. at 2231 (internal quotation marks omitted), such conduct is immune from antitrust scrutiny. See GSK Br. 22–23; Teva Br. 22–26, 34. In short, defendants argue GSK's concession not to produce an authorized generic during Teva's 180–day exclusivity period is an “exclusive license” exempt from antitrust scrutiny.

But the “right” defendants seek is not in fact a patentee's right to grant licenses, exclusive or otherwise. 27 Instead, it is a right to use valuable licensing in such a way as to induce a patent challenger's delay. The *Actavis* Court rejected the latter. The thrust of the Court's reasoning is not that it is problematic that money is used to effect an end to the patent challenge, but rather that the patentee leverages some part of its patent power (in *Actavis*, its supracompetitive profits) to cause anticompetitive harm —namely, elimination of the risk of competition. There, the patentee gave the challenger a license to enter 65 months before patent expiration, plus a reverse payment of “millions of dollars.” *Actavis*, 133 S.Ct. at 2229. This reverse payment was not immunized, of course, simply because of that early-entry “license.” Similarly, the *407* fact that a patent holder may generally have the right to grant licenses, exclusive or otherwise, does not mean it also has the right to give a challenger a license along with a promise not to produce an authorized generic—i.e., a promise not to compete—in order to induce the challenger “to
King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp., 791 F.3d 388 (2015)

2015-2 Trade Cases P 79,223

respect its patent and quit [the competitor's] patent invalidity or noninfringement claim without any antitrust scrutiny.” *Id.* at 2233 (internal quotation marks omitted). In the *Actavis* Court's view, the question is not one of patent law, but of antitrust law, the latter of which invalidates “the improper use of [a patent] monopoly.” *Id.* at 2231 (alteration in original) (quoting *Line Material*, 333 U.S. at 310, 68 S.Ct. 550). But see *id.* at 2243 (Roberts, C.J., dissenting). And as we read the Court's opinion, even exclusive licenses cannot avoid antitrust scrutiny where they are used in anticompetitive ways. See *id.* at 2227 (citing *Palmer*, 498 U.S. 46, 111 S.Ct. 401); *Palmer*, 498 U.S. at 50, 111 S.Ct. 401 (holding an agreement not to compete based on an exclusive copyright license *unlawful on its face*). We make no statement about patent licensing more generally. But in this context we believe the fact that the Patent Act expressly authorizes licensing does not necessarily mean it also authorizes reverse payments to prevent generic competition. *29*

We also disagree with defendants' attempt to recharacterize Teva's gain as resulting from its early entry alone. First, that characterization is inaccurate as a descriptive matter. What GSK gave Teva was a 180–day monopoly over the generic market. The first-filing generic cannot capture this value by early entry alone. It can only hope to obtain this value with the brand's self-restraint, and here, without GSK's no-AG commitment, GSK allegedly would have introduced an AG. Second, although we agree that the *Actavis* “Court expressly identified early-entry licensing as a traditional form of settlement whose legality the opinion took pains not to disturb,” *408* Teva Br. 25–26, *30* a no-AG agreement is no more solely an early-entry licensing agreement than the settlement in *Actavis* itself, where entry was permitted 65 months before patent expiration. *Actavis*, 133 S.Ct. at 2229. Notwithstanding such “early entry,” the antitrust problem was that, as the Court inferred, entry might have been earlier, and/or the risk of competition not eliminated, had the reverse payment not been tendered. See *Actavis*, 133 S.Ct. at 2237 (“They may, as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point.”); see also FTC Amicus Br. 21–22 (“[C]ompetitors do not normally raise antitrust concerns if they agree on a date for generic entry but do *not* simultaneously agree that the brand-name manufacturer will compensate the generic company for staying out of the market until that date, thereby sharing (while enlarging) their aggregate pool of monopoly profits.”).

3.

Defendants present additional arguments as to why no-AG agreements, as “exclusive licenses,” should not be subjected to antitrust scrutiny. Noting that public policy favors settlements, they contend that subjecting such agreements to scrutiny will discourage settlements. GSK Br. 37. Furthermore, they contend that “courts should not review pro-competitive conduct to determine whether an even more pro-competitive transaction exists.” GSK Br. 37 (citing *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 415–16, 124 S.Ct. 872, 157 L.Ed.2d 823 (2004) (“The Sherman Act ... does not give judges *carte blanche* to insist that a monopolist alter its way of doing business whenever some other approach might yield greater competition.” (citation omitted))); see Teva Br. 32.

But *Actavis* addressed and rejected these arguments. First, the Court thought the possible discouragement of settlements was “outweigh[ed]” by other considerations and stated that “parties may well find ways to settle patent disputes without the use of reverse payments.” *Actavis*, 133 S.Ct. at 2237, *31* But whatever the effect on settlements, we do not perceive how the noncash nature of no-AG agreements alters that balance. Second, we think *Trinko* inapposite. *Actavis* *409* does not stand for the proposition that parties must reach the most procompetitive settlements possible. Instead, we read *Actavis* to hold that antitrust law may prohibit settlements that are anticompetitive because, without justification, they delay competition for longer than the patent's strength would otherwise permit. *32*
For the reasons we have explained, we think this no-AG agreement, because it may represent an unusual, unexplained transfer of value from the patent holder to the alleged infringer that cannot be adequately justified—whether as compensation for litigation expenses or services, or otherwise—is subject to antitrust scrutiny under the rule of reason. But even if that is the rule, defendants contend, plaintiffs fail to state a claim under Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007), and Ashcroft v. Iqbal, 556 U.S. 662, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009), because their “allegations are far too speculative to satisfy their burden of plausibly alleging that the settlement was anticompetitive.” See GSK Br. 44–45. In particular, defendants argue that “[p]laintiffs fail to plausibly allege that in this but-for world, the parties would have successfully negotiated an alternative, competition-maximizing agreement,” Teva Br. 44; that continued litigation in favor of settlement “would have yielded a more competitive result,” Teva Br. 45; or that Teva would have launched their generics “at risk,” Teva Br. 46.

We believe plaintiffs' allegations, and the plausible inferences that can be drawn from them, are sufficient to state a rule-of-reason claim under Twombly and Iqbal for violation of the Sherman Act on the ground that GSK sought to induce Teva to delay its entry into the lamotrigine tablet market by way of an unjustified no-AG agreement. As recited earlier, plaintiffs alleged that GSK agreed not to launch a competing authorized generic during Teva's 180–day exclusivity period, which was to begin near the expiration of the *410 '017 patent; that such promises can be worth “many millions of dollars of additional revenue”; that “GSK had an incentive to launch its own authorized generic versions of tablets”; that Teva had a history of launching “at risk”; and that the '017 patent was likely to be invalidated—as, in fact, its main claim had been. Because marketing an authorized generic was allegedly in GSK's economic interest, its agreement not to launch an authorized generic was an inducement—valuable to both it and Teva—to ensure a longer period of supracompetitive monopoly profits based on a patent at risk of being found invalid or not infringed. (Indeed, Teva asserted in other litigation that the no-AG agreement “formed part of the inducement to Teva to relinquish the rights and defenses it was asserting against GSK in the Patent Litigation.” JA 76 (alteration and emphases omitted).) And although plaintiffs concede that Teva entered the lamotrigine chewables market about 37 months early, see, e.g., GSK Br. 7, the chewables market, allegedly worth only $50 million annually, was orders of magnitude smaller than the alleged $2 billion tablet market the agreement is said to have protected. Accordingly, at the pleading stage plaintiffs have sufficiently alleged that any procompetitive aspects of the chewables arrangement were outweighed by the anticompetitive harm from the no-AG agreement.

Moreover, we do not read Actavis to require allegations that defendants could in fact have reached another, more competitive settlement. Actavis embraces the concept that a patent “may or may not be valid, and may or may not be infringed,” 133 S.Ct. at 2231, and holds that the anticompetitive harm is not certain consumer loss through higher prices, but rather the patentee's “avoid[ance of] the risk of patent invalidation or a finding of noninfringement”—that is, “prevent[ion of] the risk of competition,” id. at 2236, beyond what the patent's strength would otherwise allow—and, thus, consumer harm. In other words, under the substantive standard, the question is not whether the defendants have only possibly acted unlawfully, but see Teva Br. 43, but whether they have acted unlawfully by seeking to prevent competition. Plaintiffs have sufficiently pleaded as much.
In the alternative, the District Court stated that “[i]t finds that the settlement ... would survive Actavis scrutiny and is reasonable.” 18 F.Supp.3d at 570. This was error. As explained above, plaintiffs have sufficiently pleaded violation of the antitrust laws so as to overcome defendants' motion to dismiss. If genuine issues of material fact remain after discovery, the rule-of-reason analysis is for the finder of fact, not the court as a matter of law.36

In addition, the District Court mistook the “five sets of considerations” that persuaded the Actavis Court “to conclude that the FTC should have been given the opportunity to prove its antitrust claim” under the rule of reason, 133 S.Ct. at 2234, as a redefinition of the “rule of reason” itself. But the general contours of the rule of reason are well-mapped. See generally, e.g., id. at 2236 (citing Ind. Fed'n of Dentists, 476 U.S. at 459, 106 S.Ct. 2009); Deutscher Tennis Bund v. ATP Tour, Inc., 610 F.3d 820, 829–30 (3d Cir.2010). We recognize the Actavis Court “le[ft] to the lower courts the structuring of [this type of] rule-of-reason antitrust litigation,” 133 S.Ct. at 2238, and that there may be some uncertainty as to how, exactly, a “defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason,” id. at 2236 (citing Ind. Fed'n of Dentists, 476 U.S. at 459, 106 S.Ct. 2009). But the Court noted that justifications might include “litigation expenses saved through the settlement” or “compensation for other services that the generic has promised to perform.” Id. And although the Court left such details of how to apply the proper antitrust theories to “the basic question—that of the presence of significant unjustified anticompetitive consequences,” id. at 2238—it suggested “the antitrust laws are likely to forbid” payment for delay (or, that is, to eliminate risk of patent invalidity or noninfringement), id. at 2237.

Here, the District Court thought the no-AG agreement was “justified” because, although the settlement amount was likely greater than litigation costs, “the consideration which the parties exchanged in the settlement [wa]s reasonably related to the removal of the uncertainty created by the dispute.” Lamictal, 18 F.Supp.3d at 570. That conclusion is in tension with Actavis in that, without proper justification, the brand cannot pay the generic simply to eliminate the risk of competition. Nor did the court properly conclude “that the potential for adverse effects on competition [wa]s minimal,” or that the settlement was reasonable, because “the duration of the No–AG Agreement was a relatively brief six months.” Id. The anticompetitive harm plaintiffs allege—consistent with Actavis—is that the promise of no authorized-generic competition during those six months induced Teva to quit its patent challenge. As discussed above, plaintiffs plausibly allege this no-AG promise was of considerable value and thus designed to protect GSK’s patents against the risk of invalidation or noninfringement, rather than reimburse litigation costs or compensate for services. Accordingly, the District Court should have permitted the litigation to proceed under the traditional rule-of-reason approach.

*412 2.

Under the traditional rule-of-reason analysis, the factfinder must

weigh all of the circumstances of a case in deciding whether a restrictive practice should be prohibited as imposing an unreasonable restraint on competition. The plaintiff bears an initial burden under the rule of reason of showing that the alleged combination or agreement produced adverse, anti-competitive effects within the relevant product and geographic markets. The plaintiff may satisfy this burden by proving the existence of actual anticompetitive effects, such as reduction of output, increase in price, or deterioration in quality of goods or services. Such proof is often impossible to make, however, due to the difficulty of isolating the market effects of challenged conduct. Accordingly, courts typically allow proof of the defendant’s market power instead. Market power, the ability to raise prices above those that would prevail in a competitive market, is essentially a surrogate for detrimental effects.
If a plaintiff meets his initial burden of adducing adequate evidence of market power or actual anti-competitive effects, the burden shifts to the defendant to show that the challenged conduct promotes a sufficiently pro-competitive objective.... To rebut, the plaintiff must demonstrate that the restraint is not reasonably necessary to achieve the stated objective.


The Actavis Court provided initial guidance on how to structure rule-of-reason litigation in the reverse payment context. The Court explained that such antitrust questions must be answered “by considering traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances, such as here those related to patents.” Actavis, 133 S.Ct. at 2231.

First, to prove anticompetitive effects, the plaintiff must prove payment for delay, or, in other words, payment to prevent the risk of competition. See id. at 2235–36. “[T]he likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.” Id. at 2237.

Second, the burden then shifts to the defendant to show “that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason.” Id. at 2235–36.

The reverse payment, for example, may amount to no more than a rough approximation of the litigation expenses saved through the settlement. That payment may reflect compensation for other services that the generic has promised to perform—such as distributing the patented item or helping to develop a market for that item. There may be other justifications.

Id. at 2236. The Court does not foreclose other justifications, and we need not decide today what those other justifications might be.

Finally, the plaintiff will have the opportunity to rebut the defendant's explanation. 37

*413 On remand, we invite the District Court to proceed with the litigation under the traditional rule of reason, tailored, as necessary, to the circumstances of this case. 38

IV.

For the foregoing reasons, we vacate the judgment of the District Court and remand for further proceedings consistent with this opinion.

All Citations

791 F.3d 388, 2015-2 Trade Cases P 79,223
Footnotes


2 “Teva” refers collectively to Teva Pharmaceutical Industries Ltd. and its subsidiary Teva Pharmaceuticals USA, Inc.

3 Plaintiffs bring their Sherman Act claims under Sections 4 (damages) and 16 (injunctive relief) of the Clayton Act, 15 U.S.C. §§ 15 & 26, respectively. The Clayton Act requires “a plaintiff to have standing to bring an antitrust claim.” Angelico v. Lehigh Valley Hosp., Inc., 184 F.3d 268, 273 (3d Cir.1999). At the motion-to-dismiss stage, “a plaintiff must allege more than that it has suffered an injury causally linked to a violation of the antitrust laws.” Pace Elecs., Inc. v. Canon Computer Sys., Inc., 213 F.3d 118, 120 (3d Cir.2000). The plaintiff must also “allege antitrust injury, ‘which is to say injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful.’ ” Id. (quoting Brunswick Corp. v. Pueblo Bowl–O–Mat, Inc., 429 U.S. 477, 489, 97 S.Ct. 690, 50 L.Ed.2d 701 (1977)). As noted below, we do not here address the issue of antitrust injury, nor do we preclude consideration of the issue on remand. See infra notes 20 & 35 and accompanying text.

4 “Rather than providing independent evidence of safety and efficacy, the typical ANDA shows that the generic drug has the same active ingredients as, and is biologically equivalent to, the brand-name drug.” Caraco, 132 S.Ct. at 1676; see 21 U.S.C. § 355(j) (ANDA requirements). Before Hatch–Waxman, a company desiring to produce a generic version of a drug approved after 1962 had to conduct its own testing and trials to show that its generic version was safe and effective for human use. H.R.Rep. No. 98–857, pt. 1, at 16–17, 1984 U.S.C.C.A.N. 2647, 2649–50.

5 The volume, officially known as Approved Drug Products with Therapeutic Equivalence Evaluations, is available at http://www.fda.gov/cder/ob/. See generally, e.g., 21 U.S.C. § 355(b)(1) (“Upon approval of the application, the Secretary shall publish information submitted....”); Caraco, 132 S.Ct. at 1676.

6 Although the FDA performs no independent patent review, it cannot approve an ANDA if the proposed generic would infringe any of the brand's asserted patents. See Caraco, 132 S.Ct. at 1676.

7 Further, an ANDA applicant making a paragraph IV certification must notify any patent holder within twenty days of the FDA's confirmation of its ANDA filing, 21 U.S.C. § 355(j)(2)(B)(ii), (iii), “of the factual and legal basis of [its] opinion ... that the patent is invalid or will not be infringed,” id. § 355(j)(2)(B)(iv)(II). See also 21 C.F.R. § 314.52 (“Notice of certification of invalidity or noninfringement of a patent”).

8 Hatch–Waxman “allows competitors, prior to the expiration of a patent, to engage in otherwise infringing activities necessary to obtain regulatory approval.” Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 671, 110 S.Ct. 2683, 110 L.Ed.2d 605 (1990); see 35 U.S.C. § 271(e)(1). As long as a generic applicant does not launch its generic “at risk” (i.e., after FDA approval after 30 months but before a determination of patent validity), it will not be forced to pay money damages. See 35 U.S.C. § 271(e)(4)(C). This feature also explains “the creation of a highly artificial act of infringement”—the paragraph IV certification—to permit the brand and generic to litigate patent validity. Eli Lilly, 496 U.S. at 678, 110 S.Ct. 2683.

9 Under current law, the specific mechanism is that an application by a non-first filer “shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug ... by any first applicant.” 21 U.S.C. § 355(j)(5)

10 “[A]ccording to the Food and Drug Administration, all manufacturers who file on the first day are considered ‘first applicants’ who share the exclusivity period. Thus, if ten generics file an application to market a generic drug on the first day, all will be considered ‘first applicants.’ ” Actavis, 133 S.Ct. at 2246 (Roberts, C.J., dissenting) (citing 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb)).

11 The facts recounted in this opinion are taken from the well-pleaded, nonconclusory factual allegations in plaintiffs' Amended Complaint and all reasonable inferences to be drawn therefrom. See Ashcroft v. Iqbal, 556 U.S. 662, 678–79, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009).

12 Because Teva's ANDAs had not yet been approved, GSK also agreed to supply Teva with lamotrigine chewables.

13 See generally 21 U.S.C. § 355a(c)(2)(B) (2002) (then in effect) (providing for situations in which the FDA may not approve ANDAs for an additional six months if the patent holder completes certain studies “relating to the use of [the] drug in the pediatric population”).

14 In July 2008, “[j]ust prior to Teva launching its generic, GSK approached various pharmacies, group purchasing organizations, and long-term care facilities and proposed that they purchase and distribute GSK’s Lamictal at a generic product price.” Teva Pharm. Indus. Ltd. v. SmithKline Beecham Corp., No. 08–3706, 2009 WL 1687457, at *2 (D.N.J. June 16, 2009). Teva sued GSK to attempt to prevent GSK from “develop[ing] a generic of lamotrigine” because the parties’ settlement agreement “made clear that [Teva’s] right [to sell generic lamotrigine] was exclusive—including as to GSK and its affiliates.” Id. at *1, *4.

15 The Supreme Court later vacated K–Dur and remanded for reconsideration in light of Actavis, see Merck & Co. v. La. Wholesale Drug Co., —— U.S. ——, 133 S.Ct. 2849, 186 L.Ed.2d 904 (2013); Upsher–Smith Labs., Inc. v. La. Wholesale Drug Co., —— U.S. ——, 133 S.Ct. 2849, 186 L.Ed.2d 904 (2013). K–Dur was inconsistent with Actavis in that we had directed application of “quick look rule of reason analysis,” K–Dur, 686 F.3d at 218, rather than the traditional, full-fledged rule of reason standard that the Supreme Court subsequently decided is proper for reverse payment settlement agreements, see Actavis, 133 S.Ct. at 2237–38.

16 See supra note 15.


18 Unlike the majority, the dissenters read the Court's precedents to stand for the proposition that a patentee's actions are subject to antitrust scrutiny only when they “go beyond the monopoly powers conferred by the patent,” with just two exceptions—settlement of sham litigation and litigation involving patents obtained by fraud on the Patent and Trademark Office. Actavis, 133 S.Ct. at 2239 (Roberts, C.J., dissenting); see also id. at 2241–42. No case cited by the majority, they said, subjected a patent settlement “to antitrust scrutiny merely because the validity of the patent was uncertain,” and no reference to “a ‘general procompetitive thrust’ ” of the Hatch–Waxman Act should be interpreted “to unsettle the
established relationship between patent and antitrust law,” especially when “Congress has repeatedly declined to enact legislation addressing the issue.” *Id.* at 2242 (quoting *id.* at 2234 (majority opinion)).

19 See also, e.g., *Actavis*, 133 S.Ct. at 2244 (Roberts, C.J., dissenting) (“The majority seems to think that even if the patent is valid, a patent holder violates the antitrust laws merely because the settlement took away some chance that his patent would be declared invalid by a court.” (emphasis in original)).

20 See supra note 3; infra note 35.

21 In addition, a comprehensive FTC study suggests that having to compete with an authorized generic will likely both cut the generic's sales and force down its price: “the presence of authorized generic competition reduces the first-filer generic's revenues by 40 to 52 percent, on average.” FTC, *Authorized Generic Drugs: Short–Term Effects and LongTerm Impact* iii (2011), available at http://www.ftc.gov/os/2011/08/2011genericedrugreport.pdf; see FTC Amicus Br. 8 (“Prices fall further when additional generic competitors enter...” (citing FTC, *Pay–for–Delay: How Drug Company Pay–Offs Cost Consumers Billions* 8 (2010), available at http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf); FTC Amicus Br. 12 (“[G]eneric wholesale prices average 70 percent of the pre-entry brand-name drug price when the first-filer faces an AG, compared to 80 percent of the brand price when it does not.” (citing FTC, *Authorized Generic Drugs, supra*, at iii))).

22 “The U.S. sales of Paxil were roughly equivalent to those of Lamictal in the year before each product faced generic competition ($2.3 billion and $2.2 billion, respectively).” Appellants' Br. 24 (quoting FTC Br. as *Amicus Curiae* at 8, *Lamictal*, 18 F.Supp.3d 560 (ECF No. 89–3)). The magnitude of these figures is proportionate to the estimated $2.6 billion average cost of developing a new brand-name drug. See Tufts Ctr. for the Study of Drug Dev., *Briefing: Cost of Developing a New Drug* (Nov. 18, 2014), available at http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study-_Nov_18,_2014.pdf.

23 When parties compromise on an early-entry date alone—rather than an early-entry date plus valuable consideration—it is possible that they may compromise on an early-entry date reflecting their assessment of the strength of the patent. The concern with combining an early-entry date with the valuable consideration of a no-AG agreement is that the generic manufacturer may be willing to accept a later early-entry date without any corresponding benefit to consumers.


25 The dissent recognized the majority's reasoning could reach noncash transactions. See *Actavis*, 133 S.Ct. at 2239 (Roberts, C.J., dissenting) (“As in any settlement, Solvay gave its competitors something of value (money) and, in exchange, its competitors gave it something of value (dropping their legal claims).”); *id.* at 2245 (“[The majority's] logic ... cannot possibly be limited to reverse-payment agreements.... The Government's brief acknowledges as much, suggesting that if antitrust scrutiny is invited for such cash payments, it may also be required for ‘other consideration’ and ‘alternative arrangements.’ ”).

26 See 35 U.S.C. § 261 (“The ... patentee, or his assigns or legal representatives may in like manner grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States.”).
We do not believe the no-AG agreement was in fact an “exclusive” license. However, since the issue of whether such agreement is an exclusive license is not necessary for our decision here, we will leave its determination for another day.

The Supreme Court opinion does not say what kind of “exclusive license” it is referring to, but the Eleventh Circuit's opinion states, “BRG and HBJ disavow any intent to restrain trade and claim that their agreement is nothing more than an ordinary copyright royalty arrangement which courts have routinely sustained.”

The defendants' arguments are much like those rejected by the majority in Actavis. The disagreement in the Court was fundamental. In the dissenters' view, “a patent claim cannot possibly impose unlawful anticompetitive harm if the patent holder is acting within the scope of a valid patent and therefore permitted to do precisely what the antitrust suit claims is unlawful.”

The Court was unpersuaded by the dissenters' arguments in this vein. The dissenters contended there was no empirical evidence that most reverse payment settlements occur in the Hatch–Waxman context, and that payments from patentee to alleged infringer “are a well-known feature of intellectual property litigation, and reflect an intuitive way to settle such disputes.”

In addition, Trinko dealt with different questions regarding unlawful monopolization and the refusal to deal—set against the background of “the long recognized right of [a] trader or manufacturer engaged in an entirely private business, freely to exercise his own independent discretion as to parties with whom he will deal,” 540 U.S. at 408, 124 S.Ct. 872 (alteration in original) (quoting United States v. Colgate & Co., 250 U.S. 300, 307, 39 S.Ct. 465, 63 L.Ed. 992 (1919))—and the role of the Telecommunications Act of 1996, which focuses on a different goal of eliminating certain monopolies, id. at 415, 124 S.Ct. 872.
It may also be (though we do not decide) that “procompetitive effects in one market cannot justify anticompetitive effects in a separate market” (i.e., the lamotrigine tablet market). Amicus Br. Nat'l Ass'n Chain Drug Stores in Support of Appellants 27–28 (citing, inter alia, Paladin Assocs., Inc. v. Mont. Power Co., 328 F.3d 1145, 1157 n. 11 (9th Cir.2003)); see Paladin Assocs., 328 F.3d at 1157 n. 11 (“It may be ... that this procompetitive effect should not be considered in our rule of reason analysis, based on the theory that procompetitive effects in a separate market cannot justify anticompetitive effects in the market for pipeline transportation under analysis.”) (citing United States v. Topco Assocs., 405 U.S. 596, 610, 92 S.Ct. 1126, 31 L.Ed.2d 515 (1972); see also Topco, 405 U.S. at 610, 92 S.Ct. 1126) (“[Competition] cannot be foreclosed with respect to one sector of the economy because certain private citizens or groups believe that such foreclosure might promote greater competition in a more important sector of the economy.”).

We do not decide the question of antitrust injury in private actions such as this litigation, see generally, e.g., Ian Simmons et al., Viewing FTC v. Actavis Through the Lens of Clayton Act Section 4, Antitrust, Fall 2013, at 24; In re Niaspan Antitrust Litig., 42 F.Supp.3d 735, 755–77 (E.D.Pa.2014), nor do we preclude the parties from raising the issue on remand.

See, e.g., Arizona v. Maricopa Cnty. Med. Soc'y, 457 U.S. 332, 343, 102 S.Ct. 2466, 73 L.Ed.2d 48 (1982) (“[T]he rule of reason requires the factfinder to decide whether under all the circumstances of the case the restrictive practice imposes an unreasonable restraint on competition.”); In re Ins. Brokerage Antitrust Litig., 618 F.3d 300, 316 & n. 12 (3d Cir.2010) (discussing the fact-bound, burden-shifting standard and noting that “[i]n the event a genuinely disputed issue of fact exists regarding the reasonableness of the restraint, the determination is for the jury”).


We note that the rule of reason allows the court, depending on the circumstances, to structure antitrust litigation so as to avoid, on the one hand, the use of antitrust theories too abbreviated to permit proper analysis, and, on the other, consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic question—that of the presence of significant unjustified anticompetitive consequences. Actavis, 133 S.Ct. at 2238. In addition, nothing in this opinion precludes a defendant from prevailing on a motion to dismiss or motion for summary judgment if, for example, there is no dispute that, under the rule of reason, the procompetitive benefits of a reverse payment outweigh the payment's alleged anticompetitive harm.
IN RE NAMENDA DIRECT PURCHASER ANTITRUST LITIGATION

331 F.Supp.3d 152
United States District Court, S.D. New York.

IN RE NAMENDA DIRECT PURCHASER ANTITRUST LITIGATION

No. 15 Civ. 7488 (CM)
Signed August 2, 2018
Filed August 16, 2018

Synopsis

Background: Direct purchasers of patented immediate release (IR) drug for treating moderate to severe stages of Alzheimer's brought putative class action asserting antitrust claims on behalf of other direct purchasers of IR drug, i.e., pharmacy retailers and pharmacy wholesalers, as well as pharmacy retailers and wholesalers that were direct purchasers of successor patented extended release (XR) drug or purchasers of generic drugs, alleging that patent licensee engaged in unlawful restraint of trade and unlawful maintenance of monopoly power in violation of Sherman Act, by scheming to delay market entry for generic versions of IR drug by entering into collusive reverse-payment settlements of patent litigation against generic drug companies, and by attempting a hard switch introduction of patented XR drug before generic IR drugs entered the market. Defendants filed motions for summary judgment and to exclude opinions and testimony of purchasers' expert witnesses, and purchasers filed motion for class certification.

Holdings: The District Court, McMahon, Chief Judge, held that:

fact issues existed as to whether reverse payment was large and unjustified;

fact issues existed as to causation for antitrust claim concerning hard switch strategy;

class definition could be expanded, to include purchasers of generic drugs;

purchasers of generic drugs had antitrust standing; and

idiosyncrasies of patient preference with respect to switching drugs did not preclude class certification.

Licensee's motion for summary judgment denied; licensee's motion to exclude expert opinions and testimony granted in part and denied in part; purchasers' motion for class certification granted.

Procedural Posture(s): Motion to Certify Class; Motion to Exclude Expert Report or Testimony; Motion for Summary Judgment.

*167 MEMORANDUM DECISION AND ORDER DENYING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT; GRANTING IN SUBSTANTIAL PART AND DENYING IN PART
DEFENDANTS' DAUBERT MOTIONS TO EXCLUDE OPINIONS AND TESTIMONY OF
PLAINTIFFS' EXPERTS; AND GRANTING PLAINTIFFS' MOTION FOR CLASS CERTIFICATION

McMahon, C.J.:

Plaintiffs J.M. Smith Corporation d/b/a Smith Drug Company (“Smith”) and Rochester Drug Co-Operative, Inc. (“RDC”) (collectively, “Direct Purchaser Plaintiffs” or “Plaintiffs”) commenced this antitrust suit on behalf of themselves and a putative class of similarly situated purchasers of Namenda. Plaintiffs allege that Defendants – Actavis PLC (now known as Allergan PLC), Forest Laboratories, LLC, Forest Laboratories, Inc., and Forest Laboratories Holdings Ltd. (collectively, “Forest” or “Defendants”) – schemed to delay entry of generic versions of an Alzheimer's disease treatment by entering into collusive settlements with various generic drug companies and attempting a hard switch in violation of sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2 (2016).

Namenda® (“Namenda”) is a branded drug used to treat moderate to severe stages of Alzheimer's, a neurodegenerative brain disease that causes memory loss, among other symptoms. Forest had a license to market both Namenda IR (immediate release), a twice-daily drug, and Namenda XR (extended release), a once-daily drug, in the United States under U.S. Patent No. 5,061,703 (the “703 Patent”). (Am. Compl. ¶ 2, Dkt. No. 29.)

Plaintiffs allege that Forest engaged in a two-part anticompetitive scheme to improperly block generic competition for Namenda IR by: (1) conspiring with manufacturers of generic versions of Namenda IR to drop their legal challenges to the ’703 Patent and delay launch of generic versions of Namenda IR until an identical date three months after the expiration of the ’703 Patent; and (2) using this improperly obtained period of additional exclusivity to launch the successor branded product, Namenda XR, in order to force the conversion of the market from Namenda IR to the clinically equivalent Namenda XR (hereinafter the “hard switch”) before market entry of the generic versions of Namenda IR. (See id. at ¶ 5.) Here, Plaintiffs allege that Defendants' illegal hard switch strategy included prematurely removing Namenda IR from the market before its patent expiration such that only Namenda XR would be available for purchase in the months before Forest faced generic competition for Namenda IR. Plaintiffs allege Defendants knew that, given the nature of Alzheimer's treatment, once a patient was on Namenda XR, there was a decreased likelihood that the patient would “reverse commute” back to a generic version of Namenda IR after cheaper generic versions of the drug became available.

Presently before the Court are two motions: Defendants' motion for summary judgment on all claims in Direct Purchaser Plaintiffs' First Amended Complaint (Dkt. No. 434) and Plaintiffs' motion to certify this as a class action. (Dkt. No. 400.) For the reasons set forth below, Defendants' motion for summary judgment is DENIED, and Plaintiffs' motion for class certification is GRANTED.

Additionally, Defendants have filed six separate motions to exclude the opinions and proposed testimony of Plaintiffs' experts (see Dkt. Nos. 437, 439, 441, 443, 445, 505), each of which is addressed below.

I. DAUBERT MOTIONS

Before I recount the facts, I must consider exactly what should and should not be part of the record on Defendants' motion for summary judgment. “If the expert testimony is excluded as inadmissible, the court must make the summary judgment determination without that evidence.” Water Pollution Control Auth. of City of Norwalk v. Flowserve US Inc., No. 3:14 Civ. 00549 (VLB), 2018 WL 1525709, at *5 (D. Conn. Mar. 28, 2018).

Defendants have moved to exclude the opinions and proposed testimony of: (1) Janet K. DeLeon (Dkt. No. 437); (2) Professor Einer Elhauge (Dkt. No. 439); (3) Dr. Russell Lamb (Dkt. No. 445); (4) Dr. Ernest Berndt and Dr. Russell Lamb regarding
their use of forecast averages (Dkt. No. 441); (5) John R. Thomas, Esq. (Dkt. No. 505); and (6) George W. Johnston, Esq. (Dkt. No. 443).

The Daubert Standard

“On a summary judgment motion, the district court properly considers only evidence that would be admissible at trial.” *Nora Beverages, Inc. v. Perrier Grp. of Am., Inc.*, 164 F.3d 736, 746 (2d Cir. 1998) (citing *Raskin v. Wyatt Co.*, 125 F.3d 55, 66 (2d Cir. 1997)). Whether expert evidence should be admitted on a motion for summary judgment is a matter committed to the district court's “broad discretion.” *Yurman Design, Inc. v. PAJ, Inc.*, 29 F. App'x 46, 48 (2d Cir. 2002) (internal citation and quotation marks omitted); see also *Nora Beverages, Inc.*, 164 F.3d at 746.

Under Rule 702 of the Federal Rules of Evidence, which codifies the standard for admissibility set forth by *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993), the court's role is to determine whether the "expert" is qualified to testify as an expert. Rule 702 provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

“The proponent of the expert testimony has the burden to establish the [Rule 702] admissibility requirements, with the district court acting as a gatekeeper to ensure that the expert's testimony both rests on a reliable foundation and is relevant to the task at hand.” *Novick v. AXA Network LLC*, 714 F. App'x 22, 25 (2d Cir. 2017) (citing *In re Pfizer Inc. Sec. Litig.*, 819 F.3d 642, 658 (2d Cir. 2016)) (internal citation omitted); see also *United States v. Apple, Inc.*, 791 F.3d 290, 335 n.24 (2d Cir. 2015) (citing *United States v. Williams*, 506 F.3d 151, 160 (2d Cir. 2007)).

Though the Rule “embodies a liberal standard of admissibility,” *Nimely v. City of New York*, 414 F.3d 381, 395 (2d Cir. 2005), “when an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusions reached, Daubert and Rule 702 mandate the exclusion of that unreliable opinion testimony.” *Cedar Petrochemicals, Inc. v. Dongbu Hannong Chem. Co.*, 769 F.Supp.2d 269, 282 (S.D.N.Y. 2011) (internal citations omitted). “In *Daubert*, the *169* United States Supreme Court confirmed that trial courts should serve as sentries, preventing juries from being overwhelmed by unsupportable speculation cloaked as expertise.” *Id.* at 281–82.

Furthermore, the Second Circuit has held that to “warrant admissibility ... it is critical that an expert's analysis be reliable at every step.” *United States v. Morgan*, 675 F. App'x 53, 55 (2d Cir. 2017), cert. denied, — U.S. ——, 138 S.Ct. 176, 199 L.Ed.2d 103 (2017) (internal citation omitted). Of course, “the district court must focus on the principles and methodology employed by the expert, without regard to the conclusions the expert has reached or the district court's belief as to the correctness of those conclusions.” *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 266 (2d Cir. 2002) (internal citation omitted). Nevertheless, as the Supreme Court has recognized,
conclusions and methodology are not entirely distinct from one another ... [N]othing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.


Moreover, “The standard to evaluate non-scientific expert testimony is whether the expert bases testimony upon professional studies or personal experience and employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Louisiana Wholesale Drug Co. v. Sanofi-Aventis*, No. 07 Civ. 7343 (HB), 2008 WL 4580016, at *6 (S.D.N.Y. Oct. 14, 2008) (*citing* Kumho Tire Ltd. v. Carmichael, 526 U.S. 137, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999)).

1. Janet K. DeLeon

Defendants move to exclude the opinions and testimony of Plaintiffs' expert, Janet K. DeLeon. The motion is GRANTED.

Plaintiffs offer Ms. DeLeon as an expert in the process of developing and launching a generic drug. Plaintiffs offer two reports from Ms. DeLeon: (1) an initial report dated September 15, 2017 (Hamburger Decl. Ex. 10, Dkt. No. 438 (“DeLeon Rep.”)); and (2) a supplemental report dated October 23, 2017 (*Id.* at Ex. 11 (“DeLeon Supp. Rep.”)). Ms. DeLeon was asked to answer the following question: whether there were any supply, equipment or manufacturing challenges that would have prevented five generic competitors – Amneal Pharmaceuticals, Dr. Reddy's Laboratories, Inc., Lupin Pharmaceuticals, Inc., Mylan Pharmaceuticals, Inc. (“Mylan”), and Sun Pharmaceutical Industries, Inc. – or Forest itself from launching a generic version of Namenda IR prior to July 2015. (*See* DeLeon Rep. ¶ 6.) Her answer is that there were none. She rests her opinion on “[h]er educational background, [h]er professional experience, [h]er knowledge and understanding of pharmaceutical industry practices, [U.S. Food and Drug Administration (“FDA”)] regulations, guidelines, and enforcement policies, and publicly-available materials such as FDA MAPPs [Manual of Policies and Procedures] and Guidelines.” (*Id.* at ¶ 6).

A. Qualifications

Ms. DeLeon's credentials certainly qualify her to offer an opinion on this question.

She has spent 30 years in the pharmaceutical industry, much of which was spent working on new drug launches, including specifically the launching of generics. She has sat on launch teams for 25 years. She has experience at Aventis as a liaison with external manufacturers of drug products and active ingredients, and she managed several applications to the FDA for approved products. At Beckloff, she helped companies develop new and generic drugs and get approval for them to go to market. Moreover, before starting her own pharmaceutical consultancy, Ms. DeLeon was Associate Director and then Director of Product Development at Cypress Pharmaceutical, Inc. and Hawthorn Pharmaceuticals, Inc. (together “Cypress”) for seven years where she handled at least 12 separate drug launches. (*Id.* at ¶ 6).

Her three decades of experience give her familiarity with both the drug launch process and with impediments to launch – including barriers to entry like supply, new technologies, or need for new equipment. In short, her credentials are impeccable.
In re Namenda Direct Purchaser Antitrust Litigation, 331 F.Supp.3d 152 (2018)
107 Fed. R. Evid. Serv. 215

B. Summary of Ms. DeLeon's Reports

Ms. DeLeon divides her analysis into three sections.

First, she explains, in considerable detail, the process for launching a new generic – a process with which she is intimately familiar – including the relevant regulatory and manufacturing background, and standard pharmaceutical industry practices employed in preparing for the launch of a new drug.

She then evaluates the extensive evidence derived during discovery about each generic's process leading up to the July 2015 launch of its generic Namenda IR. This revealed that each generic had followed precisely the launch process she outlined based on her own experience.

Finally, she opines – “based on her review of the evidence and [her] almost 30 years of pharmaceutical industry experience,” – that nothing would have prevented the generic competitors from doing exactly the same thing as early as 2012. (Id. at ¶ 3.) She writes: “[I]n my opinion, there would have been no supply, equipment, or manufacturing challenges that would have prevented the Generics from launching their respective generic Namenda IR tablet products during that time period.” (Id. at ¶ 23.) She continues, “I have seen no evidence in the record suggesting that Defendants could not have followed the same process and launched an authorized generic concurrently with the five Generics, if the Generics had a launch date any time between June 2012 and July 2015.” (Id. at ¶ 28.)

In reaching her conclusions, Ms. DeLeon stressed that Namenda IR is categorized as a solid oral dose product, which is among the most common pharmaceutical products on the market; that immediate release tablets are among the easiest pharmaceutical products to manufacture; and that the supply of the active ingredient in Namenda IR (memantine hydrochloride) was readily available at all relevant times. (See id. at ¶ 3.)

Plaintiffs asked Ms. DeLeon to draft a supplemental report – in light of her review of additional documents and deposition testimony that became available after her initial report – in which her opinions and conclusions about the generics' and Forest's ability to launch generic Namenda IR in 2012 did not change. (See generally DeLeon Supp. Rep.)

C. Analysis: Motion to Exclude Ms. DeLeon's Reports

Defendants' principal argument is that Ms. DeLeon's conclusions are highly speculative. The Court agrees that her *171 opinion is little more than expert “ipse dixit.” Gen. Elec. Co. v. Joiner, 522 U.S. 136, 145, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997). As discussed below, the problem lies in the way Ms. DeLeon derived her opinion. It adds nothing to the direct evidence that cannot be elicited from fact witnesses – nothing other than the use of Ms. DeLeon's impressive credentials to bolster the credibility of those witnesses impermissibly.

Ms. DeLeon did not review in-house documents or deposition testimony from any of the generics or Forest to support her conclusion that the generics and Forest could have launched Namenda IR in 2012. Instead, she relies solely on her review of documents and testimony regarding the actual product launches by these parties in 2015. Defendants cite to several portions of Ms. DeLeon's deposition testimony in which she admitted as much. (See Hamburger Decl. Ex. 25, Dkt. No. 438 (“DeLeon Dep. Tr.”) at 91:2 – 11; 143:24 – 144:8.)

Of course, Ms. DeLeon has a perfectly sensible and credible explanation for the lack of contemporaneous evidence; she specifically opines that drug companies place a low priority on tasks related to a drug that they cannot manufacture for a few years, so it was no surprise that they did not engage in pre-launch activity three years before they were permitted, by the terms of the settlements, to enter the generic market. (See id. at ¶ 36.)
Lacking the kind of evidence she was able to connect to the 2015 launches, Ms. DeLeon relied on three things in order to reach her conclusion about the lack of barriers to entry in 2012: the companies had been able to effectuate a normal launch, without experiencing any disruption or challenge arising from supply, equipment or manufacturing issues, in July 2015; the companies were all major drug manufacturers with the capacity to have done exactly the same thing in earlier years; and a representative of each generic, testifying pursuant to Fed. R. Civ. P. 30(b)(6), had indicated under oath that his/her employer could in fact have undertaken the launch process for Namenda IR much sooner than it did.

According to Plaintiffs, Ms. DeLeon's conclusions are based on an application of her extensive experience in the pharmaceutical industry to the facts presented. However, Ms. DeLeon's experience is no substitute for "scientifically sound analysis." United States v. Apple Inc., 952 F.Supp.2d 638, 694 (S.D.N.Y. 2013), aff'd, 791 F.3d 290 (2d Cir. 2015).

Ms. DeLeon could have obtained data, from the generics or elsewhere, about matters that might have impacted the generics' ability to enter the market earlier: matters like whether there were any problems with the supply of drug ingredients in earlier years; whether there were equipment failures or manufacturing issues at any of the generics in 2011-12 (issues that apparently did not exist in 2014-15); whether the manufacturing capacity at those companies was already being used to manufacture other drugs such that it could not readily have been converted to Namenda at that time; and about whether Namenda IR would have been prioritized over those other drugs had there been a business reason to consider diverting manufacturing capacity to Namenda during earlier years.

Had Ms. DeLeon reviewed data of the above sort, and concluded, based on her substantial experience, that the generics (or some of them) could have launched as much as three years earlier, it would certainly have been within her expertise to so opine. But simply saying, “They could do it in 2015, so they could have done it in 2012,” without any analysis of the market and corporate conditions that might have impacted the generics' ability to launch generic Namenda in 2012, is a conclusion tethered to nothing whatever. This Court must exclude “unsupported speculation cloaked as expertise.” Cedar Petrochemicals, Inc. v. Dongbu Hannong Chem. Co., 769 F.Supp.2d 269, 281–82 (S.D.N.Y. 2011).

To the extent that Plaintiffs point to the testimony of the generics' 30(b)(6) witnesses – all of whom testified that they could have launched generic Namenda as early as 2013 (not 2012) – to undergird Ms. DeLeon's opinion, their reliance exposes another problem with Ms. DeLeon's proposed testimony. Those fact witnesses can be called to testify at trial. They can repeat their testimony that then respective employers could have entered the generic Namenda market earlier but for the settlement of the patent suit. And they can offer an explanation, grounded in the actual circumstances facing each individual generic, about why that was so. Plaintiffs can then argue that the patent settlements were anticompetitive, and the trier of fact can accept or reject that argument after evaluating the credibility of these witnesses.

"[T]he amended Rules of Evidence require that expert testimony be based on ‘sufficient facts or data’ and on ‘reliable principles and methods’ that the expert ‘witness has applied reliably to the facts of the case.’ ” United States v. Dukagjini, 326 F.3d 45, 54 (2d Cir. 2003) (citing Fed. R. Evid. 702). Here, the only thing that Ms. DeLeon's “expert” opinion does is bolster the credibility of the 30(b)(6) witnesses – misleading the trier of fact into thinking that, if an “expert” like Ms. DeLeon accepts the testimony of the 30(b)(6) witnesses, so should it. That is not the province of an expert; indeed, it is an arrogation of the function of the trier of fact. See Amorgianos v. Nat'l R.R. Passenger Corp., 303 F.3d 256, 266 (2d Cir. 2002). While Ms. DeLeon's experience might make her capable of assessing Defendants' adherence to “standard pharmaceutical industry practice,” that experience does not transform her into an oracle. (DeLeon Dep. Tr. at 109:1 – 4.) Her opinions and testimony are inadmissible and will not be considered on the motion for summary judgment.
2. Professor Einer Elhauge

Defendants move to exclude the opinions and testimony of Plaintiffs' expert, Professor Einer Elhauge, who opines in support of Plaintiffs' theory that the reverse payment from Forest to Mylan delayed generic entry. In the professor's opinion, without a reverse payment to generic competitors, the generic competitors would have entered the market on November 2, 2012, approximately 26.3 months earlier than they did.

Plaintiffs offer Revised Expert Report of Professor Einer Elhauge dated September 20, 2017 (Hamburger Decl. Ex. 1, Dkt. No. 438 ("Elhauge Rep.").) Plaintiffs retained Professor Elhauge to address, among other things, what economic analysis reveals about Forest and Mylan's settlement of the Namenda IR patent litigation. He was asked to opine on: (a) whether an alleged reverse payment from Forest to Mylan delayed generic entry into the market; (b) what the settlement entry date would have been in a no-payment settlement; (c) whether a reverse payment was reasonably necessary and the least restrictive means to achieve a settlement between Forest and Mylan; and (d) whether there were any procompetitive justifications for the reverse payment. (See Elhauge Rep. ¶ 1.) Professor Elhauge was asked to model a but-for world “with no payment.” (Hamburger Decl. Ex. 14, Dkt. No. 438 (“Elhauge Dep. Tr”) at 80:11 – 17.)

*173 A. Qualifications

Professor Elhauge is the Petrie Professor of Law at Harvard Law School, where he teaches and writes about the economic analysis of antitrust law, health policy, and various other subjects. (See Elhauge Rep. ¶ 3.) He has authored and co-authored several leading antitrust casebooks, and written articles on monopolization, bundled discounts, loyalty discounts, and reverse-payment settlements. (See id.) Professor Elhauge has served as an expert on antitrust economics before Congress, arbitration panels, and foreign competition agencies. He has also testified as an expert witness on antitrust economics in dozens of federal cases. (See id. at ¶ 4.)

B. Summary of Professor Elhauge's Reports

Professor Elhauge begins by summarizing the settlement agreement, signed on July 21, 2010, between Forest and Mylan, which resulted in Mylan dropping its challenge to the Namenda IR patent. (See Elhauge Rep. ¶¶ 6 – 11.) He then estimates the parties' actual bargaining strength based on the settlement terms. (See id. at ¶¶ 28 – 33.) He uses this estimate – along with other factors, such as the two companies' profit projections and their expectations regarding the pending patent litigation – to predict what the generic entry date would have been in a no-payment settlement. (See id.) Finally, Professor Elhauge considers how sensitive his analysis is to changes in the estimates of each parties' strengths (e.g., patent strength, litigation costs, litigation end date, etc.). (See id. at ¶¶ 33 – 54.) He concludes that his finding – that the reverse payment caused a significant delay in entry of generic memantine hydrochloride into the market – is robust enough to hold true even given changes to these estimates. Finally, he posits that Defendants' risk aversion could not have justified the reverse payment. (See id. at ¶¶ 56 – 58.)

C. Analysis: Motion to Exclude Professor Elhauge's Reports

Defendants move to exclude the reports and testimony of Professor Elhauge's on three grounds.

First, Defendants argue that Professor Elhauge's opinions are at odds with the Supreme Court's decision in F.T.C. v. Actavis, Inc., 570 U.S. 136, 133 S.Ct. 2223, 186 L.Ed.2d 343 (2013), because Professor Elhauge presumes that any payment from a patentee to a prospective generic, regardless of its size or the reasons for making it, causes anticompetitive delay. That, however, is a mischaracterization of Professor Elhauge's analysis.
In re Namenda Direct Purchaser Antitrust Litigation, 331 F.Supp.3d 152 (2018)

The Supreme Court in *Actavis* specifically declined to hold that “reverse payment settlement agreements are presumptively unlawful.” *Actavis*, 570 U.S. at 158, 133 S.Ct. 2223. It instructed courts reviewing such agreements to proceed by applying a “rule of reason” analysis to reverse payment agreements. *Id.* at 159, 133 S.Ct. 2223. Under this analysis, courts have to assess the payment’s “size, its scale in relation to the payor’s anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.” *Id.* at 159, 133 S.Ct. 2223. Thus, only those reverse payments that are “‘large and unjustified’” violate the antitrust laws. *Sergeants Benevolent Ass’n Health & Welfare Fund v. Acta Vis, PLC*, No. 15 Civ. 6549 (CM), 2016 WL 4992690, at *13 (S.D.N.Y. Sept. 13, 2016) (quoting *Actavis*, 570 U.S. at 158, 133 S.Ct. 2223).

As an initial matter, Professor Elhauge explains in his report that “a reverse payment is large enough to anticompetitively delay entry whenever the payment amount exceeds the litigation costs the patent holder avoided by settling.” (Elhauge Rep. ¶ 42.) He determines that the reverse payment from Forest to Mylan, which he estimates to be $30.9 million, was large enough to exceed Forest’s avoided litigation costs (an estimated $3.5 million) and was thus potentially anticompetitive. *(Id.* at ¶ 11, 20.) Only after determining that the payment exceeded avoided litigation costs did Professor Elhauge proceed to use economic analysis to assess the degree of delay the reverse payment caused. This approach is fully consistent with *Actavis*.

Next, Defendants argue that Professor Elhauge's opinions are speculative, internally inconsistent, and contradicted by the evidence. The Court will not waste time on this, except to say that this part of their *Daubert* motion, “like so many such motions, is nothing more than a ‘we do not agree with his opinion so it is junk science’ motion, of the sort that causes this and many judges to view all *Daubert* motions with a certain degree of skepticism.” Bank of New York Mellon Tr. Co., Nat’l Ass’n for Registered Certificate Holders of Morgan Stanley Capital I Inc. v. Morgan Stanley Mortg. Capital, Inc., No. 11 Civ. 505 (CM), 2017 WL 733225, at *1 (S.D.N.Y. Feb. 10, 2017). Here, Defendants' disagreements with Plaintiffs' expert are appropriate subjects for cross-examination.

Lastly, Defendants argue that Professor Elhauge's opinions about when entry “would have” occurred improperly attempt to usurp the role of the jury. Defendants cite to *United Food and Commercial Workers Local 1776 & Participating Employers Health and Welfare Fund v. Teikoku Pharma USA*, 296 F.Supp.3d 1142, 1149 (N.D. Cal. 2017) (hereinafter “*Lidoderm*”), in support. In that case, which also involved an alleged reverse payment settlement, Professor Elhauge similarly opined in support of plaintiffs' alternate causation theory that in the hypothetical but-for world, even without a reverse payment, the defendants would have agreed to a settlement allowing a competitor into the market a year earlier than they did. The defendants in *Lidoderm* moved to exclude Professor Elhauge's economic model and but-for conclusions as unsound, difficult to understand, and not transparent. The court granted the motion in part, holding that “Elhauge may opine that in his view the parties would have been rationally motivated to agree to settlement allowing [a competitor] early entry by specific dates.” *Id.* at 1149. The court then held that Elhauge could not “testify that the parties would have agreed to entry on a date certain, as that impinges on a determination left up to the jury.” *Id.* So too here.

Professor Elhauge must qualify his opinions by testifying that “it would have been economically rational for both parties” to enter into a no-payment settlement in a but-for world by specific dates, not that they necessarily *would have*. (Opper Decl. Ex. 2, Dkt. No. 421 (“Elhauge Dep. Tr. II”) at 225:18-227:18.) That ultimate issue is for the trier of fact to decide.

With that modification, Defendants' motion is DENIED.

3. Dr. Russell Lamb
Defendants move to exclude the opinions and testimony of Plaintiffs' expert, Dr. Russell Lamb, who opines on class certification and damages caused by Defendants' alleged anticompetitive conduct.


Dr. Lamb, an economist, was asked to analyze (1) whether the delay in generic entry impacted prices paid by proposed class members; (2) whether Defendants' allegedly unlawful hard switch impacted prices paid by proposed class members; (3) whether it is possible to establish, using economic analyses and evidence common to the proposed class as a whole, rather than specific to individual members, that proposed class members were injured by Defendants' alleged anticompetitive conduct under two separate but-for worlds (as described below); and (4) the amount of aggregate damages suffered by proposed class members as a result of the alleged misconduct under the two separate but-for worlds. (See Lamb Rep. ¶ 5.)

For the purposes of his report, Dr. Lamb conducted economic research on the market and prices paid for memantine hydrochloride by members of the proposed class and reviewed transaction-level data produced by Forest and several generic manufacturers. He also reviewed documents produced by various parties in this matter (including documents, expert reports and testimony from the previous action brought by the New York Attorney General), documents or filings presented before the FDA, as well as a variety of publicly-available documents including trade press and academic literature. (Id. at ¶ 12.)

**A. Qualifications**

Dr. Lamb, an expert in antitrust economics, has testified in U.S. district court on matters concerning antitrust liability, impact, and damages. For more than 20 years, Dr. Lamb has consulted on the economics of markets and prices. (Id. at ¶ 2.) Courts have relied upon his economic analyses of the market in certifying classes of direct purchasers and indirect purchasers in litigations involving allegations of anticompetitive conduct. (Id. at ¶ 3.) Additionally, he has been hired as an economic consultant to the World Bank and the Government of Peru, and has assisted on various economic consulting projects for private firms, government agencies, and law firms. (Id.)

He is the President of an economic consulting firm known as Monument Economics Group, based in Arlington, Virginia. The firm provides economic research and quantitative and statistical analysis to clients in the United States, Canada, and elsewhere internationally. (Id. at ¶ 1.) He also currently teaches “Law and Economics” at The George Washington University. (Id.)

**B. Summary of Dr. Russell Lamb's Reports**

Dr. Lamb's reports describe, in part, the relevant pharmaceutical regulatory framework, competitive effects of generic entry, background on the memantine hydrochloride market, and an analysis of the proposed class members. He emphasizes that “By September 2015, three months after generic entry, Forest had lost 89.9[%] of Namenda IR sales to generic manufacturers” who were selling the drug at about a 95% price discount. (Lamb Rep. ¶ 81 – 82.) He notes that the “rapid substitution of generic memantine hydrochloride for branded Namenda IR, is consistent with the literature describing the effects of generic entry on prices and sales in pharmaceutical markets.” (Id. at ¶ 83.)

By way of example, Dr. Lamb suggests that, as a result, proposed class members “who purchased Namenda IR at a price of $0.58 per tablet in July 2015, would have purchased the generic at a price below $0.58 in July 2015 had generic competition started in 2012, rather than July 2015, because had generic competition started in 2012, the decline in generic prices that actually occurred after July 2015 would have occurred much earlier.” (Id. at ¶ 85.)
Dr. Lamb analyzes “two but-for scenarios that Plaintiffs allege would have occurred in a world free of the Defendants' alleged misconduct” – a No Reverse Payment But-For World and a No Hard Switch But-For World. (Lamb Rep. ¶ 7.)

**No Reverse Payment But-For World.** Under the first scenario, Dr. Lamb considers damages arising from Forest's alleged reverse payment to Mylan (the “No Reverse Payment But-For World”). He assumes that had “Defendants not entered into an allegedly illegal agreement with Mylan, they still would have settled, but without a large reverse payment and with an entry date [in 2012] (rather than in 2015 as provided for in their ... agreement).” (Id. at ¶ 8.) Using an economic model, Dr. Lamb compares the actual price purchasers paid for memantine hydrochloride to the prices that would have prevailed but for Defendants' conduct, and compares the actual volumes of brand Namenda purchased to the volumes of Namenda that would have been purchased but for Defendants' conduct. (Id. at ¶ 127 – 42.)

He concludes that “all or nearly all proposed [c]lass members were impacted by Defendants' allegedly anticompetitive agreement with Mylan, assuming that generic entry was delayed and would have occurred earlier otherwise, in that they paid higher prices for brand-name Namenda IR, Namenda XR, and/or generic memantine hydrochloride than they otherwise would have had generic competition started sooner, because they would have purchased (or purchased more) generic memantine hydrochloride at prices below branded Namenda and would have purchased the generic at lower prices.” (Id. at ¶ 13(a).)

**No Hard Switch But-For World.** Under the second scenario, Dr. Lamb considers damages suffered by direct purchasers of Namenda products arising solely from Forest's announcement of a hard switch from Namenda IR to Namenda XR (the “No Hard Switch But-For World”). To confirm his hypothesis that Forest's February 2014 discontinuation announcement had an impact on the market, Dr. Lamb conducted a statistical analysis called a “structural break test” to analyze conversion to Namenda XR using market share data from NSP. (See id. at ¶ 119.) He concludes that “there is a structural break in the Namenda XR conversion rate at the time the Hard Switch strategy was implemented beginning in February 2014,” (id.), which illustrates that the hard switch was effective in converting more Namenda IR prescriptions to Namenda XR than otherwise would have been the case. He goes on to analyze the case in which Defendants did not engage in their hard switch strategy (never announced that they would remove Namenda IR from the market) and no generic entry occurred prior to the actual date at which AB-rated generics for Namenda IR became available (i.e., July 2015).

*177* He concludes that “all or nearly all proposed [c]lass members who purchased at least Namenda IR and XR, or XR, were impacted by Defendants' anticompetitive [h]ard [s]witch strategy in that they paid higher prices for Namenda XR than they otherwise would have for generic memantine hydrochloride, and they would have purchased the less expensive generic (or more of it) in place of the more expensive branded Namenda.” (Id. at ¶ 13(b).)

For purposes of class certification, Dr. Lamb finds that aggregate overcharge damages can be proven through classwide economic models using formulas and methodologies that do not require individualized analysis. (Id. at ¶ 121–61.) Where available, he uses transaction-level data produced by Forest and some of the generic manufacturers to calculate damages. He calculates the “aggregate, class-wide damages arising from Defendants' alleged misconduct under the two separate but-for worlds.” (Id. at ¶ 13.) He estimates that “Total damages suffered by Proposed Class members are between $6.09 billion and $6.93 billion under the No-Reverse Payment But-For World, and between $776 million and $814 million under the No Hard Switch But-For World.” (Id.)

**C. Analysis: Motion to Exclude Dr. Lamb's Reports**

An antitrust claim has three elements: (1) a violation of antitrust law; (2) injury and causation; and (3) damages. *In re Visa Check/MasterMoney Antitrust Litig.*, 280 F.3d 124, 136 (2d Cir. 2001). This portion of Defendants' motion centers on proof of the second element of an antitrust claim – commonly referred to as “antitrust injury” – which requires “an antitrust plaintiff [to] prove that its injury was, in fact, caused by the defendant's violation of the antitrust laws.” *US Airways, Inc. v. Sabre Holdings*
In re Namenda Direct Purchaser Antitrust Litigation, 331 F.Supp.3d 152 (2018)

107 Fed. R. Evid. Serv. 215

Corp., No. 11 Civ. 2725 (LGS), 2017 WL 1064709, at *16 (S.D.N.Y. Mar. 21, 2017) (quoting U.S. Football League v. NFL, 842 F.2d 1335, 1377 (2d Cir. 1988)).

Defendants move to exclude the reports and testimony of Dr. Lamb on three grounds.

First, Defendants argue that Dr. Lamb's structural break test does not prove antitrust injury. Defendants claim that Dr. Lamb's test fails because it utilizes market-wide data rather than purchaser-specific information, which approach fails to isolate and measure those patients who switched from Namenda IR to XR because of the February 2014 announcement from those patients who switched for other reasons. Stated otherwise, Defendants claim that Dr. Lamb's analysis understates the degree to which Namenda XR could have captured the market even without the hard switch strategy.

This argument is unpersuasive.

Dr. Lamb's conclusion that the hard switch announcement increased conversion to Namenda XR was based on a number of observations that are consistent with Plaintiffs' allegations. Plaintiffs allege “that as a result of Forest's dissatisfaction with the extent of conversion to Namenda XR for several months after its launch, Forest began to consider an option where it would discontinue or dramatically restrict the supply of Namenda IR several months before the availability of generic memantine hydrochloride in order to accomplish a ‘forced switch’ whereby physicians and patients would have little choice but to switch to Namenda XR.” (Id. at ¶ 89.) In support of this theory, Dr. Lamb reviewed Forest's internal documents and forecasts confirming the company's formation and implementation of their strategy to reduce the level of competition from generic memantine hydrochloride products. *178 (See id. at ¶ 95.) Dr. Lamb relied on forecasts that contained both a “withdrawal” (or “hard switch”) scenario and a “conventional” (or “soft switch”) scenario, as well as internal high-level discussions of and reliance upon these forecasts to reach conclusions about what the conversion rate of Namenda IR to XR would have been absent initiation of the hard switch strategy. For example, Figure 6 entitled Forest Namenda Forecasts, is a copy of Forest's soft switch and hard switch projections which show that Namenda XR's share of the memantine hydrochloride market would be significantly higher under the hard switch strategy versus the soft switch strategy. (Id.) Dr. Lamb also notes that:

In a May 2013 speech concerning the launch of Namenda XR, Mark Devlin of Forest stated: ‘[T]he core of our brand strategy with XR is to convert our existing IR business to Namenda XR as fast as we can and also gain new starts for Namenda XR. We need to transition volume to XR to protect our Namenda revenue from generic penetration in 2015 when we lose IR patent exclusivity.’ Mr. Devlin added that the ‘better job we do moving business form IR to XR, the more Forest revenue we hopefully shelter from generic threats down the road,’

(Id. at ¶ 94.)

Furthermore, the evidence includes sworn statements from doctors stating that they stopped prescribing Namenda IR after the hard switch announcement. (See id. at ¶ 104.) Dr. Lamb concludes that the evidence demonstrates that Forest's intention to withdraw Namenda IR was to trigger wide-spread conversion to Namenda XR and that the February announcement was successful in starting to do so.

To confirm his hypothesis, Dr. Lamb conducted a regression analysis called a “structural break test” showing that Forest's implementation of its hard switch strategy would impact the market by increasing conversion to Namenda XR. He used actual sales data from IMS National Sales Perspectives (“NSP”). He concludes that “there is a structural break in the Namenda XR conversion rate at the time the Hard Switch strategy was implemented beginning in February 2014,” (id. at ¶ 119), which illustrates that the hard switch was effective in converting more Namenda IR prescriptions to Namenda XR than otherwise would have been the case.
Defendants’ complain that Dr. Lamb's structural break test fails because it does not isolate the cause of the February 2014 break. However, Dr. Lamb testified that the test was not designed to do so. He testified that “[the test] is not able to tease out where the source of the structural break comes from by itself. One has to implement it because one believes that there is some event which leads to a structural break... I had reason to believe that the hard switch strategy which began somewhat before February ’14 and which included the announcement... would have an effect at that point. And that's why I chose that date.” (Hamburger Decl. Ex. 19, Dkt. No. 438 (“Lamb Dep. Tr. I”) at 96:2 – 19.)

In other words, Dr. Lamb's test demonstrates that there was a “structural break” in February 2014, which happened to be the date when the hard switch was announced. Correlation does not prove causation, but the coincidence in timing between the announcement and the structural break shown by the data is some evidence of causation in support of Plaintiffs' theory. Perhaps other things were happening in the market in February 2014, and Forest may go into them to undercut Dr. Lamb's data. Taken together with the other evidence analyzed by Dr. Lamb, the *179 regression is designed to confirm a hypothesis that is itself based on other indicia. For the purposes of Daubert, Dr. Lamb's analysis passes muster. “At most, [Forest's] arguments concerning the assumptions in [Dr. Lamb’s] analysis go to its weight, not admissibility of that testimony.” Dial Corp. v. News Corp., No. 13 Civ. 6802, 2016 WL 690868, at *4 (S.D.N.Y. Feb. 17, 2016).

Moreover, contrary to Defendants' argument, a plaintiff is only required to show that alleged illegal conduct is “a material cause of the [antitrust] injury; a plaintiff need not exhaust all possible alternative sources of injury in fulfilling his burden of proving compensable injury.” Id. (quoting Zenith Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100, 114 n.9, 89 S.Ct. 1562, 23 L.Ed.2d 129 (1969) ) (emphasis added). “[T]o prove a ‘causal connection’ between the defendant's unlawful conduct and the plaintiff's injury, the plaintiff need only ‘demonstrate that [the defendant's] conduct was a substantial or materially contributing factor’ in producing that injury.” In re Publ’n Paper Antitrust Litig., 690 F.3d 51, 66 (2d Cir. 2012) (quoting Litton Sys., Inc. v. AT & T Co., 700 F.2d 785, 823 n.49 (2d Cir. 1983) ). Second Circuit precedent makes clear that in order to prove causation:

[P]laintiffs do not have to prove that the unlawful activity that the defendants allegedly engaged in was the sole cause of their injuries. Plaintiffs meet their burden if they show that the defendants' unlawful facts substantially contributed to their injuries, even though other facts may have contributed significantly. An antitrust plaintiff is not required to show that the defendants’ acts were a greater cause of the injury than other factors. Plaintiffs need only show that their injury to some degree resulted from defendants' violation.

NFL, 842 F.2d at 1377 (emphasis in original).

Second, Defendants argue that Dr. Lamb improperly expanded the time period of alleged injury to include data from before the February 2014 Namenda IR discontinuation announcement and after the injunction on Namenda XR conversion.

Specifically, Defendants claim that his methodology improperly includes alleged injury from before the February 2014 announcement, in violation of this Court's earlier conclusion about the proper damages period. See Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, PLC, Nos. 15 Civ. 6549, 15 Civ. 7488, 2016 WL 4992690, at *11 (S.D.N.Y. Sept. 13, 2016) (“According to the Second Circuit: The hard switch began on February 14, 2014 with the announcement of Defendants' intention to withdraw Namenda IR and was suspended in September 2014 when Defendants agreed to a “standstill” during the litigation proceedings.”) (internal citation omitted.) In his report, Dr. Lamb cites documents demonstrating that, before the February 2014 announcement, Forest had already begun discussed its hard switch plan outside the company. (See Lamb Rep. ¶¶ 89, 102.)
Plaintiffs argue that Dr. Lamb included discussion of pre-February 2014 conduct in order to undercut Forest's theory – that increased conversion to Namenda XR after February 2014 was the result of better formulary placement for XR rather than the hard switch. (Lamb Reply Rep. ¶ 51; see also Lamb Rep. ¶¶ 89, 102; Berndt Rep. ¶ 56; Berndt Reply Rep. ¶ 29; PRSoF ¶ 373; PASoF ¶ 67 (collecting evidence of Forest's leveraging of withdrawal plan to achieve better formulary placement).) These opinions are admissible. Defendants' difference of opinion is fair ground for cross examination. Likewise are Dr. Lamb's opinions about any lasting impact *180 the anticompetitive conduct had post-injunction.

Lastly, Defendants argue that the flaws in Dr. Lamb's “No Hard Switch” methodology make his No Reverse Payment methodology unreliable as well. For the reasons discussed above, this argument is without merit.

Defendants' motion is DENIED.

**4. Forecast Averages from Dr. Russell Lamb and Dr. Ernst Berndt**

Defendants move to exclude the opinions and testimony of Plaintiffs' experts, Dr. Russell Lamb and Dr. Ernst Berndt, regarding their use of forecast averages in their respective analyses. This motion is DENIED.

Dr. Berndt, a Professor in Applied Economics at the Sloan School of Management at the Massachusetts Institute of Technology, submitted: (1) an initial report dated September 15, 2017 (Hamburger Decl. Ex. 7, Dkt. No. 438 (“Berndt Rep.”)); (2) a reply expert report dated October 25, 2017 (Id. at Ex. 8 (“Berndt Reply Rep.”)); and an amended reply expert report dated November 8, 2017 (Id. at Ex. 9 (“Berndt Am. Reply. Rep.”)). In his initial report, Dr. Berndt opines on (1) “whether it is reasonable as a matter of economics to conduct a damages analysis of the impact of Forest's announcement and conduct of a 'hard switch' marketing campaign ... based upon use of relevant Forest projections and forecasts” and if so, (2) “what objectively reasonable expected market share Namenda XR would have had if there had been no Hard Switch announcement and marketing campaign (as shown by Forest's reasonable forecasts).” (See Berndt Rep. ¶ 6.)

In his report, Dr. Lamb relies on Dr. Berndt's “opinion that these forecasts of the Namenda XR conversion rate are a reliable basis for an analysis of the incremental effect of the Hard Switch on the conversion from branded Namenda IR to branded Namenda XR.” (Lamb Rep. ¶ 144.) Thus, Dr. Lamb factored Forest's forecasts into his damages analysis. Specifically, based on Forest's predictions of Namenda XR conversion absent the hard switch, he concluded that the “Namenda XR conversion rate would rate 30 percent in 18 months after Namenda XR entered the market absent the Hard Switch.” (Id. at ¶ 150.) For purposes of his damages calculation, “The difference between the actual and but for Namenda XR conversion rates, multiplied by total market DOT [days of therapy] times the generic penetration rate, yields the amount of branded XR purchases that would have been generic Namenda IR purchases but for the Hard Switch. This volume multiplied by the difference in price between branded Namenda XR and generic Namenda IR then yields the amount of overcharges to the Hard Switch.” (Id. at ¶ 13.)

**A. Analysis: Motion to Exclude Dr. Berndt's and Dr. Lamb's Forecast Averages**

Defendants' principal complaint is that the experts blindly adopt certain of Forest's forecasts without first scrutinizing them. However, a substantial portion of Dr. Lamb's report and the entirety of Dr. Berndt's report are dedicated to analyzing and evaluating Forest's forecasts for reliability. *181 That hardly renders their conclusions inadmissible.

Defendants advance three reasons why this testimony should not be admitted.
First, Defendants argue that Dr. Berndt and Dr. Lamb did not perform any economic analysis to determine what the conversion rate would have been in the but-for world.

Second, Defendants argue that neither of the doctors applied any expert methodology to average forecasts or to select which forecasts to include in their averages, and that as a result both doctors haphazardly selected forecasts for their averages.

Third, Defendants argue that neither doctor tested the forecasts to determine their reliability.

None of these arguments holds water.

In his report, Dr. Berndt undertook a robust analysis of the process by which Forest came to its forecasts and expectations for the conversion rate between Namenda IR and Namenda XR under a soft switch and a hard switch scenario. He closely studied the inputs into Forest's analysis, analyzed the evolution over time of that analysis, and Forest's internal and external use and reliance upon that analysis. In particular, Dr. Berndt considered that Forest had been in the market for many years, was very familiar with the dynamics between physicians, caregivers, patients, and the various health care entities involved in the treatment of Alzheimer's patients. (Berndt Rep. ¶ 40.)

Dr. Berndt considered that Forest had done a searching analysis of analogous situations in which pharmaceutical manufacturers had brought an extended release product into a market in which that company already had an immediate release product. (Id. at ¶ 41.)

Dr. Berndt considered that Forest surveyed physicians, caregivers, pharmacists and health care entities about the Namenda XR launch and conversion. (Id. at ¶ 26.)

Dr. Berndt considered that Forest specifically factored in the impact of a cost-conscious and critical segment of the market for Namenda Alzheimer's patients, Long Term Care. (Id. at ¶ 28.) Dr. Berndt considered that Forest's analysis evolved over time, including with the assistance of actual sales data after Namenda XR launched. (Id. at ¶ 51–55.)

Dr. Berndt also considered that Forest's executives valued these analyses as reliable and accurate as they used them when communicating their expectations about Namenda XR share in the soft switch scenario internally (including to Forest's Board of Directors) and externally to the investing community. (Id. at ¶ 32–38, 48–50.)

Thus, Dr. Berndt did not just assume, as Defendants argue, that Forest's estimates of a 30% conversion in a "soft switch" scenario were reliable (as found by Judge Sweet and adopted for purposes of the motion to dismiss by me). (See Dkt. No. 253 at 24 – 25 (citing New York v. Actavis, PLC (Namenda I ), No. 14 Civ. 7473, 2014 WL 7015198, at *28, 40–41 (S.D.N.Y. Dec. 11, 2014) ). Instead, Dr. Berndt applied his scholarship, knowledge, and experience from his many decades of studying the pharmaceutical industry. He analyzed the work that Forest put into its forecasting, as well as the extent to which Forest relied upon those forecasts in making business decisions and communicating with the investor community. He endeavored to determine that the forecasting effort was robust and reliable.

Dr. Berndt concludes that "the [internal] forecasts reviewed by Dr. Lamb [were] reliable," as they were based on Forest's own study of the Namenda market and *182* analogous experiences of other drugs. (Id. at ¶ 40; see also Berndt Reply Rep. ¶¶ 4 – 20.) He further concludes that "[t]he appropriate ‘but for’ analysis in this case is one in which Forest makes no hard switch announcement of any kind, executes no communications campaign of any kind aimed at alerting patients ... and others of the impending withdrawal of Namenda IR, and makes no other effort of any kind to implement the hard switch.” (Berndt Rep. ¶ 69.)
Likewise, Dr. Lamb independently reviewed and analyzed Forest's internal document and testimony regarding the soft-switch conversion rate. He did not blindly adopt Dr. Berndt's analysis. He factored in the fact that, "Forest used various analogues of drug franchises that had experienced conversion from an immediate release to an extended release product when forecasting the conversion rate from Namenda IR to XR." (Id. at ¶ 151.) He noted that Forest updated the Namenda XR conversion forecasts regularly, sometimes creating multiple forecasts in a few weeks. (See id.) Using the forecast documents that were created after Namenda XR had entered the market and before the hard switch was implemented, Dr. Lamb averaged the forecasted soft switch Namenda IR to XR conversion rate for November 2014, 18 months after Namenda XR entered the market, and found the but-for conversion rate to be approximately 30 percent. (Id. at ¶ 152; see also id. at Tbl. 3.) Contrary to Defendants' argument, Dr. Lamb did not “cherry-pick.” He averaged multiple iterations of Forest's forecasts and came up with a 30% conversion rate. He then confirmed this number was reasonable based on its specific use in numerous company presentations, statements by company executives on earnings calls, and testimony by these executives. (See id. at ¶ 154.)

The use of Defendants' own forecasts to model a but-for world has been held to be a sound economic methodology. Indeed, it is commonly used in courts considering generic delay damages. See, e.g., King Drug Co. of Florence, Inc. v. Cephalon, Inc., 309 F.R.D. 195, 212 (E.D. Pa. 2015), rev’d and remanded on other grounds, In re Modafinil Antitrust Litig., 837 F.3d 238 (3d Cir. 2016). Defendants may not hide behind the fact that forecasts are predictions, and by their very nature incorporate some uncertainty – particularly given the controlling legal rule that a defendant may not benefit from any uncertainty concerning damages its own wrongful conduct has caused.

Defendants' complaint that Drs. Berndt and Lamb did not consider all forecasts from the relevant period before the hard switch conduct is of no moment to the admissibility of their testimony. This is a matter for cross-examination. If Forest contends that important forecasts were omitted from the experts' analysis, it can introduce them at trial.

The motion is DENIED.

5. Professor John R. Thomas, Esq.

Defendants move to exclude the opinions and testimony of Plaintiffs' expert, Professor John R. Thomas, Esq. Plaintiffs substituted Professor Thomas in place of their proposed expert, Deborah Jaskot, after this Court granted Teva Pharmaceutical USA, Inc.'s nonparty motion to disqualify Ms. Jaskot from serving as Plaintiffs' regulatory expert due to her conflicts as a former Teva executive. (See Dkt. No. 355.)

Plaintiffs offer a report from Professor Thomas dated November 14, 2017 (Johnson Decl. Ex. 1, Dkt. No. 506 (Expert Report of Professor John R. Thomas, Esq. (“Thomas Rep.”) )- Professor Thomas to (1) provide testimony concerning the Drug Price Competition Act and Patent Term Restoration Act (the "Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585, “and its ‘grand bargain’ between the competing interests of promoting the innovation of new drugs and promoting competition from generic drugs;” (2) “determine whether there would be any impediments to certain generic drug companies obtaining final approval from [the] FDA to sell their generic versions of Namenda at any point from April 17, 2011 through July 11, 2015;” and (3) “determine whether there would have been any impediments to Forest obtaining approval from [the] FDA to market an authorized generic version of Namenda from April 17, 2011 through July 11, 2015.” (Thomas Rep. ¶¶ 3 – 5.)

A. Qualifications

Professor Thomas has taught courses on the Hatch-Waxman Act at Georgetown Law School since 2002, has written a textbook concerning the Hatch-Waxman Act, patent law, and pharmaceutical drugs, and has been qualified to opine on AND As in district court before. See, e.g., Apotex, Inc. v. Cephalon, Inc., 06 Civ. 02768, 2011 U.S. Dist. LEXIS 154863 (E.D. Pa. Mar.
B. Summary of Professor John R. Thomas, Esq.'s Report
Professor Thomas divides his analysis into three sections.

First, he discusses the relevant regulatory background regarding drug approval under the Hatch-Waxman Act, including the FDA approval process for brand name and generic drugs generally, the FDA's orange book listing of approved drug products, along with the various marketing exclusivities made available by the Act.

Second, Professor Thomas gives background on the FDA approval of branded and generic Namenda, including the various generic challenges to Forest's Namenda patent, Forest's settlement of these challenges, and the generics' respective approval and launch timelines.

Third, Professor Thomas opines that based on his analysis of the available data, there were no regulatory impediments to the five generics seeking and obtaining final approval for their generic versions of Namenda on or after April 17, 2011.

C. Analysis: Motion to Exclude Professor John R. Thomas, Esq.'s Reports
Defendants move to exclude the reports and testimony of Professor Thomas on three grounds.

First, Defendants call certain portions of Professor Thomas's opinion irrelevant and prejudicial. For example, the professor writes, “When competitors within the pharmaceutical industry ... choose to bypass or subvert the legislative framework, they potentially engage in strategic behavior that defies the policy goals embodied in the Hatch-Waxman Act.” (Thomas Rep. ¶ 30.) They argue that Professor *184 Thomas implies that all Hatch-Waxman patent settlements are “suspect” or “inherently ‘subvert’ Congressional intent to make low-cost generic pharmaceuticals broadly available to the public.” (Defs.' Mem. of Law at 1.) This argument lacks even a scintilla of merit. Defendants cannot point to a single instance where Professor Thomas actually offers such an opinion. As for what Defendants believe he “implied,” their beliefs are of no moment. This basis for the motion to exclude is DENIED.

Second, Defendants argue that Professor Thomas should not be allowed to explain the Hatch-Waxman statutory scheme, its regulations, and how they relate to the generics and potential authorized generics in this case. According to Defendants, those explanations would constitute improper legal opinions. They are wrong.

While, “This circuit is in accord with other circuits in requiring exclusion of expert testimony that expresses a legal conclusion,” Hygh v. Jacobs, 961 F.2d 359, 363 (2d Cir. 1992), “expert testimony is viewed as helpful in cases, like this one, involving complex statutes or issues outside of the general knowledge of the jury.” United States v. Universal Rehab. Servs., Inc., No. 94 Cr. 147, 1996 WL 297575, at *10 (E.D. Pa. May 31, 1996), aff'd sub nom.United States v. Universal Rehab. Servs. (PA), Inc., 205 F.3d 657 (3d Cir. 2000). In his report, Professor Thomas explains the procedures under the complex law governing approvals of generic drugs, which is subject matter that is foreign to the average person. He does not provide “legal conclusions”
or opine on whether Defendants violated the Act, but simply explains the mechanics of drug approval, which provides context that is likely to “assist the trier of fact.” Fed. R. Evid. 702. I will not preclude this testimony. If Thomas's testimony strays beyond that into matters that are irrelevant or otherwise inadmissible, I will be the first to disallow it.

Finally, Defendants claim that Professor Thomas is not qualified to opine on Abbreviated New Drug Application ("ANDA") approval, since he has neither personally prepared nor filed an ANDA, has never communicated with the FDA regarding an ANDA, and has never worked within the FDA or any pharmaceutical company. That all may be true, but it is of no moment. Professor Thomas has taught courses on the Hatch-Waxman Act at Georgetown Law School since 2002, has written a textbook concerning the Hatch-Waxman Act, patent law, and pharmaceutical drugs, and has been qualified to opine on ANDAs in district court before. See, e.g., Apotex, 2011 WL 12818164, 2011 U.S. Dist. LEXIS 154863. Defendants are free to argue to the jury that Dr. Thomas' lack of practical experience undermines his conclusions; the jury can evaluate that argument for what it is worth. I personally would find it unpersuasive.

6. George W. Johnston

Defendants move to exclude the opinions and testimony of Plaintiffs' expert, George W. Johnston, Esq.

Plaintiffs offer a report from George W. Johnston, Esq., dated September 15, 2017 (Hamburger Decl. Ex. 12, Dkt. No. 438 (“Johnston Rep.”).) Plaintiffs retained Mr. Johnston to assess what a reasonable and competent patent attorney would have advised the litigants at the time they settled the Namenda patent litigation in terms of 1) their likelihood of success in the litigation; 2) each of the parties' likely litigation costs; and 3) the likely litigation timing, if the parties had not settled, but rather had continued to litigate through a final, non-appealable *185 judgment. (See Johnston Rep. ¶ 15.)

A. Qualifications

Mr. Johnston has spent his entire legal practice as a patent attorney, has over 40 years of experience, and has prosecuted hundreds of patent applications before the United States Patent and Trademark Office (“USPTO”). His experience with patents includes evaluating the patentability of inventions, the scope of patent claims, the validity and enforceability of patents, and the infringement of patents. (Id. at ¶ 2.)

He served for 17 years as Chief Patent Counsel for Hoffmann-La Roche Inc. (“Roche”) – a global pharmaceutical, biotechnology, and diagnostic health care organization. (Id. at ¶¶ 3, 6.) During his tenure at Roche, Mr. Johnston “advise[d] senior management on the likelihood that Roche would prevail in potential and actual patent litigations, the cost of the associated litigations, and the possible timing and duration of the litigations.” (Id. at ¶ 5.)

Mr. Johnston retired from Roche in 2013 as a Vice President and Chief Patent Counsel. (Id. at 10.) He continues to practice intellectual property law as Counsel at Gibbons P.C. (Id. at ¶ 11.)

Mr. Johnston has impressive credentials as a patent attorney and legal adviser to drug companies. He is certainly an expert in that capacity. The question is whether the opinions he offers in his report go beyond his area of expertise. I conclude that they do not.

B. Summary of George W. Johnston, Esq.'s Report

Mr. Johnston's detailed report begins with a brief description of the patenting process – clarifying that a “U.S. patent provides the patent holder with the right to seek to exclude others from making, using, selling, or importing the invention claimed in the patent for the period during which the patent is in force.” (Id. at ¶ 19.) He also “discuss[es] the process for extending the term
of a pharmaceutical patent under the Hatch-Waxman [and] the procedure under the Hatch-Waxman Act by which a generic manufacturer can challenge pharmaceutical patents listed in the Orange Book so it can enter the market before the patents expire.” (Id. at ¶ 21.)

Then he provides summarized factual information about the Namenda patent ('703 patent) that would be known to a general counsel who was advising his client whether or not to settle a lawsuit – information about the patent's filing, its alleged inventive concept, and Forest's New Drug Application. (Id. at ¶ 26–35.) He notes that “The '703 patent relates generally to methods for the treatment or prevention of cerebral ischemia using adamantine derivatives, including memantine and amantadine. [It] recognizes that certain adamantine derivatives, including memantine, were already known and described in the art for the treatment of central nervous system disorders.” (Id. at ¶ 31.) The '703 patent describes an alleged “new mode” of action of certain adamantine derivatives. As named inventor, Dr. Bormann, explained: “[t]he invented concept is that neurodegeneration is caused by calcium overload of the cells and that you can prevent neurodegeneration by memantine or by adamantine derivatives. That's the invention.” (Id. at ¶ 32.) This summary of background information sets the stage for his opinion.

Mr. Johnston also recounts the prosecution history of the '703 patent, the USPTO's reexamination of the patent in 2004, and Forest's receipt of Paragraph IV challenges from 15 generic companies in 2007 and 2008. “In their Notice Letters, the Generic Companies argued a variety of defenses including noninfringement and invalidity of the '703 patent under 35 U.S.C. §§ 101, 102, 103, 112, 156, and 305.” (Id. at ¶ 58.) “In response to the ... Notice Letters, Forest and Merz instituted a number of Hatch-Waxman litigations in the United States District Court for the District of Delaware and elsewhere.” (Id. at ¶ 59.) “In their Answers and Counterclaims in the Namenda Litigation, the Generic Companies asserted a number of defenses including: noninfringement; invalidity under 35 U.S.C. §§ 101, 102, 103, 112, 156, and 305; failure to state a claim; lack of subject matter jurisdiction; unclean hands; prosecution history estoppel; inequitable conduct; failure to comply with 35 U.S.C. § 156; patent misuse; equitable intervening rights; as well as counterclaims seeking: declaratory judgment of noninfringement and invalidity; an order to de-list the '703 patent from the Orange Book; and a declaratory judgment of invalidity of the patent term extension of the '703 patent.” (Id. at ¶ 63.) A patent lawyer advising a client about the probability of success in an infringement lawsuit would of course have studied the file wrapper and become familiar with the patent's prosecution.

He then summarizes the history of all 15 of Forest's '703 patent litigations against the generic companies leading up to and including settlements in 2009-2010. That information is, of course, a matter of public record. He notes that “Mylan's case progressed the farthest,” not settling until August 26, 2010.

He then examines other information that a reasonable patent counsel who was evaluating whether or not to settle a case would have taken into account. He explained data that showed the statistical likelihood that either a patentee or a challenger would win a Hatch-Waxman lawsuit – the actual track record in real litigations. He then evaluated, in the manner that a reasonable and competent patent attorney would, the information that was available to him about the merits of the Namenda litigation between Forest and Mylan. And as part of that analysis, he discussed in depth the legal claims and defenses raised. For example, he evaluates the strength of Mylan's invalidity defenses, including anticipation, obviousness, enablement and patent term extension. In doing so, he brought to bear his extensive knowledge of patent law and patent litigation. He reviews the evidence and expert opinions that Forest and Mylan planned to offer at trial. He analyzes them, and assesses the likelihood that a trier of fact would accept that evidence and those opinions. (See id. at ¶¶ 398 – 401.)

In short, he does exactly what he did time and again during his years as Chief Patent Attorney at Hoffman-LaRoche. And his conclusions are summarized in a table on page 94. (See id. at ¶ 395.)

After conducting this thorough analysis, he offers the opinion on which Plaintiffs rely: “In my opinion, a reasonable and competent patent attorney at the time of the settlement of the Namenda Litigation likely would have concluded that overall
Mylan had greater than a 60% chance of prevailing and that Forest Merz had less than a 40% chance of prevailing in this litigation through trial and appeal.” (Id. at ¶ 16.)

Finally, he estimates the expected length and cost of the Namenda litigation, assuming Mylan and Forest had not settled and the case went to trial.

**C. Analysis: Motion to Exclude George W. Johnston, Esq.’s Report**

Defendants first argue the Mr. Johnston does not have the technical expertise required to opine on patent infringement and validity, because he is not one skilled in the art covered by the patent – he is a lawyer, not a chemist. They urge that allowing Johnston to offer his opinion would run counter to the Federal Circuit's holding in Sundance, Inc. v. DeMonte Fabricating Ltd., 550 F.3d 1356, 1363 (Fed. Cir. 2008).

Plaintiffs counter that Mr. Johnston is not offering independent technical expertise about whether the claims of the '703 patent were in fact valid or whether they were infringed by Mylan. They argue that he opines, from the perspective of a reasonable patent attorney with extensive experience in the area of patent law, about the likelihood that Mylan would succeed in its lawsuit against Forest. Plaintiffs note that Johnston relies on the conclusions of the parties' technical experts – persons who are “skilled in the art” – in reaching his own conclusions. (See Opper Decl. Ex. 8, Dkt. No. 421 (“Johnston Dep.”) at 172:23 – 173:6 (“I had a different role than that of a technical expert. I had a very focused role in terms of what a reasonable patent attorney ... say, a chief patent counsel, because we did it all the time, would have perceived as the likelihood of success at the time of settlement.”).) Plaintiffs thus argue that his testimony does not run afoul of Sundance.

Sundance was a patent infringement case. In that case the district court had denied Sundance's motion in limine to exclude the testimony of an opposing expert, Bliss. Bliss was “a patent attorney with extensive experience in patent law and procedure.” Sundance, 550 F.3d at 1360. He opined, on behalf of the alleged infringer, that the patent was invalid, and that if it were valid it was not infringed – even though Mr. Bliss had no technical expertise in the field of the patent. See id.

The Federal Circuit reversed, concluding that the district court had abused its discretion by admitting Bliss' opinion evidence. The court emphasized that “Mr. Bliss is not qualified to testify as an expert witness on the issues of infringement or validity [as] these issues are analyzed in great part from the perspective of a person of ordinary skill in the art” and Mr. Bliss lacked such skill. Id. at 1361 (emphasis added). In other words, “Unless a patent lawyer is also a qualified technical expert, his testimony on these kinds of technical issues is improper and thus inadmissible.” Id. at 1362 (emphasis added).

“Sundance actually advises district courts to consider the perspective from which the relevant issue of patent law will be analyzed when the court determines whether an expert is qualified to testify as an expert on that issue.” Network-I Techs., Inc. v. Alcatel-Lucent USA, Inc., No. 6:11 Civ. 492 (RWS), 2017 WL 4173468, at *3 (E.D. Tex. Sept. 21, 2017) (citing Aevoe Corp. v. AE Tech Co., No. 2:12 Civ. 0053 (GMN), 2014 WL 4182343, at *2 (D. Nev. Aug. 20, 2014) ).

This case differs from Sundance in two important ways.

First and foremost, this is an antitrust case, not a patent infringement case; the Court's concern with the technical issues of patent infringement and validity is indirect.

Second, Mr. Johnston is not opining that the '703 is invalid, or that Mylan did not infringe the patent. Instead, he offers a “reasonable patent attorney's” assessment of the likelihood that Mylan would win its patent case – exactly the sort of assessment he would have offered his client during the nearly two decades when he served as Chief Patent Counsel of Hoffman-LaRoche.
Nonetheless, it would be naïve to conclude that Mr. Johnston's assessment of Mylan's likelihood of succeeding on its claims in the lawsuit does not include some tangential assessment on his part on the issues of the validity and infringement. True, he does not offer the sort of opinion that one skilled in the art would offer – a black-and-white, yes or no, opinion that the patent was or was not valid or infringed. But Johnson's assessment that Mylan's experts were more likely to be believed that Forest's, and his assignment of statistical likelihoods to those technical opinions necessarily depends on his lawyerly assessment of how the ultimate issues in that patent litigation would play out. His conclusion – that Mylan would more likely than not have managed to prove either invalidity or lack of infringement – had to rest on some assessment of the patent's validity and Mylan's defenses to Forest's charge of infringement.

That said, testimony by experienced lawyers about the likelihood that patent litigations will succeed or not succeed has been admitted in several post-Actavis reverse-payment cases. See In re Solodyn (Minocycline Hydrochloride) Antitrust Litig., No. CV 14-MD-02503, 2018 WL 563144, at *16 (D. Mass. Jan. 25, 2018); In re Wellbutrin XL Antitrust Litig., 133 F.Supp.3d 734 (E.D. Pa. 2015), aff'd sub nom. In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class, 868 F.3d 132 (3d Cir. 2017), judgment entered sub nom. In re Wellbutrin XL Antitrust Litig., No. 15-2875, 2017 WL 3529114 (3d Cir. Aug. 9, 2017); see also In re Lidoderm Antitrust Litigation, 2017 U.S. Dist. LEXIS 182940, *117 (Nov. 3, 2017 N.D. Cal.). Unfortunately, in none of those opinions does the court analyze the lawyer's credentials in any detail or so much as mention the issue identified by this Court in the preceding paragraph. But in every such case the issue was litigation risk and lawyers, not chemists, normally assess litigation risk for their clients.

Mr. Johnson unquestionably has the expertise to evaluate the things he assessed – from expert reports to patent file folders – and to draw conclusions about who is more likely to win a patent lawsuit. He has done it dozens of times for his employer; there is no reason why he should not be able to do it for Plaintiffs in this lawsuit. To the extent that his opinions rest on his evaluation of technical material – the opinions of the technical experts – he can be cross-examined about his knowledge of the underlying art, or the lack of the same. And of course Forest is offering the testimony of its own expert (see Hamburger Decl. Ex. 13, Dkt. No. 438 (Expert Report of Roderick McKelvie, Esq. ("McKelvie Rep."))) who will be testifying about his assessment of the merit or lack of merit to the Mylan patent case – the assessment that was actually made before the case settled.

As Judge Casper noted when she admitted “Johnston-like” expert testimony in In re Solodyn, “To the extent Defendants seek to challenge [an expert's] conclusions as to the likely outcome of the patent challenges, they may do so with their own expert testimony – as they have proposed to do.” 2018 WL 563144, at *16.

Defendants also argue that Mr. Johnston's opinion is flawed because he opines on the likelihood of succeeding on issues that Forest and Mylan did not intend to raise at trial. Defendants point to a “301-page pretrial order, which includes 187 pages of proposed findings of fact and conclusions of law from both sides” in the '703 patent case that Forest and Mylan were prepared to try. (Defs. Mot. to Exclude at 8.) Defendants complain that many of Mr. Johnston's opinions raise issues and legal arguments that were either undeveloped or completely absent from the parties' pretrial order.

However, Defendants have failed to identify any issue raised by Mr. Johnston that cannot be traced back to documentary evidence related to at least one of the Mylan's defenses identified in its pretrial order. That specific cases or facts were not identified with sufficient granularity in the pretrial order does not justify tying Mr. Johnston's hands. As Defendants do not point to either facts or case law that would justify such a conservative approach, the Court refuses to accept this argument. That said, if Mr. Johnson really did go beyond the issues that were actually in the Mylan-Forest litigation, it should be an interesting cross-examination.

Defendants also protest that Mr. Johnston's opinions constitute impermissible legal opinions and conclusions. However, this is a complex antitrust case involving a secondary body of law – here, patent law – that is not directly at issue. Given the nature of what Mr. Johnston was asked to opine on – the likelihood of success in a patent suit – he necessarily incorporates patent law
into his opinion. The Court will not exclude this analysis. As I held with respect to Professor John Thomas's legal testimony, if Mr. Johnston strays beyond into matters that are irrelevant or otherwise inadmissible, I will be the first to disallow it.

Finally, Defendants complain that Mr. Johnston is not allowed to provide opinions that undermine the statutory presumption of patent validity – a presumption, they argue, that can be overthrown only by clear and convincing evidence. After a review of the challenged portions of Mr. Johnston's report, it is clear that his opinions do nothing of the sort. (See Johnston Rep. ¶ 76 – 86; 87 – 109; 112 – 20.) Again, Defendants are free to cross-examine Mr. Johnston and to argue that he gave insufficient weight to that hard-to-disprove presumption.

Defendants' motion is DENIED.

II. DEFENDANTS' SUMMARY JUDGMENT MOTION AND PLAINTIFFS' MOTION FOR CLASS CERTIFICATION

Factual Background


In light of these prior rulings, the Court will not recite all of the facts of this case, but instead addresses only the factual and procedural background relevant to the motions addressed herein. The summary of facts in the following pages is drawn from Namenda I–IV, as well as from Defendants' Rule 56.1 Corrected Statement of Undisputed Material Facts (“DSoF”), Plaintiffs' Responses and Objections to DSoF (“PRSoF”), Plaintiffs' Affirmative Statement of Material Facts (“PASoF”), and Defendants' Objections and Responses to PASoF (“DRASoF”).

Unless otherwise noted, these facts are not in dispute.

Parties

Forest manufactures and sells brand name pharmaceutical products, including the prescription pharmaceutical memantine hydrochloride (“memantine”), which is sold in the United States under the trade names “Namenda” (referred to here as “Namenda IR” to distinguish from Namenda XR) and “Namenda XR.” Namenda IV, 2017 WL 4358244, at *2. Memantine is a treatment for moderate-to-severe forms of Alzheimer's disease. Forest developed Namenda IR pursuant to an exclusive license and cooperation agreement with Merz GmbH & Co. KGaA, Merz Pharma GmbH & Co. KGaA, and Merz Pharmaceuticals GmbH (collectively, “Merz Entities”), which owned the relevant patent for a memantine-based drug. 4 Id. applicable.

Named Plaintiff Smith is a South Carolina corporation that purchased Namenda IR directly from Forest. Smith alleges that, during the class period, it paid prices higher than it would have absent Defendants' anticompetitive conduct. Id.
Named Plaintiff RDC is a New York corporation that also purchased Namenda IR directly from Forest which it alleges were at supracompetitive prices.\footnote{Id.}

**Regulatory Background**

This case involves the rules set forth in (1) the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., which governs the manufacture, sale, and marketing of pharmaceuticals in the United States; and (2) the Drug Price Competition and Patent Term Restoration Act (the "Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585; \textit{id.} at *2-*3.

Under the FDCA, a pharmaceutical company must submit a New Drug Application ("NDA") to the FDA before it may bring a new drug to market. \textit{See generally} 21 U.S.C. § 355; \textit{Namenda IV}, 2017 WL 4358244, at *2. Because the NDA must provide the FDA with sufficient scientific data to demonstrate that the new drug is safe and effective, the testing and approval process is generally "long, comprehensive, and costly." \textit{FTC v. Actavis, Inc.}, 570 U.S. 136, 142, 133 S.Ct. 2223, 186 L.Ed.2d 343 (2013); \textit{Namenda IV}, 2017 WL 4358244, at *2. Once approved, though, a patented drug enjoys a period of market exclusivity. \textit{Namenda IV}, 2017 WL 4358244, at *2. That period ends when the drug's patent expires and one or more low-cost generic versions of the drug enter the market and compete with the brand-name drug – what *191 is referred to as going off the "patent cliff." \textit{Namenda II}, 787 F.3d at 643.

The Hatch-Waxman Act makes it easier for manufacturers of generic drugs to compete with brand-name drug producers. \textit{Namenda IV}, 2017 WL 4358244, at *3. As relevant here, the Hatch-Waxman Act provides two methods by which a brand-name drug manufacturer can extend its period of market exclusivity. \textit{Id.}

First, a manufacturer can seek an extension of its patent from the USPTO to account for the time the manufacturer spent obtaining approval from the FDA for its brand-name drug. 35 U.S.C. § 156. That extension can last no more than five years. \textit{Id.} at § 156(g)(6); \textit{Namenda IV}, 2017 WL 4358244, at *3.

Second, a brand-name drug manufacturer can obtain a six-month period of "pediatric exclusivity" if it conducts certain pediatric studies and the FDA determines that use of the drug in children may produce health benefits. 21 U.S.C. § 355a. A grant of pediatric exclusivity does not extend the length of the underlying patent, but can operate to exclude generic competition by delaying the date by which the FDA may approve generics for sale. \textit{Namenda IV}, 2017 WL 4358244, at *3.

Under the Hatch-Waxman Act, the manufacturer of a generic version of an FDA-approved drug may file an Abbreviated New Drug Application ("ANDA"), which allows the generic manufacturer to rely upon the studies submitted by the brand-name drug manufacturer in connection with the original NDA to prove that the generic version of the drug is safe and effective. \textit{Id.} The ANDA filer must certify that its generic drug, among other things, has the same active ingredient as, and is "bioequivalent" to, the previously-approved drug. 21 U.S.C. § 355(j)(2)(A)(ii), (iv); \textit{Namenda II}, 787 F.3d at 644. A generic drug is bioequivalent to the brand-name drug if it has the same "rate and extent of absorption" of the active ingredient as that of the brand-name drug. 21 U.S.C. § 355(j)(8)(B)(i); \textit{Namenda IV}, 2017 WL 4358244, at *3. "In other words, two drugs are bio equivalent if they deliver the same amount of the same active ingredient content into a patient's blood stream over the same amount of time." \textit{Namenda II}, 787 F.3d at 644.

**Facts of the Case**

\textbf{A. Settlement Agreements}

and received a five-year extension to the ’703 Patent, which was set to expire in April 2010 (an extension permitted under 35 U.S.C. § 156 for the time Forest spent obtaining FDA approval). *Id.* Namenda IR was also approved for six months of pediatric exclusivity in June 2004. *Id.* at *6.

At least 17 generic drug manufacturers filed ANDAs seeking to market generic versions of Namenda IR. *Id.* Defendants timely brought suits for patent infringement, but ultimately reached a number of settlement agreements. *Id.* Each agreement contained a virtually identical provision that Plaintiffs assert was anticompetitive, which granted the competitors a license to begin selling a generic version of Namenda IR beginning three months prior to the later of: (1) the expiration of the ’703 Patent or (2) the end of any pediatric exclusivity period attached to the ’703 Patent. *Id.* With the six-month exclusivity period in place, this meant that the generic competitors could not begin selling generic versions of Namenda IR until July 11, 2015. *Id.*

---

**B. The “Hard Switch”**

Forest obtained FDA approval for Namenda XR in June 2010 and began marketing Namenda XR in July 2013. *Id.* at *7. Namenda IR and Namenda XR contain the same active ingredient and have the same therapeutic effect, but Namenda IR is a tablet taken twice a day that releases directly into the bloodstream while Namenda XR is a capsule that is taken once a day and releases gradually. *Id.* They are not, therefore, “bioequivalents” under the FDA’s definition of that term, and so cannot be substituted for one another under any drug substitution law that requires substitutes to be certified by the FDA as bioequivalents. Similarly, generic drugs that are bioequivalents of Namenda IR cannot be substituted for Namenda XR under the same standards.

The key non-pharmacological difference between Namenda IR and Namenda XR relates to their patent protection. Namenda XR’s period of patent exclusivity does not expire until 2029, while Namenda IR’s expired in 2015. *Namenda II*, 787 F.3d at 647.

When Forest brought Namenda XR to market in 2013, it engaged in a variety of “soft-switch” tactics to encourage patients and physicians to convert from Namenda IR to Namenda XR before Namenda IR lost its patent protection in 2015. See *id.* at 647–48. For example, it priced Namenda XR below Namenda IR; it stopped actively marketing Namenda IR; and it heavily promoted the benefits of Namenda XR, including its lower price and once-daily dosage. *Namenda IV*, 2017 WL 4358244, at *7.

Judge Sweet concluded in Namenda I that Forest executives were concerned about the company’s ability to convince a sufficient number of patients to convert to Namenda XR prior to generic entry, making a “hard switch” necessary. *Namenda I*, 2014 WL 7015198, at *18. It is undisputed that, on February 14, 2014, Forest announced by press release, notice to the FDA, and letters to physicians and patients, that it was taking Namenda IR off the market on August 15, 2014. *Id.* Four months later, however, Forest announced that it would continue selling Namenda IR through the fall of 2014 due to manufacturing issues with Namenda XR. *Id.* at *22.

---

**C. The Mylan Reverse Payment Agreement**

By 2002, Forest had a license to market a drug named Lexapro. (DSof ¶ 180.) On October 3, 2005, Forest and Alphapharm (later acquired by Mylan), entered into a distribution and supply agreement for authorized generic Lexapro (“the Original Lexapro Agreement.”) (*Id.* at ¶ 182.) By the terms of the Original Lexapro Agreement, Forest would supply Alphapharm’s requirements of generic Lexapro for sale and distribution, and Alphapharm would market, but not manufacture, an authorized generic version of Lexapro. (*Id.* at ¶ 184–87.)

Alphapharm agreed to pay Forest a 40% share of its “product profit,” which the agreement defined as Alphapharm’s net sales less Forest’s manufacturing costs. (*Id.* at ¶ 189–90.)
The ‘712 Patent was set to expire on March 12, 2012, at which point Teva, the sole first-filing ANDA applicant, was permitted to launch its version of generic Lexapro on March 12, 2012 and was entitled to 180 days of exclusivity under the Hatch-Waxman Act, in that the FDA would not finally approve another ADNA during that time. (DSoF ¶ 194; PRSoF ¶ 194.) Under the Agreement, Alphapharm was allowed to launch its authorized generic two weeks before Teva's date of entry on February 27, 2012. (Id. at ¶¶ 188, 193; *193 PRSoF ¶ 193.) The Original Lexapro Agreement had a five year term (starting with Lexapro patent expiry), with a one-year minimum. (PRSoF ¶ 218(e).) Mylan acquired Alphapharm in 2007. (DSoF ¶ 218.)

The Medicaid Drug Rebate Program (“MDRP”), which was established by Congress in 1990, required brand manufacturers to pay a rebate to the government on prescription drugs reimbursed by Medicaid. (DSoF ¶ 197.) The MDRP requires participating drug manufacturers to pay a rebate on those drugs for which a state's Medicaid agency has paid pharmacies to dispense the drug to Medicaid beneficiaries. (Id. at ¶ 198.) To determine the rebate amount owed by a manufacturer, the Centers for Medicare & Medicaid Services (“CMS”) calculates a per-unit rebate amount (“URA”) based on a statutory formula. (Id. at ¶ 199.)

The URA for a drug is tied to a product’s “Best Price” or, “the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States...” (Id. at ¶ 200.) The URA is calculated, in part, using a brand manufacturer's commercial sales and discount data. (Id. at ¶ 201.)

The Deficit Reduction Act of 2005 (“DRA”), in large part, became effective on January 1, 2007. (Id. at ¶ 202.) The Final Rule implementing the DRA (the “DRA Final Rule”) became effective October 1, 2007. (Id. at ¶ 203.) The DRA amended the definition of Best Price to include, for the first time, the lowest price of an authorized generic drug. (Id. at ¶ 206.) On January 23, 2008, the CMS clarified that the DRA Final Rule “provides that the primary manufacturer include the best price of an authorized generic drug in its calculation of best price when the drug being sold by the primary manufacturer to the secondary manufacturer. In accordance with this provision, we expect that the primary manufacturer report a BP [best price] which incorporates the transfer price at the time of sale to the secondary manufacturer for the quarter in which the sale occurs, regardless of when the product is launched.” (Id. at ¶ 207.) The transfer price is generally reflective of the cost to manufacture a drug. (Id. at ¶ 209.)

Under the Original Texapro Agreement, Forest was a primary manufacturer, and Alphapharm was a secondary manufacturer. (Id. at ¶ 208.) Generally, the lower a manufacturer's best price is, the higher its Medicaid Rebate liability will be. (Id. at ¶ 212.) It is undisputed that the DRA exposed Forest to more Medicaid liability than it was exposed to when it entered the agreement in 2005, since under the new rule Forest would now have to include the best price of generic Lexapro in its calculation of best price. (Id. at ¶ 214.) It is also undisputed that the parties negotiated and amended its Lexapro Agreement (“the Lexapro Amendment”), which was executed on July 21, 2010. (DSoF ¶ 255.)

The parties dispute, however, the content and validity of Forest's cost-benefit analysis while it was negotiating the Lexapro Amendment.

According to Defendants, Forest performed three analyses to assess the potential benefits of amending the Original Lexapro Agreement: (1) a comparison of Forest's post-DRA Medicaid Liability under the Original Lexapro Agreement and Forest's liability pursuant to a potential amendment requiring Mylan to manufacture generic Lexapro (“Medicaid Liability Analysis”), (2) a forecast projecting Forest's profit share revenue under the Original Lexapro Agreement and a potential amendment to that agreement (“The Lexapro Sales Forecasts”), and (3) a projection of the potential costs of goods sold savings Mylan could achieve if it manufactured generic Lexapro (“COGS Summary”). (DSoF ¶ 215.)

According to Plaintiffs, the documents underlying Forest's analysis are unreliable. Plaintiffs point out that the final analyses were not created until after Forest and Mylan told the Namenda IR patent court that it had reached a settlement in principle;
thus, they could not have been performed to assess the “potential benefits” of the transaction, which had already been agreed to. (PRSoF ¶ 214.)

D. The Other Reverse Payments

The parties do not provide the Court with the same level of detail about the other reverse payment agreements. Here is what we know: Forest settled with approximately eleven generic companies, with each settlement providing for up to a $2 million cash payment, and generic launch dates three months prior to Forest's statutory exclusivity, absent any extension for pediatric exclusivity or the triggering of the accelerated launch provisions if other generics came in early.

Procedural History

There have been two dispositive motions in this case.

On September 13, 2016, this Court denied Defendants' motion to dismiss – finding, in brief, that Plaintiffs stated a claim for product hopping (based on the planned “hard switch”), stated a claim based on the settlement agreements with generic manufacturers, and Plaintiff claims were not time-barred. (Dkt. No. 106.) This Court dismissed Plaintiffs' overarching scheme claim (Count II) as duplicative. (See id.)

A few months later, Plaintiffs moved for collateral estoppel and partial summary judgment on Count One (Dkt. No. 134) and for partial summary judgment on Count Five (Dkt. No. 138). Defendants cross-moved for partial summary judgment on Count Five (Dkt. No. 161). On May 23, 2017, this Court denied both motions for partial summary judgment on Count IV. This Court also granted Plaintiffs' motion for collateral estoppel, finding:

Because all of the elements of collateral estoppel are met, Forest is precluded from relitigating the questions of (1) whether it possessed monopoly power over the U.S. memantine market up until the entry of generic competition; (2) whether its February 2014 announcement of the upcoming discontinuation of Namenda IR was coercive and anticompetitive; and (3) whether Forest had any non-pretextual procompetitive justification for its illegal conduct. Plaintiffs' motion for collateral estoppel on these issues of fact is GRANTED. They will be presented to the jury as already decided.

Namenda IV, 2017 WL 4358244, at *16.

This Court, however, denied Plaintiffs' motion for partial summary judgment on Count One since outstanding questions of material fact remained regarding antitrust injury, which is a necessary element of Plaintiffs' Section 2 claim.

Defendants now move for summary judgment dismissing all claims in Plaintiffs' First Amended Complaint. (Dkt. No. 434.)

Plaintiffs move to certify a class comprised of 62 direct purchasers of Namenda. (Dkt. No. 400.)

Discussion
Summary Judgment Standard
A party is entitled to summary judgment when there is no “genuine issue of material fact” and the undisputed facts warrant judgment for the moving party as a matter of law. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986); see also Fed. R. Civ. P. 56. In addressing a motion for summary judgment, “[t]he court must view the evidence in the light most favorable to the party against whom summary judgment is sought and must draw all reasonable inferences in [its] favor.” L.B. Foster Co. v. Am. Piles, Inc., 138 F.3d 81, 87 (2d Cir. 1998). Whether any disputed issue of fact exists is for the Court to determine. See Balderman v. United States Veterans Admin., 870 F.2d 57, 60 (2d Cir. 1989). The moving party has the initial burden of demonstrating the absence of a disputed issue of material fact. See Celotex v. Catrett, 477 U.S. 317, 323, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). Once such a showing has been made, the nonmoving party must present “specific facts showing that there is a genuine issue for trial.” El-Nahal v. Yassky, 835 F.3d 248, 256 (2d Cir. 2016), cert. denied, — U.S. ——, 137 S.Ct. 2187, 198 L.Ed.2d 255 (2017) (internal quotation marks and citations omitted). The party opposing summary judgment “may not rely on conclusory allegations or unsubstantiated speculation.” Scotto v. Almenas, 143 F.3d 105, 114 (2d Cir. 1998).

Moreover, not every disputed factual issue is material in light of the substantive law that governs the case. “Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment.” Anderson, 477 U.S. at 248, 106 S.Ct. 2505. Finally, the nonmoving party “must do more than simply show that there is some metaphysical doubt as to the material facts.” Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986). To withstand a summary judgment motion, sufficient evidence must exist upon which a reasonable jury could return a verdict for the nonmovant. With these principles in mind, I turn to the claims presented.

Analysis
Defendants move for summary judgment dismissing all claims.

All remaining claims assert that Defendants violated the Sherman Antitrust Act. Count I alleges unlawful maintenance of monopoly power under Section 2 of the Sherman Act for forcing Namenda IR consumers to switch to Namenda XR. Count III alleges unlawful maintenance of monopoly power under Section 2 of the Sherman Act for entering into agreements with generic manufacturers to delay generic entry for three months past the expiration of the '703 patent. And Counts IV and V allege restraint of trade under Section 1 of the Sherman Act for entering into agreements with potential generic manufacturers to delay their entry into the market for three months beyond the expiration of the '703 patent term.

Defendants have moved for summary judgment on the following grounds: (1) there is no evidence in the summary judgment record that Forest's settlements with the generic manufacturers contained an unlawful reverse payment; (2) there is no triable issue of fact related to Plaintiffs' overarching conspiracy claim; (3) Plaintiffs have failed to make the requisite showings of causation; and (4) Plaintiffs have failed to establish that they have suffered antitrust injury as a result of Forest's February 2014 announcement.

A. Plaintiffs' Overarching Conspiracy Claim Was Dismissed
As an initial matter, Forest's motion for summary judgment on Plaintiffs' “overarching conspiracy claim,” which was Count II of their complaint is moot. (See Am. Compl., Dkt. No. 26 at ¶¶ 244 – 50.) As mentioned above, this Court dismissed this count in its September 13, 2016 decision on Defendants' motions to dismiss. (See Dkt. No. 106 at 33.)

Moreover, Plaintiffs have abandoned their inter-generic conspiracy claim (Count IV). (See Pls.' Mem. of Law in Opp'n to Defs. Mot. for Summary Judgment at 1.)
There are genuine issues of material fact precluding summary judgment with respect to Forest's two other grounds for summary judgment, which I address in turn below.

**B. Defendants' Motion for Summary Judgment on all Claims Arising from Forest's Alleged Reverse Payments to Generic Manufacturers is DENIED**

Defendants move for summary judgment on all claims arising from Forest's patent settlement agreements with generics, arguing that Forest made no illegal reverse payments as part of their settling of the various Namenda patent challenges.

The Court concludes that Plaintiffs have offered sufficient evidence such that a reasonable juror could find that Forest's payments to generics did not merely compensate them for avoided litigation costs or fair value for services – and thus were large and unjustified reverse payment in violation of the antitrust laws.

**1. Which Settlement Agreements Are at Issue**

As an initial matter, Forest argues that discovery eliminated the vast majority of Plaintiffs' reverse payment claims. In their First Amended Class Action Complaint (Dkt. No. 29), Plaintiffs asserted that Forest entered into anticompetitive reverse payment settlement agreements with approximately eleven first filer generic manufacturers. (Am. Compl. at ¶ 113.) Forest contends that, after discovery failed to support their wide-ranging allegations, Plaintiffs functionally abandoned their challenges to all but one of these agreements – the Forest-Mylan Agreement.

The following discussion analyzes the Forest-Mylan Agreement only. The fact remains, however, that the anticompetitive conduct at issue in this case is premised on the alleged barriers to entry put in place by Forest to prevent all generic competition, not just Mylan's. Given that the Forest-Mylan settlement was the very last patent settlement agreement Forest entered into, all of the other settlements to keep generic companies from competing that were signed before the Forest-Mylan settlement undergird and compound the anticompetitive effect of the Forest-Mylan deal. This fact is well-illustrated by a February 11, 2010 Forest-Mylan settlement presentation, in which Forest explained that if Mylan would have won the Namenda patent litigation, there would have been “No Financial Upside” because Mylan's profits would have been “miniscule” due to the ... prior settling Namenda generics having provisions in their agreements that provided for immediate and simultaneous market entry if Mylan won the patent dispute, [thereby] lowering Mylan's potential generic Namenda profits.” PASoF ¶ 236 – 37.

Nonetheless, Forest argues that Plaintiffs have abandoned their claims relating to all but Mylan. As a result, in the papers supporting its motion, Forest does not make a particularized showing about why summary judgment should be granted with regard to any of the other agreements that were identified in the complaint as anticompetitive. It simply asserts that Plaintiffs have abandoned those claims, and offers evidence and argument about why the Forest-Mylan settlement does not violate the antitrust laws.

*197* Plaintiffs have taken no affirmative steps to indicate that it has abandoned all claims related to its other eleven or so alleged reverse payments – that is simply an assertion by Forest. In its responsive papers, it neither agrees with Forest that those claims have been abandoned nor offers any evidence that would tend to show that the agreements were in fact anti-competitive. Of course, as the party opposing the motion for summary judgment, Plaintiffs had no obligation to discuss agreements that were not addressed on the merits by Forest. But they should have addressed Forest's contention that they were abandoning those claims.
I am going to address the Forest-Mylan agreement, as to which there are myriad genuine issues of material fact that preclude summary judgment. Plaintiffs have ten days from the date of this decision to advise the Court whether they are pursuing claims related to the other reverse payment agreements. If they are, we will simply take those claims to trial.

2. Legal Standards

In *F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 133 S.Ct. 2223, 186 L.Ed.2d 343 (2013), the Supreme Court held that a reverse payment settlement – that is, a payment by a patentee to a claimed infringer – is not presumptively either lawful or unlawful, but will be subject to antitrust scrutiny in certain circumstances. Reverse payments are of particular concern when they demonstrate “that the patentee [sought] to induce the ... [infringer] to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market.” *Id.* at 154, 133 S.Ct. 2223. To violate antitrust law, a reverse payment must be both “large and unjustified.” *Id.* at 158, 133 S.Ct. 2223.

A payment's size may indicate that “the patentee likely possesses the power to bring [an unjustified anticompetitive] harm about in practice.” *Id.* at 157, 133 S.Ct. 2223. In other words, a large reverse payment may signal that the patentee possessed “the power to charge prices higher than the competitive level” and may be using that power to keep others from entering its market. *Id.* Such a payment may also indicate a patent holder's concern about the validity of its patent, such that “the size of the payment may very well correspond with the magnitude of that concern.” *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 251 (3d Cir. 2017), cert. denied sub nom. *Pfizer Inc. v. Rite Aid Corp.*, ––– U.S. ––––, 138 S.Ct. 983, 200 L.Ed.2d 300 (2018), and cert. denied sub nom. *Wyeth LLC v. Rite Aid Corp.*, ––– U.S. ––––, 138 S.Ct. 984, 200 L.Ed.2d 300 (2018).

The Supreme Court in *Actavis*, however, acknowledged that there also might be “legitimate justification[s]” for a reverse payment settlement, including, but not limited to, “avoided litigation costs or fan value for services.” *Actavis*, 570 U.S. at 156, 133 S.Ct. 2223. The Court directed district courts to apply the traditional rule of reason analysis when evaluating reverse payment settlements. See *id.*

Rule of reason analysis proceeds in three steps. First, the plaintiff bears the initial burden of showing that the defendant's conduct “had an actual adverse effect on competition as a whole in the relevant market.” *Capital Imaging Assocs., P. C. v. Mohawk Valley Med. Assocs., Inc.*, 996 F.2d 537, 543 (2d Cir. 1993) (emphasis in original). If plaintiff satisfies this burden, the burden then shifts to defendant to offer evidence that its conduct had pro-competitive effects. *Id.* If defendant is able to offer such proof, the burden shifts back to plaintiff, who must prove that any legitimate competitive effects could have been achieved through less restrictive alternatives. *Id.*

*198* *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98, 104 (2d Cir. 2010), as corrected (June 17, 2010).

“To survive summary judgment, the plaintiffs must present a ‘genuinely disputed issue of material fact’ as to the elements of the rule of reason analysis; only then will the case go to a jury.” *In re Wellbutrin XL Antitrust Litig.*, 133 F.Supp.3d 734, 754 (E.D. Pa. 2015), aff’d sub nom. *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132 (3d Cir. 2017), judgment entered sub nom. *In re Wellbutrin XL Antitrust Litig.*, No. 15 Civ. 2875, 2017 WL 3529114 (3d Cir. Aug. 9, 2017).

3. Reverse Payment Analysis

This Court predicted in *Namenda IV* that, “Whether the settlement agreements were anticompetitive or procompetitive will depend on several complex factual questions that cannot be decided on summary judgment.” 2017 WL 4358244, at *19. As
demonstrated by the host of genuine issues of material fact emanating from the papers filed in connection with this motion, I was correct.

In their briefing on the alleged unlawful reverse payment, the parties analyze several components of the Forest-Mylan agreement, including a cash payment from Forest to Mylan, an agreed early entry date with the possibility of acceleration, and the Lexapro Amendment. Since I am denying the motion, I will use the Lexapro Amendment to illustrate why.6

The Court finds that Plaintiffs have offered enough evidence to allow a reasonable finder of fact to conclude that Plaintiffs have established a prima facie case for imposing antitrust liability. Although Defendants have offered procompetitive justifications for the Lexapro Amendment—particularly evidence that may indicate that the Lexapro Amendment was a fair market value deal—Plaintiffs have offered some evidence that the Amendment was not fair, but instead, constituted overcompensation for agreeing not to compete.

a. Lexapro Amendment

The initial burden of proof lies with Plaintiffs, who must show that Defendants' conduct had an actual adverse effect on competition.

As a threshold issue, the parties disagree about whether the Lexapro Amendment was even a part of the Forest-Mylan patent settlement.

Forest claims that its in-house counsel negotiated the Namenda patent settlement with Mylan and that a “largely separate team” of Forest business people negotiated the Lexapro Amendment with Mylan. Nonetheless, it is undisputed that both the settlement agreement and Lexapro Amendment were executed on the same day, July 21, 2010, and that there were certain personnel of whom were aware of both agreements. (PASoF ¶ 239.)

Plaintiffs, on the other hand, contend that the Lexapro Amendment was linked to the Namenda patent settlement. As evidence, they point to Mylan Deal Concept documents reflecting the “proposed structure” of the Namenda patent settlement, which featured the amendment to the Original Lexapro Agreement. (PASoF ¶ 229.) The January 20 document listed, as “Potential Transaction Benefits to Mylan,” “at least $1.5MM in manufacturing cost savings gained through Mylan's control of drug product manufacturing and packaging!]

Plaintiffs also point to Forest's in-house and outside counsel repeatedly referring to the Lexapro Amendment as a “side-deal” to the Namenda patent dispute (PASoF ¶ 243), along with a February 11, 2010 Forest-Mylan meeting presentation that explicitly presents the Lexapro Amendment and Namenda patent settlement as a package. (PASoF ¶ 240.)

On this point, Plaintiffs have presented enough evidence to allow a rational juror to conclude that the Lexapro Agreement was a part of the Forest-Mylan patent settlement.

Plaintiffs have also presented sufficient evidence to allow a rational juror to conclude that the Lexapro Amendment had an anticompetitive effect that outweighed its procompetitive effects.

Forest contends that the Lexapro Amendment did not disguise a payment for delayed generic entry, but was instead a fair value business deal between Forest and Mylan, based on arm's length negotiations and reasonable business expectations at the time of the agreement. Plaintiffs counter that the Lexapro Amendment was both large and unjustified. They claim that the Lexapro Amendment conferred $32.5 million to Mylan—ten times Forest's saved litigation costs of $3.5 million. (PRSoF ¶
280.) Plaintiffs point again to Forest's 2011 settlement presentation, in which Forest points out that “the money it was proposing to pay to Mylan – including ‘millions of dollars’ from modifying the ‘LEXAPRO authorized generic deal’ – ‘provides more value than Mylan's forecasted profits for generic memantine[.]’” (PASoF ¶ 235-38 (emphasis added.).)

This admission is enough to create a genuine issue of material fact. “A reasonable jury could find that a reverse payment to a generic manufacturer that comes close to or exceeds the expected profits to be earned by prevailing in the patent litigation could induce a generic manufacturer to forfeit its claim.” *King Drug Co. of Florence v. Cephalon, Inc.*, 88 F.Supp.3d 402, 417 (E.D. Pa. 2015).

Part of Forest's explanation for the $32.5 million reverse payment is that it compensated Mylan for accepting manufacturing responsibility for authorized generic Lexapro, thereby allowing Forest to avoid $26.5 million in Medicaid rebate liability.

Plaintiffs argue that this claimed reduction was both inflated and pretextual. Plaintiffs point out that the final analyses were not created until after Forest and Mylan told the Namenda IR patent court that it had reached a settlement in principle. (PRSoF ¶ 214.) Plaintiffs claim that Forest employees manipulated the rebate liability analyses to inflate the forecasted rebate savings to just about equal the reverse payment to Mylan. They point to conveniently-timed changes to the royalty rate rates made in March 2010, which inflated the purported rebate savings. (PASoF at ¶¶ 265 – 67.)

Plaintiffs have presented enough evidence that rebuts Defendants' procompetitive justifications to get to trial.

Defendants' motion for summary judgment dismissing Plaintiffs' claims related to Forest's settlement agreements with generics is DENIED.

C. Defendants Are Not Entitled to Summary Judgment Because Plaintiffs Carry Their Burden on Causation

Defendants argue that they are entitled to summary judgment because Plaintiffs have not raised a genuine issue of material fact on the issue of causation.

“Causation in fact is, of course, a necessary element of any claim for relief” *In re Actos End-Payor Antitrust Litig.*, 848 F.3d 89, 97 (2d Cir. 2017) (quoting *Argus Inc. v. Eastman Kodak Co.*, 801 F.2d 38, 41 (2d Cir. 1986). “An antitrust plaintiff must show that a defendant's anticompetitive act was a “material” and “but-for” cause of plaintiff's injury, although not necessarily the sole cause.” *In re Actos*, 848 F.3d at 97 (quoting *In re Publ'n Paper Antitrust Litig.*, 690 F.3d 51, 65–66 (2d Cir. 2012) ).

A plaintiff “need not exhaust all possible alternative sources of injury in fulfilling his burden of proving compensable injury.” *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 114 n.9, 89 S.Ct. 1562, 23 L.Ed.2d 129 (1969); see also *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 695 (2d Cir. 2009).

Here, Plaintiffs offer two alternative causation theories: (1) but for Forest's reverse payment, Forest and Mylan would have entered a no-payment settlement with an earlier entry date based on the bargaining strength of the parties; and (2) absent a settlement Mylan would have prevailed in the patent litigation and entered earlier than the agreed-to entry date.

Defendants argue that both theories are based on insufficient evidence and are speculative. Against, the Court disagrees.

1. Early Entry Date But for Reverse Payment

Plaintiffs' first causation theory is that the parties would have agreed to an earlier generic entry date but for the alleged reverse payment. Plaintiffs rely primarily on expert opinions to support this causation theory.
As discussed in section I.2, supra, Plaintiffs rely on a report from Professor Einer Elhauge addressing what economic analysis reveals about Forest and Mylan's settlement of the Namenda IR patent litigation, including whether an alleged reverse payment from Forest to Mylan delayed generic entry into the market and what the settlement entry date would have been in a no-payment settlement. (See Elhauge Rep. ¶ 1.) Professor Elhauge's report was admitted with the caveat that he cannot offer an opinion about when entry “would have” occurred, so as not to usurp the role of the factfinder. Professor Elhauge is, however, allowed to testify that by specific dates “it would have been economically rational for both parties” to enter into a no-payment settlement in a “but for” world (e.g., November 2012). (Elhauge Dep. Tr. at 225:18 – 227:18.)

Forest attacks Professor Elhauge's assertions as speculative and largely repeats the arguments made in its motion to exclude. This Court has already held that it will not prevent Professor Elhauge from offering his opinion on this but-for scenario as a general matter. (See section I.2., supra.)

Forest argues that the evidence suggests that it would not have agreed to a settlement allowing generic Namenda entry in November 2012. In support of this argument, Forest cites to post hoc testimony of its own employees. For example, Forest points to testimony from its Chief Intellectual Property Counsel, who was responsible for overseeing the Namenda patent litigation at the time of the settlement. He testified that a settlement agreement with Mylan allowing generic entry in 2012 would have been neither feasible nor acceptable to Forest. (See Hamburger Decl. Ex. 18, Dkt. No. 438 (“Ryan Dep. Tr.”) at 394:21 – 395:4.) “At most defendants criticize plaintiffs' experts for failing to consider or adequately consider certain points they believe are significant ... disagreements *201 [of which] are the subject for cross-examination.” Lidoderm, 296 F.Supp.3d at 1164. It is up to the jury to weigh the evidence.


2. Early Entry Date After Mylan Won '703 Patent Litigation

Plaintiffs' second causation theory is that if Forest and Mylan had not settled, Mylan would have likely prevailed in the patent litigation through trial and appeal and entered the market earlier than it did.

While Defendants argue that Plaintiffs may not establish causation and antitrust injury by reference to a hypothetical patent trial between Forest and Mylan, this Court has already held that it could. See Namenda III, 2017 WL 4358244, at *19 (The viability of Plaintiffs' Section 1 claim “will depend on the presence of ‘evidence suggesting that the settlement agreements did, in fact, delay generic entry,’ which will presumably require proof that the '703 Patent would likely have been found invalid or not infringed by the Generic Competitors.’")

Defendants point to the patent court's favorable Markman ruling and the subsequent settlements by Forest and the generics of the patent challenges as evidence that Forest's patent was unlikely to fail. Plaintiffs counter that the subsequent settlements had nothing to do with the patent merits, but are instead evidence – as Forest explained to Mylan during settlement discussions – that the generics recognized that there was “no financial upside to litigating.” (PASoF ¶¶ 56 – 57.) In other words, they argue that the settlements were recognition that there were fourteen first filers who would share the 180-day exclusivity window and that sales and profits for generic memantine would be miniscule as a result. However, the Court need not resolve this issue for purposes of summary judgment.
In re Namenda Direct Purchaser Antitrust Litigation, 331 F.Supp.3d 152 (2018)
107 Fed. R. Evid. Serv. 215

As discussed in section I.6.C., supra, the court admits the opinions of Plaintiffs' expert George W. Johnson, Esq. Given this testimony, Plaintiffs have proffered evidence sufficient to raise a genuine dispute of material fact on this causation theory.

Defendants' summary judgment motion is DENIED.

D. Defendants are Not Entitled to Summary Judgment on Plaintiffs' Hard Switch Claims
Defendants move for summary judgment on Forest's hard switch claims arguing that Defendants cannot establish that the proposed class members suffered antitrust injury as a result of Forest's February 2014 announcement. In support of this motion, Defendants rely on the same arguments made in their motion to exclude the testimony of Plaintiffs' expert, Dr. Lamb, addressed in section I.3., supra. (See Dkt. No. 445.)

For the reasons discussed therein, Defendants' motion is DENIED.

Plaintiffs' Motion for Class Certification is GRANTED

Class Certification Standard

A. Rule 23(a)
A putative class must meet the four prerequisites set forth in Rule 23(a) to be certified: numerosity, commonality, typicality, and adequacy of representation. Brown v. Kelly, 609 F.3d 467, 475 (2d Cir. 2010).

If even one of the Rule 23(a) requirements is not met, certification must be denied. Gomez v. Lace Entmt', Inc., No. 15 Civ. 3326 (CM), 2017 WL 129130, at *4 (S.D.N.Y. Jan. 6, 2017). As the Supreme Court observed in Wal-Mart Stores, Inc. v. Dukes, 564 U.S. 338, 349, 133 S.Ct. 2541, 180 L.Ed.2d 374 (2011), the requirements of Rule 23, by effectively confining the class claims to those “fairly encompassed” by the claims of the named plaintiffs, ensure that those plaintiffs are “appropriate representatives of the class whose claims they wish to litigate.”

1. Numerosity – Rule 23(a)(1)
Numerosity requires that the class must be “so numerous that joinder of all members is impracticable.” Fed. R. Civ. P. 23(a) (1). As certain presumptions attach depending on the sheer size of the class, the number of members in a putative class is the starting point of the Rule 23(a)(1) analysis. Classes with forty or more putative members raise a rebuttable presumption that joinder is impracticable. See Sanchez v. New York Kimchi Catering, Corp., 320 F.R.D. 366, 375 (S.D.N.Y. 2017); Shayler v. Midtown Investigations, Ltd., No. 12 Civ. 4685 (KBF), 2013 WL 772818, at *4 (S.D.N.Y. Feb. 27, 2013). For classes with fewer than twenty members, however, joinder is generally deemed practical. See, e.g., Ansari v. New York Univ., 179 F.R.D. 112, 114 (S.D.N.Y. 1998) (twenty-one or fewer members suggests no class); CL–Alexanders Laing & Cruickshank v. Goldfeld, 127 F.R.D. 454, 455 (S.D.N.Y. 1989) (twenty-one members insufficient to certify class); see also Wilson v. Corelogic SafeRent, LLC, No. 14 Civ. 2477 (JPO), 2017 WL 4357568, at *6 (S.D.N.Y. Sept. 29, 2017) (quoting William B. Rubenstein, Newberg on Class Actions § 3:11 (5th ed. 2017)).
772 F.3d 111, 120 (2d Cir. 2014), the district court must analyze each case separately to determine whether the numerosity requirement has been satisfied, considering the following factors:

1. judicial economy;
2. geographic dispersion of the proposed class members;
3. financial resources of the proposed class members;
4. the ability of proposed class members to file individual suits;
5. requests for relief that could affect future class members;
6. knowledge of the names and existence of potential class members; and
7. whether potential class members have already joined in other actions.

See *Robidoux*, 987 F.2d at 935.

2. **Commonality – Rule 23(a)(2)**

Commonality requires that there exist questions of law or fact that are both common to the class and answerable through a class-wide proceeding. *Fed. R. Civ. P. 23(a)(2); Dial Corp. v. News Corp.*, 314 F.R.D. 108, 113 (S.D.N.Y. 2015). The Supreme Court has clarified that this prong also requires the plaintiff to “demonstrate that the class members ‘have suffered the same injury.’” *Wal–Mart*, 564 U.S. at 350, 131 S.Ct. 2541 (quoting *203 Gen. Tel Co. of Southwest v. Falcon*, 457 U.S. 147, 157, 102 S.Ct. 2364, 72 L.Ed.2d 740 (1982) ). Where, as here, plaintiffs move to certify a class under Rule 23(b)(3), the commonality requirement is subsumed under, or superseded by, the more demanding predominance requirement of Rule 23(b)(3), discussed *infra*. See *Dial*, 314 F.R.D. at 113.

3. **Typicality – Rule 23(a)(3)**

Typicality “is satisfied when each class member's claim arises from the same course of events, and each class member makes similar legal arguments to prove the defendant's liability.” *Marisol A. v. Giuliani*, 126 F.3d 372, 376 (2d Cir. 1997) (internal quotation marks omitted) (quoting *In re Drexel Burnham Lambert*, 960 F.2d 285, 291 (2d Cir. 1992) ). Similar considerations animate commonality and typicality such that the analyses under Rules 23(a)(2) and (3) tend to merge. See *Marisol A.*, 126 F.3d at 376.

4. **Adequacy – Rule 23(a)(4)**

Adequacy requires that “‘the representative parties fairly and adequately protect the interests of the class.” *Fed. R. Civ. P. 23(a) (4); see also Brown, 609 F.3d at 475. Class counsel must be “qualified, experienced, and generally able to conduct the litigation.” *Marisol A*, 126 F.3d at 378 (internal quotation marks omitted) (quoting *In re Drexel Burnham Lambert Grp., Inc.*, 960 F.2d at 291).
Rule 23(a)(4) also requires that the class representative “be aware of the basic facts underlying the lawsuit and not likely to abdicate his obligations to fellow class members.” *Gordon v. Sonar Capital Mgmt. LLC*, 92 F.Supp.3d 193, 200 (S.D.N.Y. 2015) (internal quotation marks omitted) (quoting *In re Monster Worldwide, Inc. Sec. Litig.*, 251 F.R.D. 132, 135 (S.D.N.Y. 2008)). This requirement is a modest one – “class representative status may be denied only ‘where the class representatives have so little knowledge of and involvement in the class action that they would be unable or unwilling to protect the interests of the class against the possible competing interests of the attorneys.’” *Id.* (quoting *In re Monster Worldwide*, 251 F.R.D. at 135).

Finally, if certain members of the class are subject to unique defenses, the court must inquire as to whether those defenses “threaten to become the focus of the litigation.” *Gordon v. Sonar Capital Mgmt. LLC*, 92 F.Supp.3d 193, 205 (S.D.N.Y. 2015) (internal quotation marks omitted) (quoting *Romero v. Flaum Appetizing Corp.*, No. 07 Civ. 7222, 2011 WL 812157, at *3 (S.D.N.Y. Mar. 1, 2011)).

5. Ascertainability

In addition to the four factors enumerated in Rule 23(a), there is an “implied requirement that the membership of the class is identifiable and ascertainable.” *Jankowski v. Castaldi*, No. 1 Civ. 0164 (SJF), 2006 WL 118973, at *5 (E.D.N.Y. Jan. 13, 2006) (quoting *In re Methyl Tertiary Butyl Ether Prods. Liab. Litig. (In re MTBE)*, 209 F.R.D. 323, 337 (S.D.N.Y. 2002)); *Noble v. 93 Univ. Place Corp.*, 224 F.R.D. 330, 337 (S.D.N.Y. 2004). A class is ascertainable if it is (1) sufficiently bounded so that it is feasible for the court to determine whether a particular individual is a member, and (2) defined by objective criteria that avoid a “mini-hearing on the merits of each case.” *In re Petrobras Sec.*, 862 F.3d 250, 266 (2d Cir. 2017).

B. Rule 23(b)

If the class proponent satisfies each of the Rule 23(a) prerequisites, he must next demonstrate that at least one of the three requirements listed in subsection 23(b) is met. *204 Wal–Mart*, 564 U.S. at 345, 131 S.Ct. 2541. Here, Plaintiffs seek certification under subsection 23(b)(3), which allows a claim for damages to proceed as a class if it is established that (1) common questions predominate over individual questions (the predominance requirement), and (2) the class action vehicle is superior to other possible methods of “fairly and efficiently adjudicating the controversy” (the superiority requirement). *Fed. R. Civ. P. 23(b)(3).*

1. Predominance

The predominance requirement, as a general matter, “tests whether proposed classes are sufficiently cohesive to warrant adjudication by representation.” *In re Nassau Cty. Strip Search Cases*, 461 F.3d 219, 225 (2d Cir. 2006) (internal quotation marks and citation omitted). Even where Rule 23(a)’s commonality requirement is satisfied, predominance under Rule 23(b)(3) is not necessarily met because the latter requires considerably more. *Comcast Corp. v. Behrend*, 569 U.S. 27, 33, 133 S.Ct. 1426, 185 L.Ed.2d 515 (2013). More than their mere presence, Rule 23(b)(3) requires that questions common to the class predominate over individual ones.

Determining whether a question is common or individual depends on the kind of proof that will be needed to resolve that question at trial. An individual question is one for which “members of a proposed class will need to present evidence that varies from member to member,” while a common question is one for which “the same evidence will suffice for each member to make a prima facie showing [or] the issue is susceptible to generalized, class-wide proof.” *Tyson Foods, Inc. v. Bouaphakeo*, — U.S. ——, 136 S.Ct. 1036, 1045, 194 L.Ed.2d 124 (2016). Plaintiffs are not, however, required to prove that these questions will be
In re Namenda Direct Purchaser Antitrust Litigation, 331 F.Supp.3d 152 (2018)

107 Fed. R. Evid. Serv. 215

answered in their favor in order to certify a class under this provision. See Amgen Inc. v. Conn. Ret. Plans & Tr. Funds, 568 U.S. 455, 468, 133 S.Ct. 1184, 185 L.Ed.2d 308 (2013).

Moreover, “individual questions need not be absent” in order to certify a class under Rule 23(b)(3); the text of Rule 23(b)(3) itself contemplates that such questions will be present. Sykes v. Mel S. Harris and Associates LLC, 780 F.3d 70, 81 (2d Cir. 2015). “The rule requires only that those questions not predominate over the common questions affecting the class as a whole.” Id. (internal quotation marks omitted) (quoting Messner v. Northshore Urn. HealthSystem, 669 F.3d 802, 815 (7th Cir. 2012) ). For example, if liability can be determined on a class-wide basis, common issues may predominate even in the face of some individualized damages issues. Sykes, 780 F.3d at 81 (quoting In re Visa Check, 280 F.3d at 139).

2. Superiority

Finally, the district court must determine that “a class action is superior to other available methods for fairly and efficiently adjudicating the controversy.” Fed. R. Civ. P. 23(b)(3). While, structurally, the four factors set forth in Rule 23(b)(3) govern both predominance and superiority, the Second Circuit has held that “they more clearly implicate” the latter. Sykes, 780 F.3d at 82. Accordingly, in determining whether the class action is a superior method, courts consider:

(A) the class members' interests in individually controlling the prosecution or defense of separate actions;

(B) the extent and nature of any litigation concerning the controversy already begun by or against class members;

(C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; and

(D) the likely difficulties in managing a class action.

Fed. R. Civ. P. 23(b)(3). Manageability is, by far, the most critical factor in the superiority determination. Id.

Analysis

Plaintiffs seek to certify a class comprising “All persons or entities in the United States and its territories who purchased branded Namenda IR 5 or 10 mg tablets, and/or generic Namenda IR 5 or 10 mg tablets (including an authorized generic), and/or branded Namenda XR capsules, directly from Forest or its successors in interest, Actavis and Allergan, and/or from any generic manufacturer at any time during the period from June 2012 until September 30, 2015.” (Pls.' Mot. for Class Certification, Ex. 1, Dkt. No. 400 (“Class Cert. Mot.”).) The proposed class consists of 62 members. (Pls.' Reply Mem. of Law in Supp. of Direct Purchaser Class Pls.' Mot. for Class Certification at 2, Dkt. No. 421 (“Pls.' Reply”) . All are major pharmacy retailers (like CVS or Walgreens) or wholesalers who sell to major pharmacy retailers. They purchase Namenda or Namenda-generics for resale to pharmacies and/or consumer patients. (Lamb Rep. ¶ 42.)

At the outset, I reject Defendants' argument that Smith and RDC are inadequate class representatives because they lack sufficient knowledge and involvement in the case, and have abdicated all control to counsel. (Defs.' Opp'n to Direct Purchaser Pls.' Mot. for Class Certification at 20, Dkt. No. 412 (“Defs.' Opp'n”).) Both RDC and Smith have indicated their knowledge of and interest in pursuing the claims of the class. (Hamburger Decl. Ex. 14, Dkt. No. 410 (“Doud Dep. Tr.”) at 10:25 – 11:21, 14:6 – 24, 155:20 – 23, 180:1 – 3; Hamburger Decl. Ex. 15, Dkt. No. 410 (“Benton Dep. Tr.”) at 25:8 – 23, 46:15 – 17, 283:14 – 284:7, 295:9 – 24.)
Defendants' remaining inadequacy arguments pertaining to specific conflicts will be addressed in the discussions of the relevant subgroup.

The proposed class can be broken down into 5 subgroups: (1) Forest Direct Customers; (2) Generic Purchasers (with a subgroup of Non-Forest Generic Purchasers); (3) Corporate Subsidiaries; and (4) allegedly uninjured entities. As Plaintiffs have removed DIK Drug, First Veterinary Supply, and H.D. Smith Wholesale from the revised list of proposed members, they are not included in the following discussion.

**Forest Direct Customers.** 19 entities (including named Plaintiffs Smith and RDC) are direct customers of Defendants (“Forest Direct Customers”). These entities purchased branded Namenda IR and XR from Defendants, and all also purchased the generic. (Dkt. No. 552.) The members of this subgroup assert both “reverse payment” and “hard switch” claims. They are Amerisource Bergen; Anda; Capital Wholesale; Cardinal Health; Dakota Drug; Drogueria Betances; Drogueria Cesar Castillo; Frank W. Kerr Inc.; HD Smith LLC; Louisiana Wholesale Drug; McKesson; Miami Luken; Morris & Dickson; North Carolina Mutual Wholesale Drug; PBA Health; Prescription Supply Inc.; RDC; Smith; and Value Drug.

With respect to this subgroup, Defendants argue that Smith and RDC are inadequate representatives because 3 members are subject to a unique defense that other members have no interest in defending against. (Defs.' Opp'n at 21.) They argue that Amerisource Bergen, Cardinal, and McKesson (“the Big Three”), are subject to a “generic bypass” defense insofar as “they may have benefitted from Forest's conduct because of the tendency for generic companies to bypass wholesalers and sell directly to retailers.” (Id. at 21.) The question here is whether the generic-bypass defense “threaten[s] to become the focus of the litigation.” Gordon, 92 F.Supp.3d at 205 (internal quotation marks omitted) (quoting Romero, 2011 WL 812157, at *3).

These arguments aside, Defendants concede that these 19 entities would be properly included in any class that might be certified. They urge, however, that a class of 19 members is not sufficiently numerous to warrant certification.

As to the other 43 members of the proposed class, Forest objects, on multiple grounds, to their inclusion in a certified class.

**Generic Purchaser Group.** 31 entities purchased only generic memantine (“the Generic Purchaser Group”). They are Albertsons LLC, American Health Packaging, Associated Pharmacies, Auburn Pharmaceutical; Bloodworm Wholesale Drugs; Blupax Pharmaceuticals, LLC; CVS Caremark; Drugs Unlimited, Inc.; Express Scripts Inc.; Genetco Inc.; Hannaford Brothers; HC Pharmacy Central Inc.; Healthsource Distributors, LLC; Humana Inc.; Independent Pharmacy Cooperative; Kaiser Permanente; Keysource Medical, Inc.; Major Pharmaceuticals/Rugby Laboratories; Masters Pharmaceutical Inc.; Medco Health Solutions Inc.; Meijer, Inc; OptumRx Inc.; Peyton's; Quest Pharmaceuticals, Inc.; Richie Pharmaceutical Company; Rx Outreach; Supervalu Inc.; Tel Drug of PA LLC; TopRx LLC; Walmart; and Winn Dixie Logistics Inc.

Defendants argue that the Generic Purchaser Group was not comprehended within the original class definition proposed in the complaint and that should not be added into the mix now. As to all thirty-one members, Defendants argue that these members' claims are not typical of the named Plaintiffs' claims (or of the claims of the Forest Direct Customers) and either lack common questions with the hard switch claims asserted by the Forest Direct Customers or any common claims do not meet the predominance standard of Rule 23(b)(3); and that the named Plaintiffs have no incentive to represent the interests of this group as a result. (Defs.' Opp'n at 10 – 12.)

In addition to the objections described above, Defendants also argue that 30 members of the Generic Purchaser Group lack antitrust standing under Illinois Brick, 431 U.S. 720, 97 S.Ct. 2061, 52 L.Ed.2d 707 (1977), because only one entity – Meijer, Inc. – purchased generic memantine directly from Forest. (Dkt. No. 552.) All other entities purchased generics from entities other than Forest and Mylan during the last two and one half months of the class period. I will call them the “Non-Forest Generic Purchaser Group.”
Corporate Subsidiaries. Defendants object to the inclusion of 4 entities on the basis that class membership should be limited to the common parent of corporate family members – Bellco, Burlington Drug, The Harvard Group, and Valley Wholesale. (Defs.' Opp'n at 13 – 14.)

Allegedly Uninjured Members. Defendants argue that 9 entities (including The Harvard Group from the previous list) must be excluded because they were not injured.

Publix, HE Butt, Kerr Drug, and Bartell allegedly suffered no injury from the purported scheme because they never bought Namenda IR and stopped buying Namenda XR before the hard switch announcement. (Id. at 12.)

DMS allegedly suffered no injury from the purported scheme because it purchased neither Namenda IR nor Namenda XR until after generic entry. (Id. at 12–13.)

Discount Drug Mart, Drogueria Central, and The Harvard Drug Group allegedly suffered no injury from the hard switch because they never purchased Namenda XR at all. (Id. at 13.)

Finally, Bartell, Drogueria Central, Kerr Drug, and Kroger allegedly were not injured by the scheme because they purchased only branded Namenda, even following generic entry. (Id. at 13.) (Bartell, Kerr Drug, and Drogueria Central were already included in the previous lists.)

I will deal with Forest's objections group by group.

A. Corporate Subsidiaries

Defendants argue that class membership should be limited to the common parent of corporate family members and object to the inclusion of four entities they claim are owned by other members in the class. They are Bellco, Burlington Drug, The Harvard Group, and Valley Wholesale. Defendants assert that Bellco is owned by Amerisource Bergen; that Burlington Drug is owned by JM Smith Corporation; that The Harvard Group is owned by Cardinal; and that Valley Wholesale is owned by H.D. Smith LLC. (Id. at 13–14.)

Plaintiffs' Exhibit 9 addresses the corporate status of these entities. (Pls.' Ex. 9, Corporate Status of Certain Entities Listed in Manufacturer Transactional Data.)

The record indicates that Bellco is the wholly owned subsidiary of Amerisource Bergen Drug Corporation and has been incorporated in New York State since May 1960. (Pls.' Ex. 9-B.) Burlington Drug is a subsidiary of JM Smith Corporation, formed under the laws of Vermont in January 1998. (Pls.' Ex. 9-C.) The Harvard Group is a majority-owned subsidiary of Cardinal, incorporated under the laws of Michigan in June 1997. (Pls.' Ex. 9-D.) And Valley Wholesale is a wholly-owned subsidiary of H.D. Smith, formed under the laws of Delaware in October 2012. (Pls.' Ex. 9-E.)

Plaintiffs argue that these subsidiaries are each entitled to a presumption of separateness from their parent corporations because the companies are separately incorporated, separately listed in the manufacturers' transactional data, and, most importantly, separately purchased (and were overcharged for) the product. (Pls.' Reply at 6.) In other words, related or not, each Class member that bought Namenda “suffered independent injury.” (Id.)

I agree. Defendants do not dispute the fact that these entities each independently purchased Namenda products. I join with other courts that have considered this issue and have ruled that where there is distinct and separate injury, a corporate relationship with

Plaintiffs provide sufficient evidence of separateness between these subsidiaries and their parent corporations. Any overcharges they paid for their own purchases of memantine are separately and distinctly applicable to them.

**B. Miscellaneous Uninjured Members**

Defendants' objections to the following entities are variations on a theme. At bottom, their arguments pertaining to Publix, HE Butt, Kerr Drug, Bartell, DMS, Drogueria, *208* Central, Kroger, Discount Drug Mart, and The Harvard Group come down to the claim that, for one reason or another, these entities were not injured by Forest's alleged misconduct.

To frame the following discussion, it is instructive to review the proposed class members' alleged injuries. All members of the class claim that they were overcharged for their memantine requirements due to Forest's allegedly anticompetitive conduct.

With respect to the reverse payment claim, Plaintiffs allege that “all or nearly all” members of the class were overcharged. (Lamb Rep. ¶ 13-a.) They allege that any member who purchased Namenda IR, Namenda XR, and/or generic memantine hydrochloride paid higher prices than they otherwise would have had generic competition started earlier, “because they would have purchased (or purchased more) generic memantine at prices below branded Namenda and would have purchased the generic at lower prices.” (Id.) In other words, Plaintiffs claim that the reverse payment injured any member who purchased Namenda XR, any member who purchased Namenda XR, and any member who purchased a generic alternative once it became available (from Forest or from a generic competitor).

With respect to the hard switch claim, Plaintiffs allege that “all or nearly all proposed Class members who purchased at least Namenda IR and XR, or XR” were overcharged. (Lamb Rep. ¶ 13-b.) In other words, Plaintiffs allege that any entity that purchased Namenda XR paid a higher price than they otherwise would have for the generic memantine they would have purchased in place of the more expensive brand name drug, and that they would have purchased more of that generic. (Id.)

Plaintiffs allege that the aggregate overcharges break down into two categories: “Brand-Generic” and “Generic-Generic.” (Id. at ¶ 125.) The former relates to Forest's alleged foreclosure of class members' switching to generic memantine via both the reverse payment and the hard switch strategy. Absent the reverse payment, Plaintiffs allege, a large volume of branded Namenda IR and Namenda XR purchases would have been replaced by generic memantine at a significantly reduced price. (Id.) “Brand-Generic” injuries thus include the higher prices paid by class members for the branded Namenda IR and XR they actually bought instead of the lower-priced generic alternative they would have bought absent the reverse payment and the hard switch strategy. (Id.)

“Generic-Generic” overcharges relate to the higher prices that class members paid for the generic alternatives they actually bought. (Id. at ¶ 126.) The reverse payment led to such overcharges because it delayed generic entry and “prices for generic drugs tend to decline over time as generic manufacturers compete against each other.” (Id.) The hard switch strategy led to Generic-Generic overcharges because it shifted the Namenda IR prescription base to Namenda XR before generics had the chance to compete for Namenda IR business. (Id. at ¶ 65.) In light of the 89.9% substitution rate of generic memantine for brand Namenda IR over the three months following generic entry, Dr. Lamb concludes that generic entry would have affected a larger base of IR prescriptions absent the hard switch. (Id. at ¶ 81.) Plaintiffs submit that generic memantine purchasers paid higher prices because this suppressed generic sales and their attendant savings. (Id. at ¶ 65.) The Generic-Generic category would apply to any member who purchased generic memantine, whether they previously purchased branded Namenda products or not.
Moving to Defendants’ specific objections, they first argue that Publix, HE*209 Butt, Kerr Drug, and Bartell were not injured because they never bought Namenda IR and stopped buying Namenda XR before the hard switch announcement. (Defs.’ Opp’n at 12.) These entities were injured under the Brand-Generic theory described above insofar as Plaintiffs allege that Namenda XR purchases would have been replaced by generic memantine at a significantly reduced price.

Publix and HE Butt were also injured to the extent they purchased generic memantine. The record indicates that Kerr Drug and Bartell never purchased generic memantine. (See Hamburger Decl. Ex. 13, Dkt. No. 410 (Expert Report of Pierre-Yves Cremieux (“Cremieux Rep.” ) , at ¶ 63 (Ex. 1.2, Summary of Findings: Reverse Payment).)

Defendants argue that DMS could not have been injured by the alleged scheme because it did not make any purchases of Namenda IR or Namenda XR until after generic entry.” (Defs.’ Opp’n at 13.) To the extent Plaintiffs allege that DMS purchased generic memantine during the class period, DMS suffered injury in the form of Generic-Generic overcharges.

Defendants argue that Bartell, Drogueria Central, Kerr Drug, and Kroger should be excluded because they did not buy generic memantine, even after it became available following generic entry. They submit that there is no basis to assume that such brand-only purchasers “would have purchased generic Namenda IR in the but-for world.” (Id. at 13.)

I understand Defendants’ argument that the decision to continue buying branded Namenda products, even after generics entered the market, casts doubt on the fact that these entities would have purchased the generic earlier had it been available to them. But Defendants are not entitled to the benefit of that doubt when the very reason we cannot know the answer to that question is because of their alleged wrongdoing. See In re DDAVP, 585 F.3d at 689.

Defendants argue that Discount Drug Mart, Drogueria Central, and The Harvard Group “could not have been injured by the hard switch” because they never purchased Namenda XR or stopped purchasing Namenda XR before the February 2014 announcement, and should therefore be excluded with respect to the hard switch claim. (Defs.’ Opp’n at 13.)

That these entities never purchased Namenda XR does not establish that they were uninjured by the hard switch. If the jury finds Forest liable on Plaintiffs’ theory of liability, these members were injured insofar as the hard switch strategy shifted the Namenda IR prescription base, thereby suppressing generic sales and their attendant savings. In the case of Discount Drug Mart, the question of whether its purchases were “due to” the hard switch strategy is a question for the trier of fact, given the evidence of Defendants’ pre-announcement communications with key stakeholders and customers regarding the launch of Namenda XR and withdrawal of Namenda IR.

* * *

That brings Plaintiffs to a total proposed class of 31 members, which is still below the commonly accepted threshold of 40 members needed to warrant class certification.

And so we turn to the largest and most complicated group of potential class members – the one as to which Forest levels the most objections. If they can be included in the class, it will easily exceed the 40 member threshold. If they cannot, certification becomes more problematic.

*C. Generic Purchaser Group

This category includes members who purchased generic memantine hydrochloride. They are Albertsons LLC; American Health Packaging; Associated Pharmacies; Auburn Pharmaceutical; Bloodworth Wholesale Drugs; Blupax Pharmaceuticals, LLC;
Forest objects to the inclusion of the entire Generic Purchaser Group because generic purchasers were not included in the original class definition proposed in the complaint. It also argues that their claims are not typical of Forest Direct Customers, and that their claims either lack common questions with the Forest Direct Customers' hard switch claim, or any common issues do not predominate. Forest argues that named Plaintiffs' interests are not aligned with the Generic Purchaser Group as a result. (Id. at 10–11.)

Finally, because all but one Generic Purchaser – Meyer, Inc. – purchased memantine from Forest's generic competitors, not from Forest itself, Forest objects to the Non-Forest Generic Purchasers on the further ground that they lack antitrust standing under *Illinois Brick Co. v. Illinois*, 431 U.S. 720, 97 S.Ct. 2061, 52 L.Ed.2d 707 (1977). (Defs.' Opp'n at 11 – 12.)

### 1. Expanded Class Definition

Defendants are correct that the inclusion of the Generic Purchaser Group expands upon the definition found in Plaintiffs' complaint, which proposed a class consisting only of members who purchased Namenda IR or XR *directly* from Forest. (See Am. Compl. ¶ 193.) They are wrong, however, when they argue Plaintiffs “were obligated to seek leave to amend the Complaint well before fact discovery closed.” (Defs.' Opp'n at 11.)

It is well-established that a certifying court “is not bound by the class definition proposed in the complaint.” *Robidoux v. Celani*, 987 F.2d 931, 937 (2d Cir. 1993). However, this principle is customarily cited as support for the court's ability to narrow a proposed class. See, e.g., *Lundquist v. Sec. Pac. Auto. Fin. Servs. Corp.*, 993 F.2d 11, 14 (2d Cir. 1993); *Madden v. Midland Funding, LLC*, 237 F.Supp.3d 130, 153 (S.D.N.Y. 2017); *Flores v. Anjost Corp.*, 284 F.R.D. 112, 125 (S.D.N.Y. 2012); *Poddar v. State Bank of India*, 235 F.R.D. 592, 595 (S.D.N.Y. 2006). Far fewer cases support the converse proposition that the court may approve the expansion of the class as it was defined in the complaint. Plaintiffs cite three cases to this end, two of which are instructive here – *Menking ex rel. Menking v. Daines*, 287 F.R.D. 174 (S.D.N.Y. 2012) and *McCarthy v. Paine Webber Grp., Inc.*, 164 F.R.D. 309 (D. Conn. 1995).

In *Menking*, 287 F.R.D. at 181, even though the plaintiff originally sought certification of a *citywide* class in her complaint, the court approved a “new and expanded *statewide* definition for the proposed class,” as requested by the plaintiff in her motion for class certification “based on evidence obtained in discovery.” In *McCarthy*, 164 F.R.D. at 311, the plaintiffs motion for class certification proposed a class comprising all persons *211* who owned limited partnership interests in a particular entity. This was broader than the definition found in the complaint, which confined the class to persons who owned a limited partnership interest *during a particular time period*. *Id.* The court certified the broader class proposed in the motion for certification, noting that it was “not bound by the class definition proposed in the complaint.” *Id.* (citing *Robidoux*, 987 F.2d at 937).

*Menking* and *McCarthy* demonstrate that a plaintiff's expansion of the class definition beyond that which was proposed in the complaint is not categorically improper. Rather, in both cases, the court went on to consider whether the newly proposed class members satisfied the substantive requirements of Rule 23(a).
In re Namenda Direct Purchaser Antitrust Litigation, 331 F.Supp.3d 152 (2018)

107 Fed. R. Evid. Serv. 215

Forest argues that, under In re Aluminum Warehousing Antitrust Litig., No. 13-md-2481 (KBF), 2016 WL 1629350, at *5-6, 2016 U.S. Dist. LEXIS 54643, at *32-33 (S.D.N.Y. Apr. 25, 2016), Plaintiffs must establish that there is good cause for expanding the class at this juncture because the time to add new members “has long passed.” (Defs.’ Opp’n at 11.) I disagree. Defendants’ reliance on the good cause standard discussed in Aluminum Warehousing is misplaced; there, the court was considering the plaintiffs’ motion for leave to file a fifth amended complaint. Aluminum Warehousing, 2016 WL 1629350, at *2, 2016 U.S. Dist. LEXIS 54643, at *21. This is a timely motion for class certification, not a belated motion for leave to file an amended complaint.

Moreover, Plaintiffs’ proposed class definition does not raise the same notice and discovery issues present in Aluminum Warehousing. There, the proposed amendments would have added two new foreign defendants, “with respect to whom service would not be completed under the Hague Convention for at least several months,” id. at *6, 2016 U.S. Dist. LEXIS 54643, at *13; changed the plaintiffs’ claims and proposed class definition “in the midst of class certification briefing in ways that could necessitate substantial new fact and expert discovery – including significant non-party and overseas discovery - that defendants could not have anticipated,” id. at *6, 2016 U.S. Dist. LEXIS 54643, at *13–14; and substantially broadened the scope of the proposed class and relevant transactions by including markets that the defendants had no “reason to address during the discovery period,” id. at *6, 2016 U.S. Dist. LEXIS 54643, at *14.

Plaintiffs here are not attempting to add any new defendants, let alone foreign parties. Nor are they attempting to broaden the class definition “in the midst of” class certification briefing – they included the expanded definition at the outset, in their initial motion for certification. (Class Cert. Mot., Ex. 1.)

Furthermore, Defendants had reason to anticipate during discovery any novel issues that the Generic Purchaser Group might introduce. While the Amended Complaint did not include the Generic Purchaser Group as members of the class, it specifically alleged that but for Defendants’ anticompetitive conduct, members of the class would have paid less for memantine by “purchasing generic Namenda IR at lower prices sooner.” (Am. Compl. ¶ 229.) It further alleged,

 Defendants' anticompetitive conduct, which delayed introduction into the United States marketplace of generic versions of Namenda IR, has caused plaintiff and the Class to pay more than they would have for memantine hydrochloride absent defendants' illegal conduct As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further due to competition among the generic manufacturers.

(Id. ¶¶ 226 – 27.) And indeed, Defendants' expert, Dr. Cremieux, addresses the claims of the Generic Purchaser Group throughout his report. (See, e.g., Cremieux Rep. ¶ 63.)

Ultimately, consistent with the certifying court's broad discretion over class definition and obligation to reassess class rulings as the case develops, Boucher v. Syracuse Univ., 164 F.3d 113, 118 (2d Cir. 1999) (quoting Barnes v. Am. Tobacco Co., 161 F.3d 127, 140 (3d Cir. 1998) ), I see no reason to disregard the class definition that Plaintiffs propose in their motion for class certification simply because it expands upon the definition found in the Amended Complaint.

2. Antitrust Standing
Defendants object to the inclusion of the Non-Forest Generic Purchasers in the class on the ground that they lack antitrust standing. Defendants rely on a line of cases beginning with *Illinois Brick*, to support their argument that “any purchases from a generic manufacturer (other than Mylan or Forest itself) could not form the basis of an antitrust claim.” (Defs.’ Opp’n at 12.)

However, these “direct-purchaser” cases are irrelevant because the Non-Forest Generic Purchasers are not *Illinois Brick* “indirect purchasers.” Indirect purchasers are those who buy from the customers of a defendant – from people to whom the defendant sold product. See *Hanover Shoe v. United Shoe Mach. Corp.*, 392 U.S. 481, 492–94, 88 S.Ct. 2224, 20 L.Ed.2d 1231 (1968); see also *California v. ARC Am. Corp.*, 490 U.S. 93, 97, 109 S.Ct. 1661, 104 L.Ed.2d 86 (1989); *Illinois Brick*, 431 U.S. at 724, 741, 97 S.Ct. 2061; *Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 550, 103 S.Ct. 897, 74 L.Ed.2d 723 (1983). The Non-Forest Generic Purchasers bought from Forest’s competitors. Vis-à-vis Forest, they are neither direct nor indirect; vis-à-vis the generic manufacturers from whom they bought their memantine, they are direct purchasers.

The Non-Forest Generic Purchasers have standing to bring antitrust claims against Forest if they (1) have suffered an antitrust injury “of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful,” and (2) are proper plaintiffs in light of the four “efficient enforcer” factors. *In re DDAVP*, 585 F.3d at 688 (internal citations and quotation marks omitted) (quoting *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489, 97 S.Ct. 690, 50 L.Ed.2d 701 (1977); *Volvo N. Am. Corp. v. Men's Int'l Prof'l Tennis Council*, 857 F.2d 55, 66 (2d Cir. 1988) ).

As to the first prong, the Non-Forest Generic Purchasers claim that they were overcharged for their purchases of generic memantine as a result of Forest's “two-part, allegedly anticompetitive and ‘unlawful scheme to maintain a monopoly and to allocate the United States market for branded and generic versions of memantine hydrochloride.’” (Lamb Rep. ¶ 5.) Monopolist overcharges are “the classic antitrust injury.” *Savory Pie Guy, LLC v. Comtec Indus., Ltd.*, No. 14 Civ. 7527 (VB), 2016 WL 7471340, at *12 (S.D.N.Y. Dec. 28, 2016); see also *Freeland v. AT&T Corp.*, 238 F.R.D. 130, 143 (S.D.N.Y. 2006). Paying higher prices for generic memantine is “inextricably intertwined” with the anticompetitive effects of Defendants' alleged conduct and thus “flows from that which makes [their] acts unlawful.” *In re DDAVP*, 585 F.3d at 688 (quoting *Blue Shield of Va. v. McCreary*, 457 U.S. 465, 484, 102 S.Ct. 2540, 73 L.Ed.2d 149 (1982) ).

As to the proper plaintiff prong, the Non-Forest Generic Purchasers satisfy the efficient enforcer criteria, which look to the (1) directness of the asserted injury, or causation; (2) self-interest of the class of persons to vindicate the public interest, or motivation; (3) speculativeness of the alleged injury; and (4) difficulty of identifying and apportioning damages so as to avoid duplicative recoveries. *Id.* at 688.

The Non-Forest Generic Purchasers' purported injuries are the direct result of the asserted antitrust violation – they allege they paid higher prices for generic memantine because Defendants intentionally restricted and manipulated generic competition.

They are also sufficiently motivated and well-positioned to vindicate the antitrust interests at play in this case. See *id.* at 689 (describing competitors as the most motivated antitrust plaintiffs); see also *In re Zinc Antitrust Litig.*, 155 F.Supp.3d 337, 361 (S.D.N.Y. 2016) (describing competitors as the traditional plaintiff in antitrust cases).

Their claims support non-speculative damages, as they define damages by the difference between the prices they paid for generic memantine in the actual world and “those they would have paid in a world free of the alleged misconduct.” *In re Zinc*, 155 F.Supp.3d at 362 (finding injury sufficiently non-speculative for antitrust standing purposes where plaintiffs defined damages by the amount by which the price at issue was inflated). While it “may be difficult to account precisely for the likely effects of generic competition,” the Court has “little doubt that those effects can be sufficiently estimated and measured here.” *In re DDAVP*, 585 F.3d at 689. Plaintiffs have submitted expert reports and analysis that speak precisely and extensively to this issue.
For example, Dr. Lamb uses the nearly 95% discount of generic memantine and corresponding 89.9% adoption rate in the three months following generic entry to estimate the price a generic purchaser would have paid if generics had entered the market earlier. (Lamb Rep. at Fig. 3 (Brand and Generic Market Sales); Fig. 4 (Brand and Generic Namenda IR Average Price); Fig. 5 (Generic Namenda IR Average Price).)

Defendants' reliance on In re Skelaxin (Metaxalone) Antitrust Litig., 2014 WL 2002887, at *7-11, 2014 U.S. Dist. LEXIS 66707, at *29–41 (E.D. Tenn. May 15, 2014), is unpersuasive. While the alleged antitrust conspiracy in that case largely tracks the facts of the scheme alleged here, I disagree with the court's conclusion that the relationship between fewer generic manufacturers and higher generic prices is “too speculative” to estimate the alleged overcharge. Id. at *9, 2014 U.S. Dist. LEXIS 66707, at *36.

And finally, the circumstances of this case do not raise the same concerns of duplicative recovery as was true in Illinois Brick and the other “direct-purchaser” rule cases.

3. Adequacy of Named Plaintiffs

Defendants claim that RDC and Smith (both Forest Direct Customers) are inadequate representatives of a class including the Generic Purchaser Group because the majority of that group faces a unique standing hurdle, and no member of that group has an interest in the product-hopping claim. (Defs.' Opp'n at 21.)

I have already addressed and rejected Defendants' argument regarding the Non-Forest Generic Purchasers' antitrust standing.

214 I disagree with Defendants that the Generic Purchaser Group has no interest in the “hard switch” claim. Plaintiffs allege that the Generic Purchaser Group was impacted by the hard switch strategy because it led to higher generic prices. Dr. Lamb concluded that absent the hard switch strategy, and given the 89.9% substitution of generic memantine for brand Namenda in the three months following generic entry, generic entry would have affected a larger base of IR prescriptions and led to increased generic memantine purchases and savings. (Lamb Rep. ¶ 81.)

* * *

With the Generic Purchaser Group included, the class comprises 62 members and the numerosity requirement is presumptively satisfied. Ramirez v. Riverbay Corp., 39 F.Supp.3d 354, 362 (S.D.N.Y. 2014) (citing Consol. Rail Corp. v. Town of Hyde Park, 47 F.3d 473, 483 (2d Cir. 1995)).

The various other factors in the numerosity analysis also weigh in favor of certification. The class members in this case are spread across the country; a fair number are located on the East Coast, others on the West, and still others in Puerto Rico. (Lamb Reply Rep. at Fig. 2.) Their disparate locations constitutes both a significant and practical difficulty to joinder. Individual suits filed in each of these locations would also impose an unnecessary and substantial burden on the judicial system.

There is also evidence that a number of the potential class members are small wholesalers that lack the financial resources to bring individual actions. (Lamb Rep. ¶ 42.) While all members might have the same incentive to bring individual actions, they do not have the same ability to do so.

D. Typicality, Commonality, and Predominance
Defendants' objections to the various subgroups addressed above are, in reality, arguments about typicality, commonality, and predominance. These analyses share a similar focus - they test whether the class is “sufficiently cohesive to warrant adjudication by representation,” In re Nassau Cty. Strip Search Cases, 461 F.3d 219, 225 (2d Cir. 2006) (internal quotation marks and citation omitted) (quoting In re Visa Check, 280 F.3d at 136).

It is a more complicated question whether common questions can be said to exist, and indeed, to predominate, when the class includes all subgroups. As commonality is subsumed under the more demanding predominance requirement, Dial, 314 F.R.D. at 113, I proceed directly to the Rule 23(b)(3) analysis, which imposes upon the court the “duty to take a ‘close look’ at whether common questions predominate over individual ones.” Comcast, 569 U.S. at 34, 133 S.Ct. 1426. That discussion also addresses the typicality argument Defendants raise with respect to the Generic Purchaser Group.

As to liability, I agree that common questions predominate over the class, including the generic-only purchasers. If each Class members were to pursue this theory individually, “each would have to prove the same course of conduct, using the same documents and witnesses.” (Id. at 17.) To establish the reverse payment claim, for example, all members will need to present evidence of the agreement and its terms. Similarly, to establish the hard switch claim, members have indicated that they will offer evidence of pre-announcement communications with key stakeholders and customers regarding the forthcoming launch of Namenda XR and withdrawal of Namenda IR; evidence of the announcement itself; evidence pertaining to Judge Sweet's December 15, 2014 order; and evidence related to the aftermath of that order, including Forest's communications regarding its intention to challenge Judge Sweet's order in the Court of Appeals.

Common questions predominate as to injury. First and foremost, at trial, all but 4 members of the class would need to prove they were injured by the Generic-Generic overcharge – that, but for Defendants' conduct, “generic prices by July 2015 would
have been lower.” (Pls.’ Reply at 4.) This is but one aspect of the injury suffered by the 27 customers who allege they also paid higher prices for the branded Namenda they actually purchased. For the remaining 31 members, the Generic Purchaser Group, this is the ultimate question with respect to injury. Therefore, 58 of the 62 members (just about 94% of the class) allege they were injured by paying higher prices for the generic memantine they actually purchased.

This issue is susceptible to generalized, class-wide proof. As Defendants point out, Plaintiffs’ proof of injury will necessarily be intertwined with proof of damages. (Defs.’ Opp’n at 23.) In other words, proving that they were injured will be bound up with proving the extent to which Plaintiffs were injured. *McLaughlin v. Am. Tobacco Co.*, 522 F.3d 215, 227 (2d Cir. 2008).

*216* The 58 members claiming Generic-Generic damages all need to establish that the less expensive generics would have entered the market earlier; that generic prices would have continued to fall over time as more generic manufacturers competed; and that they would have paid less for their actual generic purchases. They will also need to show that the hard switch strategy further suppressed generic competition (and therefore savings) by shifting the Namenda IR prescription base to Namenda XR before generic entry.

All class members indicate that they plan to rely on Dr. Lamb’s analysis of antitrust injury and damages, which, in turn, is based on three categories of proof that he states is “common to the proposed Class as a whole rather than specific to individual members.” (Lamb Rep. ¶ 67.) His conclusions are based on: (1) peer-reviewed economic and government research showing that generics typically enter the market at lower prices than their brand name counterparts and capture a significant share of the total unit sales for that drug; (2) Forest’s internal forecasts of the impact that generic competition would have on the memantine market; and (3) data on the actual sales volumes and prices of Namenda IR, Namenda XR, and generic memantine (which shows a 95% price discount for the generic and an 89.9% substitution rate by September 2015), derived from IMS Health’s NSP database. (Id. at ¶¶ 68 – 85.)

They also intend to rely on his analysis of the impact that the hard switch had on generic competition. (Id. at ¶ 119.) For example, while Forest lost 96.5% of Namenda IR sales within six months of generic entry, it retained significant sales of branded Namenda because over 50% of existing Namenda patients had already switched to Namenda XR – “far more than the approximately 30 percent that [Forest’s] own planning indicated would be possible in the absence of a hard switch.” (Id. at ¶ 87; see also Pls.’ Reply at 16.) This analysis again relies in part on internal forecasts, including Forest’s comparison of its loss of exclusivity over Namenda IR with the Hard Switch strategy and without it. Other common evidence includes communications from Forest to various stakeholders (physicians, caregivers, pharmacies) and customers regarding Forest’s “Namenda IR to XR Conversion Project” and informing them of the withdrawal of Namenda IR “immediately and for the next six months.” (Pls.’ Reply at 11; Lamb Rep. ¶ 98.) All members indicate they will rely on this evidence at trial to prove that, while Namenda IR was never fully removed from the market, due to Judge Sweet’s December 15, 2014 order, “this communications strategy was successful for Forest in triggering wide-spread conversion to Namenda XR.” (Lamb Rep. ¶ 63.)

While the Generic Purchaser Group will not (and could not) prove that they were injured by any Brand-Generic overcharges, determining Brand-Generic damages does not overwhelm the predominantly common issues that govern the class. To determine Brand-Generic damages, Plaintiffs indicate that they will rely on some of the same evidence discussed in connection with the Generic-Generic damages. To determine Brand-Generic damages, Dr. Lamb used the NSP database to calculate both “the price differential between the actual average Namenda IR and Namenda XR prices and but-for average monthly generic memantine hydrochloride prices” and “the price differential between the actual average Namenda XR monthly prices and but-for average monthly generic memantine hydrochloride prices.” (Id. at ¶ 125 (emphasis added).) For both Brand-Generic and Generic-Generic damages, class members will need to establish the price of *217* average monthly generic memantine but for Defendant's alleged misconduct. The additional factor in the Brand-Generic computation is the actual average monthly price of Namenda IR and Namenda XR, which is a far less complicated question. It does not overwhelm the predominating issues in this case.
Damages. Defendants argue that Dr. Lamb's models do not provide a sufficient method of measuring class-wide damages. It is not enough that Plaintiffs supply a method to measure and quantify damages on a class-wide basis; the court must be satisfied that “the methodology [is] a just and reasonable inference,” and is not speculative. Comcast Corp., 569 U.S. at 35, 133 S.Ct. 1426. Defendants argue that Plaintiffs cannot meet this burden.

Plaintiffs must demonstrate that Dr. Lamb's methodology identifies only damages that result from Defendants' wrong – i.e., it must isolate damages that inhere from a valid theory of antitrust impact from those that do not. In Comcast, 569 U.S. at 36, 133 S.Ct. 1426, the Supreme Court held that the plaintiffs' proposed methodology failed to do so where their expert's model assumed the validity of all four alleged theories of antitrust impact, but the district court credited only one of those theories. The expert's testimony confirmed that his model “calculated damages resulting from ‘the alleged anticompetitive as a whole’ and did not attribute damages to any one particular theory.” Id.

Dr. Lamb's methodology in this case does not suffer from the same infirmity identified in Comcast, 569 U.S. at 37, 133 S.Ct. 1426. Dr. Lamb's methodology would in fact be able “to bridge the differences between supra-competitive prices in general and supra-competitive prices attributable” to each step of the alleged two-part maneuver that Plaintiffs allege in this case. Comcast, 569 U.S. at 38, 133 S.Ct. 1426. In Comcast, the plaintiffs' expert established a single “‘but-for’ baseline – a figure that would show what the competitive prices would have been if there had been no antitrust violations.” Id. By contrast, Dr. Lamb has provided multiple models that account for different “but-for” scenarios. (Lamb Rep. ¶ 121 (“I have applied benchmark methodologies to measure damages associated with each of the two components of the alleged misconduct.”).)

In his report, Dr. Lamb discusses the measurement of class-wide damages in both the “No Reverse-Payment But-For World,” id. at ¶¶ 139 – 42, and the “No Hard Switch But-For World.” (Id. at ¶¶ 158 – 60.) These various models allowed Dr. Lamb to isolate and analyze damages arising from each aspect of Forest's alleged anticompetitive conduct. (Id. at ¶¶ 141, 158.; see also In re Solodyn, 2017 WL 4621777, at *10 (approving the plaintiffs' expert's model which provided for twelve but-for scenarios, “contemplating the different possible points of sustained generic entry absent the [alleged conduct] and the varying competitive conditions that would have followed”).

Defendants challenge the ability of Dr. Lamb's hard switch and reverse payment models to measure classwide damages. Their overarching objection is that Dr. Lamb's models assume the injury that they purport to prove. To the extent I have addressed these objections in connection with Defendants' motion to exclude Dr. Lamb as an expert, I will not readdress them here.

1. Hard Switch Methodology

To calculate hard switch damages, Dr. Lamb started with actual Namenda XR sales volume over the class period. (Lamb Rep. ¶ 146.) He subtracted from that number the estimated sales volume of Namenda XR that Forest predicted would occur if it did not commence the hard switch (lawful conversion). (Id.) The difference between those figures, Dr. Lamb concludes, is attributable to the hard switch. (Pls.' Reply at 11; Lamb Rep. ¶ 146.) He performed a structural break / statistical significance test to confirm this conclusion. He then used this figure (the difference between actual and but-for Namenda XR sales) to calculate the price that class members who purchased Namenda XR would have paid for generic memantine instead of purchasing Namenda XR. (Lamb Rep. ¶ 147.)

Defendants argue that Dr. Lamb's hard switch model, including the structural break test that purports to confirm his conclusion, fail to prove causation. (Defs.' Opp'n at 31.) Without proving that proposed class members' Namenda XR purchases were made because of the hard switch, Defendants claim that Dr. Lamb's models fail to show that members were injured. This is more
In re Namenda Direct Purchaser Antitrust Litigation, 331 F.Supp.3d 152 (2018)
107 Fed. R. Evid. Serv. 215

or less the same argument made in Defendants' motion to exclude Dr. Lamb's expert testimony. Defendants again argue that Dr. Lamb's hard switch methodology fails to show causation because it includes market-wide, rather than purchaser-specific information, and imposes a 30% threshold of lawful Namenda XR adoption. I remain unpersuaded.

In the class certification context, Defendants emphasize that market-wide data cannot establish causation because it does not account for patient and physician prescribing preferences, which would require individualized proof. I reiterate what I said in my discussion of Defendants' motion to exclude Dr. Lamb's expert testimony – Plaintiffs' allegation is that Forest worked to ensure a “‘forced switch’ whereby physicians and patients would have little choice but to switch to Namenda XR.” (Lamb Rep. ¶ 89.) They allege that limiting patient and physician preferences was precisely the point of “discontinu[ing] or dramatically restrict[ing] the supply of Namenda IR several months before the availability of generic memantine.” (Id.)

In this case, the idiosyncrasies of patient preferences do not require a degree of individualized proof that makes class certification inappropriate. Defendants' reliance on McLaughlin is undermined by the fact that the proposed members were not individual consumers – a fact of fundamental importance to the court's decision in that case. See, e.g., McLaughlin, 522 F.3d at 224; id. at 229; id. at 225 n.7. Here, proposed members are not patients; they are “wholesalers and other direct purchasers.” (Pls.' Reply at 14.) Forest does not contest the fact that it “deals with wholesalers, not patients.” (Id.) I agree with those courts that have rejected the argument that a class comprising direct purchasers must show that individual patient decisions were the result of the defendant's alleged conduct. See In re Warfarin Sodium Antitrust Litig., 391 F.3d 516, 528–29 (3d Cir. 2004) (plaintiffs' allegation of overpayment for drug was “purely an economic injury” supporting a finding of commonality and predominance); In re Solodyn, 2017 WL 4621777, at *10; Teva Pharm. USA, Inc. v. Abbott Labs., 252 F.R.D. 213, 229 (D. Del. 2008).

As to the 30% lawful adoption rate imposed in Dr. Lamb's model, I have already addressed the propriety of this figure in response to Defendants' motion to exclude Dr. Lamb and Dr. Berndt's use of forecast averages in their respective analyses. This threshold was derived from Forest's own documents and forecasts, which compared hard switch and soft switch scenarios, as well as internal high-level analysis of how these forecasts impacted potential Namenda XR conversion rates. These forecasts were not, as Defendants state, “cherry-picked.” Dr. Lamb relied on forecasts that were (1) “closest in time to Forest's decision to enact the hard switch, after Forest had market experience with Namenda XR and predicted generic entry in July 2015 (when it actually occurred), and thus incorporated the best analysis Forest had at the time”; and (2) “consistent with Forest's actual conversion rate through January 2014, before the switch announcement.” (Pls.' Reply at 18.)

In any event, disputes over which forecasts are the appropriate forecasts do not discredit Dr. Lamb's methodology at the class certification stage. It is for the jury to decide whether the his opinions are persuasive. See In re Solodyn, 2017 WL 4621777, at *10.

It is also worth noting that, when estimating the adoption rate of Namenda XR absent the hard switch, it stands to reason that Forest took factors such as patient and physician prescribing preferences into account. As Dr. Lamb indicates, Forest's Namenda XR conversion rates were both thorough and kept up to date, with multiple forecasts being created in the space of a few weeks. (Lamb Rep. ¶ 151.)

Defendants raise the additional argument that Dr. Lamb dismisses the impact of Judge Sweet's injunction and Forest's “campaign to comply with it.” (Defs.' Opp'n at 30.) Dr. Lamb considered this possibility at length. He concluded, however, that the injunction “was unlikely to have eliminated the anticompetitive effects of Forest's Hard Switch strategy.” (Pls.' Reply at 12; Lamb Reply Rep. ¶ 69 – 75.) He reached this conclusion based on two categories of evidence.

First, when Forest informed customers of the injunction, it indicated that it was “appealing” the order and intended to “convince the higher court that, in fact, the lower court's decision was in error.” (Opper Decl. Ex. 13, Dkt. No. 421 (“Cremieux Dep. Tr.”)) at 13:18 – 21.) After the Second Circuit upheld the injunction, Forest continued to challenge it through November 2015, and
communicated this to its customers. (Pls.’ Reply at 12; Lamb Rep. ¶ 114.) Plaintiffs’ argue that the effects of the hard switch continued because, contrary to Forest’s alleged campaign to comply with the injunction, Forest “intentionally sowed doubt” as to whether it would stand. (Pls.’ Reply at 12.) This is supported by evidence cited in Dr. Lamb’s report that “physicians were often hesitant to prescribe Namenda IR following the Court’s injunction.” (Lamb Rep. ¶ 116.)

Second, Dr. Lamb reviewed evidence indicating the difficulty of transitioning patients back to Namenda IR once they had switched to Namenda XR. This includes evidence that physicians were hesitant to prescribe, and pharmacies and health plans no longer covered, Namenda IR following the injunction. (Id. at ¶ 118.) Plaintiffs thus argue that, regardless of the injunction, “the marketplace, once shifted, would be slow to revert back to IR.” (Pls.’ Reply at 12.)

2. Reverse Payment Methodology

Because Dr. Lamb’s reverse payment model incorporates hard switch damages, Defendants argue that it suffers from the same flaws described above. That discussion applies with respect to those objections.

Defendants claim that the reverse payment model suffers from additional flaws. They argue both that it is “premised on assumptions regarding generic pricing and penetration that are untethered from the actual world and sound economic theory,” and that it allocates damages on the assumption that each member was injured by the reverse payment and the hard switch strategy. (Defs.’ Opp’n at 31.)

The first objection is without merit. I disagree that Dr. Lamb’s methodology in connection with the reverse payment model is divorced from sound economic theory. Dr. Lamb explains that he used a “benchmark analysis” to measure the overcharge resulting from the reverse payment, which “has been widely used for many years in calculating damages that arise from anticompetitive conduct of the sort alleged in this case.” (Lamb Rep. ¶ 131.) I have reviewed Dr. Lamb’s qualifications and the soundness of his expert testimony in the motion to exclude that testimony. To the extent that Forest disagrees with the generic entry date and number of generics that Dr. Lamb uses in his calculations, they are free to explore those issues on cross-examination.

The second part of Defendants’ challenge to the reverse payment model speaks to their previous objections about which members were and were not injured. For example, they state, “Dr. Lamb’s allocation awards damages for the hard switch to entities that never even purchased Namenda XR,” and “allocates damages and assumes injury to entities that never purchased generic IR and thus could not have been injured by any of Forest’s conduct.” (Defs.’ Opp’n at 32.) These are arguments about Plaintiffs’ theory of injury, not about Dr. Lamb’s methodology. I have already addressed these arguments in the discussion of which members could and could not be included in the class.

E. Superiority

Finally, a class action is superior to other available methods for fairly and efficiently adjudicating this controversy, as required under Rule 23(b)(3).

The first consideration under Rule 23(b)(3)(A) is whether the class members have an interest in controlling the prosecution of separate actions. There is no evidence that any of the direct purchasers would prefer to control the prosecution of their claims through separate lawsuits. On the contrary, Plaintiffs submit that many members of the class would forego their claims altogether rather than pursue them individually because, as small wholesalers, they “lack the resources to bring complex, expert-intensive antitrust suits on their own.” (Class Cert. Mot. at 9.) The Court is not aware of any other litigation concerning this controversy by or against the direct purchaser class members. See Fed. R. Civ. P. 23(b)(3)(B).
Class treatment is appropriate in such “negative value cases,” in which each class members' interest in the litigation is less than the cost to maintain an individual action. Royal Park Invs. SA/NV v. Wells Fargo Bank, N.A., No. 14 Civ. 9764 (KPF), 2018 WL 739580, *16 (S.D.N.Y. Jan. 10, 2018) (citing Noble, 224 F.R.D. at 346). “As the Supreme Court has said, Rule 23(b)(3) class actions can be superior precisely because they facilitate the redress of claims where the costs of bringing individual actions outweigh the expected recovery.” In re U.S. Foodservice Inc. Pricing Litig., 729 F.3d 108, 130 (2d Cir. 2013) (quoting Amchem Prods., Inc. v. Windsor, 521 U.S. 591, 617, 117 S.Ct. 2231, 138 L.Ed.2d 689 (1997)).

Turning to Rule 23(b)(3)(C), several considerations weigh in favor of concentrating the litigation in this particular forum. First, the current litigation has been before this Court for nearly three years, since September 2015. In that time, I have made a number of dispositive rulings that govern the claims of all direct purchasers. The parties have thus already litigated several issues that would surely arise in any new case. I also have before me the claims of the indirect purchasers in this case, which I have stayed pending the outcome of this litigation. (Dkt. No. 106.) *221 These considerations make concentrating this litigation here particularly desirable.

Turning to the fourth and most important consideration in the superiority analysis, the manageability of a particular class action is “an issue peculiarly within a district court's discretion.” Adkins v. Morgan Stanley, 307 F.R.D. 119, 147 (S.D.N.Y. 2015), aff'd, 656 F. App’x 555 (2d Cir. 2016) (internal quotation marks omitted) (quoting Seijas v. Repub. of Argentina, 606 F.3d 53, 58 (2d Cir. 2010)). This class does not present any unique manageability issues that would preclude certification. As far as classes go, this class is relatively small. Moreover, certification would promote uniformity of decision as to all direct purchasers, without sacrificing procedural fairness. Id. at 141.

For the reasons described above, Plaintiffs' motion for class certification is GRANTED.

I am certifying a direct purchaser plaintiff class including the 62 members proposed in Plaintiffs' revised list. These include Albertsons LLC; American Health Packaging; Amerisource Bergen; Anda; Associated Pharmacies; Auburn Pharmaceutical; Belco; Bartell; Bloodworth Wholesale Drugs; Blupax Pharmaceuticals, LLC; Burlington Drug; Capital Wholesale; Cardinal Health; CVS Caremark; Dakota Drug; Discount Drug Mart; DMS; Drogueria Betances; Drogueria Central; Drogueria Cesar Castillo; Drugs Unlimited, Inc.; Express Scripts Inc.; Frank W. Kerr Inc.; Genetco Inc.; Hannaford Brothers; HC Pharmacy Central Inc.; Healthsource Distributors, LLC; HE Butt; HD Smith LLC; Humana, Inc.; Independent Pharmacy Cooperative; Kaiser Permanente; Kerr Drug; Keysource Medical, Inc.; Kroger; Louisiana Wholesale Drug; Major Pharmaceuticals/Rugby Lab; Masters Pharmaceutical Inc.; McKesson; Medco Health Solutions Inc.; Meijer Inc.; Miami Luken; Morris & Dickson; North Carolina Mutual Wholesale Drug; Optumrx Inc.; PBA Health; Peytons; Prescription Supply Inc.; Quest Pharmaceuticals, Inc.; Publix; Richie Pharmaceutical Company; RDC; RX Outreach; Smith; Supervalu Inc.; Tel Drug of PA LLC Joann Christens; The Harvard Group; Top RX LLC; Valley Wholesale; Value Drug; Walmart; Winn Dixie Logistics Inc.

CONCLUSION

This constitutes the decision and order of the Court.

Forest's motion for leave to file a letter of supplemental authority (Dkt. No. 561) is DENIED. The Clerk of the Court is directed to remove the motions at Dkt. Nos. 400, 434, 437, 439, 441, 443, 445, 505, and 561 from the Court's list of pending motions.
Footnotes

1 For the purposes of calculating damages under this scenario, Dr. Lamb relies on an analysis conducted by Professor Einer Elhauge in which he determines that a payment-free settlement would have provided for an entry date of November 2, 2012. Dr. Lamb alternatively assumes a June 2012 generic entry date based on George Johnston's alternative theory that absent a settlement agreement, Mylan would have prevailed in the patent litigation brought against it, resulting in generic entry by it in June 2012, and by other generic competitors under the terms of their agreements with Forest.

2 Defendants ask the Court to strike Dr. Bemdt's Amended Reply Report as an improper sur-rebuttal based on Dr. Bemdt's treatment of issues and documents raised during his deposition about his initial report. The Court will do no such thing. See Cedar Petrochemicals, Inc. v. Dongbu Hannong Chem. Co., 769 F.Supp.2d 269, 277–79 (S.D.N.Y. 2011). Defendants are not unduly prejudiced by Dr. Bemdt's review and informed response to their challenges raised at deposition.

3 Unless otherwise noted, all references to the Namenda opinions are to the public, redacted versions where

4 The Merz Entities were originally named defendants to some of the counts in the amended complaint. On April 20, 2017, the parties entered a stipulation naming Forest Laboratories, Inc. and Forest Laboratories Holdings Ltd. as defendants to Counts III, IV, and V, and dismissing the Merz Entities as defendants (See Dkt No. 207.)

5 On December 28, 2015, RDC filed an identical complaint against Forest and Merz. All parties stipulated to consolidation of the two duplicative actions, with the Smith Complaint serving as the operative complaint in the consolidated action (see Dkt. No. 12, Case No. 15 Civ. 10083), and an amended caption to reflect consolidation: In Re Namenda Direct Purchaser Antitrust Litigation. (See Dkt. No. 22, Case No. 15 Civ. 10083.)

6 Because Plaintiffs have raised genuine issues of material fact regarding whether the Lexapro Amendment constituted an unlawful reverse payment, they have likewise raised genuine issues of material fact as to whether the deal, taken as a whole, constituted an unlawful reverse payment. The Court need not discuss each component. All claims related to Forest's settlement agreements with Mylan will go to trial.
Synopsis

**Background:** Direct purchasers of, and end payors for, prescription drug used for maintenance treatment of opioid dependence sued drug's manufacturer and its affiliates asserting, inter alia, federal and state antitrust violations and seeking damages and injunctive and declaratory relief. Defendants filed motions to dismiss.

**Holdings:** The District Court, Goldberg, J., held that:

- “product hopping” from tablet to film form alleged sufficiently constituted exclusionary conduct;
- complaint sufficiently pled injury to competition;
- direct purchasers failed to state plausible antitrust claim for unlawful maintenance of monopoly power through intentional delay of Single Shared Risk Evaluation and Mitigation Strategy (SSRS) process and violation of section of Federal Food, Drug and Cosmetic Act concerning risk evaluation and mitigation strategies;
- direct purchasers stated plausible claims for unlawful maintenance of monopoly power by filing “sham” citizen petition and alleged antitrust injury regarding citizen petition from delay of generic entry into market;
- end payors had Article III standing under the laws of only eighteen of the 48 states and two territories under which they brought claims;
- end payors could assert claims under laws of both home states and purchase states;
- even applying AGC factors, end payors had standing to bring antitrust claims under laws of states that had passed *Illinois Brick* repealer statutes, and they pled sufficient nexus to intrastate commerce under laws of Mississippi and Nevada;
- end payors stated claims under consumer protection laws of eight of eleven states;
- end payors stated claims for unjust enrichment under laws of nine of eleven states; and
- end payors’ claim for injunctive relief under Clayton Act was not procedurally or substantively deficient.

Motions granted in part and denied in part.
MEMORANDUM OPINION

GOLDBERG, District Judge.

This multidistrict litigation raises the following question: can a pharmaceutical company marketing brand-name prescription drugs be subject to antitrust liability for engaging in what has been referred to as a “product hopping” scheme? Plaintiffs urge that the answer to this question is “yes,” and allege that as the period of exclusivity on the brand-name drug, Suboxone, expired and generic versions of that drug were to become available, Reckitt Benckiser, Inc. effectuated inconsequential changes to the Suboxone dosage form to prevent competition from generic formulations. More specifically, Plaintiffs, the Direct Purchasers of Suboxone (“Direct Purchasers”) and the End Payors of Suboxone (“End Payors”) claim that Reckitt and its affiliates (“Reckitt”) switched from sublingual Suboxone tablets to a sublingual Suboxone film for the purpose of stymying generic competition. This switch was allegedly accompanied by Reckitt falsely disparaging the tablet through fabricated safety concerns and ultimately removing Suboxone tablets from the market just as generic Suboxone tablets were able to begin competing. Reckitt is also alleged to have manipulated FDA regulations to delay the entry of generic Suboxone onto the market, thereby unlawfully maintaining a monopoly in violation of § 2 of the Sherman Act and state law. According to Plaintiffs, Reckitt's conduct negatively affected competition and resulted in ongoing overpayments by consumers.

Before me is Reckitt's motion to dismiss which essentially argues that Plaintiffs' complaint describes nothing more than new product development and marketing. Reckitt is correct that the development and marketing of new products is typically viewed as procompetitive. However, due to market characteristics unique to the pharmaceutical industry, I conclude that some of Plaintiffs' claims do plausibly allege antitrust violations and should survive Defendants' motions to dismiss. This opinion explains the bases for my ruling.

I. FACTUAL AND PROCEDURAL BACKGROUND

The facts alleged by Plaintiffs are as follows: 1 Suboxone (Buprenorphine Naloxone *673 or “BPN/NLX”) is a prescription drug used for the maintenance treatment of opioid dependence. It is the only pharmaceutical on the market that provides maintenance treatment for patients suffering from opioid addiction that can also be prescribed in an office setting for the patient's home use. All other opioid addiction maintenance treatments, such as methadone, can only be dispensed at a clinic. Suboxone has been approved for home use because it is co-formulated to help prevent abuse, containing both: (1) buprenorphine, an opioid which treats the withdrawal symptoms; and (2) naloxone, an opioid antagonist, which causes the immediate onset of withdrawal symptoms if the product is inappropriately melted and injected. Today, Suboxone has annual sales of over one billion dollars and accounts for 20% of Reckitt's profits. (DP Compl. ¶¶ 5, 74–77.)

Under the Federal Food, Drug and Cosmetic Act (“FDCA”), 21 U.S.C. §§ 301 et seq., a manufacturer that creates a new drug must obtain the approval of the Food and Drug Administration (“FDA”) to sell the drug by filing a New Drug Application (“NDA”). Under the Drug Price Competition and Patent Term Restoration Act, Pub.L. No. 98–417 (1984), commonly known as the Hatch–Waxman Act, certain pioneer drugs can gain periods of exclusivity. However, Hatch–Waxman also simplified the process by which generic manufacturers can compete with brand-name drugs on the market through the filing of an Abbreviated New Drug Application (“ANDA”). For example, Hatch–Waxman eliminated the need for generic manufacturers seeking ANDA approval to duplicate clinical studies that had already been performed by a bioequivalent brand-name drug manufacturer. (Id. at ¶¶ 38–42.)
In order for a drug to be deemed bioequivalent, the generic product must be shown to deliver the same amount of active ingredient into a patient's blood stream for the same amount of time as the brand-name drug. ANDA filers demonstrating bioequivalence generally seek to have their product deemed “AB-rated” to the brand-name drug. This rating means that in addition to being bioequivalent, the two drugs are also pharmaceutically equivalent—which includes such considerations as having the same active ingredient, the same strength, the same route of administration and the same dosage form. A pharmacy may not substitute a generic drug for a brand-name drug unless the generic is AB-rated. (Id. at ¶¶ 42–44.)

Competition from low cost AB-rated generic drugs saves consumers billions of dollars a year. When an AB-rated generic drug enters the market, the brand-name company often suffers a rapid, steep decline in sales—on average 80% within the first year. AB-rated generic competition enables direct and indirect purchasers to obtain both the generic drugs and the brand-name drugs at substantially lower prices. (Id. at ¶¶ 9, 51, 55.)

The FDA approved Reckitt's NDA for Suboxone tablets in 2002. Although Reckitt did not have a patent for Suboxone tablets, it was able to obtain a seven-year period of exclusivity from the FDA because Suboxone was found to be an orphan drug. Reckitt's period of exclusivity for Suboxone tablets was scheduled to expire on October 8, 2009. (Id. at ¶¶ 78–80.) Plaintiffs allege that Reckitt, knowing its period of exclusivity would soon be over, began developing Suboxone film and obtaining patent protection for this new product. Reckitt's actions while developing and marketing its new product are described as a "product-hopping scheme" and are alleged to be anticompetitive with the aim of maintaining Reckitt's monopoly in the Suboxone market.

A. Description of Alleged Conduct

1. Product-Hopping: Development of Suboxone Film and the Alleged Destruction of the Tablet Market

The NDA for Suboxone film was submitted on October 20, 2008 and was approved August 30, 2010. The patent for Suboxone film—patent 8,017,150 (“the ‘150 patent”)—expires september 2023. GENeric suboxone tablets cannot be AB-rated to branded Suboxone film due to the differences in dosage form—that is, sublingual tablet versus sublingual film. Therefore, a pharmacist cannot provide a patient with generic Suboxone tablets when a patient has a prescription for Suboxone film. (Id. at ¶¶ 81, 88.)

Plaintiffs allege that there are few differences between Suboxone film and Suboxone tablets, and that the film is not superior to the tablets. In support of this assertion, Plaintiffs claim that the two products are so similar that Reckitt submitted safety and efficacy studies performed on Suboxone tablets when seeking approval of the Suboxone film NDA. The two products are alleged to have equivalent bioavailability, meaning that the products release the same amount of active ingredients into a patient's bloodstream. Although Reckitt indicated in its NDA that the film's individual packaging reduced the risk for accidental pediatric exposure to the drug, Plaintiffs assert that the evidence provided by Reckitt on this issue was flawed. Indeed, Plaintiffs argue that the film may present increased risk for accidental pediatric exposure because the filmstrip dissolves more quickly than the tablet, and therefore may be more difficult for a child to spit out in the event of exposure. Plaintiffs also allege that the film has a higher risk of abuse than the tablets. (Id. at ¶¶ 82–86, Exs. A, B.)

Plaintiffs explain that once the FDA approved the Suboxone film NDA in 2010, Reckitt launched a fraudulent sales and marketing campaign against the tablet for the purpose of diverting sales from the tablet, which would soon face generic competition, to the patent-protected film. Reckitt sales associates allegedly met with physicians and, in addition to promoting Suboxone film, disparaged Suboxone tablets and warned of false safety concerns. It is also alleged that Reckitt publicly announced the removal of Suboxone tablets from the market for these fabricated safety reasons, although it did not actually remove the tablets until six months later—once the generic Suboxone ANDAs obtained FDA approval. Reckitt also reportedly
raised the price of its tablets in relation to the film formulation despite the fact that the film was more expensive to manufacture and package. Plaintiffs conclude that Reckitt was successful in its scheme, and had managed to convert 64% of all *675 Suboxone prescriptions from tablet to film by the end of 2012. (Id. at ¶¶ 89–92.) 3

2. Reckitt Allegedly Delayed ANDA Approvals by Feigning Cooperation in the REMS Process

On December 22, 2011, the FDA approved a Risk Evaluation and Mitigation Strategy ("REMS") 4 performed by Reckitt on the issue of the risk of pediatric exposure to Suboxone tablets. Through the REMS, the FDA required that Reckitt address pediatric exposures via FDA-approved labeling. (DP Compl. ¶ 99.) Pharmaceutical companies Actavis, Inc. and Amneal ("the Generics") filed ANDAs for generic Suboxone tablets in 2009 and May 2011 respectively. On January 6, 2012, the FDA sent all sponsors of pending ANDAs for Suboxone tablets a notification letter stating that all branded and generic Suboxone products would be subject to a Single Shared REMS program ("SSRS"). ANDA filers were directed to contact Reckitt to collaborate on the creation of an SSRS program. The FDA gave a compliance date of May 6, 2012 for the SSRS. Plaintiffs explain that the FDA gave a short turn-around time, assuming that the recently approved REMS performed by Reckitt would simply be amended to add the bioequivalent generic products. (Id. at ¶¶ 98–102.)

Plaintiffs allege that Reckitt used the SSRS as a means to undermine and delay generic entry by making unnecessary, unprecedented and unreasonable demands on the generic companies as a condition precedent to Reckitt's cooperation in the SSRS, despite the fact that such delay tactics are expressly prohibited by 21 U.S.C. § 355–1t(f)(8). Reckitt reportedly turned down numerous invitations to participate in meetings with the Generics, and refused to engage in substantive discussions until the Generics agreed to a number of conditions the Generics found unfavorable, including "an upfront agreement that all manufacturers would share the costs of product liability for future potential lawsuits." It is further alleged that Reckitt refused to share non-public information from its REMS program until its demands were met. (Id. at ¶¶ 98–102.)

The Generics complained to the FDA about Reckitt's alleged delay tactics and a meeting was held on June 18, 2012. The FDA acknowledged during this meeting that it could not compel Reckitt to share its non-public REMS program, and suggested that the Generics develop a new SSRS without using Reckitt's information. Although the FDA implored Reckitt and the Generics to work together in good faith and to not attempt to block or delay, Plaintiffs claim that Reckitt's obstructionist actions continued, and that Reckitt refused to cooperate unless the Generics agreed to provide Reckitt veto authority or a super-majority vote on all issues relating to the SSRS. Two days before the SSRS was submitted, Reckitt allegedly argued for the first time that an important element of the REMS had been omitted and refused to sign the SSRS. Ultimately, the Generics sought a waiver for approval of *676 their Generics-only SSRS on October 3, 2012. (Id. at ¶¶ 105–12.)

3. Reckitt Allegedly Files a Sham Citizen Petition and Fraudulently Delays That Filing to Maximize Delay of Generic Tablet Approval

Plaintiffs explain that Reckitt publicly announced the withdrawal of Suboxone tablets from the market due to false safety concerns on September 25, 2012, just prior to the Generic REMS waiver request. On that same date, Reckitt filed a Citizen Petition with the FDA for the alleged purpose of blocking approval of the pending Suboxone ANDAs on purported safety grounds. The Petition requested that the FDA take three actions: (1) refrain from approving any BPN/NLX NDA or ANDA for the treatment of opioid addiction that did not include a targeted pediatric exposure education program, a condition not required for branded Suboxone tablets; (2) refrain from approving applications for BPN/NLX for opioid addiction that lacked unit-dose packaging, which was also not a condition for the branded Suboxone tablets; and (3) not approve any BPN/NLX ANDA for
addiction treatment until the FDA determined whether Reckitt had discontinued Suboxone tablets for safety reasons. (Id. at ¶¶ 113–15.)

Plaintiffs urge that Reckitt's Citizen Petition was a sham because the FDA had no statutory or regulatory authority to grant much of the relief requested. For example, the FDA has no authority to require ANDA filers to mimic non-approved labeling and REMS materials in order to obtain ANDA approval. Nonetheless, Reckitt requested that ANDA filers seeking approval for generic Suboxone be required to include a pediatric exposure education program that was not part of the FDA-approved REMS or labeling for Suboxone tablets. Further, Reckitt's request for an FDA investigation into the removal of Suboxone tablets from the market is alleged to be a sham because Reckitt had not withdrawn Suboxone tablets from the market at the time the request was made. Plaintiffs also argue that Reckitt's request that all ANDA filers be required to use unit-dose packaging is a sham because Reckitt continued to sell Suboxone tablets in bulk packaging during that time period. Finally, the FDA found that the study in Reckitt's Citizen Petition—which Reckitt argued supported its unit-dose packaging argument—acknowledged that it had insufficient information from which to draw definitive conclusions. (Id. at ¶¶ 117–31.)

In addition to alleging that the Citizen Petition was a sham, Plaintiffs also argue that it included a false certification regarding its timeliness and support. Citizen Petitions require the filer to certify when they first learned of the issues raised. Reckitt certified that it learned of the risk of accidental pediatric exposure on September 15, 2012 even though its own study indicated that Reckitt had learned of the risk several years earlier. (Id. at ¶¶ 132–40.)

The FDA denied Reckitt's Citizen Petition on February 22, 2013, noting that Reckitt's announcement that it was withdrawing Suboxone tablets, “given its close alignment with the period in which generic competition for this product was expected to begin, cannot be ignored.” The FDA further referred Reckitt's conduct to the Federal Trade Commission (“FTC”) for antitrust investigation. (Id. at ¶¶ 141–43.)

Plaintiffs assert that once the Citizen Petition was denied, the FDA immediately granted final approval of the ANDAs of two generic manufacturers, Amneal and Actavis, for generic Suboxone tablets. Three weeks later, on March 18, 2013, Reckitt withdrew branded Suboxone tablets from the market, which Plaintiffs characterize “as a last ditch effort to further coerce the market to switch to the non-improved film product.” (Id. at ¶¶ 143–44.)

4. Alleged Effects of Reckitt's Scheme

Plaintiffs urge that Reckitt's multifaceted scheme outlined above foreclosed or severely limited generic competition to branded Suboxone. In addition to delaying the Generic's entry onto the market, Plaintiffs claim that by the time the generic ANDAs were approved, Reckitt had coerced physicians to largely convert to prescriptions for Suboxone film, which cannot be substituted for a generic product. Plaintiffs assert these actions have caused an ongoing antitrust injury to the Direct Purchasers, the End Payors, and the public at large by preventing Generics from meaningfully and efficiently competing with Reckitt. Plaintiffs conclude that these actions were all designed to maintain monopoly profits in violation of the Sherman Act and state law. (Id. at ¶¶ 145–50, 156.)

B. Specific Causes of Action

The Direct Purchasers seek damages and injunctive relief through the following claims, all of which are alleged to violate § 2 of the Sherman Act: (1) unlawful maintenance of monopoly power through an overarching scheme to prevent or delay generic competition (“Count I”); (2) unlawful maintenance of monopoly power by conversion of the market from tablet to
In re Suboxone (Buprenorphine Hydrochloride and..., 64 F.Supp.3d 665 (2014)

film formulation (“Count II”); (3) unlawful maintenance of monopoly power by intentionally delaying the SSRS process and violating 21 U.S.C. § 355–1(f)(8) (“Count III”); (4) unlawful maintenance of monopoly power by filing a sham Citizen Petition (“Count IV”); and (5) unlawful maintenance of monopoly power by fraudulently delaying the filing of the Citizen Petition (“Count V”). (Id. at ¶¶ 166–200.)

The End Payors assert the following causes of action: (1) monopolization and monopolistic scheme under state law (listing 29 state statutes) (“Count I”); (2) attempted monopolization under state law (listing 29 state statutes) (“Count II”); (3) unfair and deceptive trade practices under state law (listing 28 state statutes) (“Count III”); (4) injunctive and declaratory relief under § 16 of the Clayton Act for Reckitt’s violations of § 2 of the Sherman Act (“Count IV”); and (5) unjust enrichment under state law (under 48 states and the District of Columbia) (“Count V”). (EP Compl. ¶¶ 163–99.)

Reckitt has filed motions to dismiss each of the Plaintiffs' amended complaints.

II. STANDARD OF REVIEW

In deciding a motion to dismiss, the court must “accept as true all allegations in the complaint and all reasonable inferences that can be drawn therefrom, and view them in the light most favorable to the non-moving party.” DeBenedictis v. Merrill Lynch & Co., Inc., 492 F.3d 209, 215 (3d Cir.2007) (quoting Rocks v. City of Philadelphia, 868 F.2d 644, 645 (3d Cir.1989)). Reckitt raises arguments for dismissal under the pleading standards of both Federal Rule of Civil Procedure 8(a) and 9(b) in their motions.

A. Pleading under Rule 8(a)

Under Rule 8(a), in order to survive a motion to dismiss brought under Federal Rule of Civil Procedure 12(b)(6), a complaint must “contain sufficient factual matter, accepted as true, to state a claim for relief that is plausible on its face.” Ashcroft v. Iqbal, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009) (quoting *678 Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007)). The plausibility standard requires more than a “sheer possibility that a defendant has acted unlawfully.” Id. To determine the sufficiency of a complaint under Twombly and Iqbal, a court must take the following three steps: (1) the court must “tak[e] note of the elements a plaintiff must plead to state a claim;” (2) the court should identify the allegations that, “because they are no more than conclusions, are not entitled to the assumption of truth;” and (3) “where there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement for relief.” Burtch v. Milberg Factors, Inc., 662 F.3d 212, 221 (3d Cir.2011) (citations omitted).

B. Pleading under Rule 9(b)

Rule 9(b) provides, “In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person’s mind may be alleged generally.” Fed.R.Civ.P. 9(b). The pleadings must be specific enough to “place the defendants on notice of the precise misconduct with which they are charged, and to safeguard defendants against spurious charges of immoral and fraudulent behavior.” Seville Indus. Mach. Corp. v. Southmost Mach. Corp., 742 F.2d 786, 791 (3d Cir.1984). “Rule 9(b) requires, at a minimum, that plaintiffs support their allegations of ... fraud with all of the essential factual background that would accompany the first paragraph of any newspaper story—that is, the who, what, when, where and how of the events at issue.” United States ex rel. Streck v. Allergan, Inc., 894 F.Supp.2d 584, 590–91 (E.D.Pa.2012) (quoting In re Rockefeller Ctr. Props., Inc. Sec. Litig., 311 F.3d 198, 217 (3d Cir.2002)).

III. LEGAL ANALYSIS
A. Overview—Reckitt's Motion to Dismiss the Direct Purchasers' Complaint

All of the Direct Purchasers' claims invoke § 2 of the Sherman Act, which states: “Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations” is guilty of an offense and subject to penalties. 15 U.S.C. § 2.

The following are elements of a § 2 monopolization claim: “(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.” United States v. Grinnell Corp., 384 U.S. 563, 570–71, 86 S.Ct. 1698, 16 L.Ed.2d 778 (1966). Simple possession of monopoly power is not enough; a defendant must also engage in exclusionary conduct to run afoul of § 2. Walgreen Co. v. AstraZeneca Pharm. L.P., 534 F.Supp.2d 146, 150 (D.D.C.2008) (quoting Phillip E. Areeda & Herbert Hovenkamp, 3 Antitrust Law § 650a(1) at 67 (rev. ed.1996)). “Exclusionary conduct is ‘that which prevents actual or potential rivals from competing or impairs their opportunities to do so effectively.’ ” Id. “The [Sherman Act] directs itself not against conduct which is competitive, even severely so, but against conduct which unfairly tends to destroy competition itself.” United States v. Microsoft Corp., 253 F.3d 34, 58 (D.C.Cir.2001) (quoting Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 458, 113 S.Ct. 884, 122 L.Ed.2d 247 (1993)).

The plaintiff bears the burden of demonstrating that a monopolist's conduct has the requisite anticompetitive effect, and if he is successful, the burden moves to the defendant to demonstrate a procompetitive justification for its conduct. Id. at 58–59 (citing Eastman Kodak Co. v. Image Tech. Servs., Inc., 504 U.S. 451, 483, 112 S.Ct. 2072, 119 L.Ed.2d 265 (1992)). Finally, “if the monopolist's procompetitive justification stands unrebutted, then the plaintiff must demonstrate that the anticompetitive harm of the conduct outweighs the procompetitive benefit.” Id.

Reckitt raises four core arguments for dismissal of the Direct Purchasers' claims: (1) Count II, relating to the introduction of Suboxone Film, fails because the law presumes that the introduction of new and different products increases competition; (2) Count III, relating to Reckitt's alleged failure to cooperate during the REMS period, fails because the Supreme Court has unequivocally held that a monopolist has no duty to deal with its competitors; (3) Counts IV and V, relating to Reckitt's Citizen Petition, should be dismissed because the Citizen Petition was not a sham and did not delay Generic market entry; and (4) Count I, which asserts a claim for the combined effect of Reckitt's actions, fails because none of the underlying actions violate the antitrust laws, and unsuccessful claims cannot be combined to state a successful one. Each of these arguments is addressed below. 6

B. Count II—Introduction of Suboxone Film

Reckitt argues that the introduction of a new product by definition increases competition in the relevant market, and therefore cannot be found to be anticompetitive. Reckitt further asserts that Plaintiffs acknowledged in their complaints that Suboxone film made improvements to the tablets which are procompetitive, not exclusionary. Finally, Reckitt argues that any harm that would arise from the introduction of a new product is inflicted upon competitors, not competition itself, and therefore is not the type of injury the antitrust laws were created to address.

I. Does the “Product–Hopping” Conduct Alleged Constitute Exclusionary Conduct?
In re Suboxone (Buprenorphine Hydrochloride and... 64 F.Supp.3d 665 (2014)
2014-2 Trade Cases P 78,983

“‘Anticompetitive conduct’ can come in too many different forms, and is too dependent upon context, for any court or commentator ever to have enumerated all the varieties.” West Penn Allegheny Health Sys., Inc. v. UPMC, 627 F.3d 85, 109 (3d Cir.2010) (quoting LePage's Inc. v. 3M, 324 F.3d 141, 152 (3d Cir.2003)). “[A]s a general rule, any firm, even a monopolist, may ... bring its products to market whenever and however it chooses.” Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc., 171 F.3d 912, 925 n. 7 (3d Cir.1999) (quoting Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263, 286 (2d Cir.1979)). New and improved products are one of the benefits brought about by healthy competition. Abbott Labs. v. Teva Pharm. USA, Inc., 432 F.Supp.2d 408, 420 (D.Del.2006) (citing Berkey Photo, 603 F.2d at 286). Even a monopolist may expand its market share and increase demand for its products through technological innovation, “and such actions are ‘perfectly consistent with the competitive forces that the Sherman Act was intended to foster.’” Id. (quoting Foremost Pro Color, Inc. v. Eastman Kodak Co., 703 F.2d 534, 546 (9th Cir.1983)).

Because ordinarily innovation will also inflict harm upon competitors, “courts should not condemn a product change ... unless they are relatively confident that the conduct in question is anticompetitive.” Id. at 421 (quoting Herbert Hovenkamp, Mark D. Janis & Mark A. Lemley, IP and Antitrust § 12.1). However, “when the introduction of a new product by a monopolist prevents consumer choice, greater scrutiny is appropriate” and the “basis for judicial deference is removed.” Id. When assessing whether conduct is exclusionary, “it is not necessary that all competition be removed from the market. The test is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit.” United States v. Dentsply Int'l, Inc., 399 F.3d 181, 191 (3d Cir.2005) (citing LePage's, 324 F.3d at 159–60; Microsoft, 253 F.3d at 69).

In support of its argument that Plaintiffs have failed to establish exclusionary conduct under a “product hopping” theory, Reckitt relies heavily upon Walgreen Co. v. AstraZeneca Pharmaceuticals L.P., 534 F.Supp.2d 146 (D.D.C.2008). In that case, AstraZeneca marketed prescription Prilosec capsules, a heartburn medication, through the expiration of its patent in October 2001. In June 2003, the FDA approved an over-the-counter version of Prilosec and granted AstraZeneca exclusivity in that market through June 2006. AstraZeneca also brought prescription Nexium, another heartburn medication, to the market during this time period, and that patent did not expire until 2014. AstraZeneca very aggressively promoted and “detailed” Nexium, while simultaneously ceasing to promote prescription Prilosec. As a result of this marketing, by the time generic prescription Prilosec entered the market, the generics were only able to capture 30% of the market, which the plaintiffs alleged was much lower than they would have captured absent AstraZeneca's intervention. AstraZeneca's conduct was alleged to be exclusionary because it used “distortion and misdirection in marketing, promoting and detailing Nexium” so as to switch the market from Prilosec, which now had generic competition, to a virtually-identical drug, Nexium, which did not. Id. at 148–49.

The court determined that AstraZeneca's actions did not violate § 2 of the Sherman Act and granted the defendants' motions to dismiss because marketing Nexium did not eliminate choices available to the consumer. Prescription Prilosec was never removed from the market, allowing consumers to obtain prescription Prilosec, and by extension generic Prilosec, if they preferred that product. Id. at 150–52. The court also found that the plaintiffs had not established an injury because “[t]he fact that a new product siphoned off some of the sales from the old product and, in turn, depressed sales of the generic substitutes for the old product” does not establish an antitrust injury, as it does not interfere with the generics' freedom to compete. Id. at 152.

Plaintiffs assert that Walgreen is factually distinguishable from the case before me, and urge that I follow the reasoning set forth in Abbott Laboratories v. Teva Pharmaceuticals USA, Inc., 432 F.Supp.2d 408 (D.Del.2006) (“TriCor”). In TriCor, the court found that the plaintiffs had stated a claim for a § 2 antitrust violation where the defendants, the brand-name manufacturer of TriCor, allegedly attempted to thwart generic competition through a product-hopping scheme. The plaintiffs in TriCor claimed that the defendants had engaged in the following conduct: (1) the defendants changed the formulation of TriCor from capsules to tablets in order to prevent generic substitution; (2) after the tablet formulation was approved, the defendants stopped selling TriCor capsules; (3) the defendants bought back the existing supplies of TriCor capsules from pharmacies; and (4) the
In re Suboxone (Buprenorphine Hydrochloride and..., 64 F.Supp.3d 665 (2014)
2014-2 Trade Cases P 78,983
defendants changed the code for TriCor capsules in the National Drug Data File (“NDDF”) to “obsolete,” which prevented pharmacies from filling TriCor prescriptions with a generic capsule formulation. *Id.* at 415–16.

The defendants in *TriCor* raised a nearly identical argument as Reckitt does here: that the introduction of a new product was procompetitive per se and that improvements had been made from one formulation to another. *Id.* at 420. The court recognized that deference is ordinarily given to innovation and the creation of new products. However, given the unique nature of the pharmaceutical drug market and the actions taken by the defendants in removing old formulations from the market and preventing consumer choice, the court determined that the plaintiffs had set forth sufficient facts to establish exclusionary conduct and survive a motion to dismiss. *Id.* at 421–22. The court reasoned that the nature of the pharmaceutical drug market warranted applying the rule of reason approach identified in *United States v. Microsoft Corp.*, 253 F.3d 34, 58 (D.C.Cir.2001), where the defendant's procompetitive justifications are weighed against the anticompetitive results. *Id.* at 422.

The defendants in *TriCor* further argued that their product-hopping could not be exclusionary because, although generic *TriCor* capsules could not be exchanged for a brand-name *TriCor* prescription, the generics were not foreclosed from marketing their own *TriCor* formulations. The court rejected this argument, finding that complete foreclosure from the market was not the appropriate standard. Instead, the court determined that the generics could not provide generic substitutes for the current *TriCor* formulation, which is alleged to be their cost-efficient means of competing in the pharmaceutical drug market. That opportunity has allegedly been prevented entirely by Defendants' allegedly manipulative and unjustifiable formulation changes. Such a restriction on competition, if proven, is sufficient to support an antitrust claim in this case.

*Id.* at 422.

The conduct alleged in the case before me seems to fall somewhere between that alleged in *Walgreen* and *TriCor*. Unlike the facts at issue in *Walgreen*, Reckitt announced that it was removing *Suboxone* tablets from the market several months prior to generic approval, and actually did remove the tablets from the market within a few weeks of generic entry. Therefore, the freedom of consumer choice that the *Walgreen* court found compelling is more limited here. However, the restriction of the market's ambit does not appear to be quite as extreme as that found in *TriCor*, as it is not alleged that Reckitt bought back existing *Suboxone* tablets or labeled the product “obsolete.” Thus, while *Walgreen* and *TriCor* are instructive, they are not dispositive of whether Plaintiffs have *pled* sufficient facts to survive Defendants' motion on Count II.

Although the issue of product-hopping is relatively novel, what is clear from the case law is that simply introducing a new product on the market, whether it is a superior product or not, does not, by itself, constitute exclusionary conduct. The key question is whether the defendant combined the introduction of a new product with some other wrongful conduct, such that the comprehensive effect is likely to stymie competition, prevent consumer choice and reduce the market's ambit. This analysis must be undertaken with the somewhat unique characteristics of the pharmaceutical market in mind.

Plaintiffs allege that the wrongful conduct included raising false safety concerns and disparaging *Suboxone* tablets, both of which played an important role in Reckitt's success in switching the market from tablets to film. Reckitt counters that false disparagement of a product cannot give rise to antitrust liability under *Santana Products Inc. v. Bobrick Washroom Equipment, Inc.*, 401 F.3d 123 (3d Cir.2005). In *Santana*, the United States Court of Appeals for the Third Circuit found that a company's disparagement of another company's product, even if the statements were untrue, was not a restraint of trade absent “coercive” measures—that is, “measures that prevented [the plaintiff] from selling its products to any willing buyer or prevented others
In re Suboxone (Buprenorphine Hydrochloride and...), 64 F.Supp.3d 665 (2014)

2014-2 Trade Cases P 78,983

from dealing with [the plaintiff].” *Id.* at 132. However, the Third Circuit has since remarked that, despite its prior holding in *Santana*, “in some cases, such defamation, which plainly is not competition on the merits, can give rise to antitrust liability, especially when it is combined with other anticompetitive acts.” *W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 109 n. 14 (3d Cir.2010) (citing *LePage's*, 324 F.3d at 153, 162).

Having carefully reviewed Plaintiffs' complaint, I find that the facts presented sufficiently allege that the disparagement of Suboxone tablets took place alongside “coercive” measures. The threatened removal of the tablets from the market in conjunction with the alleged fabricated safety concerns could plausibly coerce patients and doctors to switch from tablet to film. A patient that preferred the tablets despite the safety concerns might be further persuaded to switch to the film, believing that their favored product would soon be removed from the market.

Reckitt also argues that Plaintiffs' allegations of false disparagement are insufficient because the complaints do not plead fraud with sufficient specificity to satisfy Rule 9(b) of the Federal Rules of Civil Procedure. *See Lum v. Bank of America*, 361 F.3d 217, 228 (3d Cir.2004) (recognizing that antitrust allegations involving fraud must comply with the pleading requirements of Rule 9(b)) (abrogation on other grounds recognized in *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 323 n. 22 (3d Cir.2010)). “Rule 9(b) requires, at a minimum, that plaintiffs support their allegations of ... fraud with all of the essential factual background that would accompany the first paragraph of any newspaper story[—]that is, the who, what, when, where and how of the events at issue.” *U.S. ex rel. Streck v. Allergan, Inc.*, 894 F.Supp.2d 584, 590–91 (E.D.Pa.2012) (quoting *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 311 F.3d 198, 217 (3d Cir.2002)).

Plaintiffs claim that in conjunction with the switch from tablet to film in 2010, Reckitt “implemented a massive fraudulent sales and marketing campaign to convert all or substantial [Suboxone] prescriptions from tablets to film.” (DP Compl. ¶ 89.) It is also alleged that Reckitt sales representatives met with physicians to promote the film formulation while simultaneously discouraging physicians from writing prescriptions for Suboxone tablets under the guise of false safety concerns—in particular, that the lack of unit dose packaging in the tablets raised the risk of pediatric exposure. *(Id. at ¶¶ 89, 95.)* Further, Plaintiffs claim that Reckitt announced the removal of the tablets from the market on September 25, 2012 due to fabricated safety concerns in an attempt to switch patients from the tablet to the film. *(Id. at ¶¶ 89, 93–94.)* Instead of actually removing the product at that time, Reckitt allegedly continued to sell tablets through March 2013, which Plaintiffs argue demonstrates the falsity of Reckitt's stated safety concerns. *(Id. at ¶ 94.)* According to Plaintiffs, Reckitt's goal in making these misrepresentations was to transfer as much of the market from tablet to film as possible prior to generic entry. *(Id. at ¶ 93.)* These allegations have been made with particularity in accordance with Rule 9(b), and are sufficient to “place the defendants on notice of the precise misconduct with which they are charged.” *See Seville*, 742 F.2d at 791. Therefore, I will consider these allegations in determining whether the complaints plausibly make out an antitrust violation.

With regard to the withdrawal of Suboxone tablets from the market, Reckitt focuses on the fact that the defendants in *TriCor* engaged in repurchasing existing supplies held by pharmacies and changing the NDDF code to obsolete—facts which are not alleged here. Reckitt asserts that because it did not engage in this conduct, the Generics are not now, nor have they ever been, foreclosed from selling their products, which undermines Plaintiffs' claims of exclusionary conduct.

While Reckitt did not repurchase existing supplies held by pharmacies or change the NDDF code on the tablets to obsolete, the withdrawal of Suboxone tablets is alleged to have created a similar effect of reducing consumer choice. While Plaintiffs acknowledge that the Generics have not been completely foreclosed from the market, neither were the generics in *TriCor*. As noted previously, complete foreclosure is not the standard articulated by the Third Circuit for establishing anticompetitive conduct. Rather, “[t]he test is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit.” *Dentsply*, 399 F.3d at 191. As recognized in *TriCor*, “[c]ompetitors need not be barred
In re Suboxone (Buprenorphine Hydrochloride and..., 64 F.Supp.3d 665 (2014)
2014-2 Trade Cases P 78,983

"from all means of distribution," if they are barred ‘from the cost-efficient ones.’ ” TriCor, 432 F.Supp.2d at 423 (quoting Microsoft, 253 F.3d at 64).

Plaintiffs have plausibly alleged that various market forces unique to the pharmaceutical industry make generic substitution the cost-efficient means of competing for companies selling generic pharmaceuticals. For example, Plaintiffs assert that a disconnect exists between the person paying for the prescription and the person selecting the appropriate treatment. Due to this disconnect, the ordinary market forces that would allow consumers to consider price when selecting a product are derailed. The patient also cannot simply request to receive a generic from his or her pharmacist because the film and the generic tablets are not AB-rated and thus may not be substituted.

For all of these reasons, as it relates to their “product-hopping” allegations, I find that Plaintiffs have plausibly pleaded exclusionary conduct, as required for an antitrust claim.

### 2. Does the Complaint Sufficiently Plead an Injury to Competition?

Having determined that Plaintiffs have sufficiently alleged exclusionary conduct as it relates to the “product-hopping” scheme, I now turn to whether an antitrust injury has been properly pleaded. Reckitt argues that Plaintiffs have failed to establish an antitrust injury on Count II because the introduction of Suboxone film in and of itself is not alleged to have delayed Generic entry into the marketplace. Reckitt urges that the only injury that could have been caused by the film's introduction stems from an increase in competition.

Lost profits attributable to increased competition is not the type of injury the antitrust laws were designed to redress. See Brunswick Corp. v. Pueblo Bowl–O–Mat., Inc., 429 U.S. 477, 488–89, 97 S.Ct. 690, 50 L.Ed.2d 701 (1977). The antitrust laws "were enacted for 'the protection of competition not competitors.' ” Id. at 488, 97 S.Ct. 690 (quoting Brown Shoe Co. v. United States, 370 U.S. 294, 320, 82 S.Ct. 1502, 8 L.Ed.2d 510 (1962)). “[W]hen an alleged antitrust conspiracy involves multiple acts, [t]he character and effect of [that] conspiracy are not to be judged by dismembering it and viewing its separate parts, but only by looking at it as a whole.” SmithKline Beecham Corp. v. Apotex Corp., 383 F.Supp.2d 686, 699, 702 (E.D.Pa.2004) (quoting Cont'l Ore Co. v. Union Carbide & Carbon Corp., 370 U.S. 690, 699, 82 S.Ct. 1404, 8 L.Ed.2d 777 (1962)) (quotation marks omitted).


Plaintiffs allege that by wrongfully suppressing generic competition on the market, they were forced to pay more for Suboxone products than they otherwise would have. “When a monopolist's actions are designed to prevent one or more new or potential competitors from gaining a foothold in the market by exclusionary, i.e. predatory, conduct, its success in that goal is not only injurious to the potential competitor but also to competition in general.” LePage's, 324 F.3d at 159; see also Dentsply, 399 F.3d at 191. Although Count II of the Direct Purchasers' complaint relates to Reckitt's introduction of Suboxone film, and generally the introduction of new products does not create antitrust injury, I must still consider Plaintiffs' allegations of Reckitt's activity as a whole, which includes the withdrawal of Suboxone tablets, the alleged fraudulent marketing campaign and tactics designed to delay ANDA approval (discussed infra). If the anticompetitive effect of this conduct is proven, and it resulted in purchasers paying inflated prices, Plaintiffs could establish harm to competition itself. See Tunis Bros. Co. v. Ford Motor Co., 952 F.2d 715, 728 (3d Cir.1991) (“An antitrust plaintiff must prove that challenged conduct affected the prices, quantity or quality of goods or services”) (quotation marks omitted). Therefore, I find that Plaintiffs have pleaded sufficient facts to establish antitrust injury.
Defendants further allege that the Direct Purchasers do not have standing because there is a more direct victim of Reckitt's conduct—the Generic manufacturers. Section 4 of the Clayton Act, which allows treble damages for violation of the antitrust laws, states as follows: “any person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws may sue therefor in any district court of the United States ... and shall recover threefold the damages by him sustained.” 15 U.S.C. § 15. The Direct Purchasers who are overcharged as a result of an antitrust violator's actions are generally considered to have antitrust standing. See Illinois Brick Co. v. Illinois, 431 U.S. 720, 729, 97 S.Ct. 2061, 52 L.Ed.2d 707 (1977) (“the overcharged direct purchaser, and not others in the chain of manufacture or distribution, is the party ‘injured in his business or property’ ”). Therefore, I do not find Reckitt's standing argument convincing.

In conclusion, I find that the Direct Purchasers' claim under Count II for introduction of the Suboxone film in the context of an alleged product-hopping scheme should survive the motion to dismiss stage.


Reckitt asserts that Count III of the Direct Purchaser's complaint should be dismissed because the SSRS process, where the parties tried to work together to establish the safe use of the drug, was simply a course of dealing and the antitrust laws do not obligate Reckitt to interact with its competitors on terms they find favorable. Reckitt garners support from a line of Supreme Court cases on the "duty to deal."

In Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 124 S.Ct. 872, 157 L.Ed.2d 823 (2004), the Supreme Court considered whether a complaint alleging that Verizon had breached its duty under the Telecommunications Act of 1996 to facilitate market entry by competitors stated a claim for violation of § 2 of the Sherman Act. The Telecommunications Act of 1996 required Verizon, and other incumbent local telephone companies, to facilitate competitors' market entry by requiring the incumbent to share its network with competitors. Verizon was also obligated to provide access to its operations support systems, which ensured quality of service.

Verizon was accused of intentionally failing to fill operations support orders in violation of the Act and was investigated by the FCC for its conduct. Customers of Verizon's competitors filed suit for antitrust violation, alleging that Verizon had engaged in an anticompetitive scheme to discourage customers from becoming or remaining customers of competing companies. Id. at 402–04, 124 S.Ct. 872. The Court held that “as a general matter, the Sherman Act ‘does not restrict the long recognized right of [a] trader or manufacturer engaging in an entirely private business, *686 freely to exercise his own independent discretion as to the parties with whom he will deal.’ ” Id. at 408, 124 S.Ct. 872 (quoting United States v. Colgate & Co., 250 U.S. 300, 307, 39 S.Ct. 465, 63 L.Ed. 992 (1919)). The Court concluded that the antitrust laws did not create a duty to deal in that instance, as they provided little additional benefit to the regulations already in place. The Court noted “[w]here such a [regulatory] structure exists, the additional benefit to competition provided by antitrust enforcement will tend to be small, and it will be less plausible that the antitrust laws contemplate such additional scrutiny.” Id. at 411–12, 124 S.Ct. 872.

The Supreme Court reaffirmed these principles in Pacific Bell Telephone Co. v. Linkline Communications, Inc., 555 U.S. 438, 129 S.Ct. 1109, 172 L.Ed.2d 836 (2009). There, the FCC required AT & T to sell transmission service to independent DSL providers for the purposes of increasing competition. Although it made its service available, AT & T was accused of “price squeezing” its competitors—that is, providing access to its DSL framework to competitors on the wholesale market at a high price, but selling its DSL services to customers on the retail market at a low price. The plaintiffs alleged that AT & T's competitors were driven out of the market because the high wholesale costs prevented them from matching AT & T's low retail prices. Linkline, 555 U.S. at 442–43, 129 S.Ct. 1109. The Court, relying on Trinko, held that the high wholesale prices to competitors did
not violate the antitrust laws in the absence of a “duty to deal.” The Court further reasoned that the plaintiffs could not establish an antitrust injury based on AT & T charging customers at low rates unless the plaintiffs demonstrated predatory pricing—that is, pricing below costs where there is a dangerous probability that the losses can be recouped. *Id.* at 450–51, 129 S.Ct. 1109.

*Trinko* and *Linkline* instruct that the antitrust laws do not create a duty for competitors to work together. Statutes and regulations requiring cooperation between rivals do not alter this analysis; in fact, regulation indicates that antitrust scrutiny is not necessary or prudent. The Court noted that although the right for a monopolist to refuse to deal with its competitors is not unqualified, it has “been very cautious in recognizing such exceptions, because of the uncertain virtue of forced sharing and the difficulty of identifying and remediying anticompetitive conduct by a single firm.” *Trinko*, 540 U.S. at 408, 124 S.Ct. 872.

The main exception to the line of cases holding that competitors do not have a duty to deal is *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 105 S.Ct. 2847, 86 L.Ed.2d 467 (1985). There, the Court considered a course of dealing between two companies that owned ski resorts in Aspen. Beginning in 1962, the companies worked together to sell skiers an interchangeable ticket that could be used on any of the four mountains in Aspen. *Id.* at 587–89, 105 S.Ct. 2847. For over fifteen years, Aspen Skiing Co. and Aspen Highlands coordinated to issue passes that covered both companies' mountains and divided the profits according to the percentage of skiers that visited a particular mountain. *Id.* at 591, 105 S.Ct. 2847. However, in 1978, Aspen Skiing Co. decided to discontinue the 4–area ticket unless Aspen Highlands would accept a 12.5% fixed percentage of the revenue, which was lower than the actual usage of its mountain. When Highlands refused, Aspen Skiing Co. began selling a pass covering only its three mountains. When Highlands attempted to purchase Aspen Skiing's lift tickets to create a multi-pass on its own, Aspen Skiing refused, even at retail price. *Id.* at 592–94, 105 S.Ct. 2847. Highlands brought an antitrust claim under § 2, arguing that Aspen Skiing had monopolized the market for downhill skiing in Aspen.

The Court ultimately held that the right to refuse to deal was not unqualified, and that a reasonable jury could find that Aspen Skiing's conduct was exclusionary. In reaching this conclusion, the Court significantly relied upon the prior cooperation between the two competitors that spanned many years. The Court noted that there was significant consumer demand for the four-mountain pass and many consumers felt that they could not go to the mountain of their choice once that pass had been eliminated. The Court determined that by prohibiting Highlands' use of its lift tickets, even at market price, Aspen Skiing's sole motivation was to harm Highlands. *Id.* at 601, 605–09, 105 S.Ct. 2847.

Here, throughout the SSRS process, the FDA directed the parties to work together in good faith to develop a REMS program that would ultimately lead to ANDA approval for the Generics. The parties engaged in negotiations, and Reckitt is alleged to have taken unreasonable positions and utilized delay tactics to keep Generics off of the market for as long as possible. This SSRS process, in which competitors were required to work together, should be analyzed in light of the precedent outlined above.

Plaintiffs rely heavily upon 21 U.S.C. § 355–1(f)(8), which requires the parties to work together in good faith and not use the SSRS process to block or delay ANDA approval. However, *Linkline* and *Trinko* undermine Plaintiffs' position, as the Supreme Court has unequivocally stated that statutes and regulations requiring cooperation between competitors do not create an antitrust duty to deal. In fact, these cases found that the regulatory structure requiring cooperation actually diminishes the need for antitrust scrutiny. *Aspen Skiing*, the only Supreme Court case recognizing a failure to deal as anticompetitive, does not apply here because there is no long-standing, preexisting course of dealing between Reckitt and the Generics.

Finally, Plaintiffs note that the only two cases from this circuit alleging antitrust violations for failure to provide information during the REMS process survived the motion to dismiss stage. See *Lannett Co., Inc. v. Celgene Corp.*, Dkt. No. 08–cv–3920, Doc. No. 42 (E.D.Pa. Mar. 30, 2011) (Savage, J.) (denying motion to dismiss without comment); *Actelion Pharm. Ltd. v. Apotex Inc.*, 12–cv–5743, Doc. No. 90 (D.N.J. Oct 21, 2013) (Hillman, J.) (denying motion for judgment on the pleadings “for reasons stated during oral argument”). While this is true, *Lannett* and *Actelion* are distinguishable because the elements to
In re Suboxone (Buprenorphine Hydrochloride and..., 64 F.Supp.3d 665 (2014)
2014-2 Trade Cases P 78,983

assure safe use in those cases prevented the generics from obtaining the brand-name pharmaceutical to conduct bioequivalency testing during the REMS process. Therefore, the generics were allegedly unable to file an ANDA as a result of the defendants’ actions. Here, the Generics were able to obtain Suboxone and conduct bioequivalency testing, as their ANDAs were pending before the SSRS process even began. The Generics were also capable of submitting an SSRS without Reckitt's involvement, and ultimately did just that. It would have been easier to have Reckitt provide its REMS to its competitors with no strings attached, and participation on Reckitt's part would have allowed the process to move more quickly. However, a monopolist “certainly has no duty to deal under terms and conditions that the rivals find commercially advantageous.” Linkline, 555 U.S. at 450, 129 S.Ct. 1109.

The antitrust laws do not impose a duty on Reckitt to aid the Generics in obtaining expeditious approval of an ANDA. While other courts have indicated that antitrust liability may attach where the SSRS process is manipulated to completely preclude a generic from filing an ANDA, that is not the situation presently before me. To the extent that § 355–1(f)(8) prohibits name-brand drug manufacturers from manipulating the process to cause delay, this statute provides for increased FDA oversight and diminishes the need for antitrust scrutiny. Accordingly, I will grant Reckitt's motion as to Count III of the Direct Purchasers' complaint.

D. Counts IV & V—Unlawful Maintenance of Monopoly Power by Filing a Sham Citizen Petition and Unlawful Maintenance of Monopoly Power by Fraudulently Delaying the Filing of the Citizen Petition

Reckitt next argues that Counts IV and V of the Direct Purchasers' complaint must be dismissed for two reasons: (1) Plaintiffs have failed to adequately plead that the Citizen Petition was a sham, such that it would be subject to antitrust scrutiny; and (2) even if the Citizen Petition was a sham, a statute forbid the FDA from delaying ANDA approval while the Petition was decided, and therefore, no injury could have resulted. I address these arguments in turn.

1. Have Plaintiffs Plausibly Pledged that the Citizen Petition was a Sham?

“Those who petition government for redress are generally immune from antitrust liability.” Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 56, 113 S.Ct. 1920, 123 L.Ed.2d 611 (1993). However, immunity is not extended to “sham” activities—that is, activity (1) that is “objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits” ; *689 and (2) which “conceals ‘an attempt to interfere directly with the business relationships of a competitor,’ through the ‘use [of] the governmental process—as opposed to the outcome of that process—as an anticompetitive weapon.’ ” Id. at 60–61, 113 S.Ct. 1920 (quoting E. R.R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 144, 81 S.Ct. 523, 5 L.Ed.2d 464 (1961); City of Columbia v. Omni Outdoor Adver., Inc., 499 U.S. 365, 380, 111 S.Ct. 1344, 113 L.Ed.2d 382 (1991)) (emphasis in original).

21 U.S.C. § 355(q)(1)(E) provides that “[i]f the Secretary determines that a [Citizen] [P]etition ... was submitted with the primary purpose of delaying the approval of an application and the petition does not on its face raise valid scientific or regulatory issues, the Secretary may deny the petition at any point based on such determination.” When Reckitt's Citizen Petition was initially submitted, several Generics requested that the FDA deny it as frivolous and intended for delay under this Section, but the FDA declined to do so. (DP Compl., Exs. E, G.)

Reckitt urges that I find as a matter of law that the Citizen Petition was not a sham based upon the Petition itself and the FDA's response thereto. Whether petitioning activity is a sham is generally a question for the jury. In re Flonase Antitrust Litig., 795 F.Supp.2d 300, 310 (E.D.Pa.2011). However, “a court may decide probable cause as a matter of law” where “there
is no dispute over the predicate facts of the underlying ... proceeding.” Prof'l Real Estate Investors, Inc., 508 U.S. at 63, 113 S.Ct. 1920. Reckitt argues that the Petition was not a sham because (1) the FDA took the full 150–day period for review and denied requests to summarily deny the petition; (2) the FDA granted partial relief on Reckitt's requests; (3) a reasonable litigant would not have known that the FDA would require Reckitt to provide stringent proof of causation; and (4) the regulations that prohibited the FDA from granting Reckitt's requested relief were being considered for amendment at the time the Petition was filed. Plaintiffs respond that questions of fact preclude the Court from determining whether the Petition was objectively baseless at this early stage.

While the FDA did not dismiss Reckitt's Citizen Petition outright as baseless and having been submitted purely for the purpose of delay, § 355(q)(1)(E) does not require such an action. It states that the FDA may deny a petition at any point based on a finding of frivolousness, but it does not require summary denial. Thus, I cannot assume that the Petition must have merit simply because the FDA did not exercise its right to dismiss it outright. Moreover, upon denying the Citizen Petition, the FDA referred Reckitt to the FTC, and noted that the timing of Reckitt's activities with announcing the withdrawal of Suboxone tablets and the filing of the Citizen Petition “given its close alignment with the period in which generic competition for [that] product was expected to begin, cannot be ignored.” (DP Compl., Ex. G, pp. 15–16.)

The FDA acknowledged in its ruling that it had no authority to grant much of Reckitt's requested relief. (See supra p. 676.) The FDA cannot require ANDA filers to mimic non-approved labeling and REMS materials in order to obtain approval, due to 21 U.S.C. § 355(j)(4)(G) and 21 C.F.R. § 314.127(a)(7). (See DP Compl., Ex. G., p. 12 (“The FD & C Act requires that labeling for an ANDA be the same as the labeling 'approved for the *690 listed drug' ”).) Additionally, despite Reckitt's request that the FDA investigate why Suboxone tablets had been withdrawn from the market, Reckitt was continuing to sell the product at that time. (Id. at pp. 14–15.) Finally, the FDA determined that Reckitt did not provide evidence that the measures it sought to impose caused any decline in accidental pediatric exposures. Indeed, the study Reckitt submitted in support of its Petition “acknowledged that the impact of education interventions and packaging on the decline in pediatric exposure was not evaluated, and that definitive conclusions about these measures could not be reached.” (Id. at p. 9.)

In short, the FDA denied all of Reckitt's requested relief. Much of the relief sought was not even available to the FDA to grant, and Reckitt sought an investigation of its own reasons for withdrawing Suboxone tablets at a time when the tablets remained on the market. As such, Plaintiffs have plausibly pleaded that the Petition was objectively baseless in that no reasonable litigant could have realistically expected success on the merits. I also find that Plaintiffs have adequately alleged that Reckitt had the subjective intent to interfere with the business of a competitor through the use of the petitioning process.

2. Have Plaintiffs Established an Antitrust Injury Regarding the Citizen Petition?

I next consider Reckitt's argument that the filing of a Citizen Petition did not cause antitrust injury. 21 U.S.C. § 355(q)(1)(A) states that the Secretary shall not delay approval of an NDA or ANDA because of a Citizen Petition unless “the Secretary determines, upon reviewing the petition, that a delay is necessary to protect the public health” and that “[c]onsideration of the petition shall be separate and apart from review and approval of any application.”

Plaintiffs have alleged that despite this statutory framework, delays still occur and did occur in this instance. Reckitt responds that Plaintiffs' failure to articulate that the FDA violated 21 U.S.C. § 355(q)(1)(A) in the complaints is fatal to their claim. Reckitt also presents documents subject to judicial notice showing that the FDA approved the Generics' ANDAs ten days after the last amendment was submitted, indicating that the amendments were the reason for any delays in ANDA approval, not the Citizen Petition. Finally, Reckitt presents an FDA ruling on a citizen petition filed by Novartis Pharmaceuticals Corporation, where the FDA noted that the petition lacked merit and had been responsible for a 25–day delay in the approval of ANDAs.
I find that the complaints plausibly allege that the Citizen Petition caused antitrust injury by delaying Generic entry into the market. The complaints state that Reckitt filed the Citizen Petition for the purpose of delaying Generic competition, and but for the filing of the Citizen Petition, “competitors would have begun marketing generic version of Suboxone well before they actually did.” (DP Compl. ¶¶ 189–90.) They further allege that, despite the enactment of § 355(q)(1)(A), “a branded firm may still be able to delay generic approval while the FDA considers whether the relevant Citizen Petition implicates issues of public health, regardless of whether the petition actually does or not, and regardless of whether the petition is [a] sham or not.” (Id. at ¶ 72.) The combination of these two allegations indicates that the FDA violated 21 U.S.C. § 355(q)(1)(A). To dismiss a claim for not using that exact language would be to place form over substance.

Furthermore, I find that the Novartis petition presented by Reckitt actually supports Plaintiffs' argument. The FDA clearly stated in its ruling that delays still occur despite the mandate of 28 U.S.C. § 355(q)(1)(A). As to Reckitt's argument that any delays in approval of the ANDA were due to amendments made by the Generics themselves, this is a classic factual issue that is properly determined by a fact finder.

For the reasons stated above, I conclude that Plaintiffs have sufficiently pleaded an antitrust injury, and accordingly, Reckitt's motion to dismiss Counts IV and V of the Direct Purchasers' complaint is denied.

**E. Count I—Unlawful Maintenance of Monopoly Power Through an Overarching Scheme to Prevent or Delay Generic Competition**

Reckitt argues that Plaintiffs cannot combine multiple unsuccessful claims to state one overarching successful claim. However, as I find that three out of the four claims discussed above will survive the motion to dismiss, I need not address this argument. Reckitt's motion will thus be denied as to Count I of the Direct Purchasers' complaint.

**F. Overview—The End Payors’ Complaint and Reckitt's Motion to Dismiss**

The facts alleged in the End Payors' complaint are largely indistinguishable from those found in the Direct Purchasers' complaint. However, in contrast to the Direct Purchasers, the End Payors raise the following claims: (1) monopolization and monopolistic scheme under state law (listing 29 jurisdictions) (“Count I”); (2) attempted monopolization under state law (listing 29 jurisdictions) (“Count II”); (3) unfair and deceptive trade practices under state law (listing 28 jurisdictions) (“Count III”); (4) injunctive and declaratory relief under § 16 of the Clayton Act for Reckitt's violations of § 2 of the Sherman Act (“Count IV”); and (5) unjust enrichment under state law (listing 49 jurisdictions) (“Count V”).

In addition to attacking each of the claims brought by the End Payors for failure to state a claim, Reckitt also argues that numerous state law claims should be dismissed for lack of Article III standing as well as antitrust standing and conflict of laws. I will address these arguments in turn.

**G. Do the End Payors Have Article III Standing?**
Constitutional standing under Article III requires the following elements: (1) “an injury-in-fact that is concrete and particularized and actual or imminent, as opposed to conjectural or hypothetical”; (2) “a causal connection between the injury and the conduct complained of”; and (3) “it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.” Edmonson v. Lincoln Nat. Life Ins. Co., 725 F.3d 406, 414–15 (3d Cir.2013) (quoting Lujan v. Defenders of Wildlife, 504 U.S. 555, 559, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992)). In addition to these immutable requirements of Article III, “the plaintiff generally must assert his own legal rights and interests, and cannot rest his claim to relief on the legal rights or interests of third parties.” Miller v. Nissan Motor Acceptance Corp., 362 F.3d 209, 221 (3d Cir.2004) (quoting Trump Hotels & Casino Resorts, Inc. v. Mirage Resorts Inc., 140 F.3d 478, 485 (3d Cir.1998)).

“[E]ach claim must be analyzed separately, and a claim cannot be asserted on behalf of a class unless at least one named plaintiff has suffered the injury that gives rise to that claim.” Griffin v. Dugger, 823 F.2d 1476, 1483 (11th Cir.1987).

Although the End Payors have brought claims under the laws of forty-eight states and two territories, they reside in only seven of these states: Alabama, Illinois, Massachusetts, Michigan, Minnesota, New York and Pennsylvania. (EP Compl. ¶¶ 102–10.) These End Payors allege that they made purchases or reimbursed customers for Suboxone in only ten additional states: Alaska, California, Florida, Iowa, Kentucky, Mississippi, Missouri, New Jersey, Nevada and Wisconsin. 14 (Id.) The complaint also notes that Reckitt is located in Virginia, and is alleged to have engaged in many of the actions leading to these claims in that state. (Id. at ¶ 11214.)

Reckitt argues that the named End Payor Plaintiffs have not been injured, and thus lack standing to assert claims, in the remaining thirty-two states and territories. 15 The End Payors do not dispute that the nine named End Payor Plaintiffs do not reside in and did not suffer a financial injury in those thirty-two states. They urge, however, that the initial inquiry should be whether they have standing to bring any state antitrust, consumer protection, or unjust enrichment claim. Then, once general standing is established, the End Payors argue that they should be allowed to pursue the claims of absent class members who may have suffered an injury in other states. According to the End Payors, the question of whether they prosecute claims brought on behalf of class members under the law of other states should be decided as a class certification issue under Federal Rule of Civil Procedure 23, not as a matter of Article III standing.

Reckitt relies heavily upon In re Wellbutrin XL Antitrust Litigation, 260 F.R.D. 143 (E.D.Pa.2009), where the Honorable Mary A. McLaughlin answered the exact question at issue here—“whether the Court should consider the named plaintiffs' standing to bring the claims asserted under each individual state's law or should wait until the class certification stage to make such an assessment.” Id. at 151. Judge McLaughlin determined that standing was a threshold inquiry that must be addressed prior to class certification, reasoning that the alternative:

... would allow named plaintiffs in a proposed class action, with no injuries in relation to the laws of certain states referenced in their complaint, to embark on lengthy class discovery with respect to injuries in potentially every state in the Union. At the conclusion of that discovery, the plaintiffs would apply for
class certification, proposing to represent the claims of parties whose injuries and modes of redress they would not share. That would present the precise problem that the limitations of standing seek to avoid.

Id. at 155. Judge McLaughlin ultimately concluded that the plaintiffs, end payor health and welfare funds, had standing to bring claims under the laws of the states where the plaintiffs themselves were located and states where the plaintiffs’ members had purchased Wellbutrin. Id. at 156–57. However, all other state law claims were dismissed for lack of standing. Id. at 158. I agree with Judge McLaughlin’s reasoning.

The End Payors attempt to distinguish Wellbutrin, arguing that the question is not one of standing but instead a question of representativeness under Rule 23, and therefore a ruling on this issue is premature. The End Payors rely upon In re Nexium (Esomeprazole) Antitrust Litigation, 968 F.Supp.2d 367 (D.Mass.2013), where the court determined that once the named plaintiffs had established that they had suffered an injury due to overpayments from the lack of generic competition, the standing inquiry ended. The court determined that after that point, whether the named plaintiffs could raise the claims of the class it purports to represent should be determined under Rule 23 at the class certification stage. Id. at 404–05; see also In re Chocolate Confectionary Antitrust Litig., 602 F.Supp.2d 538, 579–80 (M.D.Pa.2009). 17

The majority of the other cases cited by the End Payors generally involve situations where a named plaintiff has suffered an injury that established standing to sue under a particular law—for example, Title VII—and the court considered whether the named plaintiffs’ claims were sufficiently similar to the claims of potential class members under the same law. See Goodman v. Lukens Steel Co., 777 F.2d 113, 122 (3d Cir.1985); see also Gratz v. Bollinger, 539 U.S. 244, 265, 123 S.Ct. 2411, 156 L.Ed.2d 257 (2003) (claims of named plaintiff and potential class brought under the equal protection clause). The named plaintiffs in those cases clearly suffered an injury that could be redressed by the statute or constitutional amendment invoked in the complaint. That is not the case here, where none of the named End Payor Plaintiffs have suffered an injury that may be redressed by the law of thirty-two of the fifty jurisdictions cited.

The fact that this is a class action should not change the analysis “for even named plaintiffs who represent a class must allege and show that they personally have been injured, not that injury has been suffered by other, unidentified members of the class to which they belong and which they purport to represent.” Lewis, 518 U.S. at 357, 116 S.Ct. 2174 (quoting Simon, 426 U.S. at 40 n. 20, 96 S.Ct. 1917). Since “each claim must be analyzed separately, and a claim cannot be asserted on behalf of a class unless at least one named plaintiff has suffered the injury that gives rise to that claim,” Griffin, 823 F.2d at 1483, the claims brought under the laws of these thirty-two different states and territories will be dismissed for lack of Article III standing. 18

H. Do Conflict of Laws Principles Require Additional State Law Claims to Be Dismissed?

Reckitt further argues that while conflict of laws principles allow the End Payor Plaintiffs to assert claims under the laws of Virginia (Reckitt’s “home state”) or the seven “home states” of the named End Payors, claims cannot be raised under the law of states where Suboxone was purchased (“purchase states”). Reckitt acknowledges that the law within this circuit and elsewhere is in considerable disarray. However, it urges that classic choice of laws considerations—i.e. the location of the injury, the conduct causing the injury, the domicile of the parties, and the center of the relationship between the parties—would require applying the “home state approach.” This approach allows plaintiffs to bring state law claims where the plaintiffs and/or the defendants reside.

The End Payors respond that both the state where the overcharge was incurred and the state where the End Payors reside have an interest in compensating the victims of the overcharges. They point to case law where an international plaintiff was permitted to sue under the Sherman Act when the overcharge was incurred within the United States. See United States
A number of cases within this district have determined that end payor plaintiffs have standing and are able to state a claim under the laws of states in which they reside, as well as the states where they have reimbursed consumers. Cephalon, 702 F.Supp.2d at 538 (end payors' “injuries would be redressed by a favorable determination under the laws of the states where their members purchased Provigil”); Wellbutrin XL, 260 F.R.D. at 156–57 (“plaintiffs' claims have clear connection to the states where plaintiffs themselves are located and the states where their members made purchases of Wellbutrin XL”). While most cases have considered whether plaintiffs have standing to assert claims in home states or purchase states, and have not framed it as a conflict of laws analysis, some courts have made statements that can provide guidance. For example, in Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC, 263 F.R.D. 205 (E.D.Pa.2009), the court commented:

Given the fact that the alleged injury occurred in each of the fifty states, and given each state's strong interest in protecting its own consumers (but a far weaker interest in protecting consumers from other states), it is clear ... that the law of a particular state will govern any overcharge injury arising in that state. Id. at 211 n. 12; see also In re Relafen Antitrust Litig., 221 F.R.D. 260, 277 (D.Mass.2004) (“the Court considers the more significant contact in this context to be the location of the injury—that is, the location of the sales to the end payor plaintiffs”).

The Restatement (2d) of Conflicts of Laws advises that courts should consider “the basic policies underlying the particular field of law.” State laws that allow indirect purchasers to assert antitrust claims aim to protect consumers within its borders. See In re Relafen, 221 F.R.D. at 277 (“the primary aim of antitrust and consumer protection laws generally—and those of indirect purchaser states particularly—is compensating consumers”). Each overpayment made by a consumer, or reimbursed by a Health and Welfare Plan, is a discrete injury that the state antitrust laws were designed to redress. Therefore, I find that the End Payors may assert claims under the laws of both home states and purchase states. 19

I. Have the End Payors Stated a Claim Under State Antitrust Law? 20

Reckitt adopts the arguments raised in their motion to dismiss the Direct Purchasers' complaint and asserts that such arguments apply to the End Payors' state antitrust claims. For the reasons explained above, I will not dismiss the End Payors' antitrust claims on those grounds. However, Reckitt also raises arguments specific to the state law claims. I address these below in the order in which they were raised.

1. Antitrust Standing

Reckitt argues that the End Payors have failed to establish antitrust standing—a separate analysis from Article III standing—under the standards articulated in Associated General Contractors of California, Inc. v. California State Council of Carpenters (“AGC”), 459 U.S. 519, 103 S.Ct. 897, 74 L.Ed.2d 723 (1983). In AGC, the Supreme Court limited federal antitrust standing, recognizing that “Congress did not intend to allow every person tangentially affected by an antitrust violation to maintain an action to recover treble damages for the injury to his business or property.” Id. at 535, 103 S.Ct. 897 (quoting Blue Shield
In re Suboxone (Buprenorphine Hydrochloride and..., 64 F.Supp.3d 665 (2014)

2014-2 Trade Cases P 78,983

of Va. v. McCready, 457 U.S. 465, 477, 102 S.Ct. 2540, 73 L.Ed.2d 149 (1982)). The AGC factors for antitrust standing are as follows: (1) the nature of the plaintiff's alleged injury, including the status of the plaintiff as a consumer or competitor in the relevant market; (2) the directness of the claimed injury; (3) whether there is a more direct victim; (4) the complexity of apportioning damages; and (5) risks of duplicative recovery. Id. at 538–45, 103 S.Ct. 897. Reckitt asserts that most of the states under which the End Payors have brought suit have adopted the AGC factors for application to its state antitrust laws either by express judicial decisions or by the incorporation of federal decisions interpreting federal antitrust laws. 21

AGC followed the Supreme Court's decision in Illinois Brick Co. v. Illinois, 431 U.S. 720, 97 S.Ct. 2061, 52 L.Ed.2d 707 (1977), where the Supreme Court determined, *697 based on principles of prudential standing, that the federal antitrust statutes do not permit indirect purchasers to sue for damages. To allow such suits, the Supreme Court feared, would create the risk of multiple liability for defendants, hopelessly complex damages calculations, and increases in the cost of antitrust litigation. Id. at 730–32, 737–44, 97 S.Ct. 2061. Following Illinois Brick, the Supreme Court further limited the class of persons who could sue under the federal antitrust laws by laying out the antitrust standing factors identified above in AGC. The majority of the state antitrust laws under which the End Payors have brought their claims have passed Illinois Brick repealer statutes, which allow indirect purchasers to bring antitrust claims for damages under state law.

Upon review of the precedent cited by the parties, it appears that some states have explicitly adopted the AGC factors and some have not. Compare Lorix v. Crompton Corp., 736 N.W.2d 619, 627–29 (Minn.2007) (explicitly rejecting application of the AGC factors to Minnesota's antitrust law) with Southard v. Visa U.S.A. Inc., 734 N.W.2d 192, 198–99 (Iowa 2007) (adopting the AGC factors in analyzing Iowa antitrust law and finding lack of antitrust standing due to remoteness of injury). The majority of the states, however, are unclear on this issue. Despite these inconsistencies, I need not go through the process of identifying which states have adopted the AGC factors and which have not because, in any event, I find that the End Payors have satisfied the standards for antitrust standing.

Regarding the first factor—the nature of plaintiff's alleged injury, including the status of the plaintiff as a consumer or competitor in the relevant market—Reckitt argues that none of the End Payor Plaintiffs clearly pleads that it is a purchaser of Suboxone, and therefore is neither a purchaser, nor a competitor of Reckitt. However, the complaint clearly states that the End Payors "purchased and/or provided reimbursement" to its members for Suboxone. Other courts have found that reimbursement and/or purchases of the product by a Health and Welfare Fund can satisfy the first factor. See In re K–Dur Antitrust Litig., 338 F.Supp.2d 517, 543 (D.N.J.2004).

The End Payors argue that the second factor, directness of the injury, has minimal weight when analyzed under state law, where the state allows claims by indirect purchasers. While this is a valid point, I must note that antitrust standing is not unlimited, even in states that allow suits by indirect purchasers. For example, in Owens Corning v. R.J. Reynolds Tobacco Co., 868 So.2d 331 (Miss.2004), the plaintiff, a former producer of asbestos materials, brought antitrust claims against several tobacco companies, seeking to recoup money paid in judgments to persons suffering from lung disease stemming from the use of both asbestos and tobacco products. Id. at 334–36. The Mississippi Supreme Court affirmed the grant of summary judgment on claims brought under Mississippi's antitrust law, holding that the injury was too attenuated. Id. at 344.

Another example of these limitations can be found in what the parties have referred to as the "Visa" cases. In these cases, Visa and Mastercard were alleged to have forced stores that accepted their credit cards to also accept Visa and Mastercard debit cards through an illegal tying scheme. The debit card transactions resulted in inflated fees being charged to the stores. The stores then proceeded to raise the prices of their products, even for customers who purchased items with cash or check. The plaintiffs were the consumers who had paid inflated prices at the store. *698 Antitrust claims in these cases were often dismissed for remoteness of injury, as the consumers had not directly engaged in any business with, nor were they competitors of, Visa and
While these cases make clear that directness of injury must be considered in states with Illinois Brick repealer statutes, I find that the factor must either carry significantly less weight or directness must be analyzed more generously than under federal law. It would be inconsistent for a state to allow indirect purchasers to bring antitrust claims, only for the courts to cursorily dismiss those claims on antitrust standing grounds simply because they have been brought by indirect purchasers. See Lorix, 736 N.W.2d at 629 (remarking that it appears inconsistent to repudiate Illinois Brick and invite indirect purchaser suits “only for courts to dismiss those suits on the pleadings based on the very concerns that motivated Illinois Brick”).

The End Payors also point out that they have purchased the product and/or provided reimbursement to their members who have purchased the product. This is not the situation in the Visa cases or Owens Corning where there are numerous links in the causal chain. The End Payors claim that they were overcharged when purchasing Suboxone due to the manufacturer’s monopolization. These allegations are sufficiently direct to satisfy the second factor in states that allow indirect purchasers to bring antitrust claims.

For the reasons just discussed, the third factor—which there is a more direct victim—must also carry little weight in states that allow suits to be brought by indirect purchasers. “[S]trict application of this factor, in the context of indirect purchasers, would always caution against standing, an outcome incompatible with the purpose of Illinois Brick repealer statutes.” D.R. Ward Constr. Co. v. Rohm & Haas Co., 470 F.Supp.2d 485, 503 (E.D.Pa.2006).

Finally, as to damages, the Third Circuit has been reluctant to grant motions to dismiss based on speculative or complex damages. See In re Lower Lake Erie Iron Ore Antitrust Litig., 998 F.2d 1144, 1169 (3d Cir.1993) (“we do not hold that litigation must be avoided solely because it might be difficult to ascertain damages”). The damages in the present action allegedly stem from overcharges due to Reckitt's scheme to keep the Generics from competing with its product. These damages do “not appear incapable of accurate calculation” such that the End Payors would not have standing. Id. As such, I conclude that, even applying the AGC factors, the End Payors have standing to bring antitrust claims under the state laws that have passed Illinois Brick repealer statutes.

2. Nexus to Intrastate Commerce

Reckitt further argues that the End Payors fail to plead a sufficient nexus between Reckitt's alleged antitrust violations and intrastate commerce under the antitrust laws of Mississippi and Nevada. Plaintiffs do not dispute the need for this nexus, and respond that the following portion of their amended complaint provides sufficient facts to satisfy the intrastate commerce requirement:

Reckitt's anticompetitive conduct occurred in part in trade and commerce within the states set forth herein, and also had substantial intrastate effects in that, inter alia, retailers within each state were foreclosed from offering cheaper generic Suboxone to end-payers inside each respective state. The foreclosure of generic Suboxone directly impacted and disrupted commerce for end-payers within each state, who were forced to pay supracompetitive prices.
Courts have found that allegations more general than these satisfy the intrastate commerce nexus requirement. See In re Digital Music Antitrust Litig., 812 F.Supp.2d 390, 408 (S.D.N.Y. 2011) (nexus requirement satisfied where complaint alleged the defendants' “conduct was in a continuous and uninterrupted flow of intrastate and interstate commerce”) (quotation marks omitted); see also In re Chocolate Confectionary Antitrust Litig., 602 F.Supp.2d at 580–82. The cases cited by Reckitt are distinguishable, in that the plaintiffs in those cases solely alleged effects on interstate commerce. See In re Flonase Antitrust Litig., 610 F.Supp.2d 409, 416 (E.D.Pa.2009); California v. Infineon Techs. AG, 531 F.Supp.2d 1124, 1155–58 (N.D.Cal.2007). Therefore, I do not find that dismissal of the Mississippi and Nevada antitrust claims is warranted.

J. Have the End Payors Failed to State a Claim Under State Consumer Protection Laws?

Reckitt argues that all of the remaining consumer protection claims brought under the laws of California, Florida, Illinois, Massachusetts, Michigan, Minnesota, Missouri, Nevada, New York, Pennsylvania and Virginia must be dismissed for a multitude of reasons. I address each of these states' consumer protection laws in turn.

1. California

With respect to California's consumer protection law, Cal. Bus. & Prof.Code §§ 17200 et seq., Reckitt simply argues that the End Payors have failed to demonstrate a nexus to intrastate commerce. For the reasons stated in section III.I.2, supra, I disagree with Reckitt's argument. The End Payors have alleged that overcharges occurred in California, which is sufficient to establish an intrastate nexus. See Meridian Project Sys., Inc. v. Hardin Constr. Co., LLC, 404 F.Supp.2d 1214, 1225 (E.D.Cal.2005) (noting that a plaintiff must allege that either misconduct or injuries occurred intrastate). As this is Reckitt's only argument to dismiss the End Payors' claim under the California consumer protection law, this claim will survive.

2. Florida


For the same reasons discussed above regarding the Direct Purchasers, the End Payors' allegations are sufficient to satisfy the particularity requirements of Rule 9(b). Specifically, they point to claims that Reckitt fabricated a safety issue regarding Suboxone tablets for the sheer purpose of impairing generic competition and eliciting monopoly proceeds from consumers. This false safety issue was then allegedly broadcast to the FDA, doctors, other industry participants, and the public in an effort to destroy demand for Suboxone tablets. Reckitt is also alleged to have made misrepresentations in their Citizen Petition, which the End Payors claim was submitted solely for the purposes of delay. (See EP Compl. ¶¶ 3, 24–35, 70–82.) The End Payors
provide numerous, specific reasons why Reckitt's actions were false and deceptive. Other cases have found that an allegedly fraudulent Citizens Petition submitted for the purposes of delay could constitute deceptive conduct that would state a claim for violation of state consumer protection laws. See, e.g., In re DDAVP Indirect Purchaser Antitrust Litig., 903 F.Supp.2d 198, 221–29 (S.D.N.Y.2012). Therefore, I find that the End Payors have sufficiently pleaded deception that satisfies the heightened pleading standard under Rule 9(b).

3. Illinois

The Illinois Antitrust Act only permits the state's Attorney General to bring a class action on behalf of indirect purchasers. 740 Ill. Comp. Stat. § 10/7(2). The End Payors recognize this prohibition, as they have withdrawn their claims under Illinois' antitrust law. Courts in this district have found that, in light of this prohibition, claims based on alleged antitrust violations under Illinois' consumer protection law must be dismissed. In re Flonase Antitrust Litig., 692 F.Supp.2d 524, 539 (E.D.Pa.2010) (to allow the indirect purchaser plaintiffs to bring a claim for antitrust conduct under Illinois' consumer protection law “would constitute an end run around the Illinois legislature's determination”). I agree with this assessment and believe the End Payors' claims under the Illinois consumer protection law should be dismissed.

4. Massachusetts

Section 11 of Massachusetts' consumer protection law provides a claim for unfair or deceptive trade practices between businesses, whereas § 9 provides a cause of action to consumers. See Mass. Gen. L. Ch. 93A §§ 9, 11; Ciardi v. F. Hoffmann-La Roche, Ltd., 436 Mass. 53, 762 N.E.2d 303, 308–09 (2002). The state legislature has extended Illinois Brick's prohibition on suits by indirect purchasers to § 11 of Massachusetts' consumer protection law, but not § 9. Ciardi, 762 N.E.2d at 308–09; see also In re Auto. Parts Antitrust Litig., 2013 WL 2456612, at *29 (E.D.Mich. June 6, 2013) (dismissing consumer protection claims brought by businesses under § 11 due to Illinois Brick ). Although the End Payors' complaint is not clear as to whether they are asserting a claim under § 9 or § 11, their brief implies § 11 would be the appropriate avenue for their claim. The End Payors *701 argue that a pre-suit demand, a requirement for § 9 claims, would “not apply to claims brought by businesses like Plaintiffs in this case.” (EP Resp., p. 47.) In any event, even if the End Payors did intend to invoke § 9, they acknowledge that they did not satisfy the pre-suit demand requirement. See Entrialgo v. Twin City Dodge, Inc., 368 Mass. 812, 333 N.E.2d 202, 204 (1975) (“A demand letter listing the specific deceptive practices claimed is a prerequisite to suit and as a special element must be alleged and proved”). Therefore, the End Payors' claims under Massachusetts' consumer protection law will be dismissed. 24

5. Michigan

Reckitt argues that Michigan's consumer protection law, Mich. Stat. Ann. §§ 445.901 et seq., does not prohibit monopolization. While this statute does require intent to deceive, which is not required to state a claim for monopolization, see In re Packaged Ice Antitrust Litig., 779 F.Supp.2d at 665–66, for the reasons stated above, the End Payors' complaint pleads with particularity that Reckitt employed fraudulent and deceptive means with the intent to deceive.

In re Suboxone (Buprenorphine Hydrochloride and..., 64 F.Supp.3d 665 (2014)
2014-2 Trade Cases P 78,983

protection law by demonstrating that plaintiffs purchased and consumed the product. See In re DDAVP, 903 F.Supp.2d at 226 (citing Gasperoni v. Metabolife, Int'l Inc., 2000 WL 33365948, at *7 (E.D.Mich. Sept. 27, 2000)). Therefore, Reckitt's motion is denied as to this claim.

6. Minnesota

Minnesota requires that the pleadings contain specific allegations of fraud or deceit that comply with the heightened standard of Federal Rule of Civil Procedure 9(b). E–Shops Corp. v. U.S. Bank Nat'l Ass'n, 795 F.Supp.2d 874, 879 (D.Minn.2011) (holding that Rule 9(b) applies to the Minnesota Consumer Fraud Act, Minn.Stat. Ann. §§ 325F.68 et seq.). For the reasons recited above, the End Payors have pleaded misrepresentations and deception with particularity so as to survive a motion to dismiss. Therefore, the claim under Minnesota's consumer protection law survives Reckitt's motion.

7. Missouri

Reckitt argues that the End Payors' claim under Missouri's consumer protection law should be dismissed due to the state's adoption of Illinois Brick. The End Payors point to Gibbons v. J. Nuckolls, Inc., 216 S.W.3d 667 (Mo.2007) for the proposition that Missouri law does not prohibit their claim. In Gibbons, a consumer sued a car dealership and a wholesaler for failure to disclose that the car he purchased had been in a prior accident. The court held that the consumer may sue the wholesaler, even though direct contractual privity did not exist between the parties. While this case does appear to support the assertion that Missouri allows indirect purchasers to bring suit under its consumer protection law, Gibbons did not consider facts in the antitrust context. The End Payors have failed to identify any cases where indirect purchasers were permitted to bring claims under Missouri's consumer protection law for antitrust injury. As with Illinois, it would appear that allowing a claim under Missouri's consumer protection law would provide an end-run around the state's prohibition of antitrust claims by indirect purchasers. See Ireland v. Microsoft Corp., 2001 WL 1868946, at *1 (Mo.Cir. Jan. 24, 2001) (dismissing claims under Missouri's antitrust law and consumer protection statute due to Illinois Brick). Therefore, the consumer protection claim under Missouri law will be dismissed.

8. Nevada

Reckitt also argues that monopolization claims are not actionable under Nevada's consumer protection law, Nev.Rev.Stat. Ann. §§ 598.0903 et seq. However, that statute prohibits deceptive trade practices, which includes “[k]nowingly making a false representation as to the characteristics, ingredients, uses, benefits, alterations or quantities of goods or services for sale.” Nev.Rev.Stat. § 598.0915. For the reasons stated above, the End Payors have sufficiently pleaded deceptive practices by Reckitt so as to state a claim under Nevada's consumer protection law. See In re DDAVP, 903 F.Supp.2d at 226 (finding allegations of fraudulent acts in the antitrust context stated a claim under Nevada's consumer protection law).

9. New York

Reckitt also argues that the End Payors have failed to establish a nexus with intrastate commerce as required by New York's consumer protection law, N.Y. Gen. Bus. L. §§ 349 et seq. As with California, the End Payors have pleaded that overcharges occurred in New York. Therefore, I do not agree with Reckitt's argument that this claim should be dismissed. See Goshen v.
Reckitt further argues that the End Payors failed to adequately plead fraud or deceit directed at consumers. Reckitt cites to In re Wellbutrin XL Antitrust Litig., 260 F.R.D. 143 (E.D.Pa.2009), where the court held that the indirect purchasers were too far removed from the allegedly fraudulent action—in that case, filing a sham Citizen Petition—to state a claim under New York's consumer protection law. The target of that deception, the court found, was the FDA, not the indirect purchasers. Id. at 164. Here, however, in addition to the Citizen Petition allegations, the End Payors have posited that Reckitt fabricated safety issues with Suboxone tablets and targeted consumers, among others, in an effort to maintain a monopoly for Suboxone. The End Payors are alleged to have either directly purchased or reimbursed their members—i.e. consumers—for the product. Therefore, I find that the End Payors have successfully stated a claim under New York's consumer protection law.

10. Pennsylvania

Reckitt argues that the End Payors have failed to plead fraud or deception with particularity under Pennsylvania's consumer protection law, 73 Pa. Stat. Ann. §§ 201–1 et seq. See In re K–Dur Antitrust Litig., 338 F.Supp.2d at 548 (dismissing claim under Pennsylvania's consumer protection law for failure to adequately plead fraud). For the reasons stated above, I disagree with Reckitt's argument, and find that the End Payors have pleaded fraud with particularity. Therefore, Reckitt's motion will be denied as to Pennsylvania's consumer protection law.

11. Virginia

Reckitt argues that the End Payors' claim under Virginia's consumer protection law, Va.Code Ann. § 59.1–196, should be dismissed because monopolization allegations are not actionable under the state's consumer protection laws. See In re New Motor Vehicles Canadian Export Antitrust Litig., 350 F.Supp.2d 160, 206–07 (D.Me.2004). For the reasons discussed above, the End Payors have sufficiently pleaded fraud and/or misrepresentations sufficient to state a claim under Virginia's consumer protection law.

K. Have the End Payors Stated a Claim for Unjust Enrichment?

“Generally speaking, in order to state a claim for unjust enrichment, a plaintiff must allege (1) at plaintiff's expense (2) defendant received [a] benefit (3) under circumstances that would make it unjust for defendant to retain [the] benefit without paying for it.” In re K–Dur Antitrust Litig., 338 F.Supp.2d at 544 (citing RESTATEMENT OF RESTITUTION § 1 (1937)).

Reckitt presents two arguments as to why all of the End Payors' unjust enrichment claims should be dismissed. First, Reckitt argues that the End Payors failed to adequately identify the state laws under which they assert such claims, and that failure to do so warrants dismissal. See In re Auto. Parts Antitrust Litig., 2013 WL 2456612, at *31 (dismissing unjust enrichment claims because plaintiffs pleaded general common law unjust enrichment law unjust enrichment without identifying under which states they were bringing these claims); In re Wellbutrin XL, 260 F.R.D. at 167 (same). However, the End Payors' complaint does allege which states' unjust enrichment laws were violated. Unlike the plaintiffs in the cases cited by Reckitt, here the End Payors invoked the laws of all fifty states (except Ohio and Indiana) and the District of Columbia. Therefore, I am not convinced that all of the End Payors' unjust enrichment claims should be dismissed on this ground.
Reckitt's second argument for complete dismissal of the unjust enrichment claims is that the End Payors did not plead the specific elements of any state's unjust enrichment law or the factual allegations that support recovery under those laws. While it is true that the elements of unjust enrichment vary state by state, “almost all states at minimum require plaintiffs to allege that they conferred a benefit or enrichment upon defendant and that it would be inequitable or unjust for defendant to accept and retain the benefit.” In re Flonase, 692 F.Supp.2d at 541. The facts set forth in the End Payors' complaint allege that Reckitt obtained ill-gotten gains—that is, monopoly profits unlawfully obtained. To the extent that a jurisdiction invoked by the End Payors requires state-specific elements that have not been satisfied by these allegations, these alleged deficiencies are addressed below.

Next, Reckitt contends that any and all “autonomous” unjust enrichment claims—claims that are not derived from a violation of some other state law—must be dismissed. Unjust enrichment claims can generally take one of two forms: (1) parasitic, which means it “arise[s] from contracts, torts, or other predicate wrongs”; or (2) autonomous, where the unjust enrichment claim alone “may also serve as independent grounds for restitution in the absence of mistake, wrongdoing, or breach of contract.” In re New Motor Vehicles Canadian Export Antitrust Litig., 350 F.Supp.2d at 207–08 (citation omitted). As with the consumer protection laws, courts have held that an autonomous unjust enrichment may not be used as an end-run around a state's prohibition against antitrust claims brought by indirect purchasers in accordance with Illinois Brick. See id. at 207–10; In re Digital Music Antitrust Litig., 812 F.Supp.2d at 413; In re Flonase, 692 F.Supp.2d at 542. States that have adopted Illinois Brick and do not provide a cause of action under either the states' antitrust law or consumer protection law, are: Illinois, Kentucky, Massachusetts, Missouri and New Jersey. Therefore, these autonomous claims for unjust enrichment will be dismissed.

To the extent that Reckitt argues that other states do not allow a stand-alone claim for unjust enrichment, I will address these states individually below.

1. Alabama

With respect to Alabama's unjust enrichment law, Reckitt first argues that because the End Payors did not plead underlying antitrust or consumer protection claims under Alabama law, the Alabama unjust enrichment claims must be dismissed. Reckitt does not cite to any Alabama case law that states an unjust enrichment claim cannot stand on its own as an independent cause of action. Therefore, I will not grant the motion on this ground.

Reckitt next argues that the End Payors failed to allege that they acted under a mistake of fact or in misreliance on a duty, or that Reckitt engaged in any unconscionable conduct, as required by Alabama law. See Matador Holdings, Inc. v. HoPo Realty Invs., LLC, 77 So.3d 139, 146 (Ala.2011). Alabama courts define unconscionable conduct to include “fraud, coercion, or abuse.” Id. at 146 (quoting Jordan v. Mitchell, 705 So.2d 453, 458 (Ala.Civ.App.1997)). As discussed previously, the End Payors have alleged that Reckitt engaged in unconscionable conduct through fraud and that indirect purchasers relied upon this fraud, resulting in injury. Therefore, the motion to dismiss the Alabama unjust enrichment claim is denied.

2. Alaska

The only argument raised as to Alaska is that unjust enrichment cannot be an autonomous, stand-alone claim. In support of its argument, Reckitt cites to Alaska Sales & Serv., Inc. v. Millet, 735 P.2d 743, 746 (Alaska 1987). However, Reckitt misreads this case. The Millet court simply noted that unjust enrichment “is a prerequisite for the enforcement of the doctrine of restitution” and noted that courts often “treat actions brought upon theories of unjust enrichment, quasi-contract, contracts implied in law and quantum meruit as essentially the same.” Id. at 746 n. 6. It did not hold that unjust enrichment could not be an autonomous cause of action. Therefore, Reckitt's motion will be denied as to Alaska.
3. California

Reckitt argues that the claim for unjust enrichment under California law must be dismissed because California does not recognize a cause of action for unjust enrichment. Courts have recognized that there is inconsistent precedent within California as to whether a claim for unjust enrichment is viable. See Baggett v. Hewlett-Packard Co., 582 F.Supp.2d 1261, 1270–71 (C.D.Cal.2007) (“California courts appear to be split on whether unjust enrichment can be an independent claim or merely an equitable remedy”) (quotation marks omitted); compare Dunkel v. eBay Inc., 2013 WL 415584, at *11 (N.D.Cal. Jan. 31, 2013) (“Simply put, there is no cause of action in California for unjust enrichment”) (quotation marks and citations omitted) with Peterson v. Cello Partnership, 164 Cal.App.4th 1583, 80 Cal.Rptr.3d 316, 323–24 (2008) (analyzing whether plaintiff had stated a claim for unjust enrichment without finding that it was unavailable under California law).

In the absence of clear authority on this issue, I find the analysis in Baggett to be persuasive. Therein, the court noted that it was unclear whether unjust enrichment was a viable cause of action in California, and in any event, found that courts seem particularly reluctant to allow an unjust enrichment claim where the remedies available for plaintiff may be pursued under other claims. Baggett, 582 F.Supp.2d at 1271; see also Falk v. General Motors Corp., 496 F.Supp.2d 1088, 1099 (N.D.Cal.2007). Here, the End Payors' have brought a viable claim for violation of California's consumer protection law, and “the unjust enrichment claim will add nothing to [their] available relief.” Baggett, 582 F.Supp.2d at 1271. Therefore, I will dismiss the unjust enrichment claim under California law.

4. Florida

Reckitt initially argues that because Florida does not permit antitrust claims by indirect purchasers, the End Payors' unjust enrichment claim must also be dismissed as an end-run around this restriction. However, as discussed above, Florida does permit indirect purchasers to bring claims under the state's consumer protection law. Therefore, because there exists a viable underlying cause of action, I do not agree with Reckitt's argument. See Flonase, 692 F.Supp.2d at 543–44.

However, I do find that Florida law requires that a benefit be conferred upon the defendant directly in order to state a claim for unjust enrichment. See Extraordinary Title Servs., LLC v. Fla. Power & Light Co., 1 So.3d 400, 404 (Fla.3d D.C.A.2009) (affirming dismissal of unjust enrichment claim for failure to demonstrate that a benefit was directly conferred on the defendant); Am. Safety Ins. Serv., Inc. v. Griggs, 959 So.2d 322, 331 (Fla. 5th D.C.A.2007) (citing Peoples Nat'l Bank of Commerce v. First Union Nat'l Bank of Fla., 667 So.2d 876, 879 (Fla.3d D.C.A.1996)) (“The plaintiffs must show they directly conferred a benefit on the defendants”); Flonase, 692 F.Supp.2d at 544 (citing Nova Info. Sys., Inc. v. Greenwich Ins. Co., 365 F.3d 996, 1007 (11th Cir.2004)) (“As best I can tell, Florida law is clear; it requires that a plaintiff confer a direct benefit upon a defendant in order to state a claim for unjust enrichment”).

By virtue of being indirect purchasers, the End Payors cannot establish that they directly conferred a benefit upon Reckitt. The facts pleaded in the End Payors' complaint establish that any overpayments for Suboxone were made to pharmacies, and the End Payors had no direct contact with Reckitt. Therefore, I will grant Reckitt's motion as to the End Payors' Florida unjust enrichment claim.

5. Iowa
Reckitt first argues that the unjust enrichment claim arising under Iowa law must be dismissed because the End Payors did not allege that they conferred a direct benefit on Reckitt. However, the Supreme Court of Iowa has held that the benefits conferred to a defendant in an unjust enrichment claim may be “direct or indirect, and can involve benefits conferred by third parties.” *State, Dep’t of Human Servs. ex rel. Palmer v. Unisys Corp.*, 637 N.W.2d 142, 155 (Iowa 2001). Instead of concentrating on the privity between the two parties, the “critical inquiry is that the benefit received be at the expense of the plaintiff.” *Id.* Thus, I do not agree with Reckitt's first argument.

Next, Reckitt argues that the Iowa unjust enrichment claim should be dismissed because the End Payors received the benefit of the bargain, citing to *Smith v. Stowell*, 256 Iowa 165, 125 N.W.2d 795, 800 (1964). In *Smith*, the plaintiffs sold ten shares of stock to the defendant, and the parties entered into an express contract where the plaintiffs reserved the option to repurchase the shares from the defendant at a set price. *Id.* at 796. Years later, the plaintiffs sought to repurchase the ten shares but also wanted thirty additional shares that had been awarded to the defendant as a stock dividend. *Id.* The defendant was willing to sell the original ten shares at the agreed upon price, but not the stock dividends. *Id.* at 800. The court held that “there can be no such implied contract on a point fully covered by an express contract and in direct conflict therewith.” *Id.* This case is clearly distinguishable from the present case, as there is no express written contract between the parties. *See In re Auto. Parts Antitrust Litig.*, 2014 WL 2993753, at *29–30 (E.D.Mich. July 3, 2014) (distinguishing *Smith* due to the express written contract).

I also find that the sheer fact that the End Payors received medication in exchange for money paid does not bar an unjust enrichment claim. Reckitt has not established that any consideration exchanged for a benefit conferred defeats a claim for unjust enrichment. Instead, the precedent indicates that courts inquire as to the “fairness” of the consideration, which would appear to be a factual issue inappropriate for disposition in a motion to dismiss. *See In re K–Dur Antitrust Litig.*, 338 F.Supp.2d at 545–46 (collecting cases considering the fairness or justness of the bargain). The End Payors have alleged that although they received *Suboxone* in exchange for their payments, they were forced to pay artificially inflated prices due to Reckitt's wrongful conduct. This is sufficient to state a claim for unjust enrichment under Iowa law.

6. Michigan


In *A & M*, the Michigan Court of Appeals affirmed the trial court's dismissal of an unjust enrichment claim due to the plaintiff's failure to prosecute the case. 2008 WL 540883, at *1–2. The court further noted that “even if the lower court had erred in dismissing a plaintiff's action for lack of progress, it was properly subject to dismissal on the merits.” *Id.* at *2. The court reasoned that a direct benefit is required under Michigan unjust enrichment law and the plaintiff failed to show a direct relationship between himself and the defendants. *Id.* However, the court provided no precedent in support of its assertion.

I agree with the reasoning presented by a court in the Eastern District of Michigan. *In re Auto. Parts Antitrust Litig.*, 2014 WL 2993753, at *31. The *In re Auto. Parts* court found that *A & M* is not persuasive or dispositive, largely because the language regarding a direct benefit requirement was made in dicta. *Id.* The district court ultimately held that “Michigan law does not require a benefit to be conferred directly by plaintiff to a defendant” and denied the defendants' motion to dismiss on this ground. *Id.*
Several Michigan courts have reached the same conclusion. See Kammer Asphalt Paving Co. v. E. China Twp. Sch., 443 Mich. 176, 504 N.W.2d 635, 641 (1993) (allowing an indirect benefit to constitute unjust enrichment because of the close relationship between the parties); Morris Pumps v. Centerline Piping, Inc., 273 Mich.App. 187, 729 N.W.2d 898, 904 (2006) (finding the defendant, a general contractor, liable for unjust enrichment where the defendant used materials that the plaintiff had supplied to another subcontractor and did not pay the plaintiff for those materials). Several federal courts interpreting Michigan law have also determined that unjust enrichment does not require a direct benefit. See In re Static Random Access Memory (SRAM) Antitrust Litig., 2010 WL 5094289, at *7 (N.D.Cal. Dec. 8, 2010) (“A claim for unjust enrichment under Michigan law does not require that the plaintiff confer a direct benefit on the defendant”); In re K–Dur Antitrust Litig., 2008 WL 2660783, at *10 (D.N.J. Mar. 19, 2008) (holding that a plaintiff is not required to show a direct benefit while noting the inconsistency in the case law); In re Cardizem CD Antitrust Litig., 105 F.Supp.2d 618, 670–71 (E.D.Mich.2000) (rejecting that “either privity or a directly conferred benefit is an essential element of an unjust enrichment claim under” Michigan common law). Without a clear pronouncement from the Michigan state courts, I will allow the End Payors’ unjust enrichment claim under Michigan law to proceed.

Reckitt next argues that the End Payors received the benefit of the bargain. Reckitt cites to two cases where the court of appeals dismissed unjust enrichment claims where the parties negotiated an explicit contract, and both parties fulfilled their obligations under that contract. See Isom v. NE Lots LLC, 2010 WL 143470, at *6 (Mich.Ct.App. Jan. 14, 2010); Russell v. Zeemering, 2006 WL 2382511, at *5 (Mich.Ct.App. Aug. 17, 2006). Because there is no explicit contract in this case, I find these cases to be distinguishable. Accordingly, Reckitt's motion to dismiss the unjust enrichment claims in Michigan will be denied.

7. Minnesota

Reckitt first argues that Minnesota requires a direct benefit to be conferred onto the defendant in order to state a claim for unjust enrichment. The only authority it provides in support of this assertion is Schumacher v. Schumacher, 627 N.W.2d 725, 729 (Minn.Ct.App.2001). However, Schumacher does not state that a direct benefit is an essential element to an unjust enrichment claim. There, the court found that “the claimant must show that another party knowingly received something of value to which he was not entitled, and that the circumstances are such that it would be unjust for that person to retain the benefit.” Id. at 729. I am not convinced that Schumacher conclusively establishes that Minnesota law requires a direct benefit. See In re Processed Egg Prods. Antitrust Litig., 851 F.Supp.2d 867, 934–35 (E.D.Pa.2012) (finding that Minnesota does not have a “direct benefit” requirement).

Reckitt also argues that the End Payors received the benefit of the bargain. It cites one case where the plaintiff, a college student who did not receive a degree upon paying tuition, claimed the university was unjustly enriched. Zinter v. Univ. of Minn., 799 N.W.2d 243, 247 (Minn.Ct.App.2011). The court rejected the argument, noting that what was bargained for was tuition in exchange for classes, not tuition in exchange for a degree. Id. The case before me is distinguishable. As described with regard to Iowa law, the fact that some consideration was exchanged does not foreclose the End Payors' claim. Instead, the operative question is whether the bargain was just or fair. Therefore, I do not agree with Reckitt's argument.

Lastly, Reckitt argues that the End Payors are barred from bringing unjust enrichment claims when they have adequate legal remedies available, citing to Southtown Plumbing, Inc. v. Har–Ned Lumber Co., Inc., 493 N.W.2d 137 (Minn.Ct.App.1992). The court in Southtown held that because the plaintiffs chose not to pursue the legal remedy available to them through a mechanics lien, they were barred from then bringing an unjust enrichment claim. Id. at 140. Reckitt seeks to use this case to show that unjust enrichment is always barred when a legal remedy is available. However, several courts applying Minnesota law have
allowed simultaneous pleadings for a legal remedy and unjust enrichment. See Daigle v. Ford Motor Co., 713 F.Supp.2d 822, 828 (D.Minn.2010); LePage v. Blue Cross & Blue Shield of Minn., 2008 WL 2570815, at *8 (D.Minn. June 25, 2008); see also In re Levaquin Prods. Liab. Litig., 752 F.Supp.2d 1071, 1081 (D.Minn.2010) (finding that Southtown only stands for the proposition that a plaintiff who chooses not to pursue available legal remedies cannot recover for unjust enrichment). Therefore, I will allow the Minnesota unjust enrichment claim to proceed.

8. Mississippi

Reckitt next argues that because the End Payors received the benefit of the bargain, the Mississippi unjust enrichment claims should be dismissed. It cites to one case that discusses unjust enrichment as it applies to third parties. Omnibank of Mantee v. United S. Bank, 607 So.2d 76, 92–93 (Miss.1992). There, the court held that the mere fact that a party is enriched does not mean that he has been unjustly enriched, “in the absence of some misleading or wrongful act.” Id. The court did *709 not state that any consideration provided by the defendant for a benefit precludes an unjust enrichment claim. Furthermore, Reckitt is alleged to have engaged in wrongful, fraudulent acts. Therefore, I do not find Reckitt's argument convincing.

Reckitt also argues that under Mississippi law, plaintiffs can only recover for unjust enrichment when the payment was made by a mistake of fact. Reckitt points to the holdings of two Mississippi Supreme Court cases. Willis v. Rehab Solutions, PLLC, 82 So.3d 583, 588 (Miss.2012); Union Nat'l Life Ins. Co. v. Crosby, 870 So.2d 1175, 1180 (Miss.2004). These cases defined unjust enrichment as applying when one party mistakenly pays another party, reasoning that the receiver should not be enriched at the expense of the giver. Id. While the court did hold that “unjust enrichment applies when one party has mistakenly paid another party,” Willis, 82 So.3d at 588, Reckitt overstates the import of this holding. See In re Auto. Parts Antitrust Litig., 29 F.Supp.3d 982, 1021–23, 2014 WL 2993742, at *34–35 (E.D.Mich.2014) (rejecting an identical argument as construing Willis too broadly). In fact, after deciding Willis, the Supreme Court of Mississippi found a claim for unjust enrichment was viable where there were no allegations of mistake, but instead the defendant “knowingly solicited [the plaintiff] to enter into an unlawful contract” and found it would be unconscionable to allow the defendant to retain those ill-gotten gains. Ground Control, LLC v. Capsco Indus., Inc., 120 So.3d 365, 371 (Miss.2013). Therefore, I do not agree with Reckitt that Mississippi law requires plaintiffs to plead a mistake in order to state a claim for unjust enrichment.

9. Nevada

Reckitt's only argument in support of its motion to dismiss the Nevada unjust enrichment claim is that Reckitt provided consideration for any benefit conferred. For support, Reckitt cites Bowyer v. Davidson, 94 Nev. 718, 584 P.2d 686, 687 (1978). The Bowyer court found that because the defendant provided the consideration that the parties had bargained for in their express contract, he could not have been unjustly enriched. Id. As with Iowa, the facts in the present case are distinguishable. Therefore, the End Payors' unjust enrichment claim under Nevada law will survive the motion to dismiss.

10. New York

With regard to the New York unjust enrichment claims, Reckitt argues that the End Payors must demonstrate that a direct benefit was conferred upon the defendant. A review of New York case law indicates that in order to state a claim for unjust enrichment, the relationship between the plaintiff and the defendant, and thus the conferral of the benefit, must not be “too attenuated.” See Mandarin Trading Ltd. v. Wildenstein, 16 N.Y.3d 173, 182–83, 919 N.Y.S.2d 465, 944 N.E.2d 1104 (N.Y.2011) (noting that an unjust enrichment claim will fail if the connection between the parties is too attenuated).
Reckitt argues that this case is similar to \textit{Sperry v. Crompton Corp.}, 8 N.Y.3d 204, 831 N.Y.S.2d 760, 863 N.E.2d 1012 (N.Y.2007), where the New York Supreme Court affirmed the dismissal of an unjust enrichment claim because the conferral of the benefit was too attenuated. The plaintiffs in that case, purchasers of tires, brought antitrust and unjust enrichment claims against the producer of chemicals used in tire manufacturing. The plaintiffs alleged that the tire manufacturers, who had been overcharged for the chemicals, passed along the overcharges to retailers, and by extension, consumers. \textit{Id.} at 209, 831 N.Y.S.2d 760, 863 N.E.2d 1012. In the absence of a connection between the two parties, the court found that the unjust enrichment claim could not survive. \textit{Id.} at 215–16, 831 N.Y.S.2d 760, 863 N.E.2d 1012.

I agree with the court's analysis in \textit{Waldman v. New Chapter, Inc.}, 714 F.Supp.2d 398 (E.D.N.Y.2010), which distinguishes \textit{Sperry}. \textit{Waldman} held that although an indirect purchaser could not bring a claim against the producer of an ingredient used in a product, that did not foreclose an indirect purchaser from pursuing an unjust enrichment claim against the manufacturer of the product itself. \textit{Id.} at 403–04 (citing \textit{Cox v. Microsoft Corp.}, 8 A.D.3d 39, 40–41, 778 N.Y.S.2d 147 (N.Y.App.Ct. 1st Dep't.2004)). Accordingly, I do not find that the End Payors are too attenuated from Reckitt so as to require dismissal of the unjust enrichment claim under New York law.

11. Pennsylvania

Reckitt argues that the End Payors are barred from bringing an unjust enrichment claim in Pennsylvania because that state does not allow indirect purchasers to bring antitrust claims under \textit{Illinois Brick}. However, as opposed to simply barring claims brought by indirect purchasers, Pennsylvania does not have a state antitrust statute at all. See \textit{XF Enterprises, Inc. v. BASF Corp.}, 2000 WL 33155746, at *1 (Pa.Com.Pl.Ct. July 13, 2000). In any event, because I have previously found that the End Payors have stated a claim for a violation of Pennsylvania's consumer protection law, I do not find that allowing an unjust enrichment claim would provide an end-run around the Pennsylvania legislature's determination. Accordingly, the End Payors' unjust enrichment claim under Pennsylvania law will survive the motion to dismiss.

12. Virginia

Reckitt initially argues that the End Payors cannot bring an autonomous unjust enrichment claim. However, I have already found that the End Payors' claim under Virginia's consumer protection law may proceed. Therefore, I disagree with Reckitt's argument. For the same reason, I disagree with Reckitt's argument that to allow a claim for unjust enrichment in Virginia would act as an end-run around the state's prohibition of antitrust claims by indirect purchasers. Therefore, the End Payors' claim for unjust enrichment under Virginia law will survive the motion to dismiss.

13. Wisconsin

The only argument Reckitt provides in support of its motion to dismiss the unjust enrichment claim arising under Wisconsin law is that Reckitt has already provided consideration for any benefit conferred. It cites to a Wisconsin Court of Appeals case where a subcontractor was barred from bringing an unjust enrichment claim against an owner that had already paid a general contractor for the services provided. \textit{Tri–State Mech., Inc. v. Northland Coll.}, 273 Wis.2d 471, 681 N.W.2d 302, 305–06 (2004). Similar to my reasoning under Florida law, the present case is distinguishable. \textit{Tri–State} did not state that any consideration exchanged would nullify a claim for unjust enrichment. Therefore, the motion to dismiss the unjust enrichment claims under Wisconsin law is denied.
L. Should the End Payors’ Claim for Injunctive Relief Be Dismissed?

Reckitt argues that the End Payors' claim for injunctive relief under § 16 of the Clayton Act should be dismissed as it is procedurally and substantively deficient. First, Reckitt asserts that because the End Payors seek the exact relief in their § 16 claim as the Direct Purchasers, the claim should be dismissed as duplicative. *711 Citing to Howard Hess Dental Laboratories, Inc. v. Dentsply International, Inc., 602 F.3d 237 (3d Cir.2010), Reckitt asserts that where no meaningful difference exists between the cases of the parties seeking an injunction, the End Payors' request for injunctive relief should be dismissed. I disagree.

In Howard Hess, the court denied the plaintiff's motion for summary judgment because the plaintiff had not established antitrust injury where a nearly identical injunction to that sought by the plaintiff had already been granted to the Government. Id. at 249. At no point did the court state that dismissal was appropriate through a motion to dismiss where two groups of plaintiffs sought the same injunction. In fact, the Howard Hess court noted that it was unaware of any antitrust authority that would “require the Plaintiffs to have established a need for an injunction that was ‘non-duplicative.’ ” Id. While Howard Hess recognizes that the court may consider an injunction that is already in place in deciding whether antitrust injury exists, that is much different from requiring dismissal here. At the very least, the End Payors should be granted the opportunity to present evidence of their injury at the summary judgment stage.

Next, Reckitt argues that the End Payors lack standing to seek injunctive relief under § 16 of the Clayton Act because they fail to allege any ongoing or future injury that would be remedied by an injunction. Specifically, Reckitt asserts that the only injury that is identified is the past payment of allegedly inflated prices due to the supposed delayed market entry of generic Suboxone tablets. The End Payors respond that the harm they suffer is ongoing because Reckitt destroyed the market for Suboxone tablets and they are continuing to pay artificially inflated prices for an inferior film product. The End Payors urge that this injury may be remedied by an injunction through compulsory licensing of the film patents to generic competitors, or by way of mandated reduction in Reckitt's price of the branded film. I agree with the End Payors that, as they have stated a claim for antitrust injury through the product-hopping scheme, and the scheme has allegedly damaged the market for generic Suboxone tablets significantly, the injury is ongoing and injunctive relief may be sought. Reckitt's reliance on In re DDAVP, is misplaced, as the patent in that case had been invalidated, and thus there was no risk of continued supra-competitive prices. 903 F.Supp.2d at 210–11.

Finally, Reckitt argues that the End Payors' claim for injunctive relief should be dismissed because they have failed to state an underlying violation of the antitrust laws. As I have found that Plaintiffs have stated a claim for antitrust violations, the End Payors' claim for injunctive relief will survive.

M. Have Plaintiffs Sufficiently Pleaded Market Power and a Relevant Market?

As noted previously, in order to state a claim for monopolization, a plaintiff must plausibly allege “(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.” Grinnell, 384 U.S. at 570–71, 86 S.Ct. 1698. Reckitt argues that both of Plaintiffs' complaints should be dismissed for failure to sufficiently allege monopoly power. *712 “Monopoly power is the ability to control prices and exclude competition in a given market.” Broadcom Corp. v. Qualcomm Inc., 501 F.3d 297, 307 (3d Cir.2007) (citing Grinnell, 384 U.S. at 571, 86 S.Ct. 1698).
In re Suboxone (Buprenorphine Hydrochloride and..., 64 F.Supp.3d 665 (2014)
2014-2 Trade Cases P 78,983

Reckitt argues that in order to allege market power, a plaintiff must first define the relevant market. While relevant market inquiries are generally fact-intensive, and dismissal on this ground is disfavored in a motion to dismiss,

[w]here the plaintiff fails to define its proposed relevant market with reference to the rule of reasonable interchangeability and cross-elasticity of demand, or alleges a proposed relevant market that clearly does not encompass all interchangeable substitute products even when all factual inferences are granted in plaintiff's favor, the relevant market is legally insufficient and a motion to dismiss may be granted.

*Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 436 (3d Cir.1997).

Plaintiffs respond that they have met the monopoly power requirement in two distinct ways: (1) directly, through allegations that Reckitt's conduct caused anticompetitive effects; and (2) indirectly, through allegations of Reckitt's dominant share of the relevant market. Where direct evidence of monopoly power is provided, Plaintiffs assert that definition of a relevant market is not required. In support of this argument, Plaintiffs cite to *Broadcom*, where the Third Circuit stated in a footnote that “[b]ecause market share and barriers to entry are merely surrogates for determining the existence of monopoly power, direct proof of monopoly power does not require a definition of the relevant market.” 501 F.3d at 307 n. 3 (citation omitted). While this statement appears to provide support to Plaintiffs’ argument, cases decided subsequent to *Broadcom* have found that at least a rough identification of the relevant market is still required in direct evidence cases, although perhaps not with the same level of precision as required for claims proven through indirect evidence. *See, e.g.*, *In re Neurontin Antitrust Litig.*, 2013 WL 4042460, at *3 (D.N.J. Aug. 8, 2013) (collecting cases).

Plaintiffs urge that they have alleged direct evidence of supra-competitive prices and restricted output. I agree. Specifically, Plaintiffs have alleged that: (1) Reckitt successfully impaired and excluded generic competition; (2) Reckitt's conduct resulted in supra-competitive prices; (3) no firm was able to respond to Reckitt's high prices by increasing output of competing goods; and (4) consumer welfare suffered from the lack of competing goods in a high-price environment—all of which demonstrates Reckitt's ability to control prices and exclude competition.

Furthermore, I need not reach the question of whether identification of a relevant market is required to establish monopoly power in direct evidence cases because Plaintiffs have also adequately defined a relevant market so as to survive a motion to dismiss. A relevant market is defined by a products' reasonable interchangeability of use or cross-elasticity of demand between the product and its substitutes. *Queen City Pizza*, 124 F.3d at 436 (quoting *Brown Shoe Co. v. United States*, 370 U.S. 294, 325, 82 S.Ct. 1502, 8 L.Ed.2d 510 (1962)). Reasonable interchangeability considers *whether two products are roughly equivalent when put to a specific use, and considers factors such as price, use and qualities. Id. at 437. Cross-elasticity of demand considers whether “the rise in the price of a good within a relevant product market would tend to create a greater demand for other like goods in that market.” *Id.* at 437–38 (quoting *Tunis Bros. Co., Inc. v. Ford Motor Co.*, 952 F.2d 715, 722 (3d Cir.1991)).

Plaintiffs have alleged that Suboxone is a unique product and that the relevant product market is limited to Suboxone in all of its forms and dosage strengths and its AB-rated generic bioequivalents. They further allege that “Suboxone does not exhibit significant, positive cross-elasticity of demand with respect to price, with any opioid dependence treatment or other product other than AB-rated generic versions of Suboxone.” The complaint further explains that Suboxone is unique because it is the only opioid replacement maintenance therapy that can be prescribed in an office setting and taken by patients at home because it is categorized as a Schedule III drug and co-formulated with an opioid antagonist to deter abuse. (EP Compl. ¶¶ 153–59.) Methadone, for example, is a Schedule II drug and must be administered in a clinic. Further, Subutex, another opioid treatment
drug marketed by Reckitt, is not alleged to be reasonably interchangeable because it lacks the opioid agonist, and therefore is not recommended for maintenance therapy. I must accept these statements as true.

Dismissal at the motion to dismiss stage for failure to define a relevant market is disfavored. Plaintiffs have referenced the rules of reasonable interchangeability and cross-elasticity of demand and have plausibly explained why other similar products do not fall within the relevant market. These allegations are sufficient to state a claim and survive a motion to dismiss, to the extent that a relevant market analysis is even necessary where direct evidence of monopoly power is provided. 30

N. Should the Four Additional Reckitt Defendants Be Dismissed?

In addition to Reckitt Benckiser Pharmaceuticals, Inc., which actually sells Suboxone, Plaintiffs have named four additional corporate entities as Defendants: Reckitt Benckiser, Inc., Reckitt Benckiser LLC, Reckitt Benckiser Healthcare (UK) Ltd., and Reckitt Benckiser Group plc. Reckitt argues that these four additional Defendants should be dismissed for failure to identify what role, if any, these entities played in the alleged anticompetitive scheme. 31 In their response, the End Payors only argue that Reckitt Benckiser Group plc and Reckitt Benckiser Healthcare (UK) Ltd. should not be dismissed. At no point do the End Payors address Reckitt’s argument that no allegations have been raised against Reckitt Benckiser Inc. or Reckitt Benckiser LLC. Accordingly, the motion will be granted as unopposed as to these two Defendants.

As to Reckitt Benckiser Group plc, the End Payors point to allegations in their complaint that its board of directors “were advised of the generic-impairing purpose of the product hop from Suboxone tablets to film, and of the related anticompetitive tactics, and specifically approved the scheme and its purpose. The board of directors approved and directed this anticompetitive scheme over the course of many years, including the period encompassing the mid–2000s.” (EP Compl. ¶ 83.) While this is sufficient to establish Reckitt Benckiser Group plc's role in the alleged scheme, the only allegation made by the End Payors for Reckitt Benckiser Healthcare (UK) Ltd. is that they conducted a similar product-hopping scheme in the United Kingdom involving the product Gaviscon. However, these allegations do not tie Reckitt Benckiser Healthcare (UK) Ltd. to the actions taken with respect to Suboxone. Therefore, I agree that the claims against Reckitt Benckiser Healthcare (UK) Ltd. should also be dismissed.

O. Should the Claims Asserted by Certain End Payors Be Dismissed for Failure to Serve the Complaint?

Finally, I address Reckitt’s argument that the claims brought by certain End Payors should be dismissed for failure to effectuate service. It appears that four End Payors have failed to serve Reckitt Benckiser Healthcare (UK) Ltd. and Reckitt Benckiser Group plc., and that one End Payor has failed to serve any Defendant. 32 The End Payors do not dispute that these Plaintiffs failed to effectuate service. Instead, they essentially argue that this failure to serve should be forgiven because dismissal of certain actions as to only the un-served defendants would be a waste of judicial resources. Further, as to the foreign entities Reckitt Benckiser Healthcare (UK) Ltd. and Reckitt Benckiser Group plc, the End Payors argue that the 120–day time period for service prescribed by Rule 4(m) does not apply.

*715 While it is true that the 120–day limit does not apply to service in a foreign country, the time period for service is not unlimited. The Knit With v. Knitting Fever, Inc., 2010 WL 2788203, at *12 (E.D.Pa. July 13, 2010) (quoting United States ex rel. Thomas v. Siemens AG, 708 F.Supp.2d 505, 522–23, 2010 WL 1688582, at *14 (E.D.Pa.2010)). Courts often apply a general due diligence standard, which “considers the reasonableness of the plaintiff’s effort and the prejudice to the defendant resulting from any delay.” Id. Courts maintain significant discretion in extending the time period for service of the complaint, even in the absence of a showing of good cause. Id. (citing Petrucelli v. Bohringer & Ratzinger, GmbH, 46 F.3d 1298, 1305 (3d Cir.1995)). Courts have granted extensions of time to serve where a defendant is already before the court in a consolidated action and
presumably the only result of a dismissal would be that the [ ] Plaintiffs would refile their complaint, resulting in a waste of judicial resources.” AIG Managed Market Neutral Fund v. Askin Capital Mgmt., L.P., 197 F.R.D. 104, 109 (S.D.N.Y.2000) (citing In re Reliance Sec. Litig., 91 F.Supp.2d 706, 719 (D.Del.2000)).

While I agree that dismissing some of the End Payors' claims for failure to serve could potentially constitute a waste of judicial resources, as it would likely result in a refiling of the complaint, the End Payors have failed to even attempt to explain why service has not been effectuated. There has been no attempt to establish good cause for failure to serve. However, there is also no prejudice to Defendants, as Reckitt has received ample notice of this lawsuit from the other Plaintiffs and has been actively defending the suit. Therefore, I find that the appropriate solution is to exercise discretion and allow an additional period of time for these End Payors to effectuate service.

IV. CONCLUSION

For the reasons recited above, the following claims will be dismissed: Count III of the Direct Purchasers' complaint; a variety of state law claims brought in the End Payors complaint for lack of standing and failure to state a claim; all claims against Reckitt Benckiser, Inc., Reckitt Benckiser LLC and Reckitt Benckiser Healthcare (UK) Ltd.; and the Direct Purchasers' claims against Reckitt Benckiser Group plc. United Food & Commercial Workers Health & Welfare Fund, A.F.L.-A.G.C. Building Trades Welfare Plan, Michigan Regional Council of Carpenters Employee Benefits Fund, I.B.E.W. 292 Health Care Plan and Teamsters Health Services & Insurance Plan Local 404 are directed to effectuate service on all remaining Defendants within thirty days.

An appropriate Order follows.

ORDER

AND NOW, this 3rd day of December, 2014, upon consideration of “Defendants' Motion to Dismiss the Direct Purchaser Plaintiffs' Consolidated Amended Class Action Complaint” and “Defendants' Motion to Dismiss the End Payor Plaintiffs' Consolidated Amended Class Action Complaint,” the responses and replies thereto, and for the reasons set forth in the accompanying memorandum opinion, it is hereby ORDERED that the motions are GRANTED in part and DENIED in part, such that:

— The motion to dismiss the Direct Purchasers' complaint (Dkt. No. 13–md–2445, Doc. No. 56; Dkt. No. 13–cv–1122, Doc. No. 24; Dkt. No. 13–cv–1164, Doc. No. 27; Dkt. No. 13–cv–3230, Doc. No. 3) is granted as to Count III. The motion is further granted in that the Direct Purchasers' claims against Reckitt Benckiser, Inc., Reckitt Benckiser LLC, Reckitt Benckiser Healthcare (UK) Ltd. and Reckitt Benckiser Group plc are dismissed. The motion is denied in all other respects.


  i. The antitrust claims under the laws of Arizona, District of Columbia, Illinois, Kansas, Maine, Massachusetts, Missouri, Nebraska, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Puerto Rico, Rhode Island, South Dakota, Tennessee, Utah, Vermont and West Virginia;
In re Suboxone (Buprenorphine Hydrochloride and..., 64 F.Supp.3d 665 (2014)
2014-2 Trade Cases P 78,983

ii. The consumer protection claims under the laws of Arkansas, Arizona, District of Columbia, Idaho, Illinois, Kansas, Maine, Massachusetts, Missouri, Nebraska, New Hampshire, New Mexico, North Carolina, North Dakota, Oregon, Rhode Island, South Dakota, Tennessee, Utah, Vermont and West Virginia; and


The motion is further granted in that the End Payors' claims against Reckitt Benckiser, Inc., Reckitt Benckiser LLC and Reckitt Benckiser Healthcare (UK) Ltd. are dismissed. The motion is denied in all other respects.

**IT IS FURTHER ORDERED** that the End Payors' United Food & Commercial Workers Health & Welfare Fund, A.F. of L.-A.G.C. Building Trades Welfare Plan, Michigan Regional Council of Carpenters Employee Benefits Fund, I.B.E.W. 292 Health Care Plan and Teamsters Health Services & Insurance Plan Local 404 shall effectuate service on all Defendants remaining in this litigation that they have not yet served (or that has not yet waived service) within thirty (30) days of the date of this Order.

All Citations

64 F.Supp.3d 665, 2014-2 Trade Cases P 78,983

Footnotes

1 The Direct Purchasers' and the End Payors' complaints contain almost identical allegations. To avoid confusion, the facts recited herein will be derived from the Direct Purchasers' consolidated amended complaint. Where the allegations in the complaints differ, I will distinguish accordingly. In reviewing Defendants' motion to dismiss, I assume that all facts found in the consolidated amended complaints are true, and to the extent any facts from outside the amended complaints are recited, they are referenced for informational purposes only. See *Ethypharm S.A. France v. Abbott Labs.*, 707 F.3d 223, 225 n. 1 (3d Cir.2013).

2 The complaint indicates that orphan drug exclusivity may be granted: “(a) on the basis that a product is intended to treat a disease or condition that has a U.S. prevalence of less than 200,000 persons; or (b) where the sponsor can show that there is no reasonable expectation that the costs of developing and making available the drug will be recovered from U.S. sales, despite the fact that the product treats a disease or condition that has a U.S. prevalence of 200,000 or more individuals.” The FDA found that the latter of these considerations applied to Suboxone. (Id. at ¶ 79.)

3 The End Payors allege that this number was closer to 85% by the time generic Suboxone tablets entered the market in February 2013. (EP Compl. ¶ 4.)

4 Under the FDA Amendments Act of 2007, the FDA has the authority to require drug manufacturers to conduct a Risk Evaluation and Mitigation Strategy (“REMS”). A REMS is a process by which a drug's manufacturer demonstrates to the FDA that the drug's benefits outweigh its risks. “A REMS can include a medication guide, a package insert, and
potential restrictions on the distribution of the drug.” If the FDA requires a generic to conduct a REMS, an ANDA will not be approved until the REMS process is completed. (Id. at ¶¶ 57–58; Oral Arg. Tr. pp. 12–15.)


6 All of the arguments raised in Reckitt's motion to dismiss the Direct Purchasers' complaint have also been incorporated as arguments requiring dismissal of the End Payors' state law antitrust claims. As the arguments raised and facts alleged apply equally to both groups of Plaintiffs, I will refer generally to Plaintiffs in this section where appropriate.

7 “ ‘Detailing’ in the retail pharmaceutical business refers to the practice of sending company representatives to doctors' offices to distribute samples and promotional materials and information.” Walgreen, 534 F.Supp.2d at 149 n. 4.

8 At oral argument, Reckitt also claimed that Mylan Pharmaceuticals, Inc. v. Warner Chilcott Public Ltd. Co., 2013 WL 5692880 (E.D.Pa. June 12, 2013), supported its position. There, the district court expressed skepticism as to whether the defendants' alleged product-hopping scheme constituted exclusionary conduct. Id. at *2. However, the court in Mylan did not dismiss the plaintiffs' claims, instead finding that the development of a record was necessary. See id.

9 I note that Plaintiffs also alleged that Reckitt engaged in anticompetitive behavior by reducing the price of its film and raising the price of the tablets, despite the fact that the film was more expensive to manufacture. Reckitt correctly notes that only predatory pricing—that is, price decreases by a monopolist below any reasonable measure of cost—can be anticompetitive. Atl. Richfield Co. v. USA Petroleum Co., 495 U.S. 328, 339, 110 S.Ct. 1884, 109 L.Ed.2d 333 (1990) (“in the context of pricing practices, only predatory pricing has the requisite anticompetitive effect”); see also Schor v. Abbott Labs., 457 F.3d 608, 610–11 (7th Cir.2006). While there are no allegations of predatory pricing here, I do not believe that this completely forecloses Plaintiffs' antitrust claims. See ZF Meritor, LLC v. Eaton Corp., 696 F.3d 254, 277 (3d Cir.2012) (finding that, where “price itself was not the clearly predominant mechanism of exclusion,” failure to establish predatory pricing did not preclude the plaintiffs' claim).

10 Although Continental Ore involved a § 1 conspiracy claim, the Third Circuit has applied its reasoning to § 2 cases as well. LePage's, 324 F.3d at 162 (“the courts must look to the monopolist's conduct taken as a whole rather than considering each aspect in isolation”).

11 Reckitt argues that even if 21 U.S.C. § 355–1(f)(8) created a duty to deal, it does not even apply under these circumstances. 21 U.S.C. § 355–1(f)(8) states:

No holder of an approved covered application shall use any element to assure safe use required by the Secretary under this subsection to block or delay approval of an application under section 355(b)(2) or (j) of this title or to prevent application of such element under subsection (i)(1)(B) to a drug that is the subject of an abbreviated new drug application.

Reckitt asserts that the complaints include no facts to indicate that the elements to assure safe use in Reckitt's REMS were used, or even could be used, to block or delay any ANDA. Instead, they frame Plaintiffs' argument as disliking the terms by which Reckitt sought to negotiate. Plaintiffs respond by pointing to sections of its complaint alleging that § 355–1(f)(8) applies, and a letter written to the FDA, which recounts that the FDA previously warned Reckitt that attempts to block or delay would violate § 355–1(f)(8). Plaintiffs argue that the FDA's interpretation of the FDCA is entitled to deference. However, there is no document attached to the complaint that actually includes a statement from the FDA on this issue. Therefore, I agree with Defendants that it is dubious whether Plaintiffs have sufficiently pleaded that the statute even applied. Nevertheless, I need not decide this issue because, even assuming the statute applies, Count III will still be dismissed.
In re Suboxone (Buprenorphine Hydrochloride and..., 64 F.Supp.3d 665 (2014)
2014-2 Trade Cases P 78,983

12 Plaintiffs' reliance on Safeway Inc. v. Abbott Laboratories, 761 F.Supp.2d 874 (N.D.Cal.2011) is misplaced. In Safeway, the court found that there had been a prior course of dealing between the manufacturer and its competitors, that there was evidence that it was only willing to negotiate on unreasonable terms, and there was evidence that the manufacturer refused to provide its competitors the same terms that it provided to its retail customers. Id. at 892–95. Plaintiffs here have only alleged that Reckitt refused to negotiate reasonably. There is no history of collaboration prior to the SSRS process. Therefore, Safeway is distinguishable.

13 While the FDA did state that it “welcomes and encourages sponsors to utilize unit-dose packaging,” it also stated “we do not believe the data at this time support refusing to approve applications that lack such packaging.” (DP Compl., Ex. G., p. 14.) Reckitt tries to argue that based on this “encouragement” some of its relief was granted. I disagree with that assertion.

14 The End Payors' customers are also alleged to have made purchases in Ohio. However, this is irrelevant for the purposes of my analysis because no claims have been brought under Ohio law.

15 While Reckitt asserts that the End Payors' claims under Virginia law should be dismissed for lack of standing, it later argues that under conflict of laws principles the End Payors “can only assert claims under the laws of Virginia or their residence” and advocates applying Virginia law. (Reckitt Mot. to Dismiss EP Compl., pp. 8, 10.) I find that the End Payors' allegations that Reckitt engaged in wrongful, anticompetitive conduct in Virginia is sufficient to establish standing in that state.

16 Wellbutrin reflected on two Supreme Court cases, Amchem Products, Inc. v. Windsor, 521 U.S. 591, 117 S.Ct. 2231, 138 L.Ed.2d 689 (1997) and Ortiz v. Fibreboard Corp., 527 U.S. 815, 119 S.Ct. 2295, 144 L.Ed.2d 715 (1999), in which the Supreme Court considered the propriety of class certification immediately prior to assessing Article III standing. However, Wellbutrin found these cases to be distinguishable. In Amchem and Ortiz the Supreme Court had been asked to determine the standing of potential class members as opposed to the standing of the named plaintiffs. Further, in Amchem and Ortiz, a finding that class certification was improper would have negated any need to determine standing, making class certification “logically antecedent” to the Article III issue. Wellbutrin, 260 F.R.D. at 153–54. Indeed, “[t]o rule on the issue of standing at that point in the case would have required the Court to make a determination as to the standing of persons who were not actually parties to the case, but who were only proposed parties to the case.” Id. at 153. Therefore, for these additional reasons, I agree with the analysis in Wellbutrin finding that Amchem and Ortiz are distinguishable, and that class certification is not logically antecedent to standing in this case.

17 The End Payors also cite to this Court's decision in King Drug Co. of Florence, Inc. v. Cephalon, Inc., 702 F.Supp.2d 514 (E.D.Pa.2010), arguing that I previously rejected the reasoning of Wellbutrin. However, in Cephalon, I did not need to reach the question at issue here—whether the named end payor plaintiffs had standing to assert state law claims on behalf of absent class members. The named end payor plaintiffs in Cephalon had reimbursed customers, and thus had standing, in every jurisdiction in which they had brought a claim. Id. at 538.

18 Accordingly, the antitrust claims brought under the laws of the following states and territories are dismissed: Arizona, District of Columbia, Kansas, Maine, Nebraska, New Hampshire, New Mexico, North Carolina, North Dakota, Oregon, Puerto Rico, Rhode Island, South Dakota, Tennessee, Utah, Vermont and West Virginia. The End Payors have also voluntarily withdrawn their antitrust claims under Illinois, Missouri and New York law. (See EP Resp., p. 34 n. 29.)

The consumer protection claims under the laws of the following states and territories are also dismissed: Arkansas, Arizona, District of Columbia, Idaho, Kansas, Maine, Nebraska, New Hampshire, New Mexico, North Carolina, North Dakota, Oregon, Rhode Island, South Dakota, Tennessee, Utah, Vermont and West Virginia.
Finally, the unjust enrichment claims brought under the laws of the following states and territories are dismissed: Arkansas, Arizona, Colorado, Connecticut, Delaware, District of Columbia, Georgia, Hawaii, Idaho, Kansas, Louisiana, Maryland, Maine, Montana, Nebraska, New Hampshire, New Mexico, North Carolina, North Dakota, Oklahoma, Oregon, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Washington, West Virginia and Wyoming.

The End Payors have identified the following states as either “home states” or “purchase states”: Alabama, Alaska, California, Florida, Illinois, Iowa, Kentucky, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nevada, New Jersey, New York, Pennsylvania and Wisconsin. (EP Compl. ¶¶ 102–15.) Claims under Virginia law may also proceed as Virginia is Reckitt's home state—the state where much of Reckitt's anticompetitive conduct is alleged to have been carried out.

Reckitt argues that the End Payors' claims for monopolization under Florida and Massachusetts law must be dismissed because these states do not permit antitrust claims by indirect purchasers. In the same vein, Reckitt argues that California antitrust law does not recognize a claim for monopolization. A review of the statutes cited in the End Payors' complaint demonstrates that the monopolization and attempted monopolization claims brought in Counts I and II have been brought under the Consumer Protection Laws of Florida, Massachusetts and California. Therefore, I will address whether the End Payors have stated a claim under these statutes in the Consumer Protection Law section infra.

Reckitt attaches exhibits to its motion that identify cases and statutes from each of the relevant state jurisdictions in support of all of Reckitt's state-specific arguments. The End Payors argue that this appendix is improper for exceeding previously ordered page limits. This argument was the subject of a motion to strike, wherein the End Payors argued that Reckitt had nearly doubled its page limit by attaching exhibits filled with authority and legal argument. (Doc. No. 61.) Reckitt responded that the tables were for the convenience of the Court and are routinely utilized in this type of litigation where numerous state statutes are at issue. Reckitt points out that it had previously consented to an increase in the page limit of the End Payors' response in order to allow them to more fully address these state-by-state arguments. (Doc. No. 62.) The motion to strike was denied, although I noted that “should the Court conclude that the numerous exhibits filed by Defendant along with its Rule 12 motions are improper, those exhibits will not be considered.” (Doc. No. 66.)

While these tables of authority do contain legal argument and thus exceed the previously-ordered page limit, the additional pages were likely necessary to address claims raised by the End Payors from nearly every state in the country. As the End Payors were provided an additional twenty pages to respond to Reckitt's motion, which allowed them to identify authority from all of the relevant jurisdictions, there has been no prejudice to the End Payors. Therefore, I will consider Reckitt's exhibits.

While California's antitrust law does not recognize unilateral conduct, as is alleged here, Reckitt has not demonstrated that any such restriction exists as to California's consumer protection law. Therefore, I will allow California's claims for monopolization and attempted monopolization to proceed under California's consumer protection law.

Although Florida's antitrust law does not permit antitrust claims by indirect purchasers and has adopted Illinois Brick, Florida courts have held that the Florida Deceptive and Unfair Trade Practices Act does not have this same restriction. Mack v. Bristol–Myers Squibb Co., 673 So.2d 100, 110 (Fla.App.1996). Therefore, I decline to dismiss the claims for monopolization and attempted monopolization brought under the MDUTPA on Illinois Brick grounds.

As previously noted, Massachusetts' consumer protection law was cited as providing a cause of action for the End Payors' monopolization and attempted monopolization claims. These claims will also be dismissed as barred by Illinois Brick.
The End Payors cite to *Cephalon*, 702 F.Supp.2d at 539, for the proposition that this Court has previously rejected the end-run argument with regard to unjust enrichment claims. However, *Illinois Brick* and various states' adoption of this limitation were not discussed in *Cephalon*. See id. at 539–40.


*Sickles v. Cabot Corp.*, 379 N.J.Super. 100, 877 A.2d 267, 275 (2005) (“an indirect purchaser is precluded from suing for antitrust violations under the [New Jersey Antitrust statute]”).

I note that some Florida precedent has not been entirely clear that the conferral of a direct benefit is required. See *Merkle v. Health Options, Inc.*, 940 So.2d 1190, 1199 (Fla. 4th D.C.A.2006); *Hillman Constr. Corp. v. Wainer*, 636 So.2d 576, 577–78 (Fla. 4th D.C.A.1994). Although these cases allowed claims to proceed where there did not appear to be a direct benefit conferred, at no point did the court make a clear statement that a direct benefit was not required. Furthermore, the appellate courts' reasoning in reversing the trial courts' dismissals seemed to focus on the trial courts improperly making factual determinations that a benefit was not conferred, as opposed to adopting the factual allegations made in the complaint. I do not find that these ambiguous rulings are sufficient to overcome the majority of Florida precedent that has clearly and affirmatively held that a direct benefit is required for an unjust enrichment claim under Florida law.

Reckitt also incorporates these arguments into its motion to dismiss the Direct Purchasers' complaint. The Direct Purchasers have adopted the arguments made by the End Payors; however, they acknowledge that they inadvertently failed to include certain allegations regarding market power that had previously been pleaded in one Direct Purchaser's original complaint. (See Dkt. No. 13–1164, Doc. No. 1, ¶¶ 98–104.) They state that they intend to file a consolidated second amended complaint to re-insert those averments upon disposition of this motion.

The allegations present in the Direct Purchasers' consolidated amended complaint also establish direct evidence of monopoly power, and to the extent required to establish a relevant market, identify it in a similar manner as the End Payors—that is, that the relevant market includes Suboxone in all of its forms and dosage strengths, including generics. They also briefly include an explanation as to why Suboxone does not have cross-elasticity of demand with other opioid dependence treatments. For the reasons explained in this section, I am not inclined to grant a motion to dismiss on monopoly power grounds, particularly where the Third Circuit has articulated that dismissal at this stage is disfavored and where it is unclear that a relevant market definition is required at all where direct evidence of monopoly power has been provided. I accept the Direct Purchasers' allegations regarding the relevant market, but acknowledge that it is a close call and urge them to file the second amended complaint to include more substantial facts on this issue.

Reckitt adopts the arguments in this section as to the Direct Purchasers as well. The Direct Purchasers do not respond, nor do they adopt the End Payors' response on this issue. The only allegation in the Direct Purchasers' complaint regarding these additional Reckitt entities is that they “manufacture[,] market[,] numerous products, including pharmaceuticals subject to FDA approval, and w[ere] in whole or in part responsible for some or all of the conduct alleged herein and attributed to Reckitt.” (DP Compl. ¶¶ 19–23.) These bare bones allegations are not sufficient to establish liability against these additional Reckitt entities. See *In re Mushroom Direct Purchaser Antitrust Litig.*, 514 F.Supp.2d 683, 699 (E.D.Pa.2007) (“In order to sustain their claims of monopolization and attempted monopolization, Plaintiffs must ... prove the required elements against each individual defendant.”) (quoting *Carpet Group Int'l v. Oriental Rug Imps. Assoc.*, 256 F.Supp.2d 249, 284 (D.N.J.2003)); see also *In re Digital Music Antitrust Litig.*, 812 F.Supp.2d 390, 417 (S.D.N.Y.2011). Accordingly, as to the Direct Purchasers, these four additional Reckitt entities will be dismissed.

While Reckitt states in their brief that three End Payors failed to serve Reckitt Benckiser Healthcare (UK) Ltd. and Reckitt Benckiser Group plc and two failed to serve any Defendant (see Reckitt's MTD EP Compl. p. 40, n. 25), a review of the dockets in this matter reveals the following: The End Payors that have failed to serve Reckitt Benckiser

The antitrust claims under the laws of Arizona, District of Columbia, Illinois, Kansas, Maine, Massachusetts, Missouri, Nebraska, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Puerto Rico, Rhode Island, South Dakota, Tennessee, Utah, Vermont and West Virginia will be dismissed.

The consumer protection claims under the laws of Arkansas, Arizona, District of Columbia, Idaho, Illinois, Kansas, Maine, Massachusetts, Missouri, Nebraska, New Hampshire, New Mexico, North Carolina, North Dakota, Oregon, Rhode Island, South Dakota, Tennessee, Utah, Vermont and West Virginia will be dismissed.

The unjust enrichment claims brought under the laws of Arkansas, Arizona, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Kansas, Kentucky, Louisiana, Maryland, Maine, Massachusetts, Missouri, Montana, Nebraska, New Jersey, New Hampshire, New Mexico, North Carolina, North Dakota, Oklahoma, Oregon, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Washington, West Virginia and Wyoming will be dismissed.
(a) **Necessity of effective approval of application**

No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug.

(b) **Filing application; contents**

(1)(A) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such persons shall submit to the Secretary as part of the application--

(i) full reports of investigations which have been made to show whether such drug is safe for use and whether such drug is effective in use;

(ii) a full list of the articles used as components of such drug;

(iii) a full statement of the composition of such drug;

(iv) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug;

(v) such samples of such drug and of the articles used as components thereof as the Secretary may require;

(vi) specimens of the labeling proposed to be used for such drug;

(vii) any assessments required under section 355c of this title; and
(viii) the patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug, and that--

(I) claims the drug for which the applicant submitted the application and is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent; or

(II) claims a method of using such drug for which approval is sought or has been granted in the application.

(B) If an application is filed under this subsection for a drug, and a patent of the type described in subparagraph (A)(viii) is issued after the filing date but before approval of the application, the applicant shall amend the application to include the patent number and expiration date.

(2) An application submitted under paragraph (1) for a drug for which the investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted shall also include--

(A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c)--

(i) that such patent information has not been filed,

(ii) that such patent has expired,

(iii) of the date on which such patent will expire, or

(iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(B) if with respect to the drug for which investigations described in paragraph (1)(A) were conducted information was filed under paragraph (1) or subsection (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

(3) Notice of opinion that patent is invalid or will not be infringed

(A) Agreement to give notice

An applicant that makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant will give notice as required by this paragraph.
(B) Timing of notice

An applicant that makes a certification described in paragraph (2)(A)(iv) shall give notice as required under this paragraph--

(i) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(ii) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(C) Recipients of notice

An applicant required under this paragraph to give notice shall give notice to--

(i) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(ii) the holder of the approved application under this subsection for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(D) Contents of notice

A notice required under this paragraph shall--

(i) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(ii) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(4)(A) An applicant may not amend or supplement an application referred to in paragraph (2) to seek approval of a drug that is a different drug than the drug identified in the application as submitted to the Secretary.

(B) With respect to the drug for which such an application is submitted, nothing in this subsection or subsection (c)(3) prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

(5)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1) or under section 262 of Title 42, which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict
of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection or section 262 of Title 42 if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size--

(i)(I) of clinical trials intended to form the primary basis of an effectiveness claim; or

(II) in the case where human efficacy studies are not ethical or feasible, of animal and any associated clinical trials which, in combination, are intended to form the primary basis of an effectiveness claim; or

(ii) with respect to an application for approval of a biological product under section 262(k) of Title 42, of any necessary clinical study or studies.

The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of the clinical trials. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant upon request.

(C) Any agreement regarding the parameters of the design and size of clinical trials of a new drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except--

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance division personnel unless such field or compliance division personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.
(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection or section 262 of Title 42 (including all scientific and medical matters, chemistry, manufacturing, and controls).

(6) An application submitted under this subsection shall be accompanied by the certification required under section 282(j)(5) (B) of Title 42. Such certification shall not be considered an element of such application.

(c) Period for approval of application; period for, notice, and expedition of hearing; period for issuance of order

(1) Within one hundred and eighty days after the filing of an application under subsection (b), or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either--

(A) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) applies, or

(B) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) on the question whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(2) Not later than 30 days after the date of approval of an application submitted under subsection (b), the holder of the approved application shall file with the Secretary the patent number and the expiration date of any patent described in subsection (b)(1)(A)(viii), except that a patent that is identified as claiming a method of using such drug shall be filed only if the patent claims a method of use approved in the application. If a patent described in subsection (b)(1)(A)(viii) is issued after the date of approval of an application submitted under subsection (b), the holder of the approved application shall, not later than 30 days after the date of issuance of the patent, file the patent number and the expiration date of the patent, except that a patent that claims a method of using such drug shall be filed only if approval for such use has been granted in the application. If the patent information described in subsection (b) could not be filed with the submission of an application under subsection (b) because the application was filed before the patent information was required under subsection (b) or a patent was issued after the application was approved under such subsection, the holder of an approved application shall file with the Secretary the patent number and the expiration date of any patent described in subsection (b)(1)(A)(viii). If the holder of an approved application could not file patent information under subsection (b) because it was not required at the time the application was approved, the holder shall file such information under this subsection not later than thirty days after September 24, 1984, and if the holder of an approved application could not file patent information under subsection (b) because no patent of the type for which information is required to be submitted in subsection (b)(1)(A)(viii) had been issued when an application was filed or approved, the holder shall file such information under this subsection not later than thirty days after the date the patent involved is issued. Upon the submission of patent information under this subsection, the Secretary shall publish it. Patent information that is not the type of patent information required by subsection (b)(1)(A)(viii) shall not be submitted under this paragraph.

(3) The approval of an application filed under subsection (b) which contains a certification required by paragraph (2) of such subsection shall be made effective on the last applicable date determined by applying the following to each certification made under subsection (b)(2)(A):
(A) If the applicant only made a certification described in clause (i) or (ii) of subsection (b)(2)(A) or in both such clauses, the approval may be made effective immediately.

(B) If the applicant made a certification described in clause (iii) of subsection (b)(2)(A), the approval may be made effective on the date certified under clause (iii).

(C) If the applicant made a certification described in clause (iv) of subsection (b)(2)(A), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in subsection (b)(3) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under paragraph (2) or subsection (b)(1) before the date on which the application (excluding an amendment or supplement to the application) was submitted. If such an action is brought before the expiration of such days, the approval may be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under subsection (b)(3) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that--

(i) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on--

(I) the date on which the court enters judgment reflecting the decision; or

(II) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(ii) if before the expiration of such period the district court decides that the patent has been infringed--

(I) if the judgment of the district court is appealed, the approval shall be made effective on--

(aa) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(bb) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(II) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of Title 35;

(iii) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in clause (i); or
§ 355. New drugs, 21 USCA § 355

(iv) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in clause (ii).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

(D) Civil action to obtain patent certainty

(i) Declaratory judgment absent infringement action

(I) In general

No action may be brought under section 2201 of Title 28 by an applicant referred to in subsection (b)(2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (C) unless--

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) Filing of civil action

If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of Title 28, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) Offer of confidential access to application

For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant referred to in subsection (b)(2) for the purpose of determining whether an action referred to in subparagraph (C) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and
disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under subsection (b)(2)(A)(iv) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) Counterclaim to infringement action

(I) In general

If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or this subsection on the ground that the patent does not claim either--

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) No independent cause of action

Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) No damages

An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).


(ii) If an application submitted under subsection (b) for a drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under subsection (b), is approved after September 24, 1984, no application which refers to the drug for which the subsection (b) application was submitted and for which the investigations described in subsection (b)(1)(A)(i) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted may be submitted under subsection (b) before the expiration of five years from the date of the approval of the application under subsection (b), except that such an application may be submitted under subsection (b) after the expiration of four years from the date of
the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in clause (iv) of subsection (b)(2)(A). The approval of such an application shall be made effective in accordance with this paragraph except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (C) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) for a drug, which includes an active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) that has been approved in another application approved under subsection (b), is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under subsection (b) for the conditions of approval of such drug in the approved subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) if the investigations described in subsection (b) (1)(A)(i) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

(iv) If a supplement to an application approved under subsection (b) is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under subsection (b) for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) if the investigations described in subsection (b) (1)(A)(i) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

(v) If an application (or supplement to an application) submitted under subsection (b) for a drug, which includes an active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) that has been approved in another application under subsection (b), was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection and for which the investigations described in subsection (b)(1)(A)(i) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted and which refers to the drug for which the subsection (b) application was submitted effective before the expiration of two years from September 24, 1984.

(4) A drug manufactured in a pilot or other small facility may be used to demonstrate the safety and effectiveness of the drug and to obtain approval for the drug prior to manufacture of the drug in a larger facility, unless the Secretary makes a determination that a full scale production facility is necessary to ensure the safety or effectiveness of the drug.

(5)(A) The Secretary may rely upon qualified data summaries to support the approval of a supplemental application, with respect to a qualified indication for a drug, submitted under subsection (b), if such supplemental application complies with subparagraph (B).

(B) A supplemental application is eligible for review as described in subparagraph (A) only if--
(i) there is existing data available and acceptable to the Secretary demonstrating the safety of the drug; and

(ii) all data used to develop the qualified data summaries are submitted to the Secretary as part of the supplemental application.

(C) The Secretary shall post on the Internet website of the Food and Drug Administration and update annually--

(i) the number of applications reviewed solely under subparagraph (A) or section 262(a)(2)(E) of Title 42;

(ii) the average time for completion of review under subparagraph (A) or section 262(a)(2)(E) of Title 42;

(iii) the average time for review of supplemental applications where the Secretary did not use review flexibility under subparagraph (A) or section 262(a)(2)(E) of Title 42; and

(iv) the number of applications reviewed under subparagraph (A) or section 262(a)(2)(E) of Title 42 for which the Secretary made use of full data sets in addition to the qualified data summary.

(D) In this paragraph--

(i) the term “qualified indication” means an indication for a drug that the Secretary determines to be appropriate for summary level review under this paragraph; and

(ii) the term “qualified data summary” means a summary of clinical data that demonstrates the safety and effectiveness of a drug with respect to a qualified indication.

(d) Grounds for refusing application; approval of application; “substantial evidence” defined

If the Secretary finds, after due notice to the applicant in accordance with subsection (c) and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) the application failed to contain the patent information prescribed by subsection (b); or (7) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As
used in this subsection and subsection (e), the term “substantial evidence” means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof. If the Secretary determines, based on relevant science, that data from one adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation) are sufficient to establish effectiveness, the Secretary may consider such data and evidence to constitute substantial evidence for purposes of the preceding sentence. The Secretary shall implement a structured risk-benefit assessment framework in the new drug approval process to facilitate the balanced consideration of benefits and risks, a consistent and systematic approach to the discussion and regulatory decisionmaking, and the communication of the benefits and risks of new drugs. Nothing in the preceding sentence shall alter the criteria for evaluating an application for marketing approval of a drug.

(e) Withdrawal of approval; grounds; immediate suspension upon finding imminent hazard to public health

The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds (1) that clinical or other experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved; (2) that new evidence of clinical experience, not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved; or (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof; or (4) the patent information prescribed by subsection (c) was not filed within thirty days after the receipt of written notice from the Secretary specifying the failure to file such information; or (5) that the application contains any untrue statement of a material fact: Provided, That if the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this proviso to suspend the approval of an application shall not be delegated. The Secretary may also, after due notice and opportunity for hearing to the applicant, withdraw the approval of an application submitted under subsection (b) or (j) with respect to any drug under this section if the Secretary finds (1) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports, in accordance with a regulation or order under subsection (k) or to comply with the notice requirements of section 360(k)(2) of this title, or the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection; or (2) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or (3) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of. Any order under this subsection shall state the findings upon which it is based. The Secretary may withdraw the approval of an application submitted under this section, or suspend the approval of such an application, as provided under this subsection, without first ordering the applicant to submit an assessment of the approved risk evaluation and mitigation strategy for the drug under section 355-1(g)(2)(D) of this title.

(f) Revocation of order refusing, withdrawing or suspending approval of application
§ 355. New drugs, 21 USCA § 355

Whenever the Secretary finds that the facts so require, he shall revoke any previous order under subsection (d) or (e) refusing, withdrawing, or suspending approval of an application and shall approve such application or reinstate such approval, as may be appropriate.

(g) Service of orders

Orders of the Secretary issued under this section shall be served (1) in person by any officer or employee of the department designated by the Secretary or (2) by mailing the order by registered mail or by certified mail addressed to the applicant or respondent at his last-known address in the records of the Secretary.

(h) Appeal from order

An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application under this section. Such appeal shall be taken by filing in the United States court of appeals for the circuit wherein such applicant resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court the record upon which the order complained of was entered, as provided in section 2112 of Title 28. Upon the filing of such petition such court shall have exclusive jurisdiction to affirm or set aside such order, except that until the filing of the record the Secretary may modify or set aside his order. No objection to the order of the Secretary shall be considered by the court unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure so to do. The finding of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive. If any person shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts by reason of the additional evidence so taken, and he shall file with the court such modified findings which, if supported by substantial evidence, shall be conclusive, and his recommendation, if any, for the setting aside of the original order. The judgment of the court affirming or setting aside any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of Title 28. The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of the Secretary's order.

(i) Exemptions of drugs for research; discretionary and mandatory conditions; direct reports to Secretary

(1) The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon--

(A) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of preclinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing;
(B) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings;

(C) the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such drug, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b); and

(D) the submission to the Secretary by the manufacturer or the sponsor of the investigation of a new drug of a statement of intent regarding whether the manufacturer or sponsor has plans for assessing pediatric safety and efficacy.

(2) Subject to paragraph (3), a clinical investigation of a new drug may begin 30 days after the Secretary has received from the manufacturer or sponsor of the investigation a submission containing such information about the drug and the clinical investigation, including--

(A) information on design of the investigation and adequate reports of basic information, certified by the applicant to be accurate reports, necessary to assess the safety of the drug for use in clinical investigation; and

(B) adequate information on the chemistry and manufacturing of the drug, controls available for the drug, and primary data tabulations from animal or human studies.

(3)(A) At any time, the Secretary may prohibit the sponsor of an investigation from conducting the investigation (referred to in this paragraph as a “clinical hold”) if the Secretary makes a determination described in subparagraph (B). The Secretary shall specify the basis for the clinical hold, including the specific information available to the Secretary which served as the basis for such clinical hold, and confirm such determination in writing.

(B) For purposes of subparagraph (A), a determination described in this subparagraph with respect to a clinical hold is that--

(i) the drug involved represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigation, taking into account the qualifications of the clinical investigators, information about the drug, the design of the clinical investigation, the condition for which the drug is to be investigated, and the health status of the subjects involved; or

(ii) the clinical hold should be issued for such other reasons as the Secretary may by regulation establish (including reasons established by regulation before November 21, 1997).

(C) Any written request to the Secretary from the sponsor of an investigation that a clinical hold be removed shall receive a decision, in writing and specifying the reasons therefor, within 30 days after receipt of such request. Any such request shall include sufficient information to support the removal of such clinical hold.
§ 355. New drugs, 21 USCA § 355

(4) Regulations under paragraph (1) shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where it is not feasible, it is contrary to the best interests of such human beings, or the proposed clinical testing poses no more than minimal risk to such human beings and includes appropriate safeguards as prescribed to protect the rights, safety, and welfare of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs. The Secretary shall update such regulations to require inclusion in the informed consent documents and process a statement that clinical trial information for such clinical investigation has been or will be submitted for inclusion in the registry data bank pursuant to subsection (j) of section 282 of Title 42.

(j) Abbreviated new drug applications

(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)(A) An abbreviated application for a new drug shall contain--

(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a “listed drug”);

(ii)(I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug;

(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 321(p) of this title, and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;
(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

(vi) the items specified in clauses (ii) through (vi) of subsection (b)(1)(A);

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c)--

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

(B) Notice of opinion that patent is invalid or will not be infringed

(i) Agreement to give notice

An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give notice as required by this subparagraph.

(ii) Timing of notice
§ 355. New drugs, 21 USCA § 355

An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph--

(I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(iii) Recipients of notice

An applicant required under this subparagraph to give notice shall give notice to--

(I) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(II) the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(iv) Contents of notice

A notice required under this subparagraph shall--

(I) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(II) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds--

(i) that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug; or
(ii) that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

(D)(i) An applicant may not amend or supplement an application to seek approval of a drug referring to a different listed drug from the listed drug identified in the application as submitted to the Secretary.

(ii) With respect to the drug for which an application is submitted, nothing in this subsection prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

(iii) Within 60 days after December 8, 2003, the Secretary shall issue guidance defining the term “listed drug” for purposes of this subparagraph.

(3)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1), which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of bioavailability and bioequivalence studies needed for approval of such application. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of such studies. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant.

(C) Any agreement regarding the parameters of design and size of bioavailability and bioequivalence studies of a drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except--

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance office personnel unless such field or compliance office personnel demonstrate to the reviewing division why such decision should be modified.
(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection (including scientific matters, chemistry, manufacturing, and controls).

(4) Subject to paragraph (5), the Secretary shall approve an application for a drug unless the Secretary finds--

(A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;

(B) information submitted with the application is insufficient to show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;

(C)(i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug;

(ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or

(iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed drug, information submitted with the application is insufficient to show--

(I) that the other active ingredients are the same as the active ingredients of the listed drug, or

(II) that the different active ingredient is an active ingredient of a listed drug or a drug which does not meet the requirements of section 321(p) of this title,

or no petition to file an application for the drug with the different ingredient was approved under paragraph (2)(C);

(D)(i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route of administration, dosage form, or strength of the listed drug referred to in the application, information submitted in the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or

(ii) if the application is for a drug whose route of administration, dosage form, or strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage form, or strength was approved under paragraph (2)(C);
(E) if the application was filed pursuant to the approval of a petition under paragraph (2)(C), the application did not contain the information required by the Secretary respecting the active ingredient, route of administration, dosage form, or strength which is not the same;

(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;

(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because the drug and the listed drug are produced or distributed by different manufacturers;

(H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

(I) the approval under subsection (c) of the listed drug referred to in the application under this subsection has been withdrawn or suspended for grounds described in the first sentence of subsection (e), the Secretary has published a notice of opportunity for hearing to withdraw approval of the listed drug under subsection (c) for grounds described in the first sentence of subsection (e), the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (6), or the Secretary has determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;

(J) the application does not meet any other requirement of paragraph (2)(A); or

(K) the application contains an untrue statement of material fact.

(5)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined by applying the following to each certification made under paragraph (2)(A)(vii):

(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.
§ 355. New drugs, 21 USCA § 355

(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B) (i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that--

(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on--

(aa) the date on which the court enters judgment reflecting the decision; or

(bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(II) if before the expiration of such period the district court decides that the patent has been infringed--

(aa) if the judgment of the district court is appealed, the approval shall be made effective on--

(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of Title 35;

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in subclause (I); or
(IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in subclause (II).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

(iv) 180-day exclusivity period

(I) Effectiveness of application

Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

(II) Definitions

In this paragraph:

(aa) 180-day exclusivity period

The term “180-day exclusivity period” means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.

(bb) First applicant

As used in this subsection, the term “first applicant” means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug.

(cc) Substantially complete application

As used in this subsection, the term “substantially complete application” means an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).

(dd) Tentative approval

(AA) In general

The term “tentative approval” means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the
application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph (F) or section 355a of this title, or there is a 7-year period of exclusivity for the listed drug under section 360cc of this title.

(BB) Limitation

A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

(v) 180-day exclusivity period for competitive generic therapies

(I) Effectiveness of application

Subject to subparagraph (D)(iv), if the application is for a drug that is the same as a competitive generic therapy for which any first approved applicant has commenced commercial marketing, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the competitive generic therapy (including the commercial marketing of the listed drug) by any first approved applicant.

(II) Limitation

The exclusivity period under subclause (I) shall not apply with respect to a competitive generic therapy that has previously received an exclusivity period under subclause (I).

(III) Definitions

In this clause and subparagraph (D)(iv):

(aa) The term “competitive generic therapy” means a drug--

(AA) that is designated as a competitive generic therapy under section 356h of this title; and

(BB) for which there are no unexpired patents or exclusivities on the list of products described in section 355(j) (7)(A) of this title at the time of submission.

(bb) The term “first approved applicant” means any applicant that has submitted an application that--

(AA) is for a competitive generic therapy that is approved on the first day on which any application for such competitive generic therapy is approved;

(BB) is not eligible for a 180-day exclusivity period under clause (iv) for the drug that is the subject of the application for the competitive generic therapy; and
(CC) is not for a drug for which all drug versions have forfeited eligibility for a 180-day exclusivity period under clause (iv) pursuant to subparagraph (D).

(C) Civil action to obtain patent certainty

(i) Declaratory judgment absent infringement action

(I) In general

No action may be brought under section 2201 of Title 28, by an applicant under paragraph (2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (B)(iii) unless--

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) Filing of civil action

If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of Title 28, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) Offer of confidential access to application

For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access,
and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) Counterclaim to infringement action

(I) In general

If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) on the ground that the patent does not claim either--

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) No independent cause of action

Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) No damages

An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(D) Forfeiture of 180-day exclusivity period

(i) Definition of forfeiture event

In this subparagraph, the term “forfeiture event”, with respect to an application under this subsection, means the occurrence of any of the following:

(I) Failure to market

The first applicant fails to market the drug by the later of--

(aa) the earlier of the date that is--
(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or

(BB) 30 months after the date of submission of the application of the first applicant; or

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

(CC) The patent information submitted under subsection (b) or (c) is withdrawn by the holder of the application approved under subsection (b).

(II) Withdrawal of application

The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4).

(III) Amendment of certification

The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.

(IV) Failure to obtain tentative approval

The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

(V) Agreement with another applicant, the listed drug application holder, or a patent owner
The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 12 of Title 15, except that the term includes section 45 of Title 15 to the extent that that section applies to unfair methods of competition).

(VI) Expiration of all patents

All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.

(ii) Forfeiture

The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant.

(iii) Subsequent applicant

If all first applicants forfeit the 180-day exclusivity period under clause (ii)--

(I) approval of any application containing a certification described in paragraph (2)(A)(vii)(IV) shall be made effective in accordance with subparagraph (B)(iii); and

(II) no applicant shall be eligible for a 180-day exclusivity period.

(iv) Special forfeiture rule for competitive generic therapy

The 180-day exclusivity period described in subparagraph (B)(v) shall be forfeited by a first approved applicant if the applicant fails to market the competitive generic therapy within 75 days after the date on which the approval of the first approved applicant's application for the competitive generic therapy is made effective.

(E) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(ii) If an application submitted under subsection (b) for a drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under subsection (b), is approved after September 24, 1984, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b), except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) for a drug, which includes an active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) that has been approved in another application approved under subsection (b), is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) for such drug.

(iv) If a supplement to an application approved under subsection (b) is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b).

(v) If an application (or supplement to an application) submitted under subsection (b) for a drug, which includes an active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) that has been approved in another application under subsection (b), was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted or which refers to a change approved in a supplement to the subsection (b) application effective before the expiration of two years from September 24, 1984.

(6) If a drug approved under this subsection refers in its approved application to a drug the approval of which was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under this paragraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this subsection shall be withdrawn or suspended--

(A) for the same period as the withdrawal or suspension under subsection (e) or this paragraph, or

(B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.
(A)(i) Within sixty days of September 24, 1984, the Secretary shall publish and make available to the public--

(I) a list in alphabetical order of the official and proprietary name of each drug which has been approved for safety and effectiveness under subsection (c) before September 24, 1984;

(II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and

(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.

(ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug which has been approved for safety and effectiveness under subsection (c) or approved under this subsection during the thirty-day period.

(iii) When patent information submitted under subsection (c) respecting a drug included on the list is to be published by the Secretary, the Secretary shall, in revisions made under clause (ii), include such information for such drug.

(iv) For each drug included on the list, the Secretary shall specify any exclusivity period that is applicable, for which the Secretary has determined the expiration date, and for which such period has not yet expired, under--

(I) clause (ii), (iii), or (iv) of subsection (c)(3)(E);

(II) clause (iv) or (v) of paragraph (5)(B);

(III) clause (ii), (iii), or (iv) of paragraph (5)(F);

(IV) section 355a of this title;

(V) section 355f of this title;

(VI) section 360cc(a) of this title; or

(VII) subsection (u).

(B) A drug approved for safety and effectiveness under subsection (c) or approved under this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or September 24, 1984, whichever is later.
(C) If the approval of a drug was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under paragraph (6) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list--

(i) for the same period as the withdrawal or suspension under subsection (e) or paragraph (6), or

(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

A notice of the removal shall be published in the Federal Register.

(D) In the case of a listed drug for which the list under subparagraph (A)(i) includes a patent for such drug, and any claim of the patent has been cancelled or invalidated pursuant to a final decision issued by the Patent Trial and Appeal Board of the United States Patent and Trademark Office or by a court, from which no appeal has been, or can be, taken, if the holder of the applicable application approved under subsection (c) determines that a patent for such drug, or any patent information for such drug, no longer meets the listing requirements under this section--

(i) the holder of such approved application shall notify the Secretary, in writing, within 14 days of such decision of such cancellation or invalidation and request that such patent or patent information, as applicable, be amended or withdrawn in accordance with the decision issued by the Patent Trial and Appeal Board or a court;

(ii) the holder of such approved application shall include in any notification under clause (i) information related to such patent cancellation or invalidation decision and submit such information, including a copy of such decision, to the Secretary; and

(iii) the Secretary shall, in response to a notification under clause (i), amend or remove patent or patent information in accordance with the relevant decision from the Patent Trial and Appeals Board or court, as applicable, except that the Secretary shall not remove from the list any patent or patent information before the expiration of any 180-day exclusivity period under paragraph (5)(B)(iv) that relies on a certification described in paragraph (2)(A)(vii)(IV).

(8) For purposes of this subsection:

(A)(i) The term “bioavailability” means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

(ii) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may assess bioavailability by scientifically valid measurements intended to reflect the rate and extent to which the active ingredient or therapeutic ingredient becomes available at the site of drug action.

(B) A drug shall be considered to be bioequivalent to a listed drug if--
(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or

(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

(C) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may establish alternative, scientifically valid methods to show bioequivalence if the alternative methods are expected to detect a significant difference between the drug and the listed drug in safety and therapeutic effect.

(9) The Secretary shall, with respect to each application submitted under this subsection, maintain a record of--

(A) the name of the applicant,

(B) the name of the drug covered by the application,

(C) the name of each person to whom the review of the chemistry of the application was assigned and the date of such assignment, and

(D) the name of each person to whom the bioequivalence review for such application was assigned and the date of such assignment.

The information the Secretary is required to maintain under this paragraph with respect to an application submitted under this subsection shall be made available to the public after the approval of such application.

(10)(A) If the proposed labeling of a drug that is the subject of an application under this subsection differs from the listed drug due to a labeling revision described under clause (i), the drug that is the subject of such application shall, notwithstanding any other provision of this chapter, be eligible for approval and shall not be considered misbranded under section 352 of this title if--

(i) the application is otherwise eligible for approval under this subsection but for expiration of patent, an exclusivity period, or of a delay in approval described in paragraph (5)(B)(iii), and a revision to the labeling of the listed drug has been approved by the Secretary within 60 days of such expiration;

(ii) the labeling revision described under clause (i) does not include a change to the “Warnings” section of the labeling;

(iii) the sponsor of the application under this subsection agrees to submit revised labeling of the drug that is the subject of such application not later than 60 days after the notification of any changes to such labeling required by the Secretary; and
(iv) such application otherwise meets the applicable requirements for approval under this subsection.

(B) If, after a labeling revision described in subparagraph (A)(i), the Secretary determines that the continued presence in interstate commerce of the labeling of the listed drug (as in effect before the revision described in subparagraph (A)(i)) adversely impacts the safe use of the drug, no application under this subsection shall be eligible for approval with such labeling.

(11)(A) Subject to subparagraph (B), the Secretary shall prioritize the review of, and act within 8 months of the date of the submission of, an original abbreviated new drug application submitted for review under this subsection that is for a drug--

(i) for which there are not more than 3 approved drug products listed under paragraph (7) and for which there are no blocking patents and exclusivities; or

(ii) that has been included on the list under section 356e of this title.

(B) To qualify for priority review under this paragraph, not later than 60 days prior to the submission of an application described in subparagraph (A) or that the Secretary may prioritize pursuant to subparagraph (D), the applicant shall provide complete, accurate information regarding facilities involved in manufacturing processes and testing of the drug that is the subject of the application, including facilities in corresponding Type II active pharmaceutical ingredients drug master files referenced in an application and sites or organizations involved in bioequivalence and clinical studies used to support the application, to enable the Secretary to make a determination regarding whether an inspection of a facility is necessary. Such information shall include the relevant (as determined by the Secretary) sections of such application, which shall be unchanged relative to the date of the submission of such application, except to the extent that a change is made to such information to exclude a facility that was not used to generate data to meet any application requirements for such submission and that is not the only facility intended to conduct one or more unit operations in commercial production. Information provided by an applicant under this subparagraph shall not be considered the submission of an application under this subsection.

(C) The Secretary may expedite an inspection or reinspection under section 374 of this title of an establishment that proposes to manufacture a drug described in subparagraph (A).

(D) Nothing in this paragraph shall prevent the Secretary from prioritizing the review of other applications as the Secretary determines appropriate.

(12) The Secretary shall publish on the internet website of the Food and Drug Administration, and update at least once every 6 months, a list of all drugs approved under subsection (c) for which all patents and periods of exclusivity under this chapter have expired and for which no application has been approved under this subsection.

(13) Upon the request of an applicant regarding one or more specified pending applications under this subsection, the Secretary shall, as appropriate, provide review status updates indicating the categorical status of the applications by each relevant review discipline.
(k) Records and reports; required information; regulations and orders; access to records

(1) In the case of any drug for which an approval of an application filed under subsection (b) or (j) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e). Regulations and orders issued under this subsection and under subsection (i) shall have due regard for the professional ethics of the medical profession and the interests of patients and shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations or orders are applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(3) Active postmarket risk identification

(A) Definition

In this paragraph, the term “data” refers to information with respect to a drug approved under this section or under section 262 of Title 42, including claims data, patient survey data, standardized analytic files that allow for the pooling and analysis of data from disparate data environments, and any other data deemed appropriate by the Secretary.

(B) Development of postmarket risk identification and analysis methods

The Secretary shall, not later than 2 years after September 27, 2007, in collaboration with public, academic, and private entities--

(i) develop methods to obtain access to disparate data sources including the data sources specified in subparagraph (C);

(ii) develop validated methods for the establishment of a postmarket risk identification and analysis system to link and analyze safety data from multiple sources, with the goals of including, in aggregate--

(I) at least 25,000,000 patients by July 1, 2010; and

(II) at least 100,000,000 patients by July 1, 2012; and

(iii) convene a committee of experts, including individuals who are recognized in the field of protecting data privacy and security, to make recommendations to the Secretary on the development of tools and methods for the ethical and scientific
uses for, and communication of, postmarketing data specified under subparagraph (C), including recommendations on the development of effective research methods for the study of drug safety questions.

(C) Establishment of the postmarket risk identification and analysis system

(i) In general

The Secretary shall, not later than 1 year after the development of the risk identification and analysis methods under subparagraph (B), establish and maintain procedures--

(I) for risk identification and analysis based on electronic health data, in compliance with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, and in a manner that does not disclose individually identifiable health information in violation of paragraph (4)(B);

(II) for the reporting (in a standardized form) of data on all serious adverse drug experiences (as defined in section 355-1(b) of this title) submitted to the Secretary under paragraph (1), and those adverse events submitted by patients, providers, and drug sponsors, when appropriate;

(III) to provide for active adverse event surveillance using the following data sources, as available:

(aa) Federal health-related electronic data (such as data from the Medicare program and the health systems of the Department of Veterans Affairs);

(bb) private sector health-related electronic data (such as pharmaceutical purchase data and health insurance claims data); and

(cc) other data as the Secretary deems necessary to create a robust system to identify adverse events and potential drug safety signals;

(IV) to identify certain trends and patterns with respect to data accessed by the system;

(V) to provide regular reports to the Secretary concerning adverse event trends, adverse event patterns, incidence and prevalence of adverse events, and other information the Secretary determines appropriate, which may include data on comparative national adverse event trends; and

(VI) to enable the program to export data in a form appropriate for further aggregation, statistical analysis, and reporting.

(ii) Timeliness of reporting
The procedures established under clause (i) shall ensure that such data are accessed, analyzed, and reported in a timely, routine, and systematic manner, taking into consideration the need for data completeness, coding, cleansing, and standardized analysis and transmission.

(iii) Private sector resources

To ensure the establishment of the active postmarket risk identification and analysis system under this subsection not later than 1 year after the development of the risk identification and analysis methods under subparagraph (B), as required under clause (i), the Secretary may, on a temporary or permanent basis, implement systems or products developed by private entities.

(iv) Complementary approaches

To the extent the active postmarket risk identification and analysis system under this subsection is not sufficient to gather data and information relevant to a priority drug safety question, the Secretary shall develop, support, and participate in complementary approaches to gather and analyze such data and information, including--

(I) approaches that are complementary with respect to assessing the safety of use of a drug in domestic populations not included, or underrepresented, in the trials used to approve the drug (such as older people, people with comorbidities, pregnant women, or children); and

(II) existing approaches such as the Vaccine Adverse Event Reporting System and the Vaccine Safety Datalink or successor databases.

(v) Authority for contracts

The Secretary may enter into contracts with public and private entities to fulfill the requirements of this subparagraph.

(4) Advanced analysis of drug safety data

(A) Purpose

The Secretary shall establish collaborations with public, academic, and private entities, which may include the Centers for Education and Research on Therapeutics under section 299b-1 of Title 42, to provide for advanced analysis of drug safety data described in paragraph (3)(C) and other information that is publicly available or is provided by the Secretary, in order to--

(i) improve the quality and efficiency of postmarket drug safety risk-benefit analysis;

(ii) provide the Secretary with routine access to outside expertise to study advanced drug safety questions; and

(iii) enhance the ability of the Secretary to make timely assessments based on drug safety data.
(B) **Privacy**

Such analysis shall not disclose individually identifiable health information when presenting such drug safety signals and trends or when responding to inquiries regarding such drug safety signals and trends.

(C) **Public process for priority questions**

At least biannually, the Secretary shall seek recommendations from the Drug Safety and Risk Management Advisory Committee (or any successor committee) and from other advisory committees, as appropriate, to the Food and Drug Administration on--

(i) priority drug safety questions; and

(ii) mechanisms for answering such questions, including through--

(I) active risk identification under paragraph (3); and

(II) when such risk identification is not sufficient, postapproval studies and clinical trials under subsection (o)(3).

(D) **Procedures for the development of drug safety collaborations**

(i) **In general**

Not later than 180 days after the date of the establishment of the active postmarket risk identification and analysis system under this subsection, the Secretary shall establish and implement procedures under which the Secretary may routinely contract with one or more qualified entities to--

(I) classify, analyze, or aggregate data described in paragraph (3)(C) and information that is publicly available or is provided by the Secretary;

(II) allow for prompt investigation of priority drug safety questions, including--

(aa) unresolved safety questions for drugs or classes of drugs; and

(bb) for a newly-approved drugs,^2^ safety signals from clinical trials used to approve the drug and other preapproval trials; rare, serious drug side effects; and the safety of use in domestic populations not included, or underrepresented, in the trials used to approve the drug (such as older people, people with comorbidities, pregnant women, or children);
(III) perform advanced research and analysis on identified drug safety risks;

(IV) focus postapproval studies and clinical trials under subsection (o)(3) more effectively on cases for which reports under paragraph (1) and other safety signal detection is not sufficient to resolve whether there is an elevated risk of a serious adverse event associated with the use of a drug; and

(V) carry out other activities as the Secretary deems necessary to carry out the purposes of this paragraph.

(ii) Request for specific methodology

The procedures described in clause (i) shall permit the Secretary to request that a specific methodology be used by the qualified entity. The qualified entity shall work with the Secretary to finalize the methodology to be used.

(E) Use of analyses

The Secretary shall provide the analyses described in this paragraph, including the methods and results of such analyses, about a drug to the sponsor or sponsors of such drug.

(F) Qualified entities

(i) In general

The Secretary shall enter into contracts with a sufficient number of qualified entities to develop and provide information to the Secretary in a timely manner.

(ii) Qualification

The Secretary shall enter into a contract with an entity under clause (i) only if the Secretary determines that the entity has a significant presence in the United States and has one or more of the following qualifications:

(I) The research, statistical, epidemiologic, or clinical capability and expertise to conduct and complete the activities under this paragraph, including the capability and expertise to provide the Secretary de-identified data consistent with the requirements of this subsection.

(II) An information technology infrastructure in place to support electronic data and operational standards to provide security for such data.

(III) Experience with, and expertise on, the development of drug safety and effectiveness research using electronic population data.

(IV) An understanding of drug development or risk/benefit balancing in a clinical setting.
(V) Other expertise which the Secretary deems necessary to fulfill the activities under this paragraph.

(G) Contract requirements

Each contract with a qualified entity under subparagraph (F)(i) shall contain the following requirements:

(i) Ensuring privacy

The qualified entity shall ensure that the entity will not use data under this subsection in a manner that--

(I) violates the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996;

(II) violates sections 552 or 552a of Title 5 with regard to the privacy of individually-identifiable beneficiary health information; or

(III) discloses individually identifiable health information when presenting drug safety signals and trends or when responding to inquiries regarding drug safety signals and trends.

Nothing in this clause prohibits lawful disclosure for other purposes.

(ii) Component of another organization

If a qualified entity is a component of another organization--

(I) the qualified entity shall establish appropriate security measures to maintain the confidentiality and privacy of such data; and

(II) the entity shall not make an unauthorized disclosure of such data to the other components of the organization in breach of such confidentiality and privacy requirement.

(iii) Termination or nonrenewal

If a contract with a qualified entity under this subparagraph is terminated or not renewed, the following requirements shall apply:

(I) Confidentiality and privacy protections

The entity shall continue to comply with the confidentiality and privacy requirements under this paragraph with respect to all data disclosed to the entity.
(II) Disposition of data

The entity shall return any data disclosed to such entity under this subsection to which it would not otherwise have access or, if returning the data is not practicable, destroy the data.

(H) Competitive procedures

The Secretary shall use competitive procedures (as defined in section 132 of Title 41) to enter into contracts under subparagraph (G).

(I) Review of contract in the event of a merger or acquisition

The Secretary shall review the contract with a qualified entity under this paragraph in the event of a merger or acquisition of the entity in order to ensure that the requirements under this paragraph will continue to be met.

(J) Coordination

In carrying out this paragraph, the Secretary shall provide for appropriate communications to the public, scientific, public health, and medical communities, and other key stakeholders, and to the extent practicable shall coordinate with the activities of private entities, professional associations, or other entities that may have sources of drug safety data.

(5) The Secretary shall--

(A) conduct regular screenings of the Adverse Event Reporting System database and post a quarterly report on the Adverse Event Reporting System Web site of any new safety information or potential signal of a serious risk identified by Adverse Event Reporting System within the last quarter; and

(B) on an annual basis, review the entire backlog of postmarket safety commitments to determine which commitments require revision or should be eliminated, report to the Congress on these determinations, and assign start dates and estimated completion dates for such commitments; and

(C) make available on the Internet website of the Food and Drug Administration--

(i) guidelines, developed with input from experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, that detail best practices for drug safety surveillance using the Adverse Event Reporting System; and

(ii) criteria for public posting of adverse event signals.

(I) Public disclosure of safety and effectiveness data and action package
(1) Safety and effectiveness data and information which has been submitted in an application under subsection (b) for a drug and which has not previously been disclosed to the public shall be made available to the public, upon request, unless extraordinary circumstances are shown--

(A) if no work is being or will be undertaken to have the application approved,

(B) if the Secretary has determined that the application is not approvable and all legal appeals have been exhausted,

(C) if approval of the application under subsection (c) is withdrawn and all legal appeals have been exhausted,

(D) if the Secretary has determined that such drug is not a new drug, or

(E) upon the effective date of the approval of the first application under subsection (j) which refers to such drug or upon the date upon which the approval of an application under subsection (j) which refers to such drug could be made effective if such an application had been submitted.

(2) Action package for approval

(A) Action package

The Secretary shall publish the action package for approval of an application under subsection (b) or section 262 of Title 42 on the Internet Web site of the Food and Drug Administration--

(i) not later than 30 days after the date of approval of such applications--

(I) for a drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under this section; or

(II) for a biological product, no active ingredient of which has been approved in any other application under section 262 of Title 42; and

(ii) not later than 30 days after the third request for such action package for approval received under section 552 of Title 5 for any other drug or biological product.

(B) Immediate publication of summary review

Notwithstanding subparagraph (A), the Secretary shall publish, on the Internet Web site of the Food and Drug Administration, the materials described in subparagraph (C)(iv) not later than 48 hours after the date of approval of the drug, except where such materials require redaction by the Secretary.
(C) Contents

An action package for approval of an application under subparagraph (A) shall be dated and shall include the following:

(i) Documents generated by the Food and Drug Administration related to review of the application.

(ii) Documents pertaining to the format and content of the application generated during drug development.

(iii) Labeling submitted by the applicant.

(iv) A summary review that documents conclusions from all reviewing disciplines about the drug, noting any critical issues and disagreements with the applicant and within the review team and how they were resolved, recommendations for action, and an explanation of any nonconcurrence with review conclusions.

(v) The Division Director and Office Director's decision document which includes--

(I) a brief statement of concurrence with the summary review;

(II) a separate review or addendum to the review if disagreeing with the summary review; and

(III) a separate review or addendum to the review to add further analysis.

(vi) Identification by name of each officer or employee of the Food and Drug Administration who--

(I) participated in the decision to approve the application; and

(II) consents to have his or her name included in the package.

(D) Review

A scientific review of an application is considered the work of the reviewer and shall not be altered by management or the reviewer once final.

(E) Confidential information

This paragraph does not authorize the disclosure of any trade secret, confidential commercial or financial information, or other matter listed in section 552(b) of Title 5.
(m) “Patent” defined

For purposes of this section, the term “patent” means a patent issued by the United States Patent and Trademark Office.

(n) Scientific advisory panels

(1) For the purpose of providing expert scientific advice and recommendations to the Secretary regarding a clinical investigation of a drug or the approval for marketing of a drug under this section or section 262 of Title 42, the Secretary shall establish panels of experts or use panels of experts established before November 21, 1997, or both.

(2) The Secretary may delegate the appointment and oversight authority granted under section 394 of this title to a director of a center or successor entity within the Food and Drug Administration.

(3) The Secretary shall make appointments to each panel established under paragraph (1) so that each panel shall consist of--

(A) members who are qualified by training and experience to evaluate the safety and effectiveness of the drugs to be referred to the panel and who, to the extent feasible, possess skill and experience in the development, manufacture, or utilization of such drugs;

(B) members with diverse expertise in such fields as clinical and administrative medicine, pharmacy, pharmacology, pharmacoeconomics, biological and physical sciences, and other related professions;

(C) a representative of consumer interests, and a representative of interests of the drug manufacturing industry not directly affected by the matter to be brought before the panel; and

(D) two or more members who are specialists or have other expertise in the particular disease or condition for which the drug under review is proposed to be indicated.

Scientific, trade, and consumer organizations shall be afforded an opportunity to nominate individuals for appointment to the panels. No individual who is in the regular full-time employ of the United States and engaged in the administration of this chapter may be a voting member of any panel. The Secretary shall designate one of the members of each panel to serve as chairman thereof.

(4) The Secretary shall, as appropriate, provide education and training to each new panel member before such member participates in a panel's activities, including education regarding requirements under this chapter and related regulations of the Secretary, and the administrative processes and procedures related to panel meetings.

(5) Panel members (other than officers or employees of the United States), while attending meetings or conferences of a panel or otherwise engaged in its business, shall be entitled to receive compensation for each day so engaged, including traveltime, at rates to be fixed by the Secretary, but not to exceed the daily equivalent of the rate in effect for positions classified above grade GS-15 of the General Schedule. While serving away from their homes or regular places of business, panel members may
be allowed travel expenses (including per diem in lieu of subsistence) as authorized by section 5703 of Title 5, for persons in the Government service employed intermittently.

(6) The Secretary shall ensure that scientific advisory panels meet regularly and at appropriate intervals so that any matter to be reviewed by such a panel can be presented to the panel not more than 60 days after the matter is ready for such review. Meetings of the panel may be held using electronic communication to convene the meetings.

(7) Within 90 days after a scientific advisory panel makes recommendations on any matter under its review, the Food and Drug Administration official responsible for the matter shall review the conclusions and recommendations of the panel, and notify the affected persons of the final decision on the matter, or of the reasons that no such decision has been reached. Each such final decision shall be documented including the rationale for the decision.

(o) **Postmarket studies and clinical trials; labeling**

(1) **In general**

A responsible person may not introduce or deliver for introduction into interstate commerce the new drug involved if the person is in violation of a requirement established under paragraph (3) or (4) with respect to the drug.

(2) **Definitions**

For purposes of this subsection:

(A) **Responsible person**

The term “responsible person” means a person who--

(i) has submitted to the Secretary a covered application that is pending; or

(ii) is the holder of an approved covered application.

(B) **Covered application**

The term “covered application” means--

(i) an application under subsection (b) for a drug that is subject to section 353(b) of this title; and

(ii) an application under section 262 of Title 42.

(C) **New safety information; serious risk**
The terms “new safety information”, “serious risk”, and “signal of a serious risk” have the meanings given such terms in section 355-1(b) of this title.

(3) Studies and clinical trials

(A) In general

For any or all of the purposes specified in subparagraph (B), the Secretary may, subject to subparagraph (D), require a responsible person for a drug to conduct a postapproval study or studies of the drug, or a postapproval clinical trial or trials of the drug, on the basis of scientific data deemed appropriate by the Secretary, including information regarding chemically-related or pharmacologically-related drugs.

(B) Purposes of study or clinical trial

The purposes referred to in this subparagraph with respect to a postapproval study or postapproval clinical trial are the following:

(i) To assess a known serious risk related to the use of the drug involved.

(ii) To assess signals of serious risk related to the use of the drug.

(iii) To identify an unexpected serious risk when available data indicates the potential for a serious risk.

(C) Establishment of requirement after approval of covered application

The Secretary may require a postapproval study or studies or postapproval clinical trial or trials for a drug for which an approved covered application is in effect as of the date on which the Secretary seeks to establish such requirement only if the Secretary becomes aware of new safety information.

(D) Determination by Secretary

(i) Postapproval studies

The Secretary may not require the responsible person to conduct a study under this paragraph, unless the Secretary makes a determination that the reports under subsection (k)(1) and the active postmarket risk identification and analysis system as available under subsection (k)(3) will not be sufficient to meet the purposes set forth in subparagraph (B).

(ii) Postapproval clinical trials

The Secretary may not require the responsible person to conduct a clinical trial under this paragraph, unless the Secretary makes a determination that a postapproval study or studies will not be sufficient to meet the purposes set forth in subparagraph (B).
(E) Notification; timetables; periodic reports

(i) Notification

The Secretary shall notify the responsible person regarding a requirement under this paragraph to conduct a postapproval study or clinical trial by the target dates for communication of feedback from the review team to the responsible person regarding proposed labeling and postmarketing study commitments as set forth in the letters described in section 101(c) of the Food and Drug Administration Amendments Act of 2007.

(ii) Timetable; periodic reports

For each study or clinical trial required to be conducted under this paragraph, the Secretary shall require that the responsible person submit a timetable for completion of the study or clinical trial. With respect to each study required to be conducted under this paragraph or otherwise undertaken by the responsible person to investigate a safety issue, the Secretary shall require the responsible person to periodically report to the Secretary on the status of such study including whether any difficulties in completing the study have been encountered. With respect to each clinical trial required to be conducted under this paragraph or otherwise undertaken by the responsible person to investigate a safety issue, the Secretary shall require the responsible person to periodically report to the Secretary on the status of such clinical trial including whether enrollment has begun, the number of participants enrolled, the expected completion date, whether any difficulties completing the clinical trial have been encountered, and registration information with respect to the requirements under section 282(j) of Title 42. If the responsible person fails to comply with such timetable or violates any other requirement of this subparagraph, the responsible person shall be considered in violation of this subsection, unless the responsible person demonstrates good cause for such noncompliance or such other violation. The Secretary shall determine what constitutes good cause under the preceding sentence.

(F) Dispute resolution

The responsible person may appeal a requirement to conduct a study or clinical trial under this paragraph using dispute resolution procedures established by the Secretary in regulation and guidance.

(4) Safety labeling changes requested by Secretary

(A) New safety or new effectiveness information

If the Secretary becomes aware of new information, including any new safety information or information related to reduced effectiveness, that the Secretary determines should be included in the labeling of the drug, the Secretary shall promptly notify the responsible person or, if the same drug approved under subsection (b) is not currently marketed, the holder of an approved application under subsection (j).

(B) Response to notification

Following notification pursuant to subparagraph (A), the responsible person or the holder of the approved application under subsection (j) shall within 30 days--
(i) submit a supplement proposing changes to the approved labeling to reflect the new safety information, including changes to boxed warnings, contraindications, warnings, precautions, or adverse reactions, or new effectiveness information; or

(ii) notify the Secretary that the responsible person or the holder of the approved application under subsection (j) does not believe a labeling change is warranted and submit a statement detailing the reasons why such a change is not warranted.

(C) Review

Upon receipt of such supplement, the Secretary shall promptly review and act upon such supplement. If the Secretary disagrees with the proposed changes in the supplement or with the statement setting forth the reasons why no labeling change is necessary, the Secretary shall initiate discussions to reach agreement on whether the labeling for the drug should be modified to reflect the new safety or new effectiveness information, and if so, the contents of such labeling changes.

(D) Discussions

Such discussions shall not extend for more than 30 days after the response to the notification under subparagraph (B), unless the Secretary determines an extension of such discussion period is warranted.

(E) Order

Within 15 days of the conclusion of the discussions under subparagraph (D), the Secretary may issue an order directing the responsible person or the holder of the approved application under subsection (j) to make such a labeling change as the Secretary deems appropriate to address the new safety or new effectiveness information. Within 15 days of such an order, the responsible person or the holder of the approved application under subsection (j) shall submit a supplement containing the labeling change.

(F) Dispute resolution

Within 5 days of receiving an order under subparagraph (E), the responsible person or the holder of the approved application under subsection (j) may appeal using dispute resolution procedures established by the Secretary in regulation and guidance.

(G) Violation

If the responsible person or the holder of the approved application under subsection (j) has not submitted a supplement within 15 days of the date of such order under subparagraph (E), and there is no appeal or dispute resolution proceeding pending, the responsible person or holder shall be considered to be in violation of this subsection. If at the conclusion of any dispute resolution procedures the Secretary determines that a supplement must be submitted and such a supplement is not submitted within 15 days of the date of that determination, the responsible person or holder shall be in violation of this subsection.
(H) Public health threat

Notwithstanding subparagraphs (A) through (F), if the Secretary concludes that such a labeling change is necessary to protect the public health, the Secretary may accelerate the timelines in such subparagraphs.

(I) Rule of construction

This paragraph shall not be construed to affect the responsibility of the responsible person or the holder of the approved application under subsection (j) to maintain its label in accordance with existing requirements, including subpart B of part 201 and sections 314.70 and 601.12 of title 21, Code of Federal Regulations (or any successor regulations).

(5) Non-delegation

Determinations by the Secretary under this subsection for a drug shall be made by individuals at or above the level of individuals empowered to approve a drug (such as division directors within the Center for Drug Evaluation and Research).

(p) Risk evaluation and mitigation strategy

(1) In general

A person may not introduce or deliver for introduction into interstate commerce a new drug if--

(A)(i) the application for such drug is approved under subsection (b) or (j) and is subject to section 353(b) of this title; or

(ii) the application for such drug is approved under section 262 of Title 42; and

(B) a risk evaluation and mitigation strategy is required under section 355-1 of this title with respect to the drug and the person fails to maintain compliance with the requirements of the approved strategy or with other requirements under section 355-1 of this title, including requirements regarding assessments of approved strategies.

(2) Certain postmarket studies

The failure to conduct a postmarket study under section 356 of this title, subpart H of part 314, or subpart E of part 601 of title 21, Code of Federal Regulations (or any successor regulations), is deemed to be a violation of paragraph (1).

(q) Petitions and civil actions regarding approval of certain applications

(1) In general

(A) Determination
The Secretary shall not delay approval of a pending application submitted under subsection (b)(2) or (j) of this section or section 262(k) of Title 42 because of any request to take any form of action relating to the application, either before or during consideration of the request, unless--

(i) the request is in writing and is a petition submitted to the Secretary pursuant to section 10.30 or 10.35 of title 21, Code of Federal Regulations (or any successor regulations); and

(ii) the Secretary determines, upon reviewing the petition, that a delay is necessary to protect the public health.

Consideration of the petition shall be separate and apart from review and approval of any application.

(B) Notification

If the Secretary determines under subparagraph (A) that a delay is necessary with respect to an application, the Secretary shall provide to the applicant, not later than 30 days after making such determination, the following information:

(i) Notification of the fact that a determination under subparagraph (A) has been made.

(ii) If applicable, any clarification or additional data that the applicant should submit to the docket on the petition to allow the Secretary to review the petition promptly.

(iii) A brief summary of the specific substantive issues raised in the petition which form the basis of the determination.

(C) Format

The information described in subparagraph (B) shall be conveyed via either, at the discretion of the Secretary--

(i) a document; or

(ii) a meeting with the applicant involved.

(D) Public disclosure

Any information conveyed by the Secretary under subparagraph (C) shall be considered part of the application and shall be subject to the disclosure requirements applicable to information in such application.

(E) Denial based on intent to delay

If the Secretary determines that a petition or a supplement to the petition was submitted with the primary purpose of delaying the approval of an application and the petition does not on its face raise valid scientific or regulatory issues, the Secretary may deny the petition at any point based on such determination. The Secretary may issue guidance to describe
§ 355. New drugs, 21 USCA § 355

the factors that will be used to determine under this subparagraph whether a petition is submitted with the primary purpose of delaying the approval of an application.

(F) Final agency action

The Secretary shall take final agency action on a petition not later than 150 days after the date on which the petition is submitted. The Secretary shall not extend such period for any reason, including--

(i) any determination made under subparagraph (A);

(ii) the submission of comments relating to the petition or supplemental information supplied by the petitioner; or

(iii) the consent of the petitioner.

(G) Extension of 30-month period

If the filing of an application resulted in first-applicant status under subsection (j)(5)(D)(i)(IV) and approval of the application was delayed because of a petition, the 30-month period under such subsection is deemed to be extended by a period of time equal to the period beginning on the date on which the Secretary received the petition and ending on the date of final agency action on the petition (inclusive of such beginning and ending dates), without regard to whether the Secretary grants, in whole or in part, or denies, in whole or in part, the petition.

(H) Certification

The Secretary shall not consider a petition for review unless the party submitting such petition does so in written form and the subject document is signed and contains the following certification: “I certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which the petition relies; (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to the petition; and (c) I have taken reasonable steps to ensure that any representative data and/or information which are unfavorable to the petition were disclosed to me. I further certify that the information upon which I have based the action requested herein first became known to the party on whose behalf this petition is submitted on or about the following date: __________. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: __________ . I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition,”, with the date on which such information first became known to such party and the names of such persons or organizations inserted in the first and second blank space, respectively.

(I) Verification

The Secretary shall not accept for review any supplemental information or comments on a petition unless the party submitting such information or comments does so in written form and the subject document is signed and contains the following verification: “I certify that, to my best knowledge and belief: (a) I have not intentionally delayed submission of this document or its contents; and (b) the information upon which I have based the action requested herein first became known to me on or about __________. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: __________ . I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition,”, with the date on which such information first became known to such party and the names of such persons or organizations inserted in the first and second blank space, respectively.
consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: __________. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.

(2) Exhaustion of administrative remedies

(A) Final agency action within 150 days

The Secretary shall be considered to have taken final agency action on a petition if--

(i) during the 150-day period referred to in paragraph (1)(F), the Secretary makes a final decision within the meaning of section 10.45(d) of title 21, Code of Federal Regulations (or any successor regulation); or

(ii) such period expires without the Secretary having made such a final decision.

(B) Dismissal of certain civil actions

If a civil action is filed against the Secretary with respect to any issue raised in the petition before the Secretary has taken final agency action on the petition within the meaning of subparagraph (A), the court shall dismiss without prejudice the action for failure to exhaust administrative remedies.

(C) Administrative record

For purposes of judicial review related to the approval of an application for which a petition under paragraph (1) was submitted, the administrative record regarding any issue raised by the petition shall include--

(i) the petition filed under paragraph (1) and any supplements and comments thereto;

(ii) the Secretary's response to such petition, if issued; and

(iii) other information, as designated by the Secretary, related to the Secretary's determinations regarding the issues raised in such petition, as long as the information was considered by the agency no later than the date of final agency action as defined under subparagraph (2)(A), and regardless of whether the Secretary responded to the petition at or before the approval of the application at issue in the petition.

(3) Annual report on delays in approvals per petitions

The Secretary shall annually submit to the Congress a report that specifies--

(A) the number of applications that were approved during the preceding 12-month period;
(B) the number of such applications whose effective dates were delayed by petitions referred to in paragraph (1) during such period;

(C) the number of days by which such applications were so delayed; and

(D) the number of such petitions that were submitted during such period.

(4) Exceptions

(A) This subsection does not apply to--

(i) a petition that relates solely to the timing of the approval of an application pursuant to subsection (j)(5)(B)(iv); or

(ii) a petition that is made by the sponsor of an application and that seeks only to have the Secretary take or refrain from taking any form of action with respect to that application.

(B) Paragraph (2) does not apply to a petition addressing issues concerning an application submitted pursuant to section 262(k) of Title 42.

(5) Definitions

(A) Application

For purposes of this subsection, the term “application” means an application submitted under subsection (b)(2) or (j) of this section or section 262(k) of Title 42.

(B) Petition

For purposes of this subsection, other than paragraph (1)(A)(i), the term “petition” means a request described in paragraph (1)(A)(i).

(r) Postmarket drug safety information for patients and providers

(1) Establishment

Not later than 1 year after September 27, 2007, the Secretary shall improve the transparency of information about drugs and allow patients and health care providers better access to information about drugs by developing and maintaining an Internet Web site that--
(A) provides links to drug safety information listed in paragraph (2) for prescription drugs that are approved under this section or licensed under section 262 of Title 42; and

(B) improves communication of drug safety information to patients and providers.

(2) Internet Web site

The Secretary shall carry out paragraph (1) by--

(A) developing and maintaining an accessible, consolidated Internet Web site with easily searchable drug safety information, including the information found on United States Government Internet Web sites, such as the United States National Library of Medicine's Daily Med and Medline Plus Web sites, in addition to other such Web sites maintained by the Secretary;

(B) ensuring that the information provided on the Internet Web site is comprehensive and includes, when available and appropriate--

(i) patient labeling and patient packaging inserts;

(ii) a link to a list of each drug, whether approved under this section or licensed under such section 262, for which a Medication Guide, as provided for under part 208 of title 21, Code of Federal Regulations (or any successor regulations), is required;

(iii) a link to the registry and results data bank provided for under subsections (i) and (j) of section 282 of Title 42;

(iv) the most recent safety information and alerts issued by the Food and Drug Administration for drugs approved by the Secretary under this section, such as product recalls, warning letters, and import alerts;

(v) publicly available information about implemented RiskMAPs and risk evaluation and mitigation strategies under subsection (o);

(vi) guidance documents and regulations related to drug safety; and

(vii) other material determined appropriate by the Secretary;

(C) providing access to summaries of the assessed and aggregated data collected from the active surveillance infrastructure under subsection (k)(3) to provide information of known and serious side-effects for drugs approved under this section or licensed under such section 262;
(D) preparing and making publicly available on the Internet website established under paragraph (1) best practices for drug safety surveillance activities for drugs approved under this section or section 262 of Title 42;

(E) enabling patients, providers, and drug sponsors to submit adverse event reports through the Internet Web site;

(F) providing educational materials for patients and providers about the appropriate means of disposing of expired, damaged, or unusable medications; and

(G) supporting initiatives that the Secretary determines to be useful to fulfill the purposes of the Internet Web site.

(3) Posting of drug labeling

The Secretary shall post on the Internet Web site established under paragraph (1) the approved professional labeling and any required patient labeling of a drug approved under this section or licensed under such section 262 not later than 21 days after the date the drug is approved or licensed, including in a supplemental application with respect to a labeling change.

(4) Private sector resources

To ensure development of the Internet Web site by the date described in paragraph (1), the Secretary may, on a temporary or permanent basis, implement systems or products developed by private entities.

(5) Authority for contracts

The Secretary may enter into contracts with public and private entities to fulfill the requirements of this subsection.

(6) Review

The Advisory Committee on Risk Communication under section 360bbb-6 of this title shall, on a regular basis, perform a comprehensive review and evaluation of the types of risk communication information provided on the Internet Web site established under paragraph (1) and, through other means, shall identify, clarify, and define the purposes and types of information available to facilitate the efficient flow of information to patients and providers, and shall recommend ways for the Food and Drug Administration to work with outside entities to help facilitate the dispensing of risk communication information to patients and providers.

(5) Referral to advisory committee

The Secretary shall--

(1) refer a drug or biological product to a Food and Drug Administration advisory committee for review at a meeting of such advisory committee prior to the approval of such drug or biological if it is--
(A) a drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under this section; or

(B) a biological product, no active ingredient of which has been approved in any other application under section 262 of Title 42; or

(2) if the Secretary does not refer a drug or biological product described in paragraph (1) to a Food and Drug Administration advisory committee prior to such approval, provide in the action letter on the application for the drug or biological product a summary of the reasons why the Secretary did not refer the drug or biological product to an advisory committee prior to approval.

(t) Database for authorized generic drugs

(1) In general

(A) Publication

The Commissioner shall--

(i) not later than 9 months after September 27, 2007, publish a complete list on the Internet Web site of the Food and Drug Administration of all authorized generic drugs (including drug trade name, brand company manufacturer, and the date the authorized generic drug entered the market); and

(ii) update the list quarterly to include each authorized generic drug included in an annual report submitted to the Secretary by the sponsor of a listed drug during the preceding 3-month period.

(B) Notification

The Commissioner shall notify relevant Federal agencies, including the Centers for Medicare & Medicaid Services and the Federal Trade Commission, when the Commissioner first publishes the information described in subparagraph (A) that the information has been published and that the information will be updated quarterly.

(2) Inclusion

The Commissioner shall include in the list described in paragraph (1) each authorized generic drug included in an annual report submitted to the Secretary by the sponsor of a listed drug after January 1, 1999.

(3) Authorized generic drug

In this section, the term “authorized generic drug” means a listed drug (as that term is used in subsection (j)) that--
(A) has been approved under subsection (c); and

(B) is marketed, sold, or distributed directly or indirectly to retail class of trade under a different labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trade mark than the listed drug.

(u) Certain drugs containing single enantiomers

(1) In general

For purposes of subsections (c)(3)(E)(ii) and (j)(5)(F)(ii), if an application is submitted under subsection (b) for a non-racemic drug containing as an active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) a single enantiomer that is contained in a racemic drug approved in another application under subsection (b), the applicant may, in the application for such non-racemic drug, elect to have the single enantiomer not be considered the same active moiety as that contained in the approved racemic drug, if--

(A) the single enantiomer has not been previously approved except in the approved racemic drug; and

(ii) the application submitted under subsection (b) for such non-racemic drug--

(I) includes full reports of new clinical investigations (other than bioavailability studies)--

(aa) necessary for the approval of the application under subsections (c) and (d); and

(bb) conducted or sponsored by the applicant; and

(II) does not rely on any clinical investigations that are part of an application submitted under subsection (b) for approval of the approved racemic drug; and

(B) the application submitted under subsection (b) for such non-racemic drug is not submitted for approval of a condition of use--

(i) in a therapeutic category in which the approved racemic drug has been approved; or

(ii) for which any other enantiomer of the racemic drug has been approved.

(2) Limitation
(A) No approval in certain therapeutic categories

Until the date that is 10 years after the date of approval of a non-racemic drug described in paragraph (1) and with respect to which the applicant has made the election provided for by such paragraph, the Secretary shall not approve such non-racemic drug for any condition of use in the therapeutic category in which the racemic drug has been approved.

(B) Labeling

If applicable, the labeling of a non-racemic drug described in paragraph (1) and with respect to which the applicant has made the election provided for by such paragraph shall include a statement that the non-racemic drug is not approved, and has not been shown to be safe and effective, for any condition of use of the racemic drug.

(3) Definition

(A) In general

For purposes of this subsection, the term “therapeutic category” means a therapeutic category identified in the list developed by the United States Pharmacopeia pursuant to section 1395w-104(b)(3)(C)(ii) of Title 42 and as in effect on September 27, 2007.

(B) Publication by Secretary

The Secretary shall publish the list described in subparagraph (A) and may amend such list by regulation.

(4) Availability

The election referred to in paragraph (1) may be made only in an application that is submitted to the Secretary after September 27, 2007, and before October 1, 2022.

(v) Antibiotic drugs submitted before November 21, 1997

(1) Antibiotic drugs approved before November 21, 1997

(A) In general

Notwithstanding any provision of the Food and Drug Administration Modernization Act of 1997 or any other provision of law, a sponsor of a drug that is the subject of an application described in subparagraph (B)(i) shall be eligible for, with respect to the drug, the 3-year exclusivity period referred to under clauses (iii) and (iv) of subsection (c)(3)(E) and under clauses (iii) and (iv) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable.

(B) Application; antibiotic drug described
(i) Application

An application described in this clause is an application for marketing submitted under this section after October 8, 2008, in which the drug that is the subject of the application contains an antibiotic drug described in clause (ii).

(ii) Antibiotic drug

An antibiotic drug described in this clause is an antibiotic drug that was the subject of an application approved by the Secretary under section 357 of this title (as in effect before November 21, 1997).

(2) Antibiotic drugs submitted before November 21, 1997, but not approved

(A) In general

Notwithstanding any provision of the Food and Drug Administration Modernization Act of 1997 or any other provision of law, a sponsor of a drug that is the subject of an application described in subparagraph (B)(i) may elect to be eligible for, with respect to the drug--

(i)(I) the 3-year exclusivity period referred to under clauses (iii) and (iv) of subsection (c)(3)(E) and under clauses (iii) and (iv) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable; and

(II) the 5-year exclusivity period referred to under clause (ii) of subsection (c)(3)(E) and under clause (ii) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable; or

(ii) a patent term extension under section 156 of Title 35, subject to the requirements of such section.

(B) Application; antibiotic drug described

(i) Application

An application described in this clause is an application for marketing submitted under this section after October 8, 2008, in which the drug that is the subject of the application contains an antibiotic drug described in clause (ii).

(ii) Antibiotic drug

An antibiotic drug described in this clause is an antibiotic drug that was the subject of 1 or more applications received by the Secretary under section 357 of this title (as in effect before November 21, 1997), none of which was approved by the Secretary under such section.

(3) Limitations
(A) Exclusivities and extensions

Paragraphs (1)(A) and (2)(A) shall not be construed to entitle a drug that is the subject of an approved application described in subparagraphs 5 (1)(B)(i) or (2)(B)(i), as applicable, to any market exclusivities or patent extensions other than those exclusivities or extensions described in paragraph (1)(A) or (2)(A).

(B) Conditions of use

Paragraphs (1)(A) and (2)(A)(i) shall not apply to any condition of use for which the drug referred to in subparagraph (1)(B)(i) or (2)(B)(i), as applicable, was approved before October 8, 2008.

(4) Application of certain provisions

Notwithstanding section 125, or any other provision, of the Food and Drug Administration Modernization Act of 1997, or any other provision of law, and subject to the limitations in paragraphs (1), (2), and (3), the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 shall apply to any drug subject to paragraph (1) or any drug with respect to which an election is made under paragraph (2)(A).

(w) Deadline for determination on certain petitions

The Secretary shall issue a final, substantive determination on a petition submitted pursuant to subsection (b) of section 314.161 of title 21, Code of Federal Regulations (or any successor regulations), no later than 270 days after the date the petition is submitted.

(x) Date of approval in the case of recommended controls under the CSA

(1) In general

In the case of an application under subsection (b) with respect to a drug for which the Secretary provides notice to the sponsor that the Secretary intends to issue a scientific and medical evaluation and recommend controls under the Controlled Substances Act, approval of such application shall not take effect until the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.

(2) Date of approval

For purposes of this section, with respect to an application described in paragraph (1), the term “date of approval” shall mean the later of--

(A) the date an application under subsection (b) is approved under subsection (c); or

(B) the date of issuance of the interim final rule controlling the drug.
§ 355. New drugs, 21 USCA § 355

(y) Contrast agents intended for use with applicable medical imaging devices

(1) In general

The sponsor of a contrast agent for which an application has been approved under this section may submit a supplement to the application seeking approval for a new use following the authorization of a premarket submission for an applicable medical imaging device for that use with the contrast agent pursuant to section 360j(p)(1) of this title.

(2) Review of supplement

In reviewing a supplement submitted under this subsection, the agency center charged with the premarket review of drugs may--

(A) consult with the center charged with the premarket review of devices; and

(B) review information and data submitted to the Secretary by the sponsor of an applicable medical imaging device pursuant to section 360e, 360(k), or 360c(f)(2) of this title so long as the sponsor of such applicable medical imaging device has provided to the sponsor of the contrast agent a right of reference.

(3) Definitions

For purposes of this subsection--

(A) the term “new use” means a use of a contrast agent that is described in the approved labeling of an applicable medical imaging device described in section 360j(p) of this title, but that is not described in the approved labeling of the contrast agent; and

(B) the terms “applicable medical imaging device” and “contrast agent” have the meanings given such terms in section 360j(p) of this title.

CREDIT(S)

§ 355. New drugs, 21 USCA § 355


Footnotes

1 So in original. Probably should be “bioavailability”.

2 So in original. Probably should be “drug.”.

3 So in original. Probably should be preceded by “the”.

4 So in original. The word “and” probably should not appear.

5 So in original. Probably should be “subparagraph”.

21 U.S.C.A. § 355, 21 USCA § 355
Current through P.L. 117-148. Some statute sections may be more current, see credits for details

Synopsis

Background: Federal Trade Commission (FTC) alleged that settlement between generic drug manufacturer and manufacturer of brand name drug was unfair method of competition under FTC Act and unreasonable restraint on trade under Sherman Act. Administrative law judge determined that agreement restricted competition but nevertheless was lawful because its pro-competitive benefits outweighed anticompetitive effects. FTC reviewed that determination de novo and found that generic drug manufacturer did not show that settlement had any pro-competitive benefits and it determined that purported benefits generic manufacturer identified could have been achieved through less restrictive agreement, but it only issued cease-and-desist order enjoining it from entering into similar reverse payment settlements going forward, 2019 WL 1552939. Generic manufacturer petitioned for review.

Holdings: The Court of Appeals, Costa, Circuit Judge, held that:

- substantial evidence supported finding by FTC using rule-of-reason analysis that reverse payment settlement threatened competition in violation of Sherman Act, and
- substantial evidence supported conclusion that manufacturer of brand name drug would have agreed to less restrictive settlement with generic drug manufacturer.

Petition denied.

Procedural Posture(s): Review of Administrative Decision.


Attorneys and Law Firms

Jay P. Lefkowitz, Kirkland & Ellis, L.L.P., New York, NY, for Petitioner.


Christopher L. Coffin, Pendley, Baudin & Coffin, L.L.P., New Orleans, LA, for Amicus Curiae Open Markets Institute.
2021-1 Trade Cases P 81,612

Jonathan D. Janow, Buchanan Ingersoll & Rooney, P.C., Washington, DC, for Amicus Curiae Association for Accessible Medicines.


Richard M. Brunell, Hilliard & Shadowen, L.L.P., Austin, TX, for Amici Curiae American Antitrust Institute, Public Knowledge, Patients for Affordable Drugs.

Maame Gyamfi, AARP Foundation Litigation, Washington, DC, for Amici Curiae American Association of Retired Persons, American Association of Retired Persons Foundation.

Michael Carrier, Rutgers University of New Jersey School of Law, Camden, NJ, for Amici Curiae 82 Law, Economics, Business and Medical Professors.

Before Southwick, Costa, and Duncan, Circuit Judges.

Opinion

Gregg Costa, Circuit Judge:

Normally, when lawsuits settle the defendant pays the plaintiff. That makes sense as the defendant is the party accused of wrongdoing.

But when a generic drug is poised to enter the market and threaten the monopoly enjoyed by a brand-name pharmaceutical, federal law can incentivize a different type of settlement. The Hatch-Waxman Act delays the entry of the generic drug if the brand-drug manufacturer files a patent infringement suit against the generic. Those patent suits are sometimes settled with the brand-drug plaintiff paying the allegedly-infringing generic. In return for the payment, the generic agrees to delay its market entry beyond the date when the FDA would allow it to compete. The result is an extension of the brand drug's monopoly.

Given the counterintuitive flow of money in this scenario—to, rather than from, the alleged wrongdoer—such deals are called “reverse payment settlements.” The Supreme Court has held that these settlements that extend the brand drug's monopoly can have anticompetitive effects that violate the antitrust laws. *FTC v. Actavis*, 570 U.S. 136, 158, 133 S.Ct. 2223, 186 L.Ed.2d 343 (2013). Reverse payment settlements, however, are not automatically invalid; they are subject to the rule of reason. *Id.* at 159, 133 S.Ct. 2223.

In its first post-*Actavis* reverse payment case, the Federal Trade Commission charged Impax Laboratories with antitrust violations for accepting payments ultimately worth more than $100 million to delay the entry of its generic drug for more than two years. The resulting administrative hearing included testimony from 37 witnesses and over 1,200 exhibits. Based on that record, the Commission conducted a rule-of-reason analysis and unanimously concluded that Impax violated antitrust law.

2021-1 Trade Cases P 81,612

On appeal, we face a narrower task: determining whether the Commission committed any legal errors and whether substantial evidence supported its factual findings. Concluding that the Commission's ruling passes muster on both fronts, we DENY the petition for review.

I.

A.

Anyone who buys pharmaceuticals knows that generic drugs are cheaper than their brand counterparts. The first generic to enter the market typically costs 10 to 25 percent less than the branded drug; those discounts grow to between 50 and 80 percent once other generics enter.

To bring competition to the drug market, the Hatch-Waxman Act promotes entry for these generics. Actavis, 570 U.S. at 142, 133 S.Ct. 2223. Rather than undergoing the lengthy and costly approval process that a new drug faces, generics can file an Abbreviated New Drug Application with the Food and Drug Administration. Id. at 142, 133 S.Ct. 2223; 21 U.S.C. § 355(j). If the generic drug is biologically equivalent to a brand drug the FDA has already approved, then the generic can essentially “piggy-back on the pioneer's approval efforts.” Actavis, 570 U.S. at 142, 133 S.Ct. 2223; 21 U.S.C. § 355(j)(2)(A)(i)–(iv). The Act offers an additional carrot to the first generic applicant: it can market its generic drug for 180 days without competition from any other generic manufacturer. Actavis, 570 U.S. at 143–44, 133 S.Ct. 2223; 21 U.S.C. § 355(j)(5)(B)(iv). During this period of exclusivity, the newly approved generic only faces competition from the brand drug or a generic sold by the brand manufacturer. Actavis, 570 U.S. at 143–44, 133 S.Ct. 2223. In effect, the statute allows a duopoly during those 180 days. A first-to-file generic often realizes most of its profits, potentially “several hundred million dollars,” during this initial six-month period. Id. at 143, 133 S.Ct. 2223 (quoting C. Scott Hemphill, Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem, 81 N.Y.U. L. REV. 1553, 1579 (2006)).

Generic entry is not so easy when there is a patent for the brand drug. The Hatch-Waxman Act also addresses this common situation. If the brand manufacturer asserts a patent in its initial drug application, then the generic manufacturer must certify in its application that the patent is invalid or that its drug will not infringe the patent. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). If the brand manufacturer disagrees (it likely will), it may file a patent infringement suit. 35 U.S.C. § 271(e)(2)(A). And if it does so within 45 days, the FDA is stayed from approving the generic application until either 30 months have passed or the patent litigation concludes. 21 U.S.C. § 355(j)(5)(B)(iii); see also Actavis, 570 U.S. at 143, 133 S.Ct. 2223 (describing these procedures). This delay for the first generic's entry also postpones the potential entry of other generics. They must wait for the same 30-month stay and then for the expiration of the first generic's 6-month exclusivity period before entering the market.

What happens if the patent suit against the first generic settles? The brand manufacturer no longer faces an immediate threat of competition from new generic entrants. The 30-month statutory stay restarts if the brand maker brings a patent suit against another generic that wishes to enter the market. Actavis, 570 U.S. at 155, 133 S.Ct. 2223 (citing 21 U.S.C. § 355(j)(5)(B)(iii)). Plus, any subsequent generic is not entitled to the exclusivity period. Id. That greatly reduces the potential benefit of challenging the brand maker's patent. Id. (noting that subsequent generics “stand to win significantly less than the first if they bring a successful” challenge to the patent).

These features of the Hatch-Waxman Act—the period of exclusivity for the first generic; the 30-month stay of the generic's FDA application when the brand maker sues for infringement; and the reduced incentive a subsequent generic has to challenge the brand maker's patent—can lead the brand maker to pay large sums for delaying entry of the first generic maker. Actavis, 570 U.S. at 155, 133 S.Ct. 2223 (recognizing that these Hatch-Waxman “features together mean that a reverse payment settlement with the
first filer ... “removes from consideration the most motivated challenger, and the one closest to introducing competition” (quoting Hemphill, Paying for Delay, supra, at 1586)).

B.

The facts of this case show those incentives in action. The drug at issue is a type of oxymorphone, which is an opioid. Endo, the brand-name drug maker in this case, started selling an extended-release formulation of oxymorphone called Opana ER in 2006. An extended-release pain reliever provides medication to the bloodstream over several hours, as opposed to immediate-release opioids which are short-acting. When it entered the market, Opana ER was the only extended-release version of oxymorphone.

In late 2007, Impax filed the first application to market generic extended-release oxymorphone. The application did not result in prompt approval of the generic, however, because Endo held patents for Opana ER that would not expire until 2013. Endo sued Impax for patent infringement in January 2008, delaying any FDA approval of the generic for 30 months—until June 2010—unless the litigation concluded earlier.

Early settlement talks failed, with Endo rejecting Impax's proposed entry dates of January 2011, July 2011, December 2011, or January 2012.

The June 2010 expiration of the Hatch-Waxman stay loomed. Delaying Impax's entry beyond the stay period would save Endo millions. Endo had projected that generic entry would cut Opana ER sales by 85 percent within three months and cost it $100 million in revenue within six months.

But extending the period in which it could sell Opana ER without competition was just one of Endo's priorities. The drug maker had something else in the works: It planned to move consumers to a new brand-name drug that would not face competition for years. Endo would remove the original Opana ER from the market, replace it with a crush-resistant version of the drug, and obtain new patents to protect the reformulated drug. While Impax's generic would still eventually reach the market, it would not be therapeutically equivalent to Endo's new branded drug and thus pharmacists would not be able to automatically substitute the generic when filling prescriptions. This automatic substitution of brand drug prescriptions, promoted by state laws, is the primary driver of generic sales. So, if Endo succeeded in switching consumers to its reformulated drug, which would be just different enough from the original formulation to preclude substitution, the market for Impax's generic would shrink dramatically, preserving Endo's monopoly profits.

The success of this “product hop” depended on the reformulated Opana ER reaching the market sufficiently in advance of Impax's generic entry to allow patients to move away from the original drug before pharmacists started substituting the generic version. This transition period to the reformulated drug would take roughly six to nine months. A successful transition to the reformulated Opana ER before generic entry would mean millions to Endo. The company projected that the reformulated Opana ER would generate about $200 million in annual sales by 2016 if the market transitioned to the new drug before the generic entered. But if the generic launched first, then 2016 sales of the new formulation would fall to $10 million.

The date when Impax could start selling its generic was thus critical. The FDA tentatively approved Impax's application in May 2010. The Hatch-Waxman stay would expire the next month. There were signs that Impax was planning to launch its generic soon thereafter.
2021-1 Trade Cases P 81,612

With the possible launch date for generic entry imminent, Endo restarted settlement negotiations just three days after the FDA's tentative approval of the generic. The parties settled the patent litigation in June 2010, just a few days after the patent trial began and less than a week before the FDA fully approved Impax's application.

C.

Under the settlement, Impax agreed to delay launching its generic until January 1, 2013—two and a half years after Impax otherwise could have entered “at-risk.” In turn, Endo agreed to not market its own generic version of extended-release oxymorphone until Impax's 180-day Hatch-Waxman exclusivity period concluded in July 2013. Additionally, Endo agreed to pay Impax a credit if sales revenues for the original formulation of Opana ER fell by more than 50 percent between the dates of settlement and Impax's entry. This credit served as an insurance policy for Impax, preserving the value of the settlement in case Endo undermined the generic oxymorphone market by transitioning consumers to the reformulated Opana ER. Endo also provided Impax with a broad license to Endo's existing and future patents covering extended-release oxymorphone. Finally, Endo and Impax agreed to collaboratively develop a new Parkinson's disease treatment, with Endo paying Impax $10 million immediately and up to $30 million in additional payments contingent on achieving sufficient development and marketing progress.

Impax's delayed entry allowed Endo to execute the product hop. In March 2012, Endo introduced its reformulated drug and withdrew the original drug. It publicly stated that the original drug was unsafe, though the FDA later disagreed that safety concerns motivated the withdrawal. Predictably, the market for the original Opana ER shrivelled. So Endo had to pay Impax $102 million in credits. Endo subsequently succeeded in securing additional patents, and in 2015 and 2016 secured injunctions that prevented all manufacturers, including Impax, from marketing generic versions of the reformulated drug. But in 2017, the FDA asked Endo to voluntarily withdraw the reformulated Opana ER from the market due to safety concerns, and it did.

For its part, Impax began marketing original formulation generic oxymorphone in January 2013, despite the damaged market Endo left behind. Because of the injunctions Endo secured against other generics and because Endo eventually withdrew the reformulated Opana ER from the market, Impax's generic is the only extended-release oxymorphone available to consumers today.

D.

The FTC brought separate actions against Endo and Impax alleging that the settlement was an unfair method of competition under the FTC Act and an unreasonable restraint on trade under the Sherman Act. Endo settled. Impax fought the charge and successfully argued that the case should proceed in an administrative proceeding rather than in federal district court where the Commission had first filed.

An administrative law judge determined that the agreement restricted competition but was nevertheless lawful because its procompetitive benefits outweighed the anticompetitive effects. Reviewing both the facts and law de novo, 16 C.F.R. § 3.54(a), the Commission reached a different conclusion. It found that Impax had failed to show that the settlement had any procompetitive benefits. Moreover, it determined that the purported benefits Impax identified could have been achieved through a less restrictive agreement. The Commission did not impose any monetary sanctions. It did not even invalidate Impax's agreements with Endo or other drug makers. Instead, it issued a cease-and-desist order enjoining Impax from entering into similar reverse payment settlements going forward.
Impax now petitions for review of the FTC's order.

II.

We review the Commission's ruling, not the ALJ's. *N. Tex. Specialty Physicians v. FTC*, 528 F.3d 346, 354 (5th Cir. 2008); *cf. Shaikh v. Holder*, 588 F.3d 861, 863 (5th Cir. 2009) (noting that we review the decision of the BIA in immigration cases). Any legal conclusions are reviewed *de novo*, though we “are to give some deference to the [FTC]’s informed judgment that a particular commercial practice is to be condemned as ‘unfair.’” *N. Tex. Specialty*, 528 F.3d at 354 (quoting *FTC v. Ind. Fed’n of Dentists*, 476 U.S. 447, 454, 106 S.Ct. 2009, 90 L.Ed.2d 445 (1986)).

The “findings of the Commission as to the facts, if supported by evidence, shall be conclusive.” 15 U.S.C. § 45(c). That statutory command is “essentially identical” to the substantial-evidence standard that often governs judicial review of agency factfinding. *492 Ind. Fed’n of Dentists*, 476 U.S. at 345, 106 S.Ct. 2009. Substantial evidence is “such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.” *Id.* (quoting *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 477, 71 S.Ct. 456, 95 L.Ed. 456 (1951)). We must accept findings supported by such evidence “even if suggested alternative conclusions may be equally or even more reasonable and persuasive.” *N. Tex. Specialty*, 528 F.3d at 354 (quoting *Colonial Stores, Inc. v. FTC*, 450 F.2d 733, 739 (5th Cir. 1971)). This deferential review should be no more searching than if we were evaluating a jury’s verdict. See *District of Columbia v. Pace*, 320 U.S. 698, 702, 64 S.Ct. 406, 88 L.Ed. 408 (1944) (explaining that substantial evidence review is less intrusive than clear error review); 3 *STEVEN ALAN CHILDRESS & MARTHA S. DAVIS, FEDERAL STANDARDS OF REVIEW § 15.04 (same); Robert L. Stern, Review of Findings of Administrators, Judges and Juries: A Comparative Analysis, 58 HARV. L. REV. 70, 84–86 (1944) (analyzing Justice Jackson’s opinion in *Pace*).

III.

A reverse payment settlement is a settlement of patent litigation in which the patentholder gives the alleged infringer cash or other valuable services or property and the alleged infringer agrees not to market its allegedly infringing product until some later date. See *Actavis*, 570 U.S. at 140, 133 S.Ct. 2223. These horizontal agreements unlawfully restrain trade, see 15 U.S.C. § 1, if they cause anticompetitive effects that outweigh any procompetitive benefits. *3 See Actavis*, 570 U.S. at 156–59, 133 S.Ct. 2223.

This rule-of-reason inquiry uses a burden-shifting framework. See *Ohio v. Am. Express*, — U.S. —–, 138 S. Ct. 2274, 2284, 201 L.Ed.2d 678 (2018). The initial burden is on the FTC to show anticompetitive effects. *Id.* If the FTC succeeds in doing so, the burden shifts to Impax to demonstrate that the restraint produced procompetitive benefits. *Id.* If Impax successfully proves procompetitive benefits, then the FTC can demonstrate that any procompetitive effects could be achieved through less anticompetitive means. *Id.* Finally, if the FTC fails to demonstrate a less restrictive alternative way to achieve the procompetitive benefits, the court must balance the anticompetitive and procompetitive effects of the restraint. *Apani Sw., Inc. v. Coca-Cola Enters., Inc.*, 300 F.3d 620, 627 (5th Cir. 2002). If the anticompetitive harms outweigh the procompetitive benefits, then the agreement is illegal. *Id.*

A.

The first question is whether the agreement caused anticompetitive effects or “created the potential for anticompetitive effects.” *Doctor's Hosp. of Jefferson, Inc. v. Se. Med. All., Inc.*, 123 F.3d 301, 310 (5th Cir. 1997); accord *Retractable Techs, Inc. v. Becton Dickinson & Co.*, 842 F.3d 883, 895 (5th Cir. 2016) (noting that an antitrust plaintiff must show that a restraint “had the
potential to eliminate, or did in fact eliminate, competition"); see also *Actavis*, 570 U.S. at 157, 133 S.Ct. 2223 (noting that the “relevant anticompetitive harm” of a reverse payment settlement is “prevent[ing] the risk of competition”). Such effects may be proved “indirectly,” with “proof of market power *493 plus some evidence that the challenged restraint harms competition.”

Anticompetitive effects are those that harm consumers. Think increased prices, decreased output, or lower quality goods. *Id.*

Eliminating potential competition is, by definition, anticompetitive. See, e.g., *United States v. Falstaff Brewing Corp.*, 410 U.S. 526, 532–33, 93 S.Ct. 1096, 35 L.Ed.2d 475 (1973) (acquiring potential competitor was anticompetitive both because of current pressure of potential entry and potentially beneficial effects of future entry). Indeed, paying a potential competitor not to compete is so detrimental to competition that normally it is a *per se* violation of the antitrust laws. See *Palmer v. BRG of Ga.*, Inc., 498 U.S. 46, 48–49, 111 S.Ct. 401, 112 L.Ed.2d 349 (1990); see also *Blue Cross & Blue Shield United of Wis. v. Marshfield Clinic*, 65 F.3d 1406, 1415 (7th Cir. 1995) (Posner, C.J.) (suggesting that market allocation agreements are even more pernicious than price-fixing agreements because the former eliminates all forms of competition); Joshua P. Davis & Ryan J. McEwan, *Deactivating Actavis: The Clash Between the Supreme Court and (Some) Lower Courts*, 67 RUTGERS U.L. REV. 557, 559 (2015) (calling “an agreement between horizontal competitors not to compete, the *bête noir* of antitrust law”).

*Actavis* concluded that, in contrast to the typical horizontal agreement to divvy up markets, reverse payment settlements might produce both anti-and procompetitive effects. On the one hand, a brand maker’s paying a generic to delay entry “in effect amounts to a purchase by the patentee of the exclusive right to sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed by the generic product.” 570 U.S. at 153–54, 133 S.Ct. 2223. In fact, reverse payment settlements may restrict competition even more than typical market allocation agreements because delaying entry of the first generic does not just eliminate one competitor—it prolongs the “bottleneck” that delays entry of other generic competitors. *In re Nexium (Esomeprazole) Antitrust Lit.*, 842 F.3d 34, 41 (1st Cir. 2016).

But the existence of patent—a lawful monopoly if valid—points in the other direction. If the patent is valid, then unlike traditional market allocation agreements, a settlement that allows generic entry after the FDA’s approval of the drug but still earlier than the patent expiration date may result in more competition than would have existed absent the settlement. *Actavis*, 570 U.S. at 154, 133 S.Ct. 2223. Given the potentially countervailing impacts of reverse payment settlements, the Supreme Court applied the rule of reason rather than automatic invalidity. *Id.* at 159, 133 S.Ct. 2223.

At this first step of the rule-of-reason analysis, we are just focused on the anticompetitive side of the equation. *Actavis* held that a “large and unjustified” reverse payment creates a likelihood of “significant anticompetitive effects.” *Id.* at 158, 133 S.Ct. 2223. “[T]he likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor’s anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.” *Id.* at 159, 133 S.Ct. 2223.

*494* In many reverse payment cases, the central dispute is whether there was in fact a reverse payment. HERBERT HOVENKAMP ET AL. IP & ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW § 16.01 (2018 Supp.); see, e.g., *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 550–51 (1st Cir. 2016) (citing numerous post-*Actavis* case addressing whether nonmonetary benefits to a generic are reverse payments). The settling party will often contend that any settlement payments are for services rather than for delayed entry. *Id.* That is not the case here. Impax has not challenged the ALJ’s original determination “that a large reverse payment helped induce settlement or that the payment was linked to the January 2013 entry date.”

That concession makes sense in light of the valuable consideration Impax received in exchange for delaying entry. *5* We will note two significant items. First, Endo committed to not market an authorized generic, which increased Impax’s projected profits by $24.5 million. See *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, 394 (3d Cir. 2015) (holding
that brand manufacturer commitments to not market a generic drug during the 180-day exclusivity period are “payments” under Actavis); see also Loestrin 24 Fe Antitrust Litig., 814 F.3d at 549–53 (explaining that Actavis recognized that a reverse payment could include more than just an exchange of money). Second, Endo would pay Impax credits for the shrunken market the latter would inherit if, as expected, Endo timely executed the product hop to the reformulated Opana ER. The $102 million Endo ultimately paid is likely a good approximation of the parties’ expected value for these credits. The size of these payments is comparable to other cases where courts have inferred anticompetitive effect. See In re Wellbutrin XL Antitrust Lit. Indirect Purchaser Class, 868 F.3d 132, 162 (3d Cir. 2017) (holding that $233 million paid to three generic manufacturers is large under Actavis); Nexium, 842 F.3d at 50, 54 (acknowledging jury finding that a $300–$690 million payment was large); accord Actavis, 570 U.S. at 145, 133 S.Ct. 2223 (brand manufacturer agreed to pay three generic manufacturers $12 million, $60 million, and an estimated $171–270 million over nine years).

The Commission rejected the argument that just showing a large payment was enough to establish anticompetitive harm. It reasoned that “[e]stablishing that the payment is not otherwise justified is necessary for demonstrating that the payment is purchasing an exclusive right and preventing the risk of competition.” See also Actavis, 570 U.S. at 156, 133 S.Ct. 2223 (stating that “a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects” (emphasis added)).

But the Commission correctly found no such justification. A large reverse payment might be justified if it represents “avoided litigation costs or fair value for services.” Id. at 156, 133 S.Ct. 2223. That is not the case here. The FTC estimated the settlement saved Endo only $3 million in litigation expenses, an amount in the ballpark of the typical cost for litigating pharmaceutical patents. See FED. TRADE COMM’N, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT 111–12 & n.27 (2011) (estimating average costs in the $5–10 million range based on research from Morgan Stanley); Michael R. Herman, *495 Note, The Stay Dilemma: Examining Brand and Generic Incentives for Delaying the Resolution of Pharmaceutical Patent Litigation, 111 COLUM. L. REV. 1788, 1795 n.41 (2011) (noting that litigation expenses can bring the costs of generic entry to about $10 million). Nor did the agreement involve any services that the generic would provide to Endo that could otherwise justify the large payment. Only the services associated with the Parkinson's collaboration could plausibly provide an appropriate basis for the payments. But even assuming that the collaboration is relevant and that the $10 million Parkinson's research agreement constituted payment for services, over $100 million of Endo's payment remains unjustified.

This large and unjustified payment generated anticompetitive effects. The Commission explained that there “was a real threat of competition from Impax” snuffed out by Endo's agreement to make the reverse payments. The FDA had just approved Impax's generic, allowing it to sell the drug. Impax had taken steps to do so, even though its market entry would be “at risk” of infringement liability. Endo's known product-hop plans increased Impax's incentive to quickly enter the market. The Commission thus had substantial evidence to conclude that the reverse payments replaced the “possibility of competition with the certainty of none.”

Impax argues that the Commission needed to do more at this first stage of the rule of reason. Its principal attack on the finding of anticompetitive effect is that the Commission needed to evaluate “the patent's strength, which is the expected likelihood of the brand manufacturer winning the litigation.” Impax reasons that if it was highly likely that Endo would win the patent suit, then the reverse payment was not anticompetitive because it allowed the generic to enter the market before the patent expired.

We disagree that Actavis requires the Commission to assess the likely outcome of the patent case in order to find anticompetitive effects. The fact that generic competition was possible, and that Endo was willing to pay a large amount to prevent that risk, is enough to infer anticompetitive effect. Actavis, 570 U.S. at 157, 133 S.Ct. 2223. In fact, Actavis squarely rejected Impax's argument: “[T]he size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself.” Id. at 158, 133 S.Ct. 2223; see also id. at 157, 133 S.Ct. 2223 (“[I]t is normally not necessary to litigate patent validity to answer the antitrust question.”); id. at 158, 133

2021-1 Trade Cases P 81,612

S.Ct. 2223 (reiterating that a court can assess the anticompetitiveness of a reverse payment “without litigating the validity of the patent”); id. at 159, 133 S.Ct. 2223 (stating yet again that the Commission need not “litigate the patent's validity” to establish anticompetitive effects). The idea is that a large reverse payment “itself would normally suggest that the patentee has serious doubts about the patent's survival.” Id. at 157, 133 S.Ct. 2223; see also HOVENKAMP, supra, § 16.01[D] (explaining that a sizeable reverse payment “raise[s] a strong inference that that the parties believed ex ante that there was a significant chance that the patent was invalid”).

Consider this settlement. If the parties thought Endo was highly likely to win the infringement suit, then Impax would have been happy with a deal giving it nothing more than entry months in advance of the likely-valid patent's expiration. Cf. In re Cipro Cases I & II, 61 Cal.4th 116, 187 Cal.Rptr.3d 632, 348 P.3d 845, 865 (2015) (noting that a settlement postponing market entry, but not accompanied by a reverse payment, would be a “fair approximation” of the strength of the patent suit). Reverse payments potentially worth nine figures would have been a windfall. The need to add that substantial enticement indicates that at least some portion of that payment is “for exclusion beyond the point that would have resulted, on average, from simply litigating the case to its conclusion.” Id., 187 Cal.Rptr.3d 632, 348 P.3d at 867; see also In re Aggrenox Antitrust Lit., 94 F. Supp. 3d 224, 240–41 (D. Conn. 2015) (explaining that a plaintiff need not prove that the patent was weak because a “large and unjustified reverse-payment” can show that the parties perceived weakness with the patent that would have made earlier entry likely). “And that fact, in turn, suggests that the payment's objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market—the very anticompetitive consequence that underlies the claim of antitrust unlawfulness.” Actavis, 570 U.S. at 157, 133 S.Ct. 2223 (emphasis added). 6

Impax also argues that the settlement does not look anticompetitive in hindsight. After all, since the settlement Endo has obtained more patents for Opana ER and proven their validity in court. On top of that, the product hop ended up failing once Endo had to take reformulated Opana ER off the market due to safety concerns. So Impax's generic is now the only version of Opana ER on the market.

But it is a basic antitrust principle that the impact of an agreement on competition is assessed as of “the time it was adopted.” See Polk Bros. v. Forest City Enters., 776 F.2d 185, 189 (7th Cir. 1985) (Easterbrook, J.); see also FTC & DOJ, ANTITRUST GUIDELINES FOR COLLABORATIONS AMONG COMPETITORS § 2.4 (2000) (stating that the agencies “assess the competitive effects of a relevant agreement as of the time of possible harm to competition”). That approach also makes sense in reverse payment cases. Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1306 (11th Cir. 2003) (refusing to consider postagreement invalidation of patent because “reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into”); Cipro, 187 Cal.Rptr.3d 632, 348 P.3d at 870 (“Just as later invalidation of a patent does not prove an agreement when made was anticompetitive, later evidence of validity will not automatically demonstrate an agreement was procompetitive.”); 12 PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 2046e1, at 399 (4th ed. 2019) (explaining that the “reasonableness of a patent settlement agreement cannot be made to depend on an ex post determination” of validity or infringement).

So the focus is on the following facts as they existed when the parties adopted the settlement. Endo agreed to make large payments to the company that was allegedly infringing its patents. In exchange, Impax agreed to delay entry of its generic drug until two-and-a-half years after the FDA approved the drug. Neither the saved costs of forgoing a trial nor any services Endo received justified these payments. Substantial evidence supports the Commissions’ finding that the reverse payment settlement threatened competition.

B.
C.

A restraint is unreasonable when any procompetitive benefits it produces “could be reasonably achieved through less anticompetitive means.” *Am. Express*, 138 S. Ct. at 2284; see generally 11 AREEDA & HOVENKAMP, *supra*, ¶ 1913, at 395–402; C. Scott Hemphill, *Less Restrictive Alternatives in Antitrust Law*, 116 COLUM. L. REV. 927, 937–42 (2016). The concept traces back to then-Circuit Judge Taft's opinion in *United States v. Addyston Pipe & Steel Co*. Hemphill, *Less Restrictive, supra*, at 938 & n.53 (citing 85 F. 271, 282 (6th Cir. 1898) (holding that a restraint of trade is unenforceable unless it is “ancillary to the main purpose of a lawful contract[ ] and necessary to protect the covenantee[’s] ... enjoyment of the legitimate fruits of the contract” (emphasis added))). The less-restrictive-alternative standard applies across a range of antitrust claims and is included in model antitrust jury instructions. *Id. at 929, 938 & n.50* (citing ABA SECTION OF ANTITRUST LAW, MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES A-10 (2005)).

The idea is that it is unreasonable to justify a restraint of trade based on a purported benefit to competition if that same benefit could be achieved with less damage to competition. Focusing on the *498* existence of less restrictive alternatives may allow courts to avoid difficult balancing of anticompetitive and procompetitive effects and to “smoke out” anticompetitive effects or pretextual justifications for the restraint. Hemphill, *Less Restrictive, supra*, at 947–63. When a less restrictive alternative exists, a party’s decision to nonetheless engage in conduct “that harms consumers” likely results from a desire “to gain from the resulting consumer harm.” *Id. at 968*. The question, in short, is whether “the good [could] have been achieved equally well with less bad.” *Id. at 929.*

*Actavis* recognizes the possibility of less restrictive alternatives to reverse payment settlements. The Court noted that parties to pharmaceutical patent litigation “may, as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without ... paying the challenger to stay out prior to that point.” 570 U.S. at 158, 133 S.Ct. 2223; see also 12 AREEDA & HOVENKAMP, *supra*, ¶ 2046c2, at 381–82 (observing that *Actavis* recognizes “that there are better, less anticompetitive ways to settle these disputes”).

The Commission found that Impax could have achieved just as much and likely more good (an entry date even earlier than 2013) without the bad (Endo's agreement not to sell a competing generic during the exclusivity period and to pay credits to Impax...
for the decline of the Opana ER market while Endo executed the product hop). The Commission explained that “[h]olding everything else equal, Impax's acceptance of payment would normally be expected to result in a later entry date than what Impax would have accepted based on the strength of the patents alone.” To support its view that Impax could have entered into a settlement without reverse payments that would have resulted in greater generic competition, the Commission relied on industry practice, economic analysis, expert testimony, and adverse credibility findings discounting the testimony of Impax's lead settlement negotiator.

“[T]he existence of a viable less restrictive alternative is ordinarily a question of fact.” 11 AREEDA & HOVENKAMP, supra, ¶ 1913b, at 398; accord O'Bannon v. NCAA, 802 F.3d 1049, 1074 (9th Cir. 2015) (applying clear-error review to district court's finding of less restrictive alternative). So the substantial deference we owe the Commission's factfinding kicks in, in particular on its determination that a no-payment settlement was feasible.

Impax nonetheless tries to lodge legal objections to the finding of a less restrictive alternative. First, it argues that the Commission only recognized what it considers an equally restrictive alternative—the possibility of a settlement with the same entry date but no reverse payments. But the Commission recognized the feasibility of no-payment settlements with both the same or an earlier entry date. Its ultimate ruling relied on an agreement with an earlier entry date as a less restrictive alternative: “A no-payment settlement allowing pre-2013 generic entry would have been a practical alternative for both Impax and Endo, but they chose instead to exchange sizeable payment for a later entry date.” (emphasis added). Impax does not dispute that an agreement with an earlier entry date would be less restrictive.

Impax does argue that the Commission “flipped the burden of proof” in finding that such a less restrictive settlement was feasible. We disagree. The Commission concluded that there was a “strong showing” of the possibility of less restrictive settlement, and only then asked whether Impax had rebutted that evidence. That is a normal way of evaluating whether a plaintiff has met its burden of persuasion.

So we turn to whether substantial evidence supports the Commission's conclusion that Complaint Counsel had established a less restrictive alternative. First is the fact that most settlements between brand and generic makers do not include reverse payments. The Commission relied on an expert witness who analyzed industry practice and studies showing that from 2004-2009 “only 30 percent of the patent settlements filed with the FTC involved both compensation from the branded firm to the generic firm and restrictions on generic entry.” In recent years, reverse payment settlements may have become even rarer; over 80 percent of brand-generic settlements reached within the year following Actavis did not include a reverse payment.

Impax suggests this evidence of industry practice is not probative of whether it had the opportunity to enter in a no-payment settlement. But leading scholars have recognized that other parties’ “actual experience in analogous situations” can help establish the feasibility or practicality of a less restrictive alternative. 11 AREEDA & HOVENKAMP, supra, ¶ 1913b, at 398; accord Hemphill, Less Restrictive, supra, at 984 (“One useful indicia of practicality is that the alternative has been implemented by this or other firms in similar circumstances.”); see also Ind. Fed’n of Dentists, 476 U.S. at 454, 106 S.Ct. 2009 (recognizing the FTC's expertise about commercial practices). Showing that the alternative is “rooted in real commercial experience” may be especially compelling as the defendant often will not want to acknowledge its willingness to enter into an arrangement that would not have included “the illicit profits arising from an anticompetitive effect.” Id. at 984–85; see also Kevin B. Soter, Note, Causation in Reverse Payment Antitrust Claims, 70 STAN. L. REV. 1295, 1336 (2018) (raising concerns about rules that would “tell[ ] defendants that all they need to do to avoid liability is to insist in settlement talks that the only agreement they would make is an illegal one”).

And the Commission did not rely on industry practice alone. It acknowledged but refused to credit the trial testimony of Impax's chief negotiator, who said that Endo was “adamant about preventing pre-2013 entry.” 9 The Commission noted that this resolute
trial testimony was inconsistent with the witness's prior statements that he could not remember discussing pre-2013 entry dates with Endo. In that earlier testimony, the negotiator said he could not remember if “Impax ever ‘tried to get a date earlier than January of 2013’ ” or whether “Endo ever told Impax that it would ‘not settle the litigation’ with an entry date before 2013.” Doubts about the negotiator's newfound certainty allowed the Commission not just to reject his testimony but also to treat it as evidence of the possibility of pre-2013 entry. See Reeves v. Sanderson Plumbing Prods., Inc., 530 U.S. 133, 147, 120 S.Ct. 2097, 147 L.Ed.2d 105 (2000) (discussing the “general principle of evidence law that the factfinder is entitled to consider a party's dishonesty about a material fact as 'affirmative evidence of guilt’ ”). The Commission further noted that while early on Impax had unsuccessfully sought entry dates during 2011 and even January 2012, a significant time gap exists between those proposed entry dates and the 2013 entry date in the final agreement. The professed failure to consider other possible 2012 entry dates thus casts doubt on the notion that an agreement with pre-2013 entry was unachievable. 10

Finally, economics support the Commission's finding that Endo would have entered into a settlement with an earlier entry date if it could have could have kept the more than $100 million it ended up paying Impax. Hemphill, Less Restrictive, supra, at 984 (recognizing that a plaintiff could use “expert testimony based on economic theory” to show a likelihood that the parties would have entered into a less restrictive alternative). If everything has a price, then those large payments were the price for Impax's delayed entry. King Drug, 791 F.3d at 405 n.23; Cipro, 187 Cal.Rptr.3d 632, 348 P.3d at 871. Such “fairly obvious” observations can show the feasibility of a less restrictive alternative. 11 AREEDA & HOVENKAMP, supra, ¶ 1913b, at 398; see also Ind. Fed'n of Dentists, 476 U.S. at 454, 106 S.Ct. 2009 (holding that deference is due FTC's assessment of business practices).

Three evidentiary legs—industry practice, credibility determinations about settlement negotiations, and economic analysis—thus supported the Commission's conclusion that Endo would have agreed to a less restrictive settlement. 11 AREEDA & HOVENKAMP, supra, ¶ 1914c, at 410 (stating that a finding of less restrictive alternative should be based on alternatives “that are either quite obvious or a proven success”). As for Impax's side of things, of course it would have preferred the settlement that paid it over $100 million. But any reluctance Impax had to agree to a no-payment settlement based on a “desire to share in monopoly rents” cannot undermine the Commission's finding that a less restrictive settlement was viable. See Hemphill, Less Restrictive, supra, at 984–85; see also Soter, supra, at 1336.

Our question is not whether the Commission could have reached a different result on the less-restrictive-alternative question. It is whether there was evidence that would allow a reasonable factfinder to conclude that a no-payment settlement was feasible. Ind. Fed'n of Dentists, 476 U.S. at 454, 106 S.Ct. 2009; see also Ripley v. Chater, 67 F.3d 552, 555 (5th Cir. 1995) (noting that substantial evidence can even be less than a preponderance). Because there was more than enough evidence to support that unanimous view of the Commissioners, we must uphold their view that a less restrictive alternative was viable. And that means the reverse payment settlement was an agreement to preserve and split monopoly profits that was not necessary to allow generic competition before the expiration of Endo's patent. As a result, Impax agreed to an unreasonable restraint of trade.

* * *

The petition for review is DENIED.

All Citations

994 F.3d 484, 2021-1 Trade Cases P 81,612
Footnotes


2 If Impax entered the market before resolution of the patent litigation, it would risk paying any damages for its sales in the event Endo later proved infringement. This is called “at risk” entry. See In re Lipitor Antitrust Lit., 868 F.3d 231, 241 (3d Cir. 2017).

3 Reverse-payment settlements are also sometimes called “pay for delay” agreements. See FTC v. Watson Pharms., Inc., 677 F.3d 1298, 1301 (11th Cir. 2012), rev’d sub nom. FTC v. Actavis, 570 U.S. 136, 133 S.Ct. 2223, 186 L.Ed.2d 343 (2013). Following the Supreme Court's lead, we use the term “reverse payment.”

4 The FTC required that showing of market power to show potential anticompetitive effect under Actavis. Impax does not argue that it lacked market power—it held a patent after all—so we need not address that issue further.

5 The Commission also considered the payments to Impax for the Parkinson's research and the licenses Endo granted Impax.

6 In addition to crediting these economic implications of a large reverse payment, the Supreme Court recognized the difficulty of trying a patent case within an antitrust case. Actavis, 570 U.S. at 157, 133 S.Ct. 2223 (discussing the Eleventh Circuit's concern with “litigat[ing] patent validity” in an antitrust case, but explaining that is not needed for antitrust scrutiny). An Eleventh Circuit colleague apparently familiar with Cajun cuisine called this the “turducken” problem. Watson, 677 F.3d at 1315.

7 The Fifth Circuit Pattern Jury Instructions does not include circuit-specific antitrust instructions, but refer courts and parties to two sources, including the ABA Antitrust Section's proposed instructions. FIFTH CIRCUIT PATTERN JURY INSTRUCTIONS (CIVIL CASES) § 6 (2020).

8 Even if Impax's entry date were the same in a no-payment settlement, the arrangement would be less anticompetitive than the actual agreement because it would not include Endo's “payment” of not selling a generic competitor during Impax's six-month exclusivity period. Thus, in a no-payment settlement, there would have been greater price competition during at least those six months. In any event, because the Commission's ultimate finding relied on the feasibility of a no-payment settlement with an earlier entry date, we only consider that agreement as a less restrictive alternative.

9 The Commission's consideration of this testimony further dispels Impax's claim that the Commission did not find a settlement with an earlier entry date to be a viable alternative.

10 The case-specific nature of this aspect of the FTC's ruling undermines Impax's concern that the agency's decision would invalidate all reverse payment settlements. So does the FTC's enforcement record. During the first fifteen years of this century, the agency challenged only 6 of the 1336 brand/generic settlements entered into during that period. FTC BUREAU OF COMPETITION, OVERVIEW OF AGREEMENTS FILED IN FY 2016, at 4.
IN RE: NEXIUM (ESOMEPRAZOLE) ANTITRUST LITIGATION

American Sales Company, LLC, on behalf of itself and all others similarly situated; Value Drug Company; Burlington Drug Company Inc.; Rochester Drug Co-Operative, Inc., on behalf of itself and others similarly situated; Meijer, Inc.; Meijer Distribution, Inc.; Allied Services Division Welfare Fund; Laborers International Union of North America Local 17 Health Care Fund; Laborers International Union of North America Local 35 Health Care Fund; A.F. of L.–A.G.C. Building Trades Welfare Plan; Fraternal Order of Police Miami Lodge 20 Insurance Trust Fund; New York Hotel Trades Council and Hotel Assoc. of New York City, Inc. Health Benefits Fund; United Food & Commercial Workers Unions and Employers Midwest Health Benefits Fund; Michigan Regional Council of Carpenters Employee Benefits Fund; International Union of Machinists and Aerospace Workers Workers District No. 15 Health Fund; International Brotherhood of Electrical Workers Local 595 Health and Welfare Fund; Walgreen Co.; The Kroger Company; Safeway Incorporated; Supervalu, Inc.; Heb Grocery Co. LP; Giant Eagle, Inc.; Rite Aid Corporation; Rite Aid Headquarters Corporation; JCG (PJC) USA, LLC; Maxi Drug, Inc., d/b/a Brooks Pharmacy; Eckerd Corporation; CVS, Inc., Plaintiffs, Appellants,

v.

AstraZeneca LP; AstraZeneca AB; Aktiebolaget Hassle; Ranbaxy Pharmaceuticals Inc.; Ranbaxy Inc.; Ranbaxy Laboratories Ltd., Defendants, Appellees.


November 21, 2016

Rehearing En Banc Denied January 10, 2017

Synopsis

Background: In multidistrict litigation, class of wholesale drug distributors/direct purchaser plaintiffs, class of individual consumers, third-party payors, union plan sponsors, and certain insurance companies/end-payors, and a number of pharmaceutical retail outlets brought claims against manufacturer of popular brand of medication used to treat heartburn and three manufacturers of generic version of drug for alleged violations of federal and state antitrust laws arising from settlement agreement to delay launch date of generic drug. Following partial grant of summary judgment in favor of manufacturers, 42 F.Supp.3d 231, jury trial was held, and judgment was entered for defendants. Plaintiffs filed motions for a new trial and for permanent injunction. The United States District Court for the District of Massachusetts, William G. Young, J., 309 F.R.D. 107, denied motions. Plaintiffs appealed.

Holdings: The Court of Appeals, Lynch, Circuit Judge, held that:

it was within district court's discretion to exclude study which purported to use econometric analysis of stock market's reaction to actual settlement to estimate objective entry date without reverse payment, and expert's corresponding testimony;

any errors in excluding expert's testimony on purpose and effect of side deals between manufacturers were harmless;
it was within district court's discretion to exclude plaintiffs' proffered rebuttal evidence regarding date on which generic launch would have occurred but for reverse payment;

evidence was insufficient to establish existence of one overarching Sherman Act antitrust conspiracy; and
district court's error, if any, in cutting off at summary judgment of causal mechanisms through which plaintiffs could have proved antitrust causation theory to a jury, was harmless.

Affirmed.

Procedural Posture(s): On Appeal.

Appeals from the United States District Court for the District of Massachusetts, [Hon. William G. Young, U.S. District Judge]

Attorneys and Law Firms


Kannon K. Shanmugam, with whom Dane H. Butswinkas, Paul B. Gaffney, John E. Schmidtlein, and Williams & Connolly LLP, Washington, DC, were on brief, for appellees AstraZeneca LP, AstraZeneca AB, and Aktiebolaget Hassle.

Jay P. Lefkowitz, P.C., with whom Steven J. Menashi, Amanda Elbogen, New York, NY, Jonathan D. Janow, Kirkland & Ellis LLP, James Douglas Baldridge, Lisa Jose Fales, Danielle R. Foley, Vincent E. Verrocchio, and Venable LLP, Washington, DC, were on brief, for appellees Ranbaxy Inc., Ranbaxy Pharmaceuticals Inc., and Ranbaxy Laboratories Ltd.

Mark S. Hegedus, Attorney, Office of the General Counsel, Federal Trade Commission, Deborah L. Feinstein, Director, Markus H. Meier, Acting Deputy Director, Bradley S. Albert, Deputy Assistant Director, Elizabeth R. Hilder, Attorney, Bureau of Competition, Daniel W. Butrymowicz, Attorney, Bureau of Competition, Jonathan E. Nuechterlein, General Counsel, and Joel Marcus, Director of Litigation, on brief for Federal Trade Commission, amicus curiae.

Before Lynch, Stahl, and Thompson, Circuit Judges.

Opinion

LYNCH, Circuit Judge.
This appeal arises from the first pharmaceutical-settlement antitrust action tried before a jury since the Supreme Court's decision in FTC v. Actavis, Inc., --- U.S. ----, 133 S.Ct. 2223, 186 L.Ed.2d 343 (2013). The jury found that although the plaintiffs had proved an antitrust violation in the form of a large and unjustified reverse payment from AstraZeneca to Ranbaxy, the plaintiffs had not shown that they had suffered an antitrust injury that entitled them to damages.

Defendant AstraZeneca is a brand-name drug manufacturer that owns the patents covering Nexium, a prescription heartburn medication that has grossed billions of dollars in annual sales. After defendant Ranbaxy notified the Food and Drug Administration (“FDA”) that it sought to market a generic version of Nexium, AstraZeneca sued Ranbaxy for patent infringement. The two companies reached a settlement agreement, under which Ranbaxy agreed to delay the launch of its generic until a certain date in return for various promises from AstraZeneca. AstraZeneca similarly sued and subsequently settled two patent infringement suits with generic manufacturers Teva and Dr. Reddy's, who were (but no longer remain) defendants in this case. The plaintiffs—various pharmaceutical retail outlets and certified classes of direct purchasers and end payors—brought suit, arguing that the terms of these settlement agreements violated federal antitrust laws and state analogues.

After summary judgment proceedings that winnowed down the number of causal mechanisms through which the plaintiffs could attempt to prove antitrust violation and injury, the case proceeded to a jury, which found as we have described. Following the verdict, the district court denied the plaintiffs' motions for a permanent injunction and for a new trial.

The plaintiffs appeal, raising four categories of claims. First, they challenge various evidentiary rulings. Second, they argue that the district court erroneously granted judgment as a matter of law in the defendants' favor on the issue of overarching conspiracy. Third, they argue that the special verdict form and jury instructions contained reversible error. The final argument, which lies at the heart of this appeal, is that the district court, at summary judgment, impermissibly cut down the number of causal mechanisms through which the plaintiffs could make their case to the jury. See In re Nexium (Esomeprazole) Antitrust Litig. (“In re Nexium [Summary Judgment]”), 42 F.Supp.3d 231 (D. Mass. 2014). This error at summary judgment pervaded the entire trial, the plaintiffs argue, and constitutes grounds to vacate the jury verdict and award a new trial.

We find no reversible error in the district court's evidentiary rulings, the formulation of the special verdict form and jury instructions, or its judgment as a matter of law on overarching conspiracy. In fact, many of the plaintiffs' objections have been forfeited or mooted by the jury's findings. We further hold that the jury verdict, finding an antitrust violation but not an antitrust injury, coupled with developments at trial on the issue of patent invalidity, renders harmless any error that may have occurred during the summary judgment proceedings. Accordingly, we need not, and indeed should not, review the summary judgment order for error. We affirm.

I. REGULATORY FRAMEWORK

An overview of the intricate pharmaceutical regulatory framework is necessary to understand the issues presented. A manufacturer that seeks to market a new brand-name drug must file a New Drug Application (“NDA”) with the FDA and “undergo a long, comprehensive, and costly testing process.” Actavis, 133 S.Ct. at 2228. Generic-drug manufacturers formerly underwent similarly rigorous processes to obtain FDA approval to market generic versions of the brand-name drug. In order to accelerate the entry of generic competitors into the market and decrease healthcare costs, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (“Hatch–Waxman Act”), Pub. L. No. 98–417, 98 Stat. 1585. The Hatch–Waxman Act has three regulatory components that are relevant here.

First, the Act permits generic manufacturers to file the notably less costly Abbreviated New Drug Application (“ANDA”), “specifying that the generic has the ‘same active ingredients as,’ and is ‘biologically equivalent’ to, the already-approved brand-
Second, the Act requires brand-name manufacturers to list the numbers and expiration dates of all relevant patents in their NDAs, which are then published in the FDA’s “Orange Book,” an annual publication of all approved drugs and the reported patents or statutory exclusivities that cover those drugs. In turn, generic manufacturers filing ANDAs must “assure the FDA that the generic ‘will not infringe’ the brand-name's patents,” and may provide this assurance in one of four ways. If the court decides the patent matter within 30 months, the FDA follows the court's determination. But if the court does not, the FDA may approve an ANDA before a court rules on patent validity or infringement. This pre-ruling approval, in turn, allows the generic manufacturer to launch its product “at risk”—that is, “with the risk of losing the infringement case against it hanging over its head. Losing an infringement case after launching at risk can result in significant liability for the generic manufacturer, as damages typically are calibrated by the amount of its at-risk sales.”

The final relevant component of the Hatch–Waxman Act is that it rewards the first generic manufacturer to file an ANDA with a paragraph IV certification by granting that first filer a 180–day period of exclusivity. During that 180–day window, the FDA cannot approve ANDAs from competing manufacturers for the same generic, leaving only the first filer with the ability to market its generic. Accordingly, this period of exclusivity can be “worth several hundred million dollars.” In fact, the “vast majority of potential profits for a generic drug manufacturer materialize during the 180–day exclusivity period.” From the market perspective, however, the first filer may create a bottleneck, as all other generic manufacturers must wait for the exclusivity period to end before launching their own generics.

Significantly, this lucrative 180–day exclusivity period is not absolute. Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, a first filer may forfeit its exclusivity period if it fails to come to market within 75 days of a final, nonappealable court judgment that the first filer's product does not infringe the brand-name's patents. Alternatively, first-filer exclusivity can be forfeited if another generic manufacturer successfully challenges the brand-name patents at issue and if the first filer fails to market its generic within 75 days of a final, nonappealable judgment in that other manufacturer's suit.

In 2013, the Supreme Court held that reverse payment settlements in paragraph IV litigation “can sometimes violate the antitrust laws.” A reverse payment refers to an arrangement in which the brand-name manufacturer and patent holder compensates the generic manufacturer and alleged patent infringer to settle the paragraph IV litigation and delay the generic's market entry. When a brand-name manufacturer pays to delay the first filer's generic launch, that reverse payment postpones not only the first filer's product but also those of all other generic manufacturers, who must wait out the
In re Nexium (Esomeprazole) Antitrust Litigation, 842 F.3d 34 (2016)
2016-2 Trade Cases P 79,835, Med & Med GD (CCH) P 305,800

180–day exclusivity period before going to market. Given that “a reverse payment, where large and unjustified, can bring with it th[is] risk of significant anticompetitive effects,” the Supreme Court held that the potential anticompetitive effects of a reverse payment are subject to the antitrust “rule of reason” test. Id. at 2237.

Earlier this year, in In re Loestrin 24 Fe Antitrust Litigation, 814 F.3d 538 (1st Cir. 2016), this circuit ruled that improper reverse payments may take the form of “non-monetary” advantages. Id. at 549. The language and logic of Actavis dictated that outcome. See id. ("[T]he Supreme Court recognized that a disguised above-market deal, in which a brand manufacturer effectively overpays a generic manufacturer for services rendered, may qualify as a reverse payment subject to antitrust scrutiny and militates against limiting the Supreme Court's decision to pure cash *42 payments."). Under this functional approach, “no-AG” provisions—in which the brand-name manufacturer agrees not to market an “authorized generic” version of the drug for a certain period of time—and other settlement provisions in which some advantage is transferred from the patent holder to the alleged infringer may constitute a reverse payment subject to antitrust scrutiny.

II. FACTS

Nexium is a proton-pump inhibitor whose active ingredient is esomeprazole magnesium. The FDA approved AstraZeneca's NDA to market Nexium in 2001. Between 2008 and 2014, Nexium grossed at least $3 billion annually in U.S. sales and joined the ranks of “blockbuster” drugs—those that generate annual sales of at least $1 billion. In 2001, AstraZeneca held fourteen active patents covering Nexium. As relevant here, two medical patents expired on May 27, 2014, two other patents expired in February 2015 and July 2015, and two more are set to expire in May 2018.

In August 2005, Ranbaxy first filed an ANDA with a paragraph IV certification in order to market a generic version of Nexium. The filing stated that Ranbaxy's launch would await the 2007 expiration of some of AstraZeneca's Nexium patents, but certified that other patents were either not infringed or invalid. As to patent invalidity, Ranbaxy contended that there was “nothing new” about Nexium, as the active compound in Nexium was effectively “one-half” of the compound in Prilosec, another blockbuster drug for stomach-acid treatment that AstraZeneca had marketed prior to Nexium.

AstraZeneca promptly brought suit, alleging that Ranbaxy had violated six of its patents: two that would expire on May 27, 2014, two that would expire in 2015, and two that would expire in May 2018. The suit stayed FDA approval of Ranbaxy's ANDA until April 2008. Meanwhile, Teva filed its ANDA for generic Nexium in November 2005, and Dr. Reddy's filed in December 2007. AstraZeneca sued Teva and Dr. Reddy's as well, and all three patent infringement suits were consolidated in the U.S. District Court for the District of New Jersey.

A. Settlement Agreements

Ranbaxy was the first defendant to settle after reaching an agreement with AstraZeneca in April 2008. Under the settlement agreement, Ranbaxy received a license to all relevant Nexium patents starting on May 27, 2014. The settlement also contained a no-AG clause, under which AstraZeneca agreed not to market an authorized generic version of Nexium during Ranbaxy's 180–day period of exclusivity. The clause thus ensured that Ranbaxy's generic would be the only one on the market if it could launch in time to avoid triggering the statutory forfeiture provisions. AstraZeneca could still continue to market its brand-name drug during that period. In return, Ranbaxy stipulated to patent validity and infringement and consented to the entry of an injunction against the sale of its generic before the license took effect on May 27, 2014.

AstraZeneca and Ranbaxy also executed three other agreements, under which Ranbaxy would serve as AstraZeneca's subcontractor and manufacture certain quantities of branded Nexium, and would also serve as AstraZeneca's distributor for
authorized generic versions of two other AstraZeneca drugs, Prilosec and Plendil. For the distribution agreement, Ranbaxy would receive 20% of AstraZeneca's profits.

After litigating for a few more years, Teva settled with AstraZeneca in January 2010. Like Ranbaxy, Teva received a license to the Nexium patents starting on May 27, 2014 and also consented to an injunction barring the sale of its generic before that license took effect. Simultaneously, AstraZeneca and Teva agreed to settle another pending patent infringement lawsuit regarding Prilosec. In that multiyear litigation, AstraZeneca had succeeded in establishing Teva's liability, but Teva had been contesting the damages amount based on its past infringing sales. Teva paid AstraZeneca $9 million to resolve that suit.

Dr. Reddy's settled with AstraZeneca in January 2011. Like Ranbaxy and Teva, Dr. Reddy's received a license for the Nexium patents starting on May 27, 2014 and also consented to an injunction barring sales before that date. Simultaneously, AstraZeneca and Dr. Reddy's settled another pending patent infringement lawsuit in which AstraZeneca agreed to drop its appeal of the entry of summary judgment in Dr. Reddy's favor.

The three settlement agreements contained parallel contingent launch provisions under which each generic manufacturer agreed to delay launching its generic in the United States until (1) May 27, 2014; (2) a hypothetical date prior to May 27, 2014 on which any third party launched generic Nexium pursuant to a final, nonappealable court order that AstraZeneca's Nexium patents were invalid, unenforceable, or not infringed by the generic; or (3) a hypothetical date prior to May 27, 2014 on which AstraZeneca authorized any third party to manufacture a generic Nexium. In re Nexium [Summary Judgment], 42 F.Supp.3d at 249 (citing ¶ 5.2 in the three settlement agreements).

B. Ranbaxy's Regulatory Troubles
Throughout Ranbaxy's paragraph IV litigation challenging AstraZeneca's Nexium patents, Ranbaxy faced serious issues with the FDA. Specifically, Ranbaxy had filed its ANDA for generic Nexium out of its manufacturing facility in Paonta Sahib, India, which meant that any FDA approval to launch generic Nexium would extend only to that facility. In February 2009, after issuing several warnings about quality control problems with the India facility, the FDA ultimately invoked its Application Integrity Policy (“AIP”) against Paonta Sahib. The AIP “halted FDA's substantive review and approval of all pending ANDAs, including amendments and post-approval supplements that relied on supporting data from the Paonta Sahib site—including the generic Nexium ANDA.” Id., at 266. The agency then rejected Ranbaxy's proposed Corrective Action Operating Plan and further turned down Ranbaxy's request that it grant a public health exception to the AIP and continue the approval process for the generic Nexium ANDA. Meanwhile, the FDA granted a public health exception for generic Lipitor, another Ranbaxy product manufactured out of the Paonta Sahib facility.

In 2010, Ranbaxy and the FDA began negotiating a Consent Decree, which they finalized on January 25, 2012. Under its terms, Ranbaxy could meet “several onerous and time-consuming milestones” to obtain potential FDA approval for generic Nexium or to obtain a site-transfer amendment to change the manufacturing site for the drug. The Consent Decree also contained a “key relinquishment date” of September 30, 2014. Id., at 274. If Ranbaxy could not meet the requisite milestones before that date, it would forfeit its 180–day exclusivity period. Id. Ranbaxy took over two and a half years to prepare a site-transfer amendment, and the manufacturer failed to receive final FDA approval for its generic Nexium ANDA prior to May 27, 2014.

On November 4, 2014, the FDA rescinded its tentative approval of Ranbaxy's generic Nexium ANDA, and Ranbaxy promptly sued the FDA in the U.S. District Court for the District of Columbia. See Ranbaxy Labs, Ltd. v. Burwell, 82 F.Supp.3d 159, 163 (D.D.C. 2015). Subsequently, in January 2015, the FDA notified Ranbaxy that it had forfeited its first-filer exclusivity period by failing to obtain approval for its generic within 30 months of submitting its ANDA. The FDA simultaneously approved Teva's ANDA for generic Nexium, which launched on February 17, 2015.
C. Dispute over Teva's Readiness to Launch Generic \textit{Nexium}

The plaintiffs' evidence at summary judgment and at trial showed that Teva was closer than Ranbaxy to obtaining FDA approval and launching generic \textit{Nexium} before May 27, 2014. An internal Teva email from February 2007 approximated Teva's “Launch Readiness date” as July 2008. And by 2009, Teva had passed FDA review in two out of the three categories necessary for tentative approval of its generic \textit{Nexium}.

The parties vehemently disagreed at summary judgment on whether the third remaining category for FDA approval was “a significant hurdle or a minor one,” an issue material to determine whether Teva was indeed close to FDA approval. \textit{In re Nexium [Summary Judgment]}, 42 F.Supp.3d at 288–89. The jury heard evidence from both sides on this issue.

III. PROCEDURAL HISTORY

A. Pretrial Proceedings

Plaintiffs commenced six different actions in three different federal district courts, alleging that AstraZeneca made improper reverse payments to Ranbaxy, Teva, and Dr. Reddy's in order to delay the market entry of generic \textit{Nexium}. On December 7, 2012, the U.S. Judicial Panel on Multidistrict Litigation consolidated and assigned the six pending actions to the U.S. District Court for the District of Massachusetts. See \textit{28 U.S.C. § 1407}. This appeal arises from that consolidated case.

On appeal, plaintiffs are a class of wholesale drug distributors (the “Direct Purchasers”); a class of individual consumers, third-party payors, union plan sponsors, and certain insurance companies (the “End Payors”); and numerous pharmaceutical retail outlets. In January 2015, a panel of this circuit affirmed the certification of the End Payors damages class over a dissent. See \textit{In re Nexium Antitrust Litig.}, 777 F.3d 9 (1st Cir. 2015). The original defendants in this litigation were AstraZeneca, Ranbaxy, Teva, and Dr. Reddy's. Teva and Dr. Reddy's have settled, leaving only AstraZeneca and Ranbaxy as defendants on appeal.

Consistent with \textit{In re Loestrin 24 Fe}, the plaintiffs' complaints identified aspects of AstraZeneca's settlements with each of the three generic manufacturers that allegedly were reverse payments in violation of the antitrust laws. In the Ranbaxy settlement, the plaintiffs pointed to the no-AG clause, as well as the side manufacturing and distribution agreements. In the Teva settlement, the plaintiffs argued that Teva's payment of only $9 million to settle the Prilosec lawsuit, rather than the higher amount that Teva actually owed AstraZeneca, constituted the reverse payment. In *45 the Dr. Reddy's settlement, the plaintiffs cited AstraZeneca's agreement to drop its appeal challenging Dr. Reddy's summary judgment win in another patent infringement lawsuit.

In December 2013, the defendants collectively filed eleven motions for summary judgment. Following the court's initial rulings from the bench, both parties filed various motions for reconsideration. In a September 4, 2014 opinion, the district court memorialized its rationale as to each summary judgment motion that it decided. See \textit{In re Nexium [Summary Judgment]}, 42 F.Supp.3d 231. This opinion grouped the motions into five categories:

First, the district court denied the defendants' motions for partial summary judgment on the existence of an overarching antitrust conspiracy, among all four original defendants, to restrain trade in the market for generic \textit{Nexium}. \textit{Id.} at 248–60. At the pretrial stage, the court found that the plaintiffs had “met their burden of establishing a reasonable inference of overarching conspiracy,” \textit{Id.} at 249, as the evidence demonstrated that each generic “manufacturer's calculus [on its entry date into the generic \textit{Nexium} market] changed ... when it received assurance that it would only have to restrict its business if its competitors did the same,” \textit{Id.} at 258. The denial of summary judgment to the defendants imposed no restrictions on the plaintiffs' ability to produce evidence
at trial. Following the plaintiffs' case in chief, the district court granted judgment as a matter of law in the defendants' favor on this overarching conspiracy claim.

Second, although the district court denied the defendants' motion for summary judgment as to the existence of an improper reverse payment from AstraZeneca to Ranbaxy, the court granted the motion as to the argument that such a reverse payment caused the plaintiffs' injury. Id. at 260. The court elaborated that the no-AG clause in the AstraZeneca–Ranbaxy settlement agreement “may be considered part of an illegal reverse payment,” id. at 265, while the lucrative “side” agreements granting Ranbaxy supply and distribution contracts likewise “raise[ ] enough suspicions to support a reasonable inference [of] improper reverse payments to induce Ranbaxy to delay its generic launch,” id. at 264.

Nonetheless, in light of the quality control issues that Ranbaxy's Paonta Sahib facility had experienced, the court found that the plaintiffs did not show how Ranbaxy could still have obtained final FDA approval and launched its generic before May 27, 2014. Id. at 270–75. The court was skeptical of the plaintiffs' analogy to generic Lipitor, which had been manufactured out of Paonta Sahib and had faced similar regulatory issues but had nonetheless launched after Ranbaxy reached a compromise with the FDA. Id. at 273–74.

“The net effect of these rulings [wa]s that the Ranbaxy Settlement [could] not [be] a basis for imposing antitrust liability.” Id. at 279. However, later at trial, the court acknowledged its error as to this ruling and reversed course.

Third, the court denied the defendants' motions for summary judgment based on the Teva settlement. The court found that the plaintiffs' evidence—that Teva's $9 million payment to AstraZeneca to settle the Prilosec lawsuit was so low a sum that it “constituted a significant forgiveness of debt” by AstraZeneca to delay the launch of Teva's generic—was sufficient to proceed to trial. Id. at 286. The court next found that the plaintiffs had also met their burden as to, what it called, antitrust causation because they showed (1) that Teva was close to obtaining tentative FDA approval but slowed down its efforts toward that goal after settling with AstraZeneca, *46 and (2) that Teva could have entered the market before May 2014, notwithstanding Ranbaxy's first-filer exclusivity period, by partnering with Ranbaxy on a joint launch. Id. at 288–89. In sum, the plaintiffs could pursue the Teva settlement as a basis for antitrust liability at trial.

Fourth, the district court granted the defendants' motion for summary judgment based on the Dr. Reddy's settlement, finding that the plaintiffs had proffered insufficient evidence both on the existence of an improper reverse payment and on “antitrust causation.” Id. at 291–95.

Finally, the district court denied three miscellaneous motions for summary judgment that AstraZeneca had filed: (1) a motion against the Direct Purchaser and Individual Retailer plaintiffs for lack of actual injury and seeking exclusion of testimony from two experts; (2) a motion barring assigned claims; and (3) a motion on the basis of the statute of limitations. Id. at 295–300.

In sum, after the summary judgment proceedings, the plaintiffs were allowed to present evidence on AstraZeneca's improper reverse payment to Teva and any antitrust liability flowing from that payment, as well as the existence of an overarching antitrust conspiracy among AstraZeneca, Ranbaxy, Teva, and Dr. Reddy's. That evidence would include testimony from the plaintiffs' expert, Dr. Thomas McGuire. The court further directed the plaintiffs to present all evidence supporting an antitrust violation arising out of the Teva settlement first, before presenting any other evidence.

After summary judgment, at a January 21, 2014 pretrial motion hearing, the district court granted the defendants' motion in limine to exclude testimony from Shashank Upadhye, a former in-house lawyer at a nondefendant generic manufacturer. The plaintiffs sought Upadhye's testimony to “augment Dr. McGuire's economic testimony with a real world business perspective on settlement negotiations for drug patent lawsuits.” The court reasoned that Upadhye, along with another proposed expert
witness (John Thomas), could not testify because they were “lawyers, not economists, and ... they d[id] not have the requisite qualifications to testify.” At an October 15, 2014 charge conference, the court reminded both parties that its decisions regarding motions in limine were “not rulings” and that the parties “must make [their] objections known during the course of the trial.”

Dr. Reddy's settled and dropped out of the lawsuit shortly before trial.

B. Trial
A six-week trial commenced on October 20, 2014. The trial transcript, exhibits, and filings comprise thousands of pages in the record. We summarize only the aspects of trial that are relevant to the arguments on appeal.

1. Plaintiffs' Statement on Patent Invalidity and Evidence Introduced During Their Case in Chief
At a conference on the second day of trial, the plaintiffs described their case in chief to the district court:

[In order to show that Teva could have gotten to market before May 27, 2014, the district court said that the *47 plaintiffs] would need to prove that Teva would have won its litigation [against AstraZeneca]. And then ... [the court] also indicated though that we could also perhaps prove that Teva would have done a deal with Ranbaxy in order to have the 180 days lifted.

... We plan to do the latter, primarily in our case in chief.... We don't plan on proving a patent case inside of an antitrust case [by pursuing the former].... We do not plan to be proving that Teva would have won the litigation.

This choice by the plaintiffs was not mandated by the district court's ruling. At trial, consistent with the district court's order, the plaintiffs first presented evidence on the existence of a reverse payment from AstraZeneca to Teva.

Dr. McGuire, an economist and one of the plaintiffs' key expert witnesses, testified twice during the plaintiffs' case in chief. McGuire first testified to “the enormous financial stakes that turned on the entry date of a lower cost generic into a market hitherto dominated by a patented, more expensive brand name drug.” In re Nexium (Esomeprazole) Antitrust Litig. (“In re Nexium [Post–Trial Opinion]”), 309 F.R.D. 107, 119 (D. Mass. 2015). He further “detailed how the benefits AstraZeneca conferred on Teva through their mutual settlement exceeded the litigation costs the parties thereby avoided.” Id.

During McGuire's second testimony, despite the summary judgment order precluding the plaintiffs from introducing evidence of a reverse payment to Ranbaxy, the court allowed McGuire to testify “for context” on the “far greater reverse payment made by AstraZeneca to Ranbaxy to induce it to forego its challenge to AstraZeneca's Nexium patents.” Id. The district court also allowed McGuire to testify about Ranbaxy's economic incentives to include a contingent launch provision in its settlement agreement with AstraZeneca. Specifically, McGuire noted that the provision made it “less likely” that subsequent ANDA filers would pursue generic entry. He further stated that the clause “had the effect of reducing the likelihood that Teva would challenge and break the bottleneck, which means for Ranbaxy[,] it became more likely that [it was] able to use [its] 180–day exclusivity period and make the profits associated with that.”

At one point during McGuire's second testimony, the court forbade him from quantifying Ranbaxy's incentive to participate in the overarching conspiracy as “about $700 million in [Ranbaxy's] pocket that [it] otherwise wouldn't have.” It ruled as such because the existence of contingent launch provisions, and not that theory, was what kept the plaintiffs’ “case against Ranbaxy alive.” The court nonetheless allowed McGuire to testify that AstraZeneca netted “hundreds of millions of dollars” by settling with Ranbaxy to “strengthen the 180–day [first-filer] barrier.”

Plaintiffs were permitted to introduce expert testimony on the but-for entry dates. For three days, starting on November 18 and after the district court articulated its “misconception,” the plaintiffs presented the testimony of Dr. Cheryl Blume, their “lead
2. The District Court's Mid-Trial Shift, Defendants' Mistrial Motion, and the Exclusion of McGuire's Event Study and Other Testimony

On November 18, 2014, the seventeenth day of the trial, the court admitted that it had had a “fairly fundamental misconception” of the plaintiffs’ theory of the case. The court then adjusted its thinking about the relevance of the AstraZeneca–Ranbaxy settlement by noting that “[t]he large and unjustified payment to Ranbaxy, which keeps Ranbaxy, given its blocking position [as first filer], off the market until May 27th, 2014, has an effect on all the later ANDA filers, such that if it were to be proved that but for that agreement, ... Teva could have partnered with Ranbaxy and come to market prior to that date.”

In light of this shift, the district court announced that it would alter the jury verdict form and allow the plaintiffs to recall McGuire to testify for a third time. The court also emphasized that its shift in thinking did “not injure[]” the plaintiffs because “they seem to have in the record enough evidence of a large and unjustified payment to Ranbaxy and based upon their expert's testimony it can be argued that it was anticompetitive.”

In response to the district court's stated reversal of its position, the defendants filed two motions, to both of which the plaintiffs objected. The first motion was for a mistrial. The second was to exclude McGuire’s additional proffered testimony—an “Event Study” that purported to “use econometric analysis of the stock market's reaction to the actual settlement reached by AstraZeneca and Ranbaxy to estimate an objective entry date without [a reverse] payment.” While the court acknowledged McGuire's expertise and stated that the Event Study's methodology was “perhaps reliable,” the Study did not meet Daubert requirements because there was “no fit” “between the event study and this culmination of the case.” The court recognized that the plaintiffs might nonetheless want to call McGuire a third time to testify to “other things” besides the Event Study. It ruled, however, that it still would not allow him to testify to those “additional matters” because to do so would be “simply unfair.”

Given that the court had said on November 18 that it would allow the plaintiffs to recall McGuire, the court acknowledged that its “no more McGuire” ruling could “change the plaintiffs' position on mistrial.” It directed the plaintiffs to make “tactical decisions” on whether to reassess their initial opposition to the defendants' mistrial motion.

The plaintiffs continued to oppose a mistrial. They pointed out that despite the summary judgment ruling precluding evidence of AstraZeneca's reverse payment to Ranbaxy, such evidence had nonetheless been presented to the jury under another theory. Indeed, the plaintiffs had introduced evidence on that payment because it was relevant and admissible under the claim of overarching conspiracy. Plaintiffs also argued that the “chopped up” way in which McGuire's earlier testimony was presented to the jury and the court's exclusion of McGuire's Event Study went “a long way to curing whatever prejudice ... these defendants may have incurred.”

Immediately following these statements, the court denied the motion for mistrial.


At the close of the plaintiffs' case, the defendants moved for judgment as a matter of law on the overarching conspiracy claim, as well as on the question of antitrust causation. The court granted the motion on the conspiracy claim, noting that “[t]here [wa]s
no sufficient evidence here that Ranbaxy and Teva conspired together, [or] that they acted otherwise than in their own individual best interest.” Although the court “came within an ace” of granting the motion on causation as well, it decided to deny the motion for “prudential reasons” and let that question go to the jury. The court did grant the defendants’ motion on causation with regard to any theory of antitrust causation based on patent invalidity, as it found “no adequate evidence that any of these patents would be adjudicated invalid.” Earlier in the trial, the plaintiffs had already told the court that they would not pursue such a theory.

To be sure of the accuracy and consequences of its ruling on patent invalidity, the court invited the parties to present further arguments on that issue following its initial ruling. The court subsequently refined its judgment regarding patent invalidity. Specifically, the court credited the plaintiffs’ argument that, as a matter separate from the absolute validity of the Nexium patents, patent holders like AstraZeneca protect their patent monopoly and maximize profit in a world in which patent infringement litigation may loom but has not taken place. Accordingly, the court allowed the plaintiffs, independent of the ruling on patent invalidity, to argue that the defendants could have been incentivized to reduce the risk of patent invalidation—for instance, by paying to delay the market entry of generics.

On November 24, 2014, Teva settled and dropped out of the suit, leaving only AstraZeneca and Ranbaxy as defendants.

4. Exclusion of Plaintiffs’ Proposed Rebuttal Evidence

At the close of the defendants’ case on December 2, 2014, the plaintiffs unsuccessfully sought to admit rebuttal evidence, which included the McGuire Event Study that the court had already excluded; a report published by Federal Trade Commission (“FTC”) staff and entitled “Pay-for-Delay: How Drug Company Pay–Offs Cost Consumers Billions”; and expert testimony from Dr. Keith Leffler. Leffler, an economist, proffered testimony that “virtually all Hatch–Waxman cases can be settled without reverse payments” and that it would have been in both AstraZeneca's and Ranbaxy's economic interest to enter into a payment-free settlement with a February 2012 entry date. The court refused to admit any of this evidence “because it [was] not true rebuttal” and should have been introduced during the plaintiffs' case in chief.

5. Special Verdict Form and Jury Instructions

The district court first provided the parties with the revised verdict form at a December 2, 2014 conference. This form contained the following seven questions:

1. Did AstraZeneca exercise market power within the relevant market?

2. Did the settlement of the AstraZeneca–Ranbaxy patent litigation include a large and unjustified payment by AstraZeneca to Ranbaxy?

*50 3. Was AstraZeneca's Nexium settlement with Ranbaxy unreasonably anticompetitive, i.e. did the anticompetitive effects of that settlement outweigh any pro-competitive justifications?

4. Had it not been for the unreasonably anticompetitive settlement, would AstraZeneca have agreed with Ranbaxy that Ranbaxy might launch a generic version of Nexium before May 27, 2014?

5. If so, what would be the effective date of such a license?

6. a. Had it not been for the unreasonably anticompetitive settlement, would Ranbaxy have agreed with Teva to launch a generic version of Nexium before May 27, 2014? b. If so, when would Teva have launched?

7. If a generic version of Nexium had come to market, would an authorized generic have entered at or about the same time?
After the court explained its revisions, it engaged in a colloquy with the parties, which focused, in relevant part, on the plaintiffs' objection that Question 4 applied a legally incorrect “subjective” test for antitrust causation.

The district court instructed the jury the next day. On Question 4, the court explained that answering “yes” to the first three questions was insufficient because “[j]ust making a deal ... is not enough for liability[;] there has to be a harm.” The court further explained that although the question mentioned by name AstraZeneca and Ranbaxy, it was “not necessarily just focusing on the AstraZeneca–Ranbaxy settlement”:

Now, the test here is an objective test. In other words I use the names “AstraZeneca” and “Ranbaxy” because those are the folks we're talking about here, but the test is not what they did ... we know what agreement they entered into, you would have found [in Question 3] that agreement is unreasonably anticompetitive. So then you're asked the question, “Well, suppose they didn't enter into such an agreement, suppose they were settling straight up without any anticompetitive effects, would that settlement license entry date have been earlier than the date they agreed to, May 27th, 2014?”

The court also reviewed Teva's role in the plaintiffs' theory—namely, that had AstraZeneca not made a reverse payment to Ranbaxy, their settlement agreement would have contained an earlier entry date, which would have allowed Teva to obtain that same earlier date or to partner with Ranbaxy for a joint launch of generic Nexium. Finally, the court informed the jury that a “no” to any question meant that the jury should not consider any subsequent question.

During the sidebar following the charge, each party objected to certain aspects of the court's instructions. The court had earlier warned that the parties had to raise their objections at the end of the charge to preserve them for appeal. The plaintiffs' objections to Question 4 were limited to the district court's colloquial framing of that question. They also objected to other aspects of the instructions unrelated to Question 4.

6. Plaintiffs' Closing Statement
The plaintiffs' closing expressly reminded the jury of the “large and unjustified payment” from AstraZeneca to Ranbaxy. Plaintiffs' counsel argued that “[i]t's large because it was worth about $690 million to Ranbaxy, or according to [one witness], about $300 million. It was going to cost AstraZeneca, in terms of lost sales, about $500 million of its own revenues that it might be able to get from the sale of an *51 authorized generic.” The plaintiffs further urged the jury to draw inferences from that payment: “By the fact that there was a payment you can infer that there was a movement of that entry date. Absolutely. And [by] the fact that this payment was so large you can infer that the entry date was moved back and should have been earlier.”

Notwithstanding the court's judgment as a matter of law on the issue of patent invalidity, the plaintiffs' closing also questioned the strength of AstraZeneca's Nexium patents and the relevance of those patents to the defendants' settlement agreement. The closing emphasized that the two defendants denied “ever talk[ing] about the strengths and weaknesses of the patent in order to negotiate some kind of date.” Further, “[b]ecause ... there was never a negotiation here where the two companies sat down and said we've got these claims on the patents ... here's infringement issues, let's see how we can negotiate on the merits of this case a resolution,” the plaintiffs urged the jury to find that the AstraZeneca–Ranbaxy deal consisted of “payoffs that weren't related to the merits.” Upon the defendants' objections to the plaintiffs' characterization of “the patent merits a[s] a coin flip” during the closing, the court reminded the jury that “on this record there is no evidence that any of these patents at the end of the day would have been held invalid.”

Finally, the plaintiffs' closing discussed at least two mechanisms through which the Ranbaxy reverse payment could have led to an antitrust injury in the form of a delayed generic launch. First, they explained that AstraZeneca faced a “major risk of potential at-risk launch ... in late 2007 and early 2008” and thus had an incentive to settle with Ranbaxy to avoid that outcome. Next, the plaintiffs reminded the jury about the Lipitor analogy. Articulating the “striking” similarities between Nexium and
Lipitor, the plaintiffs emphasized that generic Lipitor launched despite Ranbaxy's regulatory troubles, while generic Nexium did not, because the Lipitor settlement agreement did not contain a no-AG clause and thus provided for an earlier entry date compared to the Nexium settlement agreement.

7. Jury Verdict
After deliberating for two and a half days, the jury returned a verdict for the defendants. The jury answered “yes” to the first three questions, finding that the AstraZeneca–Ranbaxy settlement contained a “large and unjustified payment” and had an “unreasonably anticompetitive” market impact. But the jury answered “no” to Question 4, finding that the plaintiffs had failed to prove that AstraZeneca would have negotiated an entry date earlier than May 27, 2014. Heeding the court's earlier instructions, the jury stopped after its “no” answer.

C. Post–Trial Proceedings

This appeal followed.

IV. ANALYSIS
Plaintiffs have chosen to focus their appeal on the partial grant of summary judgment, the exclusion of certain evidence at trial, alleged errors in the district court's special verdict form and jury instructions, and the grant of judgment as a matter of law on the claim of overarching conspiracy. Plaintiffs argue that any one of these alleged errors entitles them to a new trial. We disagree and affirm the district court's evidentiary rulings, judgment as a matter of law on overarching conspiracy, and decision to structure the special verdict form and jury instructions in the manner that it did. Further, in light of the jury verdict and other critical developments at trial on the issue of patent invalidity, we decline to revisit the district court's summary judgment rulings. It would be improper for an appeals court to wade into such pretrial matters when, as here, a confluence of the plaintiffs' trial strategy, the district court's rulings, and the jury verdict rendered harmless any alleged error at the summary judgment stage.

A. Evidentiary Rulings
The plaintiffs challenge numerous evidentiary rulings of the district court. We find no error and affirm.

1. Exclusion of McGuire's Event Study Testimony
The plaintiffs argue that the district court committed reversible error by refusing to allow Dr. Thomas McGuire to testify for a third time after it concluded that the subject of his testimony, the Event Study, was inadmissible under Daubert. We review Daubert determinations for abuse of discretion. Ruiz–Troche v. Pepsi Cola of P.R. Bottling Co., 161 F.3d 77, 81 (1st Cir. 1998) (citing General Elec. Co. v. Joiner, 522 U.S. 136, 141–42, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997)). Federal Rule of Evidence 702 requires district courts to “ensur[e] that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand” before admitting it into evidence. Daubert, 509 U.S. at 597, 113 S.Ct. 2786. The district court, as gatekeeper, must “ensure that there is an adequate fit between the expert's methods and his conclusions.” Samaan v. St. Joseph Hosp., 670 F.3d 21, 32 (1st Cir. 2012).
We conclude on the merits that the district court did not abuse its discretion in excluding the Event Study and McGuire's corresponding testimony. The court properly found that the Event Study methodology—which purported to use econometric analysis of stock market data to "estimate an objective entry date without [a reverse] payment"—did not fit the conclusions for which it was offered. Although such studies had previously been "admitted on valuation, something much more germane to stock price," the study had questionable relevance to hypothesizing the outcome of a settlement agreement, especially one as crucial as the but-for entry date in a reverse-payment case. Furthermore, when asked to offer an example of another study that had used the Event Study methodology to predict settlement terms, the plaintiffs could not produce anything but an unpublished, non-peer-reviewed working paper that McGuire co-authored during the course of this litigation. The exclusion of McGuire's Event Study testimony under these circumstances did not constitute an abuse of discretion.

2. Exclusion of Other Aspects of McGuire's Testimony

The plaintiffs also accuse the district court of improperly forbidding McGuire from testifying about three other issues: (1) specific but-for entry dates, (2) "the purpose and effect of the side deals" between AstraZeneca and Ranbaxy, and (3) the exact size of the reverse payment from AstraZeneca to Ranbaxy. We can quickly dispose of these arguments.

First, as to McGuire's testimony on the but-for entry dates, examining the district court's decision in the context of the overall record makes clear that the exclusion did not prejudice the plaintiffs. During McGuire's second testimony, which took place before the district court's mid-trial epiphany on the Ranbaxy reverse payment's relevance, the court did not allow McGuire to testify that Ranbaxy and Teva "would have been able to enter in 2011" but for the reverse payments. This ruling did not constitute reversible error in light of events at trial that took place both before and after the court's epiphany.

Even before its shift in thinking, the district court gave McGuire leeway to testify about Ranbaxy's economic incentives to enter into the settlement agreement with AstraZeneca. That testimony, in turn, implied how the AstraZeneca–Ranbaxy settlement could have led to delayed generic entry. In particular, McGuire testified, during his second time on the stand, that the contingent launch provision in Ranbaxy's settlement agreement diminished the likelihood of subsequent ANDA filers seeking to enter the generic Nexium market. "In fact," McGuire testified, "there were no subsequent ANDA filers that pursued this [generic entry] through litigation." The district court also permitted plaintiffs' counsel to ask McGuire whether he had "reach[ed] a conclusion as to whether Ranbaxy had an economic motive to agree to the [contingent launch] clause." McGuire answered in the affirmative and, over an objection, was allowed to elaborate that the contingent launch provision "had the effect of reducing the likelihood that Teva would challenge and break the bottleneck, which mean[t] for Ranbaxy[,] it became more likely that [it was] able to use [its] 180–day exclusivity period and make the profits associated with that." Notwithstanding McGuire's inability to testify to exact but-for entry dates, the district court afforded him great latitude to give testimony on Ranbaxy's economic incentives to block other ANDA filers and thus delay generic entry.

Next, after the court's adjustment in thinking, it informed the parties that it would not allow McGuire to testify a third time out of principles of fairness and that the plaintiffs should consider this ruling's implications on their mistrial-motion calculus. In addition, independent of its rulings regarding McGuire, the court allowed testimony on but-for entry dates from another expert, Dr. Cheryl Blume, whom the court described as the plaintiffs' "lead witness" on this very issue. Blume testified as part of the plaintiffs' case in chief over three days of trial (November 18 to 20).

In the context of the court's rulings on McGuire and Blume, the plaintiffs continued to oppose a mistrial. The record does not show that they made any objections that they should have been allowed to present cumulative evidence on specific but-for entry dates through McGuire in addition to Blume. In short, the plaintiffs had an opportunity to present evidence on hypothetical earlier entry dates through Blume, and the district court was under no obligation to also permit McGuire to testify on that same issue. The plaintiffs' argument to the contrary seems to be little more than an effort to admit cumulative and weaker evidence.
See McDonald v. Fed. Labs., Inc., 724 F.2d 243, 248 (1st Cir. 1984); cf. Fed. R. Evid. 403 (“The [trial] court may exclude relevant evidence if its probative value is substantially outweighed by a danger of... unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence.”). Plaintiffs have not shown any prejudice resulting from the district court's decision not to permit cumulative evidence, particularly from a witness who had already been allowed to testify twice.

Next, the alleged errors in excluding McGuire's testimony on the side deals and the size of the reverse payment were harmless in light of the jury verdict. The “yes” answer to Question 2 reflects the jury's finding that AstraZeneca made a large and unjustified payment to Ranbaxy. Furthermore, as to the size of the reverse payment, although McGuire could not assign a specific dollar figure to the value of the reverse payment, the district court did allow him to testify that it was worth “hundreds of millions of dollars.”

3. Pretrial Exclusion of Upadhye's Testimony
The plaintiffs also fault the district court for its pretrial decision in limine to exclude testimony from Shashank Upadhye, who sought to provide “a real world business perspective on settlement negotiations for drug patent lawsuits.”

Before reaching the merits, we must point out that, despite the district court's clear instructions that its pretrial decisions were “not rulings” and that the parties “must make [their] objections known during the course of the trial,” the plaintiffs did not renew at trial their objections to the court's in limine decision regarding Upadhye. In fact, although the plaintiffs listed Upadhye as a witness whom they “might call” at trial, they never actually attempted to do so. Under these circumstances, the district court's in limine decision may not even serve as proper grounds for a reversal. See, e.g., Littleton v. McNeely, 562 F.3d 880, 891 (8th Cir. 2009).

But even if the plaintiffs had properly objected to the exclusion of Upadhye's testimony, there would be no error. “Whether a witness is qualified to express an opinion is a matter left to the sound discretion of the trial judge.” McDonald, 724 F.2d at 248 (quoting A. Belanger & Sons, Inc. v. U.S. for Use & Benefit of Nat'l U.S. Radiator Corp., 275 F.2d 372, 376 (1st Cir. 1960)). Here, the district court excluded Upadhye's proposed testimony because he was “not [an] economist[,]” and “[d]id not have the requisite qualifications to testify.” That decision, especially given Upadhye's reliance on his general experience and his failure to cite any methodology undergirding his opinions, was not an abuse of discretion. The district court may also have “regarded [Upadhye's] proffered testimony as cumulative,” as McGuire had already testified about the Ranbaxy reverse payment and Upadhye would have offered only a “real world” spin on that testimony. Id.

4. Exclusion of Plaintiffs' Proposed Rebuttal Evidence
The plaintiffs next seek reversal on the ground that the district court's exclusion of their “rebuttal” evidence was error. Not so. “The principal objective of rebuttal is to permit a litigant to counter new, unforeseen facts brought out in the other side's case.” Faigin v. Kelly, 184 F.3d 67, 85 (1st Cir. 1999). “[T]he decisions as to what constitutes proper rebuttal evidence ... lie within the sound discretion of the trial judge and are subject to substantial deference.” United States v. LiCausi, 167 F.3d 36, 52 (1st Cir. 1999).

The plaintiffs sought to admit three pieces of evidence, purportedly in an effort to rebut the testimony of two defense witnesses, “that AstraZeneca never ‘express[ed] any willingness to agree to any' date other than May 27, 2014.” The proposed rebuttal evidence consisted of (1) McGuire's Event Study testimony, which the district court had already rejected as part of the plaintiffs' case in chief; (2) an economic analysis of a no-payment settlement by another expert, Dr. Keith Leffler; and (3) a study published by FTC staff. At oral argument, the plaintiffs insisted that their inability to admit any rebuttal evidence, coupled with other
In re Nexium (Esomeprazole) Antitrust Litigation, 842 F.3d 34 (2016)
2016-2 Trade Cases P 79,835, Med & Med GD (CCH) P 305,800

alleged errors of the district court, meant that “all the jury heard was some officers of [the defendants'] company saying they wouldn't do things differently.”

Contrary to the plaintiffs' statement, the district court properly refused to admit the plaintiffs' proposed rebuttal evidence, reasoning that it “was hardly true rebuttal testimony because establishing [the date on which the defendants would have agreed to a generic launch but for a reverse payment] was an essential part of the Plaintiffs' prima facie case.” Indeed, given the centrality of this date to the entire litigation and especially to the plaintiffs' need to prove an antitrust injury, it was entirely foreseeable that the defendants would assert that the date would not have been earlier than May 27, 2014. It was thus within the district court's discretion to rule that the defendants' testimony to that effect offered nothing “new” to warrant use of the plaintiffs' proffered evidence as rebuttal. See Faigin, 184 F.3d at 85.

The plaintiffs respond by emphasizing the unique circumstances of this trial. Given that the district court first directed them to focus their case on the Teva reverse payment but radically adjusted its understanding mid-trial to recognize the relevance of the Ranbaxy reverse payment, the plaintiffs argue that the district court was required to give them an opportunity, at rebuttal, “to present evidence relating to the newly revived issue.” Alberty–Vélez v. Corporación de Puerto Rico para la Difusión Pública, 242 F.3d 418, 422 (1st Cir. 2001) (quoting Leddy v. Standard Drywall, Inc., 875 F.2d 383, 386 (2d Cir. 1989)). But the record does not support the plaintiffs' contention that the district court did not afford them such an opportunity. Instead, the record portrays the plaintiffs' neglect in seeking to admit relevant testimony after the court course-corrected (with the exception of McGuire's Event Study, which was supportably excluded on Daubert grounds, as discussed above).

The plaintiffs made no effort to seek admission of the FTC study or Leffler's testimony as part of their case in chief, even though they had two days between the district court's epiphany and the end of their case in chief to do so. They offer no explanation on appeal of their failure to seek admission of the FTC study before resting their case. And while they do explain that they could not call Leffler on short notice because he resided in Seattle, the record does not indicate that the plaintiffs brought this geographical limitation to the district court's attention. In short, the plaintiffs had a window of opportunity to seek admission of the FTC study and Leffler's testimony before resting their case. Given their own failure to do so, we conclude that it was within the district court's discretion to refuse to admit that evidence, which properly belonged in the plaintiffs' case in chief, and not in their rebuttal.

B. Judgment as a Matter of Law on Overarching Conspiracy
The plaintiffs argue that the district court erroneously granted judgment as a matter of law (“JMOL”) on the overarching conspiracy claim. They argue that they had proved the existence of contingent launch provisions in the defendants' settlement agreements, that this evidence had sufficed to survive summary judgment, and that thus it necessarily was enough to defeat JMOL. But this reasoning mixes apples and oranges.

We review de novo a district court's decision to grant JMOL. Malone v. Lockheed Martin Corp., 610 F.3d 16, 19 (1st Cir. 2010). An antitrust conspiracy claim under Section 1 of the Sherman Act, 15 U.S.C. § 1, requires evidence of an actual “agreement[ ]”—whether tacit or express.” White v. R.M. Packer Co., 635 F.3d 571, 575 (1st Cir. 2011). “[I]ndependent decisions, even if they lead to the same anticompetitive result as an actual agreement among market actors,” are insufficient to sustain a Section 1 conspiracy claim. Id. As a result, mere parallel conduct and “[e]ven ‘conscious parallelism,’ a common reaction of firms in a concentrated market that recognize their shared economic interests and their interdependence with respect to price and output decisions[,] is not in itself unlawful.” Bell Atl. Corp. v. Twombly, 550 U.S. 544, 553–54, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007) (alterations omitted) (quoting Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp., 509 U.S. 209, 227, 113 S.Ct. 2578, 125 L.Ed.2d 168 (1993)).
In re Nexium (Esomeprazole) Antitrust Litigation, 842 F.3d 34 (2016)

2016-2 Trade Cases P 79,835, Med & Med GD (CCH) P 305,800

The law distinguishes illegal tacit agreements from “mere conscious parallelism” through evidence of “uniform behavior among competitors, preceded by conversations implying that later uniformity might prove desirable or accompanied by other conduct that in context suggests that each competitor failed to make an independent decision.” White, 635 F.3d at 576 (emphasis added) (quoting Brown v. Pro Football, Inc., 518 U.S. 231, 241, 116 S.Ct. 2116, 135 L.Ed.2d 521 (1996)); see also Dickson v. Microsoft Corp., 309 F.3d 193, 203 (4th Cir. 2002) (concluding that a “rimless wheel conspiracy”—in which “various defendants enter into separate agreements with a common defendant, but where the defendants have no connection with one another, other than the common defendant's involvement in each transaction”—is “not a single, general conspiracy but instead amounts to multiple conspiracies between the common defendant and each of the other defendants” (citing Kotteakos v. United States, 328 U.S. 750, 755, 66 S.Ct. 1239, 90 L.Ed. 1557 (1946))).

The plaintiffs point to parallel contingent launch provisions in AstraZeneca's settlements with each generic manufacturer as evidence of the existence of one overarching conspiracy. Under these provisions, the generic manufacturers agreed to delay launching generic Nexium until May 27, 2014, or an earlier date on which AstraZeneca or a court order permitted them to do so. Beyond the provisions, however, the plaintiffs fail to present any evidence that Ranbaxy and Teva agreed to engage in anticompetitive conduct.

Given the dearth of additional evidence, the district court correctly recognized that “[t]here is no sufficient evidence here that Ranbaxy and Teva conspired together, that they acted otherwise than in their own individual best interest.” Indeed, some evidence that Ranbaxy and Teva, independent of AstraZeneca, agreed to engage in anticompetitive conduct was critical because self-interest could explain equally well why each might execute a contingent launch provision. After all, as defendant Ranbaxy explains, “[e]ach generic company would have wanted to ensure that no other generic preceded its entry into the market—and would have sought that assurance by obtaining a contingent launch provision in its settlement agreement.” In short, without proving “the existence of a ‘rim’ to the wheel in the form of an agreement among” the generic manufacturers, the plaintiffs did not have a viable claim of *57 overarching conspiracy to survive JMOL. United States v. Apple, Inc., 791 F.3d 290, 314 n.15 (2d Cir. 2015).

The three cases that the plaintiffs string cite do not alter our assessment. See United States v. Masonite Corp., 316 U.S. 265, 62 S.Ct. 1070, 86 L.Ed. 1461 (1942); Interstate Circuit v. United States, 306 U.S. 208, 59 S.Ct. 467, 83 L.Ed. 610 (1939); Toys “R” Us, Inc. v. FTC, 221 F.3d 928 (7th Cir. 2000). The cases do not say, as plaintiffs argue, that interdependent conduct, absent more, suffices to establish overarching conspiracy. Properly read, they in fact reinforce the opposite proposition.

First, contrary to the plaintiffs' argument, Masonite makes no holding on horizontal conspiracy. There, Masonite, a manufacturer of building materials, developed a product called hardboard and obtained patents for both the product and the process for manufacturing it. 316 U.S. at 267–68, 62 S.Ct. 1070. When competitors began manufacturing hardboard, Masonite sued each of them for patent infringement, id. at 268–70, 62 S.Ct. 1070, but eventually settled each suit on identical terms, including a price-fixing term, id. at 270–73, 62 S.Ct. 1070. The Supreme Court upheld the district court's factual findings that each of Masonite's competitors had “acted independently of the others, negotiated only with Masonite, desired the agreement regardless of the action that might be taken by any of the others, did not require as a condition of its acceptance that Masonite make such an agreement with any of the others, and had no discussions with any of the others.” Id. at 275, 62 S.Ct. 1070. The Court then held that the individual vertical contracts between Masonite and each competitor violated § 1 of the Sherman Act. Id. That was the extent of Masonite's holding. Indeed, to read Masonite as having found an overarching horizontal conspiracy would be “nonsensical” because “an essential conspiracy element [wa]s missing—namely, a motive for joint action or interdependence.” 6 Areeda & Hovenkamp, Antitrust Law ¶ 1427d (2d ed. 2003).

The second case that the plaintiffs cite, Interstate Circuit, is also of no help to their claim of error. Unlike this case, in which the district court found no evidence to infer any agreement between Ranbaxy and Teva, the Court in Interstate Circuit saw enough circumstantial evidence to find a “tacit agreement” among all defendants. 306 U.S. at 225–27, 59 S.Ct. 467; White, 635 F.3d
In re Nexium (Esomeprazole) Antitrust Litigation, 842 F.3d 34 (2016)

2016-2 Trade Cases P 79,835, Med & Med GD (CCH) P 305,800

at 576. There, “a dominant movie theater company sent a letter openly addressed to all eight major national film distributors stating that it would show a distributor's films only if the distributor imposed certain restrictions on later runs of the films in secondary theaters.” White, 635 F.3d at 576. “[T]he economic context made it clear that all eight needed to act uniformly or all would lose business, and all eight did in fact impose the conditions.” Id. By contrast, here, the district court found that the plaintiffs had presented insufficient evidence from which to infer even a tacit agreement.

Finally, Toys “R” Us is also inapposite because evidence in that case showed that entering into parallel agreements with Toys “R” Us (“TRU”) was against each toy manufacturer's interest unless all of them did so. TRU, “a giant in the toy retailing industry,” had executed agreements with various toy manufacturers that TRU would carry the manufacturers' toys only if they promised to curb sales to warehouse club stores like Costco that sold toys at lower prices than did TRU. 221 F.3d at 930. The Seventh Circuit affirmed an FTC finding of a horizontal conspiracy among the toy manufacturers for two reasons. First, “the record included the direct evidence of communications” among the toy manufacturers. *58 Id. at 935. Second, the evidence showed that it was actually against the toy manufacturers' economic interest to curb sales to warehouse clubs unless they all did so:

The evidence showed that the companies wanted to diversify from TRU, not to become more dependent upon it; it showed that each manufacturer was afraid to curb its sales to the warehouse clubs alone, because it was afraid its rivals would cheat and gain a special advantage in that popular new market niche.... [T]he only condition on which each toy manufacturer would agree to TRU's demands was if it could be sure its competitors were doing the same thing.

Id. at 936. The record in this case contains no such evidence.

In Interstate Circuit and Toys “R” Us, there were “plus factors”—i.e. “additional facts or factors required ... as a prerequisite to finding that parallel action amounts to a conspiracy.” 6 Areeda & Hovenkamp, supra, ¶ 1433e (“Even those courts that say that conscious parallelism is a factor 'to be weighed, and generally to be weighed heavily' in establishing a § 1 violation are usually speaking about fact situations in which there is other evidence of conspiracy.”) (emphasis added) (footnote omitted)).

The plaintiffs' briefs do not focus on the lack of evidence to prove their claim of overarching conspiracy. Instead, they primarily argue that the district court initially ruled in their favor at summary judgment and that the court should not have reversed itself at the JMOL stage. In so doing, the plaintiffs fail to consider that the summary judgment ruling may have been in error. Nor do they recognize that the JMOL reasoning, not the summary judgment reasoning, has found agreement in at least two other trial courts that have considered the issue. See In re Actos End Payer Antitrust Litig., No. 13–CV–9244(RA), 2015 WL 5610752, at *24 (S.D.N.Y. Sept. 22, 2015); King Drug Co. of Florence, Inc. v. Cephalon, Inc., No. 2:06–CV–1797, 2014 WL 2813312, at *14 (E.D. Pa. June 23, 2014). There was no error.

Finally, the Individual Retailer plaintiffs misrepresent the district court's opinion denying them a new trial. They contend that after the court recognized its summary judgment ruling as “a bit too sweeping,” it nonetheless “reverted to the summary judgment rationale ... that the evidence was sufficient to support a finding that ‘AstraZeneca was the hub of a hub-and-spoke conspiracy.’ ” Quoted in full, however, the district court actually reaffirmed its JMOL ruling, noting that “[a]t trial, the evidence warranted, at most, a finding that AstraZeneca was the hub of a hub-and-spoke conspiracy with the three generic manufacturers acting as competitors vis-à-vis each other, not conspirators.” In re Nexium [Post–Trial Opinion], 309 F.R.D. at 115 n.13 (emphasis added). In other words, the court recognized that although the evidence might show one conspiracy between AstraZeneca and Ranbaxy and another disparate conspiracy between AstraZeneca and Teva, the evidence was legally insufficient to tie all three players in an overarching conspiracy. We find no error in the district court's decision to grant JMOL.
on the overarching conspiracy claim in light of the plaintiffs' inability to cite any supporting evidence other than the parallel contingent launch provisions.

C. Special Verdict Form and Jury Instructions
The final verdict form that went to the jury asked seven questions and was structured so that a “no” answer to any question *59 meant that the jury could stop considering the rest. As relevant here, the first four questions asked:

1. Did AstraZeneca exercise market power within the relevant market?

2. Did the settlement of the AstraZeneca–Ranbaxy patent litigation include a large and unjustified payment by AstraZeneca to Ranbaxy?

3. Was AstraZeneca's Nexium settlement with Ranbaxy unreasonably anticompetitive, i.e. did the anticompetitive effects of that settlement outweigh any pro-competitive justifications?

4. Had it not been for the unreasonably anticompetitive settlement, would AstraZeneca have agreed with Ranbaxy that Ranbaxy might launch a generic version of Nexium before May 27, 2014?

On appeal, the plaintiffs argue that Question 4 impermissibly “require[d] a specific factual sequence of causation,” that it was duplicative of Question 3, that it erroneously posed a “subjective” test about the intent of the defendants, and that its wording was “confusing” and “misled the jury.” The defendants respond that all of these objections were either waived or forfeited.

If a party fails to preserve its objections to jury instructions after the jury is charged, those objections are forfeited on appeal and reviewed only for plain error. Booker v. Mass. Dep't of Pub. Health, 612 F.3d 34, 42 (1st Cir. 2010). Plain error, “a hard-to-meet standard,” requires the appellant to show “that '(1) an error occurred (2) which was clear or obvious and which not only (3) affected the [appellant's] substantial rights, but also (4) seriously impaired the fairness, integrity, or public reputation of the judicial proceedings.' ” Tasker v. DHL Ret. Savings Plan, 621 F.3d 34, 40–41 (1st Cir. 2010) (alteration in original) (quoting Dávila v. Corp. de P.R. Para La Difusión Pública, 498 F.3d 9, 14–15 (1st Cir. 2007)).

Furthermore, “with respect to special verdicts, ‘the law is perfectly clear that parties waive any claim of internal inconsistency by failing to object after the verdict is read and before the jury is discharged.’ ” Trainer v. HEI Hosp., LLC, 699 F.3d 19, 34 (1st Cir. 2012) (alterations omitted) (quoting Peckham v. Cont'l Cas. Ins. Co., 895 F.2d 830, 836 (1st Cir. 1990)). This has been an “iron-clad rule” in our circuit. Rodriguez–García v. Mun. of Caguas, 495 F.3d 1, 9 (1st Cir. 2007). Although we could altogether decline to hear the plaintiffs' arguments about the verdict form on waiver grounds, the FTC's amicus brief highlights the importance of straightening out the conflation of antitrust violation and antitrust injury that crept into the district court's post-trial opinion and into some of the parties' arguments on appeal. We accept the FTC's invitation to provide greater clarity.

Two of the plaintiffs' four objections seem to arise from this wrongful conflation. The plaintiffs protest that Question 4 was duplicative of Question 3 and that Question 4 held the plaintiffs to an impermissibly stringent causation standard. Neither argument holds water, and in fact each shows that the plaintiffs may have obscured the clear law that, as private plaintiffs seeking damages, they must prove not only an antitrust violation but also an antitrust injury that allows recovery of damages. 6

*60 Private plaintiffs and the FTC as government enforcer stand in different shoes. Under the governing antitrust statutes, the FTC is empowered to directly enforce the substantive antitrust laws. See 15 U.S.C. § 45(a)(2). Meanwhile, private plaintiffs derive their authority to sue from Section 4 or 16 of the Clayton Act and must therefore satisfy the additional evidentiary burdens that those provisions impose. See id. §§ 15, 26. As the FTC's amicus brief aptly explains, “[t]his distinction is rooted in public...
In re Nexium (Esomeprazole) Antitrust Litigation, 842 F.3d 34 (2016)

2016-2 Trade Cases P 79,835, Med & Med GD (CCH) P 305,800

policy. The interest of private plaintiffs is to remediate an injury they have suffered or may suffer. The interest of the government is to ‘prevent and restrain’ violations of the antitrust laws along with the attendant social costs such violations can cause.”

The Supreme Court has consistently held private plaintiffs to this standard of proving both antitrust violation and antitrust injury. See, e.g., Atl. Richfield Co. v. USA Petroleum Co., 495 U.S. 328, 344, 110 S.Ct. 1884, 109 L.Ed.2d 333 (1990) (“ '[P]roof of [an antitrust] violation and of antitrust injury are distinct matters that must be shown independently.' For this reason, ... the right of action under § 4 of the Clayton Act is available only to those private plaintiffs who have suffered antitrust injury.” (quoting Areena & Hovenkamp, Antitrust Law ¶ 334.2c (1989 Supp.))). A private plaintiff seeking monetary relief must show actual, quantifiable damages “by reason of” the antitrust violation. Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters, 459 U.S. 519, 543, 103 S.Ct. 897, 74 L.Ed.2d 723 (1983); see also Brunswick Corp. v. Pueblo Bowl–O–Mat, Inc., 429 U.S. 477, 489, 97 S.Ct. 690, 50 L.Ed.2d 701 (1977) (defining “antitrust injury” as “injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful”).

Assessed under this framework, Questions 3 and 4 are neither duplicative nor both aimed at causation. Rather, the former asks the jury about antitrust violation, while the latter asks about antitrust injury. The jury's “yes” answers to Questions 2 and 3 (large and unjustified payment with anticompetitive effects) confirm its finding that some antitrust violation resulted from the AstraZeneca–Ranbaxy settlement. Question 4, by contrast, inquires whether these private plaintiffs have suffered an “injury of the type the antitrust laws were intended to prevent” by asking whether Ranbaxy (in partnership with Teva) would have launched a generic earlier than May 27, 2014 but for the antitrust violation found in Question 3. Brunswick, 429 U.S. at 489, 97 S.Ct. 690. The “no” answer to Question 4 thus confirms the jury's finding that notwithstanding the existence of an antitrust violation, the plaintiffs failed to establish an antitrust injury that entitled them to monetary relief.

As Questions 3 and 4 played discrete and independently necessary roles in adjudicating an antitrust suit brought by private plaintiffs, we reject the plaintiffs' protests that the questions led to an “absurd” outcome. There was nothing absurd in the jury verdict. In fact, this circuit has reached similar conclusions in past antitrust cases. See, e.g., Ocean State Physicians Health Plan, Inc. v. Blue Cross & Blue Shield of R.I., 883 F.2d 1101, 1105 (1st Cir. 1989) (observing that district court granted a renewed motion for JMOL in defendant's favor in part because “the jury's award of 'no damages' on the antitrust claim meant that plaintiffs had failed *61 to prove that they had been injured by any illegal conduct by [the defendant]”).

The plaintiffs next object that Question 4 erroneously used the defendants' names and framed the relevant inquiry as a subjective, rather than an objective, test. The record refutes this argument. After the plaintiffs initially raised these concerns at the December 2, 2014 conference, the court clarified to the jury that “the test here is an objective test. In other words[,] I use the names ‘AstraZeneca’ and ‘Ranbaxy’ because those are the folks we're talking about here, but the test is not what they did.” The plaintiffs failed to renew their objections following these instructions. Examining Question 4 in the context of the verdict form and jury instructions “as a whole,” Johnson v. Teamsters Local 559, 102 F.3d 21, 28 (1st Cir. 1996), we conclude that the use of defendants' names did not constitute reversible error.

The plaintiffs lastly argue that Question 4 was confusingly worded and capable of multiple “legally erroneous” interpretations. This objection suffers from the same defect as the others in that it was not preserved during the post-charge sidebar. The forfeited argument is unable to withstand plain error review, especially when examined in the context of the comprehensive instructions that the court provided to facilitate the jury's understanding of the verdict form. First, the plaintiffs' suggestion that the jury could have interpreted Question 4 to be asking “whether AstraZenea would allow Ranbaxy to get Ranbaxy's product to market” is meritless in light of the court's jury charge:
The plaintiffs' claim is not that Ranbaxy would have launched, no evidence of that, their claim is that had AstraZeneca not made a large payment to Ranbaxy, they would have settled with a date for generic entry before May 27th, 2014.... And that Teva then would have obtained the same or earlier date ... or that ... Teva would have made a deal with Ranbaxy allowing Teva to launch.

Likewise, the plaintiffs' concern that Question 4 imprecisely used the phrase “anticompetitive settlement,” rather than “large and unjustified payment,” is alleviated by jury instructions explaining how the presence of a large and unjustified payment in a paragraph IV litigation settlement renders that settlement anticompetitive.

Perhaps the verdict form was inartfully phrased. But in the context of the thorough jury instructions and the plaintiffs' own failure to preserve objections, the plaintiffs cannot argue that any phrasing imperfection “seriously impaired the fairness, integrity, or public reputation of the judicial proceedings.” Tasker, 621 F.3d at 41 (quoting Dávila, 498 F.3d at 14–15).

D. Summary Judgment

We finally arrive at the core of the plaintiffs' appeal. The plaintiffs argue that they had but one antitrust causation theory at trial: “In this regulatory climate, generics will get to market in some way, and we can't know exactly how.” The district court erred, they say, in prematurely cutting off at summary judgment many causal mechanisms through which they could have proved this theory to a jury. The defendants respond in three ways: (1) the plaintiffs' theory of antitrust causation is actually a hodgepodge of disparate theories, none of which independently proves causation, (2) later events at trial moot any potential summary judgment error, and (3) the summary judgment ruling was correct on its merits.

Even accepting dubitante the level of generality at which the plaintiffs characterize their causation theory, we agree *62 with the defendants that any error at summary judgment was rendered harmless by the jury verdict and by later trial proceedings on the issue of patent invalidity. We are satisfied that the evidence in support of even those causal mechanisms purportedly excluded at summary judgment was in fact put before the jury, as that evidence was relevant under other concededly admitted theories. The district court recognized the relevance of that evidence and generously admitted much of it notwithstanding the summary judgment ruling (which it later reversed).

Plaintiffs identify four causal theories they say were cut off at summary judgment. First, Ranbaxy could have launched its generic Nexium at risk before February 2009. Second, Teva could have won a final, nonappealable judgment in its paragraph IV suit against AstraZeneca, thereby forcing Ranbaxy to launch its generic within 75 days or forfeit its exclusivity, which would have allowed Teva to launch before May 2014. Third, Ranbaxy could have negotiated an earlier license date with AstraZeneca and launched (either alone or in partnership with Teva) before May 2014. Finally, Ranbaxy could have negotiated an earlier license date with AstraZeneca and then forfeited its first-filer exclusivity, which would have allowed another manufacturer like Teva to launch before May 2014.

Ordinarily, “[w]e review the merits of the entry of partial summary judgment de novo.” Vélez v. Awning Windows, Inc., 375 F.3d 35, 41 (1st Cir. 2004). But we have refused to “reenter th[e] morass” of summary judgment where it was “perfectly clear that, even if [a plaintiff's claim] should not have been dismissed on partial summary judgment, any such mistake was harmless, given the jury's verdict in [the defendant's] favor on [other claims] addressed to the very same [factual circumstances].” Fite v. Dig. Equip. Corp., 232 F.3d 3, 6 (1st Cir. 2000). We have so held in the antitrust context. See Fraser v. Major League Soccer, LLC, 284 F.3d 47, 60–61 (1st Cir. 2002).
In re Nexium (Esomeprazole) Antitrust Litigation, 842 F.3d 34 (2016)  
2016-2 Trade Cases P 79,835, Med & Med GD (CCH) P 305,800

An examination of the four supposedly foreclosed causal mechanisms, in light of later events at trial, reveals that the outcome would have been in the defendants' favor even had the mechanisms been explicitly put in questions to the jury. In particular, the first two mechanisms were mooted by the district court's grant of JMOL on any theory involving the invalidity of AstraZeneca's patents. Indeed, the argument that Ranbaxy would have incurred the risk of launching at risk or that Teva would have won its paragraph IV suit against AstraZeneca depends on the theory that AstraZeneca's Nexium patents were invalid or not infringed by a generic version. The district court's JMOL ruling, however, found "no adequate evidence that any of [the Nexium] patents would be adjudicated invalid." Accordingly, even if the district court had allowed the plaintiffs to present these two causal mechanisms at trial, the court's later judgment would have yielded the same outcome in favor of the defendants.

Plaintiffs respond that they should not have to prove patent invalidity or noninfringement to be able to present their at-risk launch causation theory. They principally rely on two circuit cases to advance this argument, but to no avail. See In re Cardizem CD Antitrust Litig., 332 F.3d 896 (6th Cir. 2003); Andrx Pharm., Inc. v. Biovail Corp. Int'l, 256 F.3d 799 (D.C. Cir. 2001). Both of these cases were decided before the Supreme Court's Actavis decision, which may call into question aspects of their analyses. Even assuming that the two decisions survive Actavis, they are still inapposite to our inquiry because both cases evaluated allegations of antitrust injury *63 at the Rule 12(b)(6) stage. See In re Wellbutrin XL Antitrust Litig., 133 F.Supp.3d 734, 765 n.46 (E.D. Pa. 2015), appeal pending. No. 15–3559 (3d Cir.). In In re Cardizem, for instance, the Sixth Circuit held that the defendants' argument—that their decision to stay out of the generic market was motivated not by a reverse payment, but rather by a fear of damages resulting from patent infringement litigation—"merely raise[d] a disputed issue of fact that [could not] be resolved on a motion to dismiss." 332 F.3d at 900. The Cardizem court did not altogether reject the potential relevance of patent invalidity or noninfringement evidence in evaluating the viability of an antitrust-injury theory based on an at-risk launch. So too in Andrx, 256 F.3d at 805, and United Food & Commercial Workers Local 1776 v. Teikoku Pharma USA, Inc., 74 F.Supp.3d 1052, 1074 (N.D. Cal. 2014), yet another case that the plaintiffs cite. 7

In re Wellbutrin XL, a post-Actavis decision at the summary judgment stage, is persuasive. 133 F.Supp.3d 734. There, the district court granted summary judgment to the defendants, who were producers and distributors of a branded antidepressant drug, on the plaintiffs' at-risk theory of antitrust injury because the plaintiffs proffered no evidence of patent invalidity or noninfringement. Id. at 764–67. The court acknowledged that, if shown, "[t]he existence of a valid and uninfringed patent would interfere with the plaintiffs' chain of causation: a valid patent independently precludes competition apart from any agreement and an 'at risk' launch is unlawful absent a later finding of patent invalidity or non-infringement." Id. at 764 (citation and alterations omitted).

But there, as here, the plaintiffs did not present such evidence that the brand-name's patents would have been declared invalid or that an at-risk launch would not have infringed the patents. And without such evidence, the "patent served as an independent regulatory bar to [a generic's] launch." Id. at 767. So too here. Upon the conclusion of the plaintiffs' case in chief, the district court saw no evidence that would allow the plaintiffs to overcome the likelihood that AstraZeneca's patents, not its reverse payment to Ranbaxy, were the bar to a generic launch. The district court thus did not err by requiring some evidence of the patents' invalidity or noninfringement before allowing the plaintiffs to pursue an at-risk launch theory.

Furthermore, the district court's ruling on patent invalidity did not prejudice the plaintiffs, for two reasons. First, the plaintiffs are simply wrong to insist that the district court decided and ruled out of the case the issue of patent invalidity at summary judgment. In fact, the plaintiffs acknowledged the availability of that line of reasoning—and their strategic choice not to pursue it—at a conference on the second day of trial: “We don't plan on proving a patent case inside of an antitrust case.... [W]e do not plan to be proving that Teva would have won the [paragraph IV] litigation.” The plaintiffs then reaffirmed their strategic choice on November 20, 2014, at the same conference during which they opposed the defendants' motion for a mistrial. At that conference, they assented to the court's characterization of their position as not having “proved that the patents *64 would have been declared invalid, and [arguing] that that plays no role in this [trial].”
The district court's statements during trial likewise reveal its consistent understanding that the summary judgment ruling did not prevent the plaintiffs from offering patent invalidity evidence if they chose to do so. For instance, in its initial instructions to the jury at the beginning of trial, the district court explained that the plaintiffs would have to “convince [the jury] ... that Teva entered into its deal with AstraZeneca, staying out of the market, letting AstraZeneca charge its supracompetitive prices for its branded Nexium product, and if it hadn't done that, it could ... have defeated the patent, AstraZeneca's patents,” received FDA approval, and partnered with Ranbaxy to jointly launch a generic. The district court's view of the impact of its summary judgment ruling on patent invalidity did not change by the end of trial. At the December 2, 2014 charge conference, it reminded the plaintiffs: “I think that you will find, when you look at the record, I've never prevented the patent evidence[;] I've said you have to lay an adequate foundation for it.” Because the ruling on patent invalidity did not take place until after the plaintiffs' case in chief, at the JMOL stage, the timing of the ruling could not have foreclosed any evidence that the plaintiffs wished to put forth at trial. Any decision to limit evidence on patent invalidity was a voluntary and strategic choice on the plaintiffs' part.

Second, even after the JMOL ruling, the district court was careful to point out, and correctly so, that its decision did not foreclose the plaintiffs from making any arguments based on AstraZeneca's assessment of risk to its patent monopoly. That is, the court recognized that regardless of the absolute validity or invalidity of patents, business players make reverse payment decisions in an environment in which that validity has not yet been adjudicated. They take into account the risk of litigation and the possibility that patents may be adjudicated invalid or uninfringed. The court explained this distinction between patent invalidity and assessment of risk to the jury: “I went into the case thinking ... that one of the things the plaintiffs had to prove was that Teva would have won its patent case against AstraZeneca. And I've come to think now that legally that's not key, that's not what the plaintiffs have to prove.” In sum, while the JMOL ruling on patent invalidity mooted the causal mechanisms based on at-risk launch and Teva's ability to win a paragraph IV litigation against AstraZeneca, the JMOL ruling did not prejudice the plaintiffs' argument that the defendants had incentives to violate antitrust laws. Indeed, the jury verdict confirms this lack of prejudice, as it found that AstraZeneca made a large and unjustified payment to Ranbaxy and that their settlement agreement had unreasonably anticompetitive effects.

As for the next two causal mechanisms claimed to have been cut off at summary judgment, the jury's "no" answer to Question 4 renders any error harmless. That answer reflected the jury's finding that AstraZeneca would not have agreed to settlement terms with a license date earlier than May 27, 2014, the date on which two of its medical patents expired. In light of that finding, it made no difference to the outcome of the trial whether the plaintiffs were able to present their theory that Ranbaxy could have negotiated an earlier license date with AstraZeneca and themselves launched or allowed Teva to launch before May 2014.

The plaintiffs respond that the jury had insufficient evidence upon which to answer Question 4 differently. At oral argument, the plaintiffs emphasized that their inability to introduce evidence on the possibility of a Ranbaxy or Teva at-risk launch, or of Ranbaxy's forfeiture of its first-filer status, had meant that the jury had had no information on what “would have motivated AstraZeneca to accept an earlier entry date.” In other words, the plaintiffs argue that without evidence on at-risk launch or forfeiture, the jury could not appreciate the threat that Ranbaxy posed to AstraZeneca or the incentive that AstraZeneca had to cut a deal with an earlier entry date.

However, the jury answered “yes” to Questions 2 and 3 in the plaintiffs' favor, despite the supposed exclusion of such evidence. Indeed, this exact evidence—about Ranbaxy's potential adverse impact on AstraZeneca's bottom line—must have, and did, come in because the jury in fact found that AstraZeneca felt enough of a threat to offer a large and unjustified payment to Ranbaxy (Question 2) and offer settlement terms in violation of the antitrust laws (Question 3). The plaintiffs fail to explain what other evidence, unique to Question 4, the district court impermissibly excluded to impede the jury's ability to answer that question. To elaborate, while the plaintiffs recycle their grievances about the exclusion of Leffler's and McGuire's testimony on the Event Study, possible but-for entry dates, the purpose and effect of AstraZeneca's side deals with Ranbaxy, and the value of the reverse payment to Ranbaxy, we have already found above that all of this evidence was properly excluded. Ultimately,
the jury had sufficient evidence to answer “yes” to Question 4, as well as Questions 2 and 3. Because the plaintiffs cannot point to improperly excluded evidence specific to Question 4, we cannot accept their argument on the insufficiency of the evidence underlying the jury verdict.

In light of the jury verdict and other events at trial that mooted any summary judgment error, we find no occasion to readjudicate the merits of the district court's pretrial decision. The plaintiffs are not entitled to set aside the jury verdict.

V. CONCLUSION

In any litigation, each party must make “tactical choices” about what pretrial motions to file, what evidence to present, and what objections to renew or forfeit. This case was no different. And despite doubts that the district court harbored about the merits of the plaintiffs' causation theory even before trial commenced, the plaintiffs were able to present their arguments to an attentive jury over six weeks. They were represented by able counsel in every step of the proceeding. Having had that opportunity but having failed to convince the jury that an antitrust injury occurred, the plaintiffs cannot now rehash summary judgment and JMOL rulings, scattered evidentiary decisions, and unpreserved objections to the verdict form in search of a do-over.

We affirm.

Footnotes

1 The pharmaceutical retail outlets are CVS, Inc.; Eckerd Corporation; Giant Eagle, Inc.; HEB Grocery Co. LP; JCG (PJC) USA, LLC; the Kroger Company; Maxi Drug, Inc. d/b/a Brooks Pharmacy; Rite Aid Corporation; Rite Aid Headquarters Corporation; Safeway Incorporated; Supervalu, Inc.; and Walgreen Co.

2 The court rejected as too speculative another causal mechanism—namely, that Teva could have won its paragraph IV suit and obtained a final, nonappealable judgment that AstraZeneca's Nexium patents were invalid or not infringed. That theoretical victory could, in turn, have triggered the regulatory 75–day window within which Ranbaxy had to launch its generic or forfeit its first-filer exclusivity. Id. at 289–90.

3 The vigor with which the plaintiffs acknowledged the admission of evidence on the Ranbaxy reverse payment is worth noting:

From the very beginning of this case the payment to Ranbaxy has been in clearly as at least an overt act in furtherance of the conspiracy.... But for [the defendants] to come here now and say, Oh, this was never in the case, that simply from our perspective is not true. It was unclear exactly how much and what role that payment was going to make, but it was clear it was in this as an overt act.... And we made our tactical choices and [the defendants] made theirs.
As a threshold matter, the defendants argue that the plaintiffs are judicially estopped from appealing the exclusion of McGuire's Event Study, as they agreed to give up that evidence to defeat the defendants' mistrial motion. We need not reach this claim.

In their proposed special jury verdict form, the plaintiffs suggested precisely the same split in questions between antitrust violation and antitrust injury (in the form of a delayed generic entry).

Because the plaintiffs do not appeal the district court's denial of their post-trial motion for an injunction, they evidently seek a new trial in order to recover damages.

In fact, the district court in Teikoku expressly distinguished In re Nexium, describing it as “a case where the generic manufacturer moved for summary judgment, and offered unrebutted evidence ‘that an at risk launch was “unlikely”’ and “extremely risky.” ’” 74 F.Supp.3d at 1074. In contrast, Teikoku dealt with “a motion to dismiss and defendants cite[d] to no comparable evidence that [wa]s properly before the [c]ourt at th[at] juncture.” Id.

Of course, as we have now repeated numerous times, the plaintiffs voluntarily chose not to pursue the causal mechanism involving Teva's at-risk launch after the district court informed them that such an argument would trigger jury instructions about their need to prove patent invalidity.
In re Aggrenox Antitrust Litigation, 94 F.Supp.3d 224 (2015)
2015-1 Trade Cases P 79,115

94 F.Supp.3d 224
United States District Court, D. Connecticut.

In re AGGRENOX ANTITRUST LITIGATION.
This Document Relates to: All Actions.

No. 3:14–md–2516 (SRU)

Synopsis

Background: Direct purchasers of brand name prescription medication consisting of particular combination of dipyridamole and aspirin, and indirect purchasers thereof, also known as end payors, brought two putative class complaints, and another end payor brought individual complaint, against several interrelated pharmaceutical companies alleging that patent-holding drug manufacturer's “reverse payment” settlement agreements with generic manufacturers violated federal and state antitrust laws. Defendants filed motions to dismiss for lack of subject matter jurisdiction and failure to state a claim.

Holdings: The District Court, Stefan R. Underhill, J., held that:

direct purchasers' federal antitrust claims were timely for all overcharges alleged to have been incurred within the four years preceding filing of claims;

direct purchasers plausibly alleged antitrust injury under Supreme Court's Actavis decision;

direct purchasers plausibly alleged large and unjustified reverse “payment”;

direct purchasers plausibly alleged monopoly power within sufficiently defined product market;

indirect purchasers lacked standing to bring antitrust claims under laws of Utah where they did not allege they were citizens or residents of that state, of Puerto Rico as it had no Illinois Brick repealer statute, or of Rhode Island in connection with overcharges occurring before effective date of its repealer statute;

indirect purchasers failed to adequately plead state consumer protection and unjust enrichment claims, which would bee dismissed without prejudice to repleading them in nonconclusory fashion; and

district court lacked personal jurisdiction over Israeli pharmaceutical company that acquired generic drug manufacturer which had entered into reverse payment settlement agreement with manufacturer of brand-name drug.

Motions granted in part and denied in part.

Procedural Posture(s): Motion to Dismiss; Motion to Dismiss for Lack of Personal Jurisdiction; Motion to Dismiss for Failure to State a Claim.
In re Aggrenox Antitrust Litigation, 94 F.Supp.3d 224 (2015)

**Attorneys and Law Firms**


**MEMORANDUM OF DECISION AND ORDER**

STEFAN R. UNDERHILL, District Judge.

This case aggregates numerous antitrust actions brought by numerous plaintiffs in various districts against several interrelated pharmaceutical companies, all transferred to this Court by the Judicial Panel on Multidistrict Litigation. Under a Practice and Procedure Order (doc. # 37), the actions are consolidated into two groups: all direct-purchaser actions, and all indirect-purchaser actions (the indirect purchasers also style themselves “end payors”). Two consolidated, putative class-action complaints have accordingly been filed. One of the indirect purchasers (or end payors), Humana, Inc. (“Humana”), which alleges that it has the greatest economic interest of any such plaintiff (and that it alone has standing in every state), is pursuing its claims individually.
In re Aggrenox Antitrust Litigation, 94 F.Supp.3d 224 (2015)

2015-1 Trade Cases P 79,115

There are thus three current complaints: (1) the direct-purchaser plaintiffs' putative class complaint (doc. # 109); (2) the indirect-purchaser plaintiffs' (or end-payor plaintiffs') putative class complaint (doc. # 120); and (3) the Humana complaint (doc. # 93).

The defendants are also divisible into several groups: (1) Boehringer Ingelheim Pharma GmbH & Co. KG and Boehringer Ingelheim International GmbH, which are organized under German law, and Boehringer Ingelheim Pharmaceuticals, Inc., which is a Delaware corporation (collectively “Boehringer”); (2) Teva Pharmaceutical Industries, Ltd. (“Teva Israel”), which is organized under Israeli law, and Teva Pharmaceuticals USA, Inc. (“Teva USA”), which is a Delaware corporation; (3) Barr Pharmaceuticals, Inc. and Barr Laboratories, Inc., which are both Delaware corporations (collectively “Barr”); and (4) Duramed Pharmaceuticals Inc. and Duramed Pharmaceuticals Sales Corp., which are both Delaware corporations (collectively “Duramed”). In 2008, Teva USA acquired Barr Pharmaceuticals. Duramed was, in turn, a subsidiary of Barr, and thus also became a subsidiary of Teva USA. Teva USA is a subsidiary of Teva Israel, making all non-Boehringer defendants at least indirect subsidiaries of Teva Israel.

There are four pending motions to dismiss, three of them filed collectively by all defendants except Teva Israel, and one filed by Teva Israel alone. Those motions are: (1) Teva Israel's motion to dismiss all complaints against it under Rule 12(b)(2) and Rule 12(b)(6) (doc. # 150); (2) the defendants' motion to dismiss the direct-purchaser complaint under Rule 12(b)(6) (doc. # 149; sealed mem., doc. 168); (3) the defendants' motion to dismiss the indirect-purchaser complaint under Rule 12(b)(6) (doc. # 151); and (4) the defendants' motion to dismiss the Humana complaint under Rule 12(b)(6) (doc. # 152).

I. Standards of Review

A. Rule 12(b)(2)

A plaintiff bears the burden of showing that the court has personal jurisdiction over each defendant. Metro. Life Ins. Co. v. Robertson–Ceco Corp., 84 F.3d 560, 566 (2d Cir.1996). Where, as here, there has been no discovery on jurisdictional issues and the court is relying solely on the parties' pleadings and affidavits, the plaintiff need only make a prima facie showing that the court possesses personal jurisdiction over the defendant. Bank Brussels Lambert v. Fiddler Gonzalez & Rodriguez, 171 F.3d 779, 784 (2d Cir.1999).

B. Rule 12(b)(6)

A motion to dismiss for failure to state a claim pursuant to Rule 12(b)(6) is designed “merely to assess the legal feasibility of a complaint, not to assay the weight of evidence which might be offered in support thereof.” Ryder Energy Distribution Corp. v. Merrill Lynch Commodities, Inc., 748 F.2d 774, 779 (2d Cir.1984) (quoting Geisler v. Petrocelli, 616 F.2d 636, 639 (2d Cir.1980)).

When deciding a motion to dismiss pursuant to Rule 12(b)(6), the court must accept the material facts alleged in the complaint as true, draw all reasonable inferences in favor of the plaintiffs, and decide whether it is plausible that plaintiffs have a valid claim for relief. Ashcroft v. Iqbal, 556 U.S. 662, 678–79, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009); Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555–56, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007); Leeds v. Meltz, 85 F.3d 51, 53 (2d Cir.1996).

Under Twombly, “[f]actual allegations must be enough to raise a right to relief above the speculative level,” and assert a cause of action with enough heft to show entitlement to relief and “enough facts to state a claim to relief that is plausible on its face.” 550 U.S. at 555, 570, 127 S.Ct. 1955; see also Iqbal, 556 U.S. at 679, 129 S.Ct. 1937 (“While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations.”). The plausibility standard set forth in Twombly and Iqbal obligates the plaintiff to “provide the grounds of his entitlement to relief” through more than “labels and conclusions, and a formulaic recitation of the elements of a cause of action.” Twombly, 550 U.S. at 555, 127 S.Ct.
II. Discussion

A. Factual and Legal Background

This case arises at the intersection of two areas of law that would seem to be naturally at odds with one another: antitrust law—procompetitive by design—which prohibits certain forms of anticompetitive conduct, and patent law—anticompetitive by design—which seeks to encourage innovation by rewarding innovators with limited legal monopolies. The question at the heart of this case is whether a patent-litigation settlement—that is, an agreement to settle litigation that had put the legitimacy of a patent's grant of monopoly at issue—constituted a violation of antitrust law. Two features dominate the background: (1) the incentives to undertake patent litigation under the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch–Waxman Act, and (2) the uncertain but disruptive effect on such litigation of the Supreme Court's recent decision in FTC v. Actavis, Inc., — U.S. —–, 133 S.Ct. 2223, 186 L.Ed.2d 343 (2013). I discuss each in turn below, followed by a brief recitation of the central facts of this case.

1. The Hatch–Waxman Act and “Pay for Delay” Settlements

A pharmaceutical manufacturer seeking to introduce a new prescription drug to market must first obtain the approval of the FDA by filing a New Drug Application and undertaking an extensive and expensive testing process to demonstrate that the drug is safe and effective for its intended purpose. Under the Hatch–Waxman Act, a later manufacturer of a generic equivalent drug need not duplicate that effort, but may instead submit an Abbreviated New Drug Application that relies on the earlier scientific findings related to the already-approved brand-name drug. The abbreviated Hatch–Waxman process benefits consumers by expediting the introduction of low-cost generics to the market.

Hatch–Waxman also establishes special procedures relating to patent disputes and contains provisions that encourage patent challenges. A drug manufacturer filing a New Drug Application must list the number and expiration date of any relevant patent, and a manufacturer filing an Abbreviated New Drug Application must indicate the relationship of its generic drug to any such previously-listed patent in one of several ways. The manufacturer of the generic must certify either that no such patent has been filed, that such patent has expired, the date on which such patent will expire, or “that such patent is invalid or will not be infringed by ... the new drug.” 21 U.S.C. § 355(j)(2)(A)(vii)(IV). That assertion of invalidity or non-infringement is known as “Paragraph IV certification,” and insofar as it is inaccurate, it statutorily constitutes infringement, see 35 U.S.C. § 271(e)(2)(A), and may therefore provoke litigation; it thus provides a procedure for challenging drug patents without starting production and sales of a possibly-infringing drug and potentially accruing damages. After Paragraph IV certification, the brand-name manufacturer may bring an infringement suit within 45 days and trigger an automatic stay of FDA approval of the generic for 30 months or, if it requires less time than that, until adjudication of the validity of the challenged patent in a district court. See 21 U.S.C. § 355(j)(5)(B)(iii).

As an incentive to make such challenges, Hatch–Waxman provides an exclusivity period of 180 days (from the first marketing of the generic) to the first manufacturer to file an Abbreviated New Drug Application with Paragraph IV certification, during which time no other Abbreviated New Drug Application will be approved. See § 355(j)(5)(B)(iv). The Supreme Court in Actavis observed that the 180–day exclusivity period can be tremendously valuable, possibly worth hundreds of millions of dollars and a majority of the potential profits for a generic drug. 133 S.Ct. at 2229 (citing scholarship and a statement of the Generic Pharmaceutical Association).
Manufacturers of generic drugs have obvious motivation to bring Paragraph IV challenges to patents they believe are vulnerable; and because brand-name drugs sell at such high premiums, their manufacturers have obvious motivation to meet those challenges with infringement suits. But defending patents can be expensive, so brand-name manufacturers may also be motivated to settle the suits—all the more so if they suspect their challenged patents may indeed be vulnerable. Such settlements result in unusual dynamics. For instance, it sometimes happens that the parties settle under terms that require the plaintiff patent-holder to pay the defendant infringer—sometimes called a “reverse payment” settlement agreement—and to permit the defendant to begin producing a generic at a future date, but a date that is earlier than the expiration of the patent, in exchange for the defendant dropping its patent challenge. Assuming the patent is valid, and that the patent-holder would ultimately prevail, such a settlement means that the patent-holder is avoiding the cost of litigation by agreeing to shorten the length of its legal monopoly and to share some of its monopoly profits with the challenger. Consumers benefit by enjoying the lower prices of generics sooner than they otherwise would under the patent. Assuming, however, that the patent is invalid, and that the challenger would ultimately prevail, then such a settlement amounts to a “pay to delay” agreement: the patent-holder's monopoly is illegitimate, and it is paying a would-be competitor to delay its entry into the market. Consumers who should enjoy competitive prices now will instead pay monopoly prices until the end of the term of the anticompetitive collusion. The availability of such settlements allows manufacturers of brand-name drugs to avoid the invalidation of potentially weak patents and keep prices high by sharing their monopoly profits with manufacturers of generics.

Is that an antitrust violation? Several courts of appeals, including the Second Circuit, have said no, at least absent fraud in obtaining the patent and so long as the settlement terms are within its scope (i.e., consumers will not face a longer period of monopoly under the settlement than they would have faced under the patent, implicitly presuming the patent's validity). See, e.g., In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187 (2d Cir.2006); In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed.Cir.2008). Other courts of appeals have said have said, at least *235 unless a presumption of unlawful restraint of trade is rebutted. See, e.g., In re K–Dur Antitrust Litig., 686 F.3d 197 (3d Cir.2012); In re Cardizem CD Antitrust Litig., 332 F.3d 896 (6th Cir.2003). The Supreme Court in Actavis, abrogating those decisions, said “sometimes.”

2. The Actavis Decision

The facts of Actavis in most essentials follow the discussion above: Solvay Pharmaceuticals filed a New Drug Application for a brand-name drug, obtained approval, and later a patent. Actavis, Inc. (among others) filed an Abbreviated New Drug Application for a generic equivalent and certified under Paragraph IV that Solvay's patent was invalid and the proposed generic would not infringe it. Solvay responded with litigation, which later settled, and the terms of the settlement guaranteed Actavis millions of dollars in annual payments from Solvay and allowed it to bring its generic to market at some time before the disputed patent expired, but not immediately. Actavis also agreed to provide some services, such as promoting the brand-name drug, and the companies described the payments as compensation for those services. The FTC sued, alleging that the services had little value and that the purpose of the payments was to compensate a would-be competitor for agreeing to delay competition. The district court held that the FTC failed to set forth an antitrust violation, In re Androgel Antitrust Litigation (No. II), 687 F.Supp.2d 1371, 1379 (N.D.Ga.2010), and the Eleventh Circuit affirmed, writing that “absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.” FTC v. Watson Pharmaceuticals, Inc., 677 F.3d 1298, 1312 (11th Cir.2012).

In a 5–3 opinion, the Supreme Court reversed the Eleventh Circuit, holding that such settlement agreements “can sometimes violate the antitrust laws,” Actavis, 133 S.Ct. at 2227, and that the plaintiff “should have been given the opportunity to prove its antitrust claim.” Id. at 2234. The Court reasoned that referring “simply to what the holder of a valid patent could do does not by itself answer the antitrust question,” because invalidated patents confer no right to exclude competition, and the Paragraph
In re Aggrenox Antitrust Litigation, 94 F.Supp.3d 224 (2015)

IV certification “put the patent's validity at issue, as well as its actual preclusive scope.” Id. at 2230–31. It cited legislative history from prior to the enactment of the 2003 amendments—specifically, statements of Senator Hatch and Representative Waxman—that clearly condemns reverse-payment settlements, and went on to conclude that “a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects.” Id. at 2237. It declined to adopt the “quick look” approach, which would make such settlements presumptively illegal, because “the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.” Id. The Court instead adopted the “rule of reason” approach, but as for more specific guidance on how to analyze “the basic question—that of the presence of significant unjustified anticompetitive consequences,” the Court “leave[s] to the lower courts the structuring of the present rule-of-reason antitrust litigation.” Id. at 2238.

Several district courts have already applied Actavis, with not entirely consistent results. See *236 King Drug Co. of Florence v. Cephalon, Inc., 88 F.Supp.3d 402, No. 2:06–CV–1797, 2015 WL 356913 (E.D.Pa. Jan. 28, 2015); United Food & Commercial Workers Local 1776 & Participating Emp'rs Health & Welfare Fund v. Teikoku Pharma USA, Inc., 74 F.Supp.3d 1052, No. 14–MD–02521–WHO, 2014 WL 6465235 (N.D.Cal. Nov. 17, 2014); In re Effexor XR Antitrust Litig., No. CIV. 11–5479 PGS, 2014 WL 4988410 (D.N.J. Oct. 6, 2014); In re Niaspan Antitrust Litig., 42 F.Supp.3d 735 (E.D.Pa.2014); In re Loestrin 24 Fe Antitrust Litig., 45 F.Supp.3d 180 (D.R.I.2014); In re Lamictal Direct Purchaser Antitrust Litig., 18 F.Supp.3d 560 (D.N.J.2014); In re Nexium (Esomeprazole) Antitrust Litig., 968 F.Supp.2d 367 (D.Mass.2013); In re Lipitor Antitrust Litig., No. 3:12–CV–2389 PGS, 2013 WL 4780496 (D.N.J. Sept. 5, 2013). As of the date of this writing, at least one case applying Actavis has been argued before a federal Court of Appeals—In re Lamictal was argued at the Third Circuit in November 2014—but none of the circuits has yet issued an opinion interpreting it. There are some questions that arise in the application of Actavis that the district courts may answer in divergent ways—questions like what constitutes a reverse “payment,” and what makes one “large” and “unjustified.” Some of those questions will surely end up in the Courts of Appeals, and perhaps eventually back again at the Supreme Court. As one of the courts above observed, “[w]e are confronting this issue early in a law refinement process that will take some time to shake out.” In re Loestrin 24 Fe Antitrust Litig., 45 F.Supp.3d at 194.

3. Aggrenox

The facts of the Aggrenox litigation, as they appear in the pleadings, are virtually identical in essential respects to those of Actavis. Aggrenox is a brand-name prescription medication consisting of a particular combination of dipyridamole and aspirin. In January 2000, Boehringer obtained U.S. Patent No. 6,015,577 on the composition (“the ’577 patent”), after having obtained FDA approval in November 1999 for its use to lower the risk of stroke in patients who have already had a stroke or transient ischemic attack. Boehringer listed the patent with the FDA and brought Aggrenox to market, where it has been a commercial success.

In January 2007—ten years before patent ’577 is set to expire—Barr filed an Abbreviated New Drug Application seeking approval to market a generic equivalent of Aggrenox, with Paragraph IV certification challenging the ’577 patent. Boehringer brought suit in the District of Delaware. At the same time, Barr also intended to introduce a generic of another Boehringer product, Mirapex, and separate litigation on that issue was pending in the District of Delaware. In August 2008, Boehringer and Barr settled all patent litigation between them, with respect to both Aggrenox and Mirapex. They contemporaneously entered a settlement agreement, an Aggrenox license, a Mirapex license, and a Co–Promotion Agreement. Among other things, Barr agreed to drop its patent challenge and not market generic Aggrenox until July 2015 (eighteen months prior to the expiration of the patent), and that Duramed (a Barr subsidiary) would use its specialized sales force to educate obstetricians and gynecologists about Aggrenox. Barr would be compensated based on several factors, including net sales of Aggrenox, regardless of whether its co-promotion generated any additional sales (the FTC estimated that the deal would cost Boehringer over $120 million in
royalties). The agreements were announced publicly in a press release. The FTC commenced an inquiry in January 2009, which is apparently ongoing.

In August 2009, at least some of the same parties and lawyers in the present *237 litigation brought suit against Boehringer in the Western District of Pennsylvania, alleging that the 2008 settlement was intended to delay entry of generic Mirapex in violation of antitrust law. When the Federal Circuit upheld the validity of the Mirapex patent, the plaintiffs in that case dropped their suit. In 2013, the various suits consolidated here began to be filed, now alleging that the 2008 settlement was intended to delay entry of generic Aggrenox in violation of antitrust law.

B. Federal Antitrust Claims

1. Statute of Limitations

The defendants argue in all of their motions to dismiss (most extensively in their motion to dismiss the direct-purchaser complaint, and that discussion is incorporated by reference in the other motions) that the 2013 claims are time-barred. There is no dispute that the statute of limitations for Sherman Act claims is four years from when “the cause of action accrued,” 15 U.S.C. § 15b, and that an antitrust cause of action generally accrues “when a defendant commits an act that injures a plaintiff's business,” *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 401 U.S. 321, 338, 91 S.Ct. 795, 28 L.Ed.2d 77 (1971) (emphasis added), but the parties differently emphasize the commission of the act itself and the consummation of the act in an injury, taking different positions on the applicability of *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263 (2d Cir.1979).

The defendants offer two possibilities: the claims accrued in August 2008, when the Aggrenox settlement was reached and publicly announced; or in August 2009, when the FDA approved Barr's Abbreviated New Drug Application for a generic equivalent to Aggrenox. If the defendants committed some discrete anticompetitive act, then surely—as the complaints allege—it was the 2008 agreement. If injury was only speculative at that date, because Barr did not yet have approval to begin production of the generic, then surely it would become real in August 2009 when that approval was obtained. Both dates put the November 2013 filing of the first direct-purchaser complaint outside of the four-year window. The defendants also argue that the end of the automatic 30–month stay of FDA approval of a generic that was triggered by the filing of Boehringer's infringement suit—though falling just within four years of the filing of the first complaint—should not be taken as the accrual date. They argue that under the plaintiffs' theory of the case (at least as the defendants understand it), the invalidity of Boehringer's patent would have been determined in court (and the avoidance of this inevitability was the motivation for the settlement), and thus the stay would have ended prior to the 30–month period. The plaintiffs cannot be permitted, the defendants insist, to argue for an earlier date when arguing that the settlement caused the specific harm of delayed entry of a generic, but to argue for a later date for purposes of the statute of limitations.

The plaintiffs, however, believe the defendants are attempting to dodge *Berkey Photo*, which distinguishes injured rivals from injured purchasers in antitrust actions. “Although the business of a monopolist's rival may be injured at the time the anticompetitive conduct occurs,” the Second Circuit reasoned, “a purchaser, by contrast, is not harmed until the monopolist actually exercises its illicit power to extract an excessive price.... So long as a monopolist continues to use the power it has gained illicitly to overcharge its customers, it has no claim on the repose that a statute of limitations is intended to provide.... The purchaser's cause of action, therefore, accrues only on the date damages *238 are suffered...” 603 F.2d at 295 (internal quotation marks omitted).

The defendants argue that *Berkey Photo* does not apply, because its analysis relied on circumstances in which plaintiffs might not yet have reason to believe they were injured within the limitations period. The case as they see it therefore stands for a narrow “speculative damages” exception, and more expansive language is mere dicta. Moreover, the defendants insist, this
case and others that the plaintiffs cite rely on ongoing instances of discrete anticompetitive conduct within the limitations period, not merely carrying out the terms of an earlier agreement. They argue that the Second Circuit has distinguished between the new and independent acts needed to maintain a conspiracy and inertial consequences flowing from a discrete act. The defendants rely most heavily on United States v. Grimm, 738 F.3d 498 (2d Cir. 2013), a criminal case dismissing a conspiracy-to-commit-wire-fraud indictment on grounds of a lapsed limitations period. The defendants also cite various other cases in addition to Grimm for the proposition that courts in the Second Circuit very strongly disfavor the “continuing violation” doctrine, and for the narrowness of the exception that the doctrine purportedly represents. See, e.g., Pressley v. City of N.Y., 2013 WL 145747 (E.D.N.Y. Jan. 14, 2013); Trinidad v. N.Y. City Dept. of Corr., 423 F.Supp.2d 151 (S.D.N.Y.2006); In re Ciprofloxacin Hydrochloride Antitrust Litig., 261 F.Supp.2d 188 (E.D.N.Y.2003); Schultz v. Texaco Inc., 127 F.Supp.2d 443 (S.D.N.Y.2001). But the cited decisions are either not antitrust cases, or they do not examine the issue pertinent here of purchasers alleging ongoing overcharges. None of them abrogates or otherwise casts doubt on the authority or reasoning of Berkey Photo, and none of them so squarely meets the allegations in this case as Berkey Photo does.

The defendants are correct that the Berkey Photo Court discusses speculative damages and the potential of anticompetitive conduct to harm even businesses that do not yet exist at the time of the conduct. It is inaccurate, however, to suggest that the court used any such limiting language in its holding, or that the plaintiffs have misplaced reliance on its dicta. On the contrary, cutting through any dispute about what is and is not mere dictum, the court expressly flags its holding: “We hold, therefore, that a purchaser suing a monopolist for overcharges paid within the previous four years may satisfy the conduct prerequisite to recovery by pointing to anticompetitive actions taken before the limitations period.” 603 F.2d at 296. That is precisely the scenario that the plaintiffs allege. They allege, in fact, not just overcharges paid within the previous four years, but overcharges that are ongoing. Even if, as defendants argue, the prerequisite anticompetitive conduct occurred wholly outside of the four-year limitations period, the plaintiffs' claims still fall clearly and squarely under the holding of Berkey Photo.

Courts in other districts and circuits have used the same reasoning applied in Berkey Photo—a purchaser suing a monopolist for overcharges is injured anew by each overcharge—and have come to the same result. See, e.g., In re Niaspan Antitrust Litig., 42 F.Supp.3d 735, 746–47 (E.D.Pa.2014) (“Every court to have considered this issue in the pay-for-delay context has held that a new cause of action accrues to purchasers upon each overpriced sale of the drug.”) (citing In re K–Dur Antitrust Litig., 338 F.Supp.2d 517, 549 (D.N.J.2004) (“Plaintiffs' claims are not barred by the statute of limitations to the extent that they bought and overpaid for K–Dur within the applicable time limitations.”)); In re Buspirone Patent Litig., 185 F.Supp.2d 363, 378 (S.D.N.Y.2002) (“If a party commits an initial unlawful act that allows it to maintain market control and overcharge purchasers for a period longer than four years, purchasers maintain a right of action for any overcharges paid within the four years prior to their filings.”); In re Skelaxin (Metaxalone) Antitrust Litig., No. 12–md–2343, 2013 WL 2181185 (E.D.Tenn. May 20, 2013) (holding that the plaintiffs' claims were timely because they were “overcharged for metaxalone well into the limitations period”).

I conclude that the federal antitrust claims are timely for all overcharges alleged to have been incurred within the four years preceding the filing of the claims.

2. Antitrust Injury Under Actavis

The defendants argue that the plaintiffs do not plausibly allege antitrust injury, because any injury at all is predicated upon the assumption that Barr would have prevailed in its patent challenge, and because the plaintiffs make only the conclusory allegation that the patent was weak. The plaintiffs, they say, simply make no allegation meeting the plausibility standard on a motion to dismiss that the '577 patent would have been found invalid, or that a generic would have been introduced “at-risk,” if only the defendants had not entered into the challenged settlement agreement. There is thus no plausible allegation of actual
injury, the argument goes, because there is no plausible allegation of actual delay of the entry of a generic. That argument, however logically compelling it might be in isolation, fails to engage seriously with the Supreme Court's reasoning in *Actavis*, which poses an insurmountable obstacle to it.

The essential problem with the divergent rules for the treatment of reverse-payment patent-litigation settlements before *Actavis* is that they made (likely unjustifiable) presumptions about the validity of the underlying patents, which was the very issue disputed in the underlying patent litigation. Under the old “scope of the patent” test, which was rejected in *Actavis*, any settlement less restrictive than the patent was immune from antitrust scrutiny. But “to refer ... simply to what the holder of a valid patent could do does not by itself answer the antitrust question,” the Court held, because the patent “may or may not be valid, and may or may not be infringed. A *valid* patent excludes all except its owner from the use of the protected process or product... But an *invalidated* patent carries with it no such right.” *Actavis*, 133 S.Ct. at 2230–31 (internal quotations and citation omitted). The patent's validity was precisely the disputed issue in the litigation, and the settlement ended that litigation. Taking the patent's exclusionary scope as the baseline does indeed make procompetitive any settlement that reflects any lesser exclusion; but that baseline presumes the validity of the patent. The opposite presumption—taking the invalidity of the patent as the baseline—would make any period of excluded competition that is agreed to in a settlement, no matter how much shorter than the patent's period of exclusion, necessarily anticompetitive. Both presumptions are impermissible.

The defendants, by expecting the plaintiffs to plead with specificity reasons to infer that the '577 patent would ultimately have been invalidated, appear to presume that the Supreme Court in *Actavis* favored a rule that required litigating the patent's merits, at least in some abbreviated fashion, in order to determine whether a settlement violates antitrust law. That would be a logical (however impractical) way to avoid presuming either the patent's validity or invalidity, but the Supreme Court expressly disclaimed it:

[I]t is normally not necessary to litigate patent validity to answer the antitrust question.... An unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival. And that fact, in turn, suggests that the payment's objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market—the very anticompetitive consequence that underlies the claim of antitrust unlawfulness.

*Id.* at 2236. The “unexplained large reverse payment” serves as a proxy for the weakness of the patent, which thus need not be proved (or pleaded) directly. Moreover, the Court identified the pertinent “anticompetitive consequence,” which does not appear to depend on the conclusive invalidity of the patent. The antecedent of the appositive clause identifying the anticompetitive consequence contains a telling subjunctive: “to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what *might have been* a competitive market” (emphasis added). The Court was still clearer a few sentences later:

The owner of a particularly valuable patent might contend, of course, that even a small risk of invalidity justifies a large payment. But, be that as it may, the payment (if otherwise unexplained) likely *seeks to prevent the risk* of competition. And, as we have said, *that consequence constitutes the relevant anticompetitive harm*. In a word, the size of the unexplained reverse payment can provide a workable
surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself.

*Id.* at 2236–37 (emphasis added). The anticompetitive harm is not that the patent surely would have been invalidated if not for the settlement, and that a generic therefore surely would have entered the market sooner; if that were the anticompetitive harm, a determination of a patent settlement's lawfulness under antitrust law would require the very same patent litigation that the settlement avoided. The anticompetitive harm, under *Actavis*, is that the reverse-payment settlement “seeks to prevent the risk of competition” (emphasis added). The plaintiffs thus need not plead (or prove) the weakness of the ′577 patent, because the patent's ultimate validity is not at issue. Rather, they must plead facts sufficient to infer (and they must ultimately prove, within the rule-of-reason framework) that a large and otherwise unjustified reverse-payment was made as part of the settlement in order to shore up some perceived risk of the ′577 patent's invalidity.

The rule of *Actavis* might seem unusual or counterintuitive given the typical settlement context. The value of a lawsuit is traditionally estimated as the expected value of judgment multiplied by the probability of liability, less litigation costs. The probabilities are of course always rough estimates, but the parties evaluate the favorability of potential settlements by their respective estimation of risk and the allocation of that value between them. In the Hatch–Waxman context, however, where litigation was provoked by Paragraph IV certification (and production of allegedly infringing product need not have begun), there may be no actual damages, and the adverse outcome for the patent-holder is measured not by the size of a potential judgment but by the forgone monopoly profits in the event of patent invalidation. Any settlement that takes the risk of patent invalidation into account will tacitly reflect the value of continuing the patent monopoly. Of course it will generally be in the interest of both patent-holder and patent-challenger to share the monopoly profits rather than compete:

Indeed, there are indications that patentees sometimes pay a generic challenger a sum even larger than what the generic would gain in profits if it won the paragraph IV litigation and entered the market. The rationale behind a payment of this size cannot in every case be supported by traditional settlement considerations. The payment may instead provide strong evidence that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market.

*Id.* at 2235 (citation omitted). In such cases, the *ex ante* probability of patent invalidation will factor only into the allocation of monopoly profits between patent-holder and patent-challenger, while the consumer bears the cost of monopoly prices irrespective of the patent's strength or weakness.

Of course, the *actual* expected cost of litigation for the patent-holder necessarily includes the risk of invalidation and forgone monopoly profits, whether or not that is a permissible settlement consideration. It is thus no surprise if pre-*Actavis* settlements in the Hatch–Waxman context frequently included large payments flowing from patent-holders to patent-challengers (that is, large “reverse” payments), and we might therefore expect *Actavis* to discourage many patent settlements, especially where the patent in question is very valuable. That may impose a cost on the judicial system, which, as the Supreme Court acknowledged in *Actavis*, prefers “a general legal policy favoring the settlement of disputes,” *id.* at 2234, but it is consistent with what the Court observed were the purposes of the Hatch–Waxman Act and Paragraph IV certification. *Id.* (observing “the general procompetitive thrust of the statute,” and “its specific provisions facilitating challenges to a patent's validity”).
In re Aggrenox Antitrust Litigation, 94 F.Supp.3d 224 (2015)

2015-1 Trade Cases P 79,115

In sum, though the defendants are correct that the several complaints in the present case plead relatively bare allegations of the '577 patent's vulnerability and the hypothetical earlier entry of a generic if not for the settlement agreement, the sparsity of those allegations does not fatally undermine the claims of antitrust injury under Actavis. The salient question is not whether the fully-litigated patent would ultimately be found valid or invalid—that may never be known—but whether the settlement included a large and unjustified reverse payment leading to the inference of profit-sharing to avoid the risk of competition.

3. “Large” and “Unjustified” Reverse “Payment” Under Actavis

In Actavis, a brand-name manufacturer and a generic manufacturer settled a lawsuit provoked by Paragraph IV certification, and the settlement terms required the generic manufacturer to drop the patent challenge and provide promotional services for the brand-name drug. In exchange, the generic manufacturer received large payments and an entry date for the competing generic that was not immediate but still earlier than the expiration of the patent. The subsequent antitrust complaint alleged that the services were mere pretext for the payment, which was in truth a payment to delay competition. Nearly identical allegations are presented here. The Court in Actavis held that large and unjustified reverse payments bring with them the risk of significant anticompetitive effects, that the plaintiffs should have been allowed to present their antitrust case, and that rule-of-reason analysis should be applied, but it did not *242 discuss in any detail whether or why the reverse payment alleged in that case was “large” or “unjustified.” District courts applying Actavis have thus had relatively little guidance on the question of what constitutes a “large” and “unjustified” reverse payment, and have diverged even on the issue of what constitutes “payment.” The defendants here dispute the plaintiffs' characterization of their settlement agreement on all three grounds. The disputed “agreement” was in fact a complicated transaction involving a series of agreements settling separate litigation over two drug patents, and the defendants argue that nothing in any of it constitutes a reverse payment, but only compensation for services; and that even if some part of it does constitute a reverse payment, it is neither large nor unjustified.

The defendants emphasize that every settlement necessarily involves consideration on both sides, and that it therefore cannot be the case that a “reverse payment” of the sort contemplated in Actavis is present merely because an alleged patent infringer may be said to have received consideration as part of a settlement. That is doubtless correct—even a promise to stop litigating has value and may constitute consideration in a settlement agreement—but the defendants go altogether too far the other way in their attempt to read a maximally restrictive sense of “payment” into the Actavis decision. They make much of the fact that Actavis contains repeated examples and references to payments of money, and not to payments of some other form of consideration, and they dispute whether “payment” under Actavis comprises transfers of value in any form other than cash. As of the date of this writing, two courts have agreed with that view, see In re Loestrin 24 Fe Antitrust Litig., 45 F.Supp.3d 180 (D.R.I.2014); In re Lamictal Direct Purchaser Antitrust Litig., 18 F.Supp.3d 560 (D.N.J.2014), though one of them did so with “significant reservations” and called that conclusion “vexing.” In re Loestrin, 45 F.Supp.3d at 192–93. A majority of courts to have examined the issue take the opposite position, that “payment” is not limited to cash transfers. See, e.g., United Food & Commercial Workers Local 1776 & Participating Emp'rs Health & Welfare Fund v. Teikoku Pharma USA, Inc., 74 F.Supp.3d 1052, No. 14–MD–02521–WHO, 2014 WL 6465235 (N.D.Cal. Nov. 17, 2014); In re Effexor XR Antitrust Litig., No. CIV. 11–5479 PGS, 2014 WL 4988410 (D.N.J. Oct. 6, 2014); In re Niaspan Antitrust Litig., 42 F.Supp.3d 735 (E.D.Pa.2014); In re Nexium (Esomeprazole) Antitrust Litig., 968 F.Supp.2d 367 (D.Mass.2013). I must agree with the latter group.

Black's Law Dictionary defines “payment” as the “[p]erformance of an obligation by the delivery of money or some other valuable thing accepted in partial or full discharge of the obligation.” (10th ed.2014) (emphasis added). The Oxford English Dictionary defines it as a “sum of money (or equivalent) paid or payable, esp. in return for goods or services or in discharge of a debt.” (3d ed.2005) (emphasis added). Those definitions quite sensibly recognize the substitutability of value, because the distinction between transfers of money and transfers of things that are worth money is, in the words of the Actavis dissent, “a distinction without a difference.” Actavis, 133 S.Ct. at 2243 (Roberts, C.J., dissenting). Indeed, if antitrust scrutiny can be
In re Aggrenox Antitrust Litigation, 94 F.Supp.3d 224 (2015)

avoided simply by making one's large and unjustifiable reverse-payment settlement in gold bullion rather than dollars, then Actavis stands for nothing but an arbitrary restriction on the form such payments can take. To read the decision that way is to cabin its reasoning to the point of meaninglessness. I must conclude that large and unjustified reverse payments that “can bring with [them] the risk of significant anticompetitive effects,” id. at 2237 (majority opinion), can bring those effects regardless of the particular form the transfer of value takes and thus are not limited to cash payments. A settlement agreement may be very simple or tremendously complex, and it may involve all manner of consideration; and if, when viewed holistically, it effects a large and unexplained net transfer of value from the patent-holder to the alleged patent-infringer, it may fairly be called a reverse-payment settlement. Such a settlement, under Actavis, is not ipso facto unlawful: the parties to the settlement might be able to explain the apparent “missing” value for the patent-holder in a procompetitive way—and they will have an opportunity to do so under the rule-of-reason framework—in which case the reverse payment may turn out to be justified, or to be entirely illusory. But if otherwise unexplained, it “likely seeks to prevent the risk of competition. And ... that consequence constitutes the relevant anticompetitive harm.” Id. at 2236.

Under Actavis, “the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.” Id. at 2237. The plaintiffs here allege that the reverse payment was quite large, including a $4 million upfront cash payment and approximately $120 million in guaranteed royalties over time even in the absence of co-promotion efforts—and that being in addition to the up-to-$2.5 million per year of payments for those co-promotion efforts, which the plaintiffs also suggest exceeds the value of the services. The defendants argue that even those sums are small in relation to the value of the patent. That relation, by the logic of Actavis, may suggest confidence in the patent, but it does not mean that the alleged reverse payment is not “large.” On the contrary, as the Supreme Court suggested in Actavis, id. at 2236–37, a patent-holder who has a high degree of confidence in a patent's strength may nevertheless be willing to share some portion of the monopoly profits in order to avoid even a small risk of invalidation if the patent is especially valuable, and even a small portion of the profits on an especially valuable patent might indeed be quite large in absolute terms. I agree with the defendants that payments smaller than avoided litigation costs are presumptively not large and unexplained under Actavis, and represent a de facto safe harbor, and also that payments exceeding avoided litigation costs are not automatically deemed unlawful for that reason alone. Even if the payments exceed avoided litigation costs, the Actavis factors—the size of the payments, their scale in relation to litigation costs, their independence from other services for which they might be fair consideration, and any other convincing justification—still matter. But I cannot conclude that the size of the reverse payments in relation to the anticipated value of the patent is dispositive of the lawfulness of the agreement. Large reverse payments that are not particularly large in relation to the value of the patent may show confidence in the patent, but if they represent payment to avoid the risk of invalidation, then they still run afoul of Actavis.

The plaintiffs allege that the total payment is far greater than the fair value of the services falling under the Co–Promotion Agreement, and therefore constitutes a large and unjustifiable reverse payment, which they allege is especially clear since payment is guaranteed even without the generation of additional sales. They also allege that Boehringer agreed not to launch its own “authorized generic” during Barr's 180–day exclusivity period under the Hatch–Waxman Act, which further enlarged the reverse payment by constituting an additional unexplained transfer of value to Barr. The defendants dispute those allegations, and the sufficiency of the pleading, with several arguments: They argue that the Co–Promotion Agreement, as part of a complex transaction that settled litigation over two drugs, was somehow separate from the Aggrenox settlement, and that the plaintiffs have failed to sufficiently plead that it was made as consideration for that settlement (or they cannot so plead) because they argued in prior litigation that it was made as consideration for delaying generic entry of the other drug. They argue that the plaintiffs fail to plead with sufficient specificity the fair value of the services, the excess of the payments over that value, or in some other way the total value of the alleged reverse payment. And they argue that any agreement not to introduce an authorized generic should not be considered part of a reverse payment because exclusive licenses are authorized by the Patent Act and are the kind of traditional form of settlement that Actavis permits, or because they only result in “payment” in the form
In re Aggrenox Antitrust Litigation, 94 F.Supp.3d 224 (2015)

2015-1 Trade Cases P 79,115

of affirmative sales, or because they are otherwise procompetitive insofar as they represent an increase in competition compared to what competition otherwise would have been under the patent. I find none of those arguments persuasive.

First, and quite notably, the defendants do not agree among themselves whether the challenged settlement agreement actually does prevent Boehringer from introducing an authorized generic: by Boehringer's interpretation, it does not; but by Barr's reckoning it does. That disagreement is consonant with the plaintiffs' theory: Barr (the alleged infringer, and would-be generic manufacturer) sees a “no-authorized generic” agreement as a thing of value it received in the settlement and wishes to preserve it in this litigation, while Boehringer (the patent-holder and brand-name manufacturer) sees such an agreement as a cost it prefers not to incur and would happily disclaim. I need not determine now who is correct by ruling on the construction of the agreement, but the plaintiffs allege that there is such a provision and that it is very valuable, and at least on the latter point the defendants clearly agree.

The defendants are correct that the plaintiffs have not attempted to assign dollar values with significant precision or very obvious methodological justification to the various provisions of the settlement, and that is among the stronger of the defendants' arguments. Some other courts interpreting Actavis, while holding that reverse “payments” are not limited to cash transfers, have observed the importance of the court's ability to calculate the value of any nonmonetary payments or have held that pleading an estimate of the total monetary value and a reliable foundation for that value are necessary to establish the plausibility required by Rule 12(b)(6). See, e.g., In re Effexor XR Antitrust Litig., No. 3:11–CV–5479 PGS, 2014 WL 4988410 (D.N.J. Oct. 6, 2014); In re Lipitor Antitrust Litig., 46 F.Supp.3d 523 (D.N.J.2014). While I share the concerns expressed by those courts, it is also clear that very precise and particularized estimates of fair value and anticipated litigation costs may require evidence in the exclusive possession of the defendants, as well as expert analysis, and that these issues are sufficiently factual to require discovery. I cannot conclude simply from the absence of precise figures that the pleadings represent formulaic recitations of elements and allegations that fail to rise *245 above the speculative; on the contrary, the complaints make specific allegations about the terms of the settlement and their relative value that are plausible on their face. Whether the plaintiffs can substantiate those allegations may be an issue for summary judgment or trial, but for purposes of the motions to dismiss, I must accept the allegations as true and draw all reasonable inferences in the plaintiffs' favor. While doing that, I cannot conclude that the plaintiffs fail to sufficiently plead a large and unjustified reverse payment.

Nor are the allegations of a large and unjustified reverse payment undermined by the permissibility of exclusive licensing under the Patent Act or in settlements generally. The defendants are surely correct that patent holders may legally grant exclusive licenses and that the particular restraint on competition such agreements represent is an exception to antitrust prohibition and expressly permissible by statute. That is not disputed. But such licenses can be worth money, and granting them can thus be the equivalent of transferring money. If some particular transfer of money would be unlawful—for whatever reason—its unlawfulness is not cured merely because the value is transferred in the form of exclusive licenses instead of cash, irrespective of whether the grant of an exclusive license would otherwise be valid. The statutory authority to grant exclusive licenses no more immunizes reverse-payment settlements that include them from antitrust scrutiny under Actavis than the statutory authority to use cash as legal tender immunizes reverse-payment settlements made in cash from such scrutiny. The issue is not whether the form of the payment was legal, but whether the purpose of the payment was legal. The plaintiffs do not appear to allege that “no-authorized generic” agreements are per se unlawful, nor that any individual feature of the settlement agreement would have necessarily constituted an antitrust violation as part of some other agreement. Rather, they allege that Boehringer gave much more than it got in the settlement agreement; and under Actavis, that can constitute an antitrust violation if it did so in order to avoid the risk of patent invalidation.

It may also be true that granting an exclusive licensing agreement is procompetitive relative to not granting it, but the anticompetitive harm described in Actavis is not measured by the exclusionary scope of the patent—that test was explicitly rejected. The question is whether a large and unjustifiable reverse payment was made in order to avoid the risk of patent invalidation. If a settlement that grants an exclusive license violates the rule of Actavis, it is not saved by comparison to the
Rule-of-reason analysis proceeds in three steps:

First, the plaintiff bears the initial burden of showing that the defendant's conduct had an actual adverse effect on competition as a whole in the relevant market. If plaintiff satisfies this burden, the burden then shifts to defendant to offer evidence that its conduct had procompetitive effects. If defendant is able to offer such proof, the burden shifts back to plaintiff, who must prove that any legitimate competitive effects could have been achieved through less restrictive alternatives.

Ark. Carpenters Health & Welfare Fund v. Bayer AG, 604 F.3d 98, 104 (2d Cir.2010) (internal quotations and citations omitted). In the present context of a motion to dismiss, the plaintiffs need only allege plausible facts that, if true, raise a reasonable *246 expectation that discovery will reveal sufficient evidence to prove their prima facie case. Under the treatment of reverse-payment settlements in Actavis, they have done so.

4. Monopoly Power

The defendants argue that the plaintiffs fail to state a claim because they do not sufficiently define a relevant product market, and the single-product market of Aggrenox alone (or of Aggrenox and potential generics) is overly narrow. Because Aggrenox is prescribed to reduce the risk of stroke, they suggest Plavix—an FDA-approved antiplatelet therapy—as an example of a pharmaceutical that shares the market with Aggrenox. The presence of that drug, they argue, means that the defendants could maintain a monopoly on Aggrenox alone without having monopoly power within a market sufficient to be governed by the Sherman Act. The plaintiffs contend that a market of Aggrenox and Aggrenox generics is sufficiently defined, and moreover that they need not define a market, because they plead actual detrimental effects, for which market power is merely a surrogate.

Monopoly power is a necessary element of Sherman Act claims, United States v. Grinnell Corp., 384 U.S. 563, 570, 86 S.Ct. 1698, 16 L.Ed.2d 778 (1966), and the Supreme court has defined that power as “the power to control prices or exclude competition.” United States v. E.I. du Pont de Nemours & Co., 351 U.S. 377, 391, 76 S.Ct. 994, 100 L.Ed. 1264 (1956). The plaintiffs are correct, however, that when direct evidence is available that a party profitably charges supracompetitive prices, the existence of market power can be established from that fact alone. Tops Markets, Inc. v. Quality Markets, Inc., 142 F.3d 90, 97–98 (2d Cir.1998) (“Monopoly power, also referred to as market power, is the power to control prices or exclude competition. It may be proven directly by evidence of the control of prices or the exclusion of competition or it may be inferred from one firm's large percentage share of the relevant market.”).

The market for prescription pharmaceuticals is an unusual one, in part because consumers are typically insulated at least to some degree from both cost (which is often largely covered by an insurance plan) and choice (which is at least limited and more likely substantially directed by the prescribing physician), so market features such as cost-sensitivity and elasticity of demand might therefore defy reasonable expectations. It is nevertheless true in antitrust analysis that “as a general rule, the process of defining the relevant product market requires consideration of cross-elasticity of demand,” Hayden Pub. Co. v. Cox Broad. Corp., 730 F.2d 64, 71 (2d Cir.1984), because the boundaries of a particular product market are determined by “the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it.” Chapman v. New York State Div. for Youth, 546 F.3d 230, 237 (2d Cir.2008). The plaintiffs allege that there is no such cross-elasticity of demand
In re Aggrenox Antitrust Litigation, 94 F.Supp.3d 224 (2015)

2015-1 Trade Cases P 79,115

between Aggrenox and other drugs sufficient to define any broader antitrust market, and that because Boehringer is able to charge supracompetitive prices for Aggrenox without losing sales, it does not share a market defined by interchangeability. That is clearly a fact-intensive inquiry, and for that reason “courts hesitate to grant motions to dismiss for failure to plead a relevant product market.” Todd v. Exxon Corp., 275 F.3d 191, 199–200 (2d Cir.2001); see also Hayden Pub. Co. v. Cox Broad. Corp., 730 F.2d 64, 70 n. 8 (2d Cir.1984) (“It frequently has been observed that a pronouncement as to market definition is not one of law, but of fact.”) (quotation and citation omitted). The Supreme Court has been clear that market definitions can sometimes only be determined “after a factual inquiry into the commercial realities faced by consumers,” Eastman Kodak Co. v. Image Technical Servs., Inc., 504 U.S. 451, 482, 112 S.Ct. 2072, 119 L.Ed.2d 265 (1992) (quotation omitted), and that “in some instances one brand of a product can constitute a separate market.” Id. Perhaps because of the peculiar features of pharmaceutical markets, the Second Circuit has even held that the relevant market can sometimes be limited to the generic of a particular drug, excluding the chemically-identical brand-name version. Geneva Pharm. Tech. Corp. v. Barr Labs. Inc., 386 F.3d 485, 496–500 (2d Cir.2004).

The plaintiffs' allegations that Boehringer is able to charge supracompetitive prices for Aggrenox in a market with no cross-elasticity of demand with other drugs are highly plausible. If that were not the case, it is not clear why Boehringer would have sued to prevent entry of Barr's generic. The defendants are free to argue otherwise on an eventual summary judgment motion or at trial, but it is premature on a motion to dismiss for the court to make a more probing factual inquiry than that, and the defendants cannot persuasively argue that the complaints should be dismissed for failure to plead monopoly power within a sufficiently defined market.

5. Attempt and Conspiracy

Attempt and conspiracy to monopolize under the Sherman Act require specific intent to monopolize, and the defendants argue that the plaintiffs' pleading on intent amounts to mere recitation of the element. The facts as alleged, the defendants argue, merely reflect an effort to enforce a valid patent and later to settle the litigation, which judicial policy favors; and even if the settlement agreement is unlawful under Actavis, it was lawful under the Second Circuit “scope of the patent” test that was controlling at the time, so there can have been no unlawful intent. The alleged anticompetitive conduct is described at length above, and I do not recite it again here; but the plaintiffs do plead an anticompetitive scheme in significant detail, as already discussed, and they allege that the scheme was intentional. Moreover, it is clearly the law in the Second Circuit that anticompetitive intent can be inferred from anticompetitive conduct. Volvo North America Corp. v. Men's Int'l. Prof'l Tennis Council, 857 F.2d 55, 74 (2d Cir.1988). The defendants' argument that unlawful intent is precluded by the lawfulness of the agreement under the now-abrogated test used in the Second Circuit at the time the agreement was made is compelling as an argument from basic fairness; but the defendants offer no support for the suggestion that the necessary intent under federal law is intent to monopolize unlawfully, rather than merely intent to monopolize (perhaps with a good-faith belief that patent law or some other antitrust exception provided safety from liability). If the settlement included a large and unjustified reverse payment that was made in order to avoid the risk of patent invalidation, then antitrust liability may attach under Actavis; and that particular anticompetitive harm is necessarily intentional (even if intent is proved by inference). The defendants offer no authority to suggest that that analysis changes because they believed they were acting lawfully at the time under the Second Circuit's rule.

C. State–Law Claims

This case is rendered much more complicated by the rules of Illinois Brick Co. v. Illinois, 431 U.S. 720, 97 S.Ct. 2061, 52 L.Ed.2d 707 (1977), and California v. ARC America Corp., 490 U.S. 93, 109 S.Ct. 1661, 104 L.Ed.2d 86 (1989). In the former case, the Supreme Court held that only the overcharged direct purchaser, and no one else in the chain of distribution, can recover damages under federal antitrust law; in the latter, the Supreme Court held that that “indirect-purchaser rule” does not prevent indirect purchasers from recovering damages under state antitrust laws where the state laws otherwise allow it (and

[248]
many states have passed so-called “Illinois Brick repealers” in order to do so. Accordingly, the indirect purchaser complaint and the Humana complaint allege very many state-law claims; a few were withdrawn in the opposition memoranda to the defendants’ motions to dismiss, but what remains includes claims under the law of nearly every state (and Washington, D.C. and Puerto Rico), including state antitrust claims, consumer-protection claims, and unjust-enrichment claims. The defendants move that all be dismissed, for a variety of reasons that respectively apply to individual claims or to particular subgroups of them.

1. Statutes of Limitations

The plaintiffs’ theories of liability under the multiplicity of state claims do not significantly differ in substance from the theory underlying the federal claims; the allegedly unlawful conduct is the very same, and the multistate pleading headache appears to be a simple consequence of Illinois Brick’s bar on indirect purchaser recovery under the federal antitrust law. The defendants argue that the claims are time-barred, but in most essentials they make common arguments that both state and federal claims are barred—the latter question has already been addressed above—and there is no argument that the analysis of the state statutes of limitations should differ materially from the federal one already discussed. The salient difference is just the number of years: the federal statute of limitations discussed above is four years, and the statutes of limitations under the state laws vary—mostly either three or four years, but some longer and some shorter. The defendants include several pages of tables that helpfully summarize that (and other) information as attachments to their memoranda in support of their motions to dismiss the indirect purchaser and Humana complaints (doc. # 152–1, pp. A–12 to A–16; doc. # 151–1, pp. A–15 to A–18). In the absence of any argument that the legislatures or courts of any particular states reject the reasoning in the Berkey Photo analysis above as it would apply to their particular statutes, I conclude that the same reasoning should apply, and that a new claim accrues with each alleged overcharge. Claims are therefore not time-barred that stem from alleged overcharges incurred within the relevant statutory period, whatever that period may be for a particular statute, measured backward from the filing of the claims.

a. Fraudulent Concealment

The indirect purchasers and Humana both initially alleged fraudulent concealment, presumably to reach overcharges otherwise outside the applicable statute of limitations. Partly in light of my ruling in In re Publication Paper Antitrust Litigation, No. 3:04–md–1631 (SRU), 2005 WL 2175139 (D.Conn. Sept. 7, 2005), the indirect purchasers dropped those allegations in their opposition brief (doc. # 182, p. 20 n. 29), but Humana did not. Essentially for the reasons discussed in Publication Paper, I reject the argument that the statutes of limitations should be tolled because the defendants fraudulently concealed their allegedly unlawful conduct.

*249 “[A]n antitrust plaintiff may prove fraudulent concealment sufficient to toll the running of the statute of limitations if he establishes (1) that the defendant concealed from him the existence of his cause of action, (2) that he remained in ignorance of that cause of action until some point within four years of the commencement of his action, and (3) that his continuing ignorance was not attributable to lack of diligence on his part.” State of New York v. Hendrickson Bros. Inc., 840 F.2d 1065, 1083 (2d Cir.1988). Concealment can be shown in one of two ways: either by demonstrating that the defendant took affirmative steps to prevent discovery of the claim or injury, or by demonstrating that the violation itself was “self-concealing”—that is, by showing that it is the type of violation that by its very nature is designed to appear innocent, essentially establishing fraud-by-omission. Id. at 1083–84. As a claim of fraud, the allegations that provide the factual basis for fraudulent concealment must meet Rule 9(b)'s heightened pleading standard.

Humana plausibly alleges that the defendants did not publicly disclose the precise terms of the challenged settlement or their associated dollar values—despite overtly publicizing the settlement in more general terms, and despite an FTC investigation.
and other litigation challenging the agreement—and that Humana did not know it contained a large and unexplained reverse payment. Those allegations do not rise to the level of deliberate concealment, and do not suggest a self-concealing violation; nor has Humana sufficiently pleaded its own diligence. In short, Humana has failed to meet its pleading burden for tolling the statute of limitations. For the reasons discussed above, tolling is unnecessary for claims of alleged overcharges incurred within the relevant statutory period measured backward from the filing date; but any claims for overcharges outside of that window are untimely, and they are dismissed.

2. Article III Standing

The defendants argue that all indirect-purchaser claims under the laws of states where the named indirect-purchaser plaintiffs do not allege they incurred overcharges must be dismissed for lack of standing. In making that argument, the defendants rely most heavily on Mahon v. Ticor Title Ins. Co., 683 F.3d 59 (2d Cir.2012). The indirect purchasers disagree, contending that the defendants confuse Article III standing with “class” standing. They rely most heavily on Gratz v. Bollinger, 539 U.S. 244, 123 S.Ct. 2411, 156 L.Ed.2d 257 (2003), and NECA–IBEW Health and Welfare Fund v. Goldman Sachs & Co., 693 F.3d 145 (2d Cir.2012). Both sides are manifestly mistaken in their assertions that this is a straightforward question with an obvious answer. The Supreme Court acknowledged in Gratz that when there is “variation” between the claims of named plaintiffs and absent class members, “there is a question whether the relevance of this variation ... is a matter of Article III standing at all or whether it goes to the propriety of class certification pursuant to Federal Rule of Civil Procedure 23(a),” 539 U.S. at 263, 123 S.Ct. 2411, and that “there is tension in our prior cases in this regard.” Id. at 263 n. 15, 123 S.Ct. 2411; see also Plumbers' Union Local No. 12 Pension Fund v. Nomura Asset Acceptance Corp., 632 F.3d 762, 768 (1st Cir.2011) (“The issue looks straightforward and one would expect it to be well settled; neither assumption is entirely true.”).

The central question on this issue is what sort of “variation” matters. Some kinds of variation are not fatal to Article III standing, and some kinds are. The defendants point out that in virtually all of the cases relied upon by the indirect purchasers, including Gratz and NECA–IBEW, the variation between the respective claims of named plaintiffs and absent class members is variation of damages or of other facts, but not of the law under which the claims are brought. On the other side, the indirect purchasers point out that the cases relied upon by the defendants examine different and arguably more significant variation in claims than present here, most notably a variation of defendants. The question before the Second Circuit in Mahon was whether a plaintiff who alleged she was injured by at least one defendant therefore had Article III standing to pursue claims in a putative class action against other defendants she did not allege injured her but who allegedly did injure absent class members (the Court held that she did not). 683 F.3d at 60. Here, the variation is of quite a different sort. Some of the claims of absent class members are brought under entirely different laws, and the laws of entirely different states, from the claims of the named plaintiffs. Still, the allegedly unlawful conduct is the same, and the different states' laws are versions of the same laws, or are least analogous laws that share essential similarities.

I generally agree with the indirect-purchaser plaintiffs' interpretation of class standing. The Second Circuit in NECA–IBEW announced a broad standard for class standing, consonant with Gratz, that turns on whether the “same set of concerns” is implicated by the defendants' allegedly injurious conduct toward the named plaintiffs and toward the absent class members. The named indirect-purchaser plaintiffs in the present case satisfy that standard, because the “same set of concerns” is implicated by the conduct of the defendants with respect to alleged overcharges incurred by indirect purchasers irrespective of the state of their residence. Still, there is a fundamental analytical distinction between class standing and Article III standing. And Article III standing, as a fundamental constitutional requisite of federal judicial power, presents a “threshold question in every federal case.” Warth v. Seldin, 422 U.S. 490, 498, 95 S.Ct. 2197, 45 L.Ed.2d 343 (1975).
The indirect purchasers seem to analyze Article III standing on a case-wide basis. They argue that, once they have sufficiently pleaded that they have suffered harm as a result of unlawful conduct by the defendants, they have Article III standing to bring the case and are then over the threshold constitutional hurdle. Any subsequent claim-by-claim analysis, the argument goes, is properly the concern of class standing. The defendants offer forceful authority to the contrary. E.g., Lewis v. Casey, 518 U.S. 343, 358 n. 6, 116 S.Ct. 2174, 135 L.Ed.2d 606 (1996) (“But standing is not dispensed in gross.”); Davis v. Fed. Election Comm’n, 554 U.S. 724, 734, 128 S.Ct. 2759, 171 L.Ed.2d 737 (2008) (“[A] plaintiff must demonstrate standing for each claim he seeks to press and for each form of relief that is sought.”) (quotations omitted)). The indirect purchasers do not effectively rebut that authority. The pleadings plausibly allege that the indirect purchasers were harmed by the defendants' unlawful conduct, so it would be difficult to doubt that they present a live case or controversy for which they have standing under Article III. But the applicability to that case or controversy of the laws of states where the named plaintiffs do not (and perhaps cannot) plead harm is dependent upon harms caused to absent (and at this stage only putative) class members.

The indirect purchasers point to numerous cases that have interpreted *Ortiz v. Fibreboard Corp.*, 527 U.S. 815, 119 S.Ct. 2295, 144 L.Ed.2d 715 (1999), and *Amchem Products, Inc. v. Windsor*, 521 U.S. 591, 117 S.Ct. 2231, 138 L.Ed.2d 689 (1997), to stand for the proposition that the question of Article III standing can be deferred until after class certification. In *Mahon*, however, the Second Circuit repudiated that interpretation of those cases, noting that the Article III issue was deferred in them not because it is always permissible to do so but because the class issue was dispositive. 683 F.3d at 63–66. The Court reasoned that “[a] federal rule cannot alter a constitutional requirement,” and therefore “with respect to each asserted claim, a plaintiff must always have suffered a distinct and palpable injury to herself.” *Id.* at 64 (emphasis in the original, quotation omitted).

I therefore grant without prejudice the defendants' motion to dismiss the indirect-purchaser complaints with respect to all claims under the laws of states (or territories) where the named indirect-purchasers do not allege to have suffered injury. The indirect purchasers have leave to replead claims for any state where the named plaintiffs specifically can allege to have incurred overcharges.

Humana makes (essentially) the same state-law claims as the indirect-purchaser plaintiffs, but standing is uncomplicated because Humana pleads that it has been an indirect purchaser of *Aggrenox* in all fifty states. Humana and the indirect-purchaser plaintiffs each incorporate by reference the relevant portions of the other's opposition memorandum, and I will thus discuss the remaining arguments on both motions to dismiss collectively.

### 3. State Antitrust Claims

#### a. Standing in *Illinois Brick* States

In the wake of *Illinois Brick*’s announcement of the indirect-purchaser rule, many states passed “*Illinois Brick* repeaters” to allow indirect purchasers to recover under their respective state antitrust laws, and the Supreme Court endorsed the permissibility of that approach in *ARC America Corp.*, 490 U.S. at 105–06, 109 S.Ct. 1661. Of course, there are also states that continue to follow the rule of *Illinois Brick*, so indirect purchasers cannot recover for overcharges under those states' antitrust laws. The defendants argue that Florida, Massachusetts, and Puerto Rico are *Illinois Brick* jurisdictions, and that Rhode Island was, too, until it passed an *Illinois Brick* repealer in 2013, which should not be applied retroactively here. They initially included Utah in that list as well, before admitting that it did pass an *Illinois Brick* repealer, but one that permits indirect-purchaser claims only by citizens or residents of the state. In response, the indirect purchasers withdraw their claims under the antitrust laws of Florida and Massachusetts, and dispute the plaintiffs’ interpretation of the laws of the other jurisdictions.
In re Aggrenox Antitrust Litigation, 94 F.Supp.3d 224 (2015)
2015-1 Trade Cases P 79,115

i. Utah

Utah has passed an *Illinois Brick* repealer, and its antitrust statute therefore does grant indirect purchasers the right to bring antitrust damages claims, but only if they are citizens or residents of Utah. See Utah Code § 76–10–3109. The indirect purchasers claim to be asserting claims under that law on behalf of residents of Utah, but they do not claim that any of the named plaintiffs are such residents. For the reasons discussed above, they lack Article III standing to assert such claims. Humana claims to be an indirect purchaser of Aggrenox in all fifty states, but does not claim to be a citizen or resident of Utah. All claims under the Utah antitrust statute are therefore dismissed without prejudice to repleading in the event that any named plaintiff is a citizen or resident of Utah.

ii. Puerto Rico

Puerto Rico has not passed an *Illinois Brick* repealer, and its territorial courts have apparently not directly addressed the issue, but its antitrust law is generally construed “as essentially embodying the jurisprudence relevant to the parallel federal law.” *Caribe BMW, Inc. v. Bayerische Motoren Werke Aktiengesellschaft*, 19 F.3d 745, 754 (1st Cir.1994). The defendants therefore urge the interpretation that *Illinois Brick* applies and bars indirect-purchaser actions, citing the persuasive authority of other district courts that have come to that conclusion. See, e.g., *United Food & Commercial Workers Local 1776 & Participating Employers Health & Welfare Fund v. Teikoku Pharma USA, Inc.*, 74 F.Supp.3d 1052, 1085–86, No. 14–MD–02521–WHO, 2014 WL 6465235, at *25–26 (N.D.Cal. Nov. 7, 2014); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F.Supp.2d 367, 409–10 (D.Mass.2013); *In re Static Random Access Memory (SRAM) Antitrust Litig.*, No. 07–md–01819 CW, 2010 WL 5094289, at *4 (N.D.Cal. Dec. 8, 2010); *In re Digital Music Antitrust Litig.*, 812 F.Supp.2d 390, 413 (S.D.N.Y.2011) (citing *In re TFT–LCD (Flat Panel) Antitrust Litig.*, 599 F.Supp.2d 1179, 1185–87 (N.D.Cal.2009)). The indirect purchasers cite *Rivera–Muñiz v. Horizon Lines Inc.*, 737 F.Supp.2d 57 (D.P.R.2010), a federal district court case that came to the contrary conclusion on the basis that Puerto Rico liberally construes its antitrust laws, and citing for that proposition *Pressure Vessels of Puerto Rico, Inc. v. Empire Gas de Puerto Rico*, 137 D.P.R. 497, 1994 P.R.-Eng. 909,547 (P.R.1994). As the defendants point out, however, *Pressure Vessels* did not address indirect-purchaser standing or the rule of *Illinois Brick*. And though I agree with the indirect purchasers’ contention that the courts of a particular jurisdiction can authoritatively interpret their laws as allowing antitrust recovery by indirect purchasers even in the absence of an express *Illinois Brick* repealer by the legislature, I cannot conclude that *Pressure Vessels* is such an authoritative statement. In the absence of a clear decision—by either the legislature or by the jurisdiction’s own courts—to allow indirect-purchaser recovery, the antitrust laws of a state (or territory) are interpreted as presumptively consistent with federal law. I therefore conclude that Puerto Rico follows the rule of *Illinois Brick* and all indirect-purchaser claims under its antitrust law are dismissed.

iii. Rhode Island

Rhode Island was an *Illinois Brick* state until its legislature enacted a repealer on July 15, 2013. See R.I. Gen. Laws § 6–36–7(d). The indirect purchasers urge (with little argument, and less authority) retroactive application, citing cases for the proposition that such application is sometimes permissible, but nothing to substantiate the claim that the Rhode Island statute is “entitled” (doc. #182, p. 19) to such application. On the contrary, in Rhode Island as elsewhere, “statutes and their amendments are presumed to apply prospectively.” *Hydro–Mfg., Inc. v. Kayser–Roth*, 640 A.2d 950, 954 (R.I.1994). Indeed, it is very widely recognized as an “almost universal rule that statutes are addressed to the future, not to the past.” *Winfree v. N. Pac. Ry.*, 227 U.S. 296, 301, 33 S.Ct. 273, 57 L.Ed. 518 (1913). In the absence of evidence of the Rhode Island legislature’s intent to the contrary, I conclude that the law applies only prospectively. All indirect-purchaser claims under the Rhode Island antitrust statute alleging
overcharges before July 15, 2013 are dismissed. The motions to dismiss claims involving Rhode Island indirect purchases are denied, however, with respect to alleged overcharges incurred after that date.

b. Intrastate Conduct or Effects Requirements

The defendants argue that the antitrust laws of Mississippi, New York, Tennessee, Wisconsin, and the District of Columbia “require that the challenged conduct take place, or that its effects occur, purely or primarily within the state” (doc. # 151–1, p. 31). None of the cited statutes contains so categorical a limitation by its plain text, however. It is true that all of the claims essentially allege national anticompetitive conduct, but it is not obvious why the *intra* state effect of anticompetitive conduct would not be reached by the cited statutes merely because *inter* state conduct predominates. A few of the cases that the defendants cite include dicta about the possibility of state antitrust laws violating the dormant Commerce Clause or being preempted by federal antitrust law, e.g., *H–Quotient, Inc. v. Knight Trading Grp., Inc.*, No. 03 CIV. 5889(DAB), 2005 WL 323750, at *4 (S.D.N.Y. Feb. 9, 2005); *Sun Dun, Inc. of Washington v. Coca–Cola Co.*, 740 F.Supp. 381, 396–97 (D.Md.1990), but the defendants do not make those arguments. I cannot conclude on the basis of the arguments that have been briefed that any claims should be dismissed for failure to allege “purely or primarily” intrastate conduct or effects.

c. Hawaii Antitrust Act

Hawaii’s antitrust statute has an “unfair or deceptive acts or practices” prong, and an “unfair methods of competition” prong. See Haw.Rev.Stat. § 480–2. Claims under the “unfair or deceptive acts or practices” prong can only be brought by “consumer[s], the attorney general or the director of the office of consumer protection,” id. § 480–2(d), and the indirect purchasers do not allege that they are any of those things. Claims under the “unfair methods of competition” prong are not limited in that way, but class actions brought under that prong require pre-suit notice to the state attorney general, who has a right of first refusal to bring claims. Id. § 480–13.3. The indirect purchasers do not allege that they have satisfied that requirement, either, but they argue that they need not follow such pre-filing requirements because they are merely procedural and not necessary to maintain a class action in federal court.

The parties differ in their analysis of the applicability of *Shady Grove Orthopedic Associates v. Allstate Ins. Co.*, 559 U.S. 393, 130 S.Ct. 1431, 176 L.Ed.2d 311 (2010), in which the Supreme Court held that Rule 23 applied in federal court to claims brought under New York law despite New York's general class action bar. It is difficult to isolate a holding in *Shady Grove* that is much broader than that, because the holding was announced by Justice Scalia in an opinion that garnered a majority only in part and a plurality in part. The fifth vote for the judgment was provided by Justice Stevens, who wrote a separate concurrence. When no single rationale garners a majority, the holding of the Court is “that position taken by those Members who concurred in the judgments on the narrowest grounds.” *Marks v. United States*, 430 U.S. 188, 193, 97 S.Ct. 990, 51 L.Ed.2d 260 (1977). The indirect purchasers argue for an expansive application of Justice Scalia's opinion, which would broadly eliminate state class-action restrictions in federal court. The defendants argue that the holding is narrowed by the scope of Justice Steven's concurrence, which would allow state procedural rules to control in federal court when they are “part of a State's framework of substantive rights or remedies.” *Shady Grove*, 559 U.S. at 419, 130 S.Ct. 1431 (Stevens, J., concurring).

The defendants point out that many courts have adopted Justice Stevens's concurrence or found it to be controlling, and that they have held that state class-action bars apply in federal court if they are part of a state statute's substantive scope. The defendants have not, however, offered any authority for that conclusion as applied to Hawaii's law, or argued persuasively that the class-action prerequisites that it contains are part of Hawaii's “framework of substantive rights or remedies.” From the language of the statute itself, it does not appear, for instance, to create a substantive right to recovery that only “vests” after some action
or inaction of the state attorney general. Rather, it creates a right to “bring an action based on unfair methods of competition” in section 480–2, without any reference to notice, and delineates procedural prerequisites for class actions under the chapter in section 480–13.3. The defendants offer nothing from the legislative history or otherwise to complicate that plain reading. I need not wade any deeper into the difficult problem of what part of the reasoning in Shady Grove is or is not controlling, because I cannot conclude on the basis of the arguments before me that the section 480–13.3 procedural prerequisites are sufficiently a “part of a State's framework of substantive rights or remedies” to be controlling in federal court even under the Stevens concurrence.

4. State Consumer–Protection and Unjust–Enrichment Claims

The defendants make many arguments that the unjust-enrichment claims and the claims brought under state consumer-protection or unfair-trade-practices laws should be dismissed. Some of those arguments apply to all such claims, others to particular subsets, and still others to the laws of individual states. They argue, for instance, that some state consumer-protection laws require pleading consumer deception or reliance; that some require pleading a specific consumer-oriented transaction or “nexus”; that some have been expressly held inapplicable to antitrust conduct; that some only allow suits in a consumer capacity; that some have unsatisfied pre-filing notice requirements; that some states require privity, a quasi-contractual or special relationship, or the absence of an adequate remedy at law in order to sustain the equitable remedy of an unjust-enrichment claim; and even that some states listed in the pleadings do not recognize an independent claim of unjust enrichment at all. The indirect purchasers and Humana respond with particular state-by-state arguments and caselaw, and the defendants reply with still more, disputing among themselves, for instance, whether particular states do or do not recognize independent unjust-enrichment claims, or whether there is a split of authority among California courts on whether a nonsemantic distinction exists between unjust enrichment, restitution, and quasi-contract (doc. # 182, p. 66; doc. # 215, pp. 15–16).

*255 Most of the defendants' arguments on this point can be reduced essentially to the assertion that the plaintiffs are not really pleading violations of all those state laws, which have various restrictions they ignore, because they are pleading a nation-wide antitrust case. The plaintiffs' argument in response is essentially that the state laws are exceedingly broad, the statutory ones generally written “in the disjunctive,” and that they cover, very generally, all “deceptive acts, unfair practices or unconscionable acts” (doc. # 182, p. 35). The defendants' arguments are persuasive on many particular points, but the more pressing issue is the broader one. The indirect purchasers and Humana have listed claims under very many state laws, but they have not truly pleaded claims under those laws sufficient to show their entitlement to recovery under them, as required by Rule 8. See Iqbal, 556 U.S. at 678, 129 S.Ct. 1937 (“A pleading that offers labels and conclusions or formulaic recitation of the elements of a cause of action will not do.”). Rather, they have pleaded federal antitrust claims and the factual foundation for them, viable under Actavis, and they merely allege that those claims are also actionable under general consumer-protection laws and as unjust enrichment.

The indirect-purchaser complaint, for instance, includes a paragraph alleging that the defendants “have violated the following state unfair trade practices and consumer fraud laws,” followed by twenty-five subparagraphs, each of which begins “[d]efendants have engaged in unfair competition or unfair acts or practices in violation of” and ends with a citation to a different state's statute, with no elaboration (doc. # 120, ¶ 204). The same complaint includes a paragraph that begins “[i]t would be inequitable under unjust enrichment principles under the laws of” and then lists forty-eight states, the District of Columbia, and Puerto Rico before finishing the sentence, the end of which is similarly bare and conclusory (¶ 214). The Humana complaint fares no better. For instance, it begins each of paragraphs 142 through 178 with the words “[d]efendants have engaged in unfair competition or unfair, deceptive or fraudulent acts or practices in violation of” followed by a citation to a different state's statute, again with no elaboration (doc. # 93). Even the state antitrust claims partly take this copy-and-paste form that simply assumes that every one of the many cited statutes is the functional equivalent of the rest, but at least those claims benefit from the very extensive pleading of factual allegations to show entitlement to relief under federal antitrust law. The pleadings fail not only
to account for any consequential differences that may exist among the undifferentiated state-law claims, but they fail to show that any but the antitrust laws entitle the plaintiffs to relief from antitrust violations. The bald assertion that the alleged antitrust conduct violates dozens of non-antitrust laws, or the implication that there are no consequential differences between those laws, is not entitled to deference, because “the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions.” *Iqbal*, 556 U.S. at 678, 129 S.Ct. 1937.

The problem for the indirect purchasers is that the indirect-purchaser rule of *Illinois Brick* blocks them from recovery under federal antitrust law. In an effort to get in on the *Actavis* game, they attempt to build a Frankensteinian equivalent of *Actavis* to reach the very same conduct but without that formidable obstacle, by stitching together a hodge-podge of state-law claims. But the plaintiffs cannot simply enumerate a long list of state-law claims for states where they might otherwise have no available antitrust recovery and rely on the defendants and the court to sort out whether or how those laws can act as surrogates for antitrust law. I need not rule on the many particular arguments the defendants make for individual state claims or subsets of them, because the indirect-purchaser plaintiffs and Humana have not pleaded state-law consumer-protection or unjust-enrichment claims sufficient to satisfy Rule 8 under *Twombly* and *Iqbal*. The defendants’ motions to dismiss are granted with respect to all such claims, without prejudice to repleading in nonconclusory fashion.

D. Personal Jurisdiction Over Teva Israel

Teva Israel moves under Rule 12(b)(2) to dismiss all claims against it for lack of personal jurisdiction. It emphasizes that it is an Israeli company with no direct physical or corporate presence in the United States, and that it and its American subsidiaries vigorously maintain corporate formalities. The settlement agreement that is the subject of the plaintiffs’ allegations was formed between Boehringer and Barr prior to Teva USA’s acquisition of Barr, so no Teva entity was a party to it. And the presence of a subsidiary alone is not sufficient to establish personal jurisdiction over the parent company. *See Jazini v. Nissan Motor Co.*, 148 F.3d 181 (2d Cir.1998). Teva Israel therefore argues that, even if all the plaintiffs’ allegations are true regarding the liability of the other defendants, and even if Teva USA is liable as a successor to Barr, the mere fact of Teva Israel’s ownership of Teva USA is not sufficient to subject Teva Israel to personal jurisdiction in this case.

The authority of a court to subject a particular defendant to personal jurisdiction has been analyzed as a constitutional question for well over a century. *See generally Pennoyer v. Neff*, 95 U.S. 714, 24 L.Ed. 565 (1877). *The statutory* authority for jurisdiction, though a necessary condition of it, is not a sufficient one. The plaintiffs seem to conflate the statutory authority for jurisdiction under the Clayton Act with the constitutional propriety. They also blur the distinction between the two forms of personal jurisdiction in the constitutional analysis: general, or all-purpose, personal jurisdiction; and specific, or case-linked personal jurisdiction. In order to show that an exercise of personal jurisdiction comports with Due Process, the plaintiffs must plead facts sufficient to support either general or specific personal jurisdiction, in addition to showing statutory authority.

“A court may assert general jurisdiction over foreign (sister-state or foreign-country) corporations to hear any and all claims against them when their affiliations with the State are so continuous and systematic as to render them essentially at home in the forum State.” *Goodyear Dunlop Tires Operations, S.A. v. Brown*, — U.S. ——, 131 S.Ct. 2846, 2851, 180 L.Ed.2d 796 (2011) (quotation omitted). Being “essentially at home” in a place is a very high bar, almost never found for corporations where they are neither incorporated nor headquartered. “[E]ven a company's engagement in a substantial, continuous, and systematic course of business is alone insufficient to render it at home in a forum.” *Sonera Holding B.V. v. Cukurova Holding A.S.*, 750 F.3d 221, 226 (2d Cir.2014) (quotation omitted). None of the complaints plead facts even close to a plausible claim of general jurisdiction over Teva Israel.

“Specific jurisdiction, on the other hand, depends on an affiliation between the forum and the underlying controversy.” *Goodyear Dunlop*, 131 S.Ct. at 2851 (quotation omitted). Importantly, “[i]n contrast to general, all-purpose jurisdiction, *specific jurisdiction is confined to adjudication of issues deriving from, or connected with, the very controversy that establishes
Pleading specific jurisdiction does not present nearly so high a bar as pleading general jurisdiction, but unlike general jurisdiction, it depends on case-specific contacts. Even frequent, substantial contacts cannot confer jurisdiction in this case unless the contacts were made in connection with the specific controversy being litigated.

The plaintiffs emphasize how thoroughly entrenched in the American generic pharmaceutical industry Teva Israel is, and they cite SEC filings and corporate web pages to argue that the Teva entities play fast and loose with the “Teva” name. The broad general contacts that the plaintiffs describe do not rise to the very high “essentially at home” standard for general jurisdiction, and such generalized contacts are not useful for establishing specific personal jurisdiction, because they have nothing to do with the particular conduct giving rise to the claims here. Teva Israel's contacts with the United States are sufficient for specific personal jurisdiction to comport with constitutional requirements in some case, but this is not such a case. Apart from the bare, conclusory assertion that Teva Israel joined the antitrust conspiracy, the complaints do not allege any action by the Israeli company that is specifically in connection with this case. It is customary to analyze the issue of statutory jurisdictional authority before analyzing comportment with Due Process, but the pleadings are so obviously insufficient with respect to the latter that it is not necessary to examine the question of jurisdiction under the Clayton Act.

In their opposition memoranda, the plaintiffs argue that the conduct of Teva USA and Barr should be attributed to Teva Israel either because the latter is successor to the antitrust conspiracy or because it controls its American subsidiaries. Those arguments do not appear to correspond to a plausible factual foundation in the pleadings, and without more facts, the prospects for repleading either a veil-piercing theory or a successor-in-interest theory do not seem bright. Limited jurisdictional discovery of Teva Israel is not appropriate because the plaintiffs failed to make a prima facie case for personal jurisdiction. See Ball v. Metallurgie Hoboken–Overpelt, S.A., 902 F.2d 194, 197 (2d Cir.1990). If discovery taken from the other defendants should turn up evidence of Teva Israel's contacts specifically in connection with the controversy underlying this case, then the plaintiffs may seek leave of the court to replead their claims against it. Accordingly, Teva Israel's motion to dismiss under Rule 12(b) (2) is granted without prejudice.

iii. conclusion

In sum, for the reasons discussed above:

(1) Teva Israel's motion to dismiss all complaints against it under Rule 12(b)(2) (doc. # 150) is granted without prejudice; the plaintiffs may seek leave to replead claims against it in the event that evidence of its participation in the specific agreements underlying this case are revealed in discovery taken from the other defendants.

(2) The defendants' motion to dismiss the direct-purchaser complaint under Rule 12(b)(6) (doc. # 149; sealed mem., doc. 168) is denied in substantial part. It is granted with respect only to any claims made in connection with overcharges allegedly incurred more than four years prior to the filing of the claims.

(3) The defendants' motion to dismiss the indirect-purchaser complaint under Rule 12(b)(6) (doc. # 151) is granted in part and denied in part. It is granted without prejudice with respect to all state-law consumer-protection and unjust-enrichment claims. It is granted with prejudice with respect to any claims made in connection with overcharges allegedly incurred before the filing of the claims by a longer period than the relevant statute of limitations. It is granted with prejudice with respect to claims under the antitrust statute of Puerto Rico, and with respect to claims under the antitrust statute of Rhode Island that are in connection with overcharges allegedly incurred before July 15, 2013. It is granted without prejudice with respect to claims under the antitrust statute of Utah; the indirect purchasers have leave to replead those claims only if some named plaintiff is a citizen or resident of that state. It is granted without prejudice with respect to other claims under the laws of states where the named plaintiffs do not plead injury; the indirect purchasers have leave to replead those claims only to the extent they can plead sufficient facts to allege harm to named plaintiffs in particular states.
(4) The defendants' motion to dismiss the Humana complaint under Rule 12(b)(6) (doc. # 152) is granted in part and denied in part. It is granted without prejudice with respect to all state-law consumer-protection and unjust-enrichment claims. It is granted with prejudice with respect to any claims made in connection with overcharges allegedly incurred before the filing of the claims by a longer period than the relevant statute of limitations. It is granted with prejudice with respect to claims under the antitrust statute of Puerto Rico, and with respect to claims under the antitrust statute of Rhode Island that are in connection with overcharges allegedly incurred before July 15, 2013. It is granted without prejudice with respect to claims under the antitrust statute of Utah; Humana has leave to replead those claims only if it is a citizen or resident of that state.

So ordered.

All Citations

94 F.Supp.3d 224, 2015-1 Trade Cases P 79,115

Footnotes

1 If the validity of the patent has not yet been determined after 30 months, the FDA can give approval to the generic irrespective of possible infringement, but the manufacturer who then begins production of the generic does so at risk of an unfavorable judgment and the accrual of damages to the vindicated patent-holder.

2 In the opposition memoranda, the indirect-purchaser plaintiffs also withdraw unjust-enrichment claims under Pennsylvania law and claims under the antitrust laws of Kansas, New York, and Tennessee; and Humana withdraws its claims under the consumer-protection laws of Hawaii and Kansas, under the state antitrust laws of Florida, Ohio, and Texas, and under the Sherman Act (which includes all of its direct-purchaser claims).

3 The defendants also make this argument with respect to the antitrust law of Massachusetts, but as mentioned above, the indirect-purchaser plaintiffs withdraw their claims under that law. Humana did not plead claims under it.
2015-1 Trade Cases P 79,048

88 F.Supp.3d 402
United States District Court, E.D. Pennsylvania.

KING DRUG COMPANY OF FLORENCE, INC., et al., Plaintiffs,
v.
CEPHALON, INC., et al., Defendants.
Vista Healthplan, Inc., et al., Plaintiffs,
v.
Cephalon, Inc., et al., Defendants.
Apotex, Inc., Plaintiff,
v.
Cephalon, Inc., et al., Defendants.
Federal Trade Commission, Plaintiff,
v.
Cephalon, Inc., Defendant.


Synopsis
Background: Direct purchasers and end payors filed proposed class actions and generic drug manufacturer and Federal Trade Commission (FTC) filed actions alleging that reverse payment settlement agreements entered into between pharmaceutical company and generic drug manufacturers violated federal and state antitrust laws. After cases were consolidated, defendants moved for summary judgment.

Holdings: The District Court, Goldberg, J., held that:

company's payments to generic manufacturers were sufficiently large to give rise to inference that payments were intended to induce them to stay off market, and

plaintiffs raised genuine factual dispute as to whether payments were reasonably necessary to achieve procompetitive benefits.

Motions denied.

Attorneys and Law Firms

GOLDBERG, District Judge.

Presently before me are several motions for summary judgment arising out of the standards recently articulated by the United States Supreme Court in *Federal Trade Commission v. Actavis, Inc.*, —— U.S. ———, 133 S.Ct. 2223, 186 L.Ed.2d 343 (2013). These motions are brought under the consolidated antitrust lawsuits referred to as the *In re Modafinil Litigation*, which centers around four “reverse-payment” settlement agreements between a pharmaceutical company and several generic drug manufacturers. 1

Defendants argue that *Actavis* requires a plaintiff challenging a reverse-payment settlement on antitrust grounds to prove, as a threshold matter, that the reverse payment was both large and unjustified. Plaintiffs, Direct Purchasers and End Payors of Provigil, the Federal Trade Commission (“FTC”), and Apotex, Inc., dispute that *Actavis* requires some type of threshold burden. These Plaintiffs assert that, in any event, they have presented sufficient evidence of a large and unjustified reverse payment to survive summary judgment.

After careful consideration of the *Actavis* case and several recent district court opinions interpreting the standards set forth by the Supreme Court, I conclude that *Actavis* primarily instructs that the familiar antitrust rule of reason analysis be applied to cases challenging reverse-payment settlements. This analysis does not include a “threshold burden,” as Defendants suggest. Rather, Plaintiffs must present evidence of a large reverse payment as part of their initial burden of demonstrating anticompetitive effects under the rule of reason. I further find that, as in other rule of reason cases, if Plaintiffs meet this standard, the burden shifts to Defendants to justify the reverse payment as procompetitive. If that occurs, Plaintiffs must then present sufficient evidence so as to raise a genuine dispute of material fact as to whether the reverse payment is unjustified or unexplained.

After considering the voluminous record in this case, I find that Plaintiffs have satisfied their burden of presenting evidence of anticompetitive effects, which includes a large reverse payment. I further find that there exists a genuine dispute of material fact that Defendants’ procompetitive justifications are pretextual, allowing Plaintiffs to survive summary judgment on their *Actavis* claims. This Opinion sets forth the reasons for these conclusions.

**1. FACTUAL AND PROCEDURAL BACKGROUND** 2
A. Administrative Framework

The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98–417, commonly known as the Hatch–Waxman Act, is designed to encourage the development and marketing of generic versions of approved drugs. It allows generic manufacturers to file an Abbreviated New Drug Application (“ANDA”) when seeking approval from the Food and Drug Administration (“FDA”) to market a generic version of an approved drug. An ANDA filer is able to adopt the safety and efficacy studies that the FDA previously approved in connection with a bioequivalent brand-name drug's New Drug Application (“NDA”). See Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc., 527 F.3d 1278, 1282 (Fed.Cir.2008).

A generic manufacturer seeking approval of an ANDA must demonstrate that the generic formulation and the approved brand-name drug share the same active ingredients and are bioequivalent. Additionally, ANDA filers must submit one of four certifications addressing any and all patents covering the brand-name drug, certifying either: (1) that the relevant patent information has not been filed with the FDA; (2) that such patent has expired; (3) the date that such patent will expire; or (4) “that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.” Id. at 1282–83 (quoting 21 U.S.C. § 355(j)(2)(A)(vii)). “If a generic drug company seeks to market a generic version of a listed drug before the expiration of the Orange–Book–listed patents covering that drug, it must file a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), i.e. a ‘Paragraph IV certification.’ ” Id. at 1283 (citing Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 676, 110 S.Ct. 2683, 110 L.Ed.2d 605 (1990)).

Paragraph IV filers are required to submit notice of the filing to the patent owner and the NDA holder, and must set forth a detailed statement of the basis for the assertion that the patent is invalid or will not be infringed. Id. Filing a Paragraph IV ANDA constitutes an act of patent infringement, often prompting the patent holder to file a lawsuit. However, as an incentive to generic companies to challenge weak patents, the first applicant to file an ANDA with a Paragraph IV certification is entitled to a 180–day period of exclusivity for its generic drug, beginning on the first day it markets its drug commercially. Actavis, 133 S.Ct. at 2228–29.

When a patent holder files an infringement lawsuit within forty-five days of a Paragraph IV ANDA filing, the FDA is barred from approving the generic company's ANDA for a period of thirty months. 21 U.S.C. § 355(j)(5)(B)(iii). If the case is resolved during the thirty-month stay, the FDA will take action on the ANDA consistent with the court's judgment. Actavis, 133 S.Ct. at 2228. If the case is still ongoing at the end of the thirty-month period, the FDA may approve the ANDA, at which point the generic company will have to decide whether to sell its drug “at risk” of incurring damages should the infringement case result in a judgment favorable to the patent holder. Id.

B. Factual History

Cephalon was issued U.S. Patent No. 5,618,845 (“the '845 patent”) in April 1997, covering specific formulations of modafinil, the active pharmaceutical ingredient (“API”) in Provigil. (CBT SUF ¶ 2.) Modafinil is a wakefulness-promoting agent used to treat narcolepsy and other sleep disorders. (Letter Decl., Ex. 1.) The FDA approved Cephalon's NDA for Provigil on December 24, 1998. In 2002, Cephalon was granted a reissue patent on modafinil, U.S. Patent No. RE 37,516 (“the RE '516 patent”), which was scheduled to expire October 6, 2014. However, as a result of studying Provigil's effects on children, Cephalon also received an additional six months of pediatric exclusivity on Provigil, extending Cephalon's exclusivity period through April 6, 2015. (CBT SUF ¶¶ 1–5.)
The Generic Defendants each filed a separate Paragraph IV ANDA with the FDA on December 24, 2002, the first date on which ANDAs were able to be filed, seeking to market a generic version of Provigil. Because each of the Generic Defendants filed ANDAs on the first possible day, all were eligible to share the 180-day exclusivity of a first-filer. Cephalon filed suit against the Generic Defendants for patent infringement on March 28, 2003. (Id. at ¶¶ 7–10.) In December 2004, the Generic Defendants moved to amend their respective pleadings, asserting that Cephalon had made material representations and omissions to the PTO, including that the named inventors did not invent the modafinil composition covered by the RE ’516 patent. 4 (Pls.’ Comb. SUF ¶ 7.)

The litigation between Cephalon and the Generic Defendants ultimately settled between December 2005 and February 2006, while motions for summary judgment were pending. All of the settlement agreements included a provision where Cephalon granted the Generic Defendants a license to market their generic modafinil products on a “date certain”—the later of October 6, 2011, or, if Provigil obtained a pediatric extension of the RE ’516 patent, April 6, 2012. The settlement agreements also provided that the Generic Defendants could enter the market earlier than the date certain if: (1) Cephalon licensed any other generic manufacturer to market generic modafinil prior to that date; (2) another generic decided to launch “at risk”; or (3) if a judgment declared that generic modafinil may be sold without infringing the RE ’516 patent. (CBT SUF ¶¶ 11, 14–15, 23–24, 31–32, 49–50.) Each of the settlement agreements included provisions and/or were signed alongside various additional agreements whereby Cephalon paid the Generic Defendants (and associates of the Generic Defendants) a total of approximately $300 million. (See CBT Mot., Exs. 8–11, 13, 16–19.) These transactions are explored in greater detail herein.

1. The Teva Settlement Agreement

Cephalon entered into a settlement agreement with Teva on December 8, 2005. In addition to the licensing provisions allowing Teva to begin selling its generic modafinil product on a date certain, Cephalon also agreed to make royalty payments to Teva in exchange for a worldwide license to Teva's modafinil-related intellectual property (“IP”). The royalty payments included lump sum payments at certain sales benchmarks and a three percent royalty on all worldwide net sales of all Cephalon Modafinil Product until either the licensed patents expired or the total royalty payments reached a maximum of $125 million. (Id. at ¶¶ 12–17.) Cephalon also entered into an API supply agreement with Teva, whereby Teva agreed to manufacture and supply Cephalon with 10,000 kg. per year of modafinil API for a five-year period at the following prices: $650/kg. in the first year, and $500/kg. to $600/kg. in subsequent years. (Id. at ¶¶ 18–20.) Cephalon and Teva further agreed to settle pending patent litigation related to the modafinil patent in the United Kingdom in exchange for Cephalon paying Teva 2.1 million British pounds and 2.5 million Euros. Finally, Cephalon agreed to appoint Teva UK Limited as the exclusive distributor of Cephalon modafinil products in the United Kingdom for five years, that Cephalon would provide Teva with modafinil at eighty percent of Teva's resale price, and Cephalon would pay Teva 2.5 million Euros. Pursuant to this settlement agreement, Cephalon has paid Teva in excess of $164 million. (Pls.’ Comb. SUF ¶ 153, 158.)

2. The Ranbaxy Settlement Agreement

Cephalon and Ranbaxy settled their patent litigation on December 22, 2005. In addition to the license for date-certain entry, Cephalon made a one-time $2 million payment to Ranbaxy for avoidance of litigation costs. Cephalon also entered into an IP licensing agreement with Ranbaxy, whereby Cephalon was granted a non-exclusive worldwide license to Ranbaxy's IP involving formulations of modafinil in exchange for $1 million upfront and certain milestone payments up to a maximum of $5 million. Ranbaxy and Cephalon also entered into an API supply agreement, under which Cephalon agreed to purchase 15,000 kg. per year of modafinil API from Ranbaxy, and to pay Ranbaxy $550/kg. in the first year, $500/kg. in the second year, $445/kg. in the third year, $385/kg. in the fourth year, and $325/kg. in the fifth year. (Id. at ¶¶ 25–28; Pls.’ Comb. SUF ¶ 163.) The API
that Cephalon purchased from Ranbaxy was not manufactured by Ranbaxy, but was instead manufactured by a third party, Matrix. Ranbaxy purchased the API from Matrix and sold it to Cephalon at a mark-up of close to seventy percent. Although Cephalon had pledged to pay Ranbaxy $40 million through these payments, the Ranbaxy API agreement was terminated in 2009 in exchange for a buyout. As a result, these agreements resulted in payments from Cephalon to Ranbaxy in an amount exceeding $25 million. (Pls.' Comb. SUF ¶¶ 163, 169, 250.)

3. The Mylan Settlement Agreement

On January 9, 2006, Cephalon and Mylan entered into a settlement agreement, which provided for date-certain entry, and a $2 million payment to Mylan for avoided litigation costs. (Pls.' Comb. SUF ¶ 173.)

On that same date, Mylan Technologies, Inc. and Cephalon entered into a Collaboration Agreement whereby Cephalon engaged Mylan Technologies to conduct a research program on the feasibility of developing a transdermal patch that would deliver naltrexone to patients. Cephalon was then provided an option to engage Mylan Technologies for further co-development and an exclusive license to develop, manufacture and sell any resulting product, with royalty and milestone payments due to Mylan. Pursuant to the Collaboration Agreement, Cephalon paid Mylan Technologies $10 million up front. The Agreement further provided for a payment of $15 million to Mylan upon Cephalon's receipt of a “positive” feasibility report. Cephalon also agreed to make royalty payments to Mylan Technologies based on product sales, ranging from twelve to twenty percent. Cephalon ultimately terminated the Naltrexone Agreement effective February 5, 2009. (Mylan SUF ¶¶ 22, 25–27, 35, 37–40, 42–43, 50, 52.)

Finally, on the same date that the patent litigation was settled and Cephalon and Mylan Technologies Inc. entered into the Naltrexone Collaboration Agreement, Cephalon and Mylan Laboratories Inc. also entered into an Option and Exclusivity Agreement regarding a seven-day transdermal fentanyl patch. The Agreement provided Cephalon an exclusive option to obtain certain rights and licenses with respect to the fentanyl patch. Cephalon purchased an exclusive option for $10 million on February 7, 2006. Cephalon was provided several months to determine whether it wished to exercise its option. Ultimately, Cephalon exercised its option and entered into a Fentanyl Collaboration, License and Supply Agreement on October 16, 2006, making an additional $10 million payment to Mylan. Cephalon terminated the Collaboration Agreement effective March 6, 2009. (Id. at ¶¶ 52, 54, 57–58, 60–67, 71.)

These agreements resulted in a total of approximately $48 million in payments from Cephalon to Mylan Pharmaceuticals Inc., Mylan Technologies, Inc. and Mylan Laboratories Inc. (Pls.' Comb. SUF ¶ 176.)

4. Barr Settlement Agreement

Cephalon and Barr entered into a settlement agreement effective February 1, 2006, providing a license to Barr to begin selling generic modafinil on the date certain. On the same date, Cephalon and Barr also entered into a modafinil license and supply agreement, as well as a separate settlement agreement for litigation over Cephalon's drug Actiq, a pain medication. Cephalon and Barr also entered into an Actiq licensing and supply agreement. Additionally, Cephalon entered into a modafinil API supply agreement with ChemAgis, Barr's modafinil partner, also effective February 1, 2006. Finally, on the same date, Cephalon and Perrigo Israel Pharmaceuticals Ltd., an affiliate of ChemAgis, entered into a product development Collaboration Agreement. (Id. at ¶¶ 181–86.) These Agreements are further described herein.
Under the Cephalon–Barr settlement agreement, Cephalon agreed to purchase from Barr a patent license related to modafinil for $1 million and to pay Barr $2 million for avoided litigation costs. Cephalon also agreed to purchase 10,000 kg. per year of modafinil API from ChemAgis for a period of five years. Pursuant to this agreement, even if Cephalon ordered less than 10,000 kg. per year, Cephalon was required to purchase the full amount from ChemAgis. The agreed upon prices for the modafinil API were $500/kg. in the first year, $450/kg. in the second year, and $400/kg. in the third through fifth years. Barr and ChemAgis agreed that Barr would receive fifty percent of all profits arising out of the API supply agreement. (Id. at ¶¶ 187, 272.)

As for Perrigo, Cephalon agreed to collaborate on the potential development of two drugs in exchange for Cephalon making certain milestone payments to Perrigo. All six agreements were discussed in a series of meetings between Cephalon, Barr and ChemAgis. Counsel for Cephalon held the signature pages for these six agreements in escrow until they had all been submitted. 8 Cephalon made payments in amounts exceeding $63 million pursuant to these agreements. (Id. at ¶¶ 191–94, 263, 267–68.)

C. Plaintiffs' Claims and the Motions for Summary Judgment

Plaintiffs assert that at the time these settlement agreements were executed, both Cephalon and the Generic Defendants knew that the RE '516 patent was invalid and unenforceable. Plaintiffs claim that, despite this knowledge, Cephalon and the Generic Defendants agreed to share Cephalon's monopoly profits in exchange for the Generic Defendants agreeing to drop their challenges to the RE '516 patent and stay off of the market until 2012. Accordingly, Plaintiffs argue that the four agreements described above were illegal reverse-payment settlements under Actavis.

In their motions for summary judgment, Defendants urge that, under Actavis, Plaintiffs must first meet a threshold burden establishing that Cephalon made a large and unjustified reverse payment to the Generic Defendants at the time of settlement. Defendants argue that they are entitled to a judgment as a matter of law because Plaintiffs cannot meet this “threshold burden.” Plaintiffs respond that Actavis does not mandate any type of threshold burden, but rather instructs that a burden-shifting rule of reason analysis applies. Plaintiffs further assert that, even if they are required to demonstrate a large and unjustified reverse payment as a “threshold” matter, sufficient evidence exists on these issues to present to a fact finder.

II. STANDARD OF REVIEW

A party moving for summary judgment bears the initial burden of demonstrating that there are no genuine issues of material fact and that judgment is appropriate as a matter of law. FED. R. CIV. P. 56(a); Celotex Corp. v. Catrett, 477 U.S. 317, 323, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). Once a properly supported motion for summary judgment has been made, the burden shifts to the non-moving party, who must set forth specific facts showing that there is a genuine issue of material fact for trial. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 250, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). An issue is “genuine” if a reasonable jury could rule in favor of the non-moving party based on the evidence presented. Kaucher v. Cnty. of Bucks, 455 F.3d 418, 423 (3d Cir.2006). The non-moving party cannot aver summary judgment with speculation or conclusory allegations, but rather must cite to the record. Ridgewood Bd. of Educ. v. N.E. for M.E., 172 F.3d 238, 252 (3d Cir.1999); FED. R. CIV. P. 56(c). On a motion for summary judgment, the court considers the evidence in the light most favorable to the non-moving party. Anderson, 477 U.S. at 256, 106 S.Ct. 2505. 9

*411 III. DISCUSSION
A. What is the Appropriate Standard for Establishing Liability under Actavis?


In Actavis, the United States Supreme Court considered the antitrust implications of what is commonly referred to as a reverse-payment settlement. This type of settlement typically occurs between a brand-name drug manufacturer (the patent holder) and an alleged generic infringer. Under these agreements, the patent holder pays the alleged infringer a substantial amount of money in exchange for the generic agreeing to drop the patent challenge and stay off of the market for a period of time, which has been characterized as anticompetitive conduct. These reverse-payment settlements arise almost exclusively within the context of pharmaceutical drug regulation, specifically the Hatch–Waxman Act. Actavis, 133 S.Ct. at 2227–28.

In Actavis, Solvay Pharmaceuticals was the patent holder of the brand-name drug, AndroGel. Actavis, Inc. and Paddock Laboratories each filed ANDAs for a generic drug modeled after AndroGel, certifying that Solvay's patent was invalid and not infringed by their generic products. Id. at 2229. Patent litigation ensued and eventually settled, with Solvay paying each of the generics millions of dollars in exchange for their agreement to stay off of the market until 2015—sixty-five months prior to the expiration of Solvay's patent. Id. The FTC sued all parties to the settlement agreements, alleging that they had unlawfully agreed to keep generic competition off of the market and share Solvay's monopoly profits in violation of the antitrust laws. Id. at 2230.

Prior to the Supreme Court's ruling in Actavis, several circuit courts had held that, absent sham litigation or fraud in obtaining the patent, reverse-payment settlements allowing for entry of a generic prior to the expiration of the brand-name patent were essentially immune from antitrust liability. These opinions were based on the premise that settlements that did not grant the patent holder any rights outside of the exclusionary bounds of the patent could not be subject to antitrust liability. See e.g., F.T.C. v. Watson Pharms., Inc., 677 F.3d 1298 (11th Cir.2012) (rev'd, Actavis, 133 S.Ct. 2223).

Finding that the scope of the patent test did not end the inquiry, the Supreme Court held that reverse-payment settlements that allow for generic entry prior to the expiration of a patent may still be subject to antitrust scrutiny under the rule *412 of reason because “[t]he patent ... may or may not be valid, and may or may not be infringed.” Id. at 2230–31, 2237. Actavis listed five factors that led the Court to conclude a rule of reason analysis is appropriate: (1) reverse-payment settlements have the “potential for genuine adverse effects on competition”; (2) the anticompetitive consequences will sometimes prove unjustified; (3) patent holders often possess market power; (4) the size of the settlement can often indicate a patent holder's belief in the strength or weakness of its patent; and (5) the risk of antitrust scrutiny does not prevent litigants from settling. Id. at 2234–37.

2. The Rule of Reason

The standard rule of reason burden-shifting analysis applied in many antitrust cases has remained relatively unchanged for nearly a century. See United States v. Brown Univ. in Providence in State of R.I., 5 F.3d 658, 668 n. 8 (3d Cir.1993) (remarking that the rule of reason analysis has largely remained unchanged since it was first defined in Chicago Board of Trade v. United States, 246 U.S. 231, 238, 38 S.Ct. 242, 62 L.Ed. 683 (1918)). “The rule of reason requires the fact-finder to ‘weigh [] all of the circumstances of a case in deciding whether a restrictive practice should be prohibited as imposing an unreasonable restraint on competition.’ ” Id. at 668 (quoting Continental T.V., Inc. v. GTE Sylvania Inc., 433 U.S. 36, 49, 97 S.Ct. 2549, 53 L.Ed.2d 568 (1977)).
“The plaintiff bears an initial burden under the rule of reason of showing that the alleged combination or agreement produced adverse, anti-competitive effects within the relevant product and geographic markets.” Id. (citing Tunis Bros. Co. v. Ford Motor Co., 952 F.2d 715, 722 (3d Cir.1991)). A plaintiff can satisfy this burden by demonstrating either “actual anticompetitive effects, such as reduction of output, increase in price, [ ] deterioration in quality of goods or services[,]” or a plaintiff can satisfy its burden by establishing that the defendant possesses market power—“the ability to raise prices above those that would prevail in a competitive market.” Id. (citations omitted).

If the plaintiff establishes adequate evidence of anticompetitive effects and/or market power, the burden shifts to the defendant “to show that the challenged conduct promotes a sufficiently pro-competitive objective.” Id. at 669. The plaintiff then has the opportunity to rebut the defendant's procompetitive justification by demonstrating that the defendant's conduct was not fairly necessary to achieve the procompetitive objective. Id. The fact-finder then weighs all of the effects and circumstances of the case and determines if the agreement is, on balance, anticompetitive. Pa. Dental Ass'n v. Med. Svc. Ass'n of Pa., 745 F.2d 248, 255 (3d Cir.1984) (citing Chicago Board of Trade, 246 U.S. at 238, 38 S.Ct. 242). Under the rule of reason, “[t]he true test of legality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition.” Race Tires Am., Inc. v. Hoosier Racing Tire Corp., 614 F.3d 57, 75 (3d Cir.2010) (quoting Orson, Inc. v. Miramax Film Corp., 79 F.3d 1358, 1368 (3d Cir.1996)).

3. Does Actavis Alter the Standard Rule of Reason Analysis?

The Actavis opinion makes clear that a rule of reason analysis must be applied to antitrust cases challenging a reverse-payment settlement. The specific contours of the rule of reason analysis to be applied under Actavis are not, however, well-defined, with the Supreme Court “leav[ing] *413 to the lower courts the structuring of the present rule-of-reason antitrust analysis.” Actavis, 133 S.Ct. at 2238. Actavis emphasizes that it is concerned with reverse-payment settlements bringing about a specific anticompetitive harm—the sharing of monopoly profits between a patent holder and a patent challenger in order “to avoid the risk of patent invalidation or a finding of noninfringement.” Id. at 2236–37. To that end, Actavis states numerous times that the risk of anticompetitive consequences is particularly pronounced where the reverse payment is “large and unjustified.” See id. at 2237 (“a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects”). “[T]he likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.” Id.

The phrase “threshold burden” does not appear anywhere in Actavis. Nonetheless, Defendants urge that Plaintiffs must establish that the reverse payment is both large and unjustified as a threshold matter, and failure to meet this burden prohibits analysis under the rule of reason. Defendants garner support for this interpretation from Chief Justice Roberts' dissent in Actavis and three district courts opinions that seem to have identified “large and unjustified” as hurdles the plaintiff must clear prior to a rule of reason analysis.

In his dissent in Actavis, Chief Justice Roberts states, “According to the majority, if a patent holder settles litigation by paying an alleged infringer a ‘large and unjustified’ payment, in exchange for having the alleged infringer honor the patent, a court should employ the antitrust rule of reason to determine whether the settlement violates antitrust law.” Id. at 2239 (Roberts, J., dissenting). Defendants argue that this statement clearly dictates that a “large and unjustified” analysis must occur prior to application of the rule of reason. However, this alleged “threshold burden” standard is the dissent's interpretation of the majority ruling and is not found in the majority opinion. Nonetheless, Defendants press that the “threshold burden” requirement also finds support in subsequent district court opinions interpreting Actavis. See In re Lamictal Direct Purchaser Antitrust Litigation, 18
In re Lamictal largely focuses on whether a settlement exchanging non-monetary consideration may constitute a reverse-payment settlement. In dicta, the court noted that Actavis appears to require a three-step analysis: first, determine whether there is a reverse payment; second, determine if the reverse payment is large and unjustified; and third, apply the rule of reason. In re Lamictal, 18 F.Supp.3d at 565; see also In re Loestrin, 45 F.Supp.3d 180 (adopting the three-step approach used in In re Lamictal ). Despite advocating this three-part test, the district court noted that “the Supreme Court's concern about a settlement size appears both in Step Two and Step 414 Three[,]” which might indicate that “Steps One and Two are not preliminary steps, but rather part of a broad, open ended balancing” under the rule of reason. In re Lamictal, 18 F.Supp.3d at 566.

Similarly, In re Nexium opines that the proper standard for a claim under Actavis requires plaintiffs to first prove that the settlement included a large and unjustified payment to the alleged patent infringer. Then, the defendants are given the opportunity to show that the payment was justified by a procompetitive objective. If the defendants provide a procompetitive justification, “the burden shifts back to the [p]laintiffs to establish, under the rule of reason, that the settlement is nevertheless anticompetitive on balance.” In re Nexium, 42 F.Supp.3d at 262–63, 2014 WL 4370333, at *23. Based upon my reading of this case, it is unclear whether “large and unjustified” is a threshold burden on the plaintiffs, analyzed separately from the rule of reason, or whether it is part of the plaintiff’s initial burden under the rule of reason. In any event, the end result under In re Nexium appears to be the same—if Plaintiffs do not establish that the payment is large and unjustified, the antitrust analysis ends.

Plaintiffs present two alternative interpretations of the parties' burdens under Actavis. The FTC and Apotex agree that Plaintiffs must establish, under the first step of the rule of reason analysis, that the payments were large.12 (See FTC's Resp., p. 6 (describing its initial burden under the rule of reason as demonstrating “that Cephalon possessed market power and made a payment to a generic challenger sufficient to induce the generic challenger to abandon its claim”); Apotex's Resp., p. 17 (“Defendants' motions should be denied because Apotex has met the initial burden under Actavis of demonstrating a large reverse payment”).) The remaining Plaintiffs, however, assert that their burden under Actavis is the same burden they would face in any other rule of reason case: demonstrating actual anticompetitive effects, such as reduction of output, increase in price and deterioration in quality of goods or services, or by establishing that Cephalon possessed market power. All Plaintiffs agree that Defendants bear the burden of justifying the reverse-payment settlement, which Plaintiffs may then rebut. I am unaware of any post-Actavis cases adopting either of the approaches suggested by Plaintiffs. However, after careful examination of applicable precedent, I conclude that the approach suggested by the FTC and Apotex most closely follows the teachings of Actavis.

Most telling is the fact that, nowhere in the Actavis opinion does the Supreme Court state that plaintiffs bear a “threshold burden” of demonstrating that the reverse payment was large and unjustified. While the terms “large” and “unjustified” are used several times in the opinion, and certainly appear to be important, perhaps the clearest guidance given to trial courts is that antitrust cases involving reverse-payment settlements must be analyzed under 415 the rule of reason. The question then becomes: when structuring a reverse-payment settlement case, where do the “large and unjustified” considerations belong within the rule of reason analysis?

As noted above, under a standard rule of reason analysis, the plaintiff bears the initial burden of demonstrating that “the alleged combination or agreement produced adverse, anticompetitive effects within the relevant product and geographic markets.” Brown Univ., 5 F.3d at 668. The plaintiff can meet this burden by demonstrating actual anticompetitive effects or by establishing that the defendant possesses market power. Id. Actavis notes that both the likelihood of anticompetitive harm and the probability that the patent holder possesses market power increase as the size of the reverse payment increases. Actavis, 133 S.Ct. at 2235–36. For example, the Court remarks that a large payment can provide strong evidence of the relevant anticompetitive harm—“that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would
otherwise be lost in the competitive market.” *Id.* at 2235. Importantly, *Actavis* instructs that “the size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of [market] power.” *Id.* at 2236 (citation omitted) (emphasis added). These statements indicate that evidence of a large payment is required for a plaintiff to satisfy its initial burden of demonstrating anticompetitive effects under the *Actavis* rule of reason analysis. See also *id.* at 2237 (“the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size ...”).

Next, I must determine which party bears the burden of addressing potential justifications for the reverse payment under *Actavis*. In explaining why antitrust scrutiny of reverse-payment settlements is appropriate, the Court noted that, at least sometimes, the anticompetitive consequences these settlements may bring about will “prove unjustified.” *Id.* at 2235–36. After discussing potential legitimate, procompetitive reasons that may justify a large reverse-payment settlement, the Court states that “[a]n antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason.” *Id.* at 2236. In making this statement, the Supreme Court cited to Federal Trade Commission v. Indiana Federation of Dentists, 476 U.S. 447, 459, 106 S.Ct. 2009, 90 L.Ed.2d 445 (1986), which analyzed the defendant's burden of proving procompetitive effects under the rule of reason. The *Actavis* Court also cited to an antitrust treatise, discussing a defendant's burden to provide evidence of procompetitive justifications under the rule of reason. See 7 Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* ¶¶ 1504a–1504b, at 401–04 (3d ed. 2010) (“Areeda & Hovenkamp”). In summarizing its decision, the *Actavis* Court notes that “a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects; [and] one who makes such a payment may be unable to explain and to justify it[.]” *Id.* at 2237.

Under a standard rule of reason analysis, after a plaintiff establishes that an agreement has brought about anticompetitive effects, the burden shifts to the defendant to show that the challenged conduct promotes a sufficiently procompetitive objective—in other words, to justify the conduct. *Brown Univ.*, 5 F.3d at 669; 7 Areeda & Hovenkamp ¶ 1504a, pp. 401–02 (under rule of reason “we look to the defendant, with its knowledge of its own *416 situation, to identify the possible justifications for its conduct”). Synthesizing this precedent with the Court's statements in *Actavis*, I find that whether or not the reverse payment is unjustified or unexplained is examined under the standard rule of reason burden-shifting framework, with the defendant bearing the burden of providing evidence that the reverse payment is justified by procompetitive considerations.

Lastly, if the defendant presents sufficient evidence of procompetitive justifications, the plaintiff must then rebut those justifications and establish that the “restraint is not reasonably necessary to achieve the stated objective.” *Race Tires Am., Inc. v. Hoosier Racing Tire Corp.*, 614 F.3d 57, 75 (3d Cir.2010) (“The plaintiff then must demonstrate that the restraint itself is not reasonably necessary to achieve the stated objective”); *Brown Univ.*, 5 F.3d at 669 (same). A plaintiff must raise a genuine dispute of material fact as to the defendant's justifications because *Actavis* indicates that where reverse payments reflect “traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement.” 133 S.Ct. at 2236. If the plaintiff provides evidence to rebut the defendant's justifications, the fact-finder will then weigh the anticompetitive and procompetitive effects, as in other rule of reason cases.

Defendants disagree with this framework and argue that placing the burden of justifying the payment on them creates a presumption of illegality that was rejected in *Actavis*. I disagree. In *Actavis*, the Court rejected the FTC's position that reverse-payment settlements should receive enhanced scrutiny under a “quick-look” approach. This approach is an intermediary standard, applied where “no elaborate industry analysis is required to demonstrate the anticompetitive character of an inherently suspect restraint.” *Brown Univ.*, 5 F.3d at 669 (quoting *Nat'l Collegiate Athletic Ass'n v. Bd. of Regents of Univ. of Okl.*, 468 U.S. 85, 109, 104 S.Ct. 2948, 82 L.Ed.2d 70 (1984)) (quotation marks omitted). Under a quick-look analysis, anticompetitive harm is assumed, and the burden is immediately placed on the defendant to justify the conduct. *Id.* Failure to provide a legitimate justification results in antitrust liability, but if the defendant provides a sound justification, the court weighs “the overall reasonableness of the restraint using a full-scale rule of reason analysis.” *Id.*
The burden-shifting framework I have adopted does not qualify as a quick-look approach because the plaintiff still maintains the initial burden—establishing anticompetitive effects through market power and evidence of a large reverse payment. While Defendants argue that bearing the burden of justifying the reverse payments will make parties less likely to settle complex patent litigation, the Supreme Court has considered this argument and rejected it. See Actavis, 133 S.Ct. at 2237 (“the fact that a large, unjustified reverse payment risks antitrust liability does not prevent litigating parties from settling their lawsuit”).

B. What Constitutes a Large Payment?

Actavis did not identify any specific formula for determining whether a reverse payment is sufficiently large. Defendants argue that the appropriate consideration is whether the unexplained portion of the payment is large in comparison to the brand manufacturer's expected monopoly profits in the absence of generic competition. However, Defendants do not indicate what percentage of the expected monopoly profits would meet this threshold. Plaintiffs respond that a reverse payment is sufficiently large if it exceeds saved litigation costs and a reasonable jury could find that the payment was significant enough to induce a generic challenger to abandon its patent claim. For the following reasons, I find that Actavis supports Plaintiffs' approach.

First, Actavis specifically instructs that an appropriate benchmark for the size of a reverse payment is “its scale in relation to the payor’s anticipated future litigation costs[.]” Id. at 2237. Examining the record before me, I note that Plaintiffs have presented evidence that the average litigation costs for patent cases with more than $25 million at stake are approximately $5.5 million per party, which could establish that Cephalon saved approximately $22 million in litigation expenses. (Noll Exp. Rep., May 26, 2011, ¶ 31.) Additionally, the Ranbaxy, Mylan and Barr Agreements specifically identified amounts paid for saved litigation costs—$2 million to each party, for a total of $6 million. (Pls.’ Comb. SUF ¶¶ 163, 173, 187.) This number reaches approximately $13 million if one includes the payments made to Teva for avoidance of litigation costs in the United Kingdom. (FTC SUF ¶¶ 119–21.) Nonetheless, by any of these measures, the total amounts paid by Cephalon to each of the Generic Defendants greatly exceed saved litigation expenses, thus satisfying the first part of the “large” standard.

Regarding the “inducement” prong, Actavis instructs that “there are indications that patentees sometimes pay a generic challenger a sum even larger than what the generic would gain in profits if it won the paragraph IV litigation and entered the market[,]” which “cannot in every case be supported by traditional settlement considerations.” Actavis, 133 S.Ct. at 2234–35. This statement seems to contradict Defendants’ argument that the brand manufacturer's expected monopoly profits constitutes the appropriate benchmark. As Actavis explains, the relevant inquiry is what would induce the generic to stay off of the market. Id. at 2235. A reasonable jury could find that a reverse payment to a generic manufacturer that comes close to or exceeds the expected profits to be earned by prevailing in the patent litigation could induce a generic manufacturer to forfeit its claim. See Herbert Hovenkamp, Anticompetitive Patent Settlements and the Supreme Court’s Actavis Decision, 15 Minn. J.L. Sci. & Tech. 3, 12 (Winter 2014) (“Even if the generic believes there is a 100% likelihood that the patent will be found invalid, it may still be more valuable for the generic to share the monopoly returns”).

Applying these principles, I find that the evidence presented by Plaintiffs on this issue creates a genuine dispute of material fact as to whether the reverse payment was large enough to induce the Generic Defendants to stay off of the market. Several of Plaintiffs’ experts have weighed in on the profits that the Generic Defendants could have expected to earn had they released a generic modafinil product as opposed to settling with Cephalon, and have concluded that the amounts paid to these Generic Defendants have come close to, or in some instances, greatly exceeded the profits they could have expected to earn through an at-risk launch. (See e.g., Hartman Exp. Rep., Dec. 20, 2013, ¶¶ 58–61; Elhauge Exp. Rep., Apr. 26, 2011, ¶¶ 17–18; Noll Exp. Rep., May 26, 2011, ¶ 200.)
Ranbaxy, the recipient of the smallest payment, also argues that the $27 million it received is less than its expected profits from an at-risk launch, pointing to calculations of some of Plaintiffs' experts. However, Plaintiffs have provided internal Ranbaxy documents and deposition testimony indicating that Ranbaxy valued its market opportunity for generic modafinil as having a net present value (“NPV”) between $7.6 and $8.8 million over a five-and-a-half year period. (Letter Decl., Ex. 114; Fabiano Dep., pp. 194–200.) By contrast, Ranbaxy projected the NPV of the expected payments from Cephalon under the settlement agreements at over $10 million. (Letter Decl., Ex. 116; Fabiano Dep., pp. 194–200.) Evidence of Ranbaxy's evaluation of the two options before it, and its determination that the settlement payments from Cephalon had greater value, creates a genuine dispute of material fact as to whether the $27 million payment to Ranbaxy was sufficiently large to induce it to abandon the challenge to the RE '516 patent.

I further disagree with Defendants' contention that only the unexplained portion of a reverse payment should be considered in assessing whether a reverse payment is large. As previously discussed, Defendants, not Plaintiffs, bear the burden of explaining the payments. Whether or not the payment constitutes “fair value for services” or some other legitimate justification will be in contention in nearly every case, with plaintiffs arguing that most, if not all, of the payment is mere pretext for a payment for delay. Therefore, I find that the entirety of the reverse payment should be considered in determining whether the payment is large under Actavis.

Plaintiffs have presented sufficient evidence to create a genuine dispute as to whether the reverse payments exceeded litigation costs and were large enough to induce the Generic Defendants to drop their patent challenge and stay off of the market. As Defendants have not challenged Plaintiffs' ability to demonstrate market power, Plaintiffs have presented sufficient evidence to meet their initial burden under the rule of reason.

**C. Plaintiffs' Evidence to Rebut Defendants' Procompetitive Justifications**

Defendants stress that the money Cephalon provided to the Generic Defendants was for avoidance of litigation expenses and fair value for services provided. See Actavis, 133 S.Ct. at 2236 (where reverse payments reflect “traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement”); (see Snyder Exp. Rep., June 10, 2011, ¶¶ 185–200; Bell Supp. Exp. Rep., Dec. 20, 2013, ¶¶ 15–39.) Whether Defendants have met that burden is not currently disputed.

Plaintiffs have presented sufficient evidence to rebut Defendants' procompetitive justifications and raise a genuine factual dispute as to whether the payments were reasonably necessary to achieve the procompetitive benefits. A reasonable jury could conclude that the payments were aimed at delaying generic entry and that Defendants' justifications are pretextual.

First, Plaintiffs cite to evidence of Cephalon's internal statements suggesting that it had knowledge of the RE '516 patent's weaknesses. In February 2005, a Cephalon consultant wrote that Provigil “faces the certain prospect of generic competition by June 2006.” (FTC SUF, Ex. 15.) Similarly, a publication issued by Cephalon's Executive Vice President and General Counsel shortly after the settlements stated that “[i]n the end, Cephalon was able to secure almost six additional years of exclusivity for PROVIGIL by allowing each generic firm to enter the market three years prior to the expiration of the particle-size patent.” (Letter Decl., Ex. 35; see also Id. at Ex. 152 (“The Provigil settlement extends the U.S. period of exclusivity on Provigil”).) Given the fact that the RE '516 patent wasn't due to expire until 2015, a jury could conclude that these statements reflected Cephalon's view that its patent was weak. Additionally, the arguments raised by the Generic Defendants in the Paragraph IV litigation largely mirrored the facts that were eventually used to invalidate and render unenforceable the RE '516 patent, demonstrating the Generic Defendants' knowledge of those facts.
Plaintiffs have also produced several experts who will opine that numerous services articulated in the settlement agreements were unnecessary and unwanted. Defendants have objected to these expert witnesses, arguing that their failure to properly assess the fair market value of the various side-agreements is fatal to their claims. In *In re Nexium*, the Honorable William G. Young considered a similar argument—that without evidence that the generic had received greater than fair market value for its services, the reverse-payment was per se lawful. Judge Young disagreed with the defendants' position, finding that:

> establishing fair market value is just one of many possible defenses available to a Defendant seeking to demonstrate procompetitive justifications for a reverse payment. Nowhere in *Actavis* does the Supreme Court suggest that fair market value is a silver bullet against antitrust scrutiny. Neither does the opinion place the initial burden on the Plaintiffs to prove, in their prima facie case, that a transaction was for something other than fair market value.

*In re Nexium*, 42 F.Supp.3d at 263–64, 2014 WL 4370333, at *24 (D.Mass.2014). I find Judge Young's analysis on this issue to be correct. While evidence that these payments exceed fair value for goods and services would certainly be helpful for Plaintiffs in rebutting Defendants' justifications, I do not find that it is a necessary element of Plaintiffs' claims.\

15 *See* *Actavis*, 133 S.Ct. at 2237 (the fact that the plaintiff must prove its case does not require it to “refute every possible pro-defense theory”). Plaintiffs have provided significant direct and circumstantial evidence that, if believed, could lead a reasonable jury to conclude that the side-deals between Cephalon and the Generic Defendants were simply a means of providing payments for delay.\

The API supply portions of the settlement agreements also create a factual issue regarding Plaintiff's ability to rebut Defendants procompetitive justification. Plaintiffs have pointed to evidence demonstrating that at the time the API agreements were reached, Cephalon already had an API agreement with Helsinn in Switzerland, as well as its own internal supply held in France. At the time that the API-supply agreements were made with Teva, Ranbaxy and ChemAgis, Cephalon was obtaining modafinil API from Helsinn for under $200/kg. The API-supply agreements called for Cephalon to pay Teva, Ranbaxy and ChemAgis two to three times that amount. (Pls.' Comb. SUF ¶¶ 206, 213–19, 221.)

Plaintiffs also point to evidence demonstrating that Cephalon disregarded its corporate “guiding principles” and due diligence checklist for obtaining API suppliers in entering into these agreements. The amount of modafinil API that Cephalon agreed to purchase from the Generic Defendants far exceeded Cephalon's projected API requirements, and internal documents and deposition testimony from Cephalon indicate that the agreement with Helsinn and Cephalon's internal supply would have met Cephalon's modafinil API needs. One Cephalon executive characterized the API side deals as “a supply chain nightmare,” and the supply agreement with Ranbaxy was terminated in 2009 in exchange for a buyout of $13.5 million. (Id. at ¶¶ 205, 207–12, 226–30, 232, 237–38, 252, 261.) Plaintiffs have also presented expert evidence suggesting that these API agreements were outside of the industry's norms, that Cephalon had no need for the additional API, and the amounts paid by Cephalon were far in excess of the amounts in which it could have received API from Helsinn or other suppliers. (McCool Exp. Rep., Apr. 25, 2011, pp. 29–35.)

As to the IP rights, Plaintiffs present evidence that Cephalon was aware of other IP involving modafinil and had never sought to license it, nor indicated that there was any infringement risk. To the contrary, in August of 2005, just months prior to the settlement agreements, Cephalon's chief patent counsel stated “[w]e know the patent landscape for modafinil and formulations of modafinil and are not aware of any potential infringement problems.” (Pls.' Comb. SUF ¶¶ 290–91, 293, 296.) A few months later, Defendants agreed to pay up to $131 million for this same IP. Plaintiffs have further presented *expert opinions*
that Cephalon went outside industry norms and failed to conduct due diligence prior to licensing the Generic Defendants' IP. (Bazerman Exp. Rep., Apr. 21, 2011, ¶ 21.)

Finally, with regard to the product development agreements between Cephalon and Mylan, Plaintiffs point to evidence demonstrating that Cephalon had not approached Mylan about the development of these products prior to the modafinil settlement. According to a Mylan financial projection prior to the settlement agreement, Mylan predicted that the option agreement for the fentanyl patch was worth $41.8 million to Mylan and negative $11.6 million to Cephalon. When Cephalon began conducting due diligence on the fentanyl product development agreement, it also determined that it likely had a negative net present value for Cephalon. Despite these findings, Cephalon exercised its option for a Collaboration Agreement in June 2006. Cephalon later terminated both of the development agreements in January 2009, after paying Mylan tens of millions of dollars. (Pls.' Comb. SUF ¶¶ 377, 380, 382, 384, 386, 388.)

While I fully appreciate that Cephalon will have vigorous procompetitive responses to all of this evidence, a jury presented with these facts could find that the side agreements between Cephalon and the Generic Defendants were a means of disguising payments for delay and/or inducing the Generic Defendants to stay off of the market. Therefore, while Defendants bear the burden of justifying the reverse payments as procompetitive, Plaintiffs have pointed to sufficient evidence to rebut these procompetitive purposes so to create a genuine dispute of material fact.

**D. Ranbaxy's Causation Argument**

Ranbaxy separately argues that, even if Plaintiffs could establish that Ranbaxy received a large and unexplained payment from Cephalon, Plaintiffs have not provided any evidence that the Ranbaxy–Cephalon settlement caused Ranbaxy to delay launching its generic modafinil product. More specifically, Ranbaxy asserts that all evidence indicates that it would not have launched “at risk,” even if it had not settled with Cephalon.

Ranbaxy's position essentially relates to antitrust injury, which has been described as follows by the Supreme Court:

Plaintiffs must prove antitrust injury, which is to say injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful. The injury should reflect the anticompetitive effect either of the violation or of anticompetitive acts made possible by the violation.

*Brunswick Corp. v. Pueblo Bowl–O–Mat, Inc.,* 429 U.S. 477, 489, 97 S.Ct. 690, 50 L.Ed.2d 701 (1977). To determine whether the injury flowed from an illegal restraint on competition, the court “must examine the causal connection between the purportedly unlawful conduct and the injury.” *City of Pittsburgh v. W. Penn Power Co.,* 147 F.3d 256, 265 (3d Cir.1998).

In support of its argument, Ranbaxy points to evidence that it had attempted to launch a generic product at risk in 2005, had been unsuccessful, and was dealing with the financial ramifications of that attempt at the time of the Cephalon settlement. (Ranbaxy SUF ¶¶ 17–19.) Ranbaxy further points to a statement from its Senior Vice President & Regional Director for North America, stating that there was no way that Ranbaxy would have launched generic modafinil at risk. (Id. at ¶ 16.)

Plaintiffs respond that genuine disputes of material fact exist as to whether Ranbaxy planned to launch at risk prior to the settlement with Cephalon. For example, Ranbaxy internal documents from April 12, 2005 identified June 2006 as the “likely launch date” for Ranbaxy's generic modafinil product. At deposition, Ranbaxy representatives also explained that after
reviewing some of these documents, it appeared Ranbaxy had begun taking steps toward an at-risk launch as of November 2005. Emails and deposition testimony from Ranbaxy representatives indicate that Ranbaxy was planning to place an order for a “launch quantity” of modafinil API in December 2005, but ultimately did not because of the settlement with Cephalon. (Pls.’ Comb. SUF ¶¶ 121–25.)

Given this conflicting evidence, a genuine dispute of material fact exists as to whether Ranbaxy would have launched at risk, and thus, whether Plaintiffs are able to establish causation as to Ranbaxy. See In re Neurontin Antitrust Litig., 2013 WL 4042460, at *10 (D.N.J. Aug. 8, 2013) (citing Rivas v. City of Passaic, 365 F.3d 181, 193 (3d Cir.2004)) (“causation is a factual issue for the jury”).

IV. CONCLUSION

For the reasons stated above, I find that a plaintiff challenging a reverse-payment settlement as anticompetitive under Actavis must demonstrate anticompetitive effects, including a large reverse payment, under the first step of the rule of reason. The defendant then bears the burden of explaining or justifying the payment as procompetitive. If the plaintiff presents evidence to raise a factual dispute as to defendant's proffered justifications, the fact-finder will weigh all relevant information and determine whether the settlement was, on balance, unreasonable, as in other rule of reason cases.

Plaintiffs have presented sufficient evidence to meet their burden under the rule of reason to survive summary judgment. An appropriate Order follows.

ORDER

AND NOW, this 28th day of January, 2015, upon consideration of “Defendants Cephalon, Barr, and Teva's Motion for Summary Judgment on Plaintiffs' Challenges to the Settlement Agreements” (Dkt. No. 06–1797, Doc. No. 626; Dkt. No. 06–1833, Doc. No. 307; Dkt. No. 06–2768, Doc. No. 710; Dkt. No. 08–2141, Doc. No. 275), “Motion of the Mylan Defendants' for Summary Judgment on All Claims Under FTC v. Actavis” (Dkt. No. 06–1797, Doc. No. 612; Dkt. No. 06–1833, Doc. No. 295; Dkt. No. 06–2768, Doc. No. 690), and “Ranbaxy Defendants' Motion for Summary Judgment” (Dkt. No. 06–1797, Doc. No. 621; Dkt. No. 061833, Doc. No. 302; Dkt. No. 06–2768, Doc. No. 702), and following oral argument, and for the reasons stated in the accompanying memorandum opinion, it is hereby ORDERED that these motions are DENIED.

All Citations

88 F.Supp.3d 402, 2015-1 Trade Cases P 79,048

Footnotes

1 As detailed infra, these agreements were entered into by Defendant, Cephalon, Inc. (“Cephalon”), the brand-name manufacturer of Provigil, and the following Defendant generic drug manufacturers: Barr Pharmaceuticals, Inc. (“Barr”); Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc. (collectively “Mylan”); Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. (collectively “Teva”); and Ranbaxy Laboratories, Ltd. and Ranbaxy Pharmaceuticals, Inc. (collectively “Ranbaxy”) (collectively referred to as the “Generic Defendants”).
All facts are undisputed, unless otherwise noted, and disputed facts are viewed in the light most favorable to Plaintiffs—the non-moving parties. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 256, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986).

The FDA publishes a list of all patents covering a drug under which a claim of patent infringement could reasonably be asserted in the “Approved Drug Products with Therapeutic Equivalence Evaluations” publication, also known as the Orange Book. Caraco Pharm. Labs., Ltd., 527 F.3d at 1282.

The same facts and defenses raised by the Generic Defendants in their Paragraph IV litigation were later presented to this Court in the Apotex v. Cephalon patent litigation, resulting in the RE ‘516 patent being declared invalid and unenforceable. (See Pls.’ Comb. SUF ¶¶ 8–28); Apotex, Inc. v. Cephalon, Inc., 2011 WL 6090696 (E.D.Pa. Nov. 7, 2011) aff’d, 500 Fed.Appx. 959 (Fed.Cir.2013).

Naltrexone is a drug used to treat alcoholism. (Mylan SUF ¶ 37.)

Fentanyl is a pain medication primarily used with cancer patients. (Id. at ¶ 53.)

Defendants argue that the Collaboration Agreement and Option and Exclusivity Agreement (described infra ) cannot be characterized as part of the settlement agreement. However, Plaintiffs have presented sufficient evidence for a reasonable jury to determine that the three contracts were separate pieces of one cohesive agreement, and that the product development agreements were necessary to the settlement. (See Letter Decl., Ex. 120 (Cephalon emailing the three agreements to Mylan for signature on the same date, insisting that all three be signed prior to a press release scheduled for the following morning); Bazerman Exp. Rep., Apr. 21, 2011, ¶ 40 (“the Cephalon/Mylan agreements would not have occurred at the same time if the contemporaneous business transactions were independent of the patent settlement”).)

Although the ChemAgis supply agreement was signed as a separate agreement, it had originally been included within the settlement agreement between Cephalon and Barr. The API supply agreement was excised and written separately pursuant to a change requested by Barr. (Pls.’ Comb. SUF ¶¶ 270–71.) In light of this evidence and the simultaneous signatures required by the parties, a reasonable jury could find that the ChemAgis and Perrigo agreements were necessary parts of the settlement agreement between Cephalon and Barr.

Cephalon, Barr and Teva suggest that there exists a “special,” heightened standard of review for motions for summary judgment in the antitrust context. The cases that these Defendants cite refer to the limited inferences that may be drawn from ambiguous, circumstantial evidence in establishing concerted action, and that summary judgment may not be thwarted by economically senseless theories. See Eastman Kodak Co. v. Image Tech. Svc., Inc., 504 U.S. 451, 468–69, 112 S.Ct. 2072, 119 L.Ed.2d 265 (1992); Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 587–88, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986); Race Tires Am., Inc. v. Hoosier Racing Tire Corp., 614 F.3d 57, 73 (3d Cir.2010); see also In re Flat Glass Antitrust Litig., 385 F.3d 350, 357–58 (3d Cir.2004). Plaintiffs have presented direct evidence of concerted action through the settlement agreements between Cephalon and each of the Generic Defendants, and Defendants have not challenged Plaintiffs’ ability to meet the concerted action requirement on these claims. Furthermore, the Supreme Court and United States Court of Appeals for the Third Circuit have made clear that “[t]he traditional summary judgment standard applies with equal force in antitrust cases [.]” Alvord–Polk, Inc. v. F. Schumacher & Co., 37 F.3d 996, 1001 (3d Cir.1994) (citing Eastman Kodak, 504 U.S. at 468, 112 S.Ct. 2072).

Paddock was paid $12 million; Par Pharmaceuticals, which joined forces with Paddock, was paid $60 million; and Actavis was paid $19–$30 million annually for a total of nine years. Id. at 2229.

I note that at oral argument, Barr acknowledged that a showing of large and unjustified may be part of Plaintiffs’ initial burden under the rule of reason. In any event, Barr argued that Plaintiffs have failed to meet their burden, regardless
of whether or not it is presented as a “threshold burden” prior to the application of the rule of reason. (Oral Arg. Tr., pp. 16–19.)

12 The private Plaintiffs argue that even if they do not satisfy their burden under Actavis, summary judgment may not be granted on their challenges to the settlement agreements due to their allegations of fraud in the procurement of Cephalon's patent. They assert that proof of Walker Process fraud renders the settlement agreements per se violations of the Sherman Act, and thus, evidence of fraud is sufficient to deny summary judgment. The Generic Defendants respond that they may not be held liable under the antitrust laws for Cephalon's fraud. I need not address this issue at this time because, as detailed infra, I find that Plaintiffs have provided sufficient evidence to survive summary judgment under Actavis.

13 I recognize that Plaintiffs' experts Hartman, Noll and Elhauge are the subject of Daubert motions filed by Defendants (see “Joint Motion to Exclude Damages Opinions of Plaintiffs' Experts Drs. Hartman, Leffler, Leitzinger and Noll”; “Defendants' Motion to Exclude the Testimony of Plaintiffs' Proposed Economic Experts”). These motions do not assert that Plaintiffs' experts understate the Generic Defendants' expected profits—in fact, the motion to exclude these experts' damages opinions appears to argue the opposite. Therefore, I will consider these figures in deciding the summary judgment motions currently before me.

14 Similarly, Defendants have not challenged the Plaintiffs' ability to demonstrate monopoly power on its conspiracy to monopolize claims. See Eastman Kodak Co. v. Image Tech. Svc., Inc., 504 U.S. 451, 481, 112 S.Ct. 2072, 119 L.Ed.2d 265 (1992) (a plaintiff asserting a claim for monopolization must establish (1) monopoly power in the relevant market; and (2) anticompetitive conduct).

15 I also disagree with Defendants' contention that Plaintiffs must establish that the value Cephalon received from the goods and services was grossly inadequate, and the transactions were a complete sham, in order to demonstrate that the reverse payments were unjustified. Cephalon, Barr and Teva urge that American Motor Inns, Inc. v. Holiday Inns, Inc., 521 F.2d 1230 (3d Cir.1975) prohibits the “second guessing” of complex business agreements. I do not read American Motor that expansively. See id. at 1248–50 (finding that the availability of alternative means of achieving a defendant's stated business purpose does not automatically render the agreement unlawful; rather, courts should determine whether the restriction was “fairly necessary in the circumstances of the particular case”).

16 This evidence distinguishes Plaintiffs' expert reports from the cases cited by Ranbaxy, wherein the plaintiffs relied upon expert opinions that were not based upon facts in the record. See In re Baby Food Antitrust Litig., 166 F.3d 112, 135 (3d Cir.1999) (quoting Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp., 509 U.S. 209, 242, 113 S.Ct. 2578, 125 L.Ed.2d 168 (1993)) (“When an expert opinion is not supported by sufficient facts to validate it in the eyes of the law, or when indisputable record facts contradict or otherwise render the opinion unreasonable, it cannot support a jury's verdict”); Advo, Inc. v. Phila. Newspapers, Inc., 51 F.3d 1191, 1198 (3d Cir.1995) (finding that expert opinions could not subvert summary judgment in predatory pricing case where there was no direct evidence of predatory pricing).
IN RE: LIPITOR ANTITRUST LITIGATION

Rite Aid Corporation; Rite Aid Hqtrs Corporation; JCG (PJC) USA, LLC; Maxi Drug, Inc. d/b/a Brooks Pharmacy; Eckerd Corporation, Appellants in No. 14-4202
Walgreen Company; The Kroger Company; Safeway, Inc.; Supervalu, Inc.; HEB Grocery Company L.P., Appellants in No. 14-4203
Giant Eagle, Inc., Appellant in No. 14-4204
Meijer Inc.; Meijer Distribution, Inc., Appellants in No. 14-4205

Rochester Drug Co-Operative, Inc.; Stephen L. Lafrance Pharmacy, Inc. d/b/a Saj Distributors; Burlington Drug Company, Inc.; Value Drug Company; Professional Drug Company, Inc.; American Sales Company LLC, Appellants in No. 14-4206
A.F.L.-A.G.C. Building Trades Welfare Plan; Mayor and City Council of Baltimore, Maryland; New Mexico United Food and Commercial Workers Union's and Employers' Health and Welfare Trust Fund; Louisiana Health Service Indemnity Company, d/b/a Blue Cross/Blue Shield of Louisiana; Bakers Local 433 Health Fund; Twin Cities Bakery Workers Health and Welfare Fund; Fraternal Order of Police, Fort Lauderdale Lodge 31, Insurance Trust Fund; International Brotherhood of Electrical Workers Local 98; New York Hotel Trades Counsel & Hotel Association of New York City, Inc., Health Benefits Fund; Edward Czarnecki; Emilie Heinle; Frank Palter; Andrew Livezey; Edward Ellenson; Jean Ellyne Dougan; Nancy Billington, On Behalf of Themselves and All Others Similarly Situated, Appellants in No. 14-4602

In re: Effexor XR Antitrust Litigation

Walgreen, Co.; The Kroger, Co.; Safeway, Inc.; Supervalu, Inc.; HEB Grocery Company LP; American Sales Company LLC, Appellants in No. 15-1184

Rite Aid Corporation; Rite Aid Hqtrs., Corporation; JCG (PJC) USA, LLC; Maxi Drug, Inc. d/b/a Brooks Pharmacy; Eckerd Corporation; CVS Caremark Corporation, Appellants in No. 15-1185
Giant Eagle, Inc., Appellant in No. 15-1186
Meijer, Inc.; Meijer Distribution, Inc., Appellants in No. 15-1187

Painters District Council No. 30 Health & Welfare Fund; Medical Mutual of Ohio, Appellants in No. 15-1323
A.F. of L.-A.G.C. Building Trades Welfare Plan; Daryl Deino; IBEW-NECA Local 505 Health & Welfare Plan; Louisiana Health Service Indemnity Company d/b/a Blue Cross/Blue Shield of Louisiana; Man-U Service Contract Trust Fund; MC-UA Local 119 Health & Welfare Plan; New Mexico United Food and Commercial Workers Union's and Employers' Health and Welfare Trust Fund; Plumbers and Pipefitters Local 572 Health and Welfare Fund; Sergeants Benevolent Association Health and Welfare Fund; Patricia Sutter (Together “End-payor Class Plaintiffs”) on Behalf of Themselves and All Others Similarly Situated, Appellants in No. 15-1342


Argued May 19, 2017

Filed: August 21, 2017
In re Lipitor Antitrust Litigation, 868 F.3d 231 (2017)
2017-2 Trade Cases P 80,101

Synopsis

**Background:** Putative class of direct purchasers of branded drugs, putative class of end payors, and several individual retailers brought actions alleging that companies holding patents related to branded drugs fraudulently procured and enforced certain of those patents, and those companies entered into unlawful, monopolistic settlement agreements with potential manufacturers of generic versions of those drugs. Those cases were referred to Judicial Panel on Multidistrict Litigation (JPML) for coordination, 856 F.Supp.2d 1355. The United States District Court for the District of New Jersey, Peter G. Sheridan, J., 2013 WL 4780496, 46 F.Supp.3d 523, 2014 WL 4988410, dismissed those claims. Plaintiffs appealed and those appeals were consolidated.

**Holdings:** The Court of Appeals, Smith, Chief Judge, held that:

direct purchasers of patentee's branded cholesterol drug sufficiently alleged that value of patent infringement claim against generic manufacturer over patentee's branded anti-hypertensive drug was large and release was unjustified, as required to state antitrust claim of unlawful reverse payment settlement agreement;

direct purchasers of patentee's branded antidepressant drug sufficiently alleged reverse payment settlement agreement;

on antitrust reverse payment settlement agreement claim, district court could not give significant weight to compliance with consent decree and Medicare Prescription Drug, Improvement, and Modernization Act (MMA);

on antitrust reverse payment settlement agreement claim, lack of objection by Federal Trade Commission (FTC) on motion to dismiss to settlement agreement did not constitute waiver of objection to or affirmauction of settlement agreement;

submission of private settlement agreement between patentee and competitor to district court in infringement litigation for entry of consent decree was not sufficient to grant agreement Noerr-Pennington immunity;

plaintiffs could not be collaterally estopped from asserting claim of Walker Process fraud, i.e., fraudulently procuring patent, based on factual resolution of issues in prior litigation, foreign or otherwise, when they were not parties to that litigation;

patent reissuance did not preclude finding of Walker Process fraud, i.e., fraudulently procuring patent; and

plaintiffs sufficiently alleged that citizen petition filed by patentee was sham petition, such that Noerr-Pennington immunity would not shield government from antitrust liability.

Reversed and remanded.

**Procedural Posture(s):** On Appeal; Motion to Dismiss; Motion to Dismiss for Failure to State a Claim.
Attorneys and Law Firms

Monica L. Kiley, Hangley Aronchick Segal Pudlin & Schiller, 4400 Deer Path Road, Suite 200, Harrisburg, PA 17110, Maureen S. Lawrence, Barry L. Refsin [ARGUED], Hangley Aronchick Segal Pudlin & Schiller, One Logan Square, 18th & Cherry Streets, 27th Floor, Philadelphia, PA 19103, Counsel for Appellants Rite Aid Corp., Rite Aid Hqtrs. Corp., Maxi Drug Inc., Eckerd Corp. and JCG (PJC) USA LLC.


James E. Cecchi [ARGUED], Lindsey H. Taylor, Carella, Byrne, Coccio, Olstein, Brody, & Afnello, P.C., 5 Becker Farm Road, Roseland, NJ 07068, Peter S. Pearlman, Cohn Lifland Pearlman Herrmann & Knopfl LLP, Park 80 West—Plaza One, 250 Pehele Avenue, Suite 401, Saddle Brook, NJ 07663, Liaison Counsel for Appellants Direct-Purchaser Class Plaintiffs Rochester Drug Co-Operative, Inc., et al.


Joseph M. Alioto, Jamie L. Miller, Theresa Driscoll Moore, Alioto Law Firm, One Sansome Street, 35th Floor, San Francisco, CA 94104, Timothy A.C. May, Gil D. Messina, Messina Law Firm, P.C., 961 Holmdel Road, Holmdel, NJ 07733, Lori A.
In re Lipitor Antitrust Litigation, 868 F.3d 231 (2017)

2017-2 Trade Cases P 80,101

Fanning, Marvin A. Miller, Matthew E. Van Tine, Miller Law LLC, 115 South LaSalle Street, Suite 2910, Chicago, IL 60603, Kevin P. Roddy, Wilentz, Goldman & Spitzer, P.A., 90 Woodbridge Center Drive, Suite 900, Woodbridge, NJ 07095, Mark S. Sandmann, Hill Carter Franco Cole & Black, P.C., 99102 Brinley Avenue, Suite 201, Louisville, KY 40243, Counsel for Appellants Painters District Council No. 30 Health & Welfare Fund and Medical Mutual of Ohio

Steve D. Shadowen, Hilliard & Shadowen LLP, 919 Congress Avenue, Suite 1325, Austin, TX 78701, Michael A. Carrier, Rutgers Law School, 217 North Fifth Street, Camden, NJ 08102, Counsel for 48 Law, Economics, and Business Professors and the American Antitrust Institute as Amici Curiae in support of Appellants

Jonathan E. Nuechterlein, Former General Counsel

David C. Shonka, Acting General Counsel

Joel Marcus, Director of Litigation

Michele Arington, Assistant General Counsel

Deborah L. Feinstein, Director

Markus H. Meier, Acting Deputy Director

Bradley S. Albert, Deputy Assistant Director

Elizabeth R. Hilder, Heather Johnson, Jamie R. Towey, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, DC 20580, Counsel for Federal Trade Commission as Amicus Curiae in support of Appellants


Jonathan D. Hacker, Edward Hassi, O'Melveny & Myers LLP, 1625 Eye Street NW, Washington, DC 20006, Counsel for Antitrust Economists as Amici Curiae in support of Appellees

Ashley Bass, Stephen Bartenstein, Andrew D. Lazerow, Covington & Burling LLP, 850 10th Street, N.W., One City Center, Washington, D.C. 20001, Counsel for Pharmaceutical Research and Manufacturers of America as Amici Curiae in support of Appellees

Roy Chamcharas, Peter J. Curtin, William A. Rakoczy, Molino Mazzochi & Siwik LLP, 6 West Hubbard Street, Suite 500, Chicago, IL 60654, Brian T. Burgess, Goodwin Procter LLP, 901 New York Avenue, NW, Suite 900 East, Washington,
OPINION

SMITH, Chief Judge.

This opinion addresses two sets of consolidated appeals concerning two pharmaceutical drugs: Lipitor and Effexor XR. In both sets of consolidated appeals, plaintiffs allege that the companies holding the patents related to Lipitor and Effexor XR fraudulently procured and enforced certain of those patents. Plaintiffs further allege that those companies holding the patents entered into unlawful, monopolistic settlement agreements with potential manufacturers of generic versions of Lipitor and Effexor XR. The same District Court Judge dismissed the complaints in the Lipitor litigation and dismissed certain allegations in the Effexor litigation. Those decisions relied on plausibility determinations that are now challenged on appeal.

We begin with a brief summary of the relevant regulatory scheme applicable to pharmaceutical drugs and then detail the factual and procedural backgrounds of these two sets of consolidated appeals. The remainder of the opinion broadly covers two issues. First, in F.T.C. v. Actavis, Inc., 570 U.S. 136, 133 S.Ct. 2223, 186 L.Ed.2d 343 (2013), the Supreme Court concluded that payments from patentees to infringers through “reverse payment settlement agreements” are subject to antitrust scrutiny. Id. at 2227. In both sets of consolidated appeals, plaintiffs allege that the companies holding the pharmaceutical patents and the generic manufacturers entered into such agreements. We are asked to decide whether those allegations are plausible. We conclude, as to both sets of appeals, that they are. Second, regarding only the Lipitor consolidated appeals, we address whether plaintiffs in those appeals pled plausible allegations of fraudulent patent procurement and enforcement, as well as other related misconduct. We again determine that those allegations are indeed plausible. Accordingly, we will reverse the District Court's dismissal of the complaints in the Lipitor litigation, reverse its dismissal of the allegations in the Effexor litigation, and remand for further proceedings.

The 1984 Drug Price Competition and Patent Term Restoration Act (the “Hatch-Waxman Act”), 98 Stat. 1585, as amended, provides a regulatory framework designed in part to (1) ensure that only rigorously tested pharmaceutical drugs are marketed to the consuming public, (2) incentivize drug manufacturers to invest in new research and development, and (3) encourage generic drug entry into the marketplace. As we have noted previously, the Hatch-Waxman Act contains four key relevant features. See In re Lipitor Antitrust Litig., 855 F.3d 126, 135 (3d Cir. 2017) (Lipitor III), as amended (Apr. 19, 2017); King Drug Co. of Florence v. Smithkline Beecham Corp., 791 F.3d 388, 394 (3d Cir. 2015), cert. denied, --- U.S. ---, 137 S.Ct. 446, 196 L.Ed.2d 328 (2016).

First, the Hatch-Waxman Act requires a drug manufacturer wishing to market a new brand-name drug to first submit a New Drug Application (“NDA”) to the Food and Drug Administration (“FDA”), see 21 U.S.C. § 355, and then undergo a long, complex, and costly testing process, see 21 U.S.C. § 355(b)(1) (requiring, among other things, “full reports of investigations” into safety and effectiveness; “a full list of the articles used as components”; and a “full description” of how the drug is manufactured, processed, and packed). If this process is successful, the FDA may grant the drug manufacturer approval to market the brand-name drug.
Second, after that approval, a generic manufacturer can obtain similar approval by submitting an Abbreviated New Drug Application (“ANDA”) that “shows that the generic drug has the same active ingredients as, and is biologically equivalent to, the brand-name drug.” Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 566 U.S. 399, 405, 132 S.Ct. 1670, 182 L.Ed.2d 678 (2012) (citing 21 U.S.C. §§ 355(j)(2)(A)(ii), (iv)). This way, a generic manufacturer does not need to undergo the same costly approval procedures to develop a drug that has already received FDA approval. Actavis, 133 S.Ct. at 2228 (“The Hatch-Waxman process, by allowing the generic to piggy-back on the pioneer's approval efforts, ’speed[es] the introduction of low-cost generic drugs to market,’’ Caraco, [566 U.S. at 405, 132 S.Ct. 1670], thereby furthering drug competition.” (first alteration in original)).

Third, foreseeing the potential for conflict between brand-name and generic drug manufacturers, the Hatch-Waxman Act “sets forth special procedures for identifying, and resolving, related patent disputes.” Id. The Hatch-Waxman Act, as well as federal regulations, requires brand-name drug manufacturers to file information about their patents with their NDA. Id. The brand-name manufacturer “is required to list any patents issued relating to the drug’s composition or methods of use.” Lipitor III, 855 F.3d at 135. That filing must include the patent number and expiration date of the patent. See Caraco, 566 U.S. at 405, 132 S.Ct. 1670 (quoting 21 U.S.C. § 355(b)(1)). Upon approval of the brand-name manufacturer's NDA, the FDA publishes the submitted patent information in its “Orange Book,” more formally known as the Approved Drug Products with Therapeutic Equivalence Evaluations. Id. at 405–06, 132 S.Ct. 1670.

Once a patent has been listed in the Orange Book, the generic manufacturer is free to file an ANDA if it can certify that its proposed generic drug will not actually violate the brand manufacturer's patents. Id. at 405, 132 S.Ct. 1670; see also id. (The FDA “cannot authorize a generic drug that would infringe a patent.”). A generic manufacturer's ANDA certification may state:

(I) that such patent information has not been filed,

*241 (II) that such patent has expired,

(III) ... the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.


If the brand-name manufacturer initiates a patent infringement suit within 45 days of the ANDA filing, the FDA must withhold approval of the generic for at least 30 months while the parties litigate the validity or infringement of the patent. Actavis, 133 S.Ct. at 2228 (citing 21 U.S.C. § 355(j)(5)(B)(iii)). If a court decides the infringement claim within this 30-month period, then the FDA will follow that determination. Id. However, if the litigation is still proceeding at the end of the 30-month period, the FDA may give its approval to the generic drug manufacturer to begin marketing a generic version of the drug. Id. The generic manufacturer then has the option to launch “at risk,” meaning that, if the ongoing court proceeding ultimately determines that the patent was valid and infringed, the generic manufacturer will be liable for the brand-name manufacturer's lost profits despite the FDA's approval. See King Drug Co., 791 F.3d at 396 n.8.

Fourth, to incentivize generic drug manufacturers to file an ANDA challenging weak patents, the Hatch-Waxman Act provides that the first generic manufacturer to file a paragraph IV certification will enjoy a 180-day exclusivity period. 21 U.S.C. § 355(j)(5)(B)(iv). This exclusivity period prevents any other generic from competing with the brand-name drug, see Actavis, 133 S.Ct. at 2229, which is an opportunity that can be “worth several hundred million dollars,” to the first-ANDA filer, id. (quoting C. Scott Hemphill, Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem, 81 N.Y.U. L. Rev. 1553, 1579
This 180-day exclusivity period belongs only to the first generic manufacturer to file an ANDA; if the first-ANDA filer forfeits its exclusivity rights, no other generic manufacturer is entitled to it. *Id.* (citing 21 U.S.C. § 355(j)(5)(D)). Importantly, the brand-name manufacturer is not barred from entering the generic market with its own generic version of the drug—a so-called “authorized generic”—during the 180-day exclusivity period. See *Lipitor III*, 855 F.3d at 135–36 (citing cases).

II

These consolidated appeals concerning *Lipitor* and *Effexor* XR involve antitrust challenges related to that pharmaceutical regulatory scheme. This panel previously detailed much of the factual background and procedural history of these appeals. See *Lipitor III*, 855 F.3d at 136–42. In relevant part, we repeat and expand on much of that earlier recitation.

A

In *In re Lipitor Antitrust Litigation*, Nos. 14-1402 et al., plaintiffs are a putative class of direct purchasers of branded *Lipitor*, a putative class of end payors, and several individual retailers asserting direct-purchaser claims.¹ We will refer to *242* these plaintiffs collectively as the “*Lipitor* plaintiffs.” Defendants are Pfizer Inc., Ranbaxy Inc., and their respective corporate affiliates; they will be referred to collectively as the “*Lipitor* defendants.” We proceed by outlining the factual background behind those consolidated appeals and then describing their procedural history.

I

*Lipitor* is a brand-name drug designed to reduce the level of *LDL cholesterol* in the bloodstream. In 1987, the U.S. Patent and Trademark Office (PTO) granted Pfizer the original patent for *Lipitor*.² That patent—designated U.S. Patent No. 4,681,893 (the ‘893 Patent)—claimed protection for atorvastatin, *Lipitor*’s active ingredient. Although initially set to expire on May 30, 2006, the ‘893 patent received an extension from the FDA, lengthening the patent’s term through March 24, 2010.

Pfizer obtained additional, follow-on patent protection for *Lipitor* in December 1993 when the PTO issued U.S. Patent No. 5,273,995 (the ‘995 Patent). That patent claimed protection for atorvastatin calcium, the specific salt form of the active atorvastatin molecule in *Lipitor*. *Lipitor* plaintiffs assert that Pfizer committed fraud in the procurement and enforcement of the ‘995 Patent. They allege that Pfizer submitted false and misleading data to the PTO to support its claim that the cholesterol-synthesis inhibiting activity of atorvastatin calcium was surprising and unexpected. Specifically, *Lipitor* plaintiffs claim that Pfizer chemists informed senior management that the ‘893 Patent already covered atorvastatin calcium; Pfizer produced a misleading chart and other data, purportedly cherry-picked, to support its claim that atorvastatin calcium was several times more effective than expected; and, in order to avoid undermining its claim of surprising results, Pfizer intentionally withheld another dataset that contradicted its claim as to the surprising effectiveness of atorvastatin calcium. The PTO originally denied the patent application for atorvastatin calcium as “anticipated” by the ‘893 Patent. In response, Pfizer submitted a declaration from one of its chemists claiming even greater, i.e., more surprising, results from testing atorvastatin calcium. The PTO again rejected the patent application for atorvastatin calcium based on its contents being covered by the ‘893 Patent. Pfizer appealed that determination to the PTO’s Patent Trial and Appeal Board (PTAB). The PTAB reversed the rejection of Pfizer’s patent application, concluding that the application was not anticipated by the ‘893 Patent. It, however, required further proceedings on Pfizer’s application, noting that “[a]n obviousness rejection ... appear[ed] to be in order.” *Lipitor* JA353 (DPP Orig. Am. Compl.)
After obtaining the '893 and '995 Patents, Pfizer launched Lipitor in 1997. Following Lipitor's 1997 launch, Pfizer obtained five additional patents, none of which, according to Lipitor plaintiffs, could delay further generic versions of the drug from coming to market. Pfizer listed all Lipitor patents in the FDA's Orange Book, with the exception of certain "process" patents, which could not be listed. Lipitor plaintiffs allege fraud only as to the procurement and enforcement of the '995 Patent.

In August 2002, Ranbaxy obtained ANDA first-filer status for a generic version of Lipitor. Sometime later in 2002, Ranbaxy notified Pfizer of its paragraph IV certifications, which asserted that Ranbaxy's sale, marketing, or use of generic Lipitor would not infringe any valid Pfizer patent. Pfizer subsequently sued Ranbaxy for patent infringement in the District of Delaware within the 45-day period prescribed by the Hatch-Waxman Act. Pfizer alleged that Ranbaxy's generic would infringe the '893 and '995 Patents. As a result of Pfizer's lawsuit, the FDA withheld approval of Ranbaxy's ANDA for 30 months pursuant to the Hatch-Waxman Act.

In May 2006, the FDA informed Pfizer that it had not yet reached a decision on the petition, citing the need for further review and analysis given the "complex issues" it raised. Lipitor JA1877. The FDA eventually denied the citizen petition in a 12-page decision issued on November 30, 2011.

In 2007, following the Federal Circuit's ruling invalidating claim 6 of the '995 Patent, Pfizer applied for a reissuance of the '995 Patent to cure the relevant error. Ranbaxy filed an objection to the reissuance with the PTO. As explained below, however, Ranbaxy withdrew its objection, and the PTO reissued the '995 Patent in April 2009, relying on Lipitor's "commercial success," without addressing whether Pfizer first obtained the patent using allegedly fraudulent submissions.

During their Lipitor patent dispute, Pfizer and Ranbaxy also litigated a patent-infringement suit regarding a separate drug, Accupril. Pfizer owned the patent on Accupril, enjoying annual sales of over $500 million. Teva Pharmaceuticals first filed an ANDA seeking approval to market a generic version of Accupril. Ranbaxy subsequently filed an ANDA for Accupril as well. Pfizer sued Teva, resulting in Teva being enjoined from selling its generic until expiration of Pfizer's Accupril patent. Meanwhile, Ranbaxy still sought to sell its version of generic Accupril but could not do so because of the 180-day exclusivity period (not yet triggered) available to Teva under the Hatch-Waxman Act. With Teva enjoined from selling its generic Accupril and Ranbaxy prevented from selling its generic because of Teva's first-filer exclusivity right, Teva and Ranbaxy entered into an agreement through which Teva became the exclusive distributor of Ranbaxy's generic. The parties agreed to split the profits.
from the sales, and Ranbaxy agreed to indemnify Teva for any liability related to the launch of its generic. Ranbaxy received approval for its generic version of Accupril in 2004.

Shortly after receiving that approval, Ranbaxy launched its generic Accupril, and Pfizer brought suit almost immediately, seeking treble damages for willful infringement. Pfizer also sought a preliminary injunction against Ranbaxy and Teva, informing the court that Ranbaxy's generic sales “decimated” its Accupril sales. The District Court in Pfizer's Accupril action granted the injunction halting Ranbaxy's generic sales, and the Federal Circuit affirmed the grant. Pfizer Inc. v. Teva Pharm. USA, Inc., 429 F.3d 1364, 1383 (Fed. Cir. 2005). Pfizer posted a $200 million bond in conjunction with the District Court's entry of the injunction. After entry of the injunction, Pfizer expressed confidence that it would succeed in obtaining a substantial monetary judgment from Ranbaxy. On June 13, 2007, in light of the disputed Accupril patent's expiration, the District Court vacated the preliminary injunction. The only issues that remained contested were Pfizer's claims for past damages and Ranbaxy's counterclaim as secured by the preliminary injunction bond.

In March 2008, Pfizer again sued Ranbaxy in the District of Delaware over Lipitor; this time, Pfizer claimed that Ranbaxy's generic Lipitor would infringe Pfizer's two Lipitor-related process patents. Lipitor plaintiffs contend that this litigation was a sham because no imminent threat of harm to Pfizer existed and because Pfizer knew Ranbaxy's generic would not violate those patents. They assert that the actual purpose of Pfizer's suit was to create “the illusion of litigation” so that the parties could enter a settlement agreement. Lipitor JA254 (DPP Sec. Am. Compl. ¶ 137).

Not long after Pfizer brought suit against Ranbaxy, on June 17, 2008, Pfizer and Ranbaxy executed a near-global litigation settlement—which Lipitor plaintiffs allege constituted an unlawful reverse payment—regarding scores of patent litigations around the world, including the Lipitor and Accupril disputes. The settlement ended the Accupril litigation with prejudice, and brought to a close not only all domestic patent infringement litigation between Pfizer and Ranbaxy pertaining to Lipitor, but also all foreign litigation between the two companies over Lipitor. By the settlement's terms, Ranbaxy agreed to delay its entry in the generic Lipitor market until November 30, 2011. In addition, Pfizer and Ranbaxy negotiated similar market entry dates for generic Lipitor in several foreign jurisdictions. Ranbaxy also paid $1 million to Pfizer in connection with the Accupril litigation, and Pfizer's $200 million injunction bond from the Accupril litigation was released. Ranbaxy further agreed to cease its protests on the '995 Patent's reissuance. (As noted above, the PTO subsequently issued the '995 Patent in March 2009.) Although not alleged in their complaints, the settlement also created a Canadian supply arrangement for generic Lipitor between the parties and resolved other litigation regarding the pharmaceutical drug Caduet.

Ranbaxy delayed generic entry until November 2011, thus extending Pfizer's exclusivity in the Lipitor market twenty months beyond the expiration of the '893 Patent and five months beyond the expiration of what Ranbaxy alleged was the fraudulently procured '995 Patent. As a result, Ranbaxy's delayed entry created a bottleneck in the entry of generic Lipitor from later ANDA filers. Due to its ANDA first-filer status, Ranbaxy was entitled to the first-filer 180-day generic market exclusivity. Under the settlement agreement, though, Ranbaxy would not trigger that period by entering the generic market until November 2011. That meant that any other would-be generic manufacturer that wanted Ranbaxy's 180-day period to begin earlier than November 2011 needed a court to hold that all of Pfizer's Lipitor patents listed in the Orange Book were invalid or not infringed. Pfizer helped to forestall this possibility, Lipitor plaintiffs assert, through a combination of lawsuits against subsequent ANDA filers. The FDA ultimately approved Ranbaxy's Lipitor ANDA on November 30, 2011, the day Ranbaxy's license to the unexpired Lipitor patents with Pfizer commenced.
Beginning in late 2011, *Lipitor* direct purchasers and end payors filed separate antitrust actions in various federal district courts. The cases were subsequently referred to the Judicial Panel on Multidistrict Litigation ("JPML") for coordination. The JPML transferred each case to the District of New Jersey, assigning the matters to District Judge Peter G. Sheridan. See *In re Lipitor Antitrust Litig.*, 856 F.Supp.2d 1355 (J.P.M.L. 2012).

Thereafter, the direct-purchaser and end-payor plaintiffs filed amended class action complaints; *Lipitor* individual-retailer plaintiffs likewise filed complaints joining the consolidated proceedings. The complaints raise two substantively identical claims: (1) a monopolization claim under Section 2 of the Sherman Act (15 U.S.C. § 2) or a state analogue against Pfizer, asserting that the company engaged in an overarching anticompetitive scheme that involved fraudulently procuring the ‘995 Patent from the PTO (Walker Process 4 fraud), falsely listing that patent in the FDA's Orange Book, enforcing the ‘995 Patent and certain process patents through sham litigation, filing a sham citizen petition with the FDA, and entering into a reverse payment settlement agreement with Ranbaxy; and (2) a claim under Section 1 of the Sherman Act (15 U.S.C. § 1) or a state analogue against both Pfizer and Ranbaxy, challenging the settlement agreement as an unlawful restraint of trade.

*Lipitor* defendants filed motions to dismiss all the complaints under Rule 12(b)(6) of the Federal Rules of Civil Procedure. During the pendency of those motions, on May 16, 2013, the District Court stayed proceedings, awaiting the Supreme Court's decision in *Actavis*. Following that decision on June 17, 2013, the District Court reopened the case and permitted the parties to file supplemental briefs on the pending motions to dismiss.

On September 5, 2013, the District Court dismissed *Lipitor* plaintiffs’ complaints  *246* to the extent they were based on anything other than the reverse payment settlement agreement. *In re Lipitor Antitrust Litig.*, 2013 WL 4780496, at *27 (D.N.J. Sept. 5, 2013) (*Lipitor I*). The Court specifically rejected the *Walker Process* fraud, false Orange Book listing, sham litigation, sham FDA citizen petition, and overall monopolistic scheme allegations related to *Lipitor* plaintiffs’ monopolization claims against Pfizer. *Id.* at *15–23. However, the Court granted leave to file amended complaints focused solely on the reverse payment settlement agreement between Pfizer and Ranbaxy. *Id.* at *25–27.

*Lipitor* plaintiffs filed amended complaints in October 2013. The direct purchasers and end payors attached their prior complaints as exhibits to their new complaints to preserve the allegations that had been dismissed for appeal. Similarly, the independent retailers stated in the first paragraph of their new complaints that they were also preserving the previously dismissed allegations. In November 2013, *Lipitor* defendants moved to dismiss the amended complaints.

On September 12, 2014, the District Court dismissed the direct purchaser's amended complaint with prejudice, rejecting the remaining allegations relating to the reverse payment settlement agreement between Pfizer and Ranbaxy. *In re Lipitor Antitrust Litig.*, 46 F.Supp.3d 523 (D.N.J. 2014) (*Lipitor II*). The complaints of the end payor and individual retailers were dismissed that same day in light of the District Court's dismissal of the direct purchasers’ complaint.

On October 10, 2014, the direct purchasers filed a motion to amend the judgment and for leave to file an amended complaint, contending that the District Court applied “a new, heightened pleading standard.” *Lipitor* JA151. That motion was denied on March 16, 2015. These timely appeals followed.

In *In re Effexor XR Antitrust Litigation*, Nos. 15-1184 et al., plaintiffs are a putative class of direct purchasers of branded *Effexor* XR, a putative class of end payors, two individual third-party payors, and several individual retailers asserting direct-purchaser claims. We will refer to these parties collectively as the “*Effexor* plaintiffs.” Defendants are Wyeth, Inc., Teva Pharmaceutical
Industries Ltd., and their respective corporate affiliates. We will likewise refer to these parties collectively as the “Effexor defendants.” As with the Lipitor appeals, we proceed by outlining the factual background behind these consolidated appeals and then describing their procedural history.

Effexor is a brand-name drug used to treat depression. In 1985, the PTO issued American Home Products, Wyeth's predecessor, a patent for Effexor's active ingredient—the compound venlafaxine hydrochloride. The patent for that compound expired on June 13, 2008.

In 1993, the FDA granted Wyeth approval to begin marketing Effexor, which Wyeth did with respect to an instant-release version of the drug (or “Effexor IR”). Four years later, the FDA granted Wyeth approval for Effexor XR, an extended-release, once-daily version of the drug. Wyeth obtained three patents for Effexor XR, all of which expired on March 20, 2017. Effexor plaintiffs contend that Wyeth obtained the Effexor XR patents through fraud on the PTO, improperly listed those patents in the FDA's Orange Book, and enforced those patents through serial sham litigation. 5

*247 On December 10, 2002, Teva obtained ANDA first-filer status for a generic version of Effexor XR. Teva's ANDA included paragraph IV certifications, asserting that Teva's sale, marketing, or use of generic Effexor would not infringe Wyeth's patents or that those patents were invalid or unenforceable. As the first company to file an ANDA with a paragraph IV certification for generic Effexor XR, Teva was entitled to the Hatch-Waxman Act's 180-day period of marketing exclusivity. Within the 45-day period prescribed by the Hatch-Waxman Act, Wyeth brought suit against Teva for patent infringement in the District of New Jersey.

In October 2005, shortly after the District Court held a Markman hearing on patent claim construction, Wyeth and Teva reached a settlement. Effexor plaintiffs allege that the District Court's ruling at the Markman hearing spurred the parties to reach a settlement agreement, as Wyeth feared that it would lose the litigation. A loss would have enabled other generic manufacturers to then enter the Effexor XR market. Under the terms of the settlement, Wyeth and Teva agreed to vacate the Markman ruling. They further agreed to a market entry date of July 1, 2010, for Teva's generic Effexor XR, nearly seven years before the expiration of Wyeth's patents. Wyeth further agreed that it would not market an authorized-generic Effexor XR during Teva's 180-day exclusivity period (the “no-AG agreement”). Effexor plaintiffs allege that Wyeth's promise to stay out of the generic Effexor XR market was worth more than $500 million, observing that Teva would gain all the sales of generic Effexor XR during Teva's generic exclusivity period. Wyeth also agreed to allow Teva to sell a generic version of Wyeth's Effexor IR before the original patent for Effexor expired in June 2008, and Wyeth promised not to launch an authorized generic to compete with Teva's instant-release generic.

In return, and in addition to the delayed entry date for generic Effexor XR, Teva agreed to pay royalties to Wyeth. With regard to its generic Effexor XR sales, Teva would pay Wyeth royalties beginning at 15% during its 180-day exclusivity period. If Wyeth chose not to introduce an authorized generic after 180 days and no other generic entered the market, Teva was required to pay Wyeth 50% royalties for the next 180 days and 65% royalties thereafter for up to 80 months. As to Teva's sales of generic Effexor IR, Teva agreed to pay Wyeth 28% royalties during the first year and 20% during the second year.

In November 2005, Wyeth and Teva filed the settlement agreement with the District Court presiding over the patent-infringement litigation. As required by a 2002 consent decree, Wyeth submitted the agreement to the Federal Trade Commission (“FTC”), which possessed the right to weigh in on and raise objections to Wyeth's settlements. The FTC offered no objection but reserved its right to take later action. The settlement was also submitted to the U.S. Department of Justice, and again to the FTC, pursuant

Following the Wyeth-Teva settlement, between April 2006 and April 2011, Wyeth brought patent-infringement suits against sixteen other companies that sought to market a generic version of Effexor XR. Each lawsuit ended in settlement and without a court order regarding the validity or enforceability of Wyeth's patents.

Beginning in May 2011, several direct purchasers of Effexor XR filed class action complaints raising various antitrust claims in the U.S. District Court for the Southern District of Mississippi. Those cases were consolidated and, on September 21, 2011, that Court transferred the action to District Judge Peter G. Sheridan in the U.S. District Court for District of New Jersey.

After the consolidation and transfer, the direct purchasers filed an amended consolidated class action complaint, a group of end payors joined the case with a consolidated class action complaint, several individual retailers filed complaints, and two individual third-party payors together filed their own complaint. As with the consolidated Lipitor appeals, their complaints each raise two substantively identical claims: (1) a monopolization claim under Section 2 of the Sherman Act (15 U.S.C. § 2) or a state analogue against Wyeth, asserting that Wyeth fraudulently induced the PTO to issue the three patents covering Effexor XR (Walker Process fraud), improperly listed those patents in the Orange Book, enforced those patents through serial sham litigation, and entered into a reverse payment settlement with Teva; and (2) a claim under Section 1 of the Sherman Act (15 U.S.C. § 1) or a state analogue against both Wyeth and Teva, alleging the reverse payment settlement agreement between them was an unlawful restraint of trade. 8

In April 2012, Effexor defendants filed motions to dismiss under Rule 12(b)(6). During the pendency of those motions, the District Court stayed proceedings in October 2012 pending the Supreme Court's decision in Actavis. Following the Actavis ruling, the District Court vacated the stay, reopened the case, and called for supplemental briefing on the pending motions to dismiss. On October 23, 2013, the direct purchasers (but no other party) filed an amended complaint. That amended complaint was met with a renewed motion to dismiss.

On October 6, 2014, the District Court granted in part and denied in part Effexor defendants’ motions to dismiss. In re Effexor XR Antitrust Litig., No. CIV.A. 11-5479 PGS, 2014 WL 4988410 (D.N.J. Oct. 6, 2014). It granted the motions to dismiss, with prejudice, as to Effexor plaintiffs’ challenges to the reverse payment settlement agreement between Wyeth and Teva under Section 1 of the Sherman Act (or its state analogue). Id. at *19–24. The District Court denied the motions as they related to the remaining allegations of Effexor plaintiffs against Wyeth. Id. at *24–26. At Effexor plaintiffs’ request, the District Court directed entry of a final judgment as to the Section 1 claims (or their state analogues) against Wyeth and Teva under Rule 54(b) of the Federal Rules of Civil Procedure. These timely appeals followed.

*249 III

The District Court had subject-matter jurisdiction with respect to the Lipitor and Effexor direct purchasers and independent retailers under 28 U.S.C. §§ 1331 and 1337(a), the Lipitor and Effexor end payors under 28 U.S.C. § 1332(d), and the Effexor independent third-party payors under 28 U.S.C. § 1332(a)(3).
We have appellate jurisdiction pursuant to 28 U.S.C. § 1291. In April 2017, this Court concluded that the Lipitor and Effexor consolidated actions did not “arise under” patent law and consequently denied Lipitor and Effexor plaintiffs’ request for a transfer to the U.S. Court of Appeals for the Federal Circuit. In re Lipitor Antitrust Litig., 855 F.3d at 145–46; see also 28 U.S.C. § 1338(a) (providing district courts with original jurisdiction over actions “arising under” federal patent law); 28 U.S.C. § 1295(a) (providing the U.S. Court of Appeals for the Federal Circuit with “exclusive jurisdiction” over “an appeal from a final decision ... in any civil action arising under” federal patent law). Appellate jurisdiction, therefore, is proper in this Court, not the Federal Circuit.

We review dismissals under Rule 12(b)(6) of the Federal Rules of Civil Procedure de novo. See Phillips v. County of Allegheny, 515 F.3d 224, 230 (3d Cir. 2008). We accept all factual allegations in the complaint as true and, examining for plausibility, “determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief.” Bronowicz v. Allegheny County, 804 F.3d 338, 344 (3d Cir. 2015) (quoting Powell v. Weiss, 757 F.3d 338, 341 (3d Cir. 2014)). As part of that review, we may consider documents “integral to or explicitly referred to in the complaint” without turning a motion to dismiss into a motion for summary judgment. Schmidt v. Skolas, 770 F.3d 241, 249 (3d Cir. 2014) (quoting In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1426 (3d Cir. 1997)).


IV

In F.T.C. v. Actavis, the Supreme Court held that reverse payments made pursuant to settlement agreements (“reverse payment settlement agreements”) may give rise to antitrust liability. 133 S.Ct. at 2227. Often arising from pharmaceutical drug litigation, reverse payment settlement agreements operate counter to conventional settlement norms. As traditionally understood, settlements involve an *250* agreement by a defendant (i.e., a patent infringer in the pharmaceutical drug context) to pay a plaintiff (i.e., the patentee) to end a lawsuit. A reverse payment settlement agreement instead “requires the patentee to pay the alleged infringer,” in return for the infringer's agreement not to produce the patented item. Id. To make that abstract explanation more concrete, the Supreme Court gave the following unadorned example: “Company A sues Company B for patent infringement. The two companies settle under terms that require (1) Company B, the claimed infringer, not to produce the patented product until the patent's term expires, and (2) Company A, the patentee, to pay B many millions of dollars.” Id.

Prior to Actavis, several courts had held that such settlement agreements “were immune from antitrust scrutiny so long as the asserted anticompetitive effects fell within the scope of the patent.” King Drug Co., 791 F.3d at 399. That categorical rule, known as the “scope of the patent” test, relied on the premise that, because a patentee possesses a lawful right to keep others
out of its market, the patentee may also enter into settlement agreements excluding potential patent challengers from entering that market. *Actavis*, 133 S.Ct. at 2230.

The Supreme Court rejected that approach. Its main concern was the use of reverse payments “to avoid the risk of patent invalidation or a finding of noninfringement.” *Id.* at 2236. It reasoned that “to refer ... simply to what the holder of a valid patent could do does not by itself answer the antitrust question. The patent ... may or may not be valid, and may or may not be infringed.” *Id.* at 2230–31. Therefore, “determin[ing] antitrust legality by measuring the settlement's anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well,” would be “incongruous.” *Id.* at 2231. Instead, “patent and antitrust policies are both relevant in determining the ‘scope of the patent monopoly’—and consequently antitrust law immunity—that is conferred by a patent.” *Id.* Hence, patent-related “reverse payment settlements ... can sometimes violate the antitrust laws[.]* *King Drug Co.*, 791 F.3d at 399 (first alteration in original) (quoting *Actavis*, 133 S.Ct. at 2227).

In determining that reverse payment settlement agreements may violate antitrust laws, the Supreme Court offered limited guidance as to when such settlements should be subject to antitrust scrutiny. It exempted “commonplace forms” of settlement from scrutiny. *Actavis*, 133 S.Ct. at 2233. One such settlement is a payment where “a party with a claim (or counterclaim) for damages receives a sum equal to or less than the value of its claim.” *Id.* at 2233 (“[W]hen Company A sues Company B for patent infringement and demands, say, $100 million in damages, it is not uncommon for B (the defendant) to pay A (the plaintiff) some amount less than the full demand as part of the settlement—$40 million, for example.”). Another such settlement is a payment by a plaintiff (i.e., the patent holder) settling a counterclaim made by a defendant (i.e., the alleged patent infringer). *Id.* (“[I]f B has a counterclaim for damages against A, the original infringement plaintiff, A might end up paying B to settle B's counterclaim.”).

In contrast to those commonplace forms of settlement, a reverse payment in pharmaceutical drug litigation occurs when “a party with no claim for damages (something that is usually true of a paragraph IV litigation defendant) walks away with money simply so it will stay away from the patentee's market.” *Id.* At base, reverse payments violate antitrust law when they *unjustifiably* seek “to prevent the risk of competition.” *Id.* at 2236. “If the basic reason [for the payment] is a desire to maintain and to share patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement.” *Id.* at 2237; *see also id.* at 2236 (“[T]he payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm.”). Stated differently, a reverse payment may demonstrate “that the patentee seeks to induce the ... challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market.” *Id.* at 2235.

Reverse payment settlement agreements give rise to those antitrust concerns—that is, the concern that a settlement seeks “to eliminate risk of patent invalidity or noninfringement,” *King Drug Co.*, 791 F.3d at 411—when the payments are both “large and unjustified.” *Actavis*, 133 S.Ct. at 2237.

Consideration of the size of the reverse payment serves at least two functions in assessing that payment's lawfulness. First, the Supreme Court observed that a large reverse payment may indicate that “the patentee likely possesses the power to bring [an unjustified anticompetitive] harm about in practice.” *Id.* at 2236; *see also King Drug Co.*, 791 F.3d at 403 (“[T]he size of a reverse payment may serve as a proxy for [the power to bring about anticompetitive harm] because a firm without such power (and the supracompetitive profits that power enables) is unlikely to buy off potential competitors.”). That is, a large reverse payment may signal that the patentee possessed “the power to charge prices higher than the competitive level” and may be using that power to keep others from entering its market. *Actavis*, 133 S.Ct. at 2236. Second, a large reverse payment may signify that the payment seeks to avoid invalidation of the disputed underlying patent. *Id.* at 2236. A patent holder may be concerned about the validity of its patent, and so the size of the payment may very well correspond with the magnitude of that concern. *See id.* at 2236–37 (“In a word, the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness....”).
The justifications underlying the reverse payment also play a role in determining whether that payment will give rise to antitrust liability. The Supreme Court observed, on the one hand, that “[w]here a reverse payment reflects traditional settlement considerations, ... there is not the same concern [as with other reverse payments] that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement.” *Id.* at 2236. Those legitimate justifications for a reverse payment include those where the payment is “a rough approximation of the litigation expenses saved through settlement” or a reflection of “compensation for other services the generic has promised to perform.” *Id.* The Supreme Court did not exclude other possible legitimate explanations from also justifying reverse payment settlement agreements. *Id.* On the other hand, in the absence of a legitimate justification or explanation, the reverse payment “likely seeks to prevent the risk of competition” in that its “objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market.” *Id.*

“In sum, a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects....” *Id.* at 2237. Therefore, to survive a motion to dismiss when raising an antitrust violation under *Actavis*, “plaintiffs *252 must allege facts sufficient to support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment under *Actavis.*” *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 552 (1st Cir. 2016). If plaintiffs do so, they may proceed to prove their allegations under the traditional antitrust rule-of-reason analysis. See *Actavis*, 133 S.Ct. at 2237.

Since *Actavis*, this Court has had occasion to assess the plausibility of allegations raising an unlawful reverse payment settlement agreement. In *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, we reached two conclusions relevant here regarding the parameters of antitrust claims brought under *Actavis*.

First, we held that a reverse payment underlying an *Actavis* antitrust claim need not be in cash form. 791 F.3d at 403–09. The allegedly unlawful reverse payment took the form of a “no-AG agreement,” a brand-name manufacturer's promise not to produce an authorized generic to compete with the generic manufacturer. *Id.* at 397. There, the direct purchasers of a drug (Lamictal) sued both GlaxoSmithKline (GSK), the brand-name manufacturer, and Teva, the generic manufacturer, for violating Sections 1 and 2 of the Sherman Act. *Id.* at 393. The direct purchasers alleged that GSK and Teva entered into an agreement settling GSK's patent infringement suit, which contained a no-AG agreement. *Id.* at 397. The no-AG agreement provided that GSK would not produce an authorized generic version of Lamictal for 180 days after Teva started marketing its generic. *Id.* The *King Drug Co.* plaintiffs argued that the no-AG agreement could constitute an anticompetitive reverse payment under *Actavis* because it worked to maintain supracompetitive prices in the Lamictal market. *Id.* at 397, 410. We agreed, holding “that a no-AG agreement, when it represents an unexplained large transfer of value from the patent holder to the alleged infringer, may be subject to antitrust scrutiny under the rule of reason.” *Id.* at 403.

We also determined that the plaintiffs in *King Drug Co.* plausibly alleged that the no-AG agreement was a large and unjustified reverse payment sufficient to support antitrust scrutiny under *Actavis*. *Id.* at 409–10. The allegations giving rise to antitrust review were that (1) “GSK agreed not to launch a competing authorized generic during Teva's 180-day exclusivity period”; (2) “GSK had an incentive to launch its own authorized generic versions of tablets”; (3) GSK's promise could be “worth many millions of dollars of additional revenue”, (4) “Teva had a history of launching ‘at risk’ ”; and (4) the relevant “patent was likely to be invalidated.” *Id.* Given those allegations, we reasoned that the complaint plausibly alleged that the reverse payment was large and unjustified and attempted to prevent the risk of competition through the sharing of monopoly profits: “Because marketing an authorized generic was allegedly in GSK's economic interest, its agreement not to launch an authorized generic was an inducement—valuable to both it and Teva—to ensure a longer period of supracompetitive monopoly profits based on a patent at risk of being found invalid or not infringed.” *Id.* at 410.

In reaching that conclusion, we specifically rejected GSK and Teva's argument that the reverse payment was justified because Teva was given permission in the settlement agreement to enter a different pharmaceutical drug market early. We observed
that, according to the complaint, the early-entry provision allowed access to a market worth “only $50 million annually,” which “was orders of magnitude smaller than the alleged $2 billion ... market the agreement is said to have protected.” *Id.* The early-entry provision thus failed to justify the large reverse payment from the patentee GSK to the alleged infringer Teva. *Id.* Because the complaint in *King Drug Co.* plausibly alleged a large and unjustified reverse payment, the plaintiffs there could proceed to prove their claim through “the traditional rule-of-reason approach.” *Id.* at 411; see also *id.* at 412 (providing a three-step rule-of-reason approach by which antitrust plaintiffs could demonstrate that the reverse payment settlement agreement imposed an unreasonable restraint on competition).

Applying *Actavis* and *King Drug Co.*, we next address whether the complaints in the *Lipitor* and *Effexor* consolidated appeals plausibly allege an actionable reverse payment settlement agreement.

We conclude that *Lipitor* plaintiffs have plausibly pled an unlawful reverse payment settlement agreement. Their allegations sufficiently allege that Pfizer agreed to release the *Accupril* claims against Ranbaxy, which were likely to succeed and worth hundreds of millions of dollars, in exchange for Ranbaxy's delay in the release of its generic version of *Lipitor*.

As part of their effort to allege an unlawful reverse payment settlement agreement, *Lipitor* plaintiffs plead, among other factual averments, the following: Ranbaxy launched a generic version of Pfizer's brand drug *Accupril* “at risk,” *Lipitor* JA257 (DPP Sec. Am. Compl. ¶ 149); Pfizer had annual *Accupril* sales over $500 million prior to Ranbaxy's launch, *id.*; Pfizer brought suit and sought to enjoin Ranbaxy's generic sales, *Lipitor* JA260 (DPP Sec. Am. Compl. ¶ 160); the District Court granted the injunction halting Ranbaxy's sales of generic Accupril, which the Federal Circuit affirmed, *Pfizer Inc. v. Teva Pharm. USA, Inc.*, 429 F.3d 1364, 1383 (Fed. Cir. 2005); Pfizer posted “a $200 million bond in conjunction with” the injunction and informed the Court that Ranbaxy's generic sales “decimated” its *Accupril* sales, *Lipitor* JA260 (DPP Sec. Am. Compl. ¶ 160); more specifically, Pfizer's *Accupril* sales dropped from $525 million in 2004 to $71 million in 2005 following Ranbaxy's launch of the generic version of *Accupril*, *Lipitor* JA260 (DPP Sec. Am. Compl. ¶ 160); Pfizer's suit was likely to be successful, *Lipitor* JA262–63 (DPP Sec. Am. Compl. ¶¶ 167–70); and Pfizer itself made statements about Ranbaxy's exposure, estimating that Ranbaxy faced “very, very substantial damages in the way of lost profits,” *Lipitor* JA263 (DPP Sec. Am. Compl. ¶ 170).

Despite the large expected damages arising from the *Accupril* suit and the high likelihood of its success, Pfizer subsequently released its *Accupril* claims as part of a settlement agreement with Ranbaxy. Ranbaxy paid $1 million to Pfizer in connection with the *Accupril* litigation and also agreed to the release of Pfizer's $200 million injunction bond. *Lipitor* plaintiffs allege that the release of the *Accupril* claims was unjustified, as the release of potential liability in *Accupril* “far exceeded” any of Pfizer's saved litigation costs or any services provided by Ranbaxy. *Lipitor* JA265 (DPP Sec. Am. Compl. ¶¶ 180, 285). Pfizer's alleged agreement to release the *Accupril* claims, therefore, “was an inducement—valuable to both it and [Ranbaxy]—to ensure a longer period of supracompetitive monopoly profits based on [the *Lipitor* patent, which was] at risk of being found invalid or not infringed.” *King Drug Co.*, 791 F.3d at 410. Those allegations sufficiently plead that the value of the *Accupril* claims was large and their release was unjustified. *See Actavis*, 133 S.Ct. at 2236 (“[T]he payment (if otherwise unexplained) likely seeks to prevent the risk of competition.... [T]hat consequence constitutes the relevant anticompetitive harm.”).

Notwithstanding *Lipitor* plaintiffs’ allegations, the District Court determined their complaints were wanting. It required that they plead a “reliable” monetary estimate of the dropped *Accupril* claims so that they “may be analyzed against the *Actavis* factors” to determine whether the value of those claims “is ‘large’ once the subtraction of legal fees and other services provided by generics occurs.” *See Lipitor II*, 46 F.Supp.3d at 543. That “reliable” monetary estimate, according to the Court, necessitated a series of calculations: a valuation of Pfizer's damages in the *Accupril* litigation incorporating both Pfizer's probability of success
in that action and an estimation of Pfizer's lost profits; a discounting of Pfizer's damages based on its saved litigation costs and Pfizer's various litigation risks; and an accounting of various other provisions within the settlement agreement, including the arrangement to allow Ranbaxy into several foreign markets, the parties’ agreement resolving other pharmaceutical litigation, and a supply arrangement between Ranbaxy and Pfizer related to generic Lipitor sales in Canada. Without these various calculations, the District Court determined that Lipitor plaintiffs had failed to allege a plausible large and unjustified reverse payment under Actavis.

Lipitor defendants largely echo the reasoning of the District Court. Their contentions broadly fall into two categories. First, and similar to the District Court, Lipitor defendants maintain that, even if the settlement could be characterized as an unlawful reverse payment, Lipitor plaintiffs insufficiently alleged the payment was “large” and “unjustified.” Second, they argue that the settlement here was no more than the sort of commonplace settlement that the Supreme Court excluded from antitrust scrutiny. Neither of these arguments withstands careful review.

Both the District Court and Lipitor defendants offer a heightened pleading standard contrary to Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007), and Ashcroft v. Iqbal, 556 U.S. 662, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009). Twombly and Iqbal require only plausibility, a standard “not akin to a ‘probability requirement.’ ” Iqbal, 556 U.S. at 678, 129 S.Ct. 1937. While Twombly and Iqbal require that “[f]actual allegations ... be enough to raise a right to relief above the speculative level,” Twombly, 550 U.S. at 555, 127 S.Ct. 1955, “those cases make it clear that a claimant does not have to ‘set out in detail the facts upon which he bases his claim.’ ” Covington v. Int'l Ass'n of Approved Basketball Officials, 710 F.3d 114, 118 (3d Cir. 2013) (quoting Twombly, 550 U.S. at 555 n.3, 127 S.Ct. 1955); see also Connelly v. Lane Const. Corp., 809 F.3d 780, 786 (3d Cir. 2016) (“[D]etailed pleading is not generally required.”).

Applying that pleading standard, neither the Supreme Court in Actavis nor this Court in King Drug Co. demanded the level of detail the District Court and Lipitor defendants would require. For its part, the Supreme Court in Actavis was deliberately opaque about the parameters of reverse payment antitrust claims. We take note, though, of the allegations in Actavis regarding the size of the reverse payment. There, the FTC alleged simply that a patentee “agreed to pay [a generic manufacturer] $10 million per year for six years,” “agreed to pay [another generic manufacturer] $2 million per year for six years,” and “projected that it would pay [a third generic manufacturer] about $19 million during the first year of its agreement, rising to over $30 million annually by the end of the deal.” Second Amended Complaint for Injunctive and Other Equitable Relief ¶¶ 66, 77, In re Androgel Antitrust Litig., No. 1:09-CV-00955-TWT (N.D. Ga. May 28, 2009), ECF No. 134. The FTC's complaint did not preemptively negate justifications for the reverse payments. It simply alleged that the payments were meant to, and did, induce delay of likely successful patent challenges through the sharing of monopoly profits. Id. ¶¶ 67, 86; see also Actavis, 133 S.Ct. at 2229. The Supreme Court did not require the advanced valuations asked for by Lipitor defendants and required by the District Court.

Perhaps equally striking in their simplicity are the allegations we concluded were sufficient to state an Actavis claim in King Drug Co. There, we elucidated no special valuation requirement in examining the alleged reverse payment. Rather, the allegations were simply that a no-AG agreement provided the alleged infringer with “many millions of dollars of additional revenue” and that the patentee otherwise had “an incentive to launch its own authorized generic.” King Drug Co., 791 F.3d at 409–10. The no-AG agreement resultantly induced the alleged infringer to agree to delay the launch of its generic drug that would compete with the patentee's drug, which purportedly relied on an invalid patent. Id. Nothing more was necessary to plausibly plead a claim under Actavis.

The allegations here, as outlined above, easily match, if not exceed, the level of specificity and detail of those in Actavis and King Drug Co. The alleged reverse payment here was “large” enough to permit a plausible inference that Pfizer possessed the power to bring about an unjustified anticompetitive harm through its patents and had serious doubts about the ability of those patents to
lawfully prevent competition. 10 Actavis, 133 S.Ct. at 2236. Pfizer purportedly suffered hundreds of millions of dollars in lost sales following Ranbaxy’s entry into the Accupril market. Lipitor JA260 (DPP Sec. Am. Compl. ¶ 160). Upon suing Ranbaxy, Pfizer sought treble damages, Lipitor JA263–64 (DPP Sec. Am. Compl. ¶¶ 159, 172–74), and posted a $200 million bond to secure an injunction, “demonstrating that Pfizer placed great value on preserving its Accupril franchise,” Lipitor JA260 (DPP Sec. Am. Compl. ¶ 160). That claim had some likelihood of success given the entry of the injunction, which was affirmed on appeal. See Pfizer, 429 F.3d at 1383. Pfizer itself told shareholders that it was likely to succeed on the merits of the case. Lipitor JA263 (DPP Sec. Am. Compl. ¶ 170). Despite those losses and the likely success of that litigation against Ranbaxy, Pfizer released its claim worth “hundreds of millions of dollars.” JA264 (DPP Sec. Am. Compl. ¶ 175). Those allegations sufficiently allege a large reverse payment; more detailed, advanced calculations related to those allegations may come later. 11

The alleged reverse payment here was also “unjustified.” As noted earlier, avoiding litigation costs, providing payment for services, or other consideration may justify a large reverse payment. See Actavis, 133 S.Ct. at 2236. To plausibly allege an unjustified reverse payment, an antitrust plaintiff need only allege the absence of a “convincing justification” for the payment. Id. at 2236–37 (observing that, if such considerations are present, “there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement”); see also King Drug Co., 791 F.3d at 412 (observing that, in the first step of the rule-of-reason analysis, a plaintiff must “prove a payment for delay, or, in other words, payment to prevent the risk of competition,” and then citing Actavis for the proposition that the “likelihood of a reverse payment bringing about anticompetitive effects” depends on its size, anticipated litigation costs, its independence from other services rendered, and other justifications).

Lipitor plaintiffs’ complaints state that the value of the released Accupril claims “far exceed[s] any litigation costs (in any or all cases) Pfizer avoided by settling.” Lipitor JA265 (DPP Sec. Am. Compl. ¶ 180). While Lipitor defendants speculate as to the actual saved litigation costs, all that need be alleged, at this juncture, is that those costs fail to explain the hundreds of millions of dollars liability released by Pfizer. Lipitor plaintiffs have alleged just that, and the finely calibrated litigation cost estimates requested by Lipitor defendants and the District Court are unnecessary at this stage in the litigation.

Lipitor defendants also argue that the alleged reverse payment was pled out of context, as the Accupril litigation settlement was part of a larger, global settlement agreement between Pfizer and Ranbaxy. Specifically, they point out that the complaints do not address other aspects of the settlement agreement, namely a supply arrangement in Canada and resolution of litigation over another pharmaceutical drug, Caduet. 12 They are correct that the complaints make little mention of those aspects of the settlement. We disagree that the absence of those allegations is fatal.

Lipitor defendants have the burden of justifying the rather large reverse payment here, and they offer no reason why those other elements of the settlement agreement do so. Actavis does not require antitrust plaintiffs to come up with possible explanations for the reverse payment and then rebut those explanations in response to a motion to dismiss. The Supreme Court clearly placed the onus of explaining or justifying a large reverse payment on antitrust defendants. In examining allegations of a reverse payment at the pleading stage, the Supreme Court acknowledged that, even if there is an explanation for a reverse payment, “that possibility d[id] not justify dismissing the [antitrust plaintiff’s] complaint. An antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason.” Id. at 2236 (emphasis added). The Supreme Court emphasized this point later, in Actavis, stating that the “one who makes [the reverse] payment” needs “to explain and to justify it.” Id. at 2237. We noted as much in King Drug Co., where we observed that the antitrust defendant has the burden “to show ‘that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason.’ ” 791 F.3d at 412 (quoting Actavis, 133 S.Ct. at 2235–36); see also In re Niaspan Antitrust Litig., 42 F.Supp.3d 735, 753 (E.D. Pa. 2014) (“While it is possible that defendants will be able to supply evidence to rebut plaintiffs’ allegations regarding the true value of the services ..., Twombly does not require an antitrust plaintiff to plead facts that, if true, definitively rule out
In re Lipitor Antitrust Litigation, 868 F.3d 231 (2017)
2017-2 Trade Cases P 80,101

all possible innocent explanations.”). Here, Lipitor plaintiffs sufficiently alleged the absence of a convincing justification for the reverse payment and were not required to plead more than that.

Our conclusion here is consistent with the persuasive decisions of other courts facing similar challenges to pleadings raising an antitrust claim under Actavis. For example, in In re Loestrin 24 Fe Antitrust Litigation, a patentee entered into a no-AG agreement with a generic manufacturer, providing the generic manufacturer with favorable promotion deals in exchange for the generic manufacturer's delaying entry into the patentee's market. 814 F.3d at 541. Addressing the specificity necessary for allegations raising an antitrust claim under Actavis, the First Circuit held: “Consistent with Twombly, which declined to ‘require heightened fact pleading of specifics’ [in an antitrust suit], we do not require that the plaintiffs provide precise figures and calculations at the pleading stage.” Id. at 552 (citations omitted). To conclude otherwise “would impose a nearly insurmountable bar for plaintiffs at the pleading stage” because “very precise and particularized estimates of fair value and anticipated litigation costs may require evidence in the exclusive possession of the defendants, as well as expert analysis.” Id. (quoting In re Aggrenox Antitrust Litig., 94 F.Supp.3d 224, 243 (D. Conn. 2015)). The First Circuit concluded that plaintiffs must simply “allege facts sufficient to support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment under Actavis.” Id. (citation omitted).

Finally, Lipitor defendants contend that the reverse payment here was no more than a commonplace settlement. That argument is unpersuasive. As they would have it, the exchange of Ranbaxy's $1 million payment to Pfizer for Pfizer's release of the claim in the Accupril action (allegedly worth hundreds of millions of dollars) constituted a lawful compromise warranting no antitrust scrutiny. Lipitor defendants rely on the Supreme Court's warning in Actavis that its opinion “should not be read to subject to antitrust scrutiny ‘commonplace forms’ of settlement, such as tender by an infringer of less than the patentee's full demand.” King Drug Co., 791 F.3d at 402 (quoting Actavis, 133 S.Ct. at 2233). We doubt that the $1 million payment from Ranbaxy to Pfizer, in exchange for an agreement not to enter a patentee's market, insulates review of the settlement agreement here. If parties could shield their settlements from antitrust review by simply including a token payment by the purportedly infringing generic manufacturer, then otherwise unlawful reverse payment settlement agreements attempting to eliminate the risk of competition would escape review. That result simply cannot be squared with Actavis.

More importantly, Lipitor defendants’ argument that the settlement agreement here is a commonplace one does not withstand Lipitor plaintiffs’ plausible allegations and the reasonable inferences arising therefrom. As referenced above, the Lipitor complaints plausibly allege that, while Ranbaxy gave Pfizer $1 million, Pfizer's release of the Accupril claims was given “[i]n exchange for Ranbaxy's agreement to delay its launch of (and not to authorize another ANDA filer to launch) generic Lipitor until November 30, 2011,” not in exchange for the $1 million. Lipitor JA257 (DPP Sec. Am. Compl. ¶ 48). Bolstering that allegation is Lipitor plaintiffs’ contention that the Accupril claims were worth hundreds of millions of dollars to Pfizer and were likely to be successful. The $1 million payment is paltry by comparison. Given those allegations, Pfizer's release of the Accupril claims plausibly sought to induce Ranbaxy to delay its entry into the Lipitor market and was not in exchange for Ranbaxy's $1 million. Cf. Actavis, 133 S.Ct. at 2229 (“The companies described these payments as compensation for other services the generics promised to perform, but the FTC contends the other services had little value. According to the FTC the true point of the payments was to compensate the generics for agreeing not to compete ... until 2015.”). Pfizer and Ranbaxy's settlement agreement is therefore properly subject to antitrust scrutiny.

Applying the same analysis to the Effexor consolidated appeals as we applied above compels the same result. We conclude that Effexor plaintiffs plausibly allege a reverse payment settlement agreement under Actavis.
As with the Lipitor appeals, we begin with a brief recitation of key allegations. Effexor plaintiffs allege that, after Teva filed an ANDA seeking approval of its generic version of Effexor XR, Wyeth brought suit. Following a ruling adverse to Wyeth, the parties entered into a settlement agreement. As part of that agreement, Wyeth agreed it would not compete with Teva by producing an authorized generic of either Effexor XR or Effexor IR. That no-AG agreement allegedly “constituted a substantial, net payment by Wyeth to Teva in exchange for Teva agreeing to delay generic entry much later than it otherwise would have.” Effexor JA210 (DPP Sec. Am. Compl. ¶ 281).13 More specifically, Effexor plaintiffs claim that the promise “amount[ed] to over $500 million in value” given to Teva. Id. In return for that value, Teva agreed it would delay entry into the Effexor XR market by not selling its generic version of the drug until a specified date. According to Effexor plaintiffs, Teva's promise to delay entry of its generic Effexor XR “meant that U.S. drug purchasers paid billions of dollars more for extended-release venlafaxine than they otherwise would have absent the Wyeth-Teva agreement.” Effexor JA210 *259 (DPP Sec. Am. Compl. ¶ 279). Wyeth was thus able to profit substantially from Teva's promise to delay the entry of its generic into the Effexor XR market.

The District Court concluded that those allegations insufficiently pled a large and unjustified reverse payment. It determined that Effexor plaintiffs had not alleged that the reverse payment here was “large” because their “analysis ... [did] not have a reliable foundation.”14 In re Effexor XR Antitrust Litig., 2014 WL 4988410, at *23. Lacking that reliable foundation, their allegation of a large reverse payment was, in the District Court's view, implausible. Effexor defendants make this same argument on appeal. Effexor plaintiffs purportedly failed to allege the specific benefit accruing to Teva from the settlement agreement and instead relied on “various general assumptions about generic penetration rates and pricing impacts.” Wyeth Br. 46. Effexor defendants also argue the reverse payment was not large because the complaints here failed to sufficiently allege that Wyeth would have released an authorized generic for its settlement agreement with Teva. Finally, they argue that the reverse payment may be explained by another provision in the settlement agreement that requires Teva to pay Wyeth certain royalties for its Effexor sales. Those arguments, though, ask too much of Effexor plaintiffs at this stage of the litigation. Their allegations, as outlined above, sufficiently allege a reverse payment settlement agreement as laid out by the Supreme Court in Actavis.

Similar to the Lipitor appeals, the District Court and Effexor defendants request a level of pleading exceeding what Twombly and Iqbal require. See Iqbal, 556 U.S. at 678, 129 S.Ct. 1937; Twombly, 550 U.S. at 555, 127 S.Ct. 1955. Moreover, neither the Supreme Court in Actavis nor this Court in King Drug Co. required such detailed allegations at the pleading stage. The complaint in Actavis simply alleged that the patentee paid various sums of money to generic manufacturers to induce them to delay their entry into the patentee's pharmaceutical drug market. See Actavis, 133 S.Ct. at 2229. Likewise, in King Drug Co., this Court viewed as sufficient allegations that the patentee agreed not to market an authorized generic to compete with a generic manufacturer, with that promise worth “many millions of dollars of additional revenue,” thereby inducing the generic manufacturer to delay its entry into the patentee's market. King Drug Co., 791 F.3d at 410. The facts alleged by Effexor plaintiffs similarly, and thus plausibly, allege that Wyeth leveraged its extremely valuable promise not to enter the generic market with an authorized generic in exchange for Teva's promise to delay entry into the Effexor XR market. See King Drug Co., 791 F.3d at 409 (allegations that patentee “sought to induce [the generic manufacturer] to delay its entry into the [relevant pharmaceutical drug] market by way of an unjustified no-AG agreement” sufficiently stated a claim “under Twombly and Iqbal for violation of the Sherman *260 Act”); see also Loestrin, 814 F.3d at 552 (“[P]laintiffs must allege facts sufficient to support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment under Actavis.”).

First, the alleged reverse payment, here in the form of Wyeth's no-AG agreement, is plausibly large. The no-AG agreement used by Wyeth to induce Teva to stay out of the Effexor XR market was alleged to have been worth more than $500 million. Effexor plaintiffs note that the Effexor XR market is a multi-billion dollar market annually, and, with the no-AG agreement, “Teva would (a) garner all of the sales of generic Effexor XR during Teva's generic exclusivity period ... and (b) charge higher prices than it would have been able to charge if it was competing with Wyeth's authorized generic.” Effexor JA211 (DPP Sec. Am. Compl. ¶ 282). Effexor plaintiffs further cite several aggregate studies noting that, historically, authorized-generic versions of a drug bring down the price of the generic drug, with one study observing that the entry “of an authorized generic causes
Effexor defendants nevertheless respond that the payment in this case cannot plausibly constitute a large reverse payment because of Effexor plaintiffs’ “failure to plead that Wyeth plausibly would have introduced an AG absent the settlement.” Wyeth Br. 36. They argue that Wyeth has rarely introduced authorized generics in response to the entry of a generic into one of their branded drugs’ markets and that, according to an FTC study, Wyeth “lack[ed] an ‘AG Strategy.’ ” *Id.* at 34; see also Effexor JA1756–77 (a FTC study indicating that Wyeth released few authorized generics). Effexor defendants thus contend that Wyeth's no-AG agreement really gave Teva little value in return for the latter's delay because Wyeth was not going to produce an authorized generic anyway. Wyeth's behavior in the absence of the agreement is certainly disputed. Yet Effexor plaintiffs state facts plausibly alleging that Wyeth would have produced an authorized generic but for the no-AG agreement. They claim that “[t]ypically, once a drug goes generic, the branded manufacturer sells both the branded version and an ‘authorized’ generic version, usually selling the same exact pills in different bottles.” Effexor JA206 (DPP Sec. Am. Compl. ¶ 265). More specifically, they allege, “Wyeth could have launched (and, but for its anticompetitive deal, would have launched) its own authorized generic at or about the time that Teva launched its generic.” Effexor JA208–09 (DPP Sec. Am. Compl. ¶ 276). Moreover, while the FTC study cited by Effexor defendants notes that Wyeth introduced only one authorized generic between 2001 and 2008, the study does not specifically analyze Wyeth or suggest that Wyeth would not have introduced an authorized generic with respect to Effexor. And even Effexor defendants admit that Wyeth had introduced at least one authorized generic in the past. Wyeth Br. 36 & n.11. So, the FTC study is, at best, evidence that Wyeth may not have introduced an authorized generic here, but it does not make Effexor plaintiffs’ allegations implausible at the pleading stage where we again consider plausibility, not probability. Effexor defendants have not—by merely arguing that Wyeth does not typically introduce authorized generics into the market—rendered the allegations about the value of the no-AG agreement implausible.

Second, the alleged reverse payment made through Wyeth's no-AG agreement is plausibly unjustified. As alleged, the no-AG agreement “cannot be excused as a litigation cost avoidance effort by Wyeth.” Effexor JA212 (DPP Sec. Am. Compl. ¶ 285). Effexor plaintiffs’ complaint states that Wyeth's litigation costs with Teva would have totaled only between $5 million to $10 million, and those costs “would have been the tiniest of a fraction the size of the payment likely over $500 million effectuated by Wyeth to Teva.” *Id.* They allege further that the no-AG agreement is not “justified on any procompetitive basis,” asserting that no exchange of goods or services or any explanation justifies the delay of Teva's entry into the Effexor XR market other than the settlement agreement. Effexor JA212 (DPP Sec. Am. Compl. ¶¶ 286–87).

Effexor defendants respond that the settlement agreement is not subject to antitrust scrutiny because the agreement is “traditional” in that it is justified by Teva's payment of royalties to Wyeth. Effexor defendants further argue that the complaints do not include allegations about the settlement agreement's royalty licensing agreements when alleging Teva's receipt of the $500 million no-AG agreement. Wyeth Br. 49–51. These arguments do not undermine the plausibility of the complaints’ allegations that the no-AG agreement was entered into in exchange for the delayed entry of Teva into the Effexor markets. As the agreement indicates, Teva paid Wyeth only 15% of its profits for the first 6 months. The rate then jumped to 50% and then 65% after that. Thus, while the royalty licensing provisions may show that the no-AG agreement is ultimately worth less than it otherwise would have been, Effexor plaintiffs’ allegations are still plausible. See *King Drug Co.*, 791 F.3d at 410 (concluding that a settlement agreement provision allowing access to a market worth “only $50 million annually” failed to make plaintiffs’ allegations implausible because the value of that provision “was orders of magnitude smaller than the alleged $2 billion ... market the agreement [was] said to have protected”). Although the royalty licensing provisions will perhaps be a valid defense, they require factual assessments, economic calculations, and expert analysis that are inappropriate at the pleading stage. Effexor plaintiffs, *again*, need not allege any more at this stage of the litigation.
In sum, *Effexor* plaintiffs need not have valued the no-AG agreement beyond their allegations summarized above. See *Loestrin*, 814 F.3d at 552; *King Drug Co.*, 791 F.3d at 409–10. Nor were they required to counter potential defenses at the pleading stage. *Actavis*, 133 S.Ct. at 2236. Their complaints contain sufficient factual detail about the settlement agreement between Teva and Wyeth to plausibly suggest that Wyeth paid Teva to stay out of the market by way of its no-AG agreement; that is the very anticompetitive harm that the Supreme Court identified in *Actavis*. *Id.* (“[T]he payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm.”); see also *id.* (identifying the anticompetitive harm as “the payment's objective ... to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market”). While *Effexor* defendants may ultimately be able to show that the payments were not in fact large or unjustified, that determination should not have been made at the pleading stage given the plausible allegations here.

*Effexor* defendants also attempt to support the District Court's decision to grant their motion to dismiss on two other, independent grounds. First, they argue that the FTC's failure to object to their settlement agreement prevents *Effexor* plaintiffs from now bringing an antitrust challenge to that agreement. Second, they contend that the *Noerr-Pennington* doctrine immunizes their settlement agreement from antitrust scrutiny. Neither argument prevails.

1

*Effexor* defendants argue that “Wyeth [could] not possibly have sought to illicitly ‘pay’ Teva [because] it submitted the settlement in full to the District Court for antitrust review and the District Court specifically invited the FTC to voice concerns, and then the FTC raised no objections.” Wyeth Br. 55. Essentially, *Effexor* defendants contend that (1) by submitting the agreement to the FTC in 2005, Wyeth lacked any anticompetitive intent; (2) while not dispositive, the lack of anticompetitive intent is “useful in determining whether a settlement should be viewed as” an unlawful reverse payment settlement agreement or a traditional settlement agreement, *id.*; and (3) the FTC's failure to object effectively sanctioned the settlement agreement. The District Court agreed, explaining that “any alleged antitrust intent held by the parties is negated by the fact that the settlement and license agreements were forwarded to the FTC.” In re *Effexor XR Antitrust Litig.*, 2014 WL 4988410, at *24. And, although the FTC reserved its rights in response to Wyeth's submission, the District Court found that reservation of rights “unconvincing,” concluding that “when a governmental agency receives an invitation from the Court to intercede in a matter by way of an Order, that agency should respond appropriately, not simply reserve that right for the future.” *Id.* We disagree—the submission of the settlement agreement to the FTC here does not protect the settlement agreement from antitrust scrutiny under *Actavis*.

First, the District Court failed to draw all reasonable inferences in *Effexor* plaintiffs’ favor. Wyeth's compliance with the 2002 consent decree fails to demonstrate that Wyeth somehow lacked anticompetitive intent. It was complying with a legal obligation, not acting altruistically. Similarly, in addition to Wyeth's submission to the FTC from the 2002 consent decree, Teva and Wyeth had to submit the settlement to the FTC for review under the MMA. § 1112, 117 Stat. at 2461–63. Therefore, taking reasonable inferences in *Effexor* plaintiffs’ favor, compliance with the 2002 consent decree and the MMA through the submission of the settlement agreement simply indicates mere compliance with the law, not the lack of antitrust intent.

Even if the submission of the settlement agreement to the FTC could create an inference that Wyeth somehow lacked antitrust intent, that intent is not an element of an antitrust claim, and benign intent does not shield anticompetitive conduct from liability. A party's “good intention” cannot “save an otherwise objectionable [restraint of trade].” *Chicago Bd. of Trade v. United States*, 246 U.S. 231, 238, 38 S.Ct. 242, 62 L.Ed. 683 (1918). The antitrust inquiry “is confined to a consideration of impact on competitive conditions,” *Nat'l Soc'y of Prof'l Eng'rs v. United States*, 435 U.S. 679, 690, 98 S.Ct. 1355, 55 L.Ed.2d 637 (1978), and “good motives will not validate an otherwise anticompetitive practice,” *NCAA v. Bd. of Regents of the Univ. of Okla.*, 468
In re Lipitor Antitrust Litigation, 868 F.3d 231 (2017)

Accordingly, the District Court erred in giving significant weight to the parties’ compliance with the 2002 consent decree and MMA.

Finally, it is erroneous to conclude that the FTC’s inaction equates to a determination that the settlement agreement does not run afoul of the Sherman Act, especially given the circumstances here. Generally, an agency decision on whether to act in a particular matter or at a particular time “often involves a complicated balancing” of factors: the agency must “assess whether a violation has occurred,” “whether agency resources are best spent” on that matter, whether that particular action “best fits the agency’s overall policies, and indeed whether the agency has enough resources to undertake the action at all.” Heckler v. Chaney, 470 U.S. 821, 831, 105 S.Ct. 1649, 84 L.Ed.2d 714 (1985). Reading agency tea leaves is therefore a vexing prospect, made all the more difficult given the limited scope of review on a motion to dismiss.

The circumstances here bear out that observation. Following the submission of the settlement agreement in 2005, the FTC offered no objection but explicitly reserved its rights to take later action on the agreement. That express reservation alone raises the plausible inference that the FTC had not accepted the legality of the agreement. Moreover, the MMA includes a savings clause which explains that the FTC’s failure to object does not prevent later litigation over the agreement:

Any action taken by ... the [FTC], or any failure of ... the [FTC] to take action, under this subtitle shall not at any time bar any proceeding or any action with respect to any agreement between a brand name drug company and a generic drug applicant, or any agreement between generic drug applicants, under any other provision of law, nor shall any filing under this subtitle constitute or create a presumption of any violation of any competition laws.

§ 1117, 117 Stat. at 2463. Thus, even though the FTC expressly reserved its rights, it did not have to do so under the law. Again, drawing all reasonable inferences in Effexor plaintiffs’ favor, the FTC’s failure to object here constitutes no waiver of objection to or affirmance of the settlement agreement.

Thus, the District Court erred in concluding that the submission of the settlement agreement to the FTC and the FTC’s lack of response immunized Effexor defendants’ settlement agreement from antitrust scrutiny under Actavis.

Effexor defendants finally contend that “[d]ismissal is appropriate for the independent reason that the [settlement agreement] became operative only after the district court overseeing the patent case incorporated the terms into a court order requested by the parties.” Wyeth Br. 61. They cite the District Court’s one-page consent decree adopting the terms of the settlement. According to them, “the operation of the settlement ... result[s] from government action—stemming from constitutionally protected petitioning activity.” Id.

Essentially, Effexor defendants argue that, because they submitted the proposed settlement agreement to the District Court for confirmation, Noerr-Pennington immunity inoculates the settlement agreement from antitrust scrutiny. “Rooted in the First Amendment and fears about the threat of chilling political speech,” Noerr-Pennington immunity provides “immun[ity] from antitrust liability” to parties “who petition[ ] the government for redress.” A.D. Bedell Wholesale Co. v. Philip Morris Inc., 263 F.3d 239, 250 (3d Cir. 2001). That immunity “applies to actions which might otherwise violate the Sherman Act because ‘[t]he federal antitrust laws do not regulate the conduct of private individuals in seeking anticompetitive action from the government.’
However, “[t]he scope of Noerr-Pennington immunity ... depends on the ‘source, context, and nature of the competitive restraint at issue.’” 428 U.S. 579, 602, 96 S.Ct. 3110, 49 L.Ed.2d 1141 (1976) (refusing to allow “state action which amounts to government action”). On the one hand, parties may be immune from liability for “the antitrust injuries which result from the [government] petitioning itself” or “the antitrust injuries caused by government action which results from the petitioning.” Id. (emphasis added). On the other hand, “[i]f the restraint directly results from private action there is no immunity.” Id. That is, immunity will not categorically apply to private actions somehow involving government action.  “Passive government approval is insufficient. Private parties cannot immunize an anticompetitive agreement merely by subsequently requesting legislative approval.” Id. A distinction therefore exists between merely urging the government to restrain trade and asking the government to adopt or enforce a private agreement. Government advocacy is protected by Noerr-Pennington immunity; seeking governmental approval of a private agreement is not.  

Effexor defendants argue that the effect of the settlement agreement at issue “was dependent entirely on the action of the court” and is therefore protected. Wyeth Br. 63. We are not persuaded. The Supreme Court explained in Local No. 93, International Association of Firefighters v. City of Cleveland, 478 U.S. 501, 106 S.Ct. 3063, 92 L.Ed.2d 405 (1986), that, while consent decrees are at some level judicial acts, a court's role in entering a consent judgment differs fundamentally from its role in actually adjudicating a dispute. Id. at 519–22, 106 S.Ct. 3063. When parties pursue litigation, courts reach determinations of facts and applicable law via the adversary process. But when courts enter consent decrees, “it is the agreement of the parties, rather than the force of the law upon which the complaint was originally based, that creates the obligations embodied in the consent decree.” Id. at 522, 106 S.Ct. 3063. “Indeed, it is the parties’ agreement that serves as the source of the court's authority to enter any judgment at all.” Id. That is because consent decrees “closely resemble contracts.” Id. at 519, 106 S.Ct. 3063. Their “most fundamental characteristic” is that they are voluntary agreements negotiated by the parties for their own purposes. Id. at 521–22, 106 S.Ct. 3063; see id. at 522, 106 S.Ct. 3063 (“[T]he decree itself cannot be said to have a purpose; rather the parties have purposes....”) (quoting United States v. Armour & Co., 402 U.S. 673, 681, 91 S.Ct. 1752, 29 L.Ed.2d 256 (1971)). Consequently, when parties seek to enforce agreements adopted in consent orders, courts construe terms of the settlement based on the intent of the parties, not of the court. See, e.g., United States v. ITT Cont'l Baking Co., 420 U.S. 223, 238, 95 S.Ct. 926, 43 L.Ed.2d 148 (1975) (“[A] consent decree or order is to be construed for enforcement purposes basically as a contract[.]”); United States v. New Jersey, 194 F.3d 426, 430 (3d Cir. 1999) (“[A] consent decree has many of the attributes of contracts, we interpret them with reference to traditional principles of contract interpretation.”); Fox v. U.S. Dept of Hous. & Urban Dev., 680 F.2d 315, 319–21 (3d Cir. 1982) (examining evidence regarding “the intention of the parties”).  

Effexor defendants nevertheless attempt to distinguish this case from a mere “rubberstamping of a private settlement.” Wyeth Br. 64. They point to four facts they believe distinguish this case from the typical unprotected settlement approval: (1) the full terms of the settlement agreement were presented to the District Court; (2) the District Court solicited feedback from the FTC; (3) the FTC was provided with time and notice of the settlement prior to its effectiveness; and (4) the full terms of the settlement agreement between Teva and Wyeth were included in the consent order. Id. at 65.  

Those differences fail to convert the otherwise passive government approval of a private settlement agreement into a protected government action. As discussed earlier, the FTC's inaction did not represent approval of the settlement agreement. In addition, court approval of a settlement agreement, even with access to the agreement's full terms, is simply not akin to a corporation's petition of the government for a monopoly or the government's grant of an exclusive license to a corporation. Cf. Cantor v. Detroit Edison Co., 428 U.S. 579, 602, 96 S.Ct. 3110, 49 L.Ed.2d 1141 (1976) (refusing to allow “state action which amounts to little more than approval of a private proposal” to immunize otherwise anticompetitive conduct). Instead, court approval of a settlement agreement of the kind alleged here is commercial activity not protected by the First Amendment right to petition the government. See In re Androgel Antitrust Litig., No. 1:09-cv-955, 2014 WL 1600331, at *6–9 (N.D. Ga. Apr. 21, 2014) (“Indeed,
providing the consent judgment with *Noerr-Pennington* immunity would largely eviscerate the ruling in *Actavis* and the Court can be sure that subsequent patent settlements would always include a consent judgment.”); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F.Supp.2d 367, 394–98 (D. Mass. 2013) (“The ways in which parties maneuver to transform a settlement agreement into a judicially approved consent judgment, then, cannot be fairly characterized as direct ‘petitioning’—at least not as that word is commonly understood in the context of the political process.”); *266 In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F.Supp.2d 188, 212–13 (E.D.N.Y. 2003) (“Even if signing the Consent Judgment could be construed as approving the Settlement Agreements, government action that ‘amounts to little more than approval of a private proposal’ is not protected.” (quoting *Cantor*, 428 U.S. at 602, 96 S.Ct. 3110)). Finally, we note that accepting *Effexor* defendants’ argument would have the practical effect of insulating many (if not most) potentially collusive settlement agreements from legal challenge. If *Effexor* defendants’ actions were sufficient to garner *Noerr-Pennington* immunity, then almost every settlement agreement would be submitted to a court for entry of a consent decree, and court approval would be likely to result given that no party before the court would be challenging the entry of the order. Effectively, then, no third party harmed by a collusive agreement could bring an antitrust lawsuit.

Accordingly, *Effexor* defendants’ actions in submitting their private agreement to the District Court for entry of a consent decree are not sufficient to grant that agreement *Noerr-Pennington* immunity.

V

In the consolidated *Lipitor* appeals, the District Court not only dismissed *Lipitor* plaintiffs’ allegations regarding an unlawful reverse payment but rather dismissed the entirety of the complaints in those appeals. In doing so, it also rejected allegations relating to Pfizer’s fraudulent procurement and enforcement of the ‘995 Patent. More specifically, it dismissed as implausible allegations that Pfizer fraudulently procured the ‘995 Patent (*Walker Process* fraud), wrongfully listed that patent in the FDA’s Orange Book, conducted sham litigation as the basis for entering into the reverse payment settlement agreement, filed a sham “citizen petition,” and entered into an overall monopolistic scheme. We now address the dismissal of those additional allegations and revive each set of allegations.

A

The District Court dismissed *Lipitor* plaintiffs’ allegations of Pfizer’s fraudulent patent procurement and enforcement. That was error.17

Fraudulent procurement of a patent or the enforcement of a patent obtained by fraud, i.e., *Walker Process* fraud, can provide the basis for antitrust liability. See *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 177, 86 S.Ct. 347, 15 L.Ed.2d 247 (1965). To prove *Walker Process* fraud, a plaintiff must, in part, demonstrate

1. a false representation or deliberate omission of a fact material to patentability, (2) made with the intent to deceive the patent examiner, (3) on which the examiner justifiably relied in granting the patent, and (4) but for which misrepresentation or deliberate omission the patent would not have been granted.
C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1364 (Fed. Cir. 1998); see also TransWeb, LLC v. 3M Innovative Props. Co., 812 F.3d 1295, 1306 (Fed. Cir. 2016) (observing that, in addition to proving that the patent was obtained through fraud, an antitrust plaintiff must show “all the other elements necessary to establish a Sherman Act monopolization claim”).

*Lipitor* plaintiffs claim that Pfizer obtained the '995 Patent by fraud and then used it to continue to sell Lipitor exclusively. To summarize those allegations, Pfizer obtained the '995 Patent, claiming protection for atorvastatin calcium, as a follow-on patent to the '893 Patent. To obtain the '995 Patent, Pfizer purportedly submitted false and misleading data to the PTO showing the cholesterol-synthesis inhibiting activity of atorvastatin calcium was surprising and unexpected. More specifically, Pfizer submitted a chart with selectively misleading data and intentionally failed to submit another set of data that undermined its '995 Patent application. Pfizer provided the PTO with that information despite its own scientists informing it that its prior '893 Patent already covered atorvastatin calcium. After once denying Pfizer's patent application for atorvastatin calcium as “anticipated” by the '893 Patent and allegedly receiving even more fraudulent data from Pfizer as a result, the PTO eventually issued the '995 Patent.

Neither Pfizer nor the District Court challenges the sufficiency or specificity of those allegations based on the face of the complaint. The District Court even stated that its “decision d[id] not rest on any failure on [Lipitor] Plaintiffs’ part under Fed. R. Civ. P. 8(a) or 9(b) to spell out these allegations.” *Lipitor I*, 2013 WL 4780496, at *18. Despite disavowing reliance on the pleading standards set forth in the Federal Rules of Civil Procedure, the District Court nonetheless ruled that the *Walker Process* fraud allegations were implausible because they “were presented at trial in the litigation before [another district court judge], in Australia and Canada, and in reissue proceedings before the PTO.” *Id.* More specifically, the District Court reasoned that the *Walker Process* fraud allegations were implausible because (1) a prior District Court Judge had already determined that similar allegations were implausible, (2) the outcomes of foreign litigation addressing the fraud allegations failed to substantiate those allegations, and (3) the PTO's reissuance of the '995 Patent in 2009, despite its awareness of the fraud allegations, meant that the PTO determined that Pfizer had committed no fraud in its original procurement of the patent. *Id.* at *19–20. Individually or in combination, none of those reasons renders the *Walker Process* fraud allegations implausible. We address them each in turn.

In concluding that *Lipitor* plaintiffs’ allegations of *Walker Process* fraud were implausible, the District Court first relied on a District Court's decision in another case. That court had determined that Pfizer had committed no wrongdoing in the procurement of the '995 Patent. Reliance on that prior decision functionally amounted to the application of collateral estoppel and was therefore improper because *Lipitor* plaintiffs were not parties in that prior case.

As described above, Pfizer sued Ranbaxy in 2002 for infringement of the '893 and '995 Patents following Ranbaxy's ANDA filing. *Pfizer*, 405 F.Supp.2d at 499. In that litigation, Ranbaxy defended against Pfizer's infringement suit by arguing in part that, because Pfizer engaged in inequitable conduct in the procurement of the '995 Patent before the PTO, the '995 Patent was unenforceable. *Id.* at 520–21. Similar to the allegations here, Ranbaxy contended that Pfizer withheld information from the PTO and misrepresented the results of testing related to atorvastatin calcium. *Id.* Following a bench trial, however, the District Court in that litigation determined that Pfizer committed no inequitable conduct in its procurement of the '995 Patent. *Id.* at 520–25.

Relying on that determination, the District Court here concluded that *Lipitor* plaintiffs’ *Walker Process* fraud allegations were implausible. In doing so, it effectively bound *Lipitor* plaintiffs to the other Court's prior determination in the other case. That
is the essence of collateral estoppel. See Doe v. Hesketh, 828 F.3d 159, 171 (3d Cir. 2016) (“Collateral estoppel prevents the relitigation of a factual or legal issue that was litigated in an earlier proceeding.”).

Applying collateral estoppel against Lipitor plaintiffs based on the prior litigation between Pfizer and Ranbaxy constitutes reversible error. Invocation of the collateral estoppel doctrine is appropriate only where “the party against whom the bar is asserted was a party or in privity with a party to the prior adjudication[ ] and ... had a full and fair opportunity to litigate the issue in question.” Id. (quoting Del. River Port Auth. v. Fraternal Order of Police, 290 F.3d 567, 573 n.10 (3d Cir. 2002)). Here, none of the Lipitor plaintiffs was a party in that prior litigation. Ruling that their allegations are implausible in light of that litigation would thus improperly estop Lipitor plaintiffs from raising Walker Process fraud. See S. Cross Overseas Agencies, Inc. v. Wah Kwong Shipping Grp. Ltd., 181 F.3d 410, 426 (3d Cir. 1999) (“[O]n a motion to dismiss, we may take judicial notice of another court's opinion—not for the truth of the facts recited therein, but for the existence of the opinion, which is not subject to reasonable dispute over its authenticity.”) (emphasis added) (citations omitted); Gen. Elec. Capital Corp. v. Lease Resolution Corp., 128 F.3d 1074, 1083 (7th Cir. 1997) (“[I]f a court could take judicial notice of a fact simply because it was found to be true in a previous action, the doctrine of collateral estoppel would be superfluous. A plaintiff cannot be collaterally estopped by an earlier determination in a case in which the plaintiff was neither a party nor in privity with a party.”) (citations omitted); United States v. Jones, 29 F.3d 1549, 1553 (11th Cir. 1994) (“If it were permissible for a court to take judicial notice of a fact merely because it has been found to be true in some other action, the doctrine of collateral estoppel would be superfluous.”) (citation omitted); see also DDAVP, 585 F.3d at 692 (concluding that the District Court improperly relied on the record in an earlier case to dismiss Walker Process fraud allegations and noting “the record in this case could be different following discovery”).

The District Court also cited the presentment of similar allegations to Australian and Canadian courts as a basis for dismissal. It concluded that the results of that foreign litigation did “nothing to alter” its conclusion that Lipitor plaintiffs’ Walker Process fraud allegations were implausible. Lipitor I, 2013 WL 4780496, at *19–20. We agree only that the past foreign litigation has no bearing on the plausibility of the Walker Process fraud allegations here. Even if the District Court were permitted to consider it, the rulings in that litigation fail to make Lipitor plaintiffs’ allegations implausible.

As stated above, the factual resolution of issues in prior litigation (foreign or otherwise) should not dictate the plausibility of Lipitor plaintiffs’ allegations when they were not parties to that litigation. See S. Cross Overseas Agencies, 181 F.3d at 426 (“[O]n a motion to dismiss, we may take judicial notice of another court's opinion—not for the truth of the facts recited therein, but for the existence of the opinion, which is not subject to reasonable dispute over its authenticity.”); Werner v. Werner, 267 F.3d 288, 295 (3d Cir. 2001) (“Taking judicial notice of the truth of the contents of a filing from a related action could reach, and perhaps breach, the boundaries of proper judicial notice.”).

Even if consideration of that other foreign litigation were appropriate, Lipitor plaintiffs’ allegations are still plausible. In the Australian litigation, the Australian trial court found that Pfizer was guilty of “false suggestion” because the record there raised “[t]he clear inference ... that the claim of surprising and unexpected inhibition of the synthesis of cholesterol ... is an artificial and unsupported claim.” Ranbaxy Australia Pty Ltd v Warner-Lambert Co LLC (No. 2) [2006] FCA 1787 (20 December 2006) ¶ 357 (Austl.). On appeal, another Australian court concluded that Pfizer's assertion that its results were surprising was “a false representation” and that the patent “was obtained by false suggestion or misrepresentation.” Ranbaxy Australia Pty Ltd (ACN 110 781 826) v. Warner-Lambert Co LLC [2008] FCAFC 82 (28 May 2008) ¶ 140 (Austl.). While the District Court and Pfizer note that the Australian courts did not go so far as to say Pfizer intentionally committed fraud, those rulings would, if anything, seem to support the plausibility of Lipitor plaintiffs’ Walker Process allegations here.
In the Canadian litigation, a Canadian court determined that Pfizer's data and statements in support of its Canadian patent (the equivalent of the '995 patent) were “incorrect” and based on “false suggestion.” Pfizer Canada Inc. v. Canada (Minister of Health), 2007 F.C. 91, paras. 122, 124 (Can. Ont. F.C.). On appeal, a Canadian appeals court reversed, concluding Pfizer's data and statements were not misleading. Pfizer Canada Inc. v. Canada (Minister of Health) (2008), [2009] 1 F.C.R. 253, paras. 53–55 (Can. Ont. C.A.). That decision, though, appears to have largely avoided the issue of Pfizer's alleged misrepresentations. Id. paras. 56–58 (applying one section of a Canadian patent statute and noting that “[t]he requirement that the specification of a patent be truthful and not be misleading” was in another section of the patent statute, which was not at issue). Were these decisions a proper basis to evaluate the plausibility of Lipitor plaintiffs’ allegations, they would do little to suggest implausibility.

In short, the factual resolution of similar Walker Process fraud allegations in foreign litigation not involving Lipitor plaintiffs has no bearing on the current litigation. Even assuming consideration of that foreign litigation was proper, it fails to suggest the implausibility of Lipitor plaintiffs’ allegations.

The District Court finally relied on the reissuance of the '995 Patent in 2009 to dismiss the Walker Process fraud allegations. It concluded that, because the PTO reissued the '995 Patent in 2009 despite being made aware of the fraud allegations, the reissuance “suggest[ed] that [Lipitor plaintiffs’] allegation that the PTO would not have issued the patent but for the alleged misrepresentations or omissions [was] implausible.” Lipitor I, 2013 WL 4780496, at *20. We disagree.

To the extent that the District Court's decision implies that a patent reissuance precludes a finding of Walker Process fraud, such reasoning is incorrect. A patent's reissuance by the PTO does not bar a later finding that the patent was originally procured by fraud. See Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1288 (Fed. Cir. 2011) (en banc) (“[I]nequitable conduct cannot be cured by reissue....”). Rather, a fact finder may conclude that inequitable conduct or fraud occurred in the patent's prosecution despite the patent's reissuance by the PTO. See Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., 326 F.3d 1226, 1236–37, 1242 (Fed. Cir. 2003) (upholding district court's finding of inequitable conduct in patent prosecution despite the PTO's reissuance of patent); see also Hoffman-La Roche Inc. v. Lemmon Co., 906 F.2d 684, 688–89 (Fed. Cir. 1990) (“[I]f the district court finds that there was inequitable conduct in the prosecution of the original patent[,] then the reissue patent is invalid....”).

Assuming the District Court did not conclude that the patent reissuance precluded a finding of fraud but that it only “suggested” that such a finding was implausible, the District Court failed to draw inferences in Lipitor plaintiffs’ favor. Lipitor plaintiffs allege that, were it not for Pfizer's fraud on the PTO in procuring the '995 Patent in 1993, the PTO would not have originally issued the '995 Patent. See Lipitor JA375 (DPP Original Compl. ¶ 242 (“Were it not for Pfizer's fraud on the PTO in the context of procuring the '995 patent, there would never have been a '995 patent in the first place.”)). Drawing reasonable inferences in their favor, Lipitor plaintiffs’ allegation is plausible. Initially, the PTO issued the '995 Patent based on data alleged to be fraudulent. Rather than rely on that data during the reissuance proceedings before the PTO, Pfizer based its request for reissuance entirely on Lipitor's “commercial success,” a basis that was clearly not available before Lipitor's launch in 1997. By Pfizer's own request, the PTO did not base its 2009 decision on the allegedly fraudulent data. During the reissuance proceedings, Pfizer told the PTO that the information it previously submitted in 1993 was “inaccurate,” that it was not “necessary to consider such evidence,” and that Pfizer was no longer relying on that data. Lipitor JA371–72 (DPP Orig. Am. Compl. ¶¶ 225–28). Finally, no allegations suggest that the PTO's reissuance made an express determination regarding Pfizer's lack of fraud during the original patent proceeding. These allegations plausibly allege that the PTO would not have issued the '995 Patent during the original patent proceedings in 1993 but for the allegedly fraudulent and misleading submissions by Pfizer.
Pfizer's arguments to the contrary are unpersuasive. First, Pfizer would have us conclude that the PTO definitively determined that Pfizer committed no past fraud based on the PTO's Manual of Patent Examining Procedure ("MPEP"), and therefore the reissuance should prevent Lipitor plaintiffs from raising Walker Process fraud allegations. As we have already observed, the PTO's reissuance of a patent does not bar a later finding that the patent was first procured by fraud. See Therasense, 649 F.3d at 1288; PIC Inc. v. Prescon Corp., 485 F.Supp. 1302, 1303 (D. Del. 1980) ("[A] result favorable to a patentee *271 in a PTO reissue proceeding on issues of invalidity by reason of prior art and fraud is not entitled to preclusive effect in the courts.").

Moreover, Pfizer's reliance on the MPEP is misplaced. Pfizer cites language from the MPEP that states, “Clearly, if a reissue patent would not be enforceable after its issue because of ‘fraud’ ... during the prosecution of the patent sought to be reissued, the reissue patent application should not issue.” MPEP § 2012 (9th ed., Nov. 2015). Pfizer fails to include the next part of that same section of the manual, though, which tells the patent examiner “not to make any investigation as to lack of deceptive intent requirement in reissue applications. Applicant's statement (in the oath or declaration) of lack of deceptive intent will be accepted as dispositive except in special circumstances such as an admission or judicial determination of fraud.” Id. (emphasis added). Pfizer also points out that Ranbaxy filed protests raising the fraud allegations before the PTO during the reissuance proceeding. It argues that the PTO was “required to consider such arguments” under the MPEP. Pfizer Br. 50 (citing MPEP § 1901.6). Section 1901.6 of the MPEP, however, states that the patent examiner receiving a protest raising issues of fraud must enter the protest into “the application file, generally without comments on those issues.” MPEP § 1901.6(I)(B). Given Pfizer's request that the PTO not consider its allegedly fraudulent data, the PTO's reissuance of the '995 Patent on a basis other than those fraudulent submissions, the lack of any explicit fraud determination by the PTO in its reissuance of the '995 Patent, and the MPEP seemingly limiting patent examiners' investigations into past fraud, we conclude that the complaint plausibly alleges that the PTO did not find a lack of fraud in initial patent proceedings through its reissuance of the '995 Patent.

Second, Pfizer contends that its disclosures of information to the PTO during the reissuance proceedings undermine the allegations that Pfizer intended to deceive the PTO in 1993. During the reissuance proceedings, Pfizer provided information on the Australian and Canadian litigations and, as noted earlier, informed the PTO that the data previously submitted in support of the '995 Patent was “inaccurate.” Pfizer's actions in 2007 before the PTO during reissuance proceedings, though, shed little light on Pfizer's intent to deceive the PTO back in 1993 when Pfizer first sought issuance of the '995 patent. 20 See Bristol-Myers Squibb Co., 326 F.3d at 1241 ("[T]he issue is [the patentee's] intent during the prosecution of the original application. Thus, [the patentee's] disclosure during reissue is irrelevant to the inquiry of whether [the patentee] acquired the ... patent by engaging in inequitable conduct."). At the very least, Pfizer's disclosures do not make Lipitor plaintiffs’ allegations implausible.

In sum, the PTO's reissuance fails to render Lipitor plaintiffs’ allegations implausible. See Therasense, 649 F.3d at 1288; Bristol-Myers Squibb Co., 326 F.3d at 1236–37, 1242.

After dismissing Lipitor plaintiffs’ Walker Process fraud allegations, the District Court also dismissed allegations that Pfizer falsely listed the '995 Patent in the FDA's Orange Book. It rejected those allegations of the false Orange Book listing based on its dismissal of the Walker Process fraud allegations. Because we *272 conclude that Lipitor plaintiffs plausibly allege Walker Process fraud, we also reinstate their allegations regarding Pfizer's false Orange Book listing.

C
The District Court next dismissed Lipitor plaintiffs’ allegations that Pfizer conducted sham litigation. The Court concluded that those allegations were implausible largely because the Walker Process fraud allegations were implausible. Again, because we conclude the Walker Process fraud allegations are plausible, that is not a ground for dismissal. The District Court also offered several other reasons for dismissing the sham litigation allegations related to Pfizer's suit against Ranbaxy in 2008, but those additional grounds fail to persuade.

Filing a lawsuit essentially petitions the government for redress and is therefore generally protected from antitrust liability by Noerr-Pennington immunity. See Cheminor Drugs, Ltd. v. Ethyl Corp., 168 F.3d 119, 122 (3d Cir. 1999). But Noerr-Pennington immunity will not shield lawsuits that are a “mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor.” Id. (quoting E. R.R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 144, 81 S.Ct. 523, 5 L.Ed.2d 464 (1961)). To demonstrate the applicability of that exception to Noerr-Pennington immunity, a plaintiff must show that the defendant's lawsuit was both “objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits” and “an attempt to interfere directly with the business relationships of a competitor.” Id. at 122–24 (quoting Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 60, 113 S.Ct. 1920, 123 L.Ed.2d 611 (1993)).

In March 2008, Pfizer sued Ranbaxy, claiming that Ranbaxy's generic Lipitor would infringe Pfizer's two Lipitor-related process patents. Lipitor plaintiffs allege that Pfizer's 2008 lawsuit was a sham. They assert that Pfizer knew Ranbaxy's generic would not violate those patents and that Pfizer simply used the 2008 suit as a way to enter into the reverse payment settlement agreement.

The District Court first concluded that those allegations were implausible because the court in the alleged sham litigation “permitted jurisdictional discovery” on subject-matter jurisdiction and because Lipitor plaintiffs failed to explain why subject-matter jurisdiction in that litigation was lacking. Lipitor I, 2013 WL 4780496, at *21. Lipitor plaintiffs, though, alleged that Pfizer's 2008 suit was not justiciable because Ranbaxy was already enjoined from selling its generic Lipitor for several more years given the earlier litigation between the parties. The grant of jurisdictional discovery is also not a determination of the action's underlying merits and certainly has limited, if any, bearing on the plausibility of Lipitor plaintiffs’ allegations. Indeed, Lipitor plaintiffs explicitly provide allegations as to why Pfizer's 2008 suit lacked merit and was thus a sham. See Lipitor JA255–56 (DPP Sec. Am. Compl. ¶¶ 140–44).

Second, the District Court observed that the timing of Pfizer's litigation “was consistent with the typical duration for litigation infringement claims.” Lipitor JA51–52. Given the pleading standard, it should not have been drawing inferences in Pfizer's favor regarding the timing of Pfizer's 2008 litigation. See In re Asbestos Prod. Liaib. Litig. (No. VI), 822 F.3d 125, 131 (3d Cir. 2016) (“[W]e must accept as true all plausible facts alleged in her amended complaint and draw all reasonable inferences in her favor.”). Lipitor plaintiffs thus *273 plausibly allege that Pfizer conducted sham litigation in its 2008 lawsuit against Ranbaxy.

The District Court next dismissed Lipitor plaintiffs’ allegations that Pfizer submitted a sham citizen petition to the FDA to prevent Ranbaxy's entrance into the Lipitor market. It reasoned that Pfizer's petition was not objectively baseless because it was supported by science and the FDA believed it had merit. Dismissal on those grounds was improper.

Beyond immunizing certain petitioning in the judicial system, Noerr-Pennington immunity also protects petitioning of “all types of government entities.” Cheminor Drugs, 168 F.3d at 122. Petitions to administrative agencies are consequently also immune from antitrust liability. See id. But as with the immunity extended for filing a lawsuit, Noerr-Pennington protection will not apply to petitions that are a “mere sham to cover what is actually nothing more than an attempt to interfere directly with
the business relationships of a competitor.” *Id.* (quoting *Noerr*, 365 U.S. at 144, 81 S.Ct. 523). Petitioning that is “objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits” and “an attempt to interfere directly with the business relationships of a competitor” will not be immune from antitrust liability. *Id.* at 122–24 (quoting *Prof'l Real Estate Inv'rs*, 508 U.S. at 60, 113 S.Ct. 1920).

Analyzing this exception to *Noerr-Pennington* immunity, the District Court first concluded that the citizen petition to the FDA could not have been “objectively baseless” because it was supported by science. That conclusion is incorrect given the pleading standard here. *Lipitor* plaintiffs contend that Pfizer filed a sham citizen petition raising baseless concerns about Ranbaxy's use of amorphous atorvastatin calcium in its generic version of *Lipitor*. *Lipitor* plaintiffs allege Pfizer's petition was a sham because (1) it “ignored more than a decade of FDA policy, the FDA's 2002 rejection of a similar argument in relation to the drug Ceftin, subsequent FDA pronouncements reinforcing that the polymorphic form of the drug (i.e., crystalline versus amorphous) [were] immaterial to ANDA approval,” *Lipitor* JA242 (DPP Sec. Am. Compl. ¶ 95), (2) it ignored Pfizer's own use of the amorphous form of atorvastatin in its clinical studies “to support the safety and efficacy of *Lipitor*,” *id.*, (3) it lacked any evidence that amorphous atorvastatin calcium “would not be pharmaceutically equivalent or bioequivalent to branded *Lipitor*,” *Lipitor* JA241 (DPP Sec. Am. Compl. ¶ 96), and (4) the FDA ultimately denied Pfizer's citizen petition. Those allegations plausibly allege Pfizer submitted a sham petition not supported by science. To conclude otherwise requires an evaluation of the scientific merit of Pfizer's petition. Such an inquiry is unsuitable for resolution on a motion to dismiss. *21*

The District Court also determined the citizen petition was not “objectively baseless” because the FDA considered the petition on its merits. To reach that factual conclusion, it observed that the FDA took several years to reach a decision on the petition and that the FDA described the petition as “complex.” Neither of those observations, however, leads to the conclusion that *Lipitor* plaintiffs’ sham citizen petition allegations are implausible. All citizen petitions are granted or denied by the FDA. *See* 21 C.F.R. § 10.30(e)(1) (“The Commissioner shall ... rule upon each petition....”). Mere consideration of a petition by an agency, even lengthy consideration, does not immunize that petition. *See Hanover 3201 Realty, LLC v. Vill. Supermarkets, Inc.*, 806 F.3d 162, 180–83 (3d Cir. 2015) (applying the sham exception to *Noerr-Pennington* to defendants’ permit objections and observing “[t]hat the [government agency] was required to consider Defendants’ challenge does not mean that their arguments had any bite”). Equating delay in consideration of a petition or its complexity with the petition's underlying merits also fails to draw inferences in *Lipitor* plaintiffs’ favor. Reasonable inferences from those facts are that the FDA's delay in deciding the petition had no connection to the petition's merits and that the petition's “complexity” also reflected little about its actual merits. Moreover, according to *Lipitor* plaintiffs, the FDA delayed in reaching a decision on the citizen petition, in part, because it knew of the settlement agreement between Ranbaxy and Pfizer. *Lipitor* JA269 (DPP Sec. Am. Compl. ¶ 193 (“[O]nce [the] FDA learned of the fact that the first generic for *Lipitor*, i.e., Ranbaxy’s, would not be marketed until November 30, 2011, [the] FDA shifted assets away from Ranbaxy's ANDA and the Pfizer petition....”)).

The District Court's dismissal of *Lipitor* plaintiffs’ sham citizen petition allegations was error.

The District Court finally dismissed *Lipitor* plaintiffs’ allegations that Pfizer participated in an overall monopolistic scheme. It dismissed those allegations based on its dismissal of all the above allegations (i.e., the allegations concerning *Walker Process* fraud, the false Orange Book listing, sham litigation, and the sham citizen petition). Because we conclude that those allegations are plausible, we conclude that the District Court's dismissal of *Lipitor* plaintiffs’ allegations that Pfizer participated in an overall scheme of monopolistic conduct was also error.
VI

For the reasons stated, we will reverse the District Court's dismissals in both the Lipitor and Effexor consolidated appeals. We will remand those consolidated cases for further proceedings consistent with this opinion.

All Citations

868 F.3d 231, 2017-2 Trade Cases P 80,101

Footnotes

1 Earlier this year, the action of a fourth group of plaintiffs—California-based pharmacists raising claims under California law—was remanded to the District Court for a federal subject-matter jurisdiction determination. See Lipitor III, 855 F.3d at 151–52. We retained jurisdiction over their appeal. Id.

2 Pfizer merged with Warner-Lambert Co. in 2002. We refer to the two entities collectively as “Pfizer.”

3 We refer to the joint appendix in Lipitor as “Lipitor JA.” Also, as Lipitor plaintiffs’ complaints contain substantively identical factual allegations, we cite only to the direct purchasers’ complaints, referring to their original amended complaint as “DPP Orig. Am. Compl.” and the second amended complaint as “DPP Sec. Am. Compl.”


5 As explained below, the District Court did not dismiss Effexor plaintiffs’ allegations related to Wyeth's fraudulent procurement and enforcement of the Effexor patents. Because those allegations are thus not at issue on appeal, we do not detail them here.


7 We refer to the joint appendix in the Effexor consolidated appeals as “Effexor JA.”

8 The individual third-party payors’ operative complaint names only Wyeth and its affiliates as defendants.

9 This conclusion renders unnecessary the need to address the Lipitor direct purchasers’ argument that they should be granted leave to submit a new complaint with economic calculations to bolster their allegations of an unlawful reverse payment.

10 Notably, Lipitor plaintiffs do not allege the size or value of Pfizer’s grant to Ranbaxy of early access into several foreign markets for Lipitor.

11 As explained infra, not only does Lipitor defendants’ request for detailed economic analyses go beyond what is required at this stage of the litigation, but that request also attempts to require Lipitor plaintiffs to disprove what Lipitor defendants must prove. Lipitor defendants suggest that the size of the reverse payment must be determined by the net reverse payment, which accounts for litigation costs and other discounting measures and justifications for the payment. In doing so, Lipitor defendants seem to conflate the Actavis requirement that the reverse payment be “large” with the
requirement that the payment be “unjustified.” Their proposed economic valuation demands that Lipitor plaintiffs disprove proffered justifications for the reverse payment settlement agreement. Lipitor plaintiffs, though, need not do so at the pleading stage. Actavis, 133 S.Ct. at 2236 (“An antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason.”) (emphasis added).

The Lipitor parties differ as to whether, under the Sherman Act, foreign or out-of-market procompetitive effects of the settlement agreement, like the Canadian supply arrangement and settlement of the Caduet litigation, can justify the domestic or in-market anticompetitive effects of the settlement, namely Ranbaxy's delayed entry into the U.S. Lipitor market. We need not decide that issue, as Lipitor plaintiffs have, at least at this point in the litigation, plausibly alleged the absence of justifications for the reverse payment. See King Drug Co., 791 F.3d at 410 n.34 (“It may also be (though we do not decide) that procompetitive effects in one market cannot justify anticompetitive effects in a separate market.”) (citation and quotation marks omitted)).

Because Effexor plaintiffs’ complaints contain substantively identical factual allegations, we cite only to the direct purchasers’ complaint, referring to their second amended complaint as “DPP Sec. Am. Compl.”

Reliability is often associated with the evidentiary standard applicable to expert testimony, see Rule 702(c) of the Federal Rules of Evidence, not the pleading standard required to survive a motion to dismiss. As the Amicus Brief submitted by the American Antitrust Institute points out, the District Court even seems to have suggested that Effexor plaintiffs at the pleading stage should have produced evidence in order to make their allegation plausible: “Since the Direct Purchaser Plaintiffs fail to provide appropriate evidence for the Court to determine the value of the payment, the allegations in the Complaint do not reach the plausibility standard established in Iqbal and Twombly.” In re Effexor XR Antitrust Litig., 2014 WL 4988410, at *23 (emphasis added); American Antitrust Institute Amicus Br. 10.

The procedural history related to the royalty licensing provisions further supports our conclusion. The Effexor direct purchasers filed a motion for leave to file a second amended consolidated complaint on August 28, 2013, attaching their proposed complaint. A week after receiving this proposed second amended complaint, Effexor defendants sent Effexor plaintiffs a copy of the un-redacted agreement containing details about the royalties, coming mere days before oral argument on Effexor plaintiffs’ request to amend. Despite the timing of its disclosure, Effexor defendants would have this panel affirm the dismissal of all the complaints, without giving any Effexor plaintiffs, even those other than the direct purchasers, a chance to amend. Given this procedural background, dismissal based on the absence of detailed, expert-derived allegations explaining the royalty licenses—as requested by Effexor defendants—would be inappropriate. This procedural history serves to underscore the concern that requiring the heightened level of specificity requested here would make settlement agreements like this one nearly impossible to challenge because the details of the agreements are closely guarded by the parties entering into them. American Antitrust Institute Amicus Br. 6–7. Accordingly, it was appropriate to look to general assumptions about authorized generics to determine the value of the agreement based on the information available to Effexor plaintiffs. They need not have brought in experts to assess the settlement based on the limited information they had.


Because we reverse the dismissal of Lipitor plaintiffs’ Walker Process fraud allegations, we will also reverse the District Court's limitation on Lipitor plaintiffs’ potential damages period, Lipitor I, 2013 WL 4780496, at *25, as that limitation was predicated on the dismissal of the Walker Process fraud allegations.

The District Court also appeared to rely on the law of the case doctrine, citing case law applying that doctrine. The law of the case doctrine does not apply here because it only applies within a single litigation. See Hamilton v. Leavy, 322
Pfizer cites several cases, but none supports the District Court's functional application of collateral estoppel here. See, e.g., CBS Outdoor Inc. v. New Jersey Transit Corp., No. CIV.A.06-2428HAA, 2007 WL 2509633, at *2, *15 (D.N.J. Aug. 30, 2007) (concluding that plaintiff's allegations were implausible, as that same plaintiff's allegations had been rejected in state court).

For a similar reason, Pfizer's later disclosures of information in the foreign litigation fail to make Lipitor plaintiffs' allegations of fraudulent intent implausible.

Pfizer also argues that its mere submission of data to the FDA in support of its petition renders implausible allegations that the petition was a sham. Reading the complaints in the light most favorable to Lipitor plaintiffs, a reasonable inference is that the data submitted with the petition only perpetuated Pfizer's baseless attempt to prevent Ranbaxy's entry into Lipitor's market. At the very least, the mere submission of data in support of a petition raises no inference that the petition itself possessed merit. Put simply, Pfizer's submission of data with its petition does not make Lipitor plaintiffs' sham petition allegations implausible.
Synopsis
Action by long-distance trucking companies and others against 24 major railroads and others for violation of Sherman Anti-Trust Act, wherein railroads filed a counterclaim charging violation of the act by the trucking companies. The United States District Court for the Eastern District of Pennsylvania, 155 F.Supp. 768, found in favor of the trucking companies and their trade association, and entered judgment adverse to the railroads and the other defendants, 166 F.Supp. 163, and they appealed. The Court of Appeals, 273 F.2d 218, affirmed, and the Supreme Court granted a petition for certiorari. The Supreme Court, Mr. Justice Black, held that publicity campaign of 24 railroads directed toward obtaining governmental action adverse to interests of trucking companies was not illegal because it may have been affected by an anticompetitive purpose and use of so-called third-party technique by railroads in publicity campaign to influence governmental action adverse to trucking companies did not violate Sherman Anti-Trust Act.

Judgments reversed.

Attorneys and Law Firms

**525 Mr. *128 Philip Price, Philadelphia, Pa., for petitioners.

Mr. Harold E. Kohn, Philadelphia, Pa., for respondents.

Opinion

Mr. Justice BLACK delivered the opinion of the Court.

American railroads have always largely depended upon income from the long-distance transportation of heavy freight for economic survival. During the early years of their existence, they had virtually no competition in this aspect of their business, but, as early as the 1920's, the growth of the trucking industry in this country began to bring about changes in this situation. For the truckers found, just as the railroads had learned earlier, that a very profitable part of the transportation business was the long hauling of heavy freight. As the trucking industry became more and more powerful, the competition between it and the railroads for this business became increasingly intense until, during the period following the conclusion of World War II, at
least the railroads, if not both of the competing groups, came to view the struggle as one of economic life or death for their method of transportation. The present litigation is an outgrowth of one part of that struggle.

The case was commenced by a complaint filed in the United States District Court in Pennsylvania on behalf of 41 Pennsylvania truck operators and their trade association, the Pennsylvania Motor Truck Association. This complaint, which named as defendants 24 Eastern railroads, an association of the presidents of those railroads known as the Eastern Railroad Presidents Conference, and a public relations firm, Carl Byoir & Associates, Inc., charged that the defendants had conspired to restrain trade in and monopolize the long-distance freight business in violation of ss 1 and 2 of the Sherman Act. The gist of the conspiracy alleged was that the railroads had engaged Byoir to conduct a publicity campaign against the truckers designed to foster the adoption and retention of laws and law enforcement practices destructive of the trucking business, to create an atmosphere of distaste for the truckers among the general public, and to impair the relationships existing between the truckers and their customers. The campaign so conducted was described in the complaint as ‘vicious, corrupt, and fraudulent,’ first, in that the sole motivation behind it was the desire on the part of the railroads to injure the truckers and eventually to destroy them as competitors in the long-distance freight business, and, secondly, in that the defendants utilized the so-called third-party technique, that is, the publicity matter circulated in the campaign was made to appear as spontaneously expressed views of independent persons and civic groups when, in fact, it was largely prepared and produced by Byoir and paid for by the railroads. The complaint then went on to supplement these more or less general allegations with specific charges as to particular instances in which the railroads had attempted to influence legislation by means of their publicity campaign. One of several such charges was that the defendants had succeeded in persuading the Governor of Pennsylvania to veto a measure known as the ‘Fair Truck Bill,’ which would have permitted truckers to carry heavier loads over Pennsylvania roads.

The prayer of the complaint was for treble damages under s 4 of the Clayton Act and an injunction restraining the defendants from further acts in pursuance of the conspiracy. Insofar as the prayer for damages was concerned a stipulation was entered that the only damages suffered by the individual truck operators was the loss of business that resulted from the veto of the ‘Fair Truck Bill’ by the Governor of Pennsylvania, and accordingly the claim for damages was limited to an amount based upon the loss of profits as a result of this veto plus the expenses incurred by the truckers’ trade association for the purpose of combatting the railroads' publicity campaign. The prayer for injunctive relief was much broader, however, asking that the defendants be restrained from disseminating any disparaging information about the truckers without disclosing railroad participation, from attempting to exert any pressure upon the legislature or Governor of Pennsylvania through the medium of front organizations, from paying any private or public organizations to propagate the arguments of the railroads against the truckers or their business, and from doing ‘any other act or thing to further the objects and purposes’ of the conspiracy.

In their answer to this complaint, the railroads admitted that they had conducted a publicity campaign designed to influence the passage of state laws relating to truck weight limits and tax rates on heavy trucks, and to encourage a more rigid enforcement of state laws penalizing trucks for overweight loads and other traffic violations, but they denied that their campaign was motivated either by a desire to destroy the trucking business as a competitor or to interfere with the relationships between the truckers and their customers. Rather, they insisted, the campaign was conducted in furtherance of their rights to inform the public and the legislatures of the several states of the truth with regard to the enormous damage done to the roads by the operators of heavy and especially of overweight trucks, with regard to their repeated and deliberate violations of the law limiting the weight and speed of big trucks, with regard to their failure to pay their fair share of the cost of constructing, maintaining and repairing the roads, and with regard to the driving hazards they create. Such a campaign, the defendants maintained, did not constitute a violation of the Sherman Act, presumably because that Act could not properly be interpreted to apply either to restraints of trade or monopolizations that result from the passage or enforcement of laws or to efforts of individuals to bring about the passage or enforcement of laws.

Subsequently, defendants broadened the scope of the litigation by filing a counterclaim in which they charged that the truckers had themselves violated ss 1 and 2 of the Sherman Act by conspiring to destroy the railroads' competition in the
long-distance freight business and to monopolize that business for heavy trucks. The means of the conspiracy alleged in the counterclaim were much the same as those with which the truckers had charged the railroads in the original complaint, including allegations of the conduct of a malicious publicity campaign designed to destroy the railroads' business by law, to create an atmosphere hostile to the railroads among the general public, and to interfere with relationships existing between the railroads and their customers. The prayer for relief of the counterclaim, like that of the truckers' original complaint, was for treble damages and an injunction restraining continuance of the allegedly unlawful practices. In their reply to this counterclaim, the truckers denied each of the allegations that charged a violation of the Sherman Act and, in addition, interposed a number of affirmative defenses, none of which are relevant here.

In this posture, the case went to trial. After hearings, the trial court entered a judgment, based upon extensive findings of fact and conclusions of law, that the railroads' publicity campaign had violated the Sherman Act while that of the truckers had not. In reaching this conclusion, the trial court expressly disclaimed any purpose to condemn as illegal mere efforts on the part of the railroads to influence the passage of new legislation or the enforcement of existing law. Instead, it rested its judgment upon findings, first, that the railroads' publicity campaign, insofar as it was actually directed at lawmaking and law enforcement authorities, was malicious and fraudulent—malicious in that its only purpose was to destroy the truckers as competitors, and fraudulent in that it was predicated upon the deceiving of those authorities through the use of the third-party technique; and, secondly, that the railroads' campaign also had as an important, if not overriding, purpose the destruction of the truckers' goodwill, among both the general public and the truckers' existing customers, and thus injured the truckers in ways unrelated to the passage or enforcement of law. In line with its theory that restraints of trade and monopolizations resulting from valid laws are not actionable under the Sherman Act, however, the trial court awarded only nominal damages to the individual truckers, holding that no damages were recoverable for loss of business due to the veto of the Pennsylvania 'Fair Truck Bill.'

The judgment did, however, award substantial damages to the truckers' trade association as well as the broad injunction asked for in the complaint.

**528** The conclusion that the truckers' publicity campaign had not violated the Sherman Act was reached despite findings that the truckers also had engaged in a publicity campaign designed to influence legislation, as charged in the counterclaim, and despite findings that the truckers had utilized the third-party technique in this campaign. Resting largely upon the fact that the efforts of the truckers were directed, at least for the most part, at trying to get legislation passed that was beneficial to them rather than harmful to the railroads, the trial court found that the truckers' campaign was purely defensive in purpose and concluded that the truckers' campaign differed from that of the railroads in that the truckers were not trying to destroy a competitor. Accordingly, it held that the truckers' campaign, though technically in restraint of trade, was well within the rule of reason which governs the interpretation of ss 1 and 2 of the Sherman Act and consequently dismissed the counterclaim.

The railroads appealed from this judgment, both as to the conclusion that they had violated the Sherman Act as charged in the original complaint and as to the conclusion that the truckers had not violated the Act as charged in the counterclaim. The Court of Appeals for the Third Circuit, one judge dissenting in part, upheld the judgment of the District Court in every respect, stating that the findings amply support the judgment and that there was sufficient evidence to support all of the findings. This was followed by a petition for certiorari filed on behalf of the railroads and Byoir limited to the question of the correctness of the judgment insofar as it held that they had violated the Sherman Act. Because the case presents a new and unusual application of the Sherman Act and involves severe restrictions upon the rights of these railroads and others to seek the passage or defeat of legislation when deemed desirable, we granted that petition.

We accept, as the starting point for our consideration of the case, the same basic construction of the Sherman Act adopted by the courts below—that no violation of the Act can be predicated upon mere attempts to influence the passage or enforcement of laws. It has been recognized, at least since the landmark decision of this Court in Standard Oil Co., of New Jersey v. United States, that the Sherman Act forbids only those trade restraints and monopolizations that are created, or attempted,
by the acts of **529 ‘individuals or combinations of individuals or corporations.’ **14 Accordingly, it has been held that where
a restraint upon trade or monopolization is the result of valid governmental action, as opposed to private action, no violation
of the Act can be made out. **15 These decisions rest upon the fact that under our form of government the question whether a
law of that kind should pass, or if passed be enforced, is the responsibility of the appropriate legislative or executive branch of
government so long as the law itself does not violate some provision of the Constitution.

We think it equally clear that the Sherman Act does not prohibit two or more persons from associating together in an attempt
to persuade the legislature or the executive to take particular action with respect to a law that would produce a restraint or a
monopoly. Although such associations could perhaps, through a process of expansive construction, be brought within the general
proscription of ‘combination(s) ** in restraint of trade,’ they bear very little if any resemblance to the combinations normally
held violative of the Sherman Act, combinations ordinarily characterized by an express or implied agreement or understanding
that the participants will jointly give up their trade freedom, or help one another to take away the trade freedom of others through
the use of such devices as price-fixing agreements, boycotts, market-division agreements, and other similar arrangements. **16
This essential dissimilarity between an agreement jointly to seek legislation or law enforcement and the agreements traditionally
condemned by s 1 of the Act, even if not itself conclusive on the question of the applicability of the **137 Act, does constitute
a warning against treating the defendants' conduct as though it amounted to a common-law trade restraint. And we do think that
the question is conclusively settled, against the application of the Act, when this factor of essential dissimilarity is considered
along with the other difficulties that would be presented by a holding that the Sherman Act forbids associations for the purpose
of influencing the passage or enforcement of laws.

In the first place, such a holding would substantially impair the power of government to take actions through its legislature
and executive that operate to restrain trade. In a representative democracy such as this, these branches of government act on
behalf of the people and, to a very large extent, the whole concept of representation depends upon the ability of the people to
make their wishes known to their representatives. To hold that the government retains the power to act in this representative
capacity and yet hold, at the same time, that the people cannot freely inform the government of their wishes would impute
to the Sherman Act a purpose to regulate, not business activity, but political activity, a purpose which would have no basis
whatever in the legislative history of that Act. **17 Secondly, and of at least equal **530 significance, **138 such a construction
of the Sherman Act would raise important constitutional questions. The right of petition is one of the freedoms protected by
the Bill of Rights, and we cannot, of course, lightly impute to Congress an intent to invade these freedoms. Indeed, such an
imputation would be particularly unjustified in this case in view of all the countervailing considerations enumerated above.
For these reasons, we think it clear that the Sherman Act does not apply to the activities of the railroads at least insofar as
those activities comprised mere solicitation of governmental action with respect to the passage and enforcement of laws. We
are thus called upon to consider whether the courts below were correct in holding that, notwithstanding this principle, the Act
was violated here because of the presence in the railroads' publicity campaign of additional factors sufficient to take the case
out of the area in which the principle is controlling.

The first such factor relied upon was the fact, established by the finding of the District Court, that the railroads' sole purpose in
seeking to influence the passage and enforcement of laws was to destroy the truckers as competitors for the long-distance freight
business. But we do not see how this fact, even if adequately supported in the record, **18 could transform conduct otherwise
lawful **139 into a violation of the Sherman Act. All of the considerations that have led us to the conclusion that the Act does
not apply to mere group solicitation of governmental action are equally applicable in spite of the addition of this factor. The
right of the people to inform their representatives in government of their desires with respect to the passage or enforcement
of laws cannot properly be made to depend upon their intent in doing so. It is neither unusual nor illegal for people to seek
action on laws in the hope that they may bring about an advantage to themselves and a disadvantage to their competitors. This
Court has expressly recognized this fact in its opinion in United States v. Rock Royal Co-op., where it was said: ‘If ulterior
motives of corporate aggrandizement stimulated their activities, their efforts were not thereby rendered unlawful. If the Act and Order are otherwise valid, the fact that their effect would be to give cooperatives a monopoly of the market would not violate the Sherman Act * * * . 19 Indeed, it is quite probably people with just such a hope of personal advantage who provide much of the information upon which governments must act. A construction of the Sherman Act that would disqualify people from taking a public position on matters in **531 which they are financially interested would thus deprive the government of a valuable source of information and, at the same time, deprive the people of their right to petition in the very instances in which that right may be of the most importance to them. We reject such a construction of the Act and hold that, at least insofar *140 as the railroads' campaign was directed toward obtaining governmental action, its legality was not at all affected by any anticompetitive purpose it may have had.

The second factor relied upon by the courts below to justify the application of the Sherman Act to the railroads' publicity campaign was the use in the campaign of the so-called third-party technique. The theory under which this factor was related to the proscriptions of the Sherman Act, though not entirely clear from any of the opinions below, was apparently that it involved unethical business conduct on the part of the railroads. As pointed out above, the third-party technique, which was aptly characterized by the District Court as involving 'deception of the public, manufacture of bogus sources of reference, (and) distortion of public sources of information,' *142 depends upon giving propaganda actually circulated by a party in interest the appearance of being spontaneous declarations of independent groups. We can certainly agree with the courts below that this technique, though in widespread use among practitioners of the art of public relations, 20 is one which falls far short of the ethical standards generally approved in this country. It does not follow, however, that the use of the technique in a publicity campaign designed to influence governmental action constitutes a violation of the Sherman Act. Insofar as that Act sets up a code of ethics at all, it is a code that condemns trade restraints, not political activity, and, as we have already pointed out, a publicity campaign to influence governmental action falls clearly into the category *141 of political activity. The proscriptions of the Act, tailored as they are for the business world, are not at all appropriate for application in the political arena. Congress has traditionally exercised extreme caution in legislating with respect to problems relating to the conduct of political activities, a caution which has been reflected in the decisions of this Court interpreting such legislation. 21 All of this caution would go for naught if we permitted an extension of the Sherman Act to regulate activities of that nature simply because those activities have a commercial impact and involve conduct that can be termed unethical.

Moreover, we think the courts below themselves recognized this fact to some extent for their disposition of the case is inconsistent with the position that the use of the third-party technique alone could constitute a violation of the Sherman Act. This much is apparent from the fact that the railroads' counterclaim against the truckers was not allowed. Since it is undisputed that the truckers were as guilty as the railroads of the use of the technique, 22 this factor could not **532 have been in any sense controlling of the holding against the railroads. Rather, *142 it appears to have been relied upon primarily as an indication of the vicious nature of the campaign against the truckers. But whatever its purpose, we have come to the conclusion that the reliance of the lower courts upon this factor was misplaced and that the railroads' use of the third-party technique was, so far as the Sherman Act is concerned, legally irrelevant.

In addition to the foregoing factors, both of which relate to the intent and methods of the railroads in seeking governmental action, the courts below rested their holding that the Sherman Act had been violated upon a finding that the purpose of the railroads was ‘more than merely an attempt to obtain legislation. It was the purpose and intent * * * to hurt the truckers in every way possible even though they secured no legislation.’ (Emphasis in original.) Specifically, the District Court found that the purpose of the railroads was to destroy the goodwill of the truckers, among the public generally and among the truckers' customers particularly, in the hope that by doing so the over-all competitive position of the truckers would be weakened, and that the railroads were successful in these efforts to the extent that such injury was actually inflicted. The apparent effect of these findings is to take this case out of the category of those that involve restraints through governmental action and thus render inapplicable the principles announced above. But this effect is only apparent and cannot stand under close scrutiny. There are
no specific findings that the railroads attempted directly to persuade anyone not to deal with the truckers. Moreover, all of the
evidence in the record, both oral and documentary, deals with the railroads' efforts to influence the passage and enforcement
of laws. Circulars, speeches, newspaper articles, editorials, magazine articles, memoranda and all other documents discuss in
one way or another the railroads' charges that heavy trucks injure the roads, violate the \(\text{143}\) laws and create traffic hazards,
and urge that truckers should be forced to pay a fair share of the costs of rebuilding the roads, that they should be compelled to
obey the laws, and that limits should be placed upon the weight of the loads they are permitted to carry. In the light of this, the
findings of the District Court that the railroads' campaign was intended to and did in fact injure the truckers in their relationships
with the public and with their customers can mean no more than that the truckers sustained some direct injury as an incidental
effect of the railroads' campaign to influence governmental action and that the railroads were hopeful that this might happen.\(^{23}\)
Thus, the issue presented \(533\) by the lower courts' conclusion of a violation of the Sherman Act on the basis of this injury is
no different than the issue presented by the factors already discussed. It is inevitable, whenever an attempt is made to influence
legislation by a campaign of publicity, that an incidental effect of that campaign may be the infliction of some direct injury
upon the interests of the party against whom the campaign is directed. And it seems equally inevitable that those conducting
the campaign would be aware of, and possibly even pleased by, the prospect of such injury. To hold that the knowing infliction
of such injury renders the campaign itself illegal would thus be tantamount to outlawing \(\text{144}\) all such campaigns. We have
already discussed the reasons which have led us to the conclusion that this has not been done by anything in the Sherman Act.

There may be situations in which a publicity campaign, ostensibly directed toward influencing governmental action, is a mere
sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor
and the application of the Sherman Act would be justified. But this certainly is not the case here. No one denies that the railroads
were making a genuine effort to influence legislation and law enforcement practices. Indeed, if the version of the facts set forth in
the truckers' complaint is fully credited, as it was by the courts below, that effort was not only genuine but also highly successful.
Under these circumstances, we conclude that no attempt to interfere with business relationships in a manner proscribed by the
Sherman Act is involved in this case.

In rejecting each of the grounds relied upon by the courts below to justify application of the Sherman Act to the campaign of
the railroads, we have rejected the very grounds upon which those courts relied to distinguish the campaign conducted by the
truckers. In doing so, we have restored what appears to be the true nature of the case—a 'no-holds-barred fight'\(^{24}\) between two
industries both of which are seeking control of a profitable source of income.\(^{25}\) Inherent in such fights, which are commonplace
in the halls of legislative bodies, is the possibility, and in many instances even the probability, that one group or the other will
get hurt by the arguments that are made. \(145\) In this particular instance, each group appears to have utilized all the political
powers it could muster in an attempt to bring about the passage of laws that would help it or injure the other. But the contest itself
appears to have been conducted along lines normally accepted in our political system, except to the extent that each group has
deliberately deceived the public and public officials. And that deception, reprehensible as it is, can be of no consequence so far
as the Sherman Act is concerned. That Act was not violated by either the railroads or the truckers in their respective campaigns
to influence legislation and law enforcement. Since the railroads have acquiesced in the dismissal of their counterclaim by not
challenging the Court of Appeals' affirmation of that order in their petition for certiorari, we are here concerned only with those
parts of the judgments below holding the railroads and Byoir liable for violations of the Sherman Act. And it follows from what
we have said that those parts of the judgments below are wrong. They must be and are reversed.

Reversed.

All Citations

365 U.S. 127, 81 S.Ct. 523, 5 L.Ed.2d 464
Footnotes

1. ‘Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal: * * *’ 15 U.S.C. s 1, 15 U.S.C.A. s 1.

2. ‘Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a misdemeanor * * *’ 15 U.S.C. s 2, 15 U.S.C.A. s 2.

3. For a discussion of the mechanics of this technique and the purposes generally underlying its use by public relations firms, see Ross, The Image Merchants, at 118, 226—227 and 266—267.

4. The ‘Fair Truck Bill’ referred to was introduced in the Pennsylvania Legislature in May 1951, as Senate bill 615.

5. ‘Any person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws may sue therefor in any district court of the United States in the district in which the defendant resides or is found or has an agent, without respect to the amount in controversy, and shall recover threefold the damages by him sustained, and the cost of suit, including a reasonable attorney's fee.’ 15 U.S.C. s 15, 15 U.S.C.A. s 15.

6. The answer to the truckers’ complaint also interposed a number of other defenses, including the contention that the activities complained of were constitutionally protected under the First Amendment and the contention that the truckers were barred from prosecuting this suit by reason of the fact that they had themselves engaged in conduct identical to that about which they were complaining with regard to the railroads and were thus in pari delicto. Because of the view we take of the proper construction of the Sherman Act, we find it unnecessary to consider any of these other defenses.

7. The opinion of the District Court on the merits of the controversy is reported at 155 F.Supp. 768. An additional opinion dealing with the question of relief is reported at 166 F.Supp. 163. For reports of earlier opinions dealing with preliminary motions, see D.C., 113 F.Supp. 737; D.C., 14 F.R.D. 189, and D.C., 19 F.R.D. 146.

8. The District Court did not expressly find that any particular part of the railroads' publicity campaign was false in its content. Rather, it found that the technique of the railroads was ‘to take a dramatic fragment of truth and by emphasis and repetition distort it into falsehood.’ 155 F.Supp. at page 814.

9. If anything, the injunction was even broader than had been requested in the complaint for it effectively enjoined the defendants from any publicity activities against the truckers whether or not the third-party technique was used. See 166 F.Supp. at pages 172—173.

10. The trial court did recognize that on at least one occasion the truckers attempted to encourage legislation that would have been directly harmful to the railroads rather than beneficial to themselves. Thus, the court found: ‘About the middle of the decade (the 1940's) PMTA had a tax manual prepared charging that the railroads of Pennsylvania themselves did not pay their fair share of taxes as compared with other states and made a wide distribution of it to legislators, banks, security investment houses, etc.’ The trial court found, however, that this action of the truckers also lay within the rule of reason because ‘the truckers had been the target of a strong campaign directed to the public with the purpose of convincing the public that trucks did not pay their fair share of taxes,’ thus making it necessary for the truckers to ‘be permitted

81 S.Ct. 523, 5 L.Ed.2d 464

to likewise show the public that their competitors, the railroads, were actually guilty of the fault charged against the truckers." 155 F.Supp. at page 803.

273 F.2d 218. Chief Judge Biggs dissented from the opinion of the majority of the Court of Appeals insofar as it upheld the District Court's conclusion that the railroads and Byoir had violated the Sherman Act. For similar reasons, he concurred in that part of the majority opinion which upheld the conclusion that the truckers had not violated the Act.

362 U.S. 947, 80 S.Ct. 862, 4 L.Ed.2d 866.


Id., 221 U.S. at page 57, 31 S.Ct. at page 514.


See Apex Hosiery Co. v. Leader, 310 U.S. 469, 491—493, 60 S.Ct. 982, 990—992, 84 L.Ed. 1311.

In Parker v. Brown, supra, this Court was unanimous in the conclusion that the language and legislative history of the Sherman Act would not warrant the invalidation of a state regulatory program as an unlawful restraint upon trade. In so holding, we rejected the contention that the program's validity under the Sherman Act was affected by the nature of the political support necessary for its implementation—a contention not unlike that rejected here. The reasoning underlying that conclusion was stated succinctly by Mr. Chief Justice Stone: 'Here the state command to the Commission and to the program committee of the California Prorate Act is not rendered unlawful by the Sherman Act since, in view of the latter's words and history, it must be taken to be a prohibition of individual and not state action. It is the state which has created the machinery for establishing the prorate program. Although the organization of a prorate zone is proposed by producers, and a prorate program, approved by the Commission, must also be approved by referendum of producers, it is the state, acting through the Commission, which adopts the program and which enforces it with penal sanctions, in the execution of a governmental policy. The prerequisite approval of the program upon referendum by a prescribed number of producers is not the imposition by them of their will upon the minority by force of agreement or combination which the Sherman Act prohibits. The state itself exercises its legislative authority in making the regulation and in prescribing the conditions of its application.' 317 U.S., at page 352, 63 S.Ct. at page 314.

A study of the record reveals that the only evidence or subsidiary findings upon which this conclusory finding could be based is the undisputed fact that the railroads did seek laws by arguments and propaganda that could have had the effect of damaging the competitive position of the truckers. There is thus an absence of evidence of intent independent of the efforts that were made to influence legislation and law enforcement. We nonetheless accept the finding of the District Court on this issue for, in our view, the disposition of this case must be the same regardless of that fact.


The extent to which the third-party technique is utilized in the public relations field is demonstrated by the fact, found by the District Court, that each of the several public relations firms interviewed by the railroads before they finally decided to hire the Byoir organization to conduct their publicity campaign included the use of this technique in its outline of proposed activities submitted for consideration by the railroads. See 155 F.Supp. at page 778.


81 S.Ct. 523, 5 L.Ed.2d 464

22 The District Court expressly recognized this fact in its opinion: ‘The record discloses that both sides used, or wanted to use, fronts and/or the propaganda technique.’ 155 F.Supp. at page 816. This conclusion was amply supported by specific findings. Thus, the court found: ‘The record establishes that the truckers wrote to and made personal contacts with legislators in support of bills increasing the weight of trucks; that they had representatives of other industries write and make personal contacts with legislators in Harrisburg without disclosing trucker connections; and that they had such persons intentionally refrain from advising the legislators and the said officials that the letters and contacts had been solicited; that they solicited from legislators statements in support of their position and had news releases issued thereon.’ 155 F.Supp. at page 803.

23 Here again, the petitioners have leveled a vigorous attack upon the trial court's findings. As a part of this attack, they urge that there is no basis in reason for the finding that some shippers quit doing business with the truckers as a result of the railroads' publicity campaign. Their contention is that since the theme of the campaign was that the truckers had an unfair competitive advantage and could consequently charge unfairly low prices, the campaign would have encouraged, rather than discouraged, shippers who availed themselves of the truckers' services. This argument has considerable appeal but, as before, we find it unnecessary to pass upon the validity of these findings for we think the conclusion must be the same whether they are allowed to stand or not.

24 We borrow this phrase from the dissenting opinion below of Chief Judge Biggs.

25 Since the commencement of this litigation, a new bill increasing truck-weight limits has passed the Pennsylvania Legislature and has become law by virtue of the Governor's approval. Thus, the fight goes on.
United Mine Workers of America v. Pennington, 381 U.S. 657 (1965)
85 S.Ct. 1585, 14 L.Ed.2d 626

85 S.Ct. 1585
Supreme Court of the United States

UNITED MINE WORKERS OF AMERICA, Petitioner,

v.

James M. PENNINGTON et al.

No. 48


Decided June 7, 1965.

Synopsis

Antitrust case by small coal mine operators against coal miners' union on basis of industry-wide collective bargaining agreement whereby employers and union agreed on wage scale that exceeded financial ability of some operators to pay for purpose of forcing some employers out of business. The United States District Court for the Eastern District of Tennessee awarded damages, and an appeal was taken. The Court of Appeals for the Sixth Circuit, 325 F.2d 804, affirmed, and certiorari was granted. The Supreme Court, Mr. Justice White, held that the jury should have been instructed that joint efforts to influence public officials do not violate the antitrust laws even though intended to eliminate competition and that such conduct is not illegal, either standing alone or as part of a broader scheme itself violative of the Sherman Act, and that the failure to so instruct was not mere harmless error.

Reversed and remanded for further proceedings.

Mr. Justice Goldberg, Mr. Justice Harlan and Mr. Justice Stewart dissented from opinion but concurred in reversal, see 85 S.Ct. 1607.

Attorneys and Law Firms

**1587  *658  Harrison Combs, Washington, D.C., for petitioner.

John A. Rowntree, Knoxville, Tenn., for respondents.

Theodore J. St. Antoine, Washington, D.C., for American Federation of Labor and Congress of Industrial *659 Organizations, as amicus curiae.

Opinion

Mr. Justice WHITE delivered the opinion of the Court.

This action began as a suit by the trustees of the United Mine Workers of America Welfare and Retirement Fund against the respondents, individually and as owners of Phillips Brothers Coal Company, a partnership, seeking to recover some $55,000 in royalty payments alleged to be due and payable under the trust provisions of the National Bituminous Coal Wage Agreement of 1950, as amended, **1588 September 29, 1952, executed by Phillips and United Mine Workers of America on or about October 1, 1953, and reexecuted with amendments on or about September 8, 1955, and October 22, 1956. Phillips filed an answer and a cross claim against UMW, alleging in both that the trustees, the UMW and certain large coal operators had conspired to restrain...
United Mine Workers of America v. Pennington, 381 U.S. 657 (1965)

and to monopolize interstate commerce in violation of ss 1 and 2 of the Sherman Antitrust Act, as amended, 26 Stat. 209, 15 U.S.C. ss 1, 2 (1958 ed.). Actual damages in the amount of $100,000 were claimed for the period beginning February 14, 1954, and ending December 31, 1958. ¹

The allegations of the cross claim were essentially as follows: Prior to the 1950 Wage Agreement between the operators and the union, severe controversy had existed in the industry, particularly over wages, the welfare fund and the union's efforts to control the working time of its members. Since 1950, however, relative peace has existed in the industry, all as the result of the 1950 Wage Agreement and its amendments and the additional understandings entered into between UMW and the large operators. Allegedly the parties considered overproduction to be the critical problem of the coal industry. The agreed solution was to be the elimination of the smaller companies, the larger companies thereby controlling the market. More specifically, the union abandoned its efforts to control the working time of the miners, agreed not to oppose the rapid mechanization of the mines which would substantially reduce mine employment, agreed to help finance such mechanization and agreed to impose the terms of the 1950 agreement on all operators without regard to their ability to pay. The benefit to the union was to be increased wages as productivity increased with mechanization, these increases to be demanded of the smaller companies whether mechanized or not. Royalty payments into the welfare fund were to be increased also, and the union was to have effective control over the fund's use. The union and large companies agreed upon other steps to exclude the marketing, production, and sale of nonunion coal. Thus the companies agreed not to lease coal lands to nonunion operators, and in 1958 agreed not to sell or buy coal from such companies. The companies and the union jointly and successfully approached the Secretary of Labor to obtain establishment under the Walsh-Healey Act, as amended, 49 Stat. 2036, 41 U.S.C. s 35 et seq. (1958 ed), of a minimum wage for employees of contractors selling coal to the TVA, such minimum wage being much higher than in other industries and making it difficult for small companies to compete in the TVA term contract market. At a later time, at a meeting attended by both union and company representatives, the TVA was urged to curtail its spot market purchases, a substantial portion of which were exempt from the Walsh-Healey order. Thereafter four of the larger companies waged a destructive and collusive price-cutting campaign in the TVA spot market for coal, two of the companies, West Kentucky Coal Co. and its subsidiary Nashville Coal Co., being those in which the union had large investments and over which it was in position to exercise control.

The complaint survived motions to dismiss and after a five-week trial before a jury, a verdict was returned in favor of Phillips and against the trustees and the union, the damages against the union being fixed in the amount of $90,000, to be trebled under 15 U.S.C. s 15 (1958 ed.). The trial court set aside the verdict against the trustees but overruled the union's motion for judgment notwithstanding the verdict or in the alternative for a new trial. The Court of Appeals affirmed. 325 F.2d 804. It ruled that the union was not exempt from liability under the Sherman Act on the facts of this case, considered the instructions adequate and found the evidence generally sufficient to support the verdict. We granted certiorari. 377 U.S. 929, 84 S.Ct. 1333, 12 L.Ed.2d 294. We reverse and remand the case for proceedings consistent with this opinion.

I.

We first consider UMW's contention that the trial court erred in denying its motion for a directed verdict and for judgment notwithstanding the verdict, since a determination in UMW's favor on this issue would finally resolve the controversy. The question presented by this phase of the case is whether in the circumstances of this case the union is exempt from liability under the antitrust laws. We think the answer is clearly in the negative and that the union's motions were correctly denied.

But neither s 20 nor s 4 expressly deals with arrangements or agreements between unions and employers. Neither section tells us whether any or all such arrangements or agreements are barred or permitted by the antitrust laws. Thus Hutcheson itself stated:

‘So long as a union acts in its self-interest and does not combine with non-labor groups, the licit and the illicit under s 20 are not to be distinguished by any judgment regarding the wisdom or unwisdom, the rightness or wrongness, the selfishness or unselfishness of the end of which the particular union activities are the means.’ 312 U.S., at 232, 61 S.Ct. at 466. (Emphasis added.)

And in Allen Bradley Co. v. Local Union No. 3, IBEW, 325 U.S. 797, 65 S.Ct. 1533, 89 L.Ed. 1939, this Court made explicit what had been merely a qualifying expression in Hutcheson and held that ‘when the unions participated with a combination of business men who had complete power to eliminate all competition among themselves and to prevent all competition from others, a situation was created not included with the exemptions of the Clayton and Norris-LaGuardia Acts.’ Id., 325 U.S. at 809, 65 S.Ct. at 1540. See also United Brotherhood of Carpenters v. United States, 330 U.S. 395, 398—400, 47 S.Ct. 775, 778, 91 L.Ed. 973; United States v. Employing Plasterers Assn., 347 U.S. 186, 190, 74 S.Ct. 452, 454, 98 L.Ed. 618. Subsequent cases have applied the Allen Bradley doctrine to such combinations without regard to whether they found expression in a collective bargaining agreement, United Brotherhood *663 of Carpenters v. United States, supra; see Local 24 of International Brotherhood of Teamsters, etc., v. Oliver, 358 U.S. 283, 296, 79 S.Ct. 297, 304, 3 L.Ed.2d 312; and even though the mechanism for effectuating the purpose of the combination was an agreement on wages, see Adams Dairy Co. v. St. Louis Dairy Co., 260 F.2d 46 (C.A.8th Cir. 1958), or on hours of work, Philadelphia Record Co. v. Manufacturing Photo-Engravers Assn., 155 F.2d 799 (C.A.3d Cir. 1946).

If the UMW in this case, in order to protect its wage scale by maintaining **1590 employer income, had presented a set of prices at which the mine operators would be required to sell their coal, the union and the employers who happened to agree could not successfully defend this contract provision if it were challenged under the antitrust laws by the United States or by some party injured by the arrangement. Cf. Allen Bradley Co. v. Local Union No. 3, IBEW, 325 U.S. 797, 65 S.Ct. 1533, 89 L.Ed. 1939; United States v. Borden Co., 308 U.S. 188, 203—205, 308 U.S. 188, 203—205, 60 S.Ct. 182, 190, 191, 84 L.Ed. 181; Lumber Prods. Assn. v. United States, 144 F.2d 546, 548 (C.A.9th Cir. 1944), aff’d on this issue sub nom. United Brotherhood of Carpenters v. United States, 330 U.S. 395, 398—400, 67 S.Ct. 775, 777, 778, 91 L.Ed. 973; Las Vegas Merchant Plumbers Assn. v. United States, 210 F.2d 732 (C.A.9th Cir. 1954), cert. denied, 348 U.S. 817, 75 S.Ct. 29, 99 L.Ed. 645; Local 175, IBEW v. United States, 219 F.2d 431 (C.A.6th Cir. 1955), cert. denied, 349 U.S. 917, 75 S.Ct. 606, 99 L.Ed. 1250. In such a case, the restraint on the product market is direct and immediate, is of the type characteristically deemed unreasonable under the Sherman Act and the union gets from the promise nothing more concrete than a hope for better wages to come.

Likewise, if as is alleged in this case, the union became a party to a collusive bidding arrangement designed to drive Phillips and others from the TVA spot market, we think any claim to exemption from antitrust liability would be frivolous at best. For this reason alone the motions of the unions were properly denied.

*664 A major part of Phillips' case, however, was that the union entered into a conspiracy with the large operators to impose the agreed-upon wage and royalty scales upon the smaller, nonunion operators, regardless of their ability to pay and regardless of whether or not the union represented the employees of these companies, all for the purpose of eliminating them from the industry, limiting production and pre-empting the market for the large, unionized operators. The UMW urges that since such an agreement concerned wage standards, it is exempt from the antitrust laws.

It is true that wages lie at the very heart of those subject about which employers and unions must bargain and the law contemplates agreements on wages not only between individual employers and a union but agreements between the union and employers in a multi-employer bargaining unit. National Labor Relations Board v. Truck Drivers Union, 353 U.S. 87, 94—96,
United Mine Workers of America v. Pennington, 381 U.S. 657 (1965)

77 S.Ct. 643, 646—647, 1 L.Ed.2d 676. The union benefit from the wage scale agreed upon is direct and concrete and the effect on the product market, though clearly present, results from the elimination of competition based on wages among the employers in the bargaining unit, which is not the kind of restraint Congress intended the Sherman Act to proscribe. Apex Hosiery Co. v. Leader, 310 U.S. 469, 503—504, 60 S.Ct. 982, 997, 84 L.Ed. 1311; see Adams Dairy Co. v. St. Louis Dairy Co., 260 F.2d 46 (C.A.8th Cir. 1958). We think it beyond question that a union may conclude a wage agreement with the multi-employer bargaining unit without violating the antitrust laws and that it may as a matter of its own policy, and not by agreement with all or part of the employers of that unit, seek the same wages from other employers.

This is not to say that an agreement resulting from union-employer negotiations is automatically exempt from Sherman Act scrutiny simply because the negotiations involve a compulsory subject of bargaining, regardless of the subject or the form and content of the agreement. Unquestionably the Board's demarcation of the bounds of the duty to bargain has great relevance to any consideration of the sweep of labor's antitrust immunity, for we are concerned here with harmonizing the Sherman Act with the national policy expressed in the National Labor Relations Act of promoting the peaceful settlement of industrial disputes by subjecting labor-management controversies to the mediatory influence of negotiation, Fibreboard Paper Prods. Corp. v. National Labor Relations Board, 379 U.S. 203, 211, 85 S.Ct. 398, 403, 13 L.Ed.2d 233. But there are limits to what a union or an employer may offer or extract in the name of wages, and because they must bargain does not mean that the agreement reached may disregard other laws. Local 24 of Intern. Broth. of Teamsters, etc. v. Oliver, 358 U.S. 283, 296, 79 S.Ct. 297, 304, 3 L.Ed.2d 312; United Brotherhood of Carpenters v. United States, 330 U.S. 395, 399—400, 67 S.Ct. 775, 778, 91 L.Ed. 973.

We have said that a union may make wage agreements with a multiemployer bargaining unit and may in pursuance of its own union interests seek to obtain the same terms from other employers. No case under the antitrust laws could be made out on evidence limited to such union behavior. But we think a union forfeits its exemption from the antitrust laws when it is clearly shown that it has agreed with one set of employers to impose a certain wage scale on other bargaining units. One group of employers may not conspire to eliminate competitors from the industry and the union is liable with the employers if it becomes a party to the conspiracy. This is true even though the union's part in the scheme is an undertaking to secure the same wages, hours or other conditions of employment from the remaining employers in the industry.

We do not find anything in the national labor policy that conflicts with this conclusion. This Court has recognized that a legitimate aim of any national labor organization is to obtain uniformity of labor standards and that a consequence of such union activity may be to eliminate competition based on differences in such standards. Apex Hosiery Co. v. Leader, 310 U.S. 469, 503, 60 S.Ct. 982, 997, 84 L.Ed. 1311. But there is nothing in the labor policy indicating that the union and the employers in one bargaining unit are free to bargain about the wages, hours and working conditions of other bargaining units or to attempt to settle these matters for the entire industry. On the contrary, the duty to bargain unit by unit leads to a quite different conclusion. The union's obligation to its members would seem best served if the union retained the ability to respond to each bargaining situation as the individual circumstances might warrant, without being strait-jacketed by some prior agreement with the favored employers.

So far as the employer is concerned it has long been the Board's view that an employer may not condition the signing of a collective bargaining agreement on the union's organization of a majority of the industry. American Range Lines, Inc., 13 N.L.R.B. 139, 147 (1939); Samuel Youlin, 22 N.L.R.B. 879, 885 (1940); Newton Chevrolet, Inc., 37 N.L.R.B. 334, 341 (1941); see National Labor Relations Board v. George P. Pilling & Son Co., 119 F.2d 32, 38 (C.A.3d Cir. 1941). In such cases the obvious interest of the employer is to ensure that acceptance of the union's wage demands will not adversely affect his competitive position. In American Range Lines, Inc., supra, the Board rejected that employer interest as a justification for the demand. ‘(A) employer cannot lawfully deny his employees the right to bargain collectively through their designated representative in an appropriate unit because he envisions competitive disadvantages accruing from such bargaining.’ 13 N.L.R.B., at 147. Such an employer condition, if upheld, would clearly reduce the extent of collective bargaining. Thus, in
Newton Chevrolet, Inc., supra, where it was held a refusal to bargain for the employer to insist on a provision that the agreed contract terms would not become effective until five competitors had signed substantially similar contracts, the Board stated that ‘(t)here is nothing in the Act to justify the imposition of a duty upon an exclusive bargaining representative to secure an agreement from a majority of an employer's competitors as a condition precedent to the negotiation of an agreement with the employer. To permit individual employers to refuse to bargain collectively until some or all of their competitors had done so clearly would lead to frustration of the fundamental purpose of the Act to encourage the practice of collective bargaining.’ 37 N.L.R.B., at 341. Permitting insistence on an agreement by the union to attempt to impose a similar contract on other employers would likewise seem to impose a restraining influence on the extent of collective bargaining, for the union could avoid an impasse only by surrendering its freedom to act in its own interest vis-a-vis other employers, something it will be unwilling to do in many instances. Once again, the employer's interest is a competitive interest rather than an interest in regulating its own labor relations, and the effect on the union of such an agreement would be to limit the free exercise of the employees' right to engage in concerted activities according to their own views of their self-interest. In sum, we cannot conclude that the national labor policy provides any support for such agreements.

On the other hand, the policy of the antitrust laws is clearly set against employer-union agreements seeking to prescribe labor standards outside the bargaining unit. One could hardly contend, for example, that one group of employers could lawfully demand that the union impose on other employers wages that were significantly higher than those paid by the requesting employers, or a system of computing wages that, because of differences in methods of production, would be more costly to one set of employers than to another. The anticompetitive potential of such a combination is obvious, but is little more severe than what is alleged to have been the purpose and effect of the conspiracy in this case to establish wages at a level that marginal producers could not pay so that they would be driven from the industry. And if the conspiracy presently under attack were declared exempt it would hardly be possible to deny exemption to such avowedly discriminatory schemes.

From the viewpoint of antitrust policy, moreover, all such agreements between a group of employers and a union that the union will seek specified labor standards outside the bargaining unit suffer from a more basic defect, without regard to predatory intention or effect in the particular case. For the salient characteristic of such agreements is that the union surrenders its freedom of action with respect to its bargaining policy. Prior to the agreement the union might seek uniform standards in its own self-interest but would be required to assess in each case the probable costs and gains of a strike or other collective action to that end and thus might conclude that the objective of uniform standards should temporarily give way. After the agreement the union's interest would be bound in each case to that of the favored employer group. It is just such restraints upon the freedom of economic units to act according to their own choice and discretion that run counter to antitrust policy. See, e.g., Associated Press v. United States, 326 U.S. 1, 19, 65 S.Ct. 1416, 1424, 89 L.Ed. 2013; Fashion Originators' Guild v. Federal Trade Comm'n, 312 U.S. 457, 465, 61 S.Ct. 703, 706, 85 L.Ed. 949; Anderson v. Shipowners Assn., 272 U.S. 359, 364—365, 47 S.Ct. 125, 71 L.Ed. 298.

Thus the relevant labor and antitrust policies compel us to conclude that the alleged agreement between UMW and the large operators to secure uniform labor standards throughout the industry, if proved, was not exempt from the antitrust laws.

II.

The UMW next contends that the trial court erroneously denied its motion for a new trial based on claimed errors in the admission of evidence.

In Eastern R. R. Presidents Conf. v. Noerr Motor Freight Inc., 365 U.S. 127, 81 S.Ct. 523, 5 L.Ed.2d 464, the Court rejected an attempt to base a Sherman Act conspiracy on evidence consisting entirely of activities of competitors seeking to influence public officials. The Sherman Act, it was held, was not intended to bar concerted action of this kind even though the resulting
United Mine Workers of America v. Pennington, 381 U.S. 657 (1965)

85 S.Ct. 1585, 14 L.Ed.2d 626

official action damaged other competitors at whom the campaign was aimed. Furthermore, the legality of the conduct ‘was not at all affected by any anticompetitive purpose it may have had,’ id., at 140, 81 S.Ct. at 531—even though the ‘sole purpose in seeking to influence the passage and enforcement of laws was to destroy the truckers as competitors for the long-distance freight business,’ Id., at 138, 81 S.Ct. at 530. Nothing could be clearer from the Court's opinion than that anticompetitive purpose did not illegalize the conduct there involved.

We agree with the UMW that both the Court of Appeals and the trial court failed to take proper account of the Noerr case. In approving the instructions of the trial court with regard to the approaches of the union and the operators to the Secretary of Labor and to the TVA officials, the Court of Appeals considered Noerr as applying only to conduct ‘unaccompanied by a purpose or intent to further a conspiracy to violate a statute. It is *670 the illegal purpose or intent inherent in the conduct which vitiates the conduct which would otherwise be legal.’ 325 F.2d, at 817. Noerr shields from the Sherman Act a concerted effort to influence public officials regardless of intent or purpose. The Court of Appeals, however, would hold the conduct illegal depending upon proof of an illegal purpose.

The instructions of the trial court to the jury exhibit a similar infirmity. The jury was instructed that the approach to the Secretary of Labor was legal unless part of a conspiracy to drive small operators out of business and that the approach to the TVA was not a violation of the antitrust laws ‘unless the parties so urged the TVA to modify its policies in buying coal for the purpose of driving the small operators out of business.’ If, therefore, the jury determined the requisite anticompetitive purpose to be present, it was free to find an illegal conspiracy based solely on the Walsh-Healey and TVA episodes, or in any event to attribute illegality to these acts as part of a general plan to eliminate Phillips and other operators similarly situated. Neither finding, however, is permitted by Noerr for the reasons stated in that case. Joint efforts to influence public officials do not violate the antitrust laws even though intended to eliminate competition. Such conduct is not illegal, either standing alone or as part of a broader scheme itself violative of the Sherman Act. The jury should have been so instructed and, given the obviously telling nature of this evidence, we cannot hold this lapse to be mere harmless error. 3

**1594**  *671* There is another reason for remanding this case for further proceedings in the lower courts. It is clear under Noerr that Phillips could not collect any damages under the Sherman Act for any injury which it suffered from the action of the Secretary of Labor. The conduct of the union and the operators did not violate the Act, the action taken to set a minimum wage for government purchases of coal was the act of a public official who is not claimed to be a co-conspirator, and the jury should have been instructed, as UMW requested, to exclude any damages which Phillips may have suffered as a result of the Secretary's Walsh-Healey determinations. 4 See also American Banana Co. v. United Fruit Co., 213 U.S. 347, 358, 29 S.Ct. 511, 513, 53 L.Ed. 826; Angle v. Chicago, St. Paul, Minneapolis & Omaha R. Co., 151 U.S. 1, 16—21, 14 S.Ct. 240, 245, 247, 38 L.Ed. 55; Okefenokee Rural Elec. Mem. Corp. v. Florida P. & L. Co., 214 F.2d 413, 418 (C.A.5th Cir. 1954). The trial court, however, admitted evidence *672 concerning the Walsh-Healey episodes for ‘whatever bearing it may have on the overall picture’ and told the jury in its final instructions to include in the verdict all damages resulting directly from any act which was found to be part of the conspiracy. The effect this may have had on the jury is reflected by the statement of the Court of Appeals that the jury could reasonably conclude ‘that the wage determination for the coal industry under the Walsh-Healey Act and the dumping of West Kentucky coal on the TVA spot market materially and adversely affected the operations of Phillips in the important TVA market * * *,’ 325 F.2d, at 815, and that ‘(t)his minimum wage determination prevented Phillips from bidding on the TVA term market * * *,’ id., at 814. 5

The judgment is reversed and the case remanded for further proceedings consistent with this opinion. It is so ordered.

Reversed and remanded.

Mr. Justice DOUGLAS, with whom Mr. Justice BLACK, and Mr. Justice CLARK agree, concurring.
**1595** As we read the opinion of the Court, it reaffirms the principles of *Allen Bradley Co. v. Local Union, No. 3, IBEW, 325 U.S. 797, 65 S.Ct. 1533, 89 L.Ed. 1939*, and tells the trial judge:

First. On the new trial the jury should be instructed that if there were an industry-wide collective bargaining agreement whereby employers and the union agreed on a *673* wage scale that exceeded the financial ability of some operators to pay and that if it was made for the purpose of forcing some employers out of business, the union as well as the employers who participated in the arrangement with the union should be found to have violated the antitrust laws.

Second. An industry-wide agreement containing those features is prima facie evidence of a violation.

In *Allen Bradley Co. v. Union, No. 3, IBEW*, supra, the union was promoting closed shops in the New York City area. It got contractors to purchase equipment only from local manufacturers who had closed-shop agreements with the union; and it got manufacturers to confine their New York City sales to contractors employing the union's members. Agencies were set up to boycott recalcitrant local contractors and manufacturers and bar from the area equipment manufactured outside its boundaries. As we said:

‘The combination among the three groups, union, contractors, and manufacturers, became highly successful from the standpoint of all of them. The business of New York City manufacturers had a phenomenal growth, thereby multiplying the jobs available for the Local's members. Wages went up, hours were shortened, and the New York electrical equipment *674* prices soared, to the decided financial profit of local contractors and manufacturers.’ *325 U.S.*, at 800, 65 S.Ct., at 1535.

I repeat what we said in *Allen Bradley Co. v. Union No. 3, IBEW*, supra, *325 U.S.*, at 811, 65 S.Ct., at 1540:

‘The difficulty of drawing legislation primarily aimed at trusts and monopolies so that it could also be applied to labor organizations without impairing the collective bargaining and related rights of those organizations has been emphasized both by congressional and judicial attempts to draw lines between permissible and prohibited union activities. There is, however, one line which we can draw with assurance that we follow the congressional purpose. We know that Congress feared the concentrated power of business organizations to dominate markets and prices. It intended to outlaw business monopolies. A business monopoly is no less such because a union participates, and such participation is a violation of the (Sherman) Act.’

Congress can design an oligopoly for our society, if it chooses. But business alone cannot do so as long as the antitrust laws are enforced. Nor should business and labor working hand-in-hand be allowed to make that basic change in the design of our so-called free enterprise **1596** system. If the allegations in this case are to be believed, organized labor joined hands with organized business to drive marginal operators out of existence. According to those allegations the union used its control over West Kentucky Coal Co. and Nashville Coal Co. to dump coal at such low prices that respondents, who were small operators, had to abandon their business. According to those allegations there was a boycott by the union and the major companies against small companies who needed major companies' coal land on which to operate. According *675* to those allegations, high wage and welfare terms of employment were imposed on the small, marginal companies by the union and the major companies with the knowledge and intent that the small ones would be driven out of business.

The only architect of our economic system is Congress. We are right in adhering to its philosophy of the free enterprise system as expressed in the antitrust laws and as enforced by *Allen Bradley Co. v. Union*, supra, until the Congress delegates to big business and big labor the power to remodel our economy in the manner charged here.

All Citations

381 U.S. 657, 85 S.Ct. 1585, 14 L.Ed.2d 626
Footnotes

1 The parties stipulated that the damages period would include the four-year limitation period, 15 U.S.C. s 15b (1958 ed.), preceding the filing of Phillips' cross claim and extend up to December 31, 1958, the date on which Phillips terminated its business.

2 Unilaterally, and without agreement with any employer group to do so, a union may adopt a uniform wage policy and seek vigorously to implement it even though it may suspect that some employers cannot effectively compete if they are required to pay the wage scale demanded by the union. The union need not gear its wage demands to wages which the weakest units in the industry can afford to pay. Such union conduct is not alone sufficient evidence to maintain a union-employer conspiracy charge under the Sherman Act. There must be additional direct or indirect evidence of the conspiracy. There was, of course, other evidence in this case, but we indicate no opinion as to its sufficiency.

3 It would of course still be within the province of the trial judge to admit this evidence, if he deemed it probative and not unduly prejudicial, under the ‘established judicial rule of evidence that testimony of prior or subsequent transactions, which for some reason are barred from forming the basis for a suit, may nevertheless be introduced if it tends reasonably to show the purpose and character of the particular transactions under scrutiny. Standard Oil Co. v. United States, 221 U.S. 1, 46, 47, 31 S.Ct. 502, 510, 55 L.Ed. 619. United States v. Reading Co., 253 U.S. 26, 43—44, 40 S.Ct. 425, 427, 428, 64 L.Ed. 760.’ Federal Trade Comm’n v. Cement Institute, 333 U.S. 683, 705, 68 S.Ct. 793, 805, 92 L.Ed. 1010; see also Heike v. United States, 227 U.S. 131, 145, 33 S.Ct. 226, 229, 57 L.Ed. 450; American Medical Assn. v. United States, 76 U.S.App.D.C. 70, 87—89, 130 F.2d 233, 250—252 (1942), aff’d. 317 U.S. 519, 63 S.Ct. 326, 87 L.Ed. 434 (certiorari limited to other issues).

4 By contrast, in Continental Ore Co. v. Union Carbide & Carbon Corp., 370 U.S. 690, 82 S.Ct. 1404, 8 L.Ed.2d 777, we held that the acts of a wartime purchasing agent appointed by the Canadian Government could be proved as part of the conspiracy and as an element in computing damages. The purchasing agent, however, was not a public official but the wholly owned subsidiary of an American corporation alleged to be a principal actor in the conspiracy. The acts complained of had been performed at the direction of the purchasing agent's American parent and there was ‘no indication that the Controller or any other official within the structure of the Canadian Government approved or would have approved of joint efforts to monopolize the production and sale of vanadium or directed that purchases from (the plaintiff) be stopped.’ 370 U.S. at 706, 82 S.Ct., at 1414. That case is wholly dissimilar to both Noerr and the present case.

5 This latter conclusion regarding the term market would seem doubly erroneous as Phillips had virtually conceded, in the course of offering evidence respecting bids of the alleged conspirators on the term market, that it was claiming no damages from its exclusion from the term market, a market it never had any immediate prospect of entering. The trial court ruled that the proffered testimony was inadmissible on the damages phase of the case.

* ‘It is elementary that an unlawful conspiracy may be and often is formed without simultaneous action or agreement on the part of the conspirators. United States v. Schenck, D.C., 253 F. 212, 213, affirmed 249 U.S. 47, 39 S.Ct. 247, 63 L.Ed. 470; Levey v. United States, 9 Cir., 92 F.2d 688, 691. Acceptance by competitors, without previous agreement, of an invitation to participate in a plan, the necessary consequence of which, if carried out, is restraint of interstate commerce, is sufficient to establish an unlawful conspiracy under the Sherman Act. Eastern States Retail Lumber Dealers' Association v. United States, 234 U.S. 600, 34 S.Ct. 951, 58 L.Ed. 1490; Lawlor v. Loewe, 235 U.S. 522, 534, 35 S.Ct. 170, 171, 59 L.Ed. 341; American Column & Lumber Co. v. United States, 257 U.S. 377, 42 S.Ct. 114, 66 L.Ed. 284; United States
United Mine Workers of America v. Pennington, 381 U.S. 657 (1965)

85 S.Ct. 1585, 14 L.Ed.2d 626

68 S.Ct. 550, 92 L.Ed. 701, 76 U.S.P.Q. 399

68 S.Ct. 550
Supreme Court of the United States

UNITED STATES
v.
LINE MATERIALS CO. et al.

No. 8.

Reargued Nov. 12, 13, 1947.

Decided March 8, 1948.

Synopsis

Suit by the United States of America against the Line Material Company and others to obtain an injunction under the Sherman Act against continuance of violations of that act by an allegedly unlawful combination or conspiracy between defendants, through contracts, to restrain interstate trade in certain patented electrical devices. From a decree of dismissal, 64 F.Supp. 970, the plaintiff appeals.

Decree reversed and case remanded.

Mr. Justice BURTON, Mr. Chief Justice VINSON, and Mr. Justice FRANKFURTER dissenting.

Attorneys and Law Firms

**551  *288  Mr. Frederick Bernays Wiener, of Providence, R.I., for appellant.

Mr. John Lord O'Brien, of Washington, D.C., for appellees.

Mr. Albert R. Connelly, of New York City, for appellee, Westinghouse Electric Corporation.

Appeal from the District Court of the United States for the Eastern District of Wisconsin.

Opinion

Mr. Justice REED delivered the opinion of the Court.

The United States sought an injunction under ss 1 and 4 of the Sherman Act in the District Court against continuance of violations of that Act by an allegedly unlawful combination or conspiracy between appellees, through contracts, to restrain interstate trade in certain patented electrical devices. The restraint alleged arose from a cross-license arrangement between the patent owners, Line Material Company and Southern States Equipment Corporation, to fix the sale price of the devices to which arrangement the other appellees, licensees to make and vend, adhered by supplemental contracts.

**552  The District Court, 64 F.Supp. 970, dismissed the complaint as to all defendants upon its conclusion that the rule of United States v. General Electric Co., 272 U.S. 476, 47 S.Ct. 192, 71 L.Ed. 362, was controlling. That case approved as lawful a patentee's license to make and vend which required the licensee in its sales of the patented devices to conform to the licensor's
I. The Facts.

The challenged arrangements enter around three product patents, which are useful in protecting an electric circuit from the dangers incident to a short circuit or other overload. Two of them are dropout fuse cutouts and the third is a housing suitable for use with any cutout. Dropout fuse cutouts may be used without any housing. The District Court found that 40.77% of all cutouts manufactured and sold by these defendants were produced under these patents. This was substantially all the dropout fuse cutouts made in the United States. There are competitive devices that perform the same functions manufactured by appellees and others under different patents than those here involved.

The challenged arrangements enter around three product patents, which are useful in protecting an electric circuit from the dangers incident to a short circuit or other overload. Two of them are dropout fuse cutouts and the third is a housing suitable for use with any cutout. Dropout fuse cutouts may be used without any housing. The District Court found that 40.77% of all cutouts manufactured and sold by these defendants were produced under these patents. This was substantially all the dropout fuse cutouts made in the United States. There are competitive devices that perform the same functions manufactured by appellees and others under different patents than those here involved.

The dominant patent, No. 2,150,102, in the field of dropout fuse cutouts with double jointed hinge construction was issued March 7, 1939, to the Southern States Equipment Corporation, assignee, on an application of George N. Lemmon. This patent reads upon a patent No. 2,176,227, reissued December 21, 1943, Re. 22,412, issued October 17, 1939 to Line Material Company, assignee, on an application by Schultz and Steinmayer. The housing patent No. 1,781,876, reissued March 31, 1931, as Re. 18,020, and again February 5, 1935, as Re. 19,449, was issued November 18, 1930 to Line, assignee, on an application by W. D. Kyle. The Kyle patent covers a wet-process porcelain box with great dielectric strength, which may be economically constructed and has been commercially successful. We give no weight to the presence of the Kyle patent in the licenses.

The applications for the Lemmon and Schultz patents were pending simultaneously. They were declared in interference and a contest resulted. The decision of the Patent Office, awarding dominant claims to Southern and subservient claims to Line on the Lemmon and the Schultz applications made it impossible for any manufacturer to use both patents when later issued without some cross-licensing arrangement. Cf. Temco Electric Motor Co. v. Apco Mfg. Co., 275 U.S. 319, 328, 48 S.Ct. 170, 173, 72 L.Ed. 298. Only when both patents could be lawfully used by a single maker could the public or the patentees obtain the full benefit of the efficiency and economy of the inventions. Negotiations were started by Line which eventuated in the challenged arrangements.

The first definitive document was a bilateral, royalty-free, cross-license agreement of May 23, 1938, between Southern and Line after the patent office award but before the patents issued. This, so far as here pertinent, was a license to Southern by Line to make and vend the prospective Schultz patented apparatus with the exclusive right to grant licenses or sublicenses to others. Line also granted Southern the right to make and vend but not to sublicense the Kyle patent. Southern licensed Line to make and vend but not to sublicense the prospective Lemmon patent for defined equipment which included the Schultz apparatus. Sublicense royalties and expenses were to be divided between Line and Southern. Although a memorandum of agreement of January 12, 1938, between the parties had no such requirement, Line agreed to sell equipment covered by the Southern patent at prices not less than those fixed by Southern. Southern made the same agreement for equipment covered solely by the Line patent. No requirement for price limitation upon sales by other manufacturers under license was included.

Six of the other manufacturers here involved were advised by Line by letter, dated June 13, 1938, that Southern had authority to grant licenses under the Schultz prospective patent. On October 3, 1938, Kearney took from Southern a license to practice the Lemmon and Schultz patents. The license had a price, term and condition of sale clause, governed by Southern's prices, which bound Kearney to maintain the prices on its sales of devices covered by the patents. On October 7, 1938, the five other manufacturers mentioned above were offered by Southern the same contract as the standard licensor's agreement. The Kearney contract was discussed at Chicago in October, 1938, by all of the above manufacturers except Railway. Pacific also participated. It never was enforced. The first patent involved in this case did not issue until March, 1939. Those manufacturers who were making double jointed open and enclosed dropout cutouts wanted to and did explore co-operatively (F.F. 15)
the validity of the patents. They failed to find a satisfactory basis for attack. They were faced with infringement suits. Other reasons developed for the refusal of the six manufacturers to accept the Kearney form contracts (F.F. 16 & 17) unnecessary to detail here. One reason was that the prospective sublicensees preferred Line to Southern as licensor because of the fact that Line, as owner and manufacturer, would license the Kyle patent. New arrangements were proposed for the licensees. After mutual discussion between the licensees and patentees, these new agreements were submitted. A finding to which no objection is made states:

‘On October 24, 1939, General Electric, Westinghouse, Kearney, Matthews, Schweitzer and Conrad, and Railway met with Line in Chicago and jointly discussed drafts of the proposed license agreements under the Lemmon, Schultz, and Kyle patents. Thereafter, identical sets of revised licenses were sent by Line to General Electric, Westinghouse, Matthews, Schweitzer and Conrad, and the attorneys for Railway and Kearney.’

A form for a proposed licensing agreement that contained the essential elements of the price provision ultimately included in the licenses had been circulated among prospective licensees by Line by letters under date of October 6, 1969.

To meet the various objections of the future licensees, the agreement of May 23, 1938, between Southern and Line was revised as of January 12, 1940. Except for the substitution of Line for Southern as licensor of other manufacturers, it follows generally the form of the earlier agreement. There were royalty free cross- licenses of the Schultz and Lemmon patents substantially as before. Line was given the exclusive right to grant sublicenses to others for Lemmon. Southern retained the privilege, royalty free, of making and vending the Kyle patent, also. Southern bound itself to maintain prices, so long as Line required other licensees to do so. Even if it be assumed that the proper interpretation of the Line-Southern agreement permitted Southern to manufacture under its own Lemmon patent without price control, the practical result is that Southern does have its price for its products fixed because the only commercially successful fabrication is under a combination of the Lemmon and Schultz patents. Findings of Fact 7 and 10.

The price maintenance feature was reflected in all the licenses to make and vend granted by Line, under the Line-Southern contract, to the other appellees. There were variations in the price provisions that are not significant for the issues of this case. A fair example appears below.

The licenses were the result of arm's length bargaining in each instance. Price limitation was actively opposed in toto or restriction of its scope sought by several of the licensees, including General Electric, the largest producer of the patented appliances. A number tried energetically to find substitutes for the devices. All the licensees, however, were forced to accept the terms or cease manufacture. By accepting they secured release from claims for past infringement through a provision to that effect in the license. The patentees through the licenses sought system in their royalty collections and pecuniary reward for their patent monopoly. Undoubtedly one purpose of the arrangements was to make possible the use by each manufacturer of
the Lemmon and Schultz patents. These patents in separate hands produced a deadlock. Lemmon by his basic patent ‘blocked’ Schultz’ improvement. Cross-licenses furnished appellees a solution.

On consideration of the agreements and the circumstances surrounding their negotiation and execution, the District Court found that the arrangements, as a whole, were made in good faith, to make possible the manufacture by all appellees of the patented devices, to gain a legitimate *298 return to the patentees on the inventions and apart from the written agreements there was no undertaking between the appellees or any of them to fix prices. 13 Being convinced, **556 as we indicated at the first of this opinion, that the General Electric case controlled and permitted such price arrangements as are disclosed in *299 the contracts the District Court dismissed the complaint. The Government attacks the rationale of the General Electric case and urges that it be overruled, limited and explained or differentiated.

II. The General Electric Case.

That case was decided in 1926 by a unanimous court, Chief Justice Taft writing. It involved a bill in equity to enjoin further violations of the Sherman Act. While violations of the Act by agreements fixing the resale price of patented articles (incandescent light bulbs) sold to dealers also were alleged in the bill, so far as here material the pertinent alleged violation was an agreement between General Electric and Westinghouse Company through which Westinghouse was licensed to manufacture lamps under a number of General Electric's patents, including a patent on the use of tungsten filament in the bulb, on condition that it should sell them at prices fixed by the licensor. On considering an objection to the fixing of prices on bulbs with a tungsten filament, the price agreement was upheld as a valid exercise of patent rights by the licensor.

Speaking of the arrangement, this Court said: ‘If the patentee * * * licenses the selling of the articles (by a licensee to make), may he limit the selling by limiting the method of sale and the price? We think he may do so provided the conditions of sale are normally and reasonably adapted to secure pecuniary reward for the patentee's monopoly.’ 272 U.S. at page 490, 47 S.Ct. at page 197, 71 L.Ed. 362. This proviso must be read as directed at agreements between a patentee and a licensee *300 to make and vend. The original context of the words just quoted makes clear that they carry no implication of approval of all a patentee's contracts which tend to increase earnings on patents. The **557 opinion recognizes the fixed rule that a sale of the patented article puts control of the purchaser's resale price beyond the power of the patentee. 272 U.S. at page 489, 47 S.Ct. at page 196, 71 L.Ed. 362. Compare United States v. Univis Lens Co., 316 U.S. 241, 62 S.Ct. 1088, 86 L.Ed. 1408. Nor can anything be found in the General Electric case which will serve as a basis to argue otherwise than that the precise terms of the grant define the limits of a patentee's monopoly and the area in which the patentee is freed from competition of price, service, quality or otherwise. Compare Mercoid Corporation v. Mid—Continent Inv. Co., 320 U.S. 661, 665, 666, 64 S.Ct. 268, 271, 272, 88 L.Ed. 376; United States v. Masonite Corporation, 316 U.S. 265, 277, 278, 280, 62 S.Ct. 1070, 1077, 1078, 1079, 86 L.Ed. 1461; Motion Picture Patents Co. v. Universal Film Mfg. Co., 243 U.S. 502, 510, 37 S.Ct. 416, 418, 61 L.Ed. 871, L.R.A. 1917E, 1187, Ann.Cas.1918A, 959.

General Electric is a case that has provoked criticism and approval. It had only bare recognition in Ethyl Gasoline Corporation v. United States, 309 U.S. 436, 456, 60 S.Ct. 618, 625, 84 L.Ed. 852. That case emphasized the rule against the extension of the patent monopoly, 309 U.S. at page 456, 60 S.Ct. at page 625, 84 L.Ed. 852, to resale prices or to avoid competition among buyers. 309 U.S. at pages 457, 458, 60 S.Ct. at pages 625, 626, 84 L.Ed. 852. We found it unnecessary to reconsider the rule in United States v. Masonite Corporation, 316 U.S. 265, 277, 280, 62 S.Ct. 1070, 1077, 1078, 1079, 86 L.Ed. 1461, although the arrangement there was for sale of patented articles at fixed prices by dealers whom the patentee claimed were del credere agents. As we concluded the patent privilege was exhausted by a transfer of the articles to certain agents who were part of the sales organization of competitors, discussion of the price fixing limitation was not required. In Edward Katzinger Co. v. Chicago Metallic Mfg. Co., 329 U.S. 394, 398, 67 S.Ct. 416, 419, where a suit was brought to recover royalties on a license with price limitations, this Court refused to examine the General Electric rule because of the claimed illegality of the Katzinger patent. If the patent were invalid, the price fixing *301 agreement would be unlawful. We affirmed the action of the Circuit Court of Appeals in remanding the
case to the District Court to determine the validity of the patent. The General Electric case was cited with approval in Carbice Corporation of America v. American Patents Development Corporation, 283 U.S. 27, 51 S.Ct. 334, 335, 75 L.Ed. 819. Other courts have explained or distinguished the General Electric rule. As a reason for asking this Court to reexamine the rule of the General Electric case, the Government states that price maintenance under patents through various types of agreements is involved in certain pending cases. Furthermore, the * point is made that there is such a 'host of difficult and unsettled questions' arising from the General Electric holding that the simplest solution is to overrule the precedent on the power of a patentee to establish sale prices of a licensee to make and vend a patented article.

Such a liquidation of the doctrine of a patentee's power to determine a licensee's sale price of a patented article would solve problems arising from its adoption. Since 1902, however, when E. Bement & Sons v. National Harrow Co., 186 U.S. 70, 22 S.Ct. 747, 46 L.Ed. 1058, was decided, a patentee has been able to control his licensee's sale price within the limits of the patent monopoly. Litigation that the rule has engendered proves that business arrangements have been repeatedly, even though hesitantly, made in reliance upon the contractors' interpretation of its meaning. Appellees urge that Congress has taken no steps to modify the rule. Such legislative attitude is to be weighed with the counter balancing fact that the rule of the General Electric case grew out of a judicial determination. The writer accepts the rule of the General Electric case as interpreted by the third subdivision of this opinion. As a majority of the Court does not agree with that position, the case cannot be reaffirmed on that basis. Neither is there a majority to overrule General Electric. In these circumstances, we must proceed to determine the issues on the assumption that General Electric continues as a precedent. Furthermore, we do not think it wise to undertake to explain, further than the facts of this case require, our views as to the applicability of patent price limitation in the various situations listed by the Government. On that assumption where a conspiracy to restrain trade or an effort to monopolize is not involved, a patentee may license another to make and vend the patented device with a provision that the licensee's sale price shall be fixed by the patentee. The assumption is stated in this was so as to leave aside the many variables of the General Electric rule that may arise. For example, there may be an aggregation of patents to obtain dominance in a patent field, broad or narrow, or a patent may be used as a peg upon which to attach contracts with former or prospective competitors, touching business relations other than the making and vending of patented devices. Compare United States v. United States Gypsum Co., decided today; United States v. Masonite Corporation, 316 U.S. 265, 62 S.Ct. 1070, 86 L.Ed. 1461.

It may be helpful to specify certain points that either are not contested or are not decided in this case. The agreements, if illegal, restrain interstate commerce contrary to the Sherman Act. No issue of monopoly is involved. (F.F. 31.) Cf. American Tobacco Co. v. United States, 328 U.S. 781, 788, 66 S.Ct. 1125, 1128, 1129. That is to say, the complaint charges restraint of trade under s 1 and does not charge 'monopoly' under s 2 of the Sherman Act, so that we need not deal with the problems of consolidation, merger, purchase of competitors or size of business as tending toward attaining monopoly. See United States v. United Shoe Machinery Co., 247 U.S. 32, 44—55, 38 S.Ct. 473, 477—481, 62 L.Ed. 968; United States v. Aluminum Co. of America, 2 Cir., 148 F.2d 416, 427—31; United States v. American Tobacco Co., 221 U.S. 106, 181—83, 31 S.Ct. 632, 648—650, 55 L.Ed. 663; United States v. United States Steel Corporation, 251 U.S. 417, 451, 40 S.Ct. 293, 299, 64 L.Ed. 343, 8 A.L.R. 1121. We are not dealing with a charge of monopoly or restraint because of the aggregation of patents, by pooling or purchase, by an owner or owners, in a single industry or field. See United States v. United Shoe Machinery Co., 247 U.S. 32, 38 S.Ct. 473, 62 L.Ed. 968. Within the limits of the patentee's rights under his patent, monopoly of the process or product by him is authorized by the patent statutes. It is stipulated by the United States that the validity of the patents is not in issue. With these points laid aside, we proceed to the issues presented by this record.

III. The Determination of the Issue.

Under the above-mentioned assumption as to General Electric, the ultimate question for our decision on this appeal may be stated, succinctly and abstractly, to be as to whether in the light of the prohibition of s 1 of the Sherman Act, note 1, supra, two or more patentees in the same patent field may legally combine their valid patent monopolies to secure mutual benefits for
The appellees urge that the findings of the District Court, quoted in note 13 supra, stand as barriers to a conclusion *306 here that s 1 of the Sherman Act has been violated by the licenses. Since there was **560 material evidence to support the District Court's finding of the evidentiary facts and the Court necessarily weighed the credibility of the witnesses and the probative value of their testimony to establish appellees' contentions, appellees insist that the inferences or conclusions as to violations of the Sherman Act, drawn by the District Court, must be accepted by us. 19 As to the evidentiary facts heretofore stated, there is no dispute. From them the District Court made findings of fact Nos. 32 to 36, inclusive, hereinbefore set out in note 13. Even though we accept, as we do, these findings on preliminary facts as correct, the last sentence in findings 32 and 34 crumbles their asserted bar to an examination by us as to whether the agreements are violative of the Sherman Act. Those sentences are to the effect that there was an agreement to fix prices between all parties in the language of the contracts as set out in notes 8 and 9 supra. If the patent rights do not empower the patentees to fix sale prices for others, the agreements do violate the Act. The previous summary in this opinion of the agreements which compose these arrangements demonstrates that the agreements were intended to and did fix prices on the patented devices. Compare *307 Interstate Circuit v. United States, 306 U.S. 208, 226, 59 S.Ct. 467, 474, 83 L.Ed. 610. While Line's sublicenses to others than General Electric, note 9, gave to Line the power which it exercised to fix prices only for devices embodying its own Schultz patent, the sublicense agreements licensed the use of the dominant Lemmon patent. As the Schultz patent could not be practiced without the Lemmon, the result of the agreement between Southern and Line for Line's sublicensing of the Lemmon patent was to combine in Line's hands the authority to fix the prices of the commercially successful devices embodying both the Schultz and Lemmon patents. Thus though the sublicenses in terms followed the pattern of General Electric in fixing prices only on Line's own patents, the additional right given to Line by the license agreement of January 12, 1940, between Southern and Line, to be the exclusive licensor of the dominant Lemmon patent, made its price fixing of its own Schultz devices effective over devices embodying also the necessary Lemmon patent. See note 9. By the patentees' agreement the dominant Lemmon and the subservient Schultz patents were combined to fix prices. In the absence of patent or other statutory 20 authorization, a contract to fix or maintain prices in interstate commerce has long been recognized as illegal per se under the Sherman Act. 21 This is true whether *308 the fixed price is reasonable **561 or unreasonable. It is also true whether it is a price agreement between producers for sale or between producer and distributor for resale.

It is equally well settled that the possession of a valid patent or patents does not give the patentee any exemption from the provisions of the Sherman Act beyond the limits of the patent monopoly. 22 By aggregating patents in one control, the holder of the patents cannot escape the prohibitions of the Sherman Act. See Standard Sanitary Mfg. Co. v. United States, 226 U.S. 20, 33 S.Ct. 9, 57 L.Ed. 107; United States v. United States Gypsum Co., decided today. During its term, a valid patent excludes all except its owner from the use of the protected process or product. United States v. United Shoe Machinery Co., 247 U.S. 32, 58, 38 S.Ct. 473, 482, 62 L.Ed. 968; Special Equipment Co. v. Coe, 324 U.S. 370, 378, 65 S.Ct. 741, 745, 89 L.Ed. 1006. This monopoly may be enjoyed exclusively by the patentee or he may assign the patent 'or any interest therein' to others. Rev.Stat. s 4898, as amended 55 Stat. 634, 35 U.S.C.A. s 47. As we have pointed out, a patentee may license others to make and vend his invention and collect a royalty therefor. Thus we have a statutory monopoly by the patent and by the Sherman Act a prohibition, not only of monopoly or attempt to monopolize, but of every agreement in restraint of trade. Public policy has condemned monopolies for centuries. The Case of Monopolies (Darcy v. Allein) 11 Co.Rep. 84-b. See United States v. Aluminum Co. of America, 2 Cir., 148 F.2d 416, 428, 449. See Employment Act of 1946, s 2, 60 Stat. 23, 15 U.S.C.A. s 1022. Our Constitution allows patents. Art. I, s 8, cl. 8. The progress of our economy has often been said to owe much to the stimulus *309 to invention given by the rewards allowed by patent legislation. The Sherman Act was enacted to prevent restraint of commerce but has been interpreted as recognizing that patent grants were an exception. Bement v. National Harrow Co., supra, 186 U.S. at page 92, 22 S.Ct. at page 755, 46 L.Ed. 1058; 21 Cong.Rec. 2457. Public service organizations, governmental and private aside, our economy is built largely upon competition in quality and prices. Associated Press v. United States, 326
The development of patents by separate corporations or by cooperating units of an industry through organized research group is a well known phenomenon. However far advanced over the lone inventor's experimentation this method of seeking improvement in the practices of the arts and sciences may be, there can be no objection, on the score of illegality, either to the mere size of such a group or the thoroughness of its research. It may be true, as Carlyle said, that ‘Genius is an infinite capacity for taking pains.’ Certainly the doctrine that control of prices, outside the limits of a patent monopoly, violates the Sherman Act is as well understood by Congress as by all other interested parties.

We are thus called to make an adjustment between the lawful restraint on trade of the patent monopoly and the illegal restraint prohibited broadly by the Sherman Act. That adjustment has already reached the point, as the precedents now stand, that a patentee may validly license a competitor to make and vend with a price limitation under the General Electric case and that the grant of patent rights is the limit of freedom from competition under the cases first cited at note 22.

With the postulates in mind that price limitations on patented devices beyond the limits of patent monopoly violate the Sherman Act and that patent grants are to be construed strictly, the question of the legal effect of the price limitations in these agreements may be readily answered. Nothing in the patent statute specifically gives a right to fix the price at which a licensee may vend the patented article. 35 U.S.C. ss 40, 47, 35 U.S.C.A. ss 40, 47. While the General Electric case holds that a patentee may, under certain conditions, lawfully control the price the licensee of his several patents may charge for the patented device, the monopoly granted by the patent laws is a statutory exception to this freedom for competition and consistently has been construed as limited to the patent grant. Ethyl Gasoline Corporation v. United States, 309 U.S. 436, 452, 455, 60 S.Ct. 618, 623, 624, 84 L.Ed. 852; United States v. Univis Lens Co., 316 U.S. 241, 62 S.Ct. 1088, 86 L.Ed. 1408; Hartford—Empire Co. v. United States, 323 U.S. 386, 65 S.Ct. 373, 89 L.Ed. 322. It is not the monopoly of the patent that is invalid. It is the use of that monopoly, improperly.

The merging of the benefits of price fixing under the patents restrains trade in violation of the Sherman Act in the same way as would the fixing of prices between producers of nonpatentable goods.
If the objection is made that a price agreement between a patentee and a licensee equally restrains trade, the answer is not that there is no restraint in such an arrangement but, when the validity of the General Electric case *312 is assumed, that reasonable restraint accords with the patent monopoly granted by the patent law. Where a patentee undertakes to exploit his patent by price fixing through agreements with anyone, he must give consideration to the limitations of the Sherman Act on such action. The patent statutes give an exclusive right to the patentee to make, use, and vend and to assign any interest in this monopoly to others. The General Electric case construes that as giving a right to a patentee to license another to make and vend at a fixed price. There is no suggestion in the patent statutes of authority to combine with other patent owners to fix prices on articles covered by the respective patents. As the Sherman Act prohibits agreements to fix prices, any arrangement between patentees runs afool of that prohibition and is outside the patent monopoly.

We turn now to the situation here presented of an agreement where one of the patentees is authorized to fix prices under the patents. The argument of respondents is that if a patentee may contract with his licensee to fix prices, it is logical to permit any number of patentees to combine their patents and authorize one patentee to fix prices for any number of licensees. In this present agreement Southern and Line have entered into an arrangement by which Line is authorized to and has fixed prices for devices produced under the Lemmon and Schultz patents. It seems to us, however, that such argument fails to take into account the cumulative effect of such multiple agreements in establishing an intention to restrain. The obvious purpose and effect of the agreement was to enable Line to fix prices for the patented devices. Even where the agreements to fix prices are limited to a small number of patentees, we are of the opinion that it crosses the barrier erected by the Sherman *313 Act against restraint of trade though the restraint is by patentees and their licensees.

As early as 1912, in Standard Sanitary Mfg. Co. v. United States, 226 U.S. 20, 33 S.Ct. 9, 57 L.Ed. 107, this Court unanimously condemned price limitation under pooled patent licenses. As the arrangement was coupled with an agreement for limitation on jobbers resale prices, the case may be said to be indecisive on patent license agreements for price control of a product without the jobber's resale provision. No such distinction appears in the opinion. This Court has not departed from that condemnation of price fixing. Even in Standard Oil Co. (Indiana) v. United States, 283 U.S. 163, 51 S.Ct. 421, 75 L.Ed. 926, where an arrangement by which the patentees pooled their oil cracking patents and divided among themselves royalties from licensees fixed by the pooling contracts was upheld, the theory was reiterated **564 that a price limitation for the product was unlawful per se. 283 U.S. at page 170, 173, 175, 51 S.Ct. at pages 423, 425, 75 L.Ed. 926. Of course, if a purpose or plan to monopolize or restrain trade is found, the arrangement is unlawful. *314 283 U.S. at page 174, 51 S.Ct. at page 425, 75 L.Ed. 926. The Government's contention in that case that the limitation on royalties in itself violated the Sherman Act by fixing an element in the price was dismissed because the Court was of the view that controlled royalties were effective as price regulators only when the patentees dominated the industry. 283 U.S. at page 174, 51 S.Ct. at page 425, 75 L.Ed. 926. This domination was thought by this Court not to have been proven.

When a plan for the patentee to fix the sale prices of patented synthetic hardboard on sales made through formerly competing manufacturers and distributors, designated at del credere agents, *26 came before this Court on allegations that the plan was in violation of the Sherman Act, we invalidated the scheme. We said that the patentee could not use its competitor's sales organization as its own agents so as to control prices. The patent monopoly, under such circumstances, we said, was exhausted on disposition of the product to the distributor. We reasoned that such an arrangement was a restriction on our free economy, 'a powerful inducement to abandon competition' and that it derogated 'from the general law (against price limitation) beyond the necessary requirements of the patent statute.' United States v. Masonite Corporation, 316 U.S. 265, 281, 280, 62 S.Ct. 1070, 1079, 1078, 86 L.Ed. 1461.

We think that this general rule against price limitation clearly applies in the circumstances of this case. Even if a patentee has a right in the absence of a purpose to restrain or monopolize trade, to fix prices on a licensee's sale of the patented product in order to exploit properly his invention or inventions, when patentees join in an agreement as here to maintain prices on their several products, that agreement, however advantageous it may be to stimulate the broader use of patents, is unlawful per se under the
Sherman Act. It is more than an exploitation of patents. There is the vice that patentees have combined to fix prices on patented products. It is not the cross-licensing to promote efficient production which is unlawful. There is nothing unlawful in the requirement that a licensee should pay a royalty to compensate the patentee for the invention and the use of the patent. The unlawful element is the use of the control that such cross-licensing gives to fix prices. The mere fact that a patentee uses his patent as whole or part consideration in a contract by which he and another or other patentees in the same patent field arrange for the practice of any patent involved in such a way that royalties or other earnings or benefits from the patent or patents are shared among the patentees, parties to the agreement, subjects that contract to the prohibitions of the Sherman Act whenever the selling price, for things produced under a patent involved, is fixed by the contract or a license, authorized by the contract. Licensees under the contract who as here enter into license arrangements, with price fixing provisions, with knowledge of the contract, are equally subject to the prohibitions.

The decree of the District Court is reversed and the case is remanded for the entry of an appropriate decree in accordance with this opinion.

Mr. Justice JACKSON took no part in the consideration or decision of this case.

Reversed and remanded.

Mr. Justice DOUGLAS, with whom Mr. Justice BLACK, Mr. Justice MURPHY and Mr. Justice RUTLEDGE, join, concurring.

While I have joined in the opinion of the Court, its discussion of the problem is for me not adequate for a full understanding of the basic issue presented. My view comes to this—it is a part of practical wisdom and good law not to permit United States v. General Electric Co., 272 U.S. 476, 47 S.Ct. 192, 71 L.Ed. 362, to govern this situation, though if its premise be accepted, logic might make its application to this case wholly defensible. But I would be rid of United States v. General Electric Co. My reasons for overruling it start with the Constitution itself.

The Constitution grants Congress the power ‘To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.’ Art. I, s 8, Cl. 8. It is to be noted first that all that is secured to inventors is ‘the exclusive Right’ to their inventions; and second that the reward to inventors is wholly secondary, the aim and purpose of patent statutes being limited by the Constitution to the promotion of the progress of science and useful arts. United States v. Masonite Corporation, 316 U.S. 265, 278, 62 S.Ct. 1070, 1077, 86 L.Ed. 1461, and cases cited.

Congress faithful to that standard, has granted patentees only the ‘exclusive right to make, use, and vend the invention or discovery.’ Rev.Stat. s 4884, 35 U.S.C. s 40, 32 U.S.C.A. s 40. And as early as 1853 the Court, speaking through Chief Justice Taney, defined the narrow and limited monopoly granted under the statutes as follows. ‘The franchise which the patent grants, consists altogether in the right to exclude every one from making, using, or vending the thing patented, without the permission of the patentee.’ Bloomer v. McQuewan, 14 How. 539, 549, 14 L.Ed. 532. But the ingenuity of man has conceived many ways to graft attractive private perquisites onto patents. The effort through the years has been to expand the narrow monopoly of the patent. The Court, however, has generally been faithful to the standard of the Constitution, has recognized that the public interest comes first and reward to inventors second, and has refused to let the self-interest of patentees come into the ascendancy. As we stated in B. B. Chemical Co. v. Ellis, 314 U.S. 495, 498, 62 S.Ct. 406, 408, 86 L.Ed. 367, ‘The patent monopoly is not enlarged by reason of the fact that it would be more convenient to the patentee to have it so, or because he cannot avail himself of its benefits within the limits of the grant.’ From Motion Picture Patents Co. v. Universal Film Mfg. Co., 243 U.S. 502, 37 S.Ct. 416, 61 L.Ed. 871, L.R.A.1917E, 1187, Ann.Cas.1918A, 959, which overruled Henry v. A. B. Dick Co., 224 U.S. 1, 32 S.Ct. 364, 56 L.Ed. 645, Ann.Cas.1913D, 880, to International Salt Co. v. United States, 332 U.S. 392, 68 S.Ct. 12, decided only the other day, the Court has quite consistently refused to allow the patentee’s ‘right to exclude’ to be expanded into a right to license the patent on such conditions as the patentee might choose. For the power to attach conditions would
enable the patentee to enlarge his monopoly by contract and evade the requirements of the general law applicable to all property. The philosophy of those decisions was summed up in Mercoid Corporation v. Mid—Continent Inv. Co., 320 U.S. 661, 666, 64 S.Ct. 268, 271, 88 L.Ed. 376, where we said: ‘The necessities or convenience of the patentee do not justify any use of the monopoly of the patent to create another monopoly. The fact that the patentee has the power to refuse a license does not enable him to enlarge the monopoly of the patent by the expedient of attaching conditions to its use. * * * The patent is a privilege. But is it a privilege which is conditioned by a public purpose. It results from invention and is limited to the invention which it defines. When the patentee ties something else to his invention, he acts only by virtue of his right as the owner of property to make contracts concerning it and not otherwise. He then is subject to all the limitations upon that right which the general law imposes upon such contracts.’

The Court, however, allowed an exception in this long line of cases. In United States v. General Electric Co., supra, decided in 1926, it followed *318 Bement v. National Harrow Co., 186 U.S. 70, 22 S.Ct. 747, 46 L.Ed. 1058, decided in 1902, and sustained a price-fixing provision of a license to make **566 and vend the patented invention. By that decision price-fixing combinations which are outlawed by the Sherman Act (United States v. Socony Vacuum Oil Co., 310 U.S. 150, 60 S.Ct. 811, 84 L.Ed. 1129) were held to be lawful when the property involved was a patent. By what authority was this done?

The patent statutes do not sanction price-fixing combinations. They are indeed wholly silent about combinations. So far as relevant here, all they grant, as already noted, is the ‘exclusive right to make, use, and vend the invention or discovery.’ Rev.Stat. s 4884, 35 U.S.C. s 40, 35 U.S.C.A. s 40. There is no grant of power to combine with others to fix the price of patented products. Since the patent statutes are silent on the subject, it would seem that the validity of price-fixing combinations in this field would be governed by general law. And since the Sherman Act outlaws price-fixing combinations it would seem logical and in keeping with the public policy expressed in that legislation to apply its prohibitions to patents as well as to other property. The Court made an exception in the case of these price-fixing combinations in order to make the patent monopoly a more valuable one to the patentee. It was concerned with giving him as high a reward as possible. It reasoned that if the patentee could not control the price at which his licensees sold the patented article, they might undersell him; that a price-fixing combination would give him protection against that contingency and therefore was a reasonable device to secure him a pecuniary reward for his invention. Thus the General Electric case inverted Cl. 8 of Art. I, s 8 of the Constitution and made the inventor’s reward the prime rather than an incidental object of the patent system.

In that manner the Court saddled the economy with a vicious monopoly. In the first place, this form of *319 price fixing underwrites the high-cost producer. By protecting him against competition from lowcost producers, it strengthens and enlarges his monopoly. It is said in reply that he, the patentee, has that monopoly anyway—that his exclusive right to make, use, and vend would give him the right to exclude others and manufacture the invention and market it at any price he chose. That is true. But what he gets by the price-fixing agreement with his competitors is much more than that. He then gets not a benefit inherent in the right of exclusion but a benefit which flows from suppression of competition by combination with his competitors. Then he gets the benefits of the production and marketing facilities of competitors without the risks of price competition. Cf. United States v. Masonite Corporation, supra. In short, he and his associates get the benefits of a conspiracy or combination in restraint of competition. That is more than an ‘exclusive right’ to an invention; it’s an ‘exclusive right’ to form a combination with competitors to fix the prices of the products of invention. The patentee creates by that method a powerful inducement for the abandonment of competition, for the cessation of litigation concerning the validity of patents, for the acceptance of patents no matter how dubious, for the abandonment of research in the development of competing patents. Those who can get stabilized markets, assured margins, and freedom from price cutting will find a price-fixing license an attractive alternative to the more arduous methods of maintaining their competitive positions. Competition tends to become impaired not by reason of the public’s preference for the patented article but because of the preference of competitors for price fixing and for the increased profits which that method of doing business promises.

*320 Price fixing in any form is perhaps the most powerful of all inducements for abandonment of competition. It offers security and stability; it eliminates much of the uncertainty of competitive practices; it promises high profits. It is therefore
one of the most effective devices to regiment whole industries and exact a monopoly price from the public. The benefits of competition disappear. The prices charged by the regimented industry are determined not by representatives of the public, as in the case of electric, water and gas rates, but by private parties who incline to charge all the traffic will bear. And the type of combination in this case has the power to inflict precisely the type of public injury which the Sherman Act condemns. This price-fixing scheme does far more than secure to inventors ‘the exclusive Right’ to their discoveries within the meaning of Cl. 8 of Art. I, s 8 of the Constitution. It gives them a leverage on the market which only a combination, not a patent by itself, can create. Yet it is ‘every’ combination in restraint of trade which s 1 of the Sherman Act condemns, price-fixing combinations dealing with patents not excluded.

Congress has much to say as to the pattern of our economic organization. But I am not clear that Congress could expand ‘the exclusive right’ specified in the Constitution into a right of inventors to utilize through a price-fixing combination the production and marketing facilities of competitors to protect their own high costs of production and eliminate or suppress competition. It is not apparent that any such restriction or condition promotes the progress of science and the useful arts. But however that may be, the Constitution places the rewards to inventors in a secondary role. It makes the public interest the primary concern in the patent system. To allow these price-fixing schemes is to reverse the order and place the rewards to inventors first and the public second. This is not the only way a patentee can receive a pecuniary reward for his invention. He can charge a royalty which has no relation to price fixing. Or he can manufacture and sell at such price as he may choose. Certainly if we read the patent statutes so as to harmonize them as closely as possible with the policy of anti-trust laws, we will strike down a combination which is not necessary to effectuate the purpose of the patent statutes. If we did that in this case we would overrule the General Electric Co. case.

This Court, not Congress, was the author of the doctrine followed in that case. The rule it sanctions is another of the private perquisites which the Court has written into the patent laws. See Special Equipment Co. v. Coe, 324 U.S. 370, 383, 65 S.Ct. 741, 747, 89 L.Ed. 1006. Since we created it, we should take the initiative in eliminating it. It is hard for me to square it with the standards which the Constitution has set for our patent system. It plainly does violence to the competitive standards which Congress has written into the Sherman Act.

Mr. Justice BURTON, with whom THE CHIEF JUSTICE and Mr. Justice FRANKFURTER concur, dissenting.

This dissent is impelled by regard for the soundness, authority and applicability to this case of the unanimous decisions of this Court in Bement v. National Harrow Co., 186 U.S. 70, 22 S.Ct. 747, 46 L.Ed. 1058, and United States v. General Electric Co., 272 U.S. 476, 47 S.Ct. 192, 71 L.Ed. 362.

The complaint charges violation of s 1 of the Sherman Anti-trust Act by the defendant patent owners and cross-licensors, Line Material Company and Southern States Equipment Corporation (here called respectively Line and Southern), and also by the ten defendants who hold licenses under the two complementary patents, owned respectively by Line and Southern. These patents are for dropout fuse cutouts. Southern's patent is the dominant patent but the product made under it alone has not been commercially successful, Line's patent is for an improvement of that product which has made it commercially successful. Each of the twelve defendants has received and exercised authority under the two complementary patents, owned respectively by Line and Southern. These patents are for dropout fuse cutouts. Southern's patent is the dominant patent but the product made under it alone has not been commercially successful, Line's patent is for an improvement of that product which has made it commercially successful. Each of the twelve defendants has received and exercised authority under both patents to make and sell this improved product, but the Government charges them with having engaged in an unlawful combination and conspiracy in restraint of trade to fix, maintain and control the prices at which they have sold, in interstate commerce, their respective products under these patents. It is not disputed that the sales were made in interstate commerce. The trial court's findings of fact demonstrate, however, that there have been no agreements between any of the defendants with respect to the prices of these products other than the price-limiting provisions contained in their respective licenses. The findings of fact show also that, unless the Government sustains its contention that those provisions constitute, per se, an unlawful restraint of trade, its complaint should be dismissed.
The question thus presented is: Do the price-limiting provisions in some or all of the licenses under Line's or Southern's patents constitute a restraint of trade in violation of § 1 of the Sherman Act? We agree with the court below that they do not. The price-limiting provisions in this case are comparable to those which, in the Bement and General Electric cases, supra, were held not to violate the Sherman Act. This Court sustained the agreement in the Bement case because the Sherman Act—"clearly does not refer to that kind of a restraint of interstate commerce which may arise from reasonable and legal conditions imposed upon the assignee or licensee of a patent by the owner thereof, restricting the terms upon which the article may be used and the price to be demanded therefor. Such a construction of the act, we have no doubt, was never contemplated by its framers." 186 U.S. at page 92, 22 S.Ct. at page 756, 46 L.Ed. 1058.

The license in that case was issued under several patents and, as here, it limited the prices at which the licensee was authorized to sell articles produced by the licensee under that license. In the General Electric case, this Court, in speaking of the patent holder's right to limit the selling prices of his licensee's products, said:

'We think he (the patent holder) may do so provided the conditions of sale are normally and reasonably adapted to secure pecuniary reward for the patentee's monopoly. One of the valuable elements of the exclusive right of a patentee is to acquire profit by the price at which the article is sold.' 272 U.S. at page 490, 47 S.Ct. at page 197, 71 L.Ed. 362.

In the present case, there are two types of license agreements. The price-limiting provisions are the same in each. The first type is that of the cross-licensing agreement between Line and Southern. In it Line granted to Southern a nonexclusive, royalty-free license to make and sell the products here in question. Line also prescribed that Southern's prices, terms and conditions of sale should be "not more favorable to the customer than those established from time to time and followed by the Line Company in making its sales." The difference between this license agreement and Line's agreements with each of the other defendants is that Southern, in return for this license, instead of paying cash royalties to Line, issued to Line a limited cross-license under Southern's complementary patent on a dropout fuse cutout. Southern also granted to Line an exclusive right to issue sublicenses under that patent. Southern inserted no price limitation in its cross-license to Line and Line made no commitment to insert price limitations in any sublicense which it might issue under Southern's patent. As far as price limitations were concerned, they all were contained in the royalty-free, nonexclusive license from Line to Southern and were applicable only to products made and sold by the latter under Line's patent. Assuming that the limitations thus placed by Line on the price of Southern's products, made and sold by it under Line's complementary patent, were reasonable limitations, especially in relation to Line's own operations under the same patent, they represented a lawful protection of Line's patent interests. They evidenced a normal exercise by a manufacturing patentee of the exclusive right of a patentee to acquire profit by the price at which the article is sold. In some ways, they were even more natural and reasonable provisions for insertion by Line than would have been a bare provision for royalties. Line evidently needed these price limitations to enable it to continue to make and sell the product which its own improvement had converted from a commercial failure into a commercial success. It will be demonstrated later that Line's receipt of a royalty-free, unconditional cross-license under Southern's complementary patent, as consideration for Line's license to Southern, did not, per se, convert this otherwise lawfully limited license into an invalid license violating the Sherman Act.

The other type of license that was used by Line was that of a direct license issued separately to each of the ten other licensee-defendants. These licenses closely resembled each other. Each was a nonexclusive license calling for the payment of a modest royalty to Line on each product made and sold by the licensee under Line's patent. Each included price limitations comparable to those in Line's license to Southern. These price-limiting licenses from Line are, as such, entirely comparable to those in the Bement and General Electric cases. Each license, however, also included a sublicense issued by Line under Southern's complementary patent. The royalties on the products made and sold under the two complementary patents were to be divided equally between Line and Southern. It will be demonstrated later that this sublicense under Southern's complementary patent and the agreement by Line to divide with Southern the royalties received upon products made and sold under the two patents did not, per se, convert these otherwise lawfully limited licenses into invalid licenses violating the Sherman Act.
Line also granted to certain licensee-defendants desiring it, a license under Line's so-called ‘Kyle patent’ for enclosed fuse boxes. Some of these licenses carried price limitations on products made and sold by the licensee under the Kyle patent. These licenses are entirely comparable to those in the Bement and General Electric cases. They are well within the scope of those precedents and carry no suggested basis for a distinction claimed to convert *328 them into invalid licenses violating the Sherman Act.

The Government now asks this Court to overrule the Bement and General Electric cases. The opinion by Mr. Justice REED rejects that request but seeks to justify a reversal of the judgment below by distinguishing this case from those precedents. This dissent undertakes not only to emphasize the soundness of the Bement and General Electric decisions, but to demonstrate that the basic principles which sustain those decisions apply to this case with at least equal force. This initial discussion will omit the consideration of the cross-license from Southern to Line, the grant from Southern to Line of the exclusive right to issue sublicenses under the Southern patent and the agreement for the division of royalties between Southern and Line. The Bement and General Electric decisions are authority for upholding the remaining portions of such agreements in the light of the previously mentioned findings of fact which show that the agreements ‘arise from reasonable and legal conditions imposed upon the assignee or licensee of a patent by the owner thereof, restricting the terms upon which the article may be used and the price to be demanded therefor’ *6 and that ‘the conditions of sale are normally and reasonably adapted to secure pecuniary reward for the patentee's monopoly.’ *7 This dissent accordingly re-examines the foundation for those decisions and emphasizes the development, nature and effect of the patent **571 rights which are decisive of the main issue both in those cases and in this.

Patent Rights.

An understanding of the historical development and of the nature of patent rights in the United States is *329 essential to a discussion of the relation between them and the restraints of trade prohibited by the Sherman Act. American patent rights find their origin in Great Britain. That nation appears to have been the first to issue ‘patents' to secure to inventors for limited times exclusive rights to their respective discoveries. These ‘patents' were called ‘literae patentes,’ i.e., 'open letters,' because they were not sealed up but were exposed to view with the Great Seal pendant at the bottom. They were addressed by the sovereign to all subjects of the realm. Such instruments were, and to a degree still are, the common form used for making grants of dignities, such as peerages, appointments to certain offices and grants of privilege of various kinds. Their form, therefore, was similar to that of the ‘patents' used to grant exclusive rights or 'monopolies' to trade guilds, corporations and, in some cases, individuals, permitting them to exclude competitors from the conduct of certain lines of profitable business.

The contrast between these two kinds of exclusive rights in their relation to the public was reflected later in acts of the British Parliament and in the Constitution and statutes of the United States. A patent to an inventor took nothing from the public which the public or the inventor's competitors already had. By hypothesis, it dealt with a new asset available to civilization only through its inventor. The royal patent served to encourage the inventor to disclose his invention. By granting *330 to the inventor the right to exclude all others from making, using or selling the invention for a limited time, it was felt that the public was well served by the invention's disclosure, its early availability under the patent and its later general availability to everyone. This procedure was popular. On the other hand, royal patents securing exclusive rights to private parties to conduct profitable enterprises to the exclusion of existing or available competitors were issued to show royal favor or to secure funds at the expense of the public. Such patents became highly unpopular. The courts, at an early date, held them invalid.

As early as 1602, Francis Bacon, in the House of Commons, supported the principle that a monopoly should be granted only for a 'new manufacture.' In 1623, there was enacted the Statute of Monopolies (21 Jac. I, c. 3, s 1; 1 Walker on Patents, pp. 18—21 (Deller's Ed.1937) which declared void all monopolies and letters patent 'of or for the sole Buying, Selling, Making, Working or Using of any Thing within this Realm, * * *.' However, s VI of this Act made an express exception in favor of
For Educational Use Only

68 S.Ct. 550, 92 L.Ed. 701, 76 U.S.P.Q. 399

10. That Section has become the foundation of the patent law securing exclusive rights to inventors not only in Great Britain but throughout the world.

The result, historically and in principle, has not been a conflict between two legislative mandates. It has been rather a long standing approval, both by the British Parliament and the Congress of the United States, of the unique value of the exercise, for limited periods, of exclusive rights by inventors to their respective inventions, paralleled by an equally sustained and emphatic disapproval of certain other restraints of trade not representative of exclusive rights of inventors to their inventions.

The long and unflattering development of our patent law often has been touched upon in our decisions. However, in the face of the direct attack now made upon some of its underlying principles, the infinite importance of our inventions justifies a brief review hereof the development and nature of the patent rights attacked. The decision in this case must turn upon this Court's understanding of the relation between the licenses before it, the patent rights to which they relate and the Sherman Act. As interpreter of the Congressional Acts that have expressed the patent policy of this nation since its beginning, this Court is entrusted with the protection of that policy against intrusions upon it. The crucial importance of the development of inventions and discoveries is not limited to this nation. As the population of the world has increased, its geographical frontiers have shrunk. However, the frontiers of science have expanded until civilization now depends largely upon discoveries on those frontiers to meet the infinite needs of the future. The United States, thus far, has taken a leading part in making those discoveries and in putting them to use.

The Constitution of the United States provides that 'The Congress shall have Power * * * To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries; * * *.' (Italics supplied.) Art. I, s 8.

The statutes primarily implementing this provision state:

1. Any person who has invented or discovered any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvements thereof, * * * not known or used by others in this country, before his invention or discovery thereof, and not patented or described in any printed publication in this or any foreign country, before his invention or discovery thereof, or more than one year prior to his application, and not in public use or on sale in this country for more than one year prior to his application, unless the same is proved to have been abandoned, may, upon payment of the *333 fees required by law, and other due proceeding had, obtain a patent therefor.' R.S. s 4886, as amended, 46 Stat. 376, 53 Stat. 1212, 35 U.S.C. s 31, 35 U.S.C.A. s 31.

2. Every patent shall contain a short title or description of the invention or discovery, correctly indicating its nature and design, and a grant to the patentee, his heirs or assigns, for the term of seventeen years, of the exclusive right to make, use, and vend the invention or discovery * * * throughout **573 the United States and the Territories thereof, referring to the specification for the particulars thereof. * * *' (Italics supplied.) R.S. s 4884, as amended, 46 Stat. 376, 35 U.S.C. s 40, 35 U.S.C.A. s 40. 11

3. Every application for patent or patent or any interest therein shall be assignable in law by an instrument *334 in writing, and the applicant or patentee or his assigns or legal representatives may in like manner grant and convey an exclusive right under his application for patent or patent to the whole or any specified part of the United States. * * *' (Italics supplied.) R.S. s 4898, as amended, 55 Stat. 634, 35 U.S.C. s 47 (Supp. V, 1946), 35 U.S.C.A. s 47.

Conway P. Coe, Commissioner of Patents of the United States from 1933 to 1945, discussed the historical significance of the early establishment of the American patent system in his testimony before the Temporary National Economic Committee in 1939. He said:

3. The American patent system was established at a time when mechanical inventions had already begun to affect not only the industrial conditions, but also the economic, social, and political status of Europe and the new Nation just erected on this
continent. The significance of the inventions put to work in England and the States of the Confederation was realized by the American statesmen of that era. It is agreed that their recognition of the value of these new economic factors prompted them to write into the Constitution the provision of article I, section 8, empowering Congress ‘to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.’ This provision, by the way, is impressive not only because it is included in the Constitution as one of the major grants of power to Congress, but equally because it bestows on patentees a complete monopoly, and therefore raises a question as to the constitutionality of an attempt to compel the owner of a patent to share with others the title, use, and avail of his property. I do not presume to determine the point; but *335 I must contemplate it as an issue to be met here or hereafter.

‘The authors of our patent system, judging by the language of article I, section 8, held the exclusiveness of the rights vested in a patentee as a powerful aid to progress in arts and sciences.’

Hearings before the Temporary National Economic Committee, 76th Cong., 1st Sess. 839—840(1939).

*336 He analyzed the ‘patent rights’ granted to the inventor and stated his reasons for **574 concluding that the ‘monopoly’ *337 vested in a patentee is not in conflict with our antitrust laws as follows:

‘It occurs to me that a great deal of misapprehension results from the failure to distinguish between the monopoly or privilege vested in a patentee and the sort of monopoly that British sovereigns once **575 conferred. It is only when we appreciate this distinction that we can understand how Jefferson could consistently advocate the monopoly of patents for inventions while condemning the traditional form of monopoly.

‘Americans generally detest monopoly in the true sense of the term because it makes possible the ruthless exercise of power. Indeed, the American Revolution was precipitated by popular resentment of the monopoly on tea held by the East India Co. It would, therefore, have been exceedingly strange if, *338 only a few years later, the delegates sent to the Constitutional Convention by Massachusetts and the other Colonies had been willing to sanction an equivalent form of monopoly under the new government they were creating. In the sixteenth and seventeenth centuries a king or queen of England could reward a favorite by granting him a monopoly on salt or some other necessary of life. This beneficiary of royal favor was not, of course, the discoverer of salt. That came ready-made from the hands of the Creator eons before the advent of man. What the darling of his or her majesty received was the power to compel others to use salt solely of his supplying and only on terms of his dictation.

‘But a patent is no such monopoly. It is a reward for the invention or discovery of something new, something before unknown, something added to the sum total of human knowledge, utility, well-being; something which the inventor or discoverer, despising the lure of money or fame, might have withheld from his fellow men. By the monopoly that goes with a patent, then, the Government recompenses and, for a limited time, protects the inventor or discoverer who gives to the world the use and benefit of his invention or discovery. This is a kind and a degree of mutuality that negatives monopoly in the old or the current concept. Monopoly in the latter sense of the term gave to an individual or a group complete dominion of something already existent. A patent awards monopoly to the producer of something original, something superadded to the common store. So it is that two things bearing the same name need not be of the same nature.

‘It has been contended that there sometimes occurs a clash between the antitrust laws and the patent *339 statutes. I might suggest that since the first anti-trust legislation in 1890, the patent laws and the anti-trust laws have coexisted without any irreconcilable conflicts between them. They have each of them at least one common objective, namely, the retention by the public of a right once acquired by it. As a matter of fact, patents accomplish more than the retention of the acquired rights. Their influence is creative; they operate to multiply and expand acquisitions by the public.’ (Id. at pp. 840, 841.)

A comparable analysis of the nature of the grant to inventors of the exclusive right to their respective inventions or discoveries for a limited time has been made by this Court.
Though often so characterized a patent is not, accurately speaking, a monopoly, for it is not created by the executive authority at the expense and to the prejudice of all the community except the grantee of the patent. Seymour v. Osborne, 11 Wall. 516, 533, 20 L.Ed. 33. The term ‘monopoly’ connotes the giving of an exclusive privilege for buying, selling, working, or using a thing which the public freely enjoyed prior to the grant. Thus a monopoly takes something from the people. An inventor deprives the public of nothing which it enjoyed before his discovery, but gives something of value to the community by adding to the sum of human knowledge. United States v. American Bell Telephone Co., 167 U.S. 224, 239, 17 S.Ct. 809 (810), 42 L.Ed. 144; **576** Paper Bag Patent Case, 210 U.S. 405, 424, 28 S.Ct. 748, (753), 52 L.Ed. 1122; Brooks v. Jenkins, 3 McLean 432, 437, Fed.Cas.No.1,953; Parker v. Haworth, 4 McLean 370, 372, Fed.Cas.No.10,738; Allen v. Hunter, 6 McLean 303, 305, 306, Fed.Cas.No. 225; Attorney General v. Rumford Chemical Works, 2 Bann. & Ard. 298, 302. He may keep his invention secret and reap its fruits indefinitely. In consideration of its disclosure and the consequent benefit to the community, *340* the patent is granted. An exclusive enjoyment is guaranteed him for seventeen years, but, upon the expiration of that period, the knowledge of the invention enures to the people, who are thus enabled without restriction to practice it and profit by its use. Kendall v. Winsor, 21 How. 322, 327, 16 L.Ed. 165; United States v. American Bell Telephone Co., supra, page 239 of 167 U.S., 17 S.Ct. 809 (at page 810, 72 L.Ed. 144). To this end the law requires such disclosure to be made in the application for patent that others skilled in the art may understand the invention and how to put it to use.' United States v. Dubilier Condenser Corporation, 289 U.S. 178, 186, 187, 53 S.Ct. 554, 557, 77 L.Ed. 1114, 85 A.L.R. 1488.

*341* This constitutional and legislative policy toward inventions is specific in contrast with the generality of the language in the Sherman Act of 1890. The constitutional and long standing statutory approval of the exclusive rights of an inventor to make, use and sell products of his invention for a limited time was an ample guaranty that the Sherman Act did not directly or impliedly repeal such approval. The prohibition of unreasonable restraints of trade and the approval of exclusive rights of inventors to their inventions for limited periods of time continued to exist together. This was nothing new. As long as the inventors kept within their statutory exclusive rights, they were not engaging in unreasonable restraints of trade violating the Sherman Act.

There was nothing to indicate an intent that the general language of the Sherman Act was to change the nation's traditional and specifically stated policy towards inventions. That policy had been widely regarded as having made a major contribution to the nation's exceptional economic progress. The Sherman Act unquestionably applied to any abuse of a patentee's exclusive rights which exceeded the limit of those rights and which amounted to an unreasonable restraint of interstate trade. Hoever, there was nothing to indicate that the Sherman Act restricted the traditional patent rights. Bement v. National Harrow Co., supra, 186 U.S. at page 92, 22 S.Ct. at page 755, 46 L.Ed. 1058.

**577** LIMITED LICENSE AGREEMENTS.

The primary issue in this case, therefore, is to determine whether or not Line by the issuance of its restricted licenses has thereby sought to exercise any right that is in excess of the exclusive right secured to Line by the *342* patent laws of the United States. If it has done so, then such licenses, like other agreements, must be scrutinized to determine whether or not they create an unreasonable restraint of trade in violation of the Sherman Act.

The first consideration is the relation of the Sherman Act to provisions in a license agreement which place limitations—as in the Bement and General Electric cases—upon the prices which may be charged by the licensee for products made and sold by it under the protection of its license. The issue corresponds to that raised by the Westinghouse license in the General Electric case. 14 The Sherman Act's invalidation of agreements in restraint of trade applies only to those in unreasonable restraint of trade and the definition of such unreasonableness depends largely upon the common law meaning of restraint of trade. 15 This permits such invalidation where, for example, a license is a mere subterfuge for price fixing which otherwise would amount to unreasonable restraint of trade in violation of the Sherman Act. See United States v. U.S. Gypsum Co., decided concurrently with this case.
The Sherman Act's prohibition of unreasonable restraints of trade, accordingly, would not invalidate an unconditional, nonexclusive license agreement which served only to release the licensee from the right of the patent holder to exclude him from making, using or selling a patented article. The original, exclusive right of the patent holder, being secured to him through the terms of his patent, was not in violation of the Sherman Act. Accordingly, his release or waiver of a part of that exclusive right by issuance of an unconditional, non-exclusive license, per se, decreased rather that increased the statutory restraint of trade to which he was entitled.

The next question is whether the insertion in such a license of some limitation upon the licensee's right to sell the articles made by the licensee under the patent, per se, converts this otherwise lawful agreement into an unreasonable restraint of trade violative of the Sherman Act. The answer is no. Just as an unlimited license is a partial, but lawful, relaxation of the lawful restraint of trade imposed by the patent so a limited license is but a correspondingly less relaxation of that same restraint.

The fact that the limitation in the license is a limitation on the price which may be charged by the licensee in making sales of the article made by the licensee under the protection of the patent does not change the answer, provided the price prescribed is 'normally and reasonably adapted to secure pecuniary reward for the patentee's monopoly.' Here again, the restraint of trade imposed by the patent itself is lawful. Therefore, as long as the license agreement has only the effect of reducing the lawful restraint imposed by the patent, such agreement merely converts the original lawful restraint into a lesser restraint, equally lawful.

Such agreements should be carefully scrutinized to make sure that they do not introduce new restrictions which, as judicially construed, unreasonably restrain trade and thus violate the Sherman Act. In the instant case the findings eliminate such possibilities and thus reduce the issue here to one comparable with the issue in the Bement and General Electric cases.

This brings us to a further discussion of the nature of the license in the present case and of the precise limitations contained in it. This requires, first of all, a consideration of the nature of the exclusive right to make, use and sell the patented product. The precise nature of such a 'patent right' has been described as follows by Chief Justice Taft in a unanimous opinion of this Court:

'It is the fact that the patentee has invented or discovered something useful and thus has the common-law right to make, use and vend it himself which induces the government to clothe him with power to exclude everyone else from making, using or vending it. In other words, the patent confers on such common-law right the incident of exclusive enjoyment and it is the common-law right with this incident which a patentee or an assignee must have (in order to bring a suit for infringement). That is the implication of the descriptive words of the grant 'the exclusive right to make, use and vend the invention.' The government is not granting the common-law right to make, use and vend, but it is granting the incident of exclusive ownership of that common-law right, which can not be enjoyed save with the common-law right. A patent confers a monopoly. So this court has decided in the Paper Bag Case, supra (210 U.S. 405, 28 S.Ct. 748, 52 L.Ed. 1122) and in many other cases. The idea of monopoly held by one in making, using and vending connotes the right in him to do that thing from which he excludes others.' Crown Co. v. Nye Tool Works, 261 U.S. 24, 36, 37, 43 S.Ct. 254, 256, 257, 67 L.Ed. 516.

This analysis is the key to the issue before us. It demonstrates that the common law right to make, use and sell the product of an unpatented invention exists without any right to exclude others from so making, using or selling such product. The additional 'exclusive right,' or so-called 'patent right,' which is added to the common law right of the inventor is added by authority of the Constitution and of the federal statutes, so as to promote the progress of science, the useful arts and, no doubt, the general welfare. The patent or any interest therein may be assigned. R.S. s 4898, as amended, 55 Stat. 634, 35 U.S.C. s 47 (Supp. V, 1946), 35 U.S.C.A. s 47. An assignee, exercising his right to exclude others during the life of the patent from making, using or selling articles under protection of the patent, does not practice a restraint of trade in violation of the Sherman Act any more than would his assignor if the assignment had not been made.
Any attempted assignment or transfer short of those indicated in the statute ‘is a mere license, giving the licensee no title in the patent, and no right to sue at law in his own name for an infringement.’

Before his receipt of his license, he had the common law right to make, use and sell the patented article as well as other articles, except to the important extent prevented by the patentee's exclusive rights. The license changed that position by withdrawing from the licensee, to the extent of the license, the restriction which the patent placed upon him. Accordingly, to the extent of his license, the restraint placed upon trade by the patent was diminished. In relation to the Sherman Act his license, instead of creating an added ground for asserting a violation of the Sherman Act, thus, per se, relaxed an existing restraint of trade. The previous restraint imposed by the patent was not a violation of the Sherman Act and, therefore, the mere lessening of that restraint was not a violation of that Act. The important point is the need to see to it that the lessening of the restraint resulting from the issuance of either an absolute license or a limited license is, in fact, no more than a mere withdrawal of the lawful restraint imposed by the patent and is not either directly or indirectly an imposition of a new restraint not within the ambit of the patent right.

An unconditional, nonexclusive and royalty-free license presents, per se, no need for special scrutiny under the Sherman Act. A royalty-yielding license presents the issue suggested by the language in the General Electric case. In order not to violate the Sherman Act, the royalty must be ‘normally and reasonably adapted to secure pecuniary reward for the patentee's monopoly.’ However, as well explained in that case, a royalty may not, by itself, satisfy the needs of the patent holder. Limitations on the price of sales by the licensee of products made by the license under the patent may be the best, or even the only, condition that is thus ‘normally and reasonably adapted’ to the situation.

The following statements illustrate the directness with which this Court repeatedly has decided in favor of the validity of limited licenses when that question has been before it:

** the general rule is absolute freedom in the use or sale of rights under the patent laws of the United States. The very object of these laws is monopoly, and the rule is, with few exceptions, that any conditions which are not in their very nature illegal with regard to this kind of property, imposed by the patentee and agreed to by the licensee for the right to manufacture or use or sell the article, will be upheld by the courts. The fact that the conditions in the contracts keep up the monopoly or fix prices does not render them illegal.’ Bement v. National Harrow Co., supra, 186 U.S. at page 91, 22 S.Ct. at page 755, 46 L.Ed. 1058.

‘As was said in United States v. General Electric Co., 272 U.S. 476, 489, 47 S.Ct. 192, 196, 71 L.Ed. 362, the patentee may grant a license ‘upon any condition the performance of which is reasonably within the reward which the patentee by the grant of the patent is entitled to secure.’ The restriction * here imposed (upon the licensee to manufacture and to sell the patented article for certain uses only) is of that character. The practice of granting licenses for a restricted use is an old one, see Providence Rubber Company v. Goodyear, 9 Wall. 788, 799, 800, 19 L.Ed. 566; Gamewell Fire-Alarm Telegraph Co. v. Brooklyn, C.C., 14 F. 255. So far as appears, its legality has never been questioned.’ General Talking Pictures Corporation v. Western Electric Co., 305 U.S. 124, 127, 59 S.Ct. 116, 117, 83 L.Ed. 81.

The normality, reasonableness and practical necessity for inserting a price-limiting condition in certain licenses, without trespassing upon the prohibited area of unlawful restraints of trade, is effectively summarized in the General Electric case, 272 U.S. at page 490, 47 S.Ct. at page 197, 71 L.Ed. 362:

‘If the patentee goes further and licenses the selling of the articles, may he limit the selling by limiting the method of sale and the price? We think he may do so provided the conditions of sale are normally and reasonably adapted to secure pecuniary reward for the patentee's monopoly. One of the valuable elements of the exclusive right of a patentee is to acquire profit by the price at which the article is sold. The higher the price, the greater the profit, unless it is prohibitory. When the patentee licenses another to make and vend and retains the right to continue to make and vend on his own account, the price at which his licensee will sell will necessarily affect the price at which he can sell his own patented goods. It would seem entirely reasonable that he should say to the licensee, ‘Yes, you may make and sell articles under my patent but not so as to destroy the profit that I wish to obtain by making them and selling them myself.’ He does not thereby sell outright to the licensee the articles the latter may
make and *349 sell or vest absolute ownership in them. He restricts the property and interest the licensee has in the goods he makes and proposes to sell.**22

**581 **350 During the hearings of the Temporary National Economic Committee, testimony was received from the Commissioner of Patents and manufacturers familiar with the commercial development of patented products bearing on the reasonableness and propriety of price limitations in patent licenses comparable to those in the present case. It was to the effect that commercially successful mechanical inventions, such as those in the electrical, communications and automotive industries, usually represent not only the intrinsic merit of the inventions themselves but a substantial investment in research, experimentation and promotion. If, after the disclosure of the invention, others are to be licensed to make the patented article, the costs of production by such licensees will reflect none of the investments above-mentioned. If the patentee is to be reimbursed for his expenditures, he will need, therefore, to secure the benefit of a royalty sufficient to accomplish this or of a restriction on the price at which licensees may sell their products under the patent. This price would have to be one that would enable the patentee to manufacture and sell the article in such quantities and at such prices as would produce a return to him commensurate with his investment in it. He might prescribe both a royalty and a restriction. As long as the royalties and the prices were ‘normally and reasonably adapted to secure pecuniary reward for the patentee's monopoly.’**23 They would perform much the same function.**24

**351 In cases where patents are owned by comparatively small industrial producers but licenses are to be issued by them to comparatively large industrial producers in the same field, the necessity for early reimbursement of the patent owners for their development costs is clear and the danger that a large licensee will undersell his smaller licensor is obvious. This is the situation in the present case. The General Electric Company and the Westinghouse Electric Corporation are among the licensees of the much smaller patent holders, Line and Southern. Similarly, where outside capital is needed to finance the development of an invention, it is normal and reasonable for the investors to require not only a valid patent but also to insist that any licenses issued during the initial operating period shall contain such price limitations as will allow the patent holder to amortize his original investment within a reasonable time. In this case, finding of fact No. 32 shows that ‘the price limitation provisions contained in the various license agreements here in evidence were insisted upon by the patent owner and were intended and reasonably adapted to protect its **582 own business and secure pecuniary reward for the patentee's monopoly.’**25

The following statement by Conway P. Coe, Commissioner of Patents, before the Temporary National Economic **352 Committee in 1939, reinforces the above conclusions:

‘Speculative capital must be encouraged to fall in behind a new enterprise and this is true whether the enterprise is wholly new or represents merely an expansion of an established organization. Some testimony has been offered to this committee by representatives of large corporations that they would continue to invent, and invent, and invent, and research, research, and research whether or not they were rewarded by the patent grant, but, if you will investigate, I believe you will find that whenever these large corporations, themselves firmly established, undertake a new development, that development is likely to be founded upon patent protection. Whatever opinions have been expressed to this committee or may hereafter be expressed as to whether or not the inventor will continue to invent without the patent system, I think I can present to you indisputable evidence that speculative capital will not back new inventions without the patent protection. And in the final analysis this is the crux and the most important thing in the whole patent question.’**26 Hearings before the Temporary National Economic Committee, supra, at pp. 857, 858.

**353 The foregoing supports the conclusions reached in the Bement and General Electric cases, supra. The basis for such support is sufficiently broad to lead to the same result in the present case.

SUBLICENSES AND CROSS-LICENSEES.
Under the foregoing principles and authorities, a simple price-limiting patent license, in which the price limitations meet the test stated in the General Electric case, is a lawful agreement. Such a license would involve, as a possible restraint of trade, only the exclusive right to make, use and sell the patented product. That restraint would exist by virtue of the statute and constitutional provision long antedating the Sherman Act. If the limitations in a license reach beyond the scope of the statutory patent rights, then they must be tested by the terms of the Sherman Act. Assuming that in the instant case the price limitations do not reach beyond the restraint of the patent, the next question is: Does the additional sublicense issued by Line under the Southern patent make a difference? The answer is no.

The sublicense, per se, further diminishes the statutory restraint of trade imposed by the patent law. It adds a release from the restraint of Southern's patent. Line's authority to issue the sublicense was an express grant by Southern to Line of an exclusive right to issue it. Per se, this sublicense certainly amounts to no more than another license under another patent. In the instant case it is under a complementary patent without which Line's license would be without commercial value. For that very reason it is a reasonable and necessary part of the transaction. In both the Bement and General Electric cases, the license in question was issued not merely under one, but under many patents held by the licensor. In those cases, apparently, it was not thought necessary to question the relation of those patents to one another or the authority of the licensor to issue the license under each of them. In any event, there hardly could have existed in those cases any closer relationship between the patents involved or a more essential and normal reason, of a patent nature, for combining rights under them than existed here between Line's and Southern's complementary patents. Except for the cross-licensing feature, to be next considered, the situation in relation to the Sherman Act is the same here as though Line had received an assignment of Southern's patent and issued licenses under it as well as under Line's patent.

In the present case, there are ten licensee-defendants instead of one as in each of the Bement and General Electric cases. In view of the positive finding that there was no agreement or understanding among the licensees amounting to an unreasonable restraint of trade, this mere multiplication of one license by ten produces a repetition of the same issue rather than a different issue. It is apparent also from the record in the General Electric case that, in that case, in addition to the Westinghouse license, there were licenses to 13 other manufacturers, which had been issued by the licensor, although the licensees under them were not made parties to the suit. 15 F.2d 715, 716.

It is suggested also that the Bement and General Electric rule does not apply because there is a cross-licensing agreement between Line and Southern. The suggestion apparently is that such an agreement, per se, reaches beyond the scope of the exclusive rights of the parties under the patents and converts the price limitations in the respective licenses into unreasonable restraints of trade violating the Sherman Act.

The cross-license from Southern carries no price-limiting feature. At most it is a royalty-free cross-license issued to Line in consideration of Line's license to Southern. It is accompanied by a grant from Southern to Line of an exclusive license to grant sublicenses under Southern's patent. Provision is made also for the equal division between Southern and Line of such royalties as shall be received by Line upon products made and sold by the respective licensees under the Southern and Line patents.

These sublicenses and the royalties derived from them do not, however, increase the restraints on trade beyond those restraints which are inherent in the respective patents. In fact, each original license decreased those restraints under Line's patent and each sublicense did the same under Southern's patent. Because of the complementary relationship between the patents, these sublicenses have served substantially to remove the restraints which the respective patents, when held separately, put in the way of production. The two patents together completely covered the product. If the price limitations were valid under Line's licenses, the issuance by Line of the sublicenses under Southern's patent has no more effect on the question involved in this case than if Southern, instead of granting to Line an exclusive right to issue sublicenses under Southern's patent, had assigned that patent to Line and Line had then issued original licenses under it on the same terms as Line issued the sublicenses.
The next consideration is the effect of the cross-license by Southern to Line, coupled with the grant of the exclusive right to issue the above-mentioned sublicenses under Southern's patent and the division of certain royalties received by Line. Where, as here, there is no agreement, course of dealing or other circumstance than the existence of the cross-licenses between complementary patent holders, the cross-licensing agreements do not, per se, reach beyond the scope of the patent rights.

Patent pools, especially those including unrelated or distantly related patents and involving the issuance of many forms of royalty-free, royalty-bearing or price-limiting licenses and cross-licenses, might present a different picture from that in this case. Such arrangements might be but a screen for, or incident to, an unlawful agreement in restraint of trade violating the Sherman Act. Here we have no such facts. The findings eliminate all bases for the claim of invalidity except the terms of the license agreements, per se. We are not here confronted with the effect of cross-licenses between unrelated patents. Here we have only that natural situation, common under our patent laws, where two or more complementary patents are separately owned. One is for an improvement that is commercially essential to the other. In such a case one solution is to combine the ownership of the two by purchase and complete assignment. That, per se, would not involve an unlawful restraint of trade.

The solution in the instant case was even more natural than a consolidation of the patents by purchase. It conduced even more to the maintenance of competition. Each patentee granted to the other a nonexclusive, royalty-free license. This cross-licensing amounted to a waiver by each patent holder of his right to exclude the other from making, using or selling the patented product. This resulted in a diminution of the restraint created by the patent statute. This, per se, was, therefore, well within the scope of the patent and not a violation of the Sherman Act. Both patentees became producers.

Unless the terms of the cross-licenses reach beyond those that are normally and reasonably adapted to the patent relationships of the parties, the cross-licenses are no more outside of the protection of the patent law than would be direct licenses. A reasonable price-limiting provision in at least one of two cross-licenses is just as normal and reasonable a patent provision as it would be in a direct license. In the present case the validity of the price limitation in Line's license to Southern is entitled to the same judicial support and for the same reasons as if no cross-license had been issued in exchange.

In the present case, the need for price-limiting provisions, both in the license to Southern and in the licenses to the other ten defendants, rest upon the need of the patent holder to protect its opportunity to continue the manufacture of its own patented product. The substance of the situation is that the patent holder needs to protect itself precisely as much and in the same way as in the case of a direct license standing alone. The Sherman Act traditionally tests its violation not by the form but by the substance of the transaction.

In distinction from patent pools and from cross-license between holders of competing or even noncompeting but unrelated patents, we have here a case of a cross-license and a division of royalties between holders of patents which are complementary and vitally dependent upon each other. We have here complementary patents each of which alone is commercially of little value, but both of which, together, spell commercial success for the product. Cross-licenses between their holders, on terms within the needs of their patent monopolies, are essential to the realization of the benefits contemplated by the patent statutes. Far from being unlawful agreements violative of the Sherman Act, such agreements provide in fact the only reasonable means for releasing to the public the benefits intended for the public by the patent laws. A cross-license between mutually deadlocked complementary patents is, per se, a desirable procedure. Standard Oil Co. v. United States, 283 U.S. 163, 170 et seq., 51 S.Ct. 421, 423, 75 L.Ed. 926. Its validity must depend upon the terms and substance of the surrounding circumstances.

The record in the General Electric case discloses that the license agreement between the General Electric Company and Westinghouse which was there upheld was itself a cross-licensing agreement. In fact, the opinion of the lower court in the instant case commented on that cross-license as follows:

---

**356**

---

---

**357**

---

---

**358**

---

---

**359**

---

---

---

**360**

---

---

---

---

---
A cross-license agreement existed between General Electric and Westinghouse which contained agreements even more restrictive than the price protection provisions of the cross-licenses involved in the case at bar. United States v. Line Material Co., D.C., 64 F.Supp. 970, 975.

The opinion in the General Electric case makes no distinction between cross-licenses and direct licenses. That case, therefore, is itself a precedent for upholding a cross-licensing agreement under facts characterized below as being ‘even more restrictive’ than those here presented.

The acquisition by a single party of patents on noncompeting machines has been held not to be, per se, a violation of the Sherman Act. In United States v. Winslow, 227 U.S. 202, 217, 33 S.Ct. 253, 255, 57 L.Ed. 481, Mr. Justice Holmes, in a unanimous opinion of the Court, said:

The machines are patented, making them a monopoly in any case, the exclusion of competitors from the use of them is of the very essence of the right conferred by the patents, Paper Bag Patent Case (Continental Paper Bag Co. v. Eastern Paper Bag Co.) 210 U.S. 405, 429, 28 S.Ct. 748 (755), 52 L.Ed. 1122, 1132, and it may be assumed that the success of the several groups was due to their patents having been the best. As, * * * they did not compete with one another, it is hard to see why the collective business should be any worse than its component parts. * * * we can see no greater objection to one corporation manufacturing 70 per cent of three noncompeting groups of patented machines collectively used for making a single product than to three corporations making the same proportion of one group each. The disintegration aimed at by the statute does not extend to reducing all manufacture to isolated units of the lowest degree. See, also United States v. United Shoe Machinery Co., 247 U.S. 32, 45, 51 et seq., 38 S.Ct. 473, 478, 480, 62 L.Ed. 968; United Shoe Machinery Corporation v. United States, 258 U.S. 451, 463, 464, 42 S.Ct. 363, 367, 66 L.Ed. 708.

In Standard Oil Co. v. United States, 283 U.S. 163, 170, 171, 175, 51 S.Ct. 421, 423, 424, 425, 75 L.Ed. 926, Mr. Justice Brandeis spoke as follows for a unanimous Court (except for Mr. Justice Stone who took no part in the case):

But an agreement for cross-licensing and division of royalties violates the Act only when used to effect a monopoly, or to fix prices, or to impose otherwise an unreasonable restraint upon interstate commerce.
68 S.Ct. 550, 92 L.Ed. 701, 76 U.S.P.Q. 399

Neither the Bement nor the General Electric cases, supra, has been overruled and the reasoning upon which they are based has not been directly or indirectly rejected by this Court. On the other hand, this Court repeatedly has recognized the existence of the principles announced in them. See, for example, Carbice Corporation v. American Patents Development Corporation, 283 U.S. 27, 31, 51 S.Ct. 334, 335, 75 L.Ed. 819; General Talking Pictures Corporation v. Western Electric Co., 305 U.S. 124, 127, 59 S.Ct. 116, 117, 83 L.Ed. 81:

‘Appellants argue that the distributors were free to license the films for exhibition subject to the restrictions, just as a patentee in a license to manufacture and sell the patented article may fix the price at which the licensee may sell it.’ (Citing the Bement and General Electric cases.) Interstate Circuit, Inc. v. United States, 306 U.S. 208, 228, 59 S.Ct. 467, 475, 83 L.Ed. 610.

*362 And see United States v. Univis Lens Co., 316 U.S. 241, 252, 62 S.Ct. 1088, 1094, 86 L.Ed. 1408; United States v. Masonite Corporation, 316 U.S. 265, 277, 62 S.Ct. 1070, 1077, 86 L.Ed. 1461. The rule of stare decisis applies to the interpretation given to the patent statutes and to the Sherman Act by the Bement and General Electric cases. There is no occasion here for such a relaxation of that rule as was suggested by Mr. Justice Brandeis in cases interpreting broad constitutional phrases. See his dissent in Burnet v. Coronado Oil & Gas Co., 285 U.S. 393, 410, 52 S.Ct. 443, 448, 76 L.Ed. 815. To the extent that the present holdings are based upon opinions of this Court, that element is inherent in the rule of stare decisis.

The exceptional recent activity in seeking, by statutory amendment, a change in the patent laws as interpreted in the Bement and General Electric cases indicates a widespread understanding that, if such interpretation is to be changed, the remedy calls for congressional action. The resistance to such a change which has been **587 shown by Congress is impressive. 30 It indicates no dissatisfaction *363 with the interpretation of existing law as expressed in the Bement and General Electric cases.

There appears, therefore, to be neither adequate reason nor authority for overruling the Bement and General Electric cases or for distinguishing this case from them.

All Citations
333 U.S. 287, 68 S.Ct. 550, 92 L.Ed. 701, 76 U.S.P.Q. 399

Footnotes
1 26 Stat. 209, as amended by 36 Stat. 1167, 15 U.S.C.A. ss 1, 4:
‘Sec. 1. Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is hereby declared to be illegal * * *.’

‘Sec. 4. The several district courts of the United States are invested with jurisdiction to prevent and restrain violations of this act; and it shall be the duty of the several district attorneys of the United States, in their respective districts, under the direction of the Attorney General, to institute proceedings in equity to prevent and restrain such violations. * * *’

2 The names of appellees and the abbreviations hereinafter used as well as the percentage of production of the dropout fuse devices manufactured under the patents are listed below:
All are corporations of various states except T. F. Johnson, doing business as Johnson Manufacturing Company, Atlanta, Georgia.


4 ‘** * The Lemmon device consists essentially of an expulsion tube supported by a double jointed hinge at its lower end. As the tube moves into closed circuit position, the hinge is locked and a latch engages a terminal on top of the tube to hold the tube in place. The hinge is released by a relatively complicated and expensive solenoid mechanism when the current becomes excessive because of a short circuit or overload. Thereupon the circuit is broken in the tube and the tube drops downwardly, its upper end disengaging from the latch, which permits the tube to swing out and down. By reason of claims covering the double jointed hinge construction in cutouts, this patent dominates the manufacture of dropout fuse cutouts involved in this suit.’ Findings of Fact, No. 6.

5 ‘** * The Schultz patent covers a dropout fuse cutout which is an improvement on the device disclosed in the Lemmon patent, and is dominated by the Lemmon patent. In the Schultz structure an expulsion tube is supported by a double jointed hinge which is held rigid by a fuse link. On overload, the fuse melts, breaking the circuit in the tube and the hinge is released automatically, which permits the tube to drop down and then swing outwardly. This Schultz dropout fuse is much simpler, and can be manufactured at considerably less than the cost of a comparable solenoid operated cutout, and has met widespread commercial demand and use.’ Findings of Fact, No. 7.

6 Schweitzer & Conrad, General Electric, Westinghouse, Railway, Kearney, Matthews. 68 S.Ct.—35 1/2
The Southern Corporation grants to the Line Company a fully paid license to make, use and sell, with the exclusive right to grant sub-licenses to others to make, use and sell, expulsion tube electric circuit interrupting equipment in which the circuit interruption is caused by the thermally initiated rupturing of a current carrying element in an expulsion tube, coming under claims 3, 4 to 10 inclusive, 15 to 22 inclusive, 25, and 27 to 30 of the patent to G. N. Lemmon, No. 2,150,102, dated March 7, 1939, entitled 'Circuit Breaker' and/or any division, continuation, substitute, renewal and/or reissue thereof.

The licenses hereby granted or agreed to be granted are on the express condition that the prices, terms and conditions of sale of the Southern Corporation for electric fuse equipment made and sold under the licenses herein granted shall, so long as such electric fuse equipment continues to be covered by Letters Patent of the Line Company under which a license is granted by this agreement, be not more favorable to the customer than those established from time to time and followed by the Line Company in making its sales.

It is the purpose and intent of this agreement that there shall not be directly, or indirectly, any modification of the prices set by the Line Company as they exist from time to time, as for instance, by including in the transaction other material or parts, or labor, or services, at less than the regular price at which the party making the same is at the time selling such other material or parts or furnishing such labor or services or by making allowances for freight or terms of payment other than those employed by the Line Company.

Prices, terms and/or conditions of sale may be changed by the Line Company from time to time through reasonable notice in writing to the Southern Corporation, but not less than ten (10) days' written notice shall be given before the change shall go into effect.

It is agreed that if the Line Company shall grant a license to a third party under any of the patents of this agreement (but excepting from the provisions of this paragraph a license to be granted to General Electric Company of Schenectady, New York, under said Kyle reissue patent 19,449), without a provision for maintenance by said third party of prices, maintenance by said third party of prices, in the first paragraph of this section, then Southern Corporation shall be relieved from its obligation under said section.

In the Line-General Electric license agreement of March 15, 1940, the first under the revised Line-Southern contract, the price maintenance provision was as follows:

9. The license hereby granted by the Licensor is subject to the express limitations that as to dropout fuse cutouts manufactured and sold by Licensee which are comparable in respect to general type and purpose, ampere and voltage rating, and rupturing capacity, to dropout fuse cutouts manufactured and sold by Licensor, Licensee's prices, terms and conditions of sale of dropout fuse cutouts for use in the United States made under the license herein granted to Licensee under the aforesaid Letters Patent, Lemmon No. 2,150,102, and Schultz and Steinmayer No. 2,176,227, and as long as such dropout fuse cutouts continue to be covered by such Letters Patent, shall be no more favorable to a customer of the Licensee than those established from time to time and followed by the Licensor in its sales. The prices, terms and conditions of sale as at present established and in force are those set forth in Schedule A annexed hereto and forming a part hereof. This schedule of prices may be changed from time to time by the Licensor upon ten (10) days' notice in writing to the Licensee.

10. The spirit and intent of this license agreement, contemplates that in no transaction shall there be any modification of Licensee's prices, either directly or indirectly, as for instance by inclusion in the transaction of other material or parts or services or labor at less than the regular prevailing prices at which the party making the sale is at the time accustomed to sell such other material or parts or furnish such services or labor, as will serve in effect to reduce Licensee's prices below those named in Schedule A as it exists from time to time.
This was repeated in the Line-General Electric revised agreement of November 17, 1941. A variable appears in the Westinghouse and other licenses. In its price provisions, the Lemmon patent is not mentioned but the Lemmon patent was included in its grant of license and the subsidiary Schultz patent could not be practiced without the right to use the dominant Lemmon.

These two produced an aggregate of less than one percent of the devices.

All appellees, except Royal, Pacific and Johnson, attended one or another of these conferences. We do not find it necessary to determine whether or not the selling prices also of the licensees were before the conference. The agreements adequately show an intention to fix prices.

The licenses contained provisions for records of sale, inspection thereof and cancellation of the license for breach.

Findings of Fact:

‘32. The price limitation provisions contained in the various license agreements here in evidence were insisted upon by the patent owner and were intended and reasonably adapted to protect its own business and secure pecuniary reward for the patentee's monopoly. Each of the licenses granted to the licensee-defendants was taken and granted in good faith, the parties to the licenses believing a license under the patents to be necessary in order that the licensee could continue lawfully to manufacture and sell its dropout fuse cutouts. Apart from the written license agreements here in evidence, there was no agreement, express or implied, between the licensor and any licensee, or between any two or more licensees, with respect to the prices of licensed dropout fuse cutouts.

‘33. All of the devices for which minimum prices were established by Line were comparable to, and competitive with, devices which Line manufactured and sold regularly or which it was ready to manufacture and sell to its customers on special order.

‘34. The cross-license agreements between Line and Southern were limited to the commercially practicable device covered by the subservient Schultz patent, and did not create additional power for price control of the licensed cutouts over that which each had before entering into the agreements. The inflexible intention to insist upon price limitation existed independently in each of the patent owners prior to any discussions or arrangements between them. Such cross-license agreements were entered into in good faith, not for the purpose of fixing prices in the industry but to permit the manufacture and sale of the cheaper device covered by the subservient patent, to facilitate the negotiation of licenses, and to provide royalty income. There was no agreement, express or implied, between Line and Southern with respect to prices on cutouts other than the written cross-license agreements.

‘35. The license agreements here in evidence did not restrain trade but promoted it by making available several sources where the patented devices could be obtained, thus increasing competition in such devices, particularly with respect to design, quality and service. Competition among the defendants for business in these devices continued to be vigorous after the making of the license agreements.

‘36. There was no combination or conspiracy among the defendants, or any of them, to fix, maintain or control prices of dropout fuse cutouts or parts thereof, or to restrain trade or commerce therein.’

For illustration and without implication as to this Court's position on the issues, we call attention to the following:

Barber—Colman Co. v. National Tool Co., 6 Cir., 136 F.2d 339. In a suit by the licensor against the licensee, injunctive relief to compel compliance with a price fixing provision in the patent license was denied. The General Electric case
was held not to permit the patentee to fix prices on unpatented hobs which were produced under a process patent by a patented machine.

Cummer—Graham Co. v. Straight Side Basket Corp., 5 Cir., 142 F.2d 646. Licensee was denied relief in an action against licensor for failing to require other licensees to comply with price fixing provisions; licensor of a patent on an attachment to a basket making machine may not fix prices on baskets produced by the machine.

United States v. Vehicular Parking, Ltd., D.C., 54 F.Supp. 828. Antitrust proceeding against patent holding company and manufacturing licensees in parking meter industry. The patent licenses fixed the prices at which parking meters could be sold and contained restrictive provisions on marketing practices. In ordering compulsory licensing at a reasonable royalty, the court distinguished the General Electric case principally on the ground that the patentee in this case did not itself manufacture the parking meters; other distinctions noted were the number and active concert of licensees, the weakness of the patents, the fixing of prices on unpatented articles, and the existence of marketing restrictions.

For example, such price arrangements under the type of agreement indicated are in litigation as follows:

United States v. Allegheny Ludlum Steel Corp., D.N.J.Civil 45—83, stainless steel company owning patents on a particular type of stainless steel allegedly issued licenses fixing prices on all types of stainless steel.

United States v. American Optical Co., S.D.N.Y.Civil 10—391, optical patents owned by patent holding company which gave exclusive licenses; exclusive licensee sublicensed to other manufacturers who agreed to maintain prices and comply with marketing restrictions.

United States v. Bausch & Lomb Optical Co., S.D.N.Y. Civil 10—394, patent holding company issued licenses to two licensees to manufacture bifocal lenses, the licenses fixing prices at which the bifocal lenses were to be sold and the selection of wholesalers and retailers for the lenses.

United States v. Catalin Corporation of America, D.N.J.Civil 7743, manufacturer of phenolic resins licensed other manufacturers under its process patents, the licensees agreeing to sell at prices established by the licensor.

United States v. General Cable Corp., S.D.N.Y.Civil 40—76, cross licenses among holders of patents on fluid filled cable, the licensees agreeing to adhere to uniform prices and to observe territorial marketing limitations.

United States v. General Electric Co., D.N.J.Civil 1364, cross licensing agreements between manufacturers of electrical bulbs providing for price and quantitative restrictions.


United States v. General Instrument Corp., D.N.J.Cr. 3960—C, Civil 8586, owners of variable condenser patents assigned patents to holding company and took back licenses with price fixing provisions; explicit price fixing provisions subsequently removed but allegedly continued by tacit agreement.

United States v. Phillips Screw Co., N.D.Ill.Civil 47—C—147, holder of patents on cross recessed head screws granted exclusive license to leading screw manufacturer who sublicensed to other manufacturers; patent holder, exclusive licensee, and sublicensees agreed on price terms for all screws produced.

FN* Case dismissed March 9, 1948.
The United States lists: Uncertainty as to the nature of the patent, process or product, which justifies price control; extent of patent domination over the device; may a patent pooling corporation control all licensees' sale prices; extent of price control in an industry. U.S.Brief 65 et seq.


Rules of Civil Procedure, Rule 52, 28 U.S.C.A. following section 723c:

Findings by the Court.—‘(a) Effect. In all actions tried upon the facts without a jury, the court shall find the facts specially and state separately its conclusions of law thereon and direct the entry of the appropriate judgment; and in granting or refusing interlocutory injunctions the court shall similarly set forth the findings of fact and conclusions of law which constitute the grounds of its action. Requests for findings are not necessary for purposes of review. Findings of fact shall not be set aside unless clearly erroneous, and due regard shall be given to the opportunity of the trial court to judge of the credibility of the witnesses. The findings of a master, to the extent that the court adopts them, shall be considered as the findings of the court.’


Appalachian Coals v. United States, 288 U.S. 344, 35 S.Ct. 471, 77 L.Ed. 825, cannot be cited to support a contrary view. In that case, this Court held that ‘The plan cannot be said either to contemplate or to involve the fixing of market prices.’ 288 U.S. at page 373, 35 S.Ct. at page 479, 77 L.Ed. 825. See the Socony-Vacuum case, supra, 310 U.S. at page 214, 60 S.Ct. at page 840, 84 L.Ed. 129 et seq. Perhaps arbitrary or monopoly prices were in mind in Appalachian. 288 U.S. at pages 358, 359, 365, 371, 35 S.Ct. at pages 473, 474, 476, 478, 77 L.Ed. 825.

23 The Interstate Commerce Act authorizes carriers to pool revenues and authorizes mergers of carriers, provided that approval of the Interstate Commerce Commission is obtained. The antitrust laws are inapplicable to such agreements. 49 U.S.C. s 5(1), (2) and (11), 49 U.S.C.A. s 5(1, 2, 11).

24 The words ‘patent pool’ are not words of art. The expression is used in this opinion to convey the idea of a linking of the right to use patents issued to more than one patentee.

25 226 U.S. at page 48, 33 S.Ct. at page 14, 57 L.Ed. 107:

‘The agreements clearly, therefore, transcended what was necessary to protect the use of the patent or the monopoly which the law conferred upon it. They passed to the purpose and accomplished a restraint of trade condemned by the Sherman law. It had, therefore, a purpose and accomplished a result not shown in the Bement Case. There was a contention in that case that the contract of the National Harrow Company with Bement & Sons was part of a contract and combination with many other companies and constituted a violation of the Sherman law, but the fact was not established, and the case was treated as one between the particular parties, the one granting and the other receiving a right to use a patented article with conditions suitable to protect such use and secure its benefits. And there is nothing in Henry v. A. B. Dick Co., 224 U.S. 1, 32 S.Ct. 364, 56 L.Ed. 645 (Ann.Cas.1913D, 880.), which contravenes the views herein expressed.’


2 ‘32. * * * Apart from the written license agreements here in evidence, there was no agreement, express or implied, between the licensor and any licensee, or between any two or more licensees, with respect to the prices of licensed dropout fuse cutouts.

‘34. * * * There was no agreement, express or implied, between Line and Southern with respect to prices on cutouts other than the written cross-license agreements.

‘36. There was no combination or conspiracy among the defendants, or any of them, to fix, maintain or control prices of dropout fuse cutouts or parts thereof, or to restrain trade or commerce therein.’ (Findings of fact.)

3 In addition to the findings quoted in note 1, supra, the trial court found:

‘9. The validity of the United States letters patent involved in the licenses of the defendants is not contested by the plaintiff in this action, and therefore is not here in issue.

‘27. None of the license agreements aforesaid restrains trade in any article moving in interstate commerce, and none of them was entered into as a result of any conspiracy to restrain such trade.

‘28. * * * The prices listed in Schedule A are Line's own selling prices, determined solely by Line without discussion with or advice from any other defendant.

‘29. Under the cross-licenses with Southern and its licenses to others, Line established minimum prices only for structures within the ambit of the claims of its own patents. The classification schedules attached to the license agreements were only such as were reasonably necessary to protect the business of the licensor and implement the license agreements.
agreement so as to prevent evasion by a licensee of lawful price limitation provisions. Line did not establish minimum
selling prices for any devise not covered by a claim of its Schultz patent Re. 22,412 or its Kyle patent Re. 19,449.

‘31. There is no charge of monopoly by the defendants. There was no fixing of resale prices on licensed dropout fuse
cutouts by the defendants or any of them. * * *

‘32. The price limitation provisions contained in the various license agreements here in evidence were insisted upon by
the patent owner and were intended and reasonably adapted to protect its own business and secure pecuniary reward for
the patentee's monopoly. Each of the licenses granted to the licensee-defendants was taken and granted in good faith,
the parties to the licenses believing a license under the patents to be necessary in order that the licensee could continue
lawfully to manufacture and sell its dropout fuse cutouts.

‘34. The cross-license agreements between Line and Southern were limited to the commercially practicable device
covered by the subservient Schultz (Line's) patent, and did not create additional power for price control of the licensed
cutouts over that which each had before entering into the agreements. * * * Such cross-license agreement were entered
into in good faith, not for the purpose of fixing prices in the industry but to permit the manufacture and sale of the cheaper
device covered by the subservient patent, to facilitate the negotiation of licenses, and to provide royalty income. * * *

‘35. The license agreements here in evidence did not restrain trade but promoted it by making available several sources
where the patented devices could be obtained, thus increasing competition in such devices, particularly with respect to
design, quality and service. Competition among the defendants for business in these devices continued to be vigorous
after the making of the license agreements.'

That the patents did not represent an industry-wide control appears from the following finding:

‘5. The defendants are all manufacturers of electrical devices of various kinds. The dropout fuse cutouts manufactured by
the defendants under the patent licenses have been and are in open competition with many other devices which perform
the same functions and are not manufactured under the patent licenses, such as open single hinge dropout fuse cutouts;
open non-dropout fuse cutouts; non-dropout fuse cutouts enclosed in materials other than cast wetprocess porcelain,
such as Prestite; automatic circuit breaker cutouts; and others listed in Defendants' Exhibit L—23. The average aggregate
annual sales of licensed dropout fuse cutouts manufactured by all the defendants from 1940 to 1944 was $1,918,247.78
and constituted only 40.77% of the average aggregate annual sales of all licensed and competitive cutouts manufactured
and sold by all the defendants, and were distributed among the defendants as follows: General Electric, 29.2%; Line
(), 25.4% (;) Kearney, 18.9%; Southern 7.9%; Westinghouse, 5.3%; Schweitzer and Conrad, 5.1%; Railway, 3.8%;
Matthews, 2%; Procelain, 1.5%; Royal, 0.5%; Pacific, 0.2%; and Johnson, 0,2%.'
In 1602, in The Case of Monopolies, Darcy v. Allein, 6 Co.Rep. (Q.B.) 159, Part XI—84b; 1 Abb.Pat.Cas. 1; Webs.Pat.Cas. 1; a royal grant of exclusive right to manufacture playing cards within the realm was held void as violating the common law and several Acts of Parliament. And see 1 Walker on Patents, pp. 12—16 (Deller's Ed. 1937).

The Statute of Monopolies created no new right either in the Crown or the people; it was simply declaratory of the common law and enacted into statute law, which bound the Sovereign, the doctrines that the courts had repeatedly affirmed, and reiterated those principles of the Magna Charta (9 Henry III, Ch. XXXVII, A.D. 1225) which declared that the liberties of his subjects shall not be infringed or broken by royal usurpation, and it limited the royal prerogative to certain definite terms and conditions under which it might be lawfully exercised. It is to be noted that there was a reservation of Letters Patent and grants of the privilege of the sole working or making of any new manufactures within the realm to the true and first inventor; conferring upon him an exclusive privilege for the term of fourteen years.’ 1 Walker on Patents, supra, at p. 22.

The first Act to implement the constitutional provision was approved April 10, 1790. It provided:

‘Section 1. * * * That upon the petition of any person or persons to the Secretary of State, the Secretary for the department of war, and the Attorney General of the United States, setting forth, that he, she, or they, hath or have invented or discovered any useful art, manufacture, engine, machine, or device, or any improvement therein not before known or used, and praying that a patent may be granted therefor, it shall and may be lawful to and for the said Secretary of State, the Secretary for the department of war, and the Attorney General, or any two of them, if they shall deem the invention or discovery sufficiently useful and important, to cause letters patent to be made out in the name of the United States, to bear teste by the President of the United States, reciting the allegations and suggestions of the said petition, and describing the said invention or discovery, clearly, truly and fully, and thereupon granting to such petitioner or petitioners, his, her or their heirs, administrators or assigns for any term not exceeding fourteen years, the sole and exclusive right and liberty of making, constructing, using and vending to others to be used, the said invention or discovery; * * *.’ (Italics supplied.) 1 Stat. 109, 110.

The Commissioner referred to the special interest of President Jefferson in this subject:

‘No American among his contemporaries or his successors has achieved a greater reputation as an opponent of monopoly than Thomas Jefferson. Yet he not merely sanctioned, he eloquently advocated the form of monopoly represented in patents. I cite his commentary on an early act of Congress, presumably that of 1790, in the administration of which he collaborated with Henry Knox, Secretary of War, and Edmund Randolph, Attorney General.

“An act of Congress authorizing the issue of patents for new discoveries has given a spring to invention beyond my conception. Being an instrument of granting the patents, I am acquainted with their discoveries.

“In the arts, and especially in the mechanical arts, many ingenious improvements are made in consequence of the patent-right giving exclusive use of them for 14 years.
“Certainly an inventor ought to be allowed a right to the benefit of his invention for some certain time. Nobody wishes more than I do that ingenuity should receive liberal encouragement.” Hearings before the Temporary National Economic Committee, supra, at p. 840.

Some conception of the degree to which the present patent system has been resorted to is found in Commissioner Coe's testimony that, up to 1939, over 2,000,000 patents had been issued, apart from design patents and reissues. The figure is now approximately 2,500,000 of which all but about 100,000 have been issued since 1870. He showed also that only about 60% of the applications filed are finally granted. (Id. at p. 844, and Exhibits 179 and 180.) See also, Official Gazette, U.S.Pat.Off., Vol. 605, pp. 714, 885 (Dec. 30, 1947).

After the final report of the Temporary National Economic Committee, the President issued Executive Order No. 8977, December 12, 1941, 1 C.F.R.Cum.Supp. 1040, establishing the National Patent Planning Commission to conduct a comprehensive survey and study of the American patent system and, among other things, to 'consider whether the system now provides the maximum service in stimulating the inventive genius of our people in evolving inventions and in furthering their prompt utilization for the public good; * * * whether there are obstructions in our existing system of patent laws, and if so, how they can be eliminated; * * * and what methods and plans might be developed to promote inventions and discoveries which will increase commerce, provide employment, and fully utilize expanded defense industrial facilities during normal times.'

The President appointed Charles F. Kettering, Chairman, Chester C. Davis, Francis P. Gaines, Edward F. McGrady and Owen D. Young as members of the Committee. The Report of the Committee, transmitted by the President to Congress June 18, 1943 (H.R.Doc. No. 239, 78th Cong., 1st Sess. 1), contained the following;

'The American patent system established by the Constitution giving Congress the 'Power * * * To promote the Progress of Science and useful Arts,' is over 150 years old. The system has accomplished all that the framers of the Constitution intended. It is the only provision of the Government for the promotion of invention and discovery and is the basis upon which our entire industrial civilization rests.

'The American people and their Government should recognize the fundamental rightness and fairness of protecting the creations of its inventors by the patent grant. The basic principles of the present system should be preserved. The system has contributed to the growth and greatness of our Nation; it has—

'(1) Encouraged and rewarded inventiveness and creativeness, producing new products and processes which have placed the United States far ahead of other countries in the field of scientific and technological endeavor;

'(2) Stimulated American inventors to originate a major portion of the important industrial and basic inventions of the past 150 years;

'(3) Facilitated the rapid development and general application of new discoveries in the United States to an extent exceeding that of any other country;

'(4) Contributed to the achievement of the highest standard of living that any nation has ever enjoyed;

'(5) Stimulated creation and development of products and processes necessary to arm the Nation and to wage successful war;

'(6) Contributed to the improvement of the public health and the public safety; and

'(7) Operated to protect the individual and small business concerns during the formative period of a new enterprise.
‘The strongest industrial nations have the most effective patent systems and after a careful study, the Commission has reached the conclusion that the American system is the best in the world.’ (Italics supplied.)

In its summary of findings and recommendations it added: ‘The patent system is the foundation of American enterprise and has demonstrated its value over a period coextensive with the life of our Government. The principle of recognizing a property right in intellectual creation is sound and should be continued as contemplated in the Constitution.’ (Id. at p. 9.)

13 In Grant v. Raymond, 6 Pet. 218, 241, 242, 243, 8 L.Ed. 376, Chief Justice Marshall said:

‘The law further declares that the patent ‘shall be good and available to the grantee or grantees by force of this act, to all and every intent and purpose herein contained.’ The amendatory act of 1793 contains the same language, and it cannot be doubted that the settled purpose of the United States has ever been, and continues to be, to confer on the authors of useful inventions an exclusive right in their inventions for the time mentioned in their patent. It is the reward stipulated for the advantages derived by the public for the exertions of the individual, and is intended as a stimulus to those exertions. The laws which are passed to give effect to this purpose ought, we think, to be construed in the spirit in which they have been made; and to execute the contract fairly on the part of the United States, where the full benefit has been actually received: if this can be done without transcending the intention of the statute, or countenancing acts which are fraudulent or may prove mischievous. The public yields nothing which it has not agreed to yield; it receives all which it has contracted to receive. The full benefit of the discovery, after its enjoyment by the discoverer for fourteen years, is preserved; and for his exclusive enjoyment of it during that time the public faith is pledged.

‘The great object and intention of the act is to secure to the public the advantages to be derived from the discoveries of individuals, and the means it employs are the compensation made to those individuals for the time and labour devoted to these discoveries, by the exclusive right to make, use and sell, the things discovered for a limited time.’

14 There is no issue here corresponding to the other issue examined and upheld in the General Electric case, namely, that involving the validity of the patentee's agency system of sales of its patented article. Another system for making sales of a patented article has been held invalid where the 'agencies' were found not to be bona fide agencies. United States v. Masonite Corporation, 316 U.S. 265, 86 L.Ed. 1461. That case, in turn, did not reach the issue raised by the Westinghouse license in the General Electric case. The Court there said (316 U.S. at page 277, 86 L.Ed. 1461): 'we need not reach the problems presented by Bement v. National Harrow Co., 186 U.S. 70, 22 S.Ct. 747, 46 L.Ed. 1058, and that part of the General Electric case which dealt with the license to Westinghouse Company.'


In discussing this patent monopoly and the patent laws of the United States this Court long ago said:

‘The monopoly thus granted is one entire thing, and cannot be divided into parts, except as authorized by those laws. The patentee or his assigns may, by instrument in writing, assign, grant, and convey, either (1) the whole patent, comprising the exclusive right to make, use, and vend the invention throughout the United States; or (2) an undivided part or share of that exclusive right; or (3) the exclusive right under the patent within and throughout a specified part of the United States. Rev.Stat. s 4898. * * * Any assignment or transfer, short of one of these, is a mere license, giving the licensee no title in the patent, and no right to sue at law in his own name for an infringement. Rev.Stat. s 4919; Gayler v. Wilder, 10 How. 477, 494, 495, (13 L.Ed. 504); Moore v. Marsh, 7 Wall. 515, (19 L.Ed. 37.)’ Waterman v. Mackenzie, 138 U.S. 252, 255, 11 S.Ct. 334, 335, 34 L.Ed. 923.

This was quoted with approval in Crown Co. v. Nye Tool Works, 261 U.S. 24, 37, 43 S.Ct. 254, 257, 67 L.Ed. 516, and was enlarged upon in the General Electric case, supra, 272 U.S. at page 489, 47 S.Ct. at page 196, 71 L.Ed. 362.

See note 18, supra.

‘As a license passes no interest in the monopoly, it has been described as a mere waiver of the right to sue by the patentee’ * * *.

Quoted with approval by Chief Justice Taft in a unanimous opinion of the Court in De Forest Co. v. United States, 273 U.S. 236, 242, 47 S.Ct. 366, 368, 71 L.Ed. 625.

Chief Justice Taft, 272 U.S. at pages 490, 491, 47 S.Ct. at page 197, 71 L.Ed. 362, made the following significant references to the Bement case:

‘This question was considered by this court in the case of Bement v. National Harrow Co., 186 U.S. 70, 22 S.Ct. 747, 46 L.Ed. 1058. A combination of manufacturers owning a patent to make float spring tool harrows licensed others to make and sell the products under the patent on condition that they would not during the continuance of the license sell the products at a less price or on more favorable terms of payment and delivery to purchasers than were set forth in a schedule made part of the license. That was held to be a valid use of the patent rights of the owners of the patent. It was objected that this made for a monopoly. The court, speaking by Mr. Justice Peckham, said (186 U.S.) page 91 (22 S.Ct. 755); 46 L.Ed. 1058);

“The very object of these laws is monopoly, and the rule is, with few exceptions, that any conditions which are not in their very nature illegal with regard to this kind of property, imposed by the patentee and agreed to by the licensee for the right to manufacture or use or sell the article, will be upheld by the courts. The fact that the conditions in the contracts keep up the monopoly or fix prices does not render them illegal.’

‘Speaking of the contract, he said (186 U.S.) page 93 (22 S.Ct. 756); 46 L.Ed. 1058):

“The provision in regard to the price at which the licensee would sell the article manufactured under the license was also an appropriate and reasonable condition. It tended to keep up the price of the implements manufactured and sold, but that was only recognizing the nature of the property dealt in, and providing for its value so far as possible. This the parties were legally entitled to do. The owner of a patented article can, of course, charge such price as he may choose, and the owner of a patent may assign it or sell the right to manufacture and sell the article patented upon the condition that the assignee shall charge a certain amount for such article.”
Judge Westenhaver, whose judgment in the District Court was affirmed by this Court in the General Electric case, said:

‘If both licensor and licensee are making and selling, it is quite conceivable that the owner of the patent could not safely grant licenses at all on any other terms; otherwise, he would risk having his business destroyed, and hence, as a matter of ordinary business prudence, would feel obliged to keep his patent monopoly wholly within his own hands. And it was so held in Bement v. National Harrow Co., 186 U.S. 70, 22 S.Ct. 747, 46 L.Ed. 1058.’ United States v. General Electric Co., D.C., 15 F.2d 715, 718.


Clarence C. Carlton, president of the Automotive Parts and Equipment Manufacturers Association, testified that in the automotive parts industry:

‘Patents are valued so much more by the small manufacturer than they are by the large manufacturer. * * * if anything happened to this patent system the fellow who would be hurt more than anyone else would be the smaller manufacturer.’ (Id. at pp. 1057, 1058.)

‘As a part consideration for the granting of the foregoing licenses, the Licensee (Westinghouse) hereby grants and agrees to grant to the Licensor (General Electric) a non-exclusive license under the United States patents which it now owns or controls and under those which may issue on pending applications now owned or controlled by it, and under any United States patents which the Licensee may own or control, during the term of this agreement, for improvements in incandescent lamps specified in paragraphs a, b, c and d of Article 2, to make, use and sell throughout the United States and the territories thereof incandescent lamps of the kinds specified in said paragraphs of Article 2 hereof, such license being personal, non-assignable, indivisible and non-transferable except to successors to substantially the entire good will and business of the Licensor, and to continue for the period during which the licenses from the Licensor to the Licensee remain in force.’ Par. (8) of Agreement between General Electric Company and Westinghouse Electric & Manufacturing Company, March 1, 1912, Exhibit A, at p. 117 of the record in the Supreme Court of the United States, No. 113, O.T. 1926.

In that Standard Oil case, 283 U.S. at page 171, 51 S.Ct. at page 424, 75 L.Ed. 926, the footnote at this point stated:

‘This is often the case where patents covering improvements of a basic process, owned by one manufacturer, are granted to another. A patent may be rendered quite useless, or ‘blocked,’ by another unexpired patent which covers a vitally
related feature of the manufacturing process. Unless some agreement can be reached, the parties are hampered and exposed to litigation. And, frequently, the cost of litigation to a patentee is greater than the value of a patent for a minor improvement.'

29 Before making this statement, Mr. Justice Brandeis already had joined in the opinion of the Court in the General Electric case, supra, and written the opinion in Carbice Corporation v. American Patents Development Corporation, 283 U.S. 27, 51 S.Ct. 334, 75 L.Ed. 819.

30 Many bills relating to these issues have been introduced in Congress and referred to appropriate committees. Not one has been reported back to either House of Congress.

As early as 1912, H.R. 22345, 62d Cong., 2d Sess., proposed that a patentee be not permitted to fix the price of articles to be sold by others under his patent.

During the hearings held by the Temporary National Economic Committee, the Department of Justice recommended many fundamental as well as minor changes in the patent law. These included the prohibition of price-limiting patent licenses comparable to those here at issue. Preliminary Report, Temporary National Economic Committee, Sen. Doc. No. 95, 62d Cong., 2d Sess., 16, 17 (1939). The Department of Commerce took an opposite position. It submitted recommendations for retaining but improving the patent system substantially in accordance with its traditional underlying policies. The Final Report of the Temporary National Economic Committee incorporated the substance of the proposals of the Department of Justice. It included a recommendation that patentees be not permitted to limit the price at which a licensee might sell a product made under the license. Final Report, Temporary National Economic Committee, Sen. Doc. No. 35, 77th Cong., 1st Sess. 36, 37 (1941).

In 1941, the President appointed the National Patent Planning Commission to submit recommendations on questions dealt with in the report. (See note 12, supra.) In 1943, among the examples of the proposed reforms which it concluded ‘would not be a beneficial innovation in our patent system,’ it listed ‘outlawing certain limitations in patent licenses, * * *.’ This evidently referred to the above-mentioned proposals of the Temporary National Economic Committee to outlaw price restrictions and other limitations in patent licenses. Report of the National Patent Planning Commission, House Doc. 239, 78th Cong., 1st Sess. 9 (1943).

Bills to the same general effect as the proposals of the Temporary National Economic Committee have been introduced and referred to Committees of Congress but have advanced no further. Among them have been the following:

S. 2491 (s 4), S. 2730 (s 3), H.R. 7713 (s 3), 77th Cong., 2d Sess. (1942); H.R. 109 (s 3), H.R. 1371 (s 29), H.R. 3874 (s 29), 78th Cong., 1st Sess. (1943); H.R. 97 (s 29), H.R. 3462 (s 29), 79th Cong., 1st Sess. (1945); S. 2482, 79th Cong., 2d Sess. (1946); S. 72, 80th Cong., 1st Sess. (1947). Section 3 of S. 2730, supra, proposed that ‘Every sale, assignment, or conveyance of a patent and every grant of a license thereunder, in connection with any condition, agreement, or understanding which restricts the price at which the purchaser, assignee, grantee, or license (licensee) may sell any article producible under the patent and customarily marketed in interstate commerce, is hereby declared to be illegal.’
UNIVERSITIES DISTRICT COURT
DISTRICT OF NEW JERSEY

MAYOR AND CITY COUNCIL OF BALTIMORE, on behalf of itself and all others similarly situated,

Plaintiff,

v.

TEVA PHARMACEUTICALS INDUSTRIES LTD., TEVA PHARMACEUTICALS USA, INC., TEVA NEUROSCIENCE, INC., and TEVA SALES & MARKETING, INC.,

Defendants.

CIVIL ACTION NO.

CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL
TABLE OF CONTENTS

I. INTRODUCTION ........................................................................................................................................1

II. JURISDICTION AND VENUE ................................................................................................................3

III. THE PARTIES ........................................................................................................................................4

IV. INDUSTRY BACKGROUND ....................................................................................................................5

A. The Hatch-Waxman Amendments provide for the approval of generic drugs that are bioequivalent to, and thus perfect therapeutic substitutes for, their brand drug counterparts .................................................................................................................................5

1. Congress relies on generic drugs to reduce healthcare expenses..............................................7

2. Brand drug manufacturers can delay potential generic competitors through litigation ........................................................................................................................................8

3. Brand drug manufacturers can prevent pharmacies from automatically substituting generic drugs for their brand counterparts ...................................................................................................................9

4. Brand drug manufacturers can limit access to generic drugs by excluding them from insurance coverage formularies .........................................................................................11

B. The BPCIA provides for the approval of biological products which are biosimilar to, but not substitutes for, their reference biological product ..............................................13

V. BACKGROUND FACTS ........................................................................................................................14

A. COPAXONE ...........................................................................................................................................14

B. Teva Employed an Entire Playbook of Anticompetitive Tactics to Thwart Generic Competition for Copaxone ..............................................................................................................................15

1. Teva Raises Prices Aggressively ........................................................................................................17

2. Teva Engineers a Product Hop to Preemptively Blunt Generic Competition and Aggressively Migrates Consumers to Its 40mg Product .........................................................................................18

3. Teva Files Eight Citizen Petitions to Forestall Generic Competition; FDA Approves Sandoz’s 20mg ANDA and, Subsequently, Mylan’s 20 and 40mg ANDA .................................................................................20

4. Teva Loses Its Bid to Use Its Five Patents to Protect 20mg Brand Copaxone from Generic Competition .................................................................................................................................21
5. Mylan Receives FDA Final Approval For 40mg and 20 mg and Launches. .................................................................24

VI. FACTS GIVING RISE TO PLAINTIFF’S CLAIMS ...............................................................25
   A. Teva’s Anticompetitive Copay “Couponing” Strategy and Illegal Kickback Scheme.................................25
   B. Teva’s Exclusionary House Brand Strategy with PBMs and PBM-Owned Specialty Pharmacies ....................29
   C. Teva’s False and Misleading “DAW” Campaign ................................................................................32

VII. MARKET POWER AND MARKET DEFINITION .................................................................38

VIII. EFFECT ON INTRASTATE AND INTERSTATE COMMERCE ..............................................40

IX. ANTITRUST IMPACT ...................................................................................................41

X. CLASS ACTION ALLEGATIONS .................................................................................42

XI. TEVA CONCEALED ITS UNLAWFUL CONDUCT ..........................................................45

XII. COMPLIANCE WITH NOTICE AND DEMAND REQUIREMENTS ..................................47

XIII. CLAIMS FOR RELIEF ...............................................................................................48

XIV. DEMAND FOR JUDGMENT ....................................................................................97

XV. JURY DEMAND ........................................................................................................98
Plaintiff, the Mayor and City Council of Baltimore (“Plaintiff” or “City of Baltimore”), brings this action on behalf of itself and all others similarly situated, against Defendants Teva Pharmaceuticals Industries Ltd. (“Teva Ltd.”), Teva Pharmaceuticals USA, Inc. (“Teva USA”), Teva Neuroscience, Inc. (“Teva Neuro”), and Teva Sales & Marketing, Inc. (“Teva S&M”) (collectively “Teva” or “Defendants”). These allegations are based on publicly available materials, investigation of counsel and knowledge, information, and belief.

I. INTRODUCTION

1. This case arises out of Teva’s anticompetitive scheme to unlawfully thwart generic competition in the United States and its territories for its prescription drug Copaxone. The active ingredient in Copaxone is glatiramer acetate (“GA”), and it is an injectable medication approved for the treatment of patients with relapsing forms of multiple sclerosis (“MS”), including for the reduction of the frequency of relapses in relapsing-remitting MS (“RRMS”). Copaxone is Teva’s best-selling product, generating more than $30 billion in revenue in the United States, including $3.5 billion in 2016 alone.

2. Since Teva began selling Copaxone in 1997, it has been able to raise the price uninhibited for decades. The annual cost of Copaxone has skyrocketed from less than $10,000 for a yearly course in 1997 to nearly $70,000 per year in 2020.

3. Following a multi-pronged strategy to delay generic competition, including through litigation and shifting the market from its 20 mg product to a 40 mg product, Teva continued its scheme both before and after Mylan Pharmaceuticals and Sandoz introduced a generic version of Copaxone 40 mg by employing multiple tactics to prevent the uptake of generic versions of Copaxone.
4. First, Teva duped health plans with an anticompetitive consumer copay “coupon” scheme that circumvented plan members’ cost-sharing obligations and helped artificially increase and protect brand Copaxone’s high prices.

5. Then, as part of a scheme to foreclose uptake of generic Copaxone, Teva entered into multi-pronged “House Brand” agreements with intermediaries, including PBMs and PBM-owned specialty pharmacies, to block generics by (i) refusing to pay any rebates to the PBMs unless generic Copaxone was excluded from formularies, and (ii) reaching agreements with PBM-owned specialty pharmacies to dispense branded Copaxone even if a prescription was written specifically for generic Copaxone. At the same time, Teva engaged in a misinformation campaign, widely spreading false and misleading statements to convince prescribers and patients that generic Copaxone was inferior to Copaxone and/or that generic Copaxone manufacturers did not offer copay assistance and training and support services. These false marketing statements convinced a substantial percentage of healthcare providers to write “DAW” prescriptions, circumventing automatic substitution laws and ensuring that they would be filled only with branded Copaxone even though less expensive generic alternatives were available.

6. Absent the Defendants’ unlawful conduct, generic manufacturers of Copaxone would have been able to fairly compete with Teva in a full and timely manner, and Plaintiff and Class members, which includes “third-party payors” such as health insurers and self-funded health plans, would have substituted lower-priced generic Copaxone for nearly all of their Copaxone purchases and paid lower prices for their branded Copaxone purchases. Plaintiff and Class members would have purchased lower-priced Copaxone in substantially larger quantities. Instead, the Defendants’ unlawful conduct allowed Teva to reap substantial amounts in ill-gotten gains and prevented uptake of the 40mg generic GA versions which has cost Plaintiff and Class members
hundreds of millions of dollars in overcharge damages. Plaintiff and the proposed class seek to recover damages, including treble damages, under the state antitrust and consumer protection laws enumerated below and declaratory and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26.

II. JURISDICTION AND VENUE

7. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d) because this is a class action involving common questions of law or fact in which the aggregate amount in controversy exceeds $5,000,000, exclusive of interest and costs, there are more than one hundred members of the class, and at least one member of the putative class is a citizen of a state different from that of one of the Defendants.

8. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1332(d), and 1337(a).

9. This Court has supplemental jurisdiction over state law claims pursuant to 28 U.S.C. § 1367(a).

10. The Court also has jurisdiction over this action pursuant to § 2 of the Sherman Act and §§ 4 and 16 of the Clayton Act.

11. The Defendants transact business within this District and/or have agents in and/or can be found in this District.

12. Venue is appropriate within this District under 28 U.S.C. § 1391.

13. Venue is also appropriate within this District under § 12 of the Clayton Act.¹

14. The Court has personal jurisdiction over each of the Defendants. The Defendants have transacted business, maintained substantial contacts, and/or committed overt acts in

furtherance of the illegal scheme throughout the United States, including in this District. The scheme has been directed at, and has had the intended effect of causing injury to individuals and companies residing in or doing business throughout the United States, including in this District.

III. THE PARTIES

15. Plaintiff, the Mayor and City Council of Baltimore, is a municipality located in Baltimore, Maryland. During the Class Period, as defined below, the City of Baltimore purchased, paid, and/or provided reimbursement for some or all of the purchase price of Copaxone and its AP-rated generic equivalent for personal and/or household use from pharmacies located in and/or on behalf of members located in at least the following states: Delaware, Florida, Illinois, Kansas, Maryland, New Jersey and Pennsylvania.

16. Defendant Teva Pharmaceuticals Industries Ltd. (“Teva Ltd.”) is an Israeli corporation with a principal place of business at 5 Basel St., Petach Tikva, Israel 4951033. Teva Ltd. owns subsidiaries, including Teva Pharmaceuticals USA, Inc., Teva Neuroscience, Inc. and Teva Sales & Marketing, Inc., which do business in the United States. Teva Ltd. has promoted itself as the largest seller of generic drugs in the United States with billions of dollars in revenue. But for Teva Ltd.’s subsidiaries, Teva USA, Teva Neuro and Teva S&M, Teva Ltd. itself would need to act directly in order to achieve its goals marketing pharmaceuticals in this District and all other states.

17. Defendant Teva Pharmaceuticals USA, Inc. (“Teva USA”) is a Delaware corporation with a principal place of business at 400 Interpace Parkway, Parsippany, NJ 07054. Teva USA is a subsidiary of Teva Ltd.

18. Defendant Teva Neuroscience, Inc. (“Teva Neuro”) is a Delaware corporation with a principal place of business at 11100 Nall Ave., Overland Park, Kansas, 66211. Teva Neuro is a subsidiary of Teva Ltd.
19. Defendant Teva Sales & Marketing, Inc. ("Teva S&M") is a Delaware corporation with a principal place of business at 11100 Nall Ave., Overland Park, Kansas, 66211. Teva S&M is a subsidiary of Teva Ltd.

20. The Defendants’ wrongful actions described in this complaint are part of and were taken in furtherance of the illegal monopolization scheme and restraint of trade alleged herein. These actions were authorized, ordered, and/or undertaken by the Defendants’ various officers, agents, employees, or other representatives while actively engaged in the management of the Defendants’ affairs within the course and scope of their duties and employment and with their actual, apparent, or ostensible authority.

IV. INDUSTRY BACKGROUND

A. The Hatch-Waxman Amendments provide for the approval of generic drugs that are bioequivalent to, and thus perfect therapeutic substitutes for, their brand drug counterparts.

21. Under the Food, Drug, and Cosmetics Act ("FDCA"), drug companies that wish to sell a new drug product must file a New Drug Application ("NDA") with the FDA. An NDA submission must include specific data concerning the safety and effectiveness of the drug, including information from at least two clinical trials.

22. An NDA applicant must also submit to the FDA information about each patent that purportedly covers the drug product, including methods of using the drug product, described in the NDA and for which “a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.”² The FDA then publishes this information in a digest titled Approved Drug Products with Therapeutic Equivalence Ratings, known as the Orange Book.

23. The Hatch-Waxman Amendments, enacted in 1984, simplified regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application (“ANDA”). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer’s original NDA and must show that the generic contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug and that it is bioequivalent, i.e., absorbed at the same rate and to the same extent as the brand.

24. The FDCA and Hatch-Waxman Amendments operate on the principle that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity, and identity are therapeutically equivalent and may be substituted for one another. Bioequivalence demonstrates that the active ingredient of the proposed generic would be present in the blood of a patient to the same extent and for the same amount of time as the brand counterpart.

25. Accordingly, when the FDA approves the sale of a generic drug under the Hatch-Waxman Amendments, it assigns that drug a therapeutic equivalence code. A generic drug which is “AP-rated” is bioequivalent to, and is thus a perfect substitute for, its brand drug counterpart.

---


5 The therapeutic equivalence code for an A-rated drug includes a second letter which generally provides information about the dosage form of the drug. For example, here Mylan’s GA products are “AP-rated” which means they are A-rated drugs (A-) in the form of “aqueous injectable solutions” (-P).
1. **Congress relies on generic drugs to reduce healthcare expenses.**

26. Through the Hatch-Waxman Amendments, Congress sought to expedite the entry of less expensive generic competitors to brand drugs, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers’ incentives to create new and innovative products.

27. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches and ushering in an era of historically high profit margins for brand pharmaceutical manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenues for brands and generics totaled $21.6 billion; by 2013, total prescription drug revenues had climbed to more than $329.2 billion, with generics accounting for 86% of prescriptions. Generics are dispensed about 95% of the time when a generic form is available.

28. Because generic versions of branded drugs contain the same active ingredients and are determined by the FDA to be just as safe and effective as their branded counterparts, the only material differences between generic drugs and their branded counterparts are their prices and manufacturers. Because generic versions of branded products are commodities that cannot be differentiated, the primary basis for generic competition is price.

29. Typically, generics are at least 25% less expensive than their branded counterparts when there is a single generic competitor. They are 50% to 80% (or more) less expensive when there are multiple generic competitors on the market for a given brand. Consequently, the launch of a bioequivalent generic drug usually results in significant cost savings to all drug purchasers.

30. Once a generic comes to market, it quickly captures sales of the corresponding brand drug, often 80% or more of the market, within the first six months after entry. In one study, the FTC found that on average, within a year of generic entry, generics had captured 90% of
corresponding brand sales and (with multiple generics on the market) prices had dropped 85%. As a result, competition from generics is viewed by brand manufacturers as a grave threat to their bottom lines.

31. Until the generic version of a brand drug enters the market, there is no bioequivalent generic to substitute for, and thus compete with, the branded drug, so the brand drug manufacturer can continue to profitably charge supra-competitive prices. As a result, brand drug manufacturers, well aware of the rapid erosion of branded drug sales by generic drugs, have a strong incentive to delay the start of generic drug competition into the market. And once a generic drug enters the market, brand drug manufacturers have strong incentives to prevent their adoption. Both delay of generic entry and prevention of uptake of generic versions are achievable by brand drug manufacturers willing to engage in illegal conduct to exploit the unique structure of the pharmaceutical marketplace.

2. **Brand drug manufacturers can delay potential generic competitors through litigation.**

32. Under the Hatch-Waxman Amendments, if patents submitted with the brand drug manufacturer’s original NDA and listed in the Orange Book have not yet expired, a generic manufacturer may certify as part of their ANDA that those patents are invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted. This certification is commonly known as a Paragraph IV or “P.IV” certification.

33. If a generic manufacturer files an ANDA containing a P.IV certification, a brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement.

---

34. If the brand manufacturer initiates a patent infringement action against the generic filer within 45 days of receiving notification of a P.IV certification, the FDA generally will not grant final approval on that ANDA until the earlier of (i) the passage of 30 months, or (ii) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer’s ANDA. This period is commonly referred to as the “30-month stay.”

35. Until the court issues a decision finding the patent invalid or not infringed or until 30 months has passed, the FDA may grant “tentative approval” to the ANDA filer, recognizing that the ANDA is approvable, but cannot grant final approval, which would allow the generic manufacturer to market its product.

3. **Brand drug manufacturers can prevent pharmacies from automatically substituting generic drugs for their brand counterparts.**

36. The marketplace for the sale of prescription pharmaceutical products in the United States is unique. In most industries, the person who pays for a product is also the person who chooses the product. When the same person has both the payment obligation and the choice of products, the price of the product plays a predominant role in the choice of products. Consequently, manufacturers have a strong incentive to lower the price of their products to maintain profitability.

37. The pharmaceutical marketplace, in contrast, is characterized by a “disconnect” between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing certain drugs to patients unless they can present a prescription written by their physician. This prohibition introduces an anomaly into the pharmaceutical marketplace between the payment obligation and the product selection. The patient (and in most cases his or her insurer)

---

has the obligation to pay for the pharmaceutical product, but his or her doctor chooses which product the patient will buy.

38. In 1984, Congress sought to ameliorate the “disconnect” by authorizing the manufacture and sale of generic pharmaceuticals under the Hatch-Waxman Amendments. Since the passage of the Hatch-Waxman Amendments, every state has adopted drug “automatic substitution” laws that either require or permit pharmacies to substitute A-rated generic equivalents for brand prescriptions. In this way, price reenters the product selection decision at the pharmacy counter, lessening the pharmaceutical marketplace “disconnect.”

39. Brand drug manufacturers can evade these automatic substitution laws in several ways. First, brand manufacturers can engage in litigation or FDA petitioning tactics to slow or prevent generic approval.

40. Second, brand drug manufacturers can prevent automatic substitutions by instead marketing slightly different versions of their drugs for which there are not yet any A-rated generics; pharmacists cannot choose to substitute generics of the previous version.

41. Third, most automatic substitution laws also include a “dispense as written” or “DAW” exception that allows physicians to explicitly prohibit pharmacies from substituting AP-rated generic drugs for their brand drug equivalents. By leveraging their dominant incumbent position and encouraging doctors to use DAW scripts to prescribe only brand drugs, a brand drug manufacturer can thus remove the pharmacist’s ability to substitute generic drugs for their brand drug counterparts, remove price from product selection, and preserve the marketplace “disconnect” that enables the brand drug manufacturer’s supracompetitive pricing.

---


9 See id.
42. Fourth, brand manufacturers may engage in anticompetitive contracting strategies meant to manipulate drug coverage or placement on formularies (i.e., the lists of “covered” drugs maintained by Pharmacy Benefit Managers (“PBMs”) and third-party payors), placement that would otherwise encourage the use of cheaper generic versions of the drug and insulate the brand drug from generic competition.

4. **Brand drug manufacturers can limit access to generic drugs by excluding them from insurance coverage formularies.**

43. A PBM is an intermediary in the pharmaceutical supply chain that manages prescription drug benefits on behalf of their third-party payor health plan clients.

44. As their name implies, PBMs sell pharmacy benefit management services to their clients—typically entities like health insurance companies, self-funded health plans, and the government. Theoretically, PBMs leverage the collective purchasing power of those clients to extract lower drug prices from drug manufacturers and lower distribution costs from pharmacies.

45. PBMs manage pharmacy benefits by developing lists of covered prescription drugs, also known as formularies, on behalf of health insurers. Because these lists determine which drugs are covered by insurance plans, formulary placement largely determines which drugs covered individuals have access to. If a drug is not on the formulary, the health plan generally will not cover it, and the patient who is prescribed that drug must pay the entire cost out-of-pocket.

46. PBMs do not themselves buy prescription drugs from drug manufacturers. Instead, they negotiate “rebates” from drug manufacturers who want their products included on the PBM’s formulary. Put another way, drug manufacturers pay PBMs to include their products on the formulary. PBMs then provide a portion of these rebates to their clients and give drug manufacturers access to their clients’ covered members.
47. Similarly, PBMs do not themselves sell prescription drugs to pharmacies. Instead, pharmacies buy their drugs from wholesalers, then turn to the PBM’s client for reimbursement after providing those drugs to an individual covered by the PBM’s client—the health plan.

48. While drug manufacturers pay PBMs rebates to include their products on formularies, some manufacturers have begun to condition those rebates on excluding competing drugs from the formulary or offering more favorable placement to the brand over the competing generic version.

49. The PBM market is extremely concentrated. The three largest PBMs—OptumRx, CVS Caremark, and Express Scripts—control almost 80% of the market for PBM services. This level of concentration means that by paying only a few different PBMs for formulary exclusivity, a drug manufacturer with monopoly power can foreclose a generic competitor from huge swaths of the market.

50. Moreover, certain PBMs own or are affiliated with specialty pharmacies and require plan members to fill their specialty prescription needs at that particular pharmacy. As illustrated below, five of the six largest PBMs, including the three largest, are vertically integrated with other health services providers, including specialty pharmacies. So, as an example, upon information and belief, members of Express Scripts’ plans are required to purchase their specialty pharmacy drugs, including Copaxone, from Accredo, which is a wholly-owned subsidiary of Express Scripts.
B. The BPCIA provides for the approval of biological products which are biosimilar to, but not substitutes for, their reference biological product.

51. Under the Public Health Service Act (PHSA), as amended by the Biologics Price Competition and Innovation Act of 2009 (BPCIA)\(^\text{10}\), the FDA also regulates biological products, also known as “biologics.”

52. In some ways the regulatory process for biologics is similar to that for pharmaceutical drugs. Under the BPCIA, a biologic manufacturer may seek approval for sale of their product by demonstrating biosimilarity or interchangeability with an already-approved biologic.

53. However, biological products are distinct from pharmaceutical drugs regulated under the FDCA and Hatch-Waxman Amendments, and biosimilarity is distinct from bioequivalence.

---

\(^{10}\) 42 U.S.C. § 262(k)(2).
54. An A-rated generic drug is bioequivalent to, and thus can be substituted for, its brand drug reference. Indeed, as described above, some states require pharmacists to substitute A-rated generics in for their brand drug counterparts. By contrast, although one biologic may be approved because it is biosimilar to another reference product, biosimilars cannot generally be substituted for their reference product “without the intervention of the health care provider who prescribed the reference product.”\(^{11}\)

55. Biosimilars can only be substituted for their reference product without the intervention of the health provider if, after additional testing, the FDA also determines that they are “interchangeable.” However, although it has been over a decade since the BPCIA was enacted, only two biosimilars have been determined to be interchangeable with their reference biologic.

V. BACKGROUND FACTS

A. COPAXONE

56. On December 20, 1996, FDA approved Teva’s NDA No. 20-622 for glatiramer acetate therapy – 20mg/mL (“20mg”) daily – an injectable drug to treat patients with relapsing forms of multiple sclerosis (“MS”), including relapsing remitting MS (“RRMS”). Copaxone is a medication for MS which helps reduce relapses; it does not cure MS. Therefore, patients typically take Copaxone for many years. Teva began marketing 20mg Copaxone in March 1997.

57. Given its characteristics as a specialty injectable drug, Copaxone is commonly dispensed through specialty pharmacies.

58. Teva’s market exclusivity for Copaxone 20mg ended in May 2014.\(^{12}\)

---

\(^{11}\) 42. U.S.C. § 262(i)(3).

\(^{12}\) The patents covering Copaxone 20mg were U.S. Patents Nos. 5,981,589; 6,054,430; 6,342,476; 6,362,161; 6,620,847; 6,939,539; and 7,199,098, all of which are listed in the Orange Book for Copaxone® 20mg and two process patents, 5,800,808 and 6,048,898.
59. Copaxone is a blockbuster drug for Teva, yielding billions in annual U.S. sales, and representing as much as 21% of Teva’s global revenue (and half of its profit) in 2014\(^1\) and 19% of Teva’s global revenue in 2017.

60. Teva’s Form 10-K for the end of fiscal year December 31, 2017 identified Copaxone as its “most significant single contributor to revenues and profits.”\(^2\) As a result, Teva has had a significant incentive to delay and thwart the uptake of generic GA, given that such entry would, absent Teva’s unlawful conduct, eviscerate brand sales and, correspondingly, its revenue.

61. Fearing the loss of Copaxone 20mg exclusivity and the concomitant dramatic drop in revenue that would result from generic competition, Teva turned to a series of strategies to prolong its monopoly on Copaxone before its 20mg formulation patents expired.

B. **Teva Employed an Entire Playbook of Anticompetitive Tactics to Thwart Generic Competition for Copaxone.**

62. Notwithstanding that Teva is the world’s largest manufacturer of generic drugs, in this case, it manufactures a brand product and called upon all of its experience on the generic side of the market to derail other generic manufacturers’ efforts to enter the glatiramer acetate market. Teva engineered a product “hop” from one non-patent covered product to another patent-covered product to move patients from the drug that was vulnerable to generic competition to the drug that had additional patent protection, thus decimating the prescription base for competing Copaxone generics. Teva also filed serial citizen petitions with FDA to delay FDA review of generic GA ANDAs and lodged multiple infringement lawsuits against ANDA filers for generic glatiramer acetate formulations. And Teva implemented an anticompetitive copay couponing program and an


\(^2\) https://www.sec.gov/Archives/edgar/data/818686/000119312518039076/d529462d10k.htm.
illegal kickback scheme, both of which further allowed it to maintain its inflated prices for Copaxone and suppress uptake of generic GA.

63. Before and after Sandoz launched a generic 20mg formulation in 2015 and Mylan launched generic 20mg and 40mg formulations in 2017, Teva aggressively sought to foreclose all avenues of generic competition to Teva’s Copaxone and to perpetuate its monopoly through anticompetitive means. Teva ran a behind-the-scenes campaign designed to manipulate doctors, PBMs, and patients to continue purchasing its more expensive Copaxone. As one district court observed in 2020, from the time that Teva first obtained FDA’s approval to market Copaxone in the United States in 1996, “Teva has pursued every available avenue to prevent other glatiramer acetate products from coming to market.”

64. Simply stated, the long history of Teva’s drug Copaxone is punctuated with attempt after attempt by Teva to snuff out generic competition. Teva’s illicit acts have caused, and continue to cause, purchasers to pay higher prices and have barred some purchasers from obtaining generic versions of glatiramer acetate entirely. In order to stifle and block the onset of generic competition and continue reaping hundreds of millions of dollars annually from its Copaxone sales, Teva embarked on a multifaceted scheme to foreclose or severely dilute generic entry. One analyst put it succinctly: “It's not just that Teva doesn't want the FDA to approve generics of its MS star, Copaxone. It really, really, really does not want the FDA to approve them.”

---


1. **Teva Raises Prices Aggressively.**

65. Since first marketing Copaxone in 1997, Teva has increased the price of the drug at least 27 *times*. In 1997, Copaxone was priced at $10,000 for an annual course of treatment. In 2020, an annual course of treatment cost nearly $70,000.

66. In fact, a September 2020 report by the Committee on Oversight and Reform of the United States House of Representatives ("House Report"), titled “Drug Pricing Investigation: Teva-Copaxone,” found that “[e]ven Teva’s own employees could not afford Copaxone at its price.” The exchange was captured in a Teva document, in which the employee lamented that she could no longer afford Copaxone, which would cost her $1,673.33 out of pocket, while Mylan’s generic GA would only cost her $12 out of pocket.

67. The prices Teva charges for Copaxone in the United States is far higher than the prices it charges for the same product in other countries. For example, in 2015, the net price of Copaxone 40mg/ml was $126 per day in the United States. In sharp contrast, the exact same dosage was only $33 in Germany, $26 in Spain, $25 in the United Kingdom, and $18 in Russia.

68. According to the House Report, Teva’s internal data demonstrates that its price increases cannot be explained by rebates, discounts, or other fees paid to pharmacy benefit managers (PBMs) or other entities in the pharmacy distribution chain. Indeed, Teva’s net revenue (after such rebates and discounts) increased from 2009 to 2017.

---

69. The House Oversight Committee also found that “Teva invested only a small portion of its Copaxone revenue in further research and development to help Copaxone patients.” It invested only $689 million in Copaxone related research and development since 1987, which is only 2% of the $34.2 billion in net U.S. revenue it has generated from Copaxone between 2002 and 2019.

70. Plaintiffs and members of the Class have borne the brunt of Teva’s price increases, paying excessive amounts for their Copaxone – a critical MS medication.

2. Teva Engineers a Product Hop to Preemptively Blunt Generic Competition and Aggressively Migrates Consumers to Its 40mg Product.

71. To prepare for entry of generic versions of Copaxone into the market, Teva decided on a product switch strategy to prevent generic substitution for its 20mg Copaxone product. Teva sought to switch the market from its once-daily 20mg Copaxone to a 40mg version that was a larger dose taken three times weekly. To this end, Teva supplemented its NDA in 2013. FDA approved the 40mg version on January 28, 2014, and Teva launched it in the U.S. immediately.

72. Teva knew this tactic would prevent pharmacists from substituting generic version of 20mg GA when patients brought in prescriptions for 40mg Copaxone.

73. The House Report described Teva’s price increase of its predecessor product and its ostensible patient transfer strategy as part of Teva’s product hop strategy:

In 2014, Teva introduced a 40 mg/ml formulation of Copaxone in part to extend its monopoly pricing for Copaxone by shifting patients to that formulation—which still enjoyed market exclusivity—before the 20 mg/ml formulation began facing lower-priced generic competition. To push patients to the 40 mg/ml formulation of Copaxone, Teva increased the price of the 20 mg/ml formulation. To press patients to make the move, Teva explored a plan to “Discontinue 20mg Financial Programs (Patient Services),” its financial assistance program for patients. Teva’s strategy was successful in maintaining its profits and limiting competition. Experts
estimate that the strategy cost the U.S. health care system between $4.3 and $6.5 billion in excess spending.  

74. The House Report reveals that Teva’s objective in introducing the 40mg version was as a “generic defense strategy.” As Teva put it, “our business strategy for Copaxone® relies heavily on the successful introduction of a three-times-a-week product and the migration of a substantial percentage of current daily Copaxone® patients to this new version. The failure to achieve our objectives for the new version would likely have a material adverse effect on our financial results and cash flow.”

75. Indeed, Teva knew there was “no supporting data for the selected dose or dosing regimen.” In fact, Teva refrained from developing a once per week 40mg formulation (which would have been more convenient than a three-times-weekly dose) for fear that it would not serve its purpose of blocking generic conversion – i.e., patients might opt to take two doses of cheaper 20mg generic GA once per week rather than Teva’s expensive 40mg product.

76. As Teva struggled to find a viable clinical justification for the three-times-a-week dosing regimen, many of Teva’s own scientists opposed the decision to pursue this dosing frequency: one scientist wrote that Teva’s Innovative Research and Development management was “strongly against” Teva’s study into the less-frequent dosing of Copaxone “since it has no scientific rationale/value.” Despite the lack of a scientific rationale, Teva recognized that “such a study has its business value.” In other words, Teva’s effort to shift the market from 20mg

---

18 House Report.
19 Id.
20 Id.
21 Id.
22 Id.
Copaxone to the 40mg formulation was pretextual and implemented solely as another barrier to
generic GA competition.

77. Sandoz 20mg launched its generic GA product on June 15, 2015. But by that time,
Teva had shifted a vast number of its U.S. Copaxone users to its 40mg formulations. Sandoz’s
generic entry into the market with its 20mg formulation thus had little effect because, as FDA itself
has stated, Teva had, by that time, “vigorously convert[ed]” patients to Teva’s 40mg formulation.”

78. Teva subsequently announced in its second-quarter 2016 earnings call, that it had
succeeded in migrating 83% of U.S. Copaxone users to its 40mg dose.

79. By shifting patients from the 20mg to the 40mg Copaxone formulation, Teva
maintained more than $3 billion in annual net revenue from 2015 to 2017, despite competition
from Sandoz’s 20mg generic GA beginning in mid-2015 and Mylan’s 20mg and 40mg generic

3. Teva Files Eight Citizen Petitions to Forestall Generic Competition; FDA
Approves Sandoz’s 20mg ANDA and, Subsequently, Mylan’s 20 and 40mg
ANDA.

80. Teva also concurrently filed a total of eight citizen petitions between September
2008 and April 2015.

23 https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/090218Orig1s000.pdf (Sandoz
FDA Approval Package).

24 Jonathan Gardner, “Teva Holds Cracking Door on Copaxone Generics,” Evaluate Vantage
copaxone-generics.


26 Docket No. FDA-2008-P-0529, received on September 26, 2008, and responded to on March
25, 2009 (First Petition); Docket No. FDA-2009-P-0555, received on November 13, 2009, and
responded to on May 11, 2010 (including Teva’s comment thereto submitted on May 10, 2010)
(Second Petition); Docket No. FDA-2010-P-0642, received on December 10, 2010, and
responded to on June 8, 2011 (including the supplement thereto submitted on February 22, 2011)
81. In the petitions, all of which were incorporated into the Eighth Petition by reference, Teva requested that FDA “consider new scientific information and refrain from approving any abbreviated new drug application until certain conditions are met.”

82. FDA eventually denied Teva’s requested relief in its citizen petitions, concluding that none of the information Teva argued was required for generic Copaxone ANDA approval was in fact required. FDA found that the experiments and data submitted by Teva “did not provide useful information relevant to the issue of the approvability of an ANDA referencing Copaxone.”

83. The same day that FDA denied the citizen petitions, on April 16, 2015, FDA approved Sandoz’s ANDA 090218 for a generic formulation of generic GA 20mg (marketed as Glatopa®). But, as noted above, Teva had already shifted the market to its 40mg Copaxone, thereby maintaining billions of dollars in sales at the expense of Plaintiff and member of the class.

4. Teva Loses Its Bid to Use Its Five Patents to Protect 20mg Brand Copaxone from Generic Competition.

84. Teva listed five patents in the Orange Book to cover its 40mg Copaxone product, all of which were due to expire in August 2030.

---

(Third Petition); Docket No. FDA-2012-P-0555, received on June 4, 2012, and responded to on November 30, 2012 (Fourth Petition); Docket No. FDA-2013-P-1128, received on September 12, 2013, and withdrawn by Teva on January 6, 2014 (Fifth Petition); Docket No. FDA-2013-P-1641, received on December 5, 2013, and responded to on May 2, 2014 (including the supplements thereto submitted on January 27, 2014, March 10, 2014, and May 2, 2014) (Sixth Petition); and Docket No. FDA-2014-P-0933, received on July 3, 2014, and responded to on November 26, 2014 (including the supplements thereto submitted on July 17, 2014, August 12, 2014, and November 13, 2014) (Seventh Petition); Docket No. FDA-2015-P-1050, received on April 1, 2015 (Eighth Petition). Teva withdrew the Fifth Petition before FDA issued a response.

27 Eighth Petition.
28 FDA CP Response at 43.
29 U.S. Patent Nos. 8,232,250; 8,399,413; 8,969,302; 9,155,776 ; and 9,402,874 (individually, the ’250, ’413, ’302, ’776 and ’874 patents, respectively) (collectively, “Copaxone Patents”). Teva also obtained two non-Orange Book patents for the 40mg formulation relating to the process of
85. Teva intended to use the purported “new” 40mg formulation and weak method Copaxone Patents and process patents to extend its monopoly and continue to effectively foreclose generic Copaxone competition.

86. Indeed, Teva stated in its Form-20F for the fiscal year ended December 31, 2013: “our business strategy for Copaxone® relies heavily on the successful introduction of a three-times-a-week product and the migration of a substantial percentage of current daily Copaxone® patients to this new version. The failure to achieve our objectives for the new version would likely have a material adverse effect on our financial results and cash flow.”

87. Following its successful product switch from a 20mg version to a 40mg version, Teva continued with its exclusionary plan, filing lawsuits between October 2014 and November 2015 (later consolidated) in the District of Delaware against five of the would be generic GA manufacturers who filed generic GA 40mg ANDAs and submitted Paragraph IV certifications challenging several of the Copaxone (40mg) patents (’250, ’413, ’302 and ’776): Sandoz, Amneal, Dr. Reddy’s, Mylan (in partnership with Natco), Synthon.

88. After a seven day bench trial, the District Court (Sleet, J.) , dealt Teva a resounding rebuke, invalidating four Copaxone Patents (’250, ’413, ’302 and ’776) as obvious, under 35 U.S.C. § 103. The court concluded:

[T]he dosing regimen disclosed in patent directed at drug used to treat patients with relapsing forms of multiple sclerosis was obvious; patent described thrice-weekly 40mg injection, 20mg and 40mg dose sizes had already been shown to be effective and safe, a daily 20mg injection had already been approved, and prior art suggested that less frequent injections manufacturing glatiramer acetate, with anticipated expiry in 2035: U.S. Patent Nos. 9,155,775 (’775 patent) and 9,763,993 (’993 patent).

30 Teva Pharmaceutical Industries Limited, Form-20F, for the fiscal year ended December 31, 2013, at 63,
were just as effective as daily injections and that less frequent injections improved patient adherence and reduced adverse reactions, i.e., that limitations in multiple sclerosis drug patent, that claimed less-frequent dosing regimen would improve tolerability and reduce adverse reactions, were obvious was not clearly erroneous; prior art had disclosed benefits of less frequent injections, and it was common sense that fewer injections would lead to fewer injection-related reactions.

89. The District Court offered a stinging opinion on four of the Teva Copaxone patents: “The court sees the ’250, ’413, ’302, and ’776 patents as nothing more than ‘life-cycle management’ – an attempt to continue to monopolize a multi-billion-dollar market for a blockbuster drug.”

90. In October 2018, after Mylan had launched generic versions of both Copaxone strengths, the Federal Circuit affirmed the district court’s finding invalidating all asserted claims of the four Copaxone patents at issue as obvious. On the same day, the Federal Circuit also affirmed rulings of the Patent Appeal and Trial Board (PTAB) invalidating the ’250, ’413 and ’302 Copaxone patents as a result of three inter partes review (IPR) filings by Mylan. In substance: every tribunal to review Teva’s Copaxone patents found the 40mg three-times-a-week dosage regimen obvious over the prior art.

91. Teva also filed a suit against nine generic glatiramer acetate ANDA filers on December 19, 2016 in the United States District Court for the District of Delaware. On May 1,

---

31 *In re Copaxone Consolidate Cases*, Civil Action No. 14-1171-GMS, 2017 U.S. Dist. LEXIS 12168 (D. Del. Jan. 30, 2017). In addition, Teva brought a separate case on the ’775 and ’993 patents against the five generics that was consolidated No. 14-1171, but which was not part of the bench trial and January 30, 2017 decision. Teva filed a stipulation of dismissal with prejudice as to this separate case on March 29, 2019.


33 IPR2015-00830, IPR2015-00643, and IPR2015-00644.

2017, the Court entered a Stipulation and Order Dismissing With Prejudice Claims and Counterclaims Regarding U.S. Patent No. 9,402,874.\textsuperscript{35} In early 2020, Teva requested removal of the ’874 Patent from the Orange Book, following court decisions on other patents directed to methods of using Copaxone.\textsuperscript{36} On March 29, 2019, the Court entered a Stipulation of Dismissal of Claims, Counterclaims, and Affirmative Defenses, with prejudice, regarding the ’775 and ’993 patents.\textsuperscript{37}

5. **Mylan Receives FDA Final Approval For 40mg and 20 mg and Launches.**

92. Following the district court win, FDA approved Mylan’s ANDA for generic Copaxone 40-mg three-times-a-week treatment on October 3, 2017 and its generic version of the 20mg formulation, a once daily injection. Mylan thus became the first ANDA applicant to obtain approval of a generic version of 40 mg Copaxone®.\textsuperscript{38} Mylan launched both generic formulations on October 5, 2017. As described below, Teva’s exclusionary scheme prevented uptake of generic Copaxone, despite Mylan reducing the list price of its generic Copaxone 40 mg product by 60% in July 2018.

\textsuperscript{35} See id. (D. Del. May 1, 2017), Dkt. No. 74.


VI. FACTS GIVING RISE TO PLAINTIFF’S CLAIMS

A. Teva’s Anticompetitive Copay “Couponing” Strategy and Illegal Kickback Scheme

93. Health plans use deductibles, copayments, coinsurance and other cost-sharing mechanisms to limit healthcare spending. Thus, cost-sharing mechanisms effectively lower costs for health plan payors.

94. Teva worked to circumvent the incentives and price pressure created by cost-sharing obligations by removing plan members’ copay obligations, thereby removing their incentives to choose the A-rated generic alternative. Since the consumer typically bears only a small portion of the drug’s total cost, this “coupon” to the consumer allows Teva to maintain and increase marketshare while artificially increasing prices above the levels that would have existed in a competitive market.

95. Specifically, Teva provided patients with “coupons” that covered all or some of the cost of their co-pays through a service called “Copaxone Co-Pay Solutions.” So when a health plan member filled a Copaxone prescription, the pharmacy would accept the coupon in lieu of the member’s co-pay obligation, and Teva would pay the pharmacy for the value of the coupon. The coupons thus allowed Teva to charge supracompetitive prices for Copaxone without provoking a natural market response; this resulted in payors, including Plaintiff and Class members, having to cover more purchases of brand Copaxone at higher costs than they would have paid in the absence of Teva’s unlawful conduct.

96. Teva’s co-pay program was one of many aspects of the anticompetitive scheme that, together, effectively inflated the price of Copaxone.

97. Teva’s internal documents show that its co-pay plan resulted in large returns for Teva in Copaxone revenue. For example, Teva’s 2008 Copaxone Work Plan estimated that Teva would spend approximately $70 million on “Private Insurance Financial Assistance” between 2008
and 2011, resulting in sales of 198,930 units of Copaxone. Assuming a list price of $1,886 per unit (the price of Copaxone on the date of the presentation), these sales were worth $373,484,580 – a 433% return on investment. These projections were conservative. In its Workplan for 2012 to 2014, Teva’s co-pay program had a reported average return on investment of 451% for commercial patients. In 2017, Teva estimated that a patient on the program was 15% more likely to stay on the drug for 12 months than a patient that was not on the program. Keeping patients on the program was key for Teva because it allowed them to charge supracompetitive prices to the respective consumer’s insurer or health plan.

98. Internal documents indicate that Teva collected $257.5 million in net revenue from its $56.4 million in expenditures on commercial programs in 2014, with $148.2 million in net revenue from $68.4 million in program expenditures in 2015. Put simply, Teva’s “coupon” scheme paid dividends. It allowed Teva to maintain supracompetitive prices for Copaxone without losing substantial sales volume, undermined generic substitution, and forced payors, like Plaintiff and the Class members, to continue paying for Copaxone in the face of supracopetitive prices. Indeed, an HHS OIG Advisory bulletin has explained harm resulting from programs like Teva’s:

Subsidies provided by traditional pharmaceutical manufacturer PAPs [patient assistance programs] have the practical effect of locking beneficiaries into the manufacturer’s product .... [C]ost-sharing subsidies can be very profitable for manufacturers, providing additional incentives for abuse. So long as the manufacturer’s sales price for the product exceeds its marginal variable costs plus the amount of the cost-sharing assistance, the manufacturer makes a profit. These profits can be considerable, especially for expensive drugs for chronic conditions.40

99. Teva used its “coupon” program to retain and obtain Copaxone sales that it would have lost or otherwise never have obtained. The co-pay program helped create a captive market that allowed Teva to preserve its Copaxone monopoly and supracompetitive profits while significantly limiting generic uptake compared to what would be expected under competitive conditions. Teva’s co-pay program has caused payors, like Plaintiff and the Class member, to pay millions of dollars more for Copaxone than lower cost generic GA that would have been prescribed absent Teva’s anticompetitive conduct. The “coupon” program allowed Teva to maintain its high prices to health plans by effectively eliminating cost-sharing obligations for plan members.

100. Teva was no stranger to this type of scheme, which it has also employed with non-commercial plans. In fact, Teva employed a similar scheme involving kickbacks to do the same thing to Medicare plans. Teva effectively eliminated cost-sharing obligations for Medicare recipients by funneling money through third-party foundations which it knew would be directed to pay those co-pays. Teva engaged in this conduct for at least a decade, and according to the House Report, it continued until at least 2018.

101. The Department of Justice filed suit against Teva in August 2020 alleging that “Teva knowingly and willfully violated the anti-kickback statute, 42 U.S.C. § 1320a-7b(b), by paying over $300 million to two third-party foundations, Chronic Disease Fund ("CDF") and The Assistance Fund ("TAF"), to cover the Medicare copay obligations of Copaxone patients.”

102. Although Teva claimed these payments were “donations,” Teva made payments only to these two foundations because “it had assurance that its money would go to patients taking . . . Copaxone” and not to patients taking other drugs.

103. The purpose of Teva’s payments to the foundations, like its “coupon” program, was to allow Teva to keep the price of Copaxone high by disincentivizing patients from switching to a
generic alternative. This combined with Teva’s other anticompetitive acts suppressed generic uptake and caused Plaintiff and the class to continue paying inflated prices for GA.

104. A January 2018 internal Teva email cited in the House Report explains how Teva’s use of the kickbacks prevented generic uptake and kept prices high for insurers. The email discusses an insurer’s decision to move Copaxone 40mg to non-preferred status for both Commercial and Medicare Part D plans, covering approximately 15 million and 1 million lives respectively. Teva’s Executive Vice President for North America explained why the insurer’s attempt to facilitate conversion to less expensive generic GA failed: “Also, the NP [non-preferred] status means little as we buy the patients [sic] copay down to zero anyway. Unless they NDC block Copaxone 40mg, we are fine. . . the actual impact is very low. . . .”41

105. Teva continued making these “donations” at least into 2018. The House Report notes that Teva made $23,286,429 in “charitable cash contributions in connection with Copaxone” in 2018.42 In drafts of its planning documents for 2018, Teva noted that “eliminating its ‘Medicare Donation’ to third-party foundations would cost Teva up to $261 million in Copaxone sales.”43

106. Through its “coupons” and “donations” Teva was able to circumvent the market effect of cost-sharing obligations for private health plan members and Medicare recipients. This allowed it to charge supracompetitive prices to all payors, including Plaintiff and members of the Class.

---

42 House Report.
43 Id.
B. Teva’s Exclusionary House Brand Strategy with PBMs and PBM-Owned Specialty Pharmacies

107. Teva knew it stood to lose hundreds of millions of dollars when FDA approved a generic version of Copaxone.

108. Teva was closely monitoring the market, obtaining market intelligence in order to determine precisely which generic(s) would enter and when. As the entry of Mylan and Sandoz’s competing generic GA product become an increasing reality, Teva unleashed the latest tactic in its arsenal to prevent and stymie competition.

109. In order to unlawfully thwart the uptake of generic 40 mg GA, first from Mylan and then from Sandoz, Teva designed and implemented a multi-part exclusionary scheme, which leveraged its dominant market position to ensure that automatic substitution laws would have little to no effect once generic entry occurred.

110. Teva referred to one part of its exclusionary scheme internally as the “House Brand” Strategy. The scheme consisted of contracting with the two types of entities: (1) PBMs and (2) PBM-owned specialty pharmacies. The scheme aimed to ensure that automatic substitution laws, which would have resulted in the substitution of Teva’s brand Copaxone product for Mylan and Sandoz’s generic Copaxone product, would have virtually no effect. Instead, by contracting with intermediaries, Teva was able to ensure that its brand Copaxone product would be covered and dispensed, even though Mylan and Sandoz were offering less-expensive generic versions.

111. First, Teva contracted with PBMs to block coverage of generic GA through what is referred to as a formulary restriction. Teva described this as “executed at the formulary level” and “blocking the generic via formulary restrictions.” Pursuant to these agreements, Teva promised additional rebates to the PBMs in exchange for filling all “glatirmer” or Copaxone scripts with Copaxone,” rather than the generic. But the strategy went further—it forced PBMs to
exclude generic GA. If the specialty pharmacy dispensed generic GA, the PBM would lose extra Copaxone-related rebates from Teva.

112. Second, this all-or-nothing rebate approach was combined with contracts with specialty pharmacies affiliated with the PBMs that required the pharmacy to replace any generic Copaxone prescriptions with the brand, even if the prescription specifically requested that it be filled with a generic version.

113. As a direct result of Teva’s exclusionary scheme, automatic substitution laws could not operate as they were intended to, and generic GA could not compete with the brand on price – even though it was less expensive and would have saved Plaintiff and members of the class millions of dollars in overcharges. For example, in July 2018, Mylan reduced its list price for 40 mg Copaxone by 60%, but the price reduction hardly impacted sales. Teva’s exclusionary tactics were successful in preventing competition, at the expense of third-party payors. According to Mylan, its price reduction “had hardly any impact on Mylan’s sales” because Teva’s contracts with PBMs and specialty pharmacies mandated substitution of Teva’s 40mg product. Mylan put it simply: “there is no price Mylan could go to that would change the equation.”44

114. In an internal slide to its Board of Directors, Teva described the scheme as follows:

---

115. Teva’s Executive Vice President for North America offered an even more direct explanation of precisely how the scheme operated to thwart generic competition: “[PBM] is getting an additional rebate to fill all “glatiramer” or Copaxone scripts with Copaxone. . .if a doctor orders generic glatiramer or the pharmacy benefit mandates it be filled as a generic, it will come in a plain box with Copaxone inside. Win-win for all. . .[Specialty Pharmacy] only ships brand Copaxone no matter how it is written or what the formulary states. This is why this [putting Copaxone on non-preferred tier] has little impact.”
116. As a direct result of its exclusionary scheme, Teva has lined its pockets with ill-gotten gains at the expense of insurers—such as Plaintiff and Class Members—who have been forced to pay supracompetitive prices for brand Copaxone, and have been prevented from buying larger quantities of the generic GA, despite the availability of less-expensive generic GA.

C. Teva’s False and Misleading “DAW” Campaign

117. Teva employs a team of sales representatives who regularly visit and communicate with medical professionals and staff across the country to market Copaxone and persuade them to prescribe it. Teva also promotes Copaxone through its Shared Solutions patient support hub, where it provides copay support, patient training, nursing support and other resources. Shared Solutions personnel also visit and communicate with medical professionals and staff in addition to MS patients.
118. In order to circumvent the automatic substitution laws and push doctors to write prescriptions for Copaxone instead of generic GA, Teva engaged in a campaign of false and misleading marketing statements about generic GA. Teva began this campaign before Mylan launched its 40 mg GA and continued after Mylan’s launch.

119. First, Teva, through its sales representatives and Shared Solutions patient support personnel, made false statements to medical practitioners and patients about the efficacy of generic GA. Teva and/or its sales representatives falsely stated, without evidence, that generic GA is only 80% or 85% as effective as Copaxone. Teva knew these statements to be false since FDA has determined that generic GA is an AP-rated equivalent substitute to Copaxone. Teva also knew, at the time these statements were made, that there were no comparative efficacy trials of Mylan’s generic GA to Copaxone.

120. According to Mylan, (i) its representatives consistently encountered medical professionals throughout the country who believed that generic GA was only 80% or 85% as effective as Copaxone; (ii) these statements had been disseminated widely among those who prescribe GA; and (iii) a significant portion of those prescribers attributed the statements to Teva and its sales representatives.

121. Second, Teva’s sales representatives and Shared Solutions personnel made false and misleading statements to medical professionals and patients that Mylan did not offer copay support for its generic GA product. Teva knew these representations were false or misleading in that it had no support for the statements and knew or should have known that Mylan had included information about its copay assistance in its press release in October 2017 announcing the launch of its product. Mylan announced that it would offer copay assistance to eligible patients through
its MS Advocate program. Teva continued to make the false and misleading statements about copay support after this date.

122. According to Mylan, (i) its representatives encountered medical professionals and staff across the country who believed that Mylan does not offer copay support for its generic GA product; (ii) these statements had been disseminated widely among those who prescribe GA; and (iii) a significant portion of those prescribers attributed the statements to Teva and its sales representatives.

123. Third, Teva’s sales representatives and Shared Solutions personnel made false and misleading statements to medical professionals and patients that Mylan did not provide patient training and nursing support for its generic GA product. Teva knew that physicians and patients valued patient training and nursing support services, which it relied on to drive additional sales of Copaxone. For example, Teva’s 2012-2014 workplan reported that its $29 million “investment” in patient services in 2011 had “generated” $363 million in sales. The workplan emphasized that this expenditure reflected a significant return on investment: “ROI of 1152%.”45 Teva executives estimated in 2017 that conducting an additional 1,200 injection trainings would cost the company $250,000, but “net $2.5M [million] in incremental sales.”46 By claiming that Mylan did not provide these services, Teva could retain a significant share of Copaxone sales by dissuading physicians and patients from switching to lower priced generic GA. Indeed, Teva viewed its Shared Solutions services as “key activities to defend Copaxone Against Generic erosion.”47 However, Teva knew these representations were false or misleading in that it had no support for the statements and knew

45 House Report.
46 Id.
47 Id.
or should have known that Mylan had included information about its patient training and nursing support in its press release in October 2017 announcing the launch of its product. Mylan announced that it would offer “in-home injection training,” “a 24/7 patient support center,” and “ongoing support from an MS-experienced nurse” through its MS Advocate program. Teva continued to make the false and misleading statements about copay support after this date.

124. According to Mylan, (i) its representatives encountered medical professionals and staff across the country who believed that Mylan does not offer patient training and nursing support for its generic GA product; (ii) these statements had been disseminated widely among those who prescribe GA; and (iii) a significant portion of those prescribers attributed the statements to Teva and its sales representatives.

125. Finally, Teva’s sales representatives and Shared Solutions personnel made false and misleading statements to medical professionals and patients that Mylan’s generic GA product was a biologic or biosimilar and therefore a more complex drug and not the same medication as Copaxone. Teva knew these representations were false or misleading in that Mylan’s product is not a biologic or biosimilar and has been deemed by FDA to be an AP-rated equivalent to Copaxone.

126. According to Mylan, its representatives encountered medical professionals throughout the country who believed that Mylan’s generic GA product is a biologic or biosimilar or otherwise materially different or more complex than Copaxone and those medical professionals were told this misinformation by Teva.48

---

48 This false and misleading campaign culminated in another attempt by Teva to abuse the court processes. Teva filed a lawsuit in March 2020 seeking to have Copaxone classified as a biologic in yet another attempt to thwart generic substitution. Teva argued that a generic would have to be deemed “interchangeable” under the BPCIA standards. The district court dismissed this
127. All of the above-described marketing statements were made without support or evidence and despite Teva’s knowledge that no support existed for these statements.

128. The purpose of Teva’s campaign of false and misleading promotional statements was to prevent uptake of generic versions of GA by persuading doctors to write “DAW” prescriptions for Copaxone so that the pharmacist could not substitute less expensive generic GA for those prescriptions, thereby circumventing automatic substitution laws.

129. Teva knew that its DAW campaign was an important part of its scheme to thwart generic competition, as reflected in its strategy documents. For example, a January 2017 Teva presentation titled “At-Risk Gx Readiness” states, “HCP [healthcare professional] loyalty and DAW strategy will help retain many of these branded units.”

130. Teva leveraged its Shared Solutions program to influence patients with its DAW campaign. An August 2017 internal analysis showed that DAW was written on 87% of Copaxone 40 mg prescriptions requested through the Shared Solutions service.

131. Teva continued this part of its scheme after Mylan launched its generic GA. A Board presentation from October 2017 includes Teva’s “Key Activities to Defend Against Generic Erosion.” These “Key Activities” included “Sales force proactively messages to HCP customers the need for “Dispense as Written” on all new Rx and refills” as well as “[o]utbound efforts to 40mg patients through Shared Solutions, which included “[e]mails to all patients with DAW
messaging[.]”\textsuperscript{52} Teva was also able to get current patient lists for practitioners to “proactively” write DAW on prescriptions.\textsuperscript{53} Likewise, an August 2018 presentation stated, “reinforce DAW on every call.”\textsuperscript{54}

132. Because of its false and misleading statements to healthcare professionals, Teva succeeded in circumventing automatic substitution and preventing uptake of generic GA. The DAW prescription rate for Copaxone was approximately 13.5% in the period leading up to Mylan’s generic launch, and it rose to 77% by February 2018. An August 2018 email from Teva’s Executive Vice President for North America stated that “[t]he DAW campaign combined with the legacy and house brand access strategy has paid great dividends.”

133. Following the entry of Mylan’s generic GA formulations in October 2017 and Sandoz’s generic 40mg GA product in February 2018, Teva continued to maintain more than 50% of the market despite the list price of Copaxone being higher than the prices of the generics.

134. According to Mylan, Teva’s misrepresentations and false statements had so thoroughly influenced healthcare professionals that many refused to even talk to Mylan’s representatives trying to correct them and/or argued against Mylan’s representatives using Teva’s false statements.

135. In sum, Teva’s DAW campaign, combined with the House Brand strategy, paid “great dividends.” In 2018, despite the availability of generic alternatives, Teva collected $1.6 billion in net revenue for Copaxone.\textsuperscript{55}

\textsuperscript{52} \textit{Id.}
\textsuperscript{53} \textit{Id.}
\textsuperscript{54} House Report.
\textsuperscript{55} \textit{Id.}
VII. MARKET POWER AND MARKET DEFINITION

136. At all relevant times, Teva has maintained monopoly power over the glatiramer acetate market: it had the power to raise and/or maintain the price of glatiramer acetate at supra-competitive levels without losing substantial sales to other products, except for AP-rated generic versions of Copaxone, to make the supracompetitive prices unprofitable.

137. Direct evidence of Teva’s market power includes the following: (a) from 2013 to 2018, the per-unit manufacturing cost for Copaxone was less than 3% of the net price of the drug, i.e., the price after adjusting for rebates and discounts; (b) when generic Copaxone eventually entered the market, it took a portion of brand Copaxone’s unit sales; (c) Teva never lost Copaxone sales in response to pricing of other brand or generic drugs, except for AP-rated generic Copaxone; (d) Teva never lowered the price of Copaxone to the competitive level in response to pricing of other brand or generic drugs; and (e) from 2006 to 2015, prior to generic entry, Defendants profitably raised the price of Copaxone 20mg by approximately 350%.

138. To the extent that Plaintiff and the class are required to prove monopoly power circumstantially by first defining a relevant product market, Plaintiff allege that the relevant product market is Copaxone and AP-rated glatiramer acetate generics.

139. Brand Copaxone is therapeutically differentiated from all RRMS products other than AP-rated generic versions of Copaxone. The availability of other RRMS disease-modifying treatments has not constrained Teva. Teva has continually increased the prices for Copaxone over the years, even when new RRMS injectable disease-modifying therapies were approved by the FDA.
140. Only the market entry of a competing, AP-rated equivalent generic version of Copaxone and the absence of Teva’s anticompetitive conduct would make Teva unable to profitably maintain its prices for Copaxone without losing substantial sales.

141. Teva has used its market power to foreclose or otherwise adversely affect competition in the market for FDA-approved AP-rated glatiramer acetate drug products by—among other unlawful tactics—engaging in an anticompetitive coupon and kickback scheme to keep Copaxone prices high, preventing uptake of generic versions of Copaxone by entering into anticompetitive agreements to block generics from formulary access and prevent generic substitution at the specialty pharmacies, and engaging in a campaign of false and misleading disinformation about generic GA products to prevent uptake.

142. Teva’s conduct has forced third-party payors to purchase Copaxone at artificially high and noncompetitive price levels and denied them the availability of a lower cost generic glatiramer acetate product.

143. Teva has had a significant incentive to maintain its monopoly over glatiramer acetate and keep prices artificially high.

144. The relevant geographic market is the United States, the District of Columbia, and the U.S. territories.

145. At all relevant times, Teva enjoyed high barriers to entry with respect to the above-defined relevant market due to patent protection, the high cost of entry and expansion, expenditures in marketing and physician detailing, and state statutes that require prescriptions for the purchase of the products at issue and restrict substitution of those products at the pharmacy counter. The products in this market require significant investments of time and money to design, develop, and distribute. In addition, the market requires government approvals to enter and/or the drugs at issue
may be covered by patents or other forms of intellectual property. Teva’s unlawful conduct further restricted entry. Thus, during the relevant time, existing and potential market entrants could not enter and/or expand output quickly in response to Teva’s higher prices or reduced output.

146. A small but significant, non-transitory price increase to Copaxone by Teva would not have caused a significant loss of sales to other drugs or products used for similar purposes, with the exception of AP-rated equivalent generic versions of glatiramer acetate.

147. Brand Copaxone does not exhibit significant, positive cross-price elasticity of demand with any other treatment for multiple sclerosis, and thus other drugs that are not AP-rated to Copaxone are not economic substitutes for, and are not reasonably interchangeable for Copaxone.

VIII. EFFECT ON INTRASTATE AND INTERSTATE COMMERCE

148. At all material times, Copaxone, manufactured and sold by Teva, was promoted, distributed, sold and/or shipped in a continuous and uninterrupted flow of commerce across state lines and sold to customers located outside its state of manufacture.

149. During the relevant time period, in connection with the purchase and sale of Copaxone, monies as well as contracts, bills, and other forms of business communications and transactions were transmitted in a continuous and uninterrupted flow across state lines.

150. During the relevant time period, various devices were used to effectuate the illegal acts described above, including United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. Teva’s activities, as alleged in this complaint, were within the flow of, and have substantially affected, interstate commerce.

151. Teva’s anticompetitive conduct occurred in part in trade and commerce within the states set forth herein. Teva’s conduct had substantial interstate and intrastate effects because physicians within each state have been wrongfully induced into prescribing brand Copaxone
instead of lower priced generic Copaxone through Teva’s DAW campaign, pharmacies within each state have dispensed brand Copaxone instead of lower priced generic Copaxone through Teva’s House Brand strategy, and patients and health plans within each state have been forced to continue paying supra-competitive prices for Copaxone prescriptions, which, in the absence of Teva’s anticompetitive conduct, would have been filled with lower priced generic Copaxone.

IX. ANTITRUST IMPACT

152. During the relevant time period, Plaintiff and members of the class purchased substantial amounts of glatiramer acetate indirectly from Teva. As a result of Defendants’ illegal conduct, Plaintiff and members of the class were compelled to pay, did pay, and continue to pay artificially inflated prices for glatiramer acetate. Those prices were substantially greater than the prices that members of the class would have paid absent the illegal conduct alleged herein, because: (1) the price of branded Copaxone was artificially inflated by the Teva’s illegal conduct, (2) class members were deprived of the opportunity to purchase lower-priced generic versions of Copaxone in greater quantities, which they would have done had they had the opportunity, and/or (3) the price of generic Copaxone was artificially inflated by the Teva’s illegal conduct. The supracompetitive prices were paid at the point of sale, which is where Plaintiff and the proposed class suffered antitrust impact.

153. As a consequence, Plaintiff and members of the class have sustained substantial damages to their business and property in the form of overcharges. The full amount and forms of components of such damages will be calculated after discovery and upon proof at trial. Commonly used and well-accepted economic models can be used to measure both the extent and the amount of the supracompetitive charges to end payors such as Plaintiff and members of the class.

154. General economic theory recognizes that any overcharge at a higher level of distribution generally results in higher prices at every level below. According to Professor
Hovenkamp, “[e]very person at every stage in the chain will be poorer as a result of the monopoly price at the top.” Professor Hovenkamp also acknowledges that “[t]heoretically, one can calculate the percentage of any overcharge that a firm at one distribution level will pass on to those at the next level.”56

155. Further, the institutional structure of pricing and regulation in the pharmaceutical drug industry assures that overcharges at the higher level of distribution are passed on to end payors. Wholesalers and retailers passed on the inflated prices of Copaxone to Plaintiffs and the Class of end-payors defined herein. Teva’s anticompetitive actions enabled it to indirectly charge end-payors prices in excess of what it otherwise would have been able to charge absent its unlawful conduct. The prices were inflated as a direct and foreseeable result of Teva’s anticompetitive conduct.

X. CLASS ACTION ALLEGATIONS

156. Plaintiff brings this action on its own behalf and on behalf of all others similarly situated as a class action under Rules 23(a), 23(b)(2), and 23(b)(3) of the Federal Rules of Civil Procedure, seeking damages pursuant to the laws of the states listed below (the “Indirect Purchaser States”), and as representative of a class defined as follows:

All third-party payors in the Indirect Purchaser States and territories that paid some or all of the purchase price for Copaxone or glatiramer acetate at any time during the period from October 1, 2017 through and until the anticompetitive effects of the defendants’ challenged conduct cease (the “Class Period”).

157. Excluded from the class are:

a. the Defendants and their counsel, officers, directors, management, employees, subsidiaries, and affiliates;

b. all federal governmental entities;
c. all judges assigned to this case and any members of their immediate families.

158. Members of the class are so numerous and widely geographically dispersed throughout the United States and its territories that joinder is impracticable. Plaintiff believes that the class numbers in the dozens at least and is geographically spread across the nation. Further, the identities of members of the class will be readily identifiable from information and records in the possession of Teva.

159. Plaintiff’s claims are typical of the claims of members of the class. Plaintiff and all members of the class were damaged by the same wrongful conduct by Teva, and all paid artificially inflated prices for Copaxone and were deprived of the benefits of competition from less expensive generic versions as a result of the Defendants’ conduct.

160. Plaintiff will fairly and adequately protect and represent the interests of the class. Plaintiff’s interests are coincident with, and not antagonistic to, the class.

161. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action litigation, and who have particular experience with class action litigation involving the pharmaceutical industry.

162. Questions of law and fact common to members of the class predominate over questions, if any, that may affect only individual class members, because the Defendants have acted on grounds generally applicable to the entire class. Such generally applicable conduct is inherent in the Defendants’ wrongful conduct.

163. Any plaintiff who was forced to pay a higher price in the absence of generic competition has a substantial and shared interest in proving that the higher price was the result of unlawful monopolizing conduct that is redressable by an award of damages.
164. Questions of law and fact common to the class include:

   a. whether Teva unlawfully maintained monopoly power through all or part of its overarching scheme;
   
   b. whether Teva’s anticompetitive scheme suppressed generic competition to Copaxone;
   
   c. as to those parts of Teva’s challenged conduct for which such justifications may be offered, whether there exist cognizable, non-pretextual procompetitive justifications, which the Defendants’ challenged conduct was the least restrictive means of achieving, that offset the harm to competition in the markets in which glatiramer acetate is sold;
   
   d. whether direct proof of Teva’s monopoly power is available, and if available, whether it is sufficient to prove Teva’s monopoly power without the need to also define a relevant market;
   
   e. to the extent a relevant market or markets must be defined, what that definition is or those definitions are;
   
   f. whether Teva’s scheme, in whole or in part, has substantially affected interstate commerce;
   
   g. whether the Teva’s scheme, in whole or in part, caused antitrust injury to the business or property of Plaintiff and members of the class in the nature of overcharges; and
   
   h. the quantum of overcharges paid by the class in the aggregate.

165. Class action treatment is a superior method for the fair and efficient adjudication of this controversy. Among other things, class treatment will permit a large number of similarly
situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

166. Plaintiff knows of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

XI. TEVA CONCEALED ITS UNLAWFUL CONDUCT

167. The claims of Plaintiff and members of the class accrue each time they suffer injury as a result of Defendants’ anticompetitive conduct. Plaintiff and members of the class were injured each time they purchased Copaxone at supracompetitive prices or purchased less generic Copaxone than they would have absent Teva’s anticompetitive scheme. Each sale of brand Copaxone constituted an overt act in furtherance of Teva’s continuing anticompetitive scheme.

168. Additional overt acts in furtherance of Teva’s continuing misconduct include, but are not limited to: implementing and enforcing exclusionary agreements with PBMs to bar generic Copaxone from formularies; obtaining and enforcing agreements with specialty pharmacies to circumvent generic substitution laws so that the brand product is always shipped, even when generic is prescribed; falsely disparaging generic Copaxone in order to convince prescribers to write DAW on all Copaxone prescriptions; and using couponing to drive up brand sales. As a result, Plaintiff and member of the class are entitled to recover damages on their brand Copaxone purchases within the applicable statute of limitations.
169. In addition, because Teva fraudulently concealed its unlawful conduct, Plaintiffs and the members of the class are entitled to recover damages extending back beyond the applicable statute of limitations in relation to the filing of this complaint. Plaintiff and the members of the class had no knowledge of Teva’s unlawful scheme and could not have discovered the scheme through the exercise of reasonable diligence prior to the applicable statute of limitations in relation to the filing of this complaint.

170. Plaintiff and the members of the class could not have known that Teva was entering into exclusionary agreements with PBMs and specialty pharmacies to bar generic Copaxone until the House Committee published its report on September 30, 2020. Teva took steps to keep these anticompetitive agreements secret. This included senior Teva executives warning subordinates that the exclusionary agreements with PBMs and specialty pharmacies should not be shared even internally with other Teva employees due to their “confidential nature.” Moreover, internal communications discussing the exclusionary contracts were prominently stamped with the admonition: “DO NOT COPY. DO NOT DISTRIBUTE.”

171. Similarly, Plaintiff and the members of the class could not have known about Teva’s “Dispense as Written” campaign until the issuance of the Staff Report. And only subsequently, when Mylan filed its lawsuit against Teva on June 29, 2021, did it come to light that Teva’s “Dispense as Written” campaign was punctuated by a misinformation campaign regarding generic Copaxone, including untrue statements about the efficacy of the generic products.

172. It was not until the House Committee issued its report a few weeks later, on September 30, 2020, that Teva’s exclusionary contracts and other key aspects of Teva’s monopolization scheme began to come to light. Notably, the Staff Report was based on the House Committee’s review of over 300,000 pages of internal, nonpublic documents and communications
produced by Teva to the Committee in response to a formal request. Similarly, the Mylan complaint filed in June 2021 set forth information that could not have been known by Plaintiffs prior to the filing of that action.

173. Teva’s illegal monopolization scheme was also inherently self-concealing because, as Defendants knew, its disclosure would have exposed it to civil liability and governmental enforcement actions, as in fact occurred when the scheme came to light. See e.g., Mylan Pharmaceuticals Inc. v. Teva Pharmaceuticals Industries Ltd, et al., case no. 21-cv-13087 (D.N.J.) (complaint filed June 29, 2021); see also Humana Inc. v. Teva Pharmaceuticals USA, Inc., case no. 21-cv-00072 (M.D.Fla.) (complaint January 8, 2021).

174. Teva’s business practices are subject to the antitrust laws, and so it was reasonable for Plaintiffs and Class members to presume that Teva was operating in a competitive market. A reasonable person under the circumstances would not have had occasion to suspect that Teva was engaged in an overarching monopolization scheme to suppress generic competition until September 30, 2020, when the Staff Report was published.

175. Because Teva’s monopolization scheme is self-concealing and was affirmatively concealed by Teva, Plaintiff and the members of the class had no knowledge of the scheme prior to the applicable statute of limitations in relation to the filing of this complaint. As a result of Teva’s fraudulent concealment, all applicable statutes of limitations affecting the claims of Plaintiff and members of the class have been tolled.

XII. COMPLIANCE WITH NOTICE AND DEMAND REQUIREMENTS

176. In accordance with the requirements of Arizona Revised Statute § 44-1415; Hawaii Revised Statute § 480-13.3(a); 815 Illinois Compiled Statutes § 505/10a(d); Kan. Stat. Ann. § 50-634(g); Minn. Stat. § 325D.63; Nevada Revised Statute § 598A.210(3); New York General
Business Law § 340(5); Or. Rev. Stat. § 646.780(5)(b); Rhode Island General Laws § 6-36-21; and Utah Code § 76-10-3109, on or about March 11, 2022, Plaintiff’s counsel sent letters regarding this class-action complaint to the Attorneys General of Arizona, Hawaii, Illinois, Kansas, Minnesota, Nevada, New York, Oregon, Rhode Island, and Utah. The letters informed the Attorneys General of the existence of this complaint, identified the relevant state antitrust provisions at issue, and enclosed a copy of this complaint.

177. On or about March 11, 2022, counsel sent demand letters to the Teva Defendants regarding this class-action complaint, which satisfy the demand-letter requirements of certain consumer-protection statutes mentioned below (e.g., California, Maine, Massachusetts, and West Virginia). The demand letters identified the claimant as Plaintiff, in its individual and representative capacity; described the allegedly unfair or deceptive acts or practices committed by Teva (i.e., its efforts to suppress competition from generic Copaxone); described Plaintiff’s and the class’s injury (increased prices for Copaxone); set forth a demand for relief (treble damages, attorneys’ fees, litigation costs, and other available sanctions); and requested an offer to cure within the statutorily prescribed time.

XIII. CLAIMS FOR RELIEF

CLAIM I:
MONOPOLIZATION AND MONOPOLISTIC SCHEME
UNDER ANTITRUST STATE LAWS

178. Plaintiff incorporates by reference all the allegations above as though fully set forth herein.

179. At all relevant times, Teva possessed substantial market power (i.e., monopoly power) in the relevant market. Teva possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.
180. Through its overarching anticompetitive scheme, as alleged above, Teva willfully maintained its monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen or a historic accident, and thereby injured Plaintiff and the class.

181. Had Teva competed on the merits instead of unlawfully maintaining its monopoly in the markets for glatiramer acetate, Plaintiff and the class members would have substituted more lower-priced generic Copaxone for the higher-priced brand-name Copaxone for some or all of their Copaxone requirements, and would have paid substantially lower prices for brand-name Copaxone and generic Copaxone.

182. The goal, purpose, and effect of Teva’s overarching anticompetitive scheme was to suppress generic competition for glatiramer acetate, extend its dominance in that market, and maintain Copaxone’s prices at supracompetitive levels.

183. Teva’s scheme substantially harmed competition in the relevant market.

184. There is and was no non-pretextual, procompetitive justification for Teva’s actions that outweighs the scheme’s harmful effects. Even if there were some conceivable justification that Teva could assert, the scheme is and was broader than necessary to achieve such a purpose.

185. But for Teva’s illegal conduct, generic manufacturers of GA would have been able to fairly compete with Teva in a full and timely manner, and Plaintiff and Class members, who are third-party payors, would have substituted lower-priced generic GA for some or all of their Copaxone purchases and/or paid lower prices for their branded Copaxone purchases. Plaintiff and Class members would have purchased lower-priced GA in substantially larger quantities.

186. By engaging in the foregoing conduct, Teva intentionally, willfully, and wrongfully monopolized the relevant market in violation of the following state laws:

b. Cal. Bus. and Prof. Code §§ 16700, et seq., with respect to purchase of Copaxone and generic GA in California by class members and/or purchases by California residents.


d. D.C. Code Ann. §§ 28-4503, et seq., with respect to purchase of Copaxone and generic GA in the District of Columbia by class members and/or purchases by D.C. residents.

e. Fla. Stat. § 501.201, et seq., with respect to purchase of Copaxone and generic GA in Florida by class members and/or purchases by Florida residents.

f. 740 Ill. Comp. Stat. 10/1, et seq., with respect to purchase of Copaxone and generic GA in Illinois by class members and/or purchases by Illinois residents.

g. Iowa Code § 553.1, et seq., with respect to purchase of Copaxone and generic GA in Iowa by class members and/or purchases by Iowa residents.

h. Kan. Stat. §§ 50-101, et seq., with respect to purchase of Copaxone and generic GA in Kansas by class members and/or purchases by Kansas residents.

i. Me. Rev. Stat. 10 § 1102, et seq., with respect to purchase of Copaxone and generic GA in Maine by class members and/or purchases by Maine residents.

j. Md. Com’l Law Code Ann. § 11-204(a), et seq., with respect to purchase of Copaxone and generic GA in Maryland by Plaintiff the City of Baltimore.

k. Mass. Gen. Laws, Ch. 93A §§ 1, et seq., with respect to purchase of Copaxone and generic GA in Massachusetts by class members and/or purchases by Massachusetts residents.

m. Minn. Stat. §§ 325D.49, *et seq.*, with respect to purchase of Copaxone and generic GA in Minnesota by class members and/or purchases by Minnesota residents.

n. Miss. Code §§ 75-21-3, *et seq.*, with respect to purchase of Copaxone and generic GA in Mississippi by class members and/or purchases by Mississippi residents.

o. Neb. Code §§ 59-802, *et seq.*, with respect to purchase of Copaxone and generic GA in Nebraska by class members and/or purchases by Nebraska residents.


r. N.M. Stat. §§ 57-1-2, *et seq.*, with respect to purchase of Copaxone and generic GA in New Mexico by class members and/or purchases by New Mexico residents.

s. N.Y. G.B.L. § 340, *et seq.*, with respect to purchase of Copaxone and generic GA in New York by class members and/or purchases by New York residents.

t. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchase of Copaxone and generic GA in North Carolina by class members and/or purchases by North Carolina residents.

u. N.D. Cent. Code § 51-08.1-01, *et seq.*, with respect to purchase of Copaxone and generic GA in North Dakota by class members and/or purchases by North Dakota residents.

v. Or. Rev. Stat. §§ 646.730, *et seq.*, with respect to purchase of Copaxone and generic GA in Oregon by class members and/or purchases by Oregon residents.

w. P.R. Laws tit. 10 § 260, *et seq.*, with respect to purchase of Copaxone and generic GA in Puerto Rico by class members and/or purchases by Puerto Rico residents.

x. R.I. Gen. Laws §§ 6-36-7, *et seq.*, with respect to purchase of Copaxone and generic GA in Rhode Island by class members and/or purchases by Rhode Island residents.
y. S.D. Codified Laws § 37-1-3.2, et seq., with respect to purchase of Copaxone and generic GA in South Dakota by class members and/or purchases by South Dakota residents.

z. Utah Code Ann. §§ 76-10-3101, et seq. with respect to purchase of Copaxone and generic GA in Utah by class members and/or purchases by Utah residents.

aa. W.Va. Code §§ 47-18-4, et seq., with respect to purchase of Copaxone and generic GA in West Virginia by class members and/or purchases by West Virginia residents.

bb. Wis. Stat. § 133.03, et seq., with respect to purchase of Copaxone and generic GA in Wisconsin by class members and/or purchases by Wisconsin residents.

187. As a direct and proximate result of Teva’s monopolistic conduct, Plaintiff and the class have suffered injury to their business and property in that they have paid more for glatiramer acetate than they would have paid in the absence of Teva’s unlawful conduct. By reason of the foregoing, Plaintiff and members of the class are entitled to seek all forms of relief available, including damages and multiple damages, as permitted by law for Teva’s violations of the foregoing statutes.

CLAIM II:

UNFAIR METHODS OF COMPETITION, AND UNFAIR DECEPTIVE ACTS, IN VIOLATION OF STATE CONSUMER-PROTECTIONS LAWS

188. Plaintiff incorporates by reference all previous allegations of fact.

189. Teva engaged in unfair methods of competition, unfair and unconscionable acts or practices, and deceptive acts or practices, in order to wrongfully restrain trade in the glatiramer-acetate market, and in violation of the state consumer-protection statutes identified below.

190. As noted in detail above, these practices include (1) duping health plans with an anticompetitive consumer copay “coupon” scheme that circumvented plan members’ cost-sharing obligations and helped artificially increase and protect brand Copaxone’s high prices; (2) entering
into exclusive agreements with PBMs, in order to block generic Copaxone’s inclusion on
formularies; (3) reaching agreements with PBM-owned specialty pharmacies to dispense branded
Copaxone even if a prescription was written specifically for generic Copaxone; (4) disparaging
generic Copaxone to providers, payors, etc.; and (5) engaging in a DAW campaign—all of which
inhibited the uptake of generic Copaxone.

191. As a proximate result of Teva’s unfair, unconscionable, and deceptive conduct,
Plaintiff and the class were: (1) denied the opportunity to purchase lower-priced generic Copaxone;
and (2) paid higher prices for brand Copaxone than they otherwise would have but for Teva’s
unlawful conduct.

192. In other words, there was and is a gross disparity between the price that the City of
Baltimore and the class members actually paid for Copaxone and the price that they would have
paid absent Teva’s conduct. Much more affordable generic Copaxone would have been available,
and prices for brand Copaxone would have been far lower, but for Teva’s unfair, unconscionable,
and deceptive conduct. This injury is of the type the state consumer-protection statutes were
designed to prevent, and (again) it directly results from Teva’s unlawful conduct.

193. To the extent deception is required under any of the state laws below, but for Teva’s
deceptive acts, Copaxone prices would have been lower. For example, if Teva hadn’t campaigned
to disparage generic Copaxone, then the generic-Copaxone market would have been more robust,
which—in turn—would have driven down the market price of brand Copaxone. Relatedly, Teva’s
deceptive conduct—such as suggesting that its brand product was superior to generic Copaxone—
allowed Teva to charge a higher price for brand Copaxone than it otherwise could have (i.e., Teva’s
misstatements allowed the company to charge a premium for brand Copaxone). In other words,
Teva’s misstatements resulted in overcharges to Plaintiff and the class, even if considered
independently of the rest of Teva’s unfair business practices (e.g., its exclusivity agreements with PBM

194. The gravity of harm from Teva’s wrongful conduct significantly outweighs any conceivable utility from that conduct. Plaintiff and the class members could not have reasonably avoided injury from Teva’s wrongful conduct.

195. By engaging in such conduct, Teva violated the following consumer-protection laws:

*Arizona:*

196. Plaintiff incorporates each allegation set forth in the preceding paragraphs of this complaint.

197. The Arizona Consumer Fraud Act (the “ACFA”) prohibits the “act, use or employment by any person of any . . . deceptive . . . act or practice . . . in connection with the sale . . . of any merchandise.” Ariz. Rev. Stat. § 44-1522(A).

198. Teva violated Arizona’s Consumer Fraud Act by (among other things) engaging in its scheme to suppress the availability of generic Copaxone, which is described above, and which included, among other things, exclusionary agreements with PBM; efforts to circumvent DAW requirements; and falsely disparaging generic competition.

199. Teva engaged in this conduct with the express intent of limiting the availability of generic Copaxone. As noted above, and as indicated by Teva’s own documents, Teva’s exclusionary behavior was part of broader, years-long campaign that was specifically designed to inhibit competition in the glatiramer-acetate market, and to allow Teva to maintain supra-competitive Copaxone prices.
200. Teva’s conduct did deceive and would have deceived reasonable persons, including Plaintiff and the class.

201. Plaintiff and/or members of the class purchased glatiramer acetate within Arizona during the Class Period.

202. Teva’s conduct was the proximate cause of injuries to Plaintiff and the class, namely in the form of overcharges for glatiramer acetate. For example, had Teva competed on the merits instead of unlawfully maintaining its monopoly in the glatiramer-acetate market, then generic Copaxone would have been more readily available to Plaintiff and the class, and they would have substituted this lower-priced generic Copaxone for the higher-priced brand-name Copaxone, or paid substantially less for brand-name Copaxone (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Teva’s efforts to denigrate generic Copaxone allowed the company to charge a price premium for brand Copaxone; i.e., as a result of Teva’s false statements, Plaintiff and the class had to pay more for brand Copaxone than that product was actually worth.

203. Because Copaxone is purchased on an ongoing basis, to treat relapsing forms of multiple sclerosis, there is a high probability that Plaintiff will suffer injury in the future, as a result of Teva’s conduct.

204. By reason of the foregoing, Plaintiff and the class are entitled to seek all forms of relief under the ACFA, including actual damages, treble damages, punitive damages (to the extent available), reasonable attorneys’ fees, costs, and injunctive relief.

California:

205. Plaintiff incorporates each allegation set forth in the preceding paragraphs of this complaint.
206. Section 17200 et seq. of the California Business and Professional Code (the “UCL”) prohibits any “unlawful, unfair, or fraudulent act or practice[].”

207. Teva violated the UCL by (among other things) engaging in its scheme to suppress the availability of generic Copaxone, which is described above, and which included, among other things, exclusionary agreements with PBMs; efforts to circumvent DAW requirements; and falsely disparaging generic competition.

208. Teva violated the UCL’s unlawful prong insofar as its conduct also violated federal antitrust law, as well as California’s antitrust law (CA BUS & PROF § 16720).

209. Teva’s conduct also constitutes unfair or unconscionable acts or practices under the UCL, regardless of whether or not that conduct violates state or federal antitrust laws.

210. Teva violated the UCL’s deception prong by, among other things, engaging in a coordinated effort to disparage its generic competition, in order to suppress generic uptake.

211. Teva’s conduct was intentional, i.e., it entered into exclusionary agreements, and falsely deprecated generic Copaxone, in order to suppress generic competition in the glatiramer-acetate market, and with the express purpose of misleading Plaintiff and members of the class.

212. Teva’s conduct did deceive and would have deceived reasonable persons, including Plaintiff and the class.

213. Plaintiff and/or members of the class purchased glatiramer acetate within California during the Class Period.

214. Teva’s conduct was the proximate cause of injuries to Plaintiff and the class, namely in the form of overcharges for glatiramer acetate. For example, had Teva competed on the merits instead of unlawfully maintaining its monopoly in the glatiramer-acetate market, then generic Copaxone would have been more readily available to Plaintiff and the class, and they
would have substituted this lower-priced generic Copaxone for the higher-priced brand-name Copaxone, or paid substantially less for brand-name Copaxone (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Teva’s efforts to denigrate generic Copaxone allowed the company to charge a price premium for brand Copaxone; i.e., as a result of Teva’s false statements, Plaintiff and the class had to pay more for brand Copaxone than that product was actually worth.

215. Because Copaxone is purchased on an ongoing basis, to treat relapsing forms of multiple sclerosis, there is a high probability that Plaintiff will suffer injury in the future, as a result of Teva’s conduct.

216. This claim is instituted pursuant to sections 17203 and 17204 of the California Business and Professions Code, to obtain restitution from Teva for acts that violated the UCL, as described above.

217. Plaintiff and the class are entitled to full restitution and disgorgement of all revenues, earnings, profits, compensation, and benefits that Teva may have obtained as a result of its efforts to suppress generic Copaxone, or as a result of its efforts to mislead patients and providers regarding the relative efficacy or safety of generic Copaxone. Plaintiff and the class are also entitled to all other appropriate relief under the UCL.

**District of Columbia:**

218. Plaintiff incorporates each allegation set forth in the preceding paragraphs of this complaint.

220. Teva’s anticompetitive conduct, which is described above—and which included, among other things, Teva’s exclusionary agreements with PBMs, its disparagement of generic competition, and its DAW scheme—violated D.C.’s antitrust laws, and therefore also violated the CPPA’s unlawful prong. D.C. CODE § 28-3905(k)(1)(A).

221. Independent of any antitrust violations, Teva’s conduct also violated the CPPA’s unfairness prong, because it constituted an unfair business practice, or otherwise violated D.C.’s public policy.

222. Teva also violated the CPPA’s deceptive prong in that (among other thing) the company disparaged its generic competition.

223. Teva’s conduct was intentional, i.e., it entered into exclusionary agreements, and falsely deprecated generic Copaxone, in order to suppress generic competition in the glatiramer-acetate market, and with the express purpose of misleading Plaintiff and members of the class.

224. Teva’s conduct did deceive and would have deceived reasonable persons, including Plaintiff and the class.

225. Teva—whose entire business is centered on the sale of drugs for use by consumers—is a “merchant” within the meaning of the CPPA. D.C. CODE § 28-3901(a)(3).

226. During the Class Period, Plaintiff and/or members of the class purchased Copaxone within the District of Columbia

227. Teva’s conduct was the proximate cause of injuries to Plaintiff and the class, namely in the form of overcharges for glatiramer acetate. For example, had Teva competed on the merits instead of unlawfully maintaining its monopoly in the glatiramer-acetate market, then generic Copaxone would have been more readily available to Plaintiff and the class, and they would have substituted this lower-priced generic Copaxone for the higher-priced brand-name
Copaxone, or paid substantially less for brand-name Copaxone (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Teva’s efforts to denigrate generic Copaxone allowed the company to charge a price premium for brand Copaxone; i.e., as a result of Teva’s false statements, Plaintiff and the class had to pay more for brand Copaxone than that product was actually worth.

228. Because Copaxone is purchased on an ongoing basis, to treat relapsing forms of multiple sclerosis, there is a high probability that Plaintiff will suffer injury in the future, as a result of Teva’s conduct.

229. Plaintiff and members of the class are entitled to seek all forms of relief under the CPPA, including treble damages or $1500 per CPPA violation (whichever is greater), plus punitive damages, reasonable attorney’s fees, costs, and injunctive relief. See D.C. Code § 28-3905(k)(2).

**Florida:**

230. Plaintiff incorporates each allegation set forth in the preceding paragraphs of this complaint.

231. The Florida Deceptive and Unfair Trade Practices Act (the “FDUTPA”) prohibits “unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce.” FLA STAT. § 501.204(1).

232. Teva engaged in unfair methods of competition by (among other things) suppressing competition in the glatiramer-acetate market, which it did by entering into agreements with PBMs to exclude generic Copaxone from formularies; convincing specialty pharmacies to ignore DAW prescriptions and to dispense brand Copaxone; and by engaging in a campaign to falsely disparage the relative efficacy of generic Copaxone.

59
233. Teva also violated the FDUTPA’s deceptive prong by, among other things, falsely disparaging its generic competition.

234. Teva’s conduct was intentional, i.e., it entered into exclusionary agreements, and falsely deprecated generic Copaxone, in order to suppress generic competition in the glatiramer-acetate market, and with the express purpose of misleading Plaintiff and members of the class.

235. Teva’s conduct did deceive and would have deceived reasonable persons, including Plaintiff and the class.

236. During the Class Period, Teva and the class purchased Copaxone in Florida.

237. Teva’s conduct was the proximate cause of injuries to Plaintiff and the class, namely in the form of overcharges for glatiramer acetate. For example, had Teva competed on the merits instead of unlawfully maintaining its monopoly in the glatiramer-acetate market, then generic Copaxone would have been more readily available to Plaintiff and the class, and they would have substituted this lower-priced generic Copaxone for the higher-priced brand-name Copaxone, or paid substantially less for brand-name Copaxone (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Teva’s efforts to denigrate generic Copaxone allowed the company to charge a price premium for brand Copaxone; i.e., as a result of Teva’s false statements, Plaintiff and the class had to pay more for brand Copaxone than that product was actually worth.

238. Because Copaxone is purchased on an ongoing basis, to treat relapsing forms of multiple sclerosis, there is a high probability that Plaintiff will suffer injury in the future, as a result of Teva’s conduct.

239. In light of the above, Plaintiff and members of the class are entitled to seek all forms of relief under the FDUTPA, including injunctive relief pursuant to Florida Statute § 501.208, as
well as a declaratory judgment, actual damages, punitive damages (to the extent available), reasonable attorneys’ fees and costs. See Fla. Stat. § 501.211.

**Hawaii:**

240. Plaintiff incorporates each allegation set forth in the preceding paragraphs of this complaint.


242. Hawaii’s Uniform Deceptive Trade Practices Act prohibits Defendants from (among other things) “[d]isparag[ing] the goods, services, or business of another by false or misleading representation of fact.” Haw. Rev. Stat. § 481A-3(8); see also id. at (5), (7), (12).

243. Teva’s anticompetitive efforts to suppress generic Copaxone, which are described above, constituted an unfair method of competition, or an unfair trade practice, under Hawaii’s Unfair and Deceptive Acts or Trade Practices Act.

244. Teva’s false or misleading statements regarding generic Copaxone (among other thing), which are also described above, constituted disparagement, false advertising, etc., under Hawaii’s Deceptive Trade Practices Act.

245. Teva’s conduct was intentional, i.e., it entered into exclusionary agreements, and falsely deprecated generic Copaxone, in order to suppress generic competition in the glatiramer-acetate market, and with the express purpose of misleading Plaintiff and members of the class.

246. Teva’s conduct did deceive and would have deceived reasonable persons, including Plaintiff and the class.
247. During the Class Period, Plaintiff and/or members of the class purchased Copaxone in Hawaii.

248. Teva’s conduct was the proximate cause of injuries to Plaintiff and the class, namely in the form of overcharges for glatiramer acetate. For example, had Teva competed on the merits instead of unlawfully maintaining its monopoly in the glatiramer-acetate market, then generic Copaxone would have been more readily available to Plaintiff and the class, and they would have substituted this lower-priced generic Copaxone for the higher-priced brand-name Copaxone, or paid substantially less for brand-name Copaxone (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Teva’s efforts to denigrate generic Copaxone allowed the company to charge a price premium for brand Copaxone; i.e., as a result of Teva’s false statements, Plaintiff and the class had to pay more for brand Copaxone than that product was actually worth.

249. Because Copaxone is purchased on an ongoing basis, to treat relapsing forms of multiple sclerosis, there is a high probability that Plaintiff will suffer injury in the future, as a result of Teva’s conduct.

250. In light of the above, Plaintiff and members of the class are entitled to seek all available relief under Hawaii’s consumer-protection laws, including actual damages, treble damages, punitive damages (to the extent available), injunctive relief, attorneys fees, costs, etc.

Idaho:

251. Plaintiff incorporates each allegation set forth in the preceding paragraphs of this complaint.

252. The Idaho Consumer Protection Act (the “ICPA”) prohibits “unfair methods of competition and unfair or deceptive acts and practices in the conduct of trade or commerce,”
IDAHO CODE §§ 48-601, which includes, among other things, “[d]isparaging the goods . . . of another by false or misleading representation of fact,” IDAHO CODE § 48-603(8); see also id. at (7), (17), (18). Idaho also prohibits “any unconscionable method, act or practice in the conduct of any trade or commerce.” IDAHO CODE § 48-603C.

253. Teva’s anticompetitive efforts to limit the availability of generic Copaxone, which are described above—and which included, among other things, exclusionary agreements with PBMs; efforts to circumvent DAW requirements; and falsely disparaging generic competition—constitute an unfair method of competition, or an unconscionable practice, under the ICPA. By disparaging its generic competition (among other thing), Teva also engaged in deceptive practices under the ICPA.

254. Teva intentionally engaged in the above conduct in order to inhibit generic competition. As noted above, Teva’s own documents, which are detailed in the Congressional report described above, indicate that its suppression of generic Copaxone was part of an intentional, long-running, focused effort by the company to preserve branded Copaxone sales and prices, even after the loss of Teva’s patent exclusivity.

255. Teva’s alleged conduct—which forced sufferers of multiple sclerosis to overpay for their medication—would outrage or offend the public conscious.

256. Teva’s conduct did deceive and would have deceived reasonable persons, including Plaintiff and the class.

257. During the Class Period, Plaintiff and/or members of the class purchased Copaxone in Idaho.

258. Teva’s conduct was the proximate cause of injuries to Plaintiff and the class, namely in the form of overcharges for glatiramer acetate. For example, had Teva competed on the
merits instead of unlawfully maintaining its monopoly in the glatiramer-acetate market, then
generic Copaxone would have been more readily available to Plaintiff and the class, and they
would have substituted this lower-priced generic Copaxone for the higher-priced brand-name
Copaxone, or paid substantially less for brand-name Copaxone (because an increased generic
presence would have exerted downward price pressure on brand prices). Relatedly, Teva’s efforts
to denigrate generic Copaxone allowed the company to charge a price premium for brand
Copaxone; i.e., as a result of Teva’s false statements, Plaintiff and the class had to pay more for
brand Copaxone than that product was actually worth.

259. Because Copaxone is purchased on an ongoing basis, to treat relapsing forms of
multiple sclerosis, there is a high probability that Plaintiff will suffer injury in the future, as a result
of Teva’s conduct.

260. In light of the above, Plaintiff and the class are entitled to seek actual damages,
along with any other form of relief that the Court deems proper under the ICPA, including actual
damages, statutory damages, punitive damages, attorneys’ fees, costs, injunctive relief, etc. See
IDaho Code § 48-608.

**Illinois:**

261. Plaintiff incorporates each allegation set forth in the preceding paragraphs of this
complaint.

262. The Illinois Consumer Fraud and Deceptive Business Practices Act (the “ICFA”)
prohibits “[u]nfair methods of competition and unfair or deceptive acts or practices.” 815 Ill.
Comp. Stat. 505/2.

263. Teva’s anticompetitive efforts to limit the availability of generic Copaxone, which
are described above—and which included, among other things, exclusionary agreements with
PBM; efforts to circumvent DAW requirements; and falsely disparaging generic competition—constitute an unfair method of competition, or an unfair practice, under the ICFA. By disparaging its generic competition (among other thing), Teva also engaged in deceptive practices under the ICFA.

264. Teva intentionally engaged in the above conduct in order to inhibit generic competition. As noted above, Teva’s own documents, which are detailed in the Congressional report described above, indicate that its suppression of generic Copaxone was part of an intentional, long-running, focused effort by the company to preserve branded Copaxone sales and prices, even after the loss of Teva’s patent exclusivity.

265. Teva’s conduct did deceive and would have deceived reasonable persons, including Plaintiff and the class.

266. During the Class Period, Plaintiff and/or members of the class purchased Copaxone in Illinois.

267. Teva’s conduct was the proximate cause of injuries to Plaintiff and the class, namely in the form of overcharges for glatiramer acetate. For example, had Teva competed on the merits instead of unlawfully maintaining its monopoly in the glatiramer-acetate market, then generic Copaxone would have been more readily available to Plaintiff and the class, and they would have substituted this lower-priced generic Copaxone for the higher-priced brand-name Copaxone, or paid substantially less for brand-name Copaxone (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Teva’s efforts to denigrate generic Copaxone allowed the company to charge a price premium for brand Copaxone; i.e., as a result of Teva’s false statements, Plaintiff and the class had to pay more for brand Copaxone than that product was actually worth.
268. Because Copaxone is purchased on an ongoing basis, to treat relapsing forms of multiple sclerosis, there is a high probability that Plaintiff will suffer injury in the future, as a result of Teva’s conduct.

269. In light of the above, Plaintiff and the class are entitled to seek actual damages, along with any other form of relief that the Court deems proper under the ICFA, including actual damages, punitive damages, attorneys’ fees, costs, injunctive relief, etc. See 815 Ill. Comp. Stat. 505/10a.

**Kansas:**

270. Plaintiff incorporates each allegation set forth in the preceding paragraphs of this complaint.

271. Among other things, the Kansas Consumer Protection Act (the “KCPA”) prohibits “deceptive” and “unconscionable act[s] or practice in connection with a consumer transaction.” KAN. STAT. §§ 50-626, 50-627.

272. Teva’s efforts to inhibit generic Copaxone, which are described above (e.g., its exclusionary agreements with PBMs, its efforts to circumvent DAW requirements, and its denigration of generic competition), constitute unconscionable practices under the KCPA. Teva also engaged in deceptive practices under the act—including the disparagement of another’s products—by (among other thing) falsely denigrating its generic competition.

273. Teva’s conduct was intentional, i.e., it entered into exclusionary agreements, and falsely depreciated generic Copaxone, in order to suppress generic competition in the glatiramer-acetate market, and with the express purpose of misleading Plaintiff and members of the class.

274. Teva’s conduct did deceive and would have deceived reasonable persons, including Plaintiff and the class.
275. During the Class Period, Plaintiff and/or members of the class purchased Copaxone in Kansas.

276. Teva’s conduct was the proximate cause of injuries to Plaintiff and the class, namely in the form of overcharges for glatiramer acetate. For example, had Teva competed on the merits instead of unlawfully maintaining its monopoly in the glatiramer-acetate market, then generic Copaxone would have been more readily available to Plaintiff and the class, and they would have substituted this lower-priced generic Copaxone for the higher-priced brand-name Copaxone, or paid substantially less for brand-name Copaxone (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Teva’s efforts to denigrate generic Copaxone allowed the company to charge a price premium for brand Copaxone; i.e., as a result of Teva’s false statements, Plaintiff and the class had to pay more for brand Copaxone than that product was actually worth.

277. At the time that Plaintiff and/or members of the class purchased Copaxone, the price of branded Copaxone grossly exceeded the price of generic Copaxone, as noted above.

278. Because Copaxone is purchased on an ongoing basis, to treat relapsing forms of multiple sclerosis, there is a high probability that Plaintiff will suffer injury in the future, as a result of Teva’s conduct.

279. In light of the above, Plaintiff and the class are seeking all forms of relief available under the KCPA, including actual damages, statutory damages, punitive damages (to the extent available), injunctive relief, attorneys’ fees, and costs. See Kan. Stat. § 50-634.

**Maine:**

280. Plaintiff incorporates each allegation set forth in the preceding paragraphs of this complaint.
281. Maine’s Unfair Trade Practices Act (“MUTPA”) prohibits “[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce.” ME. REV. STAT. tit. 5, § 207.

282. Teva’s efforts to inhibit generic Copaxone, which are described above (e.g., its exclusionary agreements with PBMs, its efforts to circumvent DAW requirements, and its denigration of generic competition), constitute unfair methods of competition under the MUTPA. Teva also engaged in deceptive practices under the act by (among other thing) falsely denigrating its generic competition.

283. Teva’s conduct was intentional, i.e., it entered into exclusionary agreements, and falsely deprecated generic Copaxone, in order to suppress generic competition in the glatiramer-acetate market, and with the express purpose of misleading Plaintiff and members of the class.

284. Teva’s conduct did deceive and would have deceived reasonable persons, including Plaintiff and the class.

285. During the Class Period, Plaintiff and/or members of the class purchased Copaxone in Maine.

286. Teva’s conduct was the proximate cause of injuries to Plaintiff and the class, namely in the form of overcharges for glatiramer acetate. For example, had Teva competed on the merits instead of unlawfully maintaining its monopoly in the glatiramer-acetate market, then generic Copaxone would have been more readily available to Plaintiff and the class, and they would have substituted this lower-priced generic Copaxone for the higher-priced brand-name Copaxone, or paid substantially less for brand-name Copaxone (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Teva’s efforts to denigrate generic Copaxone allowed the company to charge a price premium for brand
Copaxone; i.e., as a result of Teva’s false statements, Plaintiff and the class had to pay more for brand Copaxone than that product was actually worth.

287. Because Copaxone is purchased on an ongoing basis, to treat relapsing forms of multiple sclerosis, there is a high probability that Plaintiff will suffer injury in the future, as a result of Teva’s conduct.

288. Given the above, Plaintiff and the class are seeking all forms of relief available under the MUTPA, including actual damages, statutory damages, punitive damages (to the extent available), restitution, injunctive relief, attorneys’ fees, costs, etc. Me. Rev. Stat. tit. 5, § 213.

Massachusetts:

289. Plaintiff incorporates each allegation set forth in the preceding paragraphs of this complaint.


291. Teva’s anticompetitive scheme to suppress generic Copaxone, which is described above, constituted an unfair act or practice under the MaCPA.

292. Teva’s efforts to falsely denigrate generic Copaxone (among other thing), as described above, constituted a deceptive act or practice under the MaCPA.

293. Teva’s conduct was intentional, i.e., it entered into exclusionary agreements, and falsely deprecated generic Copaxone, in order to suppress generic competition in the glatiramer-acetate market, and with the express purpose of misleading Plaintiff and members of the class.

294. Teva’s conduct did deceive and would have deceived reasonable persons, including Plaintiff and the class.
295. During the Class Period, Plaintiff and members of the class purchased glatiramer acetate within the Commonwealth of Massachusetts.

296. Teva’s conduct was the proximate cause of injuries to Plaintiff and the class, namely in the form of overcharges for glatiramer acetate. For example, had Teva competed on the merits instead of unlawfully maintaining its monopoly in the glatiramer-acetate market, then generic Copaxone would have been more readily available to Plaintiff and the class, and they would have substituted this lower-priced generic Copaxone for the higher-priced brand-name Copaxone, or paid substantially less for brand-name Copaxone (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Teva’s efforts to denigrate generic Copaxone allowed the company to charge a price premium for brand Copaxone; i.e., as a result of Teva’s false statements, Plaintiff and the class had to pay more for brand Copaxone than that product was actually worth.

297. Because Copaxone is purchased on an ongoing basis, to treat relapsing forms of multiple sclerosis, there is a high probability that Plaintiff will suffer injury in the future, as a result of Teva’s conduct.

298. In light of the above, Plaintiff and the class are seeking all forms of relief under the MaCPA, including actual damages, treble damages, punitive damages (to the extent available), reasonable attorney’s fees, costs, and injunctive relief. See Mass. Gen. Laws ch. 93A § 9(3A).

Michigan:

299. Plaintiff incorporates each allegation set forth in the preceding paragraphs of this complaint.

300. The Michigan Consumer Protection Act (the “MiCPA”) prohibits “Unfair, unconscionable, or deceptive methods, acts, or practices in the conduct of trade or commerce.”
MICH. COMP. LAWS § 445.903(1). Among other things, this includes “[c]harging the consumer a price that is grossly in excess of the price at which similar property or services are sold” (id. at (z)), as well as “[d]isparaging the goods . . . of another by false or misleading representation of fact” (id. at (f)).

301. Teva’s anticompetitive conduct, which is described above (e.g., its exclusionary agreements with PBMIs, its efforts to circumvent DAW requirements, and its denigration of generic competition), and which inhibited competition in the Copaxone market, constituted an unfair or unconscionable method, act, or practice under the MiCPA. By disparaging its generic competition (among other thing), Teva also engaged in deceptive practices under the MiCPA.

302. Teva’s conduct was intentional, i.e., it entered into exclusionary agreements, and falsely deprecated generic Copaxone, in order to suppress generic competition in the glatiramer-acetate market, and with the express purpose of misleading Plaintiff and members of the class.

303. Teva’s conduct did deceive and would have deceived reasonable persons, including Plaintiff and the class.

304. During the Class Period, Plaintiff and/or members of the class purchased Copaxone in Michigan.

305. Teva’s conduct was the proximate cause of injuries to Plaintiff and the class, namely in the form of overcharges for glatiramer acetate. For example, had Teva competed on the merits instead of unlawfully maintaining its monopoly in the glatiramer-acetate market, then generic Copaxone would have been more readily available to Plaintiff and the class, and they would have substituted this lower-priced generic Copaxone for the higher-priced brand-name Copaxone, or paid substantially less for brand-name Copaxone (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Teva’s efforts
to denigrate generic Copaxone allowed the company to charge a price premium for brand Copaxone; i.e., as a result of Teva’s false statements, Plaintiff and the class had to pay more for brand Copaxone than that product was actually worth.

306. Because Copaxone is purchased on an ongoing basis, to treat relapsing forms of multiple sclerosis, there is a high probability that Plaintiff will suffer injury in the future, as a result of Teva’s conduct.

307. Given the above, Plaintiff and the class are seeking all forms of relief available under the MiCPA, including actual damages, statutory damages, punitive damages (to the extent available), and injunctive relief. See Mich. Comp. Laws § 445.911.

**Minnesota:**

308. Plaintiff incorporates each allegation set forth in the preceding paragraphs of this complaint.

309. Under Minnesota’s Deceptive Trade Practices Act (the “MDTPA”), it is illegal to “disparage the goods . . . of another by false or misleading representation of fact,” or to “represent[] that goods . . . have . . . characteristics, . . . uses, [or] benefits . . . that they do not have.” Minn. Stat. § 325D.44(8), (5); see also id. at (7), (11), (13). Under Minnesota’s Consumer Fraud Act, it is illegal to employ “misleading statement[s] or deceptive practice[s]” in the sale of a good. Minn. Stat. § 325F.69.

310. Teva’s efforts to inhibit generic Copaxone, which are described above (e.g., its exclusionary agreements with PBMs, its efforts to circumvent DAW requirements, and its denigration of generic competition), constitute violations of Minnesota’s consumer-protection laws. Teva also engaged in deceptive practices under these laws by (among other thing) disparaging its generic competition.
311. Teva’s conduct was intentional, i.e., it entered into exclusionary agreements, and falsely deprecated generic Copaxone, in order to suppress generic competition in the glatiramer-acetate market, and with the express purpose of misleading Plaintiff and members of the class.

312. Teva’s conduct did deceive and would have deceived reasonable persons, including Plaintiff and the class.

313. During the Class Period, Plaintiff and/or members of the class purchased Copaxone in Minnesota.

314. Teva’s conduct was the proximate cause of injuries to Plaintiff and the class, namely in the form of overcharges for glatiramer acetate. For example, had Teva competed on the merits instead of unlawfully maintaining its monopoly in the glatiramer-acetate market, then generic Copaxone would have been more readily available to Plaintiff and the class, and they would have substituted this lower-priced generic Copaxone for the higher-priced brand-name Copaxone, or paid substantially less for brand-name Copaxone (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Teva’s efforts to denigrate generic Copaxone allowed the company to charge a price premium for brand Copaxone; i.e., as a result of Teva’s false statements, Plaintiff and the class had to pay more for brand Copaxone than that product was actually worth.

315. Because Copaxone is purchased on an ongoing basis, to treat relapsing forms of multiple sclerosis, there is a high probability that Plaintiff will suffer injury in the future, as a result of Teva’s conduct.

316. In light of the above, Plaintiff and members of the class are seeking all forms of relief under Minnesota’s consumer-protection statutes, including actual damages, punitive damages (to the extent available), reasonable attorneys’ fees, costs, and injunctive relief.
Montana:

317. Plaintiff incorporates each allegation set forth in the preceding paragraphs of this complaint.

318. Montana’s Consumer Protection Act of 1970 (the “MtCPA”) prohibits “[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce.” MONT. CODE § 30-14-103.

319. Teva’s efforts to inhibit generic Copaxone, which are described above (e.g., its exclusionary agreements with PBMs, its efforts to circumvent DAW requirements, and its denigration of generic competition), constitute unfair methods of competition under the MtCPA. Teva also engaged in deceptive practices under the act by (among other thing) disparaging its generic competition.

320. Teva’s conduct was intentional, i.e., it entered into exclusionary agreements, and falsely deprecated generic Copaxone, in order to suppress generic competition in the glatiramer-acetate market, and with the express purpose of misleading Plaintiff and members of the class.

321. Teva’s conduct did deceive and would have deceived reasonable persons, including Plaintiff and the class.

322. During the Class Period, Plaintiff and/or members of the class purchased Copaxone in Montana.

323. Teva’s conduct was the proximate cause of injuries to Plaintiff and the class, namely in the form of overcharges for glatiramer acetate. For example, had Teva competed on the merits instead of unlawfully maintaining its monopoly in the glatiramer-acetate market, then generic Copaxone would have been more readily available to Plaintiff and the class, and they would have substituted this lower-priced generic Copaxone for the higher-priced brand-name
Copaxone, or paid substantially less for brand-name Copaxone (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Teva’s efforts to denigrate generic Copaxone allowed the company to charge a price premium for brand Copaxone; i.e., as a result of Teva’s false statements, Plaintiff and the class had to pay more for brand Copaxone than that product was actually worth.

324. Because Copaxone is purchased on an ongoing basis, to treat relapsing forms of multiple sclerosis, there is a high probability that Plaintiff will suffer injury in the future, as a result of Teva’s conduct.

325. In light of the above, Plaintiff and the class seeks all available relief under the MtCPA, including actual damages, punitive damages (to the extent available), injunctive relief, and all other forms of relief that the Court deems necessary and/or appropriate.

Nebraska:

326. Plaintiff incorporates each allegation set forth in the preceding paragraphs of this complaint.

327. Nebraska’s Consumer Protection Act prohibits “[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce.” Neb. Rev. Stat. § 59-1602. Nebraska’s Uniform Deceptive Trade Practices Act makes it illegal to (among other things) “disparages the goods, services, or business of another by false or misleading representation of fact.” Neb. Rev. Stat. § 87-302(9); see also id. at (5), (6), (8), (22)(ii).

328. Teva’s efforts to inhibit generic Copaxone, which are described above (e.g., its exclusionary agreements with PBMs, its efforts to circumvent DAW requirements, and its denigration of generic competition), constitute unfair methods of competition under Nebraska’s consumer-protection laws. Teva also engaged in deceptive practices under these laws—including
the disparagement of another’s products—by (among other thing) falsely denigrating its generic competition.

329. Teva’s conduct was intentional, i.e., it entered into exclusionary agreements, and falsely depreciated generic Copaxone, in order to suppress generic competition in the glatiramer-acetate market, and with the express purpose of misleading Plaintiff and members of the class.

330. Teva’s conduct did deceive and would have deceived reasonable persons, including Plaintiff and the class.

331. During the Class Period, Plaintiff and/or members of the class purchased Copaxone in Nebraska.

332. Teva’s conduct was the proximate cause of injuries to Plaintiff and the class, namely in the form of overcharges for glatiramer acetate. For example, had Teva competed on the merits instead of unlawfully maintaining its monopoly in the glatiramer-acetate market, then generic Copaxone would have been more readily available to Plaintiff and the class, and they would have substituted this lower-priced generic Copaxone for the higher-priced brand-name Copaxone, or paid substantially less for brand-name Copaxone (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Teva’s efforts to denigrate generic Copaxone allowed the company to charge a price premium for brand Copaxone; i.e., as a result of Teva’s false statements, Plaintiff and the class had to pay more for brand Copaxone than that product was actually worth.

333. Because Copaxone is purchased on an ongoing basis, to treat relapsing forms of multiple sclerosis, there is a high probability that Plaintiff will suffer injury in the future, as a result of Teva’s conduct.
334. Given the above, Plaintiff and the class are seeking all forms of relief available under Nebraska’s consumer-protection statutes, including actual damages, statutory damages, punitive damages (to the extent available), injunctive relief, attorneys’ fees, costs, and all other relief the Court deems necessary and/or appropriate. See Neb. Rev. Stat. §§ 59-1609, 59-1614.

Nevada:

335. Plaintiff incorporates each allegation set forth in the preceding paragraphs of this complaint.

336. Nevada’s Deceptive Trade Practices Act (the “NDTPA”) makes it illegal (among other things) to “[d]isparages the goods . . . of another . . . by false or misleading representation of fact,” and to “[f]raudulently alter[] any contract . . . or other document in connection with the sale . . . of goods.” Nev. Rev. Stat. § 598.0915(8), (14); see also id. at (5), (7), (15). Nevada also makes it illegal to “[m]ake[] an assertion of scientific, clinical or quantifiable fact in an advertisement” without being able to “substantiate the assertion” with “scientific . . . evidence.” Nev. Rev. Stat. § 598.0925(1)(a).

337. Teva’s efforts to inhibit generic Copaxone, which are described above (e.g., its exclusionary agreements with PBMs, its efforts to circumvent DAW requirements, and its denigration of generic competition), constitute deceptive trade practices under the NDTPA (its DAW campaign, for example, constituted the fraudulent alteration of prescriptions). Teva also engaged in deceptive practices under the act—including the disparagement of another’s products—by (among other thing) falsely denigrating its generic competition, and by making unsubstantiated, scientific assertions regarding the relative inefficacy of generic Copaxone.

338. Teva’s conduct was intentional, i.e., it entered into exclusionary agreements, and falsely deprecated generic Copaxone, in order to suppress generic competition in the glatiramer-
acetate market, and with the express purpose of misleading Plaintiff and members of the class. Plaintiff and member of the class.

339. Teva’s conduct did deceive and would have deceived reasonable persons, including Plaintiff and the class.

340. During the Class Period, Plaintiff and/or members of the class purchased Copaxone in Nevada.

341. Teva’s conduct was the proximate cause of injuries to Plaintiff and the class, namely in the form of overcharges for glatiramer acetate. For example, had Teva competed on the merits instead of unlawfully maintaining its monopoly in the glatiramer-acetate market, then generic Copaxone would have been more readily available to Plaintiff and the class, and they would have substituted this lower-priced generic Copaxone for the higher-priced brand-name Copaxone, or paid substantially less for brand-name Copaxone (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Teva’s efforts to denigrate generic Copaxone allowed the company to charge a price premium for brand Copaxone; i.e., as a result of Teva’s false statements, Plaintiff and the class had to pay more for brand Copaxone than that product was actually worth.

342. Because Copaxone is purchased on an ongoing basis, to treat relapsing forms of multiple sclerosis, there is a high probability that Plaintiff will suffer injury in the future, as a result of Teva’s conduct.

343. Given the above, Plaintiff and the class are seeking all forms of relief available under the NDTPA, including actual damages, punitive damages (to the extent available), reasonable attorneys’ fees, costs, and a civil penalty of up to $5,000 per violation. See e.g., Nev. Rev. Stat. §§ 598.0993, 598.099.
New Hampshire:

344. Plaintiff incorporates each allegation set forth in the preceding paragraphs of this complaint.

345. New Hampshire’s Consumer Protection Act (the “NHCPA”) prohibits any “unfair method of competition or any unfair or deceptive act or practice in the conduct of any trade or commerce.” N.H. Rev. Stat. § 358-A:2; see also id. at (V), (VII), (VIII).

346. Teva’s efforts to inhibit generic Copaxone, which are described above (e.g., its exclusionary agreements with PBMs, its efforts to circumvent DAW requirements, and its denigration of generic competition), constitute unfair methods of competition under NHCPA. Teva also engaged in deceptive practices under the act—including the disparagement of another’s products—by (among other thing) falsely denigrating its generic competition.

347. Teva’s conduct was intentional, i.e., it entered into exclusionary agreements, and falsely deprecated generic Copaxone, in order to suppress generic competition in the glatiramer-acetate market, and with the express purpose of misleading Plaintiff and members of the Class.

348. Teva’s conduct did deceive and would have deceived reasonable persons, including Plaintiff and the class.

349. During the Class Period, Plaintiff and/or members of the class purchased Copaxone in New Hampshire.

350. Teva’s conduct was the proximate cause of injuries to Plaintiff and the class, namely in the form of overcharges for glatiramer acetate. For example, had Teva competed on the merits instead of unlawfully maintaining its monopoly in the glatiramer-acetate market, then generic Copaxone would have been more readily available to Plaintiff and the class, and they would have substituted this lower-priced generic Copaxone for the higher-priced brand-name
Copaxone, or paid substantially less for brand-name Copaxone (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Teva’s efforts to denigrate generic Copaxone allowed the company to charge a price premium for brand Copaxone; i.e., as a result of Teva’s false statements, Plaintiff and the class had to pay more for brand Copaxone than that product was actually worth.

351. Because Copaxone is purchased on an ongoing basis, to treat relapsing forms of multiple sclerosis, there is a high probability that Plaintiff will suffer injury in the future, as a result of Teva’s conduct.

352. In light of the above, Plaintiff and the class are seeking all forms of relief available under NHCPA, including actual damages, statutory damages, treble damages, punitive damages (to the extent available), injunctive relief, attorneys’ fees, and costs. See N.H. REV. STAT. §§ 358-A:10(I), 358-A:10-a(I).

New Mexico:

353. Plaintiff incorporates each allegation set forth in the preceding paragraphs of this complaint.

354. New Mexico’s Unfair Trade Practices Act (the “NMUTPA”) prohibits “[u]nfair or deceptive trade practices and unconscionable trade practices in the conduct of any trade or commerce.” N.M. STAT. § 57-12-3.

355. Teva’s efforts to inhibit generic Copaxone, which are described above (e.g., its exclusionary agreements with PBMs, its efforts to circumvent DAW requirements, and its denigration of generic competition), constitute unfair methods of competition under the NMUTPA. Teva also engaged in deceptive practices under the act by (among other thing) falsely denigrating its generic competition.
356. Teva’s conduct was intentional, i.e., it entered into exclusionary agreements, and falsely deprecated generic Copaxone, in order to suppress generic competition in the glatiramer-acetate market, and with the express purpose of misleading Plaintiff and members of the class.

357. Teva’s conduct did deceive and would have deceived reasonable persons, including Plaintiff and the class.

358. During the Class Period, Plaintiff and/or members of the class purchased Copaxone in New Mexico.

359. Teva’s conduct was the proximate cause of injuries to Plaintiff and the class, namely in the form of overcharges for glatiramer acetate. For example, had Teva competed on the merits instead of unlawfully maintaining its monopoly in the glatiramer-acetate market, then generic Copaxone would have been more readily available to Plaintiff and the class, and they would have substituted this lower-priced generic Copaxone for the higher-priced brand-name Copaxone, or paid substantially less for brand-name Copaxone (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Teva’s efforts to denigrate generic Copaxone allowed the company to charge a price premium for brand Copaxone; i.e., as a result of Teva’s false statements, Plaintiff and the class had to pay more for brand Copaxone than that product was actually worth.

360. Because Copaxone is purchased on an ongoing basis, to treat relapsing forms of multiple sclerosis, there is a high probability that Plaintiff will suffer injury in the future, as a result of Teva’s conduct.

361. In light of the above, Plaintiff and the class are seeking all available forms of relief under NMUTPA, including actual damages, statutory damages, treble damages, punitive damages (to the extent available), injunctive relief, attorneys’ fees, and costs. See N.M. STAT. § 57-12-10.
New York:

362. Plaintiff incorporates each allegation set forth in the preceding paragraphs of this complaint.

363. New York’s General Business Law prohibits “[d]eceptive acts or practices in the conduct of any business, trade or commerce.” N.Y. GEN. BUS. LAW § 349(a), (g); N.Y. GEN. BUS. LAW § 350 (prohibiting false advertising).

364. Teva’s efforts to inhibit generic Copaxone, which are described above (e.g., its exclusionary agreements with PBMs, its efforts to circumvent DAW requirements, and its denigration of generic competition), constitute deceptive acts or practices under the GBL.

365. Teva’s conduct was intentional, i.e., it entered into exclusionary agreements, and falsely deprecated generic Copaxone, in order to suppress generic competition in the glatiramer-acetate market, and with the express purpose of misleading Plaintiff and members of the class.

366. Teva’s conduct did deceive and would have deceived reasonable persons, including Plaintiff and the class.

367. During the Class Period, Plaintiff and/or members of the class purchased Copaxone in New York.

368. Teva’s conduct was the proximate cause of injuries to Plaintiff and the class, namely in the form of overcharges for glatiramer acetate. For example, had Teva competed on the merits instead of unlawfully maintaining its monopoly in the glatiramer-acetate market, then generic Copaxone would have been more readily available to Plaintiff and the class, and they would have substituted this lower-priced generic Copaxone for the higher-priced brand-name Copaxone, or paid substantially less for brand-name Copaxone (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Teva’s efforts
to denigrate generic Copaxone allowed the company to charge a price premium for brand Copaxone; i.e., as a result of Teva’s false statements, Plaintiff and the class had to pay more for brand Copaxone than that product was actually worth.

369. Because Copaxone is purchased on an ongoing basis, to treat relapsing forms of multiple sclerosis, there is a high probability that Plaintiff will suffer injury in the future, as a result of Teva’s conduct.

370. In light of the above, Plaintiff and the class are seeking all available forms of relief under the GBL, including actual damages, treble damages, statutory damages, punitive damages (to the extent available), reasonable attorneys’, costs, and injunctive relief.

North Carolina:

371. Plaintiff incorporates each allegation set forth in the preceding paragraphs of this complaint.

372. North Carolina’s Unfair and Deceptive Trade Practices Act (the “NCUDTPA”) prohibits “Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce.” N.C. Gen. Stat. § 75-1.1(a).

373. Teva’s efforts to inhibit generic Copaxone, which are described above (e.g., its exclusionary agreements with PBMs, its efforts to circumvent DAW requirements, and its denigration of generic competition), constitute unfair methods of competition under the NCUDTPA. Teva also engaged in deceptive practices under the act by (among other thing) falsely denigrating its generic competition.

374. Teva’s conduct was intentional, i.e., it entered into exclusionary agreements, and falsely deprecated generic Copaxone, in order to suppress generic competition in the glatiramer-acetate market, and with the express purpose of misleading Plaintiff and members of the class.
375. Teva’s conduct did deceive and would have deceived reasonable persons, including Plaintiff and the class.

376. Teva’s conduct constituted consumer-oriented deceptive acts or practices within the meaning of North Carolina law, which resulted in consumer injury and a broad adverse impact on the public at large, and which harmed the public interest of North Carolina consumers in an honest marketplace where economic activity is conducted in a competitive manner.

377. During the Class Period, Plaintiff and/or members of the class purchased Copaxone in North Carolina.

378. Teva’s conduct was the proximate cause of injuries to Plaintiff and the class, namely in the form of overcharges for glatiramer acetate. For example, had Teva competed on the merits instead of unlawfully maintaining its monopoly in the glatiramer-acetate market, then generic Copaxone would have been more readily available to Plaintiff and the class, and they would have substituted this lower-priced generic Copaxone for the higher-priced brand-name Copaxone, or paid substantially less for brand-name Copaxone (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Teva’s efforts to denigrate generic Copaxone allowed the company to charge a price premium for brand Copaxone; i.e., as a result of Teva’s false statements, Plaintiff and the class had to pay more for brand Copaxone than that product was actually worth.

379. Because Copaxone is purchased on an ongoing basis, to treat relapsing forms of multiple sclerosis, there is a high probability that Plaintiff will suffer injury in the future, as a result of Teva’s conduct.
380. In light of the above, Plaintiff and the class are seeking all available forms of relief under the NCUDTPA, including actual damages, treble damages, attorneys’ fees, costs, punitive damages (to the extent available), and injunctive relief. See N.C. GEN. STAT. §§ 75-1.1, 75-16.1.

*Oregon:*

381. Plaintiff incorporates each allegation set forth in the preceding paragraphs of this complaint.


383. Teva’s efforts to inhibit generic Copaxone, which are described above (e.g., its exclusionary agreements with PBMs, its efforts to circumvent DAW requirements, and its denigration of generic competition), constitute “unconscionable tactics” under the OUTPA. Teva also engaged in false advertisement under the act by (among other thing) falsely denigrating its generic competition.

384. Teva’s conduct was intentional, i.e., it entered into exclusionary agreements, and falsely deprecated generic Copaxone, in order to suppress generic competition in the glatiramer-acetate market, and with the express purpose of misleading Plaintiff and members of the class.

385. Teva’s conduct did deceive and would have deceived reasonable persons, including Plaintiff and the class.

386. During the Class Period, Plaintiff and/or members of the class purchased Copaxone in Oregon.

387. Teva’s conduct was the proximate cause of injuries to Plaintiff and the class, namely in the form of overcharges for glatiramer acetate. For example, had Teva competed on the merits instead of unlawfully maintaining its monopoly in the glatiramer-acetate market, then
generic Copaxone would have been more readily available to Plaintiff and the class, and they
would have substituted this lower-priced generic Copaxone for the higher-priced brand-name
Copaxone, or paid substantially less for brand-name Copaxone (because an increased generic
presence would have exerted downward price pressure on brand prices). Relatedly, Teva’s efforts
to denigrate generic Copaxone allowed the company to charge a price premium for brand
Copaxone; i.e., as a result of Teva’s false statements, Plaintiff and the class had to pay more for
brand Copaxone than that product was actually worth.

388. Because Copaxone is purchased on an ongoing basis, to treat relapsing forms of
multiple sclerosis, there is a high probability that Plaintiff will suffer injury in the future, as a result
of Teva’s conduct.

389. In light of the above, Plaintiff and the class are seeking all available forms of relief
under the OUTPA, including actual damages, statutory damages, punitive damages (to the extent
available), attorneys’ fees, costs, and injunctive relief. See Or. Rev. Stat. § 646.638.

Rhode Island:

390. Plaintiff incorporates each allegation set forth in the preceding paragraphs of this
complaint.

391. Rhode Island’s Deceptive Trade Practices Act (the “RIDTPA”) prohibits “[u]nfair
methods of competition and unfair or deceptive acts or practices in the conduct of any trade or

392. Teva’s efforts to inhibit generic Copaxone, which are described above (e.g., its
exclusionary agreements with PBMs, its efforts to circumvent DAW requirements, and its
denigration of generic competition), constitute unfair practices under the RIDTPA. Teva also
engaged in deceptive conduct under the act by (among other thing) falsely denigrating its generic competition.

393. Teva’s conduct was intentional, i.e., it entered into exclusionary agreements, and falsely deprecated generic Copaxone, in order to suppress generic competition in the glatiramer-acetate market, and with the express purpose of misleading Plaintiff and members of the class.

394. Teva’s conduct did deceive and would have deceived reasonable persons, including Plaintiff and the class.

395. During the Class Period, Plaintiff and/or members of the class purchased Copaxone in Oregon.

396. Teva’s conduct was the proximate cause of injuries to Plaintiff and the class, namely in the form of overcharges for glatiramer acetate. For example, had Teva competed on the merits instead of unlawfully maintaining its monopoly in the glatiramer-acetate market, then generic Copaxone would have been more readily available to Plaintiff and the class, and they would have substituted this lower-priced generic Copaxone for the higher-priced brand-name Copaxone, or paid substantially less for brand-name Copaxone (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Teva’s efforts to denigrate generic Copaxone allowed the company to charge a price premium for brand Copaxone; i.e., as a result of Teva’s false statements, Plaintiff and the class had to pay more for brand Copaxone than that product was actually worth.

397. Because Copaxone is purchased on an ongoing basis, to treat relapsing forms of multiple sclerosis, there is a high probability that Plaintiff will suffer injury in the future, as a result of Teva’s conduct.
398. In light of the above, Plaintiff and the class are seeking all available forms of relief under the OUTPA, including actual damages, statutory damages, punitive damages (to the extent available), attorneys’ fees, costs, and injunctive relief. See R.I. GEN LAWS § 6-13.1-5.2.

South Carolina:

399. Plaintiff incorporates each allegation set forth in the preceding paragraphs of this complaint.

400. South Carolina’s Unfair Trade Practices Act (the “SCUTPA”) prohibits “[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce.” S.C. CODE §§ 39-5-20.

401. Teva’s efforts to inhibit generic Copaxone, which are described above (e.g., its exclusionary agreements with PBMs, its efforts to circumvent DAW requirements, and its denigration of generic competition), constitute unfair methods of competition under the SCUTPA. Teva also engaged in deceptive practices under the act by (among other thing) falsely denigrating its generic competition.

402. Teva’s conduct was intentional, i.e., it entered into exclusionary agreements, and falsely deprecated generic Copaxone, in order to suppress generic competition in the glatirameracetate market, and with the express purpose of misleading Plaintiff and members of the class.

403. Teva’s conduct did deceive and would have deceived reasonable persons, including Plaintiff and the class.

404. During the Class Period, Plaintiff and/or members of the class purchased Copaxone in South Carolina.

405. Teva’s conduct was the proximate cause of injuries to Plaintiff and the class, namely in the form of overcharges for glatiramer acetate. For example, had Teva competed on the
merits instead of unlawfully maintaining its monopoly in the glatiramer-acetate market, then
generic Copaxone would have been more readily available to Plaintiff and the class, and they
would have substituted this lower-priced generic Copaxone for the higher-priced brand-name
Copaxone, or paid substantially less for brand-name Copaxone (because an increased generic
presence would have exerted downward price pressure on brand prices). Relatedly, Teva’s efforts
to denigrate generic Copaxone allowed the company to charge a price premium for brand
Copaxone; i.e., as a result of Teva’s false statements, Plaintiff and the class had to pay more for
brand Copaxone than that product was actually worth.

406. Because Copaxone is purchased on an ongoing basis, to treat relapsing forms of
multiple sclerosis, there is a high probability that Plaintiff will suffer injury in the future, as a result
of Teva’s conduct.

407. In light of the above, Plaintiff and the class are seeking all available forms of relief
under the SCUTPA, including actual damages, statutory damages, punitive damages (to the extent
available), treble damages, attorneys’ fees, costs, and injunctive relief. See S.C. Code § 39-5-140.

South Dakota:

408. Plaintiff incorporates each allegation set forth in the preceding paragraphs of this
complaint.

409. The South Dakota Deceptive Trade Practices and Consumer Protection Act (the
“SDCPA”) prohibits any “deceptive act or practice . . . in connection with the sale or advertisement

410. Teva’s efforts to inhibit generic Copaxone, which are described above (e.g., its
exclusionary agreements with PBMs, its efforts to circumvent DAW requirements, and its
denigration of generic competition), constitute deceptive acts or practices under the SDCPA.
411. Teva’s conduct was intentional, i.e., it entered into exclusionary agreements, and falsely deprecated generic Copaxone, in order to suppress generic competition in the glatiramer-acetate market, and with the express purpose of misleading Plaintiff and members of the class.

412. Teva’s conduct did deceive and would have deceived reasonable persons, including Plaintiff and the class.

413. During the Class Period, Plaintiff and/or members of the class purchased Copaxone in South Dakota.

414. Teva’s conduct was the proximate cause of injuries to Plaintiff and the class, namely in the form of overcharges for glatiramer acetate. For example, had Teva competed on the merits instead of unlawfully maintaining its monopoly in the glatiramer-acetate market, then generic Copaxone would have been more readily available to Plaintiff and the class, and they would have substituted this lower-priced generic Copaxone for the higher-priced brand-name Copaxone, or paid substantially less for brand-name Copaxone (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Teva’s efforts to denigrate generic Copaxone allowed the company to charge a price premium for brand Copaxone; i.e., as a result of Teva’s false statements, Plaintiff and the class had to pay more for brand Copaxone than that product was actually worth.

415. Because Copaxone is purchased on an ongoing basis, to treat relapsing forms of multiple sclerosis, there is a high probability that Plaintiff will suffer injury in the future, as a result of Teva’s conduct.

416. In light of the above, Plaintiff and the class are seeking all available forms of relief under the SDCPA, including actual damages and injunctive relief. See S.D. CODIFIED LAWS § 37-24-31.
Utah:

417. Plaintiff incorporates each allegation set forth in the preceding paragraphs of this complaint.


419. Teva’s efforts to inhibit generic Copaxone, which are described above (e.g., its exclusionary agreements with PBMs, its efforts to circumvent DAW requirements, and its denigration of generic competition), constitute unconscionable and unfair practices under the UCSPA and the UUPA. Teva also engaged in deceptive practices under the acts by (among other thing) falsely denigrating its generic competition.

420. Teva’s conduct was intentional, i.e., it entered into exclusionary agreements, and falsely deprecated generic Copaxone, in order to suppress generic competition in the glatiramer-acetate market, and with the express purpose of misleading Plaintiff and members of the class.

421. Teva’s conduct did deceive and would have deceived reasonable persons, including Plaintiff and the class.

422. During the Class Period, Plaintiff and/or members of the class purchased Copaxone in Utah.

423. Teva’s conduct was the proximate cause of injuries to Plaintiff and the class, namely in the form of overcharges for glatiramer acetate. For example, had Teva competed on the merits instead of unlawfully maintaining its monopoly in the glatiramer-acetate market, then generic Copaxone would have been more readily available to Plaintiff and the class, and they
would have substituted this lower-priced generic Copaxone for the higher-priced brand-name Copaxone, or paid substantially less for brand-name Copaxone (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Teva’s efforts to denigrate generic Copaxone allowed the company to charge a price premium for brand Copaxone; i.e., as a result of Teva’s false statements, Plaintiff and the class had to pay more for brand Copaxone than that product was actually worth.

424. Because Copaxone is purchased on an ongoing basis, to treat relapsing forms of multiple sclerosis, there is a high probability that Plaintiff will suffer injury in the future, as a result of Teva’s conduct.

425. In light of the above, Plaintiff and the class are seeking all available forms of relief under the UCSPA and the UUPA, including actual damages, statutory damages, punitive damages (to the extent available), attorneys’ fees, costs, and injunctive relief. See Utah Code §§ 13-11-19(5), 13-11-20.

Vermont:

426. Plaintiff incorporates each allegation set forth in the preceding paragraphs of this complaint.

427. Title 9 of the Vermont Statutes prohibits “[u]nfair methods of competition in commerce and unfair or deceptive acts or practices in commerce.” Vt. Stat. tit. 9, § 2453.

428. Teva’s efforts to inhibit generic Copaxone, which are described above (e.g., its exclusionary agreements with PBMs, its efforts to circumvent DAW requirements, and its denigration of generic competition), constitute unfair practices under § 2453. Teva also engaged in deceptive practices under the statute by (among other thing) falsely denigrating its generic competition.
429. Teva’s conduct was intentional, i.e., it entered into exclusionary agreements, and falsely deprecated generic Copaxone, in order to suppress generic competition in the glatiramer-acetate market, and with the express purpose of misleading Plaintiff and members of the class.

430. Teva’s conduct did deceive and would have deceived reasonable persons, including Plaintiff and the class.

431. During the Class Period, Plaintiff and/or members of the class purchased Copaxone in Vermont.

432. Teva’s conduct was the proximate cause of injuries to Plaintiff and the class, namely in the form of overcharges for glatiramer acetate. For example, had Teva competed on the merits instead of unlawfully maintaining its monopoly in the glatiramer-acetate market, then generic Copaxone would have been more readily available to Plaintiff and the class, and they would have substituted this lower-priced generic Copaxone for the higher-priced brand-name Copaxone, or paid substantially less for brand-name Copaxone (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Teva’s efforts to denigrate generic Copaxone allowed the company to charge a price premium for brand Copaxone; i.e., as a result of Teva’s false statements, Plaintiff and the class had to pay more for brand Copaxone than that product was actually worth.

433. Because Copaxone is purchased on an ongoing basis, to treat relapsing forms of multiple sclerosis, there is a high probability that Plaintiff will suffer injury in the future, as a result of Teva’s conduct.

434. In light of the above, Plaintiff and the class are seeking all available forms of relief under Vermont’s consumer-protection statute, including actual damages, punitive damages (to the extent available), attorneys’ fees, costs, and injunctive relief.
Virginia:

435. Plaintiff incorporates each allegation set forth in the preceding paragraphs of this complaint.


437. Teva’s efforts to inhibit generic Copaxone, which are described above (e.g., its exclusionary agreements with PBMs, its efforts to circumvent DAW requirements, and its denigration of generic competition), constitute unfair and deceptive practices under the VCPA.

438. Teva’s conduct was intentional, i.e., it entered into exclusionary agreements, and falsely deprecated generic Copaxone, in order to suppress generic competition in the glatiramer-acetate market, and with the express purpose of misleading Plaintiff and members of the class.

439. Teva’s conduct did deceive and would have deceived reasonable persons, including Plaintiff and the class.

440. During the Class Period, Plaintiff and/or members of the class purchased Copaxone in Virginia.

441. Teva’s conduct was the proximate cause of injuries to Plaintiff and the class, namely in the form of overcharges for glatiramer acetate. For example, had Teva competed on the merits instead of unlawfully maintaining its monopoly in the glatiramer-acetate market, then generic Copaxone would have been more readily available to Plaintiff and the class, and they would have substituted this lower-priced generic Copaxone for the higher-priced brand-name Copaxone, or paid substantially less for brand-name Copaxone (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Teva’s efforts to denigrate generic Copaxone allowed the company to charge a price premium for brand
Copaxone; i.e., as a result of Teva’s false statements, Plaintiff and the class had to pay more for brand Copaxone than that product was actually worth.

442. Because Copaxone is purchased on an ongoing basis, to treat relapsing forms of multiple sclerosis, there is a high probability that Plaintiff will suffer injury in the future, as a result of Teva’s conduct.

443. In light of the above, Plaintiff and the class are seeking all available forms of relief under Vermont’s consumer-protection statute, including actual damages, statutory damages, punitive damages (to the extent available), attorneys’ fees, costs, and injunctive relief. See VA. CODE § 59.1-204.

West Virginia:

444. Plaintiff incorporates each allegation set forth in the preceding paragraphs of this complaint.

445. The West Virginia Consumer Credit and Protection Act (the “WVCCPA”), prohibits, inter alia, “unfair or deceptive acts or practices in the conduct of any trade or commerce.” W. VA. CODE § 46A-6-104.

446. Teva’s efforts to inhibit generic Copaxone, which are described above (e.g., its exclusionary agreements with PBMs, its efforts to circumvent DAW requirements, and its denigration of generic competition), constitute unfair and deceptive practices under the VCPA.

447. Teva’s conduct was intentional, i.e., it entered into exclusionary agreements, and falsely deprecated generic Copaxone, in order to suppress generic competition in the glatiramer-acetate market, and with the express purpose of misleading Plaintiff and members of the class.

448. Teva’s conduct did deceive and would have deceived reasonable persons, including Plaintiff and the class.
449. During the Class Period, Plaintiff and/or members of the class purchased Copaxone in Virginia.

450. Teva’s conduct was the proximate cause of injuries to Plaintiff and the class, namely in the form of overcharges for glatiramer acetate. For example, had Teva competed on the merits instead of unlawfully maintaining its monopoly in the glatiramer-acetate market, then generic Copaxone would have been more readily available to Plaintiff and the class, and they would have substituted this lower-priced generic Copaxone for the higher-priced brand-name Copaxone, or paid substantially less for brand-name Copaxone (because an increased generic presence would have exerted downward price pressure on brand prices). Relatedly, Teva’s efforts to denigrate generic Copaxone allowed the company to charge a price premium for brand Copaxone; i.e., as a result of Teva’s false statements, Plaintiff and the class had to pay more for brand Copaxone than that product was actually worth.

451. Because Copaxone is purchased on an ongoing basis, to treat relapsing forms of multiple sclerosis, there is a high probability that Plaintiff will suffer injury in the future, as a result of Teva’s conduct.

452. In light of the above, Plaintiff and the class are seeking all available forms of relief under Vermont’s consumer-protection statute, including actual damages, statutory damages, punitive damages (to the extent available), attorneys’ fees, costs, and injunctive relief. See W. V.A. CODE § 46A-6-106.

CLAIM III:
DECLARATORY AND INJUNCTIVE RELIEF

453. Plaintiff incorporates by reference all previous allegations of fact as though fully set forth herein.

455. Plaintiffs request that the Court grant injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S. C. § 26 as may be necessary and appropriate to restore competition in the market for glatiramer acetate.

**XIV. DEMAND FOR JUDGMENT**

WHEREFORE, Plaintiff, on behalf of themselves and the class of all others similarly situated, respectfully request judgment against the Defendants as follows:

456. The Court determine that this action may be maintained as a class action under Rule 23(a), (b)(2), and (b)(3) of the Federal Rules of Civil Procedure, appoint Plaintiff as class representatives and their counsel of record as class counsel, and direct that notice of this action, as provided by Rule 23(c)(2) of the Federal Rules of Civil Procedure, be given to the class, once certified;

457. The unlawful conduct alleged herein be adjudged and decreed in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2 and the listed state antitrust laws, unfair competition laws, state consumer protection laws, and common law;

458. Plaintiff and the class recover damages, to the maximum extent allowed under the applicable laws, and that a joint and several judgment in favor of Plaintiff and members of the class be entered in an amount to be trebled to the extent such laws permit;

459. The Court grant permanent injunctive relief: a. enjoining the Defendants from continuing their illegal conduct; b. enjoining the Defendants from engaging in future anticompetitive conduct with the purpose or effect of delaying the entry of generic glatiramer acetate or other generic drugs;
460. The Court Grant Plaintiff and the proposed class equitable relief in the nature of
disgorgement and restitution;

461. Plaintiff and the members of the proposed class be awarded pre- and post-judgment
interest as provided by law, and that such interest be awarded at the highest legal rate from and
after the date of service of this complaint;

462. Plaintiff and members of the proposed class recover their costs of suit, including
reasonable attorneys’ fees, as provided by law; and

463. Plaintiff and members of the proposed class be awarded such other and further relief
as the case may require and the Court may deem just and proper.

XV. JURY DEMAND

464. Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff, on behalf of
themselves and the proposed class, demand a trial by jury of all issues so triable.

Dated: March 11, 2022

/s/ Christopher A. Seeger
Christopher A. Seeger Seeger
Weiss LLP
55 Challenger Road, 6th Floor
Ridgefield Park, NJ 07660
cseeger@seegerweiss.com
Telephone: (973) 639-9100
Facsimile: (973) 679-8656

Local Counsel for the Proposed Class and Plaintiff
the Mayor and City Council of Baltimore

Sharon K. Robertson (pro hac vice forthcoming)
Donna M. Evans (pro hac vice forthcoming)
Cohen Milstein Sellers & Toll PLLC
88 Pine Street, 14th Floor
New York, NY 10005
Telephone: (212) 838-7797
Facsimile: (212) 838-7745
srobertson@cohenmilstein.com
devans@cohenmilstein.com
Archana Tamoshunas (pro hac vice forthcoming)
Taus, Cebulash & Landau, LLP
80 Maiden Lane, Suite 1204
New York, NY 10038
Telephone: 212-931-0704
atamoshunas@tcilaw.com

Counsel for the Proposed Class and Plaintiff the Mayor and City Council of Baltimore
Synopsis

**Background:** Federal Trade Commission (FTC) and seven states, including New York, filed action against founder, who was largest shareholder and former chief executive officer (CEO) of pharmaceutical company, claiming violations of Sherman Act, Federal Trade Commission Act, and state statutes, arising from alleged scheme to block lower-cost generic drug competition against company's branded drug, resulting in delaying entry of generic competition for at least 18 months and yielding over $64 million in excess profits, after company raised price of branded drug by 4000%. Bench trial was held.

**Holdings:** The District Court, Denise L. Cote, Senior District Judge, held that:

- monopolistic scheme violated Sherman Act and state laws;
- anticompetitive scheme violated Sherman Act and state laws;
- founder was individually liable for antitrust violations;
- founder was banned for life from pharmaceutical industry; and
- founder was jointly and severally liable for disgorging $64.6 million.

Ordered accordingly.

**Procedural Posture(s):** Judgment.

**Attorneys and Law Firms**


DENISE COTE, District Judge:

*1 Procedural History...——

Background...——
I. FDA Drug Approval Process for Generic Drugs...——

II. Retrophin...——

III. Vyera is Founded...——

A. Vyera Acquires Daraprim...——

B. Daraprim's 2015 Price Hike and Vyera's Revenues...——

IV. Vyera's Implementation of a Closed Distribution System for Daraprim...——

A. Class of Trade Restrictions...——

B. Bottle Limits...——

C. Surveillance...——

D. Benefits to Distributors...——

V. Vyera's Restriction of Access to the API Pyrimethamine...——

2022-1 Trade Cases P 81,945

A. Fukuzyu...——

B. RL Fine...——

VI. Delay of Generic Entry...——

A. Barriers to Entry...——

B. Cerovene and Dr. Reddy's Laboratories...——

C. Fera...——

D. InvaTech...——

E. Mylan...——

VII. Impact of Competition on Prices of Daraprim...——

VIII. The Role of Martin Shkreli at Vyera...——

Discussion...——

I. Legal Standard...——

A. Section 5 of the FTC Act...——

B. Section 1 of the Sherman Act...——

C. Section 2 of the Sherman Act...——

   a. Monopoly Power...——

   b. Anticompetitive Conduct...——

II. Plaintiff States’ Laws...——

A. New York...——

B. California...——

C. Illinois...——

D. North Carolina...——

E. Ohio...——

F. Pennsylvania...——

G. Virginia...——

III. Liability...——

2022-1 Trade Cases P 81,945

A. The Relevant Market...——

B. Monopoly Power...——

C. Anticompetitive Conduct...——
   a. Distribution Contracts...——
   b. Exclusive Supply Agreements...——
   c. Degree of Burden on Generic Competitors...——

D. Shkreli is Individually Liable...——

IV. Remedies...——

A. Injunctive Relief...——

B. Disgorgement...——
   a. Cerovene and Dr. Reddy's Hypothetical Entry Date...——
   b. Fera's Hypothetical Entry Date...——
   c. Vyera's Excess Profits...——

C. Shkreli's Liability for Vyera's Excess Profits...——

Conclusion...——

In 2015, Martin Shkreli raised the price of the life-saving pharmaceutical Daraprim by 4,000% and initiated a scheme to block the entry of generic drug competition so that he could reap the profits from Daraprim sales for as long as possible. Through his tight control of the distribution of Daraprim, Shkreli prevented generic drug companies from getting access to the quantity of Daraprim they needed to conduct testing demanded by the Food and Drug Administration (“FDA”). Through exclusive supply agreements, Shkreli also blocked off access to the two most important manufacturers of the active pharmaceutical ingredient (“API”) for Daraprim. Through these strategies, Shkreli delayed the entry of generic competition for at least eighteen months. Shkreli and his companies profited over $64 million from this scheme.

The Federal Trade Commission (“FTC”) and seven States (the “States”; collectively, “Plaintiffs”) filed this action in 2020. At a bench trial held over seven days between December 14 and 22, 2021, the Plaintiffs carried their burden to establish that Shkreli violated federal and state laws that ban anticompetitive conduct. Based on the trial evidence, Shkreli will be barred for life from participating in the pharmaceutical industry and is ordered to disgorge $64.6 million in net profits from his wrongdoing. This Opinion contains the Findings of Fact and Conclusions of Law from the trial.

Procedural History

*2 The Plaintiffs filed this action on January 27, 2020 and brought claims for violations of §§ 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1-2, § 5(a) of the FTC Act, 15 U.S.C. § 45(a), and various state statutes. They brought these claims against
Shkreli, Vyera Pharmaceuticals, LLC and its parent company Phoenixus AG ("Phoenixus"; together, "Vyera"), and Kevin Mulleady ("Mulleady"), former Vyera CEO and member of the Phoenixus Board of Directors (collectively, "Defendants"). The Defendants’ motion to dismiss was largely denied through an Opinion of August 18, 2020. \(^3\) See *Fed. Trade Comm'n v. Vyera Pharms., LLC*, 479 F. Supp. 3d 31 (S.D.N.Y. 2020).


Only Shkreli proceeded to trial; on the eve of trial Vyera and Mulleady settled with both the FTC and the States. Before those settlements were reached, the parties’ submitted their Joint Pretrial Order, proposed findings of fact and conclusions of law, motions in limine, and pretrial memoranda on October 20. Following rulings on redactions, these submissions were filed on November 29.

As is customary for this Court's non-jury proceedings, and with consent of the parties, the direct testimony of those witnesses under a party's control were submitted with the Joint Pretrial Order. \(^5\) The parties also served copies of all exhibits and deposition testimony that they intended to offer as evidence in chief at trial. \(^6\)

*3 Prior to trial, the motions in limine were decided. On November 5, Shkreli's motion in limine to preclude evidence relating to Retrophin, Inc. ("Retrophin"), a pharmaceutical company that Shkreli and Mulleady founded in 2011, was denied. Id., 2021 WL 5154119 (S.D.N.Y. Nov. 5, 2021). On November 10, motions by Shkreli and Mulleady to exclude the testimony of current and former employees of Vyera were addressed in an Opinion that set forth the standards that would govern the admissibility of such testimony. Id., 2021 WL 5236333 (S.D.N.Y. Nov. 10, 2021). An Opinion of November 12 denied the Defendants’ motion to exclude certain testimony of Plaintiffs’ expert Professor C. Scott Hemphill ("Hemphill"), an economist and Professor of Law at New York University, and granted the Plaintiffs’ motion to exclude certain opinions offered by Dr. Anupam B. Jena ("Dr. Jena"), a physician, economist, Professor of Health Care Policy and Medicine at Harvard Medical School, and Internal Medicine Specialist in the Department of Medicine at Massachusetts General Hospital. Id., 2021 WL 5279465 (S.D.N.Y. Nov. 12, 2021). Opinions of November 15 granted the Plaintiffs’ motion to exclude designated deposition testimony of Rule 30(b)(6), Fed. R. Civ. P., deponents that were not based on personal knowledge, id., 2021 WL 5300019 (S.D.N.Y. Nov. 15, 2021), and excluded testimony from Defendants’ expert Justin McLean, id., 2021 WL 5300031 (S.D.N.Y. Nov. 15, 2021). An Opinion of November 16 struck most of the testimony offered by Defendants’ expert Sheldon Bradshaw. Id., 2021 WL 5336949 (S.D.N.Y. Nov. 16, 2021). *7 On November 18, the Plaintiffs’ motion to exclude portions of testimony by Defendants’ expert John S. Russell ("Russell"), Managing Partner for ASDO Consulting Group, a pharmaceutical consulting company, was largely granted. Id., 2021 WL 5403749 (S.D.N.Y. Nov. 18, 2021).

At trial, eleven fact witnesses and four expert witnesses called by the Plaintiffs testified. The Plaintiffs’ fact witnesses included one current Vyera executive -- Nicholas Pelliccione ("Pelliccione"), Vyera's Senior Vice President of Research and Development ("R&D") -- and four former executives and employees: Howard Dorfman, Vyera's General Counsel between December 2014 and August 2015; Christina Ghorban, Vyera's Head of Marketing and Business Analytics between April 2015 and October 2016; Dr. Eliseo Salinas ("Dr. Salinas"), Vyera's President of R&D between June 2015 and April 2017 and interim CEO between April and July 2017; and Mulleady, who worked at Vyera from October 2014 to June 2016, was appointed to Vyera's Board in June 2017, served as Executive Director and then CEO between October 2017 and February 2019, and was chairman of the Phoenixus
Hong, Kenneth 7/11/2022
For Educational Use Only


2022-1 Trade Cases P 81,945

Board of Directors until December 2020. The Plaintiffs called six additional fact witnesses: Frank DellaFera (“DellaFera”), CEO and founder of Fera Pharmaceuticals, Inc. (“Fera”); Susan McDougal (“McDougal”), Fera's Vice President; Abhishek Mukhopadhyay (“Mukhopadhyay”), Head of Business Development at Dr. Reddy's Laboratories, Inc. (“Dr. Reddy's”); Nilesh Patel (“Patel”), co-founder and Compliance and Regulatory Officer of InvaTech Pharmaceuticals LLC (“InvaTech”); Manish Shah (“Shah”), co-founder and President of Cerovene Health, Inc. (“Cerovene”); and Satya Valiveti (“Valiveti”), co-founder and co-owner of Reliant Specialty LLC (“Reliant”).

The Plaintiffs’ expert witnesses were James R. Bruno, managing director of Chemical and Pharmaceuticals Solutions, Inc., a pharmaceutical consulting company; Edward V. Conroy, President and Chief Operating Officer of Ed Conroy & Associates, a pharmaceutical consulting firm; Dr. W. David Hardy, a physician and Adjunct Clinical Professor of Medicine in the Division of Infectious Diseases at the Keck School of Medicine at the University of Southern California and former Chair of the Board of Directors of the HIV Medicine Association (“HIVMA”) of the Infectious Diseases Society of America (“IDSA”); and Hemphill.

The Plaintiffs also intended to call at trial three additional fact witnesses to testify: Shkreli; Eve Costopoulos (“Costopoulos”), Vyera's former General Counsel from November 2015 to July 2017; and Anne Kirby (“Kirby”), a member of Vyera's sales team from June 2015 to late 2018, CEO from late 2018 to early 2019, and current Executive Vice President of Commercial and Operations. Shkreli is incarcerated in federal prison, serving a sentence on an unrelated federal conviction. He opted not to attend the trial. The parties agreed that the affidavit that he had prepared to present as his direct testimony would be received at the trial and that his cross-examination and redirect examination would be conducted through the designation of his pretrial deposition testimony.

Neither Kirby nor Costopoulos appeared at trial. The parties agreed that Kirby's affidavit would be received as her direct testimony and that cross-examination and redirect would be conducted by deposition designation. The parties also agreed to designate portions of Costopoulos’ deposition to serve as her trial testimony.

At the time the Pretrial Order was submitted, Shkreli intended to call eleven of the Plaintiffs’ witnesses in his own case in addition to testifying on his own behalf: Mulleady, Pelliccione, Kirby, Costopoulos, Dr. Salinas, DellaFera, McDougal, Mukhopadhyay, Patel, Shah, and Valivet. Affidavits constituting the direct testimony of defense witnesses Shkreli, Mulleady, Pelliccione, and Kirby were received into evidence. Shkreli also called two expert witnesses: Russell and Dr. Jena.

The parties offered excerpts from the depositions of the following additional witnesses associated with Vyera: Jonathan Haas, Vyera's Former Director of Patient Access; Christopher Lau (“Lau”), Vyera's Director of Analytics and Business Intelligence; Akeel Mithani (“Mithani”), Senior Vice President of Business Development of Vyera and former member of the Phoenixus Board of Directors; Averill Powers, CEO and former Chairman of the Phoenixus Board, and Vyera's General Counsel; Marco Polizzi, CEO of Vyera subsidiary Oakrum Pharma, LLC; Nancy Retzlaff (“Retzlaff”), Vyera's former Chief Commercial Officer; Michael Smith (“Smith”), co-founder of Vyera and former member of the Business Development team; and Ron Tilles (“Tilles”), Vyera's former CEO and Chairman of the Phoenixus Board. They also offered excerpts from the depositions of seventeen additional fact witnesses: Nilaben Desai, former manager at ASD Healthcare (“ASD”); Michael Hatch, Head of Global Project Management for R&D for Mylan N.V. (“Mylan”) affiliate Viaftris Inc.; Courtney Johnson, former Director of Global Sourcing & Business Development for Cardinal Specialty (“Cardinal”); Hamilton Lenox, Senior Vice President of Business Development at LGM Pharma; Amanda Lopez, Clinical Trial Supervisor for Durbin USA; Jacob Mathew, Chairman of RL Fine Chem. Pvt. Ltd. (“RL Fine”); Ravi Patel, part-owner of Espee Biopharma & Fine Chem; Donovan Quill, founder and CEO of Optime Care, Inc. (“Optime”); Paula Raese, Senior Director of API Sourcing for Mylan; A.R. Ramachandra, General Manager of Marketing and Sales at RL Fine; Dennis Saadeh, Chief of Formulation Strategy for Harrow Health, parent company of Imprimis; Dr. Lucas Schulz, Clinical Coordinator for Infectious Diseases in the Department of Pharmacy at the University of Wisconsin Health;
As noted, the bench trial was held from December 14 to December 22, 2021, and this Opinion presents the Court's findings of fact and conclusions of law. The findings of fact appear principally in the Background section, but also appear in the remaining sections of the Opinion.

Background

I. FDA Drug Approval Process for Generic Drugs

Shkreli's scheme unfolded against the backdrop of the U.S. regulatory process for the approval and sale of pharmaceutical drugs. The FDA is the federal agency that approves the sale of branded and generic drugs in the United States. The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, commonly known as the Hatch–Waxman Act, allows a generic manufacturer of an already approved brand-name drug to obtain expedited approval from the FDA to market the generic equivalent by filing an Abbreviated New Drug Application, or ANDA. See FTC v. Actavis, Inc., 570 U.S. 136, 142, 133 S.Ct. 2223, 186 L.Ed.2d 343 (2013) (“Actavis”). The ANDA process is designed to help expedite market introduction of low-cost generic drugs in order to further competition. Id.

Any pharmaceutical company applying for FDA approval of a generic competitor to a branded drug must obtain the API used in the branded drug -- that is, the drug's critical ingredient that provides its therapeutic effect -- from an approved supplier. The API to be used in the generic drug is evaluated for impurities and stability. 21 C.F.R. §§ 211.165, 211.170.

An API supplier's manufacturing process must also comply with FDA standards known as current Good Manufacturing Practices (“cGMPs”). FDA regulations set minimum standards for the methods, facilities, controls, and documentation for manufacturing, processing, and packing of the pharmaceutical, including its API.

A pharmaceutical company may demonstrate that the manufacturing process of the API used in its drug product complies with cGMPs either by supplying that information to the FDA in the ANDA itself or, more commonly, by referencing information filed by an API supplier with the FDA in a standalone drug master file (“DMF”). The FDA categorizes DMFs for APIs as Type II DMFs. To file a Type II DMF, an API supplier must pay a fee and submit enough materials, including confidential documents about the manufacturer's facilities, processing, packaging, and storing of human drug products, to permit the FDA to conduct a full scientific review for any ANDAs that reference the DMF. The FDA conducts a completeness assessment of an API supplier's newly-filed DMF at the time it is submitted, but does not fully review a DMF's documented manufacturing process for cGMPs compliance until the DMF is referenced in a new drug application (“NDA”) or ANDA. 21 CFR § 314.420(a).

In order to obtain the API for a particular drug product a pharmaceutical company may invest in developing an API supplier's manufacturing processes, or it may shorten the process significantly by partnering with an API supplier that has already filed a DMF for the API. Because developing and documenting a cGMPs-compliant API manufacturing process from scratch is time-consuming and expensive -- it can take twelve to eighteen months or more and may cost over $1 million -- generic pharmaceutical companies prefer to use a supplier that already has an FDA-approved DMF for the API.

*6 Therefore, any generic company that seeks to launch a product as fast as possible generally attempts to partner with a DMF-holding supplier whose API is already in use in another FDA-approved product. A less desirable option is partnering with an
API manufacturer that currently produces the API but does not have a DMF filed in the U.S. The least attractive option is to develop a cGMPs-compliant manufacturing process from scratch, which is costly and can take years.

Proof of therapeutic equivalency is also central to the ANDA process. A generic manufacturer applying for approval of its drug must demonstrate that the generic drug “has the same active ingredients as, and is biologically equivalent to, the already-approved brand-name drug.” Actavis, 570 U.S. at 142, 133 S.Ct. 2223 (citation omitted); see also 21 C.F.R. §§ 314.92(a)(1), 314.3(b).

Bioequivalence (“BE”) testing compares the generic product to samples of the branded drug, commonly referred to as the reference listed drug (“RLD”). BE studies are used to evaluate whether there is any significant difference in the rate and extent to which the product's active ingredient becomes available in the body. \(^{12}\) 21 C.F.R. § 320.33. BE testing demonstrates to the FDA that the proposed generic drug product is safe, effective, and comparable to the RLD.

In a BE study, human subjects are given dosages of the generic drug and the RLD. These studies, which take two to six weeks to complete, are typically run by a third-party clinical organization concurrently with the FDA-required shelf stability testing for the first batch of the finished generic product. The stability testing can take three to six months.

In order to conduct BE testing, a generic drug applicant must procure sufficient quantities of the brand-name drug or RLD and retain those quantities before and after approval of an ANDA. FDA regulations require applicants to retain at least five times the amount of the RLD needed to perform BE testing. 21 C.F.R. § 320.38(c).

The RLD used in the testing must come from the same manufacturing lot and be unexpired. Obtaining sufficient quantities of RLD usually takes only a few days or, at most, a month.

Consistent with its policy of encouraging price competition for prescription pharmaceuticals, the FDA expresses the view that “a path to securing samples of brand drugs for the purpose of generic drug development should always be available.” \(^{13}\) By utilizing an RLD license permitting them to buy prescription drugs without a prescription, pharmaceutical companies often procure the RLD samples needed to develop generic drug products through drug wholesalers or specialty pharmacies.

If the FDA determines that a proposed generic drug is therapeutically equivalent to the brand-name drug listed in the FDA's “Orange Book,” \(^{14}\) the agency assigns an “AB” rating to that drug. But if the FDA finds major deficiencies in an ANDA and the applicant does not address its inquiries during the review period, the FDA sends the applicant a complete response letter detailing the identified deficiencies.

*7 To foster price competition among pharmaceuticals, the law provides various incentives to pharmaceutical companies. See Generic Drug User Fee Act, 21 U.S.C. § 356h. These include the FDA's prioritization of its review of the first generic entrant to file an ANDA. The first generic drug product to enter a market in competition against the brand name drug is known in the pharmaceutical industry as the “first-to-market” generic.

As generic drugs typically enter a market at a discount, the entry of the first generic competitor generally results in price erosion of approximately 30% to 40% from the prevailing price of the brand-name drug. The brand name drug's sales volume also experiences a significant decline of approximately 60% to 70% when the first generic enters the market. Six months after generic entry, the brand name drug's sales will typically have fallen by 80%. The branded drug's sales volume and price usually continue to decline as additional generic products enter the market. The full decline in the price of the drug usually occurs after three or four generic drugs have entered the market.
A. Distribution of Prescription Drugs in the U.S.
When introducing a branded drug or its generic equivalent into the U.S. market, the manufacturer can choose to distribute it with fewer or more restrictions. The poles of this spectrum are referred to in the pharmaceutical industry as open distribution, representing the least restrictive means, and specialty distribution, which can range from minor limitations to severe restrictions on how freely a drug is sold. Restrictions are set by the manufacturer in agreements with its distribution partners.

Seventy percent of prescription drugs sold in the U.S. is in open distribution. In an open system, the manufacturer typically partners with a major distributor to deliver the product to licensed dispensaries such as retail pharmacies, hospitals, clinics, and nursing homes. Open distribution maximizes patient access to a given drug and is generally appropriate for pharmaceutical products that do not require special handling, do not present safety concerns, and are self-administered by the patient or are clinically simple to administer.

By contrast, approximately 30% of the volume of U.S. prescription drugs is sold through some degree of specialty distribution. Also known as closed distribution, a drug that is circulated in a specialty distribution system is referred to in the pharmaceutical industry as being “in specialty” or as having a “class of trade” restriction. Drugs in specialty distribution tend to be novel drugs, have special shipping, handling, and storage requirements (such as cold-chain storage), or require ongoing clinical monitoring or skilled patient administration (such as injections). Highly closed distribution systems usually lower patient access and reduce sales.

Safety concerns may also mark a particular drug as a prime candidate for specialty distribution. Specialty distribution is more frequent, for instance, when the FDA requires a “black box” warning on the label of drugs that present safety risks or when it has put the drug in a Risk Evaluation and Mitigation Strategies (“REMS”) program. REMS is a drug safety program that the FDA may require for certain medications that present serious safety risks.

The percentage of prescription drugs on the U.S. market that are sold in specialty distribution has risen in recent years. This trend, however, is largely driven by the advent of new, complex therapies for illnesses such as cystic fibrosis and cancer. Drug manufacturers do not commonly put oral tablets that do not require complex patient administration in specialty distribution, as closed distribution reduces sales.

II. Retrophin
*8 Shkreli road-tested the scheme at issue here at another company that he founded, Retrophin. Shkreli is thirty-eight years old. He graduated from Baruch College in 2004 with a degree in Business Administration. After graduation, he worked as a healthcare and technology analyst for a hedge fund until he left in 2006 to found his own investment firm. In 2009, Shkreli founded the hedge fund MSMB Capital Management (“MSMB”).

While still working at MSMB, in 2011 Shkreli co-founded Retrophin, a publicly-traded biopharmaceutical company, with Mulleady. Mulleady is now thirty-nine years old. He graduated from Rutgers University in 2005, having majored in mechanical and aerospace engineering. He worked in real estate and finance following graduation. While working at Morgan Stanley Smith Barney (now Morgan Stanley Wealth), he met Shkreli in 2011. Shkreli hired Mulleady as Chief Operating Officer at MSMB, where Mulleady worked from 2011 to 2013.

Shkreli served as Retrophin's CEO from December 2012 to September 2014, and designed its business model. Retrophin acquired brand-name drugs approved to treat so-called orphan diseases 15 that were the sole source in the U.S. for that treatment, closed the drugs’ distribution to prevent generic drug manufacturers from acquiring the RLD, and substantially increased the drugs’ prices. This was a pattern that Shkreli would repeat at Vyera.
At Retrophin, Shkreli closed the distribution systems of two branded drugs, Chenodal and Thiola, to cut off access to the RLD needed for BE testing and impede generic drug competition. Shkreli described his strategy and its purpose frankly in calls with Retrophin investors. On one such call, he explained that “we do not sell Retrophin products to generic companies” and “[t]he whole model that generics rely upon is turned upside down with specialty pharmacy distribution.” He explained in another call that a closed distribution system did not allow generic drug companies to access the branded product “to conduct bioequivalence studies.” Shkreli boasted in an email to a potential investor that the specialty distribution method Retrophin had adopted “reliably eliminated” generic competition “by refusing to supply the product to generic companies for [BE] studies required for ANDAs.”

As noted, Shkreli put his strategy into practice with two drugs. Retrophin acquired Chenodal, a drug approved for the treatment of cerebrotendinous xanthomatosis (“CTX”), and restricted distribution through distributor agreements. Retrophin then raised Chenodal’s price from $100,000 to $515,000 per patient per year. Retrophin also licensed Thiola, a drug approved for the prevention of cystine stone formation in patients with cystinuria, restricted its distribution, and raised its price from $4,000 to $80,000 per patient per year.

III. Vyera is Founded.

Only one month after departing Retrophin, in October 2014 Shkreli founded Turing Pharmaceuticals LLC (“Turing”), a privately-held pharmaceutical company with its principal place of business in New York. Shkreli also founded Turing Pharmaceuticals AG (“Turing AG”), Turing's parent company, based in Switzerland. Turing's name was later changed to Vyera, and Turing AG became Phoenixus.

*9 From day one, Shkreli focused his new venture on acquiring sole-source drugs that were the gold standard treatment option for life-threatening diseases with a small patient population and inferior alternative treatments, with the intent to raise their prices, block generic competition, and reap extraordinary profits. Shkreli highlighted to early Turing investors his “track record of successful transactions” at Retrophin and explained that “[e]xclusivity (closed distribution) creates a barrier and pricing power.”

Shkreli remained CEO of Turing until his arrest on December 18, 2015 for securities fraud related to his prior business ventures, including at Retrophin. He served as chairman of the Board of Turing AG until January 20, 2016, resigning from the Board entirely on February 10, 2016. After Shkreli departed, Turing was renamed Vyera and Turing AG was renamed Phoenixus in order to distance the companies from Shkreli in the public mind. Shkreli remained the largest shareholder, however, and continued to control them and direct their strategy. At no time after Shkreli left the Board did Vyera deviate from the strategy Shkreli had designed and initiated.

Shkreli brought with him to Vyera several Retrophin executives, including Mulleady, Tilles, Smith, Lau, Edwin Urrutia (a Vyera co-founder and Chief Financial Officer between October 2014 and June 2016), and Patrick Crutcher (a Vyera co-founder and Senior Vice President and Head of Business Development between October 2014 and May 2017). Mulleady in particular was one of Shkreli’s closest allies at Vyera before earning Shkreli’s ire in 2020. Mulleady held the title of Phoenixus’ Managing Director from October 27, 2014 until Vyera terminated his employment on June 3, 2016. Mulleady returned to Vyera a year later when, on June 21, 2017, he was elected to Phoenixus’ Board of Directors in a Shkreli power play.

A. Vyera Acquires Daraprim.

At Shkreli’s direction, Vyera's sales and business development teams evaluated market opportunities for Vyera to acquire sole-source drugs. By the Spring of 2015, Vyera focused on Daraprim as a prime candidate. Smith, Vyera's Senior Director of Business Development, instructed the sales team in April 2015 to investigate acquiring both Daraprim and another sole-source
drug, sulfadiazine (often used in combination with Daraprim), because it would be “the classic closed distribution play.” Smith testified that Daraprim provided an opportunity to build a foothold “where no one is paying attention to it.” Daraprim was first approved by the FDA in 1953, and approved by the FDA in 1958 for the treatment of toxoplasmosis specifically.

Toxoplasmosis is a parasitic infection that can cause severe disease and death. The parasite is present in approximately 10% of the population, but is usually dormant. An opportunistic infection, toxoplasmosis principally impacts immunosuppressed and immunocompromised individuals such as patients who are HIV positive or recipients of organ transplants. Toxoplasmosis can cause disease in many parts of the body, but the most common manifestations are infections of the brain (toxoplasma encephalitis), eye (ocular toxoplasmosis), and in utero.

Toxoplasma encephalitis is the most common and acute presentation of the disease among immunosuppressed patients. Toxoplasmosis fatalities have dropped significantly since the launch of antiretroviral therapies in 1996, which significantly limited opportunities for a toxoplasmosis infection to become acute in HIV-positive patients. If an infection becomes active and advanced, a patient presenting with toxoplasma encephalitis could die within twelve to twenty-four hours unless treated. There is also a risk of severe brain damage in those who survive. As a result, physicians must have an effective treatment on hand to halt the progress of an active infection as quickly as possible.

*10 The Opportunistic Infections Guidelines (the “Guidelines”), an authoritative publication on which physicians depend, gives its highest recommendation to a pyrimethamine-based regimen for the treatment of acute toxoplasmosis. Pyrimethamine is the API of Daraprim.

The Guidelines rank recommended treatment options for certain diseases with a letter and a numeral. The letter grade signifies the strength of the recommendation and the Roman numerals indicate the quality of the evidence supporting the recommendation. Accordingly, an A-I grade is a recommendation based on the strongest, highest-quality evidence derived from randomized control clinical trials, or, if randomized control trials have not been conducted, methodologically sound cohort studies or meta-analyses. Lower grades are given to treatment options that have been shown to be effective but are not preferred, or are based on less methodologically reliable studies.

Under the Guidelines, pyrimethamine plus sulfadiazine and leucovorin is given the strongest possible recommendation for treating active toxoplasma encephalitis: A-I. The recommended dosage of Daraprim, available only as a 25 milligram tablet, is an initial dose of 200 milligrams (eight pills) followed by 50 to 75 milligrams (two to three pills) daily for at least six weeks. For patients who cannot tolerate a sulfa drug, the recommended treatment is pyrimethamine plus clindamycin.

The pyrimethamine-based regimen is preferred to alternative treatments because of its efficacy and safety, long history of successful clinical use, superior potency in comparison to other treatments, and diagnostic utility when a biopsy is not feasible. A significant decrease in the size, inflation, or number of lesions in the brain following a week or more of treatment confirms the diagnosis. Because a biopsy of the brain carries extreme risks, pyrimethamine's diagnostic utility is particularly important. Pyrimethamine remains the only drug approved by the FDA for the treatment of toxoplasmosis. And, until the entry of FDA-approved generic pyrimethamine in 2020, Daraprim was the only FDA-approved pyrimethamine product on the market.

Before Vyera acquired Daraprim, it commissioned a physician survey to determine whether doctors “would continue to prescribe Daraprim” following a price hike. In response to the survey, doctors indicated that they considered the drug to be the “backbone of therapy” for toxoplasmosis and were “at a loss to think of an appropriate alternative.” Shkreli and others at Vyera recognized Daraprim as “the gold standard” therapy for toxoplasmosis, rendering Daraprim “essentially unsubstitutable.”
In April 2015, Vyera made Impax Laboratories, Inc. (“Impax”), then the owner of the U.S. licensing rights to Daraprim, an unsolicited offer of $60 million. This offer represented a considerable premium over Daraprim’s market value. Annual net sales of Daraprim constituted roughly $4 million at the time, and Impax assessed its net present value as $19 million. In a transaction that closed on August 7, 2015, Vyera paid Impax $55 million, more than eleven times Daraprim’s 2014 net revenues.

B. Daraprim's 2015 Price Hike and Vyera's Revenues

Until 2010, Daraprim had been owned by GlaxoSmithKline (“GSK”), a global pharmaceutical company based in the United Kingdom. Between 2011 and 2015, the new owners of Daraprim had raised the list price -- also called the wholesale acquisition cost (“WAC”) -- of a tablet from $6.74 to $17.60. These price increases ranged from 15% to 30% at a time. Within days of Vyera's purchase of Daraprim and at Shkreli's direction, Vyera raised the WAC from $17.60 to $750 per tablet effective August 11, 2015. From roughly 2016 to 2019, the average net price of Daraprim (the price per tablet after subtracting discounts, chargebacks, and rebates off the WAC) ranged between $228 and $305 per tablet. Dr. Salinas testified that the price hike was the “poster child of everything that is considered wrong about the pharmaceutical industry.”

Comparing the nine-month period preceding and following Vyera's price hike, Daraprim's sales volume dropped by 66%. In September 2015, sales data from IQVIA (formerly IMS Health), a commercial data aggregator commonly used for market research in the pharmaceutical industry, indicated that the market size for Daraprim was around one million tablets annually. After that steep decline, the sales volume stabilized at roughly 200,000 to 250,000 tablets per year between 2016 and 2019. These sales remained steady until the first generic pyrimethamine product entered the market in March 2020.

From 2016 through 2019, Vyera made between $55 and $74 million in annual gross profits from its sales of Daraprim. Daraprim revenues in the years between 2010 to 2014 had amounted at most to $10 million a year. Vyera's estimated gross profit margin from Daraprim, calculated by subtracting Vyera's reported production costs, ranged between 89% and 98% in 2016 through 2019. The Figure below illustrates net revenue and gross profit for Daraprim sales between 2010 and 2020.
IV. Vyera's Implementation of a Closed Distribution System for Daraprim

Even before finalizing its acquisition of the rights to the drug, Shkreli made it a priority to close the Daraprim distribution channels. In June 2015, Shkreli directed Retzlaff, who ran Vyera's sales team, to move Daraprim from retail distribution into a closed distribution system “as swiftly as possible.” As the interim project manager in charge of the initiative, Mulleady ensured that Shkreli's wishes for Daraprim's closed distribution system were implemented.

Shkreli recognized that generic entry into the pyrimethamine market was inevitable, but Shkreli hoped to delay that entry for at least three years. In July 2015, Shkreli remarked to an investor that he felt “very good that there are no incoming generics and now that it is closed distribution there will not be any going forward ... even if we get 3 years, it is a great payout.”

Daraprim had been in open distribution from its introduction into the market in the 1950s until 2015. After he had initiated his own plans to move Daraprim into specialty distribution, Shkreli learned that a prior owner of Daraprim had already begun to do so. By the time Vyera acquired Daraprim, Daraprim was distributed through two wholesale distributors and specialty pharmacies, AmerisourceBergen Corporation (“ABC”) and Walgreens Specialty Pharmacy (“Walgreens”). Vyera continued the terms of the assigned contract with Walgreens and slowly expanded the number of distribution partners for Daraprim to five distributors and specialty pharmacies. They were ASD (a subsidiary of ABC), BioRidge Pharma LLC (“BioRidge”), Cardinal, Optime, and Walgreens (together, the “Distributors”). Despite expanding the number of distribution partners, however, Vyera imposed class of trade restrictions in its distribution contracts, limiting the types of customers who could buy Daraprim. The end result was that no Distributor could sell Daraprim to a retail pharmacy or a generic drug company without Vyera's approval.
Vyera's distribution restrictions on Daraprim were not justified by a need to protect either patient health or Vyera from lawsuits asserting that a patient had experienced an adverse drug reaction. As noted above, Daraprim had been sold through open distribution for decades. It was considered a safe drug; the FDA never put Daraprim in a REMS program or required a black box warning on the label. Daraprim is an oral tablet that does not require special shipping, handling, storage, or administration. When the first generic pyrimethamine product was launched in March 2020, it was sold through an open distribution system.

A. Class of Trade Restrictions
Between 2015 and 2020, Vyera's Distributors were restricted to selling only to authorized customers that included government customers, hospitals, specialty pharmacies, and other specialized entities. The authorized customers or types of customers approved to buy Daraprim did not include generic drug companies or their agents. No Distributor was permitted to sell Daraprim to a generic drug manufacturer or their agent without Vyera's express approval. There is no evidence that Vyera ever gave such approval.

Vyera's contract with ASD, executed on September 2015, provides an example of the class of trade restrictions. It simply stated that the “Distributor may only sell Daraprim to Government Customers and hospitals.” In 2016, Vyera expanded ASD's authorized customer list to include “certain state AIDS Drug Assistance Programs (ADAPs), subject to the Company's prior written approval.” An amendment in 2018 revised the authorized customer clause as follows:

Distributor may only sell Daraprim to licensed wholesalers and specialty pharmacies that support certain state [ADAPs], subject to the Company's prior written approval, Government Customers, hospitals, and 'covered entities', as defined by Section 340B of the Public Health Services Act (“340B Customers”). [Vyera] will approve any new authorized customers via email and will maintain and update a monthly authorized customer file.

Effective February 25, 2020 -- just as the first generic competitor to Daraprim was about to receive FDA approval -- the authorized customer list was expanded to permit sales to “340B contract pharmacies, any customers on the approval list provided by Company, and any new customers approved by Company in writing (with email being sufficient).”

Vyera also had contracts with roughly a hundred hospitals to supply them with Daraprim directly at a discounted price so long as they agreed to limit their use of it to their “own use” and not to resell Daraprim. For example, Vyera's agreement with one distinguished medical system provided that “[p]rices available under this Term Sheet shall only apply with respect to product purchased by Hospital for its ‘own use’ as that term is described in Abbott Laboratories Inc. v. Portland Retail Druggists, 425 U.S. 1, 96 S.Ct. 1305, 47 L.Ed.2d 537 (1976), [without regard to whether Company is a non-profit entity described in section 501 of the Internal Revenue Code].”

B. Bottle Limits
Vyera also controlled the distribution of Daraprim by imposing limits on the number of Daraprim bottles that a single customer could purchase at a time. For example, in December 2015, ASD agreed to cap orders from § 340B program participants to five bottles “per week per order,” with any exceptions for larger orders requiring approval from Vyera. Vyera's Director of Patient Access openly admitted that the quantity limits imposed in 2015 were introduced to make it harder for generic drug companies
to acquire “large quantities” of Daraprim “in order to copy the drug and compete with it.” He was quoted in a news article published on October 5, 2015, stating that if a generic drug maker tried to order Daraprim,

Most likely I would block that purchase.... We spent a lot of money for this drug. We would like to do our best to avoid generic competition. It's inevitable. They seem to figure out a way [to make generics], no matter what. But I'm certainly not going to make it easier for them.

Vyera added similar restrictions to its contracts with other Distributors. For example, under its 2018 contract with Optime, “[a]ll orders greater than 3 bottles require[d] Vyera approval.”

As the entry of generic competition became more imminent, Shkreli urged that the limits on the sale of Daraprim bottles be further tightened. On August 8, 2019, while incarcerated following his conviction for securities fraud, Shkreli was recorded asking Mithani about the likelihood that a doctor could order more than one bottle of Daraprim at a time. When Mithani responded that it is “very likely”, Shkreli responded that “that's what I've been stressing to you guys for the last three years, to look at that very carefully, you know, meet those doctors.” Shkreli went on to say “there has to be some way to tighten the supply chain a bit ... I just want to make sure you guys are doing everything you can.” When Mithani told Shkreli that Vyera “can't say no” to hospitals, Shkreli responded, “Okay. Well, that's a shame.”

Just days before, upon learning of the efforts made by the generic pharmaceutical company Fera to purchase Daraprim RLD, Shkreli had urged Vyera to limit all sales of Daraprim to one bottle at a time. Shkreli told Mulleady that

the company should, you know, just make sure it really doesn't sell more than one bottle at a time, you know. That would be -- the number one thing I would do and just really screen every doctor that, you know -- even if it drops sales a little bit, it's a good -- you know, really make sure he's [referring to Fera's owner] not getting his hands on anything.

C. Surveillance

Vyera monitored its Distributors’ daily and weekly sales reports to prevent the diversion of Daraprim to generic drug companies for BE testing. It promptly followed up on any sales it considered unusual to stop any leakage.

The monitoring began as soon as Vyera acquired Daraprim. For example, on August 13, 2015 -- just two days after the Daraprim price hike -- Vyera saw a sales report from ICS reflecting a sale of 40 bottles to a customer. Vyera asked ICS to cap the maximum number of bottles sold to any one customer, explaining Vyera's

concern that a generic company could access multiple bottles of our product, perhaps attained through a hospital reselling it or distributing product to surrounding retail pharmacies, and use it to create a generic version.
In response, ICS agreed to limit sales to five bottles at a time. Shkreli was informed of the “[n]eed to investigate the 40 unit buy.”

Vyera repeatedly instructed its Distributors to refrain from selling Daraprim to potential competitors for clinical trials. For example, in February 2017, a company that obtains RLD for generic pharmaceutical companies ordered a 30-count bottle of Daraprim from ASD. ASD advised Vyera that it had denied the request due to “the conversation around generics.” Later in 2017, Vyera directed ASD to rebuff another company that reached out to ASD to buy Daraprim for use in a clinical trial.

The speed and effectiveness of Vyera's surveillance system is dramatically illustrated by its interception of five bottles of Daraprim intended for a generic drug distributor -- Dr. Reddy's -- in April 2018. On April 5, ASD delivered the five bottles to a pharmacy pursuant to an order placed on April 4. Vyera's surveillance system flagged the purchase on April 5, investigated the purchaser, learned the bottles were destined for a company that supplies RLD for bioequivalence and clinical trials, and by April 6, Mulleady met with the company's owner in a parking lot to repurchase the bottles for $750,000. This was twice the price the pharmacy had paid for the bottles.

Vyera's frantic interception of this purchase prompted it to lock down Daraprim distribution even more strictly. Vyera instructed ASD to block that pharmacy's access to any Daraprim. It then dramatically shrank the number of customers to which ASD and Cardinal were permitted to sell Daraprim without specific prior authorization from Vyera. For ASD, this resulted in a reduction of approved customers from approximately 13,000 to roughly 555. Vyera similarly cut Cardinal's list of approved accounts from about 14,700 to fewer than 1,500. Vyera also reduced the number of bottles that ASD could sell to any one of the pre-approved customers, reducing the number to four bottles unless the customer was a § 340B customer.

D. Benefits to Distributors

The Distributors benefitted financially from their contracts with Vyera despite the restrictions on their sales of Daraprim. This was true for as long as Daraprim was sold at a high price. Vyera compensated the Distributors with either a fixed fee (Optime) or a percentage of WAC based on volume sold (ASD, Cardinal, BioRidge, and Walgreens). ASD, for example, received $2,062.50 for each 100-count bottle of Daraprim it sold. By contrast, when Dr. Reddy's launched its generic pyrimethamine product in March 2020, it offered ASD's parent company a price of only $877.50 per bottle.

V. Vyera's Restriction of Access to the API Pyrimethamine

Besides blocking access to the Daraprim that generic drug manufacturers needed to conduct BE testing, Shkreli also worked to block their access to pyrimethamine, the API in Daraprim. He was well aware that the sooner a generic company could find an established API manufacturer the sooner it could launch a generic version of Daraprim. Vyera locked up the supply of pyrimethamine to U.S.-based generic drug companies through exclusive supply agreements with the two most attractive pyrimethamine suppliers: Japan's Fukuzyu Pharmaceutical Company (“Fukuzyu”) and India's RL Fine.

A. Fukuzyu

Fukuzyu, an established and prominent Japanese chemical manufacturer, was the long-term supplier of pyrimethamine for Daraprim. Fukuzyu had been producing pyrimethamine since 1966, had held a DMF for pyrimethamine since 1992, and is the manufacturer referenced in Daraprim's NDA. The only other manufacturer to have filed a pyrimethamine DMF, Ipca, had lost its right to sell pyrimethamine in the United States in 2015. 24

Fukuzyu typically requires a customer to provide an estimate of how much API it will require for a given period. Such clauses mitigate a purchaser's supply risk and help Fukuzyu manage its production schedule.
Fukuzyu's contract with GSK, for example, requires GSK to produce forecasts of how much API it will need for a defined period and requires Fukuzyu to deliver that amount. GSK holds the worldwide rights to Daraprim outside of North America. The contract states that GSK “[s]hall provide [Fukuzyu's] Agent with a rolling forecast schedule of demand showing their estimated requirements for PYRIMETHAMINE for the following twelve (12) months (‘Forecast Schedule’),” and “[t]he Product detailed in the first 3 months (‘Firm Order Period’) of each Forecast Schedule will represent firm orders for PYRIMETHAMINE” to which Fukuzyu must respond within five days. “[E]ach Firm Order will be regarded by the Parties as a binding irrevocable commitment” to purchase pyrimethamine from Fukuzyu, which in turn obligates Fukuzyu to manufacture enough API to meet the order. The GSK contract also requires Fukuzyu to ensure that it has “at all times sufficient manufacturing capacity to meet [GSK]’s ... requirements for PYRIMETHAMINE as shown in the Forecast Schedule.” GSK's contract with Fukuzyu does not include an exclusivity clause.

Impax, the company from which Vyera purchased Daraprim, had purchased pyrimethamine from Fukuzyu through a broker without even entering into a supply contract. Shkreli was immediately interested in reversing that practice. He wanted an exclusive supply agreement with Fukuzyu. With the help of a consultant, Vyera eventually succeeded by representing that it had several ambitious projects and hoped to use Fukuzyu as a long-term API supplier for each of those projects. In October 2016, three Vyera executives traveled to Japan to visit Fukuzyu. They were Pelliccione, then Vyera's Senior Vice President for Regulatory Affairs, Dr. Salinas, and Vyera's Head of Chemistry, Manufacturing, and Controls.

Vyera bluntly explained to Fukuzyu that it needed an exclusive supply contract to prevent generic Daraprim from entering the United States market. In November 2016, Dr. Salinas directed Vyera's consultant to inform Fukuzyu that “[i]f generic products are put on the U.S. market’ Vyera will face a “serious problem, and may eventually terminate the marketing of Daraprim as well as the R&D in toxoplasmosis”; that generic pyrimethamine “will hamper” Vyera's plans to develop new pharmaceutical products and “may leave toxoplasmosis as a forgotten disease with insufficient therapeutic effects”; and that Vyera's plans are “ONLY POSSIBLE” if Vyera has exclusive access to Fukuzyu's API. The consultant was also to stress that Fukuzyu would “not benefit” if generic companies sold pyrimethamine in the U.S. market since generic companies would sell pyrimethamine at a “significantly lower” price.

*16 By November 22, 2016, Fukuzyu had agreed not to sell pyrimethamine “to generic companies.” According to Vyera's consultant, Fukuzyu's CEO was particularly pleased that Vyera planned to “develop four more new compounds and would like [Fukuzyu] to work together” with it on those compounds. 25

On January 25, 2017, Phoenixus entered into a three-year exclusive supply agreement with Fukuzyu. The exclusivity term states that

[Fukuzyu] shall provide the API Bulk Drug Substance, pyrimethamine exclusively to [Phoenixus] for the use, sale, and/or distribution in the Territory. To be clear, the use, sale, and/or distribution of pyrimethamine described in this section refers to the use, sale, and/or distribution of the API Bulk Drug Substance for humans only. 26

The Territory was defined as the United States.
The Fukuzyu contract also provided that the minimum purchase quantity of pyrimethamine was 50 kilograms. Vyera, which contracts for the manufacture of pyrimethamine, needs 35 kilograms for a batch of Daraprim to be manufactured. Since executing the exclusive supply agreement, Vyera has twice purchased pyrimethamine from Fukuzyu.

The agreement with Fukuzyu does not ensure that Vyera will have a supply of pyrimethamine or require Fukuzyu to prioritize Vyera's orders over those from its other customers. It does not, for instance, require Vyera to forecast its API requirements or obligate Fukuzyu to reserve any quantity of pyrimethamine or manufacturing capacity to produce pyrimethamine. It does not even require Fukuzyu to fill a Vyera order.

Under the agreement, Vyera must submit a purchase order to Fukuzyu. If Fukuzyu does not acknowledge the order in writing within ten days, it has no obligation to fill the order. The agreement states that:

[Daraprim] is historically a low volume product for [Vyera]. Due to the infrequent need to manufacture [Daraprim], [Vyera] will provide [Fukuzyu] a Firm Order for API, in the form of a Purchase Order. Receipt of the Purchase Order denotes [Vyera]'s binding request to purchase API within 180 days of date of Purchase Order. [Fukuzyu] will accept Firm Orders by sending an acknowledgement to [Vyera] within 10 business days of its receipt of the Firm Order.

What Vyera obtained through its agreement with Fukuzyu was the right to bar other buyers, and Vyera strictly enforced that right. For example, in November 2017, Fukuzyu inquired whether it could sell pyrimethamine to a company that intended to resell it to a U.S.-based pharmaceutical company for a drug to be sold in South America. Vyera asked Fukuzyu to include in the sales agreement that the API sold to the US company “will not be used to make pyrimethamine drug product, for human use, that will find its way back to the US for commercial purposes,” and “that the API will ONLY be used for drug products sold and used in South America.” Fukuzyu agreed.

B. RL Fine
As of 2015, most generic drug companies would have sought to purchase pyrimethamine from Fukuzyu. Vyera closed off that avenue of supply with its exclusive supply agreement with Fukuzyu. After Fukuzyu, RL Fine was the second most attractive source of supply. In 2017, after Shkreli learned that generic companies were going to obtain pyrimethamine from RL Fine, he moved quickly to cut off that source of supply as well.

*17 RL Fine is based in Bangalore, India and had been manufacturing pyrimethamine since at least 2004. RL Fine sells pyrimethamine directly to customers; it does not use distributors. As of 2016, RL Fine had a European pyrimethamine DMF but had not filed a U.S. DMF.

In 2017, in defending against an investigation that preceded the filing of this lawsuit, Vyera emphasized the importance of RL Fine to generic drug manufacturers. It downplayed the significance of its exclusive supply agreement with Fukuzyu in a letter to the Office of the New York Attorney General dated May 5, 2017, by asserting that “generics manufacturers can obtain pyrimethamine API from a variety of sources, even without the option to purchase it from Fukuzyu”. It cited RL Fine as one of those alternatives. Vyera explained that
the cost for a potential competitor to qualify API from the European DMF holder RL Fine Chemicals would be less than $100,000, as the company has already validated its production process and has a DMF ready to file in the United States. Such a cost can hardly be deemed a barrier to entry, especially when viewed as part of the overall process of drug development.

Yet when Vyera learned from its consultant on August 7, 2017, that two generic drug companies, Mylan and Sandoz, were planning to buy pyrimethamine from RL Fine, Shkreli acted quickly to block their access. On August 24, Shkreli drafted an email from prison for Mithani to send to RL Fine. The email represented that Vyera was “looking to purchase 10-20kg/annually of pyrimethamine API with a US DMF” for a “combination product with leucovorin.” Mithani sent Shkreli’s drafted email to RL Fine verbatim. RL Fine replied that it was “already working on pyrimethamine and would not be able to offer [it] to you.” Vyera was undeterred and continued to negotiate with RL Fine.

In October 2017, Vyera received independent confirmation from executives attending a trade conference in Frankfurt that RL Fine was supporting generic drug companies that would soon file ANDAs. On October 25, Shkreli texted Mulleady from prison using a contraband phone: “its shkreli -- trying to get in touch with you urgently -- hearing pyri ANDA approval in december 2017.”

Within eight days of that email, on November 2 Mulleady offered RL Fine $1,250,000 per year and other financial enticements “to formalize our exclusive agreement” for pyrimethamine API. In late November, Mulleady and Mithani flew to India to meet with RL Fine. By November 25, Vyera and RL Fine had agreed on the terms of an exclusive supply agreement.

Vyera made no bones about its motive for entering this exclusive supply agreement. It needed to block the access of generic manufacturers to RL Fine pyrimethamine. The minutes of the December 15, 2017 Phoenixus board meeting present the rationale for Vyera's costly agreement with RL Fine as “the potential market entry by generics manufacturers and distributors.” According to the minutes, “one or two potential competitors are currently in the process of preparing their market entry.” The minutes report that Mulleady and Mithani, by then Board members of Phoenixus and in control of the company's management functions, believed “addressing potential generic competitors are in the Vyera Group's interest” and justified the extraordinary price Vyera agreed to pay RL Fine.

*18 On December 17, Vyera executed two contracts with RL Fine: A Distribution and Supply Agreement (“Supply Agreement”) and a Product Collaboration Agreement (“Collaboration Agreement”). The twenty-five-page Supply Agreement gave Vyera “the exclusive right to sell, distribute, and market” RL Fine's pyrimethamine for five years and limited RL Fine to selling pyrimethamine for use outside India only “with the consent” of Vyera.

In return, Vyera paid RL Fine $1 million “towards expenses for filing the US” DMF for pyrimethamine. Vyera also agreed to pay RL Fine royalty payments in the amount of 7.5% of net revenues on its sales of Daraprim, with a guaranteed minimum payment of $3 million. Under the Supply Agreement, Vyera's obligation to make royalty payments other than the guaranteed amount of $3 million would terminate if and when a generic pyrimethamine product entered the U.S. market.

Under the Collaboration Agreement, which had a one-year term, Vyera paid a non-refundable $1 million towards R&D expenses and preparation of a DMF. The Collaboration Agreement acknowledged the parties' Supply Agreement.
Having signed the Supply Agreement, RL Fine stopped supplying pyrimethamine to the generic drug manufacturers Cerovene and InvaTech. Vyera has paid RL Fine approximately $300,000 to $450,000 a month in royalty payments. By October 2019, Vyera had paid RL Fine almost $7 million in monthly royalty payments alone, and almost $9.5 million in total. Vyera's payments to Fukuzyu pale in comparison. Over this time period, Vyera has paid Fukuzyu approximately $500,000.

Neither the Supply Agreement nor the Collaboration Agreement required RL Fine to file a DMF with the FDA or conditioned any payment on RL Fine completing any of the steps necessary to file a U.S. DMF. RL Fine never paid even the $57,795 DMF filing fee to the FDA, despite receiving $1 million from Vyera to do so, or took any other steps toward filing a DMF for pyrimethamine. Similarly, Vyera never sought FDA approval to use RL Fine's API in Daraprim, or took any other steps to be able to use RL Fine as a backup supplier of pyrimethamine. Pelliccione, Vyera's executive in charge of regulatory matters, didn't even know of the RL Fine contract until he was preparing for this trial. It had never even crossed his mind that Vyera needed a second source for pyrimethamine. In sum, Vyera received nothing in return for the millions of dollars it paid to RL Fine except the foreclosure of generic competitors’ access to RL Fine's pyrimethamine.

Facing regulatory pressure, on October 20, 2019, Vyera paid RL Fine $750,000 to terminate the Supply Agreement. RL Fine threatened to speak to the FTC if it did not get a termination fee.

VI. Delay of Generic Entry
Shkreli's efforts to delay the entry of generic competition to Daraprim succeeded. The following chart sets out the dates on which the four generic manufacturers filed their ANDAs, and the dates on which three of those ANDAs were approved.

<table>
<thead>
<tr>
<th>Generic</th>
<th>ANDA Filed</th>
<th>Approved</th>
<th>Time to Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cerovene/Dr. Reddy's</td>
<td>5/8/2014</td>
<td>2/28/2020</td>
<td>70 months</td>
</tr>
<tr>
<td>InvaTech</td>
<td>7/28/2017</td>
<td>Pending as of January 2022</td>
<td>53+ months</td>
</tr>
<tr>
<td>Fera</td>
<td>12/19/2019</td>
<td>7/27/2021</td>
<td>31 months</td>
</tr>
<tr>
<td>Teva Pharmaceuticals</td>
<td>1/27/2021</td>
<td>8/13/2021</td>
<td>7 months</td>
</tr>
</tbody>
</table>

Vyera's multifaceted campaign to delay the entry of generic pyrimethamine succeeded in substantially delaying the entry of at least Cerovene and Fera. Vyera made it exceedingly difficult for each of them to obtain the pyrimethamine API and a sufficient quantity of Daraprim RLD for BE testing.

A. Barriers to Entry
As of 2015 only two API suppliers held a pyrimethamine DMF in the United States: Fukuzyu and Ipca. Fukuzyu was the long-term supplier of the API for Daraprim. Because Ipca's supply of pyrimethamine became subject to an FDA-imposed import ban, Fukuzyu was the only option for any pharmaceutical company in the United States seeking a pyrimethamine API supplier that held an active DMF.

*19 RL Fine was the next-best option for a supply of pyrimethamine for generic drug companies seeking to compete with Daraprim because it was familiar with the FDA's requirements; it had DMFs on file with the FDA for other APIs. In addition, it marketed its drug products globally, already manufactured significant quantities of pyrimethamine, and held a European pyrimethamine DMF. Possession of a European DMF typically indicates that one can also meet U.S. DMF standards.
With its exclusive supply agreements, Vyera blocked access to these two sources of API. Shkreli began efforts to obtain an exclusive supply agreement with Fukuzyu in 2015. Vyera and Fukuzyu came to terms in November of 2016 and executed their contract in January of 2017. In 2017, at Shkreli's urging, Vyera also entered into an exclusive supply agreement with RL Fine. It paid RL Fine millions of dollars to do so.

Shkreli also cut off access to the RLD that generic drug companies needed to do the BE testing required for FDA approval of an ANDA. Understanding the importance of access to the RLD, Shkreli adopted a closed distribution system for the sale of Daraprim. This was the model he had adopted at Retrophin to block generic competition to Retrophin's pharmaceuticals.

Against this backdrop, several generic drug companies worked for years to obtain an API supplier and quantities of the RLD, a process that in the ordinary course should have taken weeks. Cerovene was the first to get its ANDA approved and its efforts to obtain an API supplier and the requisite RLD will be described first. Fera's path to entering the market will be described next. Finally, there will be brief descriptions of the experiences of InvaTech and Mylan.

B. Cerovene and Dr. Reddy's Laboratories

Cerovene, a pharmaceutical research and development firm founded in 2006, is focused on the development of generic drugs. Cerovene does not manufacture API, but manufactures the finished drug product, creates the documents necessary to submit the ANDA to the FDA, works with the FDA to gain approval, and produces a finished product for distribution after approval.

Dr. Reddy's is Cerovene's generic pyrimethamine marketing partner. Dr. Reddy's is a large multinational pharmaceutical company that sells about 150 drug products, primarily generic versions of innovator drugs (that is, the first FDA-approved drug created containing a specific API). As it did with Cerovene, Dr. Reddy's often licenses a third party's developed drug or partners with a third party to develop a drug for Dr. Reddy's to bring to market. After a seven-year effort, Cerovene received FDA approval of its ANDA for generic pyrimethamine on February 28, 2020, and Dr. Reddy's launched the generic product on March 20, 2020.

Cerovene began developing generic Daraprim in 2013 and submitted its ANDA to the FDA on May 8, 2014. It expected that a generic version of Daraprim would be profitable based on the price of Daraprim at the time, which was approximately $12 per tablet. In late 2015, Dr. Reddy's explored developing a generic version after Vyera dramatically hiked up Daraprim's price. It learned in March 2016 that Cerovene had already filed an ANDA, and on January 3, 2017, Dr. Reddy's and Cerovene entered into a licensing agreement.

In evaluating the market opportunity of generic Daraprim, Dr. Reddy's conservatively expected that Cerovene's ANDA would be approved by August 2017, with the product launch occurring by early 2018. Dr. Reddy's also projected that Cerovene's generic would launch at a 55-70% discount off Daraprim's list price (depending on how many other generic competitors entered the market) and expected to take a significant fraction of the branded drug's sales.

Cerovene's experience in acquiring RLD to support its 2014 ANDA was typical of the process generic drug companies generally encounter. Cerovene had done the BE testing that it included in its May 2014 ANDA with nine 100-tablet bottles of Daraprim that it had purchased in 2013 from an independent pharmacy for a total price of just over $10,000. Shah, Cerovene's co-founder and President, recalled that it had taken approximately one day for the pharmacy to acquire the nine Daraprim bottles on Cerovene's behalf.

Cerovene then encountered a setback. It had planned to obtain pyrimethamine from Ipca and had referenced Ipca's DMF in its ANDA, but the 2015 FDA import ban on Ipca's products required it to find a new supplier. In October 2015 and March 2016,
Cerovene and Ipca wrote letters to the FDA seeking an exemption to the import ban for Ipca-manufactured pyrimethamine. The FDA denied the requests on April 15, 2016.

Meanwhile, Cerovene attempted to purchase 50 kilograms of *pyrimethamine* from Fukuzyu. Cerovene first contacted Fukuzyu in 2015, and Fukuzyu supplied a sample of *pyrimethamine* for Cerovene to assess for suitability. By September 2016, Shah believed that Fukuzyu had agreed to supply Cerovene with *pyrimethamine* to develop its generic product. But in October -- the same month that Vyera executives visited Japan -- Fukuzyu refused to supply the API. In a letter to Cerovene dated October 4, 2016, Fukuzyu explained that it would not supply pyrimethamine “to anyone because of low business potential and high risk associated with the business.” Yet, as described above, Fukuzyu executed an exclusive supply agreement with Vyera in January 2017.

Cerovene promptly turned its sights on RL Fine as the next-best option. Although RL Fine did not have an FDA-approved DMF for pyrimethamine, Cerovene considered it a promising alternative supplier due to its experience manufacturing pyrimethamine for use outside the U.S. and because it held DMFs for other products.

On November 16, 2016, Cerovene and RL Fine executed a five-year supply agreement. The agreement obligated RL Fine to provide a pyrimethamine DMF that would be referenced in an amendment to Cerovene's ANDA. In return, Cerovene paid RL Fine $100,000, with another $100,000 due upon approval of its ANDA.

Cerovene's agreement with RL Fine had an exclusivity provision. That provision was intended to protect Cerovene's investment in getting RL Fine qualified as an API supplier in the United States and forestall free riding by other generic drug companies on Cerovene's investment. RL Fine confirmed that it would support Cerovene's pyrimethamine ANDA in early 2017 and supplied 33.5 kilograms of API, which was enough for Cerovene to test and launch its product.

On April 2, 2017, Cerovene submitted a major amendment to its ANDA changing its API supplier from Ipca to RL Fine. In the amendment, Cerovene informed the FDA that RL Fine had been manufacturing pyrimethamine on a commercial basis in European and Asian markets and noted that the FDA had inspected RL Fine as recently as June 2015. Cerovene included RL Fine's manufacturing information as an amendment to its ANDA instead of relying on RL Fine to handle the DMF process separately. This appeared to Cerovene to be the fastest way to get FDA approval.

Because of the switch in supplier from Ipca to RL Fine, the FDA issued a complete response letter to Cerovene's amended ANDA dated December 26, 2017, requiring Cerovene to conduct new BE testing using RL Fine's API and an unexpired lot of RLD. New BE testing was the only substantial correction required by the FDA, but the *Daraprim* that Cerovene had purchasing in 2013 had expired, so Cerovene immediately tried to buy five more bottles.

Cerovene made an extensive search for the RLD that proved futile. It tried and failed to acquire RLD from five different suppliers, on occasion making simultaneous prepayments. It made multiple applications to the FDA requesting partial waivers of the BE retesting requirement. After roughly twelve months of effort, Cerovene had purchased only three bottles of *Daraprim*. It did so in November 2018 at a total cost of $375,000.

Cerovene first sought RLD on December 29, 2017, from the pharmacy that had supplied it with *Daraprim* bottles in 2013, but the pharmacy was no longer able to supply it with *Daraprim*. The next day, Cerovene ordered five bottles at a cost of $112,000 each from another pharmacy but cancelled the order in February 2018 when the pharmacy proved unable to fill the order.

On January 22, 2018, Cerovene asked the FDA to reconsider its new BE testing requirement due to its difficulty acquiring *Daraprim* RLD. Cerovene explained that “the RLD is inaccessible and unavailable in the US for BE or other testing because it is the subject of a restricted distribution program.” On June 29, 2018, the FDA denied Cerovene's requests to conduct new BE
testing by using its expired lots of Daraprim or to conduct alternative studies. The FDA noted that it “did not have additional recommendations that can address the issue of RLD inaccessibility” and that “Daraprim is not subject to a REMS, and the restrictions on supply of Daraprim described in your letter are not required by the [FDA].” The agency added,

If you have been unable to obtain supplies of the drug from the manufacturer or other distributors, and you believe this refusal constitutes anticompetitive behavior, we encourage you to raise the matter with the Federal Trade Commission, which is responsible for addressing anticompetitive practices.

Throughout 2018, Cerovene struggled to find a distributor that could deliver sufficient RLD. Dr. Reddy's did not typically help its partners procure RLD but by the end of January, it had stepped in to aid Cerovene. As a far larger company, Dr. Reddy's believed that its connections might work.

Dr. Reddy's efforts included prepaying $550,000 in March 2018 to Reliant for five bottles of Daraprim. Reliant is a New Jersey-based pharmaceutical wholesale company that “procure[s] branded Innovator Samples/Reference Listed Drugs for bioequivalence and clinical trials.” Reliant, however, was unable to purchase any Daraprim from its normal sources.

When Reliant tried to buy Daraprim bottles from ASD, ASD directed Reliant to place its order directly with Vyera. Vyera never responded to Reliant's request for five bottles.

Relying on a family connection, Reliant turned to a small New Jersey pharmacy and arranged for the pharmacy to order five bottles of Daraprim from ASD. As described above, Vyera immediately flagged that transaction and hurried to repurchase the five bottles for twice their purchase price during a meeting in a Starbucks parking lot in New Jersey.

The pharmacy had placed its order with ASD on April 4, 2018 for five bottles, which were delivered the next day. Vyera's Kirby emailed ASD on April 5 to verify that the pharmacy was an “approved account type[ ]” and requested that ASD put a hold on the pharmacy's account for “placing further orders until we can determine if there is alignment with our distribution model.” ASD answered that it had approved the sale in error and confirmed that the purchase could not be stopped as the bottles had already shipped. A Vyera employee then called the pharmacy and spoke to the owner.

Vyera repurchased the five bottles for $750,000 on April 6, 2018. Vyera's CEO Mulleady drove to Parsippany, New Jersey to meet Reliant's owner in a Starbucks parking lot and repurchased the bottles. Mulleady also handed the owner of Reliant a draft contract titled “Product Purchase and Collaboration Agreement.” The document proposed that Reliant and its affiliates “agree not to purchase, directly or indirectly, or their own account or on account of others, or to cause or direct any third party to purchase, directly or indirectly, any Daraprim, except directly through normal commercial channels.” Reliant never signed the document. Despite its continuing efforts, Reliant only delivered one bottle of Daraprim in June of 2018.

Cerovene and Dr. Reddy's also used a Swiss distributor, ProSupplier GmbH (“ProSupplier”), which also required an advance payment to begin locating Daraprim RLD. Cerovene and Dr. Reddy's initially resisted prepaying both Reliant and ProSupplier for RLD that may never materialize; they had also heard that ProSupplier was in fact attempting to obtain Daraprim through Reliant. As more time passed, however, Dr. Reddy's and Cerovene decided to accept the risk of holding open two orders at the same time and prepaid $375,000 to ProSupplier in September for three bottles of Daraprim, with another $375,000 to be paid after delivery.
ProSupplier delivered three bottles of Daraprim in November 2018, but as they came from a different manufacturing lot than the one bottle obtained by Reliant, the four bottles could not be combined to meet the FDA's BE testing and the RLD retention requirements. With the three bottles in hand, Dr. Reddy's cancelled its outstanding order with Reliant.

Cerovene had written the FDA again in July 2018 to stress that Daraprim appeared to be subject to a restricted distribution program and was inaccessible in the United States. It requested a reduction in the amount of RLD needed for BE testing and retention. In April 2019, the FDA permitted Cerovene to conduct BE testing with just the three bottles of Daraprim that it had been able to acquire from ProSupplier.

Meanwhile, due to Vyera's interference, Cerovene was forced to search for yet another API supplier. During a November 30, 2017 meeting in India, RL Fine informed Cerovene's Shah that, notwithstanding their five-year contract, it would no longer supply Cerovene with any more pyrimethamine.

Cerovene returned to Ipca, which had acquired another company with manufacturing facilities. Cerovene executed a supply agreement on February 19, 2019, that was conditioned on FDA approval of Ipca's affiliate as Cerovene's API supplier. Cerovene invested in developing the company's pyrimethamine manufacturing capacity from scratch, but even with Ipca transferring its manufacturing process, it took until late 2019 for the company to provide Cerovene with the materials necessary to supplement its ANDA.

From May to June 2019, Cerovene proceeded to conduct BE testing using the RL Fine API that it had received in 2017 and the three bottles of Daraprim obtained from ProSupplier in November 2018. It submitted its results to the FDA in September 2019. Then, on February 25, 2020 -- after Vyera terminated its exclusive agreement with RL Fine in October 2019 -- RL Fine agreed once more to supply Cerovene with pyrimethamine pursuant to their 2016 agreement. Three days later, Cerovene's generic pyrimethamine product received FDA approval and an AB rating to Daraprim. Dr. Reddy's launched the generic on March 20, 2020. Cerovene began manufacturing commercial batches of generic pyrimethamine using RL Fine's API in 2021.

Vyera delayed Cerovene's entry into the market by roughly thirty months, that is, from September 2017 to its actual entry date of March 2020. This timeline is premised on Cerovene having been able to obtain API from Fukuzyu in October 2016 and being able to obtain Daraprim without any delay. Cerovene, as explained at trial by its principal, would have needed approximately eleven months to obtain approval for an amended ANDA in these circumstances. Shah testified that it would have taken one month to manufacture a registration batch of the generic drug product. He would have redone the BE testing during the three-month period needed for stability testing. He predicted that he would have filed an amended ANDA changing Cerovene's API supplier to Fukuzyu in or around February 2017. Assuming that the FDA would have taken six months to review of Cerovene's amendment, it would have approved Cerovene's ANDA by August 2017. Dr. Reddy's would have launched Cerovene's FDA-approved generic pyrimethamine one month later, by September 2017.

As was true when Dr. Reddy's actually launched Cerovene's generic competitor to Daraprim in 2020, the effect of the entry of FDA-approved generic pyrimethamine on the price of Daraprim would have been immediate. Upon the entry of the Dr. Reddy's generic product, Vyera began to compete on price by offering steep rebates and brand-for-generic deals to various pharmacies and pharmaceutical benefit managers.

C. Fera
The second pharmaceutical company to bring FDA-approved generic pyrimethamine to the market is Fera. Fera is based in Locust Valley, New York, and develops generic and branded drugs. Dellafera founded Fera in 2009 to develop niche products that face barriers to entry and are often overlooked by the pharmaceutical industry.
Fera is a virtual drug company, which means that it does not have its own manufacturing capacity; it contracts with other manufacturers to produce its products. When developing a new drug, Fera usually partners with reputable API suppliers that have experience complying with the FDA's cGMPs regulations.

In September 2015, Fera decided to develop generic pyrimethamine after learning about Vyera's Daraprim price hike in the media. After confirming that about one million tablets of Daraprim were being sold per year at the time, Fera began to search for API suppliers holding a U.S. DMF for pyrimethamine.

In February 2016, Fera inquired of Fukuzyu about purchasing pyrimethamine. Fukuzyu did not respond.

On June 13, 2016, Fera entered into an agreement with another manufacturer to develop a pyrimethamine API manufacturing process exclusively for Fera's use. That manufacturer had never made pyrimethamine. Fera invested about $2 million for the development of a pyrimethamine manufacturing process. The company completed its work in October 2017.

Meanwhile, Fera continued its efforts to acquire the API from an already established source. Despite its investment in an API development process, Fera understood that its ANDA would be approved more quickly if it relied on a supplier that already had an FDA-approved pyrimethamine DMF.

In September 2017, Fera reached out to Fukuzyu a second time. Fera sought a sample of pyrimethamine API to test against the API being produced by its manufacturing partner, and also hoped that Fukuzyu would agree to become its pyrimethamine supplier for generic Daraprim. That proved to be impossible. At Vyera's direction, Fukuzyu's agent told Fera that it had to guarantee that Fukuzyu's pyrimethamine would not be used in a drug for human use in the United States “either via normal prescription drug distribution” or via compounding.

In the Fall of 2016, Fera also sought to purchase Daraprim RLD for BE testing and to use as a comparator with the product being produced by its manufacturing partner. Its efforts were largely fruitless.

*24 On November 7, 2016, Fera's McDougal reached out to Pharmaceutical Buyers, Inc. (“PBI”), a distributor, to acquire samples of Daraprim. PBI responded that Daraprim was “only available to hospitals and government facilities at this time.” McDougal next inquired of a hospital pharmacist at a major university, who responded that “according to our hospital policy and distributor contract, I can only procure from what is defined as own use for hospital business.” Fera was finally able to acquire small amounts of Daraprim by using a physician's prescription at a pharmacy. That Daraprim would not meet FDA requirements for BE testing, however, because the sample contained too few tablets, was provided in an unsealed vial, and had no manufacturing lot number.

Fera also attempted to procure Daraprim through its contract research organization (“CRO”), Xcelience. Fera had entered into an agreement with Xcelience on December 22, 2016, to develop a generic prototype and manufacture the end product. Xcelience quickly ran into the same roadblocks Fera had met in its own efforts to acquire RLD. On January 4, 2017, Xcelience relayed to Fera that “the manufacturer is now limiting distribution of Daraprim only to hospitals and government agencies directly.” When Xcelience reached out to Vyera, Vyera explained that Fera would have to enter into an agreement accepting full liability from any use of Daraprim. This is the first time a purchase of RLD had been conditioned on Fera executing an indemnification clause. Fera replied by striking the proposed indemnity clause, which ended negotiations.

McDougal continued to inquire of PBI in February and again in May of 2017, to no avail. In July 2017, Fera ended its relationship with Xcelience at least in part because it had failed to procure the RLD.
Fera signed a development contract with another CRO in November 2017. Fera also negotiated a partnership with a contract manufacturing organization (“CMO”). That CMO completed its first manufacture of Fera's generic pyrimethamine product in March 2019.

Meanwhile, in January 2018, Fera succeeded in purchasing two 100-count bottles of Daraprim from Reliant at a cost of $115,000 per bottle. Fera declined to purchase more bottles at that time, partly because the bottles came from a manufacturing lot that expired in Summer 2019, that is, before Fera was sure that it could conduct BE testing. Fera intended to purchase additional bottles from Reliant as its development timeline became clearer. In April 2018, Reliant informed Fera that Vyera's Mulleady had repurchased its inventory of Daraprim and that it could not acquire more.

Using an industry broker, Vyera's Mulleady asked to meet with Fera in April of 2018. DellaFera met with Mulleady in April and May of 2018. Following instructions from Shkreli, Mulleady quizzed DellaFera about his plans, dangling the possibility of a joint venture as he did. Mulleady told DellaFera that he had repurchased Reliant's entire stock of Daraprim. He also related that he had flown to India to lock RL Fine into an exclusive contract in order to prevent it from supplying two major pharmaceutical companies, Mylan and Sandoz, with pyrimethamine. He explained that Vyera was paying RL Fine a royalty on Daraprim sales. When Mulleady added that he knew the identity of Fera's API supplier, DellaFera understood this as a threat that Vyera was willing to interfere with Fera's source of API as well. At this point, DellaFera became concerned that Fera might never get pyrimethamine into the market. DellaFera had no interest in a joint venture with Vyera and the discussions came to a close.

Like Cerovene, Fera had already asked the FDA for a waiver of its BE testing requirements due to difficulty acquiring RLD. In October 2017, Fera proposed performing a pharmacokinetic study, which would not require Daraprim RLD, in lieu of BE testing. Fera explained that

\*25 the unavailability due to the restricted access program created by the RLD has made the development of a generic version of the product largely impossible. Additionally, the cost of the RLD is exorbitant, forcing even patients to forego this medically necessary treatment.

The FDA denied Fera's request.

On June 1, 2018, Fera requested a competitive generic therapy designation from the FDA that would allow for expedited review of Fera's application. It also asked for a meeting with the relevant FDA officials to ensure that its ANDA was on track. In August 2018, Fera sought a waiver “for the minimum number of RLD samples required to be retained from the conduct of the Fed and Fasting BE studies.” Fera pointed out that

\[\text{the RLD sponsor for this drug product, Vyera, utilizes a closed pharmacy distribution model. This has resulted in extreme difficulty in obtaining sufficient samples of drug product normally needed to meet all ANDA test analysis and BE study requirements.}\]

In January 2019, the FDA again denied Fera's request.
On March 4, 2019, Fera's team participated in a call with the FDA's Office of Generic Drugs. DellaFera stressed how difficult it was to locate RLD and that it had taken over a year to buy just two bottles. He described his conversations with Mulleady, including Mulleady's admission that Vyera had entered an exclusive API supply agreement with RL Fine to eliminate competition from Mylan and Sandoz. In April, Fera formally requested another waiver to conduct BE testing with only two bottles of Daraprim, which the FDA granted in June.

Fera immediately conducted BE testing of its generic pyrimethamine product, undertook six months of stability testing, and filed its ANDA in December 2019. The FDA responded by requiring Fera to conduct additional tests on its API, and in August 2020, the FDA sent Fera a complete response letter citing deficiencies in the impurity profile of Fera's API. Due to the COVID-19 pandemic, it took Fera until December 2020 to complete the resubmission. On July 27, 2021, the FDA approved Fera's generic pyrimethamine ANDA.

Vyera delayed Fera's entry into the generic pyrimethamine market by roughly twenty-four months. This timeline assumes that Fukuzyu would have agreed to supply Fera with pyrimethamine after Fera reached out to it for a second time in September 2017 and that Fera had unimpeded access to Daraprim RLD. DellaFera estimates that, operating on those assumptions, Fera's generic Daraprim would have entered the market twenty-three months later, or in August 2019 instead of shortly after Fera's ANDA was approved in July of 2021.

As DellaFera explained at trial, Fera would have acted promptly to finalize an agreement with a CMO partner to manufacture the drug. The CMO would have taken between three or four months -- or up to April 2018 at the latest -- to manufacture the necessary batches of generic pyrimethamine for six months of stability testing, bringing the timeline to October 2018. During this six-month period, Fera would have conducted BE testing, assembled its ANDA, and been prepared to file its ANDA by November 2018. Presuming eight months for review, the FDA would have approved Fera's ANDA in July 2019, avoiding any delays caused by the COVID-19 pandemic. As Fera's CMO would have been producing batches of generic pyrimethamine for commercial sales while awaiting FDA approval, Fera would have been ready to launch its product within a month, or by August 2019. 32

D. InvaTech

InvaTech has also filed an ANDA for generic pyrimethamine. Identifying RL Fine as its supplier of API, InvaTech filed an ANDA on July 28, 2017. Due to its exclusive supply agreement with Vyera, however, RL Fine stopped cooperating with InvaTech and InvaTech was forced to find a new supplier of API. Although Vyera's actions have delayed InvaTech's entry into the market, there are too many unknowns to attribute any particular period of delay to Vyera. InvaTech has still not received FDA approval for its ANDA.

InvaTech, founded in 2009, is a New Jersey pharmaceutical company that develops and markets around twenty products. In 2014, it began its effort to develop generic pyrimethamine. In October of 2014, InvaTech bought six 100-tablet bottles of Daraprim for a total of just over $8,000.

Like Cerovene, InvaTech initially chose Ipca as its API supplier, but was forced to look elsewhere following the FDA's 2015 Ipca import ban. In the summer of 2015, RL Fine agreed to supply pyrimethamine to InvaTech. In February 2017, InvaTech and RL Fine executed a Preliminary Collaboration Agreement covering pyrimethamine and two other products for which RL Fine would supply the API. RL Fine agreed to file a DMF for pyrimethamine. While the Agreement left RL Fine free to supply pyrimethamine to other companies, InvaTech was given preferential pricing. The Agreement specified that InvaTech would file its pyrimethamine ANDA in either 2017 or 2018.
Invatech used RL Fine's API to conduct BE testing. Because RL Fine had not yet filed a DMF, Invatech requested in June 2017 that RL Fine provide it with the documentation regarding its pyrimethamine manufacturing process for Invatech to include in its ANDA. With that information, on July 28, 2017, Invatech filed its pyrimethamine ANDA.

On September 11, 2017, the FDA sent a response that included questions about RL Fine's API, setting an answer deadline of September 18. Invatech sought assistance from RL Fine, but RL Fine ignored each of its requests. By that time, Vyera and RL Fine were in the midst of negotiating their exclusive supply agreement.

Given the urgency of the situation, Patel flew to India in September for a two-hour meeting with RL Fine. In that meeting and through other communications, Patel learned that RL Fine would no longer support Invatech's pyrimethamine ANDA even though it continued to support Invatech's work on the other two products.

On May 22, 2018, the FDA issued a complete response letter to Invatech's ANDA. The FDA cited major deficiencies, including deficiencies with the API information. RL Fine again ignored Invatech's requests for help.

Having lost first Ipca and then RL Fine as its API supplier, Invatech turned to a third company. On July 31, 2019, Invatech amended its ANDA to reflect the transfer of its API source to that third company. To this day, Invatech continues to work toward approval of a generic Daraprim product.

E. Mylan

Vyera was successful in preventing one of the largest manufacturers of generic drugs in the United States from entering the market. Prompted by the dramatic increase in Daraprim's price, Mylan explored developing generic pyrimethamine. In February 2016, Mylan began to search for potential pyrimethamine API suppliers. By December 2016 Mylan concluded that RL Fine was the only supplier that could provide pyrimethamine “off the shelf and not require a development agreement.” By that time, however, RL Fine had entered the exclusive supply agreement with Cerovene.

Like Cerovene and Fera, Mylan was also unable to acquire Daraprim RLD through its regular distributors and approved vendors. It could not get “even a single bottle.” Mylan's Head of Global Project Management can only recall two or three other times out of hundreds of projects in which Mylan had such trouble. In those instances, the difficulties were easily explained by the fact that the RLD was part of a REMS program. Unable to find a source of the API or to obtain Daraprim, Mylan abandoned its nascent plans to develop generic pyrimethamine.

VII. Impact of Competition on Prices of Daraprim

*27 In early 2020, Vyera braced for the imminent approval of Cerovene's ANDA and subsequent launch of Dr. Reddy's FDA-approved generic pyrimethamine product. In an internal forecast prepared in March 2020, Vyera projected that the net price for a Daraprim tablet would immediately drop from $278 to $126 after generic entry, based on the assumption that Dr. Reddy's generic would launch at a 61% discount on April 1, 2020. Assuming that another generic competitor would enter the market on September 1, Vyera projected that the business lost by the end of the year due to generic competition would increase to $2.1 million per month and amount to close to $13 million for the year 2020.

Dr. Reddy's FDA-approved generic pyrimethamine launched with a WAC of $292.50. Daraprim immediately faced stiff price competition, and the net price of FDA-approved pyrimethamine products dropped substantially. During its first nine months on the market, the average net price of Dr. Reddy's generic pyrimethamine was $197 per tablet, a significant discount from $228, which was the average net price of Daraprim in the prior year. By the end of 2020, Dr. Reddy's generic pyrimethamine had captured 41% of the sales volume for all FDA-approved pyrimethamine. At the same time as the price of FDA-approved
pyrimethamine dropped, the total volume of FDA-approved pyrimethamine sales increased. The sales volume expanded by 9% when 2020 sales are compared to 2019 sales. This expansion recovered some of the sales lost when Vyera hiked Daraprim’s price by 4,000% in 2015.

In March 2020, Vyera launched its own generic pyrimethamine tablet (the “Vyera AG”). The Vyera AG had captured only 16% of the FDA-approved pyrimethamine market by the end of 2020.

The chart below illustrates the relative market share of Daraprim, the Vyera AG (identified as “Authorized Generic”), and Dr. Reddy’s generic pyrimethamine (identified as “DRL”) between the first quarter of 2019 and the last quarter of 2020. The next chart illustrates the change in the average net price of all FDA-approved pyrimethamine, which dropped from $228 in 2019 to $166 in 2020 -- a decrease of 27%. This rate of decrease exceeded any year-over-year net price drop that had occurred since 2016.
In response to the entry of Dr. Reddy's generic pyrimethamine, Vyera cut the net price of Daraprim through steep rebates and brand-for-generic offers to pharmacies and pharmacy benefit managers. Despite these offers from Vyera, the availability of generic alternatives to Daraprim allowed pharmacy benefit managers to cover the cheaper generic competitors at the lowest tiers of their formularies and to exclude Daraprim from their formularies. For example, in January 2021 CVS Caremark moved Daraprim to “excluded status” on its standard control formulary. It explained its decision as follows: CVS Caremark, like most payors, promotes a “generic-first strategy.” Where the branded drug is expensive and two generics became available, it is “a very cost-effective strategy” to exclude the brand from the formulary. With the entry of more generic competitors in the FDA-approved pyrimethamine market, the price of FDA-approved pyrimethamine can be expected to fall further.

VIII. The Role of Martin Shkreli at Vyera
Shkreli founded Vyera. He did so with the intention to use Vyera to acquire a pharmaceutical that was the sole source of treatment for a life-threatening ailment, raise the drug's price sky-high, and keep it sky-high for as long as possible by blocking generic competition.

*28 Shkreli was Vyera's first CEO, a position he held from October 10, 2014 to December 18, 2015. It was Shkreli who made the decision to acquire Daraprim and to implement his scheme with Daraprim. He directed his team to identify a small, essential drug out of patent protection and without generic competition that could be priced exorbitantly. That drug was Daraprim. Shkreli signed off on Vyera's unsolicited bid to acquire it at a price far above its present value.

Shkreli raised the price of Daraprim to $750 per tablet. When Vyera's General Counsel objected to the price hike, Shkreli fired him.
To block generic competition, Shkreli devised a highly restrictive, closed distribution system for Daraprim and told Vyera that it was a top priority to put it in place by the time of the price hike. Shkreli also instructed his staff to buy back Daraprim inventory from wholesalers and distributors.

Having checked the FDA's pyrimethamine DMF list, Shkreli decided to pursue an exclusive supply contract with Fukuzyu. As Tilles, Shkreli's immediate successor as CEO, explained, the 2017 Fukuzyu contract was “something [Shkreli] wanted and it happened.” As the arrival of a generic competitor grew more likely, in 2017 Shkreli decided to pursue an exclusive supply contract with pyrimethamine manufacturer RL Fine as well.

Shkreli remained in functional control of Vyera's management and its business strategy even after his arrest in December 2015 and in spite of management's occasional resistance. He was Vyera's largest shareholder and at any one time controlled between 43.07% and 49.44% of its voting shares. Even during his incarceration, Shkreli worked to ensure that his grand strategy not only remained in place but actually worked. Critically, none of the resistance put up by Shkreli's successors included unwinding Vyera's anticompetitive strategy. To the contrary, all of Vyera's CEOs pursued Shkreli's original vision.

Shkreli recruited employees and agents to carry out his vision at Vyera and picked the men who ran Vyera after he stepped down as its CEO. That those agents' names appear on documents executed after Shkreli's formal departure in lieu of his own does not shield him as the scheme's prime mover from individual liability. Shkreli initiated every anticompetitive decision that Vyera pursued to its conclusion. He maintained “shadow control” of the company, staying in close contact with Vyera's directors and officers, providing guidance on how to maintain control of the market, and threatening to use his authority as the largest shareholder to call an extraordinary general meeting (“EGM”) that would install more pliant officers and directors. He did exactly that in 2017 and again in 2020, each time installing loyalists.

As Tilles has testified, he couldn't do anything “major” as CEO of Vyera without Shkreli's approval. When Shkreli became frustrated with Tilles, he replaced him with Dr. Salinas. Shkreli quickly became dissatisfied with Dr. Salinas too, proclaiming in one email that Dr. Salinas was a “cockroach that needed to be stomped or crushed.”

Utilizing his controlling voting shares, Shkreli replaced Dr. Salinas with Mulleady. In June of 2017, Shkreli called an EGM of the shareholders to vote on a new slate of Directors. The Phoenixus Board and Shkreli put up competing slates.

In its Invitation to shareholders, the Board strongly opposed Shkreli's slate as unqualified and conflicted. The Board advised that

*29 many third parties -- including regulatory authorities -- will likely deem the newly elected Board members to be serving merely as straw men acting on Mr. Shkreli's behalf, and could further deem Mr. Shkreli to be in a position to influence, direct or control the Board and thus, the Company as well.

At the EGM held on June 21, 2017, Shkreli's slate was elected.

The new Board members notably lacked experience in the pharmaceutical industry. Those new members included Mulleady and Mithani. Tilles had fired Mulleady after Shkreli's arrest because Mulleady lacked “any skills” to offer the company. Mithani had graduated from college just three years earlier. His only prior employment was at a distressed debt brokerage firm, which he had quit to manage his own investment portfolio. Mithani has admitted that he was not qualified to join the board of a pharmaceutical company and that he was placed on the Board because Shkreli wanted “people he can trust.”
The next day, the Board placed Dr. Salinas, then interim CEO, on leave and established an Executive Committee to “perform executive functions and take over the task of the Senior Management (CEO, CFO, CCO and CLO).” The Executive Committee had only two members: Mulleady and Mithani.

Mulleady promptly sent a reassuring email to Vyera's sales force, which was confronting an FDA announcement that it would expedite review of pyrimethamine ANDAs. He explained,

In my opinion, this not an immediate concern. Getting to the point of filing an ANDA is a cumbersome process. Personally, I can tell you the FDA approval is generally not the main barrier to entry for generics in our class. Amongst other necessities, a company would have to successfully create the active ingredient on scale using a well-controlled process and then formulate. Next they would have to obtain RLD (registered listed drug), 10 labelled and unexpired bottles (informed estimation), of Daraprim to complete a study in healthy volunteers to demonstrate bioequivalence.

Getting to the front of the line is helpful, but getting to the line is not an easy task. I can't imagine ANDA submission preparation taking less than 18 months (extremely conservative). Since [Vyera] actively collects competitive intelligence concerning other potential developers, we would most likely be aware of this process going on and have plenty of time to prepare.

Mulleady also ordered a “full out audit” of Daraprim to know where “every bottle” of Daraprim went. He made sure that Shkreli got the audit results.

If anything, Shkreli tightened his control over Vyera as his criminal problems progressed. Concern was expressed at an August 30, 2017 Board meeting that the company was buying back shares at a price below par value “to increase Martin Shkreli's holding in the Company and to facilitate his control over it.” At Mulleady and Mithani's urging, the Board nonetheless approved the buyback. The Board then appointed Mulleady CEO in October 2017.

*30 Shkreli kept in regular contact with both Mulleady and Mithani to discuss when a generic Daraprim drug might enter the market and what should be done to slow that entry. As shown in an Excel spreadsheet maintained by Mulleady, between December 26, 2019 and July 14, 2020 alone, at a time when Shkreli was in prison, Mulleady and Shkreli communicated over 1,500 times.

In the few recordings of Shkreli's conversations from prison with Vyera management that are part of the trial record, Shkreli openly discussed his control over Vyera. He observed that he had “EGM power.” Shkreli said “I have no problem firing everybody to be frank, if you guys can't figure it out.” In September 2020, Shkreli told Mulleady that any dissenters amongst the Directors needed to understand that “being on the board of Phoenixus means, you know, you're on the Martin and Kevin board.” Shkreli compared himself to Mark Zuckerberg and Vyera to Facebook, noting that Zuckerberg “just happens to own the thing and that's the way it is,” and “[y]ou can't go in there and tell Zuckerberg what to do.”

In February 2020, Shkreli used his EGM power to change Vyera's management team once again. This time, he removed Mulleady. Mulleady had added a “confidential” item to the agenda of an upcoming Board meeting. It was intended to address Shkreli's meddlesome involvement with Vyera. But before it could be discussed, Shkreli called for an EGM, Mulleady was removed from the Board, and Shkreli's new directors were installed.

**Discussion**

The FTC has brought claims against Shkreli for violations of §§ 1 and 2 of the Sherman Act. The States have brought claims against Shkreli based on violations of various state statutes and Pennsylvania common law, all of which follow federal precedent. After finding that the Plaintiffs have carried their burden of proving by a preponderance of the evidence that Shkreli violated §§ 1 and 2 of the Sherman Act and the state laws at issue here, the Plaintiffs’ requests for relief will be addressed.

I. Legal Standard

A. Section 5 of the FTC Act


B. Section 1 of the Sherman Act

Section 1 of the Sherman Act outlaws “[e]very contract, combination ..., or conspiracy, in restraint of trade or commerce among the several States.” 15 U.S.C. § 1. The “primary purpose of the antitrust laws is to protect interbrand competition. Low prices ... benefit consumers.” State Oil Co. v. Khan, 522 U.S. 3, 15, 118 S.Ct. 275, 139 L.Ed.2d 199 (1997).

To prove a § 1 violation, a plaintiff must show that there was “a combination or some form of concerted action between at least two legally distinct economic entities that constituted an unreasonable restraint of trade.” United States v. Apple, Inc., 791 F.3d 290, 313 (2d Cir. 2015) (citation omitted). “[O]fficers or employees of the same firm do not provide the plurality of actors imperative for a § 1 conspiracy” because “an internal agreement to implement a single, unitary firm's policies does not raise the antitrust dangers that § 1 was designed to police.” Copperweld Corp. v. Indep. Tube Corp., 467 U.S. 752, 769, 104 S.Ct. 2731, 81 L.Ed.2d 628 (1984).

*31 “The first crucial question in a Section 1 case is ... whether the challenged conduct stems from independent decision or from an agreement, tacit or express.” Apple, 791 F.3d at 314–15 (citation omitted). Courts presumptively apply a rule of reason analysis to challenged agreements to determine whether they restrain trade. 1-800 Contacts, Inc. v. Fed. Trade Comm’n, 1 F.4th 102, 114 (2d Cir. 2021) (citing Texaco Inc. v. Dagher, 547 U.S. 1, 5, 126 S.Ct. 1276, 164 L.Ed.2d 1 (2006)). Therefore, “antitrust plaintiffs must demonstrate that a particular contract or combination is in fact unreasonable and anticompetitive before it will be found unlawful.” Texaco, 547 U.S. at 5, 126 S.Ct. 1276. Anticompetitive effects may be shown through direct evidence of increased prices in the relevant market. 1-800 Contacts, 1 F.4th at 118.

Under the rule of reason,

[a] plaintiff bears the initial burden of showing that the challenged action has had an actual adverse effect on competition as a whole in the relevant market. After a prima facie case of anticompetitive conduct has been established, the burden shifts to the defendant to proffer procompetitive justifications for the agreement. Assuming defendants can provide such proof, the burden shifts back to the plaintiffs to prove
that any legitimate competitive benefits offered by defendants could have been achieved through less restrictive means.

_id_ at 114 (citation omitted).

The rule of reason analysis requires a court to weigh “the relevant circumstances of a case to decide whether a restrictive practice constitutes an unreasonable restraint on competition.” _Anderson News, L.L.C. v. Am, Media, Inc._, 680 F.3d 162, 183 (2d Cir. 2012) (quoting _Monsanto Co. v. Spray–Rite Service Corp._, 465 U.S. 752, 761, 104 S.Ct. 1464, 79 L.Ed.2d 775 (1984)). Such factors may include “specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect.” _State Oil Co._, 522 U.S. at 10, 118 S.Ct. 275.

Exclusive dealing arrangements “implicate § 1 because they have the potential unreasonably to exclude competitors or new entrants from a needed supply, or to allow one supplier to deprive other suppliers of a market for their goods.” _Geneva Pharms. Tech. Corp. v. Barr Lab'y's Inc._, 386 F.3d 485, 508 (2d Cir. 2004). Exclusive dealing is a § 1 violation “only when the agreement freezes out a significant fraction of buyers or sellers from the market.” _Id_.

Exclusive dealing agreements may “have pro-competitive purposes and effects, such as assuring steady supply, affording protection against price fluctuations, reducing selling expenses, and promoting stable, long-term business relationships.” _Id_. In analyzing the procompetitive effects of these agreements, “courts must take care to consider the competitive characteristics of the relevant market.” _Id_.

**C. Section 2 of the Sherman Act**

Under § 2 of the Sherman Act, it is unlawful to “monopolize, or attempt to monopolize ... any part of the trade or commerce among the several States.” 15 U.S.C. § 2. A claim brought under § 2 of the Sherman Act has two elements: “(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.” _United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Takeda Pharm. Co.,_ Ltd., 11 F.4th 118, 137 (2d Cir. 2021) (quoting _United States v. Grinnell Corp._, 384 U.S. 563, 570–71, 86 S.Ct. 1698, 16 L.Ed.2d 778 (1966)). “To safeguard the incentive to innovate, the possession of monopoly power will not be found unlawful unless it is accompanied by an element of anticompetitive conduct.” _In re Adderall XR Antitrust Litig._, 754 F.3d 128, 133 (2d Cir. 2014) (quoting _Verizon Commc'n's Inc. v. Law Offices of Curtis V. Trinko, LLP_, 540 U.S. 398, 407, 124 S.Ct. 872, 157 L.Ed.2d 823 (2004)).

**a. Monopoly Power**

*32* Monopoly power is “the power to control prices or exclude competition.” _Geneva Pharms._, 386 F.3d at 500 (quoting _United States v. E. I. du Pont de Nemours & Co._, 366 U.S. 316, 334, 81 S.Ct. 1243, 6 L.Ed.2d 318 (1961)). Defendants with monopoly power have “the ability (1) to price substantially above the competitive level and (2) to persist in doing so for a significant period without erosion by new entry or expansion.” _AD/SAT, Div. of Skylight, Inc. v. Associated Press_, 181 F.3d 216, 227 (2d Cir. 1999). A plaintiff can establish a defendant's monopoly power either “directly through evidence of control over prices or the exclusion of competition, or it may be inferred from a firm's large percentage share of the relevant market.” _Geneva Pharms._, 386 F.3d at 500.
“While market share is not the functional equivalent of monopoly power, it nevertheless is highly relevant to the determination of monopoly power.” Tops Markets, Inc. v. Quality Markets, Inc., 142 F.3d 90, 98 (2d Cir. 1998). As such, “defining a relevant market is generally a necessary component of analyzing a monopolization claim.” PepsiCo, Inc. v. Coca-Cola Co., 315 F.3d 101, 108 (2d Cir. 2002). “Once a relevant market is determined, the defendant's share in that market can be used as a proxy for market power.” Id.

“The relevant market must be a market for particular products or services, the outer boundaries of which are determined by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it.” US Airways, Inc. v. Sabre Holdings Corp., 938 F.3d 43, 64 (2d Cir. 2019) (quoting Brown Shoe Co. v. United States, 370 U.S. 294, 325, 82 S.Ct. 1502, 8 L.Ed.2d 510 (1962)). “[A] single brand of a product or service may be a relevant market under the Sherman Act if no substitute exists for that brand's products or services.” US Airways, 938 F.3d at 66 (citation omitted). On the other hand, products “need not be identical” to exist in the same market. AD/SAT, 181 F.3d at 227. Pharmaceutical drugs that are “therapeutically equivalent” can nevertheless exist in separate markets. Geneva Pharms., 386 F.3d at 496. To define the boundaries of the relevant market, courts can look toward such practical indicia as industry or public recognition of the submarket as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors.

US Airways, 938 F.3d at 64 (quoting Brown Shoe, 370 U.S. at 325, 82 S.Ct. 1502).

Courts will find sufficient cross-elasticity of demand if “consumers would respond to a slight increase in the price of one product by switching to another product.” Geneva Pharms., 386 F.3d at 496. One of the tests that courts employ to discern the relevant market is the hypothetical monopolist test (“HMT”). Under that test, courts ask “[w]hether a hypothetical monopolist acting within the proposed market would be substantially constrained from increasing prices by the ability of customers to switch to other products.” United States v. Am. Express Co., 838 F.3d 179, 198-199 (2d Cir. 2016) (citation omitted).

The Court implements the HMT by imagining that a hypothetical monopolist has imposed a small but significant non-transitory increase in price (“SSNIP”) within the proposed market. If the hypothetical monopolist can impose this SSNIP without losing so many sales to other products as to render the SSNIP unprofitable, then the proposed market is the relevant market. By contrast, if consumers are able and inclined to switch away from the products in the proposed market in sufficiently high numbers to render the SSNIP unprofitable, then the proposed market definition is likely too narrow and should be expanded.

Id. at 199.

The Department of Justice and the FTC most often use a SSNIP of five percent. U.S. Dep't of Justice & Fed. Trade Comm'n, Horizontal Merger Guidelines § 4.1.2 (2010). Once the relevant market is established, courts have found that “a market share of over 70 percent is usually strong evidence of monopoly power.” Tops Markets, 142 F.3d at 99.
b. Anticompetitive Conduct

The second element of the monopolization claim “requires a plaintiff to establish that the defendant has engaged in improper conduct that has or is likely to have the effect of controlling prices or excluding competition.” Takeda, 11 F.4th at 137 (citation omitted). “For there to be an antitrust violation, generics need not be barred from all means of distribution if they are barred from the cost-efficient ones.” New York ex rel. Schneiderman v. Actavis PLC, 787 F.3d 638, 656 (2d Cir. 2015) (“Actavis PLC”) (citation omitted).

“[O]nce a plaintiff establishes that a monopolist's conduct is anticompetitive or exclusionary, the monopolist may proffer nonpretextual procompetitive justifications for its conduct. The plaintiff may then either rebut those justifications or demonstrate that the anticompetitive harm outweighs the procompetitive benefit.” Actavis PLC, 787 F.3d at 652 (citation omitted).

II. Plaintiff States’ Laws
Seven States have joined in this action. They are the States of New York, California, Ohio, Illinois, and North Carolina, and the Commonwealths of Pennsylvania and Virginia.

A. New York

The New York Donnelly Act, New York's antitrust statute, declares illegal

Every contract, agreement, arrangement or combination whereby ... [c]ompetition or the free exercise of any activity in the conduct of any business, trade or commerce or in the furnishing of any service in this state is or may be restrained or whereby ... for the purpose of establishing or maintaining any such monopoly or unlawfully interfering with the free exercise of any activity in the conduct of any business, trade or commerce or in the furnishing of any service in this state any business, trade or commerce or the furnishing of any service is or may be restrained.


Section 63(12) of the New York Executive Law authorizes the New York Attorney General to seek equitable relief. In relevant part, § 63 provides:

Whenever any person shall engage in repeated fraudulent or illegal acts or otherwise demonstrate persistent fraud or illegality in the carrying on, conducting or transaction of business, the attorney general may apply ... for an order enjoining the continuance of such business activity or of any fraudulent or illegal acts, [and] directing restitution and damages .... The term “persistent fraud” or “illegality” as used herein shall include continuance or carrying on of any fraudulent or illegal act or conduct. The term
“repeated” as used herein shall include repetition of any separate and distinct fraudulent or illegal act, or conduct which affects more than one person.

*N. Y. Exec. Law § 63(12).*

“Any conduct which violates state or federal law or regulation is actionable” under *Executive Law § 63(12).* *People ex rel. Vacco v. World Interactive Gaming Corp.*, 185 Misc.2d 852, 714 N.Y.S.2d 844, 848 (N.Y. Sup. Ct. 1999). When a defendant engages in conduct within New York prohibited by *Executive Law § 63(12)*, the Attorney General is authorized to seek relief on behalf of out-of-state residents injured by the wrongdoing. *People ex rel. Cuomo v. H & R Block, Inc.*, 58 A.D.3d 415, 870 N.Y.S.2d 315, 316 (1st Dep't 2009); see also *Vyera*, 2021 WL 4392481, at *4.

**B. California**


The California Unfair Competition Law prohibits “any unlawful, unfair or fraudulent business act or practice.” *Cal. Bus. & Prof. Code § 17200*. In actions brought by the Attorney General, courts may “grant such mandatory injunctions as may be reasonably necessary to restore and preserve fair competition in the trade or commerce affected by the violation.” *Cal. Bus. & Prof. Code § 16754.5*.

**C. Illinois**

The Illinois Antitrust Act (“IAA”) instructs that “[w]hen the wording of this Act is identical or similar to that of a federal antitrust law, the courts of this State shall use the construction of the federal law by the federal courts as a guide in construing this Act.” 740 Ill. Comp. Stat. 10/11. “Illinois courts interpret the state antitrust law in harmony with federal case law construing analogous provisions of federal legislation.” *McGarry & McGarry, LLC v. Bankr. Mgmt. Sols., Inc.*, 937 F.3d 1056, 1062 (7th Cir. 2019) (citation omitted). Section 10/7(1) of the IAA authorizes the Illinois Attorney General to bring actions to prevent and restrain violations of § 3 of the IAA, and courts are directed to enter such judgment as they consider necessary to remove the effects of any such violations. 740 Ill. Comp. Stat. 10/7(1).

**D. North Carolina**

Under the North Carolina Unfair or Deceptive Practices Act, *N.C. Gen. Stat. § 75-1*, “[e]very contract, combination in the form of trust or otherwise, or conspiracy in restraint of trade or commerce in the State of North Carolina is hereby declared to be illegal.” *N.C. Gen. Stat. § 75-1*. The Attorney General is authorized to investigate “all corporations or persons doing business in this State ... with the purpose of acquiring such information as may be necessary to enable him to prosecute any such corporation, its agents, officers and employees for crime, or prosecute civil actions against them if he discovers they are liable and should be prosecuted.” *N.C. Gen. Stat. § 75-9*. 
E. Ohio


F. Pennsylvania

To establish a claim under Pennsylvania's common law doctrine against unreasonable restraint of trade, the plaintiff may show that “the illegal bargain tends to create or has for its purpose to create a monopoly in prices or products,” or that “competition has in fact been restricted by the monopolistic agreement.” Collins v. Main Line Board of Realtors, 452 Pa. 342, 304 A.2d 493, 496-97 (1973) . The Pennsylvania Supreme Court has applied federal courts’ interpretation of the Sherman Act to state common law antitrust claims. See id.

G. Virginia

Virginia Code § 59.1-9.5 parallels § 1 of the Sherman Act and provides that “[e]very contract, combination or conspiracy in restraint of trade or commerce of this Commonwealth is unlawful.” Section § 59.1-9.6 parallels § 2 of the Sherman Act and provides that “[e]very conspiracy, combination, or attempt to monopolize, or monopolization of, trade or commerce of this Commonwealth is unlawful.” The Virginia Antitrust Act, Va. Code Ann. § 59.1 et seq, requires that the statute “shall be applied and construed to effectuate its general purposes in harmony with judicial interpretation of comparable federal statutory provisions.” Va. Code Ann. § 59.1-9.17. The Virginia Attorney General may seek “injunctive relief” for violations of the Act. Virginia Code § 59.1-9.15(a).

III. Liability

The Plaintiffs have shown that Shkreli is liable for Vyera's unreasonable restraint of trade and monopolization of the FDA-approved pyrimethamine market in violation of §§ 1 and 2 of the Sherman Act. His conduct also violated the competition laws of each of the Plaintiff States.

Shkreli’s anticompetitive scheme was made up of two simple but effective sets of vertical restraints. 35 Shkreli does not dispute that it was his intention to impede generic pharmaceutical companies from launching competitive products that would threaten the price of Daraprim. The Plaintiffs have shown that the restraints Vyera implemented succeeded in doing just that.

The two restraints -- restrictive distribution contracts for Daraprim and exclusive supply agreements for pyrimethamine -- exploited features of the FDA approval process for generic drug products by unreasonably and unlawfully restricting the markets for RLD and API. These agreements violated § 1 of the Sherman Act. Through these agreements, Shkreli and Vyera unlawfully and willfully maintained a monopoly in FDA-approved pyrimethamine, which is the relevant market in which Shkreli and Vyera operated their anticompetitive scheme. Vyera maintained that monopoly through anticompetitive conduct and not “from
growth or development as a consequence of a superior product, business acumen, or historic accident.” Takeda, 11 F.4th at 137 (citation omitted).

A. The Relevant Market

*36 The analysis under §§ 1 and 2 of the Sherman Act relies, as a threshold matter, on the definition of the relevant market. The Plaintiffs have proven that, by any established method, FDA-approved pyrimethamine is the relevant product market and the United States is the relevant geographic market. Shkreli does not dispute that the United States is the relevant geographic market.

Apart from a generic equivalent to Daraprim that receives FDA approval, no reasonably interchangeable substitute for Daraprim exists for the treatment of toxoplasmosis. This is true in terms both of the use of Daraprim to treat toxoplasmosis, particularly active toxoplasma encephalitis, as well as the cross-elasticity of demand for FDA-approved pyrimethamine for treatment of that disease.

In terms of its use, Daraprim is the only pharmaceutical to receive an A-I rating in the Guidelines for the treatment of active toxoplasma encephalitis. It has many unique features. Among other qualities, FDA-approved pyrimethamine targets toxoplasmosis specifically, has been successfully used in its treatment for decades, and permits a diagnosis of toxoplasma encephalitis without resort to a biopsy of the brain, which would present significant risks to patients if performed. Because death and/or significant brain damage can occur within hours, its endorsement in the Guidelines assists physicians throughout the United States to treat a highly dangerous infection with confidence, quickly, and successfully.

An analysis of the cross-elasticity of demand for FDA-approved pyrimethamine confirms this definition of the relevant market. Even in response to Vyera's drastic price hike in August 2015, appreciable numbers of physicians and their patients continued to use Daraprim. Vyera was profitably able to keep Daraprim's list price at $750 per tablet and maintain a high average net price for the drug for the four years and seven months that it marketed Daraprim without generic competition. The average net price was very substantially above the competitive price level, whether that level is measured by Daraprim's price in the years before Vyera acquired it, or in the period after its first generic competitor entered the market. As more generic competitors enter the market, of course, the average net price will fall even further.

The high degree of cross-elasticity in demand between Daraprim and FDA-approved generic pyrimethamine is demonstrated as well by the market reaction to Dr. Reddy's March 2020 launch of its first-to-market generic. In the period following that launch, both the price and sales of Daraprim (as well as Vyera's revenue and profits) promptly declined as Dr. Reddy's generic tablet was substituted for Daraprim. Daraprim sales dropped 49% in the nine-month period after March 2020 compared to the same period prior to entry, and Vyera's revenue and gross profits from Daraprim sales declined 59% between 2019 and 2020.

Finally, practical indicia of the relevant market support a finding that it is FDA-approved pyrimethamine. Shkreli and Vyera considered that to be the relevant market, as did Vyera's consultants and those the consultants interviewed. Generic drug companies also assessed the relevant market to be FDA-approved pyrimethamine. There is no evidence that the price hike for Daraprim affected the prices of any other pharmaceutical. Lastly, FDA-approved pyrimethamine is the only FDA-approved drug that specifically targets toxoplasmosis.

*37 In response to this cascade of evidence that FDA-approved pyrimethamine is the relevant product market, Shkreli argues that drug therapies trimethoprim-sulfamethoxazole (“TMP-SMX”) and compounded pyrimethamine are sufficient economic and medical substitutes for Daraprim and that they must be included in the relevant antitrust market. These therapies are not part of the relevant market.
TMP-SMX is a broad-spectrum antibiotic medication approved by the FDA in 1973 and sold under the brand names Bactrim and Septra. TMP-SMX is FDA-approved to treat certain infections, including pneumocystis jirovecii pneumonia (“PCP”). It is also available as a generic. Although TMP-SMX is not FDA-approved to treat toxoplasmosis, a fact that Vyera itself emphasized to the market, it is prescribed in certain circumstances.

TMP-SMX is an effective prophylactic treatment because it has been effective at preventing multiple opportunistic infections that tend to occur together. For example, TMP-SMX is the recommended medication as primary prophylaxis for PCP, and patients at risk for toxoplasma encephalitis but who are not suffering from an acute infection of the brain are also at risk for PCP. These patients are often prescribed TMP-SMX medications to prevent both infections and reduce the “pill burden” for patients. For this reason, TMP-SMX is also effective at the secondary prophylaxis stage, in which the goal is to prevent a relapse in a patient that has recovered from an active infection. TMP-SMX, which may be administered intravenously, is a recommended alternative treatment when a patient is incapable of swallowing pills; pyrimethamine may only be taken orally.

The most difficult stage in treating toxoplasmosis, however, is an active infection. At that point the treatment goal is to medicate the patient within hours of presenting symptoms. A pyrimethamine treatment regimen is the gold standard treatment in the case of an acute infection of toxoplasmosis. Even Vyera's Dr. Salinas viewed TMP-SMX as “medically inferior” because not enough of the drug reaches the brain or the retina (in the case of ocular toxoplasmosis) to treat an infection properly. Studies have shown that TMP-SMX is 25- to 50-times less potent than pyrimethamine. In the Guidelines, TMP-SMX is graded B-I for the treatment of toxoplasma encephalitis and recommended only “if pyrimethamine is unavailable or there is a delay in obtaining it.” As a broad-spectrum antibiotic, TMP-SMX also cannot be reliably used to confirm the diagnoses of toxoplasma encephalitis, while pyrimethamine aids in diagnosis because it is targeted to treat toxoplasmosis. Finally, TMP-SMX cannot be taken by patients with a sulfa hypersensitivity or allergy, which constitutes roughly 30-35% of all HIV-positive patients.

*38 The other therapy suggested by Shkreli as a potential substitute for Daraprim is compounded pyrimethamine, which two specialty pharmacies began selling in 2015. Compounding contains no assurance that the end product will deliver the correct amount of the API, and compounded products are not FDA-approved.

Vyera itself objected to the mass production of compounded drugs as dangerous. On November 30, 2015, Vyera warned the FDA that Imprimis, a compounding pharmacy, intended to mass produce compounded pyrimethamine. Vyera objected that compounded drugs can pose serious health risks to patients. Compounded drugs are not FDA-approved. There is no FDA premarket review. No data and information are required to demonstrate a compounded drug is safe and effective for its intended purposes .... Compounding large volumes of drugs without obtaining FDA approval, which Imprimis apparently intends to do, circumvents important public health requirements. As a result, it is not appropriate to use a compounded product in lieu of an FDA approved, commercially available product unless the compounded drug provides a medically necessary and unavailable drug for a specific patient.

Vyera's alarm that compounded pyrimethamine sales might eat into Daraprim sales was unfounded. Despite compounded pyrimethamine capsules being priced at $1 to $5, there were never significant sales of the compounded drug produced by Imprimis. The only way a patient could get Imprimis’ compounded pyrimethamine product was with a specific prescription for that product, which did not permit en masse market substitution. Imprimis sold fewer than 22,000 compounded pyrimethamine
capsules in 2016, and its sales declined thereafter. Avella, another compounding pharmacy, sold a total of 1,280 compounded pyrimethamine capsules, with no sales after 2018 due to a lack of customers.

Shkreli has pointed out that demand for Daraprim, represented by sales volume, dropped precipitously immediately after the 2015 price hike. The defendant suggests that consumers must have substituted alternative therapies for Daraprim. None of the parties have offered comparative data regarding TMP-SMX to support or contradict that hypothesis. It would be difficult to draw any conclusions from TMP-SMX data in any event because it is a broad-spectrum antibiotic prescribed for multiple infectious diseases. Sales of mass-production compounded pyrimethamine during the period of Vyera's sale of Daraprim were minimal at best. What can be said with certainty is that the market for FDA-approved pyrimethamine was sufficiently bound that Vyera was able to raise Daraprim's price to never before seen heights and earn record revenues and profits after doing so.

The practical indicia enumerated in Brown Shoe and the other evidence described above strongly support the conclusion that doctors and pharmaceutical buyers did not react to the astronomical rise in Daraprim's price by freely switching to other, cheaper drugs to treat toxoplasmosis. The demand for FDA-approved pyrimethamine remained relatively stable at approximately 250,000 tablets per year between 2016 and 2019 after the initial drop in sales in 2015. If there had been any material cross-price elasticity between Daraprim and other products at the time of the 4,000% price hike in 2015, purchasers would have abandoned Daraprim in favor of cheaper products on the market. And if alternative toxoplasmosis treatments had been constraining the price of Daraprim before March 2020, generic entry would not have resulted in the significant drop in the price for FDA-approved pyrimethamine that occurred.

*39 In sum, as a result of its distinctive attributes, FDA-approved pyrimethamine constitutes the relevant market. It treats a distinct patient population; in economic terms, it has a distinct kind of customer.

B. Monopoly Power

Having defined the relevant market, the conclusion that Vyera had a monopoly in that market follows easily. Vyera controlled 100% of the market for FDA-approved pyrimethamine market between August 2015 and March 2020. Shkreli controlled the price of Daraprim, which he acquired precisely because it was a sole-source drug in a market of its own. Vyera profitably charged a per-tablet average net price for Daraprim ranging between $228 and $305 during the full years of 2016, 2017, 2018, and 2019. These prices were also substantially above any competitive price level, which was at most $160.

C. Anticompetitive Conduct

The Plaintiffs have met their burden under § 1 of the Sherman Act of showing that the contracts at issue here were an unreasonable restraint on trade and had an adverse effect on competition. In response, Shkreli has not shown that the contracts had procompetitive benefits.

Shkreli does not dispute that he intended to block generic competition to Daraprim and strove to do so for as long as possible. Each of the API supply agreements and the restrictive distribution agreements was entered in service of that strategy. Similarly, Vyera's continued monopolistic control of the FDA-approved pyrimethamine market did not occur by accident and self-evidently harmed competition. Shkreli raised the price of Daraprim by 4,000%. Over more than four years, the average net price of a single Daraprim tablet remained hundreds of dollars. Its price did not meaningfully decline until Dr. Reddy's generic pyrimethamine penetrated the market barriers Vyera had erected.
a. Distribution Contracts

Vyera's restrictions in its distribution contracts substantially delayed generic pharmaceutical companies from acquiring sufficient RLD to conduct BE testing and receive FDA approval of their ANDAs. Those restrictions included class of trade restrictions and caps on the number of bottles that could be sold to a customer. Vyera drastically reduced the number of customers to which its distributors were authorized to sell. Vyera monitored distributors' sales closely to ensure there was no leakage. It repurchased inventory and conducted audits to learn where every bottle of Daraprim was heading. Vyera's Mulleady even went to a parking lot in New Jersey to buy back five bottles of Daraprim, paying twice the purchase price, to prevent those bottles from going to a generic pharmaceutical company.

This extraordinarily tight control of the supply of Daraprim had its intended effect. It actually delayed the entry of generic pharmaceutical companies.

*40 Vyera paid a sizeable premium to its downstream partners to keep Daraprim RLD out of the hands of its competitors. Those partners agreed to and enforced the resale restrictions, and in doing so benefitted significantly. They profited handsomely with each sale so long as Daraprim's price remained inflated.

All of Shkreli's purportedly procompetitive justifications for these distribution agreements are pretextual. He has argued that putting Daraprim in specialty distribution benefitted patients by giving them access to services that specialty pharmacies can provide. These purported benefits include advice on defraying the high cost of the drug, assistance in getting insurance coverage, and help reducing and monitoring adverse effects.

Shkreli offered no evidence, however, that patients were assisted in any of these ways. Patients didn't need help figuring out how to pay for Daraprim, of course, until Shkreli raised its price to a scandalous level and put his anticompetitive scheme in place to protect that price. And there is no evidence that FDA-approved pyrimethamine has any serious side effects, much less side effects that could be or were addressed by any specialty pharmacy. Specialty pharmacies and closed distribution are tailor-made for the administration and monitoring of drugs that have an altogether different profile from that of Daraprim. For decades Daraprim was administered safely and without problems through open distribution, and both Dr. Reddy's and Vyera's own generic entrant, the Vyera AG, returned to the open distribution model. In sum, Shkreli has failed to justify his choice of a closed distribution system. It was designed and used solely to restrict competition.

b. Exclusive Supply Agreements

Vyera's agreements with Fukuzyu and RL Fine closed off access to the two most viable suppliers of pyrimethamine for years. Vyera's exclusive supply agreements achieved their intended effect and delayed the entry of generic pyrimethamine into the market.

While the pyrimethamine manufacturing process is relatively simple, it still takes time and money to design the process, set it up, and test it. Shut out of access to Fukuzyu's and then RL Fine's API, Fera, Cerovene, and InvaTech were required to undertake a time-consuming and costly journey to develop alternative API manufacturers. Other than a desire to block competition, there was no reason to tie either Fukuzyu or RL Fine to exclusive supply agreements.

Fukuzyu had provided pyrimethamine for Daraprim in the United States without any exclusive supply agreement, and at times without any supply agreement at all, to Vyera's predecessors. Shkreli decided to change that. After months of courting, Vyera
and Fukuzyu entered into an exclusive supply agreement in January 2017. In October 2016, the same month that Vyera's science executives visited Fukuzyu in Japan, Fukuzyu upset Cerovene's plans and refused to supply it with pyrimethamine. In September of 2017, Fukuzyu refused to supply Fera with pyrimethamine in a message that repeated, word-for-word, the restrictions against human use in the United States that Vyera's Pelliccione relayed to Fukuzyu.

Vyera's agreement with RL Fine had a similarly anticompetitive purpose and effect. Vyera had no need for any agreement at all with RL Fine. Learning that generic competitors were working with RL Fine to obtain pyrimethamine, however, Vyera entered into an exclusive supply agreement with RL Fine on December 17, 2017. Vyera's pursuit of this agreement had the immediate effect of disrupting and delaying Cerovene's and InvaTech's ANDA approval process. Vyera paid millions of dollars to RL Fine for the sole purpose of blocking its rivals from access to RL Fine's pyrimethamine. The Phoenixius Board Minutes of December 2017 justified the expense in these very terms. Witness after witness from Vyera has confirmed as much.

Shkreli's attempt to justify the exclusivity provisions in these two agreements fail. He relies on the following procompetitive justifications: that the agreements ensured a steady supply of pyrimethamine and, in the case of Fukuzyu, promoted a long-term business relationship. Shkreli contends that the exclusivity clauses thus mitigated Vyera's supply risk. Neither contract did so.

Shkreli has offered no evidence that any manufacturer of Daraprim had ever been unable to obtain pyrimethamine from Fukuzyu. Moreover, Vyera's contract with Fukuzyu contained no provision that protected it against the risk that Fukuzyu might be unable to supply Vyera with FDA-approved pyrimethamine. For example, it contained no provision requiring Fukuzyu to maintain cGMPs-compliant facilities, to ensure the purity of its API, or to keep an active DMF. It did not even require Fukuzyu to fill Vyera's orders for pyrimethamine. There is nothing in the agreement that prevented Fukuzyu from selling its entire inventory of pyrimethamine to others for use outside the United States or for the treatment of animals in the United States.

There are standard provisions that protect against the risk of a loss of supply. Those provisions were absent in the Vyera contracts, but tellingly, were present in the GSK contract with Fukuzyu. Those provisions include clauses addressed to the forecasting of requirements, customer priority, reserve capacity, and firm order dates.

Moreover, while it may be common for companies to enter into exclusive supply agreements with API manufacturers when a company has invested time and money with that manufacturer to develop a new API manufacturing process, there was no such justification here. Fukuzyu already had a DMF on file and had been supplying pyrimethamine for Daraprim for decades.

Shkreli suggests that its contract with Fukuzyu was motivated by a desire to build a long-term relationship for future toxoplasmosis products. Dr. Salinas testified that Vyera has even filed INDs for some of these nascent projects. While Vyera may have used its promise of future projects to entice Fukuzyu during the contract negotiations, Shkreli has failed to explain the relevance of those projects to his desire to include a pyrimethamine exclusivity clause in the contract. The exclusivity clause had only one purpose, to eliminate competition with Daraprim.
Shkreli's justification for the RL Fine contract fails entirely. Shkreli asserts that it is common in the pharmaceutical industry to have a backup supplier. But, Vyera has failed to offer any evidence that either Vyera or any of its predecessors ever needed a backup supplier of pyrimethamine. Vyera didn't even pursue a contract with RL Fine until it learned that RL Fine was going to supply generic drug companies with pyrimethamine.

Moreover, Vyera's contract with RL Fine did not ensure that RL Fine could operate as a backup supplier if Vyera ever needed it to do so. The contract did not require RL Fine to file a DMF and RL Fine never did. Nor did the contract require RL Fine to do anything to support Vyera if Vyera amended Daraprim's NDA to include RL Fine's manufacturing process. Instead, during the life of the contract, Vyera paid RL Fine almost $9.5 million to do nothing except stop cooperating with Vyera's competitors. To put this outlay in perspective, through March 2019, Vyera spent only $500,000 buying pyrimethamine from Fukuzyu.

*42 Finally, Shkreli highlights the fact that the exclusive supply agreements were not executed until a date after each supplier refused to supply each generic company. Sophisticated contracts are not executed on the same day they are negotiated. The evidence is overwhelming that Fukuzyu and RL Fine stopped cooperating with generic drug companies who wanted to enter the U.S. market because they were negotiating exclusive supply contracts with Vyera that they considered to be more attractive. The incentives that Vyera offered to RL Fine were so enticing that it even stopped performing on its five-year contract with Cerovene.

c. Degree of Burden on Generic Competitors

Finally, Shkreli argues that the plaintiffs failed to establish that the contracts had a substantial anticompetitive effect in the relevant market. Relying on Ohio v. American Express Co., —— U.S. ——, 138 S. Ct. 2274, 2284, 201 L.Ed.2d 678 (2018) ("American Express"), he emphasizes that it is the Plaintiffs' burden to show a “substantial” anticompetitive effect from his activities and that they have failed to do so. Shkreli contends that, whatever his intent may have been, the generic manufacturers made a series of bad business decisions and were unwilling to spend the money necessary to enter the market faster. Shkreli principally points to occasions on which Fera or Cerovene did not accept an offer by an RLD supplier to find more bottles of Daraprim for them.

Shkreli did not actually prove at trial that RLD suppliers were able to acquire more bottles of Daraprim for generic pharmaceutical companies after Vyera set up its closed distribution system. To the contrary, RLD suppliers struggled to fill orders for Daraprim. And, when Reliant used its personal connection to a pharmacy to circumvent Vyera's closed distribution system and succeeded in obtaining five bottles of Daraprim, Mulleady rushed to buy those bottles back and paid twice their purchase price to do so.

Shkreli similarly argues that Vyera's competitors foolishly pursued doomed requests to the FDA to modify BE testing requirements, and in doing so lost precious time waiting for waivers that never came. He argues that it was their flawed tactics and not his restrictive agreements that were responsible for the delays that occurred here. He is wrong.

The Plaintiffs proved that Shkreli's actions had a very substantial impact on competition. Under § 1, the Plaintiffs may show the existence of anticompetitive effects from restraints on trade through direct evidence of increased prices in the relevant market, which they have done. See 1-800 Contacts, 1 F.4th at 118. Under the rule of reason test, the Plaintiffs have the burden of showing an “actual adverse effect on competition as a whole in the relevant market.” Id. at 114. Under § 2, the Plaintiffs must show that Shkreli's improper conduct “has or is likely to have the effect of controlling prices or excluding competition.” Takeda, 11 F.4th at 137 (citation omitted). The Plaintiffs have more than carried each of these burdens.
Shkreli's reliance on American Express is misplaced. The holding in that case turned on whether the plaintiffs’ direct evidence of price increases on just one side of the two-sided credit card transaction market demonstrated any anticompetitive effect at all. American Express, 138 S. Ct. at 2287.

More importantly, American Express’ unremarkable statement of the law did not revise the longstanding rule of reason test in antitrust cases. As the Supreme Court has explained, the rule of reason steps do not represent a rote checklist, nor may they be employed as an inflexible substitute for careful analysis.... [W]hat is required to assess whether a challenged restraint harms competition can vary depending on the circumstances. The whole point of the rule of reason is to furnish an enquiry meet for the case, looking to the circumstances, details, and logic of a restraint to ensure that it unduly harms competition before a court declares it unlawful.

Even under Shkreli's rigid view of the law, Shkreli's Daraprim scheme substantially impacted competition in the market for FDA-approved pyrimethamine.

Generic drug companies need not undertake herculean efforts to overcome significant anticompetitive barriers specifically erected to prevent their entry into a market. It bears repeating that “generics need not be barred from all means of distribution if they are barred from the cost-efficient ones.” Actavis PLC, 787 F.3d at 656 (citation omitted). “The test is not total foreclosure, but rather whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit.” Id. While exclusive supply and restrictive distribution agreements are not inherently unlawful, here their sole purpose and effect was to foreclose generic pharmaceutical companies from acquiring the API and RLD that would have otherwise been readily available to them in the ordinary course and that were critical to their efforts to compete with Vyera.

D. Shkreli is Individually Liable

An individual may be held liable under the Sherman Act to the extent that the individual has “participated in violations of” the antitrust laws, such as by “negotiating, voting for[,] or executing agreements which constituted steps in the progress of the conspiracy.” Hartford-Empire Co. v. United States, 323 U.S. 386, 407, 65 S.Ct. 373, 89 L.Ed. 322 (1945); see also Lorain Journal Co. v. United States, 342 U.S. 143, 145 n.2, 72 S.Ct. 181, 96 L.Ed. 162 (1951) (officers and directors “participated in the conduct alleged to constitute the attempt to monopolize”).

Shkreli is liable for the violations of §§ 1 and 2 of the Sherman Act and the parallel violations of state law. Shkreli conceived of, implemented, maintained, and controlled Vyera's anticompetitive and monopolistic scheme. His control continued after he stepped down as Vyera's CEO and even after he entered federal prison. As the company's largest shareholder, he freely changed its management and directed its policy.

Shkreli pioneered Vyera's business model at Retrophin and brought many of Retrophin's employees with him to replicate the “classic closed distribution play” at Vyera. Shkreli frankly and repeatedly acknowledged that his goal was to delay entry of a generic competitor with Daraprim for at least three years. He then planned, managed, and controlled the execution of his scheme. He erected and policed barriers around the FDA-approved pyrimethamine market in order to maintain a monopoly price for Daraprim.
Shkreli emphasizes that he did not sign any of the contracts at issue. The absence of his signature from a document does not immunize him from antitrust liability.

Shkreli argues that after December 2015 he was no longer a Vyera executive and that his ability to influence Vyera's operations was severely restricted after he was imprisoned in September 2017. The Plaintiffs have shown that Vyera remained under Shkreli's control throughout the years it maintained its monopoly on FDA-approved Daraprim. Even when incarcerated, Shkreli managed to direct its policies and choose Vyera's executives. Whether he used a smuggled phone or the prison's authorized phones, he stayed in touch with Vyera's management and exercised his power over Vyera as its largest shareholder.

IV. Remedies
*44 The Plaintiffs seek injunctive relief and the State Plaintiffs seek disgorgement. They have shown that Shkreli should be banned for life from the pharmaceutical industry and required to pay $64.6 million in disgorgement.

A. Injunctive Relief

Section 13(b) of the FTC Act authorizes the FTC to pursue permanent injunctive relief in federal court only “in proper cases ... and after proper proof.” 15 U.S.C. § 53(b). Plaintiffs must prove an ongoing or likely future violation of the antitrust laws and that injunctive relief will not only remedy that violation but also “be in the interest of the public.” Id. § 53(b)(1)-(2).

A permanent injunction is appropriate where a plaintiff shows that

there exists some cognizable danger of recurrent violation, something more than the mere possibility which serves to keep the case alive... To be considered are the bona fides of the expressed intent to comply, the effectiveness of the discontinuance and, in some cases, the character of the past violations.


To assess the likelihood of recurrence, courts consider

the fact that defendant has been found liable for illegal conduct; the degree of scienter involved; whether the infraction is an “isolated occurrence;” whether defendant continues to maintain that his past conduct was blameless; and whether, because of his professional occupation, the defendant might be in a position where future violations could be anticipated.

Sec. & Exch. Comm'n v. Commonwealth Chem. Sec., Inc., 574 F.2d 90, 100 (2d Cir. 1978).

In assessing whether to issue injunctive relief, a court balances the equities and considers the public interest. E.E.O.C. v. KarenKim, Inc., 698 F.3d 92, 100 (2d Cir. 2012). “A Government plaintiff, unlike a private plaintiff, must seek to obtain relief necessary to protect the public from further anticompetitive conduct and to redress anticompetitive harm.” Apple, 791 F.3d at
In New York, pursuant to the Donnelly Act, the Attorney General may seek and obtain an order on behalf of the State “to restrain and prevent the doing in this state of any act herein declared to be illegal, or any act in, toward or for the making or consummation of any contract, agreement, arrangement or combination herein prohibited.” N.Y. Gen. Bus. Law § 342. Pursuant to § 63(12) of the Executive Law, New York may seek “an order enjoining the continuance of [illegal or fraudulent] business activity or of any fraudulent or illegal acts.” N.Y. Exec. Law § 63(12). Upon finding a violation under Executive Law § 63(12), a court may exercise its discretion to issue a permanent and plenary ban in a particular industry. See, e.g., People v. Imported Quality Guard Dogs, Inc., 88 A.D.3d 800, 930 N.Y.S.2d 906, 907 (2nd Dep't 2011) (permanently enjoining the appellant “from selling, breeding, or training dogs, or advertising or soliciting the sale, breeding, or training of dogs”).

*45 The Plaintiffs seek a lifetime ban against Shkreli participating in the pharmaceutical industry. Banning an individual from an entire industry and limiting his future capacity to make a living in that field is a serious remedy and must be done with care and only if equity demands. Shkreli's egregious, deliberate, repetitive, long-running, and ultimately dangerous illegal conduct warrants imposition of an injunction of this scope.

The Plaintiffs presented a wealth of evidence that Shkreli conducted a comprehensive scheme that violated the antitrust laws of the United States and the competition laws of the seven States. The FTC and the States are empowered by federal and State law to seek comprehensive equitable relief. The Plaintiffs have demonstrated that a lifetime ban against Shkreli's future participation in the pharmaceutical industry will protect the public from suffering a repetition of the unlawful schemes proven in this case.

Without a lifetime ban, there is a real danger that Shkreli will engage in anticompetitive conduct within the pharmaceutical industry again. Shkreli established two companies, Retrophin and Vyera, with the same anticompetitive business model: Acquiring sole-source drugs for rare diseases so that he could profit from a monopolist scheme on the backs of a dependent population of pharmaceutical distributors, healthcare providers, and the patients who needed the drugs. The Daraprim scheme was particularly heartless and coercive. Daraprim must be administered within hours to those suffering from active toxoplasma encephalitis.

Moreover, in the face of public opprobrium, Shkreli doubled down. He refused to change course and proclaimed that he should have raised Daraprim's price higher.

The context in which Shkreli conducted his schemes cannot be ignored. He cynically took advantage of the requirements of a federal regulatory scheme designed to protect the health of a nation by ensuring that its population has access to drugs that are not only effective but also safe. He recklessly disregarded the health of a particularly vulnerable population, those with compromised immune systems. His scheme burdened those patients, their loved ones, and their healthcare providers.

A lifetime ban would not deprive Shkreli of the opportunity to practice a profession or to exercise a lawful skill for which he trained. In his trial testimony Shkreli does not even express a clear desire to return to the pharmaceutical industry. He reports that he is considering pursuing opportunities “within and outside” the pharmaceutical industry upon his release from prison.

The risk of a recurrence here is real. Shkreli has not expressed remorse or any awareness that his actions violated the law. While he takes full responsibility in his direct testimony for the increase of Daraprim's price from $17.50 to $750 per pill, he denies responsibility for virtually anything else. He argues in his testimony that he is not responsible for Vyera's anticompetitive
contracts because he did not negotiate or sign the exclusive supply agreements or the restrictive distribution agreements. He has also denied that what happened here was egregious, arguing that the Plaintiffs have not proven that any patient died due to the price he set for Daraprim. He chose to not even attend the trial.

*46* Shkreli presents several legal arguments against a lifetime industry ban. He contends that it amounts to a penalty beyond the proper scope of a court's power in equity. He argues that an industry ban is uncommon and reserved only for the most egregious cases and for cases of fraud. He argues that a ban of this scope is not narrowly tailored to match the challenged conduct. For the reasons laid out above, these arguments are unavailing. This is an egregious case; death is not the only relevant metric. If a court sitting in equity is powerless to impose a lifetime industry ban to protect the public against a repetition of the conduct proven at this trial, then the public could rightfully ask whether its wellbeing has been adequately weighed.

Shkreli appears to suggest that any injunction could be limited to banning him from acquiring commercial assets or engaging in the “day-to-day affairs of commercializing medicine.” There is no reason to believe that a narrowly crafted injunction will succeed in providing adequate protection against a repetition of illegal conduct. Shkreli has demonstrated that he can and will adapt to restrictions. With help at times from a contraband phone, Shkreli managed to control his company even from federal prison.

Shkreli's anticompetitive conduct at the expense of the public health was flagrant and reckless. He is unrepentant. Barring him from the opportunity to repeat that conduct is nothing if not in the interest of justice. “If not now, when?” Mishnah, Pirkei Avot 1:14.

B. Disgorgement

The State Plaintiffs seek disgorgement in the amount of $64.6 million to return to victims nationwide. Disgorgement is “a remedy tethered to a wrongdoer's net unlawful profits” and “has been a mainstay of equity courts.” Liu v. Sec. & Exch. Comm'n, —— U.S. ———, 140 S. Ct. 1936, 1943, 207 L.Ed.2d 401 (2020). “The district court has broad discretion not only in determining whether or not to order disgorgement but also in calculating the amount to be disgorged.” S.E.C. v. First Jersey Sec., Inc., 101 F.3d 1450, 1474–75 (2d Cir. 1996) (federal securities laws violations). “The amount of disgorgement ordered need only be a reasonable approximation of profits causally connected to the violation.... So long as the measure of disgorgement is reasonable, any risk of uncertainty should fall on the wrongdoer whose illegal conduct created that uncertainty.” S.E.C. v. Razmilovic, 738 F.3d 14, 31 (2d Cir. 2013), as amended (Nov. 26, 2013).

The Second Circuit has “adopted a two-step burden-shifting framework for calculating equitable monetary relief. That framework requires a court to look first to the [plaintiff] to show that its calculations reasonably approximated the amount of the defendants’ unjust gains and then shift the burden to the defendants to show that those figures were inaccurate.” Fed. Trade Comm’n v. Moses, 913 F.3d 297, 310 (2d Cir. 2019) (citation omitted).

New York Executive Law § 63(12) empowers the New York Attorney General to disgorge unlawfully gained profits wherever they were derived. Vyera, 2021 WL 4392481, at *4. Contrary to Shkreli's contention, there is no legal distinction between equitable monetary remedies available for fraudulent conduct and other illegal conduct occurring in the State of New York. The Plaintiffs have shown that the anticompetitive conduct in this case is at least as egregious in terms of its willfulness and harm to victims as the frauds typically subject to this equitable remedy under § 63(12).

The excess profits that Vyera gained from its sales of Daraprim amount, conservatively, to $64.6 million and must be disgorged to the States, subject to a set-off of any amount paid by the settling defendants. Shkreli is liable for this relief.
In arriving at this amount, a threshold determination is the hypothetical date or dates on which generic drug companies would have entered the market but-for Vyera's anticompetitive conduct. Here, the evidence is sufficiently robust to select those dates for two competitors, Cerovene and Fera. The record is insufficiently developed regarding the three other competitors who have entered or tried to enter the market.

a. Cerovene and Dr. Reddy's Hypothetical Entry Date

Cerovene's president Shah estimates that his company's FDA-approved generic pyrimethamine tablet, which entered the market in March of 2020, would have entered the market in September of 2017 if Cerovene had had unfettered access to Fukuzyu's API and the RLD. This is a thirty-month delay. This estimate was unchallenged at trial.

Plaintiff's economic expert Hemphill calculated Vyera's excess profits using two alternative hypothetical entry dates for Cerovene: October 2018 and December 2018. The October 2018 entry date is an extremely conservative date on which to base the calculations, and is adopted for the calculation of excess profits. The difference between October 2018 and March 2020 represents an eighteen-month delay.

b. Fera's Hypothetical Entry Date

Fera's DellaFera estimates that his FDA-approved pyrimethamine tablet, which entered the market soon after it received FDA approval in July of 2021, would have entered the market in August of 2019 if Fera had unfettered access to Fukuzyu's API and to the RLD. This is a delay of roughly twenty-four months. His estimate was unchallenged at trial.

Hemphill calculated Vyera's excess profits on the assumption that Fera's generic drug would have entered the market in October 2019, representing a twenty-three month delay. The October 2019 date is a conservative estimate and is adopted for the calculation of excess profits.

c. Vyera's Excess Profits

Hemphill's model for calculating these counterfactual profits involves four steps. First, he calculated Daraprim's actual revenue from October 2018 to December 2020. Conservatively, it was $130.6 million.

Next, he calculated Vyera's revenue in the but-for world during that same period under a number of conditions, including different generic entry dates, the numbers of generic competitors, and the effect from Vyera launching its own authorized generic earlier. Those calculations based on the October 2018 entry date for Cerovene's drug and the October 2019 entry date for Fera's drug are the relevant calculations here.

Third, using simple arithmetic, Hemphill calculated the difference between Vyera's actual profit and its profits in the but-for world in which competitive entry was not impeded by Vyera's conduct. Hemphill determined that, but-for Vyera's illegal conduct, it would have earned $67.6 million less in Daraprim revenue during that period.
Finally, taking into account that in the counterfactual world Vyera's incremental costs would have been lower because it would be selling less Daraprim, Hemphill deducted an estimated $3 million in costs that Vyera would have avoided. This four-step process yields a conservative estimate of $64.6 million in excess profits.

Shkreli has offered no different calculation of excess profits, including any opposing calculation based on later generic entry dates or competing assumptions. Accordingly, the Plaintiff States’ calculation of $64.6 million in excess profits from the sale of Daraprim is adopted.

C. Shkreli's Liability for Vyera's Excess Profits

*48 Disgorgement may be imposed against multiple defendants so long as the order is consistent with equitable principles. See Liu, 140 S. Ct. at 1949 (remanding to the Ninth Circuit to determine whether “circumstances would render a joint-and-several disgorgement order unjust”). Joint and several liability for disgorgement is properly imposed when multiple defendants have collaborated in an illegal scheme. S.E.C. v. Pentagon Cap. Mgmt. PLC, 725 F.3d 279, 288 (2d Cir. 2013). In First Jersey, an individual defendant was required to disgorge net profits accruing to his company where he was “primarily liable” for the fraud that created these profits, was “intimately involved” in the perpetration of the fraud, and was a “controlling person” of the company. 101 F.3d at 1475 (citation omitted).

Shkreli was the prime mover in this anticompetitive scheme. It was his brainchild and he drove it each step of the way. As Vyera's founder and its largest shareholder, any excess profit gained from Shkreli's scheme directly benefited him. Shkreli explains in his direct testimony that he took the actions he did at Vyera based on his belief that the "entry of a generic alternative to Daraprim ... would have a significant effect on my investment in the company." Liability for the sum of equitable monetary relief determined in this Opinion is, therefore, properly imposed against him.

The sum owed by Shkreli will be reduced by any monies paid by the settling defendants. A settlement payment may properly "be taken into account by the court in calculating the amount to be disgorged." Id.

Shkreli argues that, following the Supreme Court's decision in Liu, he may no longer be held jointly and severally responsible for Vyera's excess profits. Shkreli relies on Liu’s statement that allowing joint and several liability alongside the remedy of disgorgement “runs against the rule to not impose joint liability in favor of holding defendants liable to account for such profits only as have accrued to themselves.” Liu, 140 S. Ct. at 1945 (citation omitted). According to Shkreli, the amount of disgorgement he may be ordered to pay is limited to any profits he actually took from the scheme, and the Plaintiffs have failed to show that Shkreli personally profited at all.

Liu did not categorically reject a disgorgement order imposed against multiple parties. Liu in fact held that joint and several liability for disgorgement orders is permissible as long as they are consistent with equitable principles. Id. at 1949. The Supreme Court specifically noted that, since the common law permitted “liability for partners engaged in concerted wrongdoing ... [t]he historic profits remedy thus allows some flexibility to impose collective liability.” Id.

In this case, imposition of a disgorgement order against Shkreli serves the interests of justice, for all the reasons explained above. Shkreli was no side player in, or a “remote, unrelated” beneficiary of, Vyera's scheme. See id. He was the mastermind of its illegal conduct and the person principally responsible for it throughout the years.
Conclusion

Shkreli is liable on each of the claims presented in this action. An injunction shall issue banning him for life from participating in the pharmaceutical industry in any capacity. He is ordered to pay the Plaintiff States $64.6 million in disgorgement.

All Citations

--- F.Supp.3d ----, 2022 WL 135026, 2022-1 Trade Cases P 81,945

Footnotes

1 The seven state plaintiffs are the States of New York, California, Ohio, Illinois, and North Carolina, and the Commonwealths of Pennsylvania and Virginia.


3 Pennsylvania's statutory claim under the Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S. §§ 201-1 et seq., was dismissed.

4 On March 30, 2021, the Plaintiffs waived their right to money damages and therefore their right to a jury trial.

5 These affidavits were ordered to be filed on the day on which the witness testified or was deemed to have testified at trial.

6 The Court's procedures for non-jury trials were discussed in detail at a conference of December 10, 2021. As the parties were informed, the Court prepared a draft opinion in advance of the bench trial based on the witness affidavits and other documents submitted with the Pretrial Order and the arguments of counsel in their trial memoranda. At trial, the affiants swore to the truth of the contents of their affidavits and were tendered for cross and redirect examination, and the other trial evidence was formally received.

7 Thereafter, Shkreli withdrew the testimony of Bradshaw and the Plaintiffs withdrew the testimony of their rebuttal expert, Mansoor A. Khan.

8 The Plaintiffs filed affidavits constituting the direct testimony of five of their fact witnesses and all of their experts. The five fact witnesses were DellaFera, McDougal, Mukhopadhyay, Patel, and Shah.

9 Shkreli was arrested in December 17, 2015 on federal criminal charges. A jury convicted him on August 4, 2017. He was sentenced on March 8, 2018, principally to a term of imprisonment of eighty-four months (seven years). Shkreli was remanded to federal custody on September 13, 2017. He is currently scheduled to be released on October 11, 2023, or one year earlier pending successful completion of an early release program.
The parties had agreed that each witness would take the stand a single time at trial. To the extent Shkreli had also intended to call the witness on his own case, his “cross-examination” of the witness was not restricted by the scope of the direct testimony.

Excerpts of the deposition of a witness from an API manufacturer, the name of which has been sealed, were also received into evidence.

FDA regulations define bioequivalence as “the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study.” 21 CFR §§ 320.1, 314.3(b).


An orphan disease is a rare condition (defined in the United States as affecting fewer than 200,000 people) or a common condition in undeveloped countries that is rare in developed countries.

CTX is a life-threatening cholate excretion disorder. The patient population for CTX is very small, with roughly 2,000 patients in the United States.

Cystinuria is a rare kidney stone disorder, also with a very small patient population.

The Guidelines are published by the Centers for Disease Control and Prevention, the National Institutes of Health, and HIVMA. The Guidelines reflect the medical consensus for the benefit of “clinicians, health care providers, patients with HIV, and policymakers in the United States.” They are updated and reviewed regularly. The section addressed to the treatment of toxoplasmosis was last updated on July 25, 2017, and last reviewed on June 26, 2019.

Leucovorin is administered to mitigate pyrimethamine's suppression of the bone marrow, which would decrease white and red blood cells if left untreated.

In that period, Vyera earned revenue only from sales of one other drug, Vecamyl.

Impax had just transitioned Daraprim from retail distribution to Walgreens specialty distribution. Orders to Walgreens were to be fulfilled by another distribution partner that Vyera inherited when it acquired Daraprim, ICS, an affiliate of ABC and ASD.

Government Customers were defined in the contract as the Department of Veterans Affairs or Department of Defense sites.
Entities covered by § 340B of the Public Health Services Act, a federal discount pricing program for entities that serve indigent populations, may purchase prescription drugs at steep discounts. 42 U.S.C. § 256b. A § 340B entity was permitted to buy Daraprim for $1 per 100-pill bottle.

The FDA imposed an import ban on Ipca in 2015.

As of 2021, Vyera has filed investigative new drug applications (“INDs”) for new potential drugs but has not launched any new product.

Since Fukuzyu sells pyrimethamine to a veterinary drug company that uses it to produce drugs for horses in the United States, there was a carveout permitting Fukuzyu to continue selling the API to other U.S. drug companies for use in animals.

For a period of time, Shkreli had a contraband phone in prison that he used to communicate with, among others, Mulleady and Mithani. Fed. Trade Comm'n v. Vyera Pharm., LLC, No. 20CV00706 (DLC), 2021 WL 2201382 (S.D.N.Y. June 1, 2021).

Shkreli did not challenge this testimony at trial.

A brand-for-generic rebate is a rebate offered on the price of a brand name drug by a pharmaceutical company in exchange for a pharmacy agreeing to dispense the brand name drug in lieu of the generic version when filling prescriptions. The end payer pays the generic cost of the copay despite receiving the brand name drug.

Due to the difficulty obtaining RLD, Fera did not begin working on a DMF until late 2018. It filed the DMF on May 28, 2019.

Drug compounding is a practice whereby a pharmacist combines, mixes, or alters pharmaceutical ingredients to create a medication in a non-FDA-approved facility. Compounded drugs are not reviewed by the FDA for safety or efficacy.

At trial, Shkreli did not take issue with this timeline.

A generic of a brand name drug may be launched under the brand's preexisting FDA approval. It is known as an authorized generic.

Mulleady served as the interim Executive Director of Vyera and Phoenixus from October to December 2017, then became Vyera's CEO from January 1, 2018 until February 19, 2019. Mulleady was removed as the Chairman of the Board of Phoenixus on November 17, 2020 and removed from the Board on December 11 at another EGM called by Shkreli.

The Plaintiffs proved at trial that separate provisions in Vyera's contracts with Distributors were intended to impede the entry of generic drug companies into the FDA-approved pyrimethamine market by depriving those companies of accurate information about Daraprim sales. Through these data-blocking provisions, Distributors agreed not to provide Daraprim sales data to data aggregators such as IQVIA, Symphony Health, and Wolters Kluwer. Because the absence of this normally available market data did not impede the entry of either Cerovene or Fera, the data-blocking scheme need not be further described. The Cerovene and Fera experiences are central to the calculation of the disgorgement the State Plaintiffs seek.

Although Shkreli made no developed argument regarding this third alternative treatment, Shkreli suggests that atovaquone was another therapeutic alternative to Daraprim for the treatment of toxoplasmosis. Atovaquone is an FDA-approved antimicrobial drug for treatment of PCP and is prescribed for patients who cannot tolerate TMP-SMX. The Guidelines give atovaquone a C-III grade for primary prophylaxis of toxoplasmosis and a B-II grade as an alternative
treatment for active toxoplasma encephalitis. Shkreli has not shown that atovaquone was either therapeutically or economically substitutable with Daraprim.

37 To arrive at a figure of $160, the Plaintiffs’ economic expert Hemphill observed the average net price of Daraprim, Dr. Reddy's generic pyrimethamine, and the Vyera AG tablet for a sustained period after Dr. Reddy's generic pyrimethamine entered the market. The real-world evidence of Daraprim's price, volume, and market share after Dr. Reddy's entry in March 2020 starkly demonstrates not only that Vyera had a monopoly over Daraprim, but also that the high price maintained in that monopoly depended entirely on the absence of competition.

38 In their memorandum, filed with the Pretrial Order, the Plaintiffs requested that Shkreli be banned for twenty years from the pharmaceutical industry.

39 The FTC is precluded from seeking disgorgement. Vyera, 2021 WL 4392481, at *2.
I. Introduction

International Union of Brick Layers and Allied Craft Workers Local 1 Health Fund (“IUB”), individually and on behalf of all others similarly situated, sued Celgene Corporation (“Celgene”) for alleged violations of federal antitrust laws and state antitrust and consumer laws. (D.E. 1 (14–6997) (“IUB Compl.”).) The City of Providence (“Providence”) filed a complaint against Celgene that raised similar allegations and claims. (D.E. 1 (15–1605) (“Providence Compl.”).) Both complaints were consolidated under docket number 14–6997. (D.E. 32 (14–6997); D.E. 5 (15–1605).) Before filing the motion to dismiss Providence's complaint, Celgene filed a reply to IUB's opposition on March 30, 2015. (D.E. 31 (14–6997)). It then filed the motion to dismiss the unique state law claims in Providence's complaint on April 20, 2015 (D.E. 35 (14–6997)), and Providence filed its opposition on May 4, 2015, joining the arguments raised by IUB in its opposition that applied to their federal claims, while addressing Celgene's reasons for dismissal of its individual state law claims. (D.E. 40 (146997).) Celgene filed its reply brief to Providence's opposition on May 11, 2015. (D.E. 41 (146997).) Together, Celgene's motions seek dismissal of the entirety of plaintiffs' complaints.

Celgene, a branded manufacturer, identifies Thalomid and Revlimid as two of its most well-known products. Their generic names are thalidomide and lenalidomide. The former has a history – it was developed originally as a sleeping pill for pregnant women, was discovered to cause serious birth defect and other side effects, and was banned for decades. Because of this, when Celgene developed thalidomide as a treatment for a form of leprosy, the FDA required restricted distribution programs before granting approval to the distribution of Thalomid and Revlimid (the latter having been developed to treat different disorders but
considered to pose similar threats). Celgene has amassed what it describes as a significant portfolio of unexpired patents which cover Thalomid and Revlimid as medicines and also their delivery without the risk of fetal exposure.

IUB, which maintains its principal place of business in Wallingford, Connecticut, purchased Thalomid and Revlimid for its members in Massachusetts and Nebraska, or partially reimbursed members who purchased the drugs. Providence, a municipal corporation, is a “self-insured health and welfare benefit plan” located in Providence, Rhode Island, that purchased and/or provided reimbursement for Thalomid and Revlimid on behalf of “its active and retired public employees and their dependents who reside in Florida, Kansas, Massachusetts, New Jersey, North Carolina, and Pennsylvania.” Central to plaintiffs' theory of their lawsuit as indirect purchasers of these drugs is Celgene's dominance over the market for thalidomide and lenalidomide, and how/if generic manufacturers will enter the market. As such, the Hatch–Waxman Act and the Food and Drug Administration (“FDA”) regulations that govern the approval of pioneer and generic drugs are critical to this litigation.

*2 Plaintiffs contend that Celgene fraudulently obtained patents covering its distribution methods, and that then Celgene manipulated the FDA regulatory scheme and Hatch–Waxman Act to prevent or delay generic manufacturers from obtaining FDA approval for generic versions of Thalomid and Revlimid by bringing sham infringement lawsuits. They contend further that Celgene withheld samples of thalidomide and lenalidomide from generic manufacturers (but not from researchers) to foil their efforts to gain FDA approval for generics. According to plaintiffs, Celgene's only purpose for the foregoing conduct was to maintain its monopoly over the market for thalidomide based drugs in order to continue to charge consumers supracompetitive prices. Plaintiffs' federal and state antitrust claims and unfair competition and unjust enrichment claims against Celgene are brought on behalf of indirect purchasers in several states, the District of Columbia, and Puerto Rico who paid or provided reimbursement for those drugs, other than for re-sale since November 7, 2010. (IUB Compl., ¶ 7; Providence Compl., ¶ 8.)

In deciding Celgene's motion to dismiss, the Court addresses the arguments raised in Celgene's moving briefs (D.E. 20–1 (“Celgene Br.”); D.E. 35–1); IUB's and Providence's opposition briefs (D.E 29; D.E 40); and Celgene's replies to plaintiffs' respective opposition briefs. (D.E. 31; D.E. 41.)

II. Background
The facts taken from the plaintiffs' complaints are assumed as true, and are construed in favor of plaintiffs for purposes of Celgene's motions. Phillips v. Cnty. of Allegheny, 51 F.3d 224, 231 (3d Cir.2008).

A. Overview of FDA Regulations

1. Development of Pioneer and Generic Drugs

The parties largely agree about what statutory and regulatory law applies, and how it works. Pharmaceutical manufacturers seeking to market a pioneer drug must obtain the Food and Drug Administration's (“FDA”) approval by filing a New Drug Application (“NDA”). 21 U.S.C. § 355(a). The NDA must include information pertaining to the proposed drug's safety and effectiveness, along with the patents that cover it. § 355(b)(1). For each patent, the NDA must list:

the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the [NDA] or which claims a method of using such drug and with respect to which a claim of
patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.

*3 The ANDA applicant must submit a certification for each patent covering the pioneer drug listed in the Orange Book that makes one of the following representations: (1) that no patent information was filed with the FDA covering the pioneer drug; (2) that the listed patent expired; (3) that the patent will expire on a certain date and that the ANDA's approval should be delayed until then; or (4) that the patent “is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.” § 355(j)(2)(B)(vii). The fourth representation is often referred to as a Paragraph IV Certification. See Janssen Pharmaceutica, N.V. v. Apotex, Inc., 540 F.3d 1353, 1356 (Fed.Cir.2008).

The ANDA applicant must notify the patent holder (frequently the pioneer manufacturer) when filing a Paragraph IV Certification. 21 U.S.C. § 355(j)(2)(B). Two contingencies affect an ANDA for which a Paragraph IV Certification is filed:

1. whether the pioneer drug company brings an infringement action within 45 days of learning of the Paragraph IV ANDA filing, and
2. whether the company seeking approval was the first one to file an ANDA containing a Paragraph IV certification to the listed patent.

Janssen, 540 F.3d at 1356. If the brand name manufacturer does not sue within 45 days, the FDA may grant final approval to the ANDA after all other requirements are satisfied. 21 U.S.C. § 355(j)(5)(B)(iii). But if an infringement action is instituted within that 45–day period, approval is stayed for 30 months or until resolution of the lawsuit. Id. In this regard, the mere act of filing a Paragraph IV Certification constitutes patent infringement allowing the patent holder to immediately file suit against the ANDA applicant. 21 U.S.C. § 271(e)(2)(A).

The Hatch–Waxman Act provides a 180 day period of exclusivity to the first generic manufacturer to file a Paragraph IV Certification once its generic drug is approved. Janssen, 540 F.3d at 1356; see also 21 U.S.C. § 355(j)(5)(B)(iv). That 180–day
period begins to run from the date the generic drug is first marketed. § 355(j)(5)(B)(iv)(I). An ANDA applicant that fails to market the drug upon the expiration of certain time frames forfeits that exclusivity period. § 355(j)(5)(D)(i)(I).

2. FDA Citizen Petitions

A private entity may file a citizen petition requesting, among other things, that the FDA issue, amend, or revoke a regulation, or that the agency take or refrain from any administrative action. 21 C.F.R. § 10.30(b). The citizen petition must contain “the factual and legal grounds on which the petitioner relies.” Id. Citizen petitions are sometimes filed in response to an ANDA, but the FDA cannot delay the application's approval unless it determines “that delay is necessary to protect the public health.” 21 U.S.C. § 355(q)(A)(ii).

B. Celgene’s Development of Thalomid and Revlimid

After the worldwide ban of thalidomide was lifted in 1998, Celgene obtained FDA approval to market and distribute it under the brand name Thalomid to treat erythema nodosum leprosum, a form of leprosy. (IUB Compl., ¶ 66–67.) In 2005, Celgene received approval to manufacture and market Revlimid, or lenalidomide, a “thalomid analogue.” (Id. ¶ 69; Providence Compl., ¶ 109.)

The FDA conditioned its approval on Celgene’s developing restricted distribution programs for the two drugs. (Providence Compl. ¶ 4.) In 1998, Celgene devised and implemented a program known as S.T.E.P.S., the acronym for the System for Thalidomide Education and Prescribing Safety. (IUB Compl., ¶ 67.) In 2010, S.T.E.P.S. was replaced by REMS, Risk Evaluation and Mitigation Strategies. (Providence Compl., ¶ 4.) All thalidomide and lenalidomide distributors, pharmacists, and recipient patients are required to enroll in the REMS program as a condition of obtaining Thalomid or Revlimid. (Id. ¶ 4.)

*4 Celgene acquired six patents covering the procedures for the approved distribution of Thalomid and Revlimid: Patent No. 6,045,501 (“the ‘501 Patent”); Patent No. 6,315,720 (“the ‘720 Patent”); Patent No. 6,561,976 (“the ‘976 Patent”); Patent No. 6,561,977 (“the ‘977 Patent”); Patent No. 6,755,784 (“the ‘784 Patent”); and Patent No. 8,513,886 (“the ‘886 Patent”) (collectively “the Distribution Patents”). (Providence Compl., ¶ 108.) In 1998, when the FDA approved Thalomid, Celgene had listed only the ‘501 Patent in the Orange Book. (Id. ¶ 110.) Celgene added the other patents under Thalomid as they were obtained: the ‘720 Patent in 2001; the ‘976 Patent and ‘977 Patent in 2003; and the ‘784 Patent in 2004. (Id. ¶¶ 108, 110.) Celgene listed the same patents under Revlimid when the FDA approved it in 2005. (Id. ¶ 110.) In 2012, Celgene added the ‘886 Patent to the Orange Book listings for both Thalomid and Revlimid. (Id. ¶¶ 108, 110.) The Distribution Patents, according to plaintiffs, generally claim “the use of registries to register patients, prescribers, and pharmacies when the patient is using a particular drug that should not be exposed to a fetus or contraindicated individual”; periodic testing of patients for risks related to the drug; patient counseling about those risks; limitations on the amount of drug dispensed; and/or prescribing or dispensing the drug to patients after determining the risks are acceptable. (Id. ¶ 110; IUB Compl., ¶ 123.)


Plaintiffs assert that Celgene had monopoly power over the markets for the drugs in question, and gained and maintained its monopoly power by anti-competitive conduct that successfully suppressed the entry of generic thalidomide and lenalidomide products into the market. According to plaintiffs, Celgene “possessed and exercised monopoly power over the markets for Thalomid and Revlimid, because it had the power to raise and/or maintain the price of Thalomid and Revlimid at supracompetitive levels without losing substantial sales.” (Providence Compl., ¶ 269.) Plaintiffs recite a “dramatic increase” in the revenue Celgene derives from sales of the drugs, which have amounted to $20.9 billion in revenue since 2006. (IUB Compl., ¶ 3.) In the first quarter of 2014 alone, Celgene recorded $3.6 billion in revenue from Revlimid sales and $164 million from
Thalomid sales. (Providence Compl., ¶ 5; IUB Compl., ¶ 3.) When it was first approved, Thalomid cost approximately $6 per capsule and now it costs between $212 and $357. (IUB Compl., ¶ 3.) Celgene charges $500 per capsule of Revlimid. (Id.)

Celgene's “overarching anti-competitive scheme” consisted of using its REMS programs as a pretext to deny generic manufacturers access to samples of Thalomid and Revlimid necessary to complete bioequivalency testing; fraudulently obtaining various patents, including the distribution method patents; engaging in sham litigation and, in certain cases, entering into confidential settlements that may have included an anti-competitive reverse payment; and filing baseless citizen petitions with the FDA. (Providence Compl. ¶ 260.) This conduct was undertaken to prevent and delay the sale of generic thalidomide and lenalidomide products “by suppressing the ability of generic manufacturers to compete through the most efficient means of competition available under the applicable statutory and regulatory construct, including the Hatch–Waxman Act.” (Id.)

1. Celgene Restricts the Supply of Thalidomide and Lenalidomide

Plaintiffs assert that Celgene actively sought to prevent generic drug manufacturers from obtaining samples of thalidomide and lenalidomide containing the active pharmaceutical ingredient (“API”) essential for bioequivalency studies and validation testing that ANDAs require. (IUB Compl., ¶¶ 70, 80; Providence Compl., ¶ 61.) They contend that Celgene used the S.T.E.P.S. and REMS programs as a pretext to deny generic manufacturers access to the samples and that it also attempted to limit the availability of samples from other potential thalidomide API suppliers.

According to the allegations, two drug manufacturers, Mylan Pharmaceuticals and Lannett Company, sought to develop and market generic versions of Thalomid, and Dr. Reddy's Laboratory wanted to develop a generic alternative to Revlimid. (Id. ¶¶ 88, 99, 118; Providence Compl., ¶¶ 73, 81.) The three companies asked Celgene for samples to use in their bioequivalency studies. (IUB Compl., ¶¶ 93, 99, 118.) Plaintiffs claim that Celgene refused, claiming that providing samples would violate its S.T.E.P.S. distribution program. (Id. ¶¶ 93, 110, 119–121.) This was contrary to FDA communications with the generic manufacturers, which they forwarded to Celgene, and which stated that the agency would not take action if Celgene provided the samples. (Id. ¶¶ 90, 93, 105, 110.)

Faced with Celgene's refusal, Lannett sought an injunction, and plaintiffs allege that Celgene settled in 2011 on confidential terms. (Id. ¶ 95–96.) Mylan sued Celgene in this district in April 2014 after it refused to provide Revlimid samples. (Id. ¶ 112.) Celgene unsuccessfully moved to dismiss. (Providence Compl., ¶ 99.) Dr. Reddy's filed a citizen petition with the FDA in June 2009, asserting that Celgene improperly denied it access to Revlimid samples for bioequivalency testing. (IUB Compl., ¶ 120.) The complaints do not indicate how that effort fared.

According to IUB's complaint, Barr Laboratories (“Barr”) successfully obtained the thalidomide API in 2004 from Seratec S.A.R.L. (“Seratec”), a French company. (Id. ¶¶ 81, 82.) After Barr completed its bioequivalency testing, it needed a Drug Master File (“DMF”) reference letter from Seratec to include with its ANDA submissions. (Id. ¶ 82.) Seratec refused Barr's request. (Id. ¶ 83.) Plaintiffs claim there was an “exclusive thalidomide supply arrangement” between Celgene and Seratec that Celgene had demanded so as “to interfere with potential generic competitors' ability to market a generic version of Thalomid.” (Id.) Barr had to find an alternative supplier and repeat its bioequivalency testing, which delayed its ANDA filing until December 2006. (Id. ¶ 84; Providence Compl., ¶ 72.) Plaintiffs assert that Barr's application would have been submitted “years earlier,” and a lower-priced generic version of Thalomid would have been available for purchase, had Celgene not interfered. (Id. ¶ 85; Providence Compl., ¶ 72.)

According to plaintiffs, despite its practice of denying generic manufacturers access to samples, Celgene has supplied samples to several research institutions when requested without raising S.T.E.P.S. or the REMS programs as a bar. (Id. ¶¶ 76, 77.)
2. **Celgene’s Fraudulently Obtained Patents**

Plaintiffs allege that Celgene fraudulently obtained the Distribution Patents covering S.T.E.P.S. and REMS in order to extend its monopoly power over the thalidomide and lenalidomide markets, and engaged in sham enforcement litigation. (Providence Compl., ¶¶ 107, 175.) They claim that when it applied for its Distribution Patents, Celgene withheld “information known to be material to patentability with the intent to deceive” the United States Patent and Trademark Office (“USPTO”) regarding prior art that it knew about. (IUB Compl., ¶¶ 129–33.) And plaintiffs take the position that Celgene listed the Distribution Patents in the Orange Book solely to discourage thalidomide and lenalidomide ANDA filings. (*Id.* ¶ 127.)

The prior art consists of ten “[p]rocedures for safe distribution and use of dangerous drugs,” which may be grouped into three categories: pharmaceutical distribution programs and packaging, publications, and meetings. From the allegations, it appears that all relate to the methods that were instituted in connection with distributing Clozaril, Clozapine, and Accutane safely, and how this might apply to thalidomide.

*6 **Pharmaceutical Distribution Programs and Packaging**

1. Clozaril Patient Monitoring Service (“CPMS”);
2. Accutane Pregnancy Prevention Program (“PPP”);

*Publications*

6. “Guide to the Clozaril Patient Monitoring Service,” (“the Guide”), which was published in 1997, and described the details of CPMS;

*Meetings*

8. CDC Meeting—a Centers for Disease Control (“CDC”) public meeting titled “Preventing Birth Defects Due to Thalidomide Exposure” and its corresponding transcript from March 26, 1997 (“CDC Transcript”);
9. CDER Meeting—a public meeting held by the Center for Drug Evaluation and Research of the FDA on September 4 and 5, 1997;

(*Id.* ¶ 131.)
Plaintiffs contend that Bruce Williams, a Celgene employee and the named inventor of the Distribution Patents, and Dr. Jerome Zeldis, then-president of medical affairs at Celgene, attended the CDC Meeting in March 1997 at which CPMS and PPP were discussed as foundations for developing similar distribution methods and controls for thalidomide. (Id. ¶¶ 160, 161.) And they go on to assert that later that same year, Williams gave presentations at both the CDER meeting and NIH meeting regarding the creation of a distribution and control program for thalidomide that was a corollary to CPMS and PPP. (Id. ¶¶ 174, 175, 179, 180.) Plaintiffs also assert that Williams, along with other Celgene employees, authored and published the Zeldis Article in 1999, which describes S.T.E.P.S. and acknowledges that the program was based on CPMS and PPP. (Id. ¶¶ 165–67.) According to plaintiffs, the Zeldis Article cites to Honigfeld I and II in its discussion of CPMS. (Id. ¶ 168.)

Plaintiffs allege that nine of the ten examples they cite are prior art to all of the Distribution Patents. The exception is the Zeldis Article, which they assert is prior art to all except the '501 Patent and '976 Patent. (IUB Compl., ¶¶ 140, 143, 146, 149, 153, 156, 162, 164, 176, 181, 183.) They contend that Celgene omitted all prior art material to the '501, '720, '976, '977, and '784 Patents' applications. (Id. ¶¶ 184–191.) As to the '886 Patent, plaintiffs maintain that Celgene disclosed eight references of prior art and only omitted the PPP Package and CDC transcript from its application. (Id. ¶ 197.) Plaintiffs charge that Celgene willfully and fraudulently withheld the prior art from the USPTO (IUB Compl., ¶¶ 190, 191, 208, 209), and as a consequence the Distribution Patents are invalid and unenforceable. Over all, plaintiffs allege that Celgene's sole purpose in listing these patents in the Orange Book was to invoke the benefits of the 30–month stay in 21 U.S.C. § 355(j)(5)(B)(iii) should an ANDA be filed. (Id. ¶¶ 192, 194, 204.)

3. Sham Litigation and Citizen Petition

Plaintiffs further contend that Celgene engaged in “sham litigation” to enforce the Distribution Patents (IUB Comp., ¶¶ 211, 213, 226–29, 238; Providence Compl., ¶¶ 195, 210), and that Celgene filed a sham citizen petition in 2007 in response to Barr's 2006 ANDA, urging the FDA to withhold approval. (IUB Compl., ¶¶ 212, 216, 220–22.) Factually, plaintiffs point to Celgene's 2007 lawsuit against Barr after it filed its Paragraph IV Certification, which triggered the 30–month stay of FDA approval for Barr's thalidomide ANDA. (Id. ¶¶ 213–15.) On May 26, 2010, not long after the stay expired, Celgene and Barr reached a confidential settlement. (Id. ¶ 126.) These events “had the anti-competitive effect of keeping generic alternatives to Thalidomide off the market.” (Id.)

Plaintiffs allege that the settlements with Barr and Lannett are “reverse payment patent settlements,” also known as pay-for-delay agreements. (Id. ¶¶ 217, 239.) They maintain that Celgene paid the manufacturers either to delay or to postpone their entrance into the thalidomide or lenalidomide markets. (Id. ¶¶ 217, 218, 242; Providence Compl., ¶ 240.)

Celgene filed a patent infringement suit against Natco, whose Paragraph IV Certification was directed against the earliest five Distribution Patents, along with Patent No. 5,635,517 (“the '517 Patent”), Patent No. 6,281,230 (“the '230 Patent”), Patent No. 6,555,554 (“the '554 Patent”), Patent No. 7,119,106 (“the '106 Patent”), and the Patent No. 7,465,800 (“the '800 Patent”), which, according to plaintiffs, covered Revlimid's chemical composition. (Id. ¶¶ 225, 226.) While the lawsuit was pending, Celgene listed two more patents in the Orange Book covering Revlimid. (Id. ¶¶ 229, 230.) Natco filed a second Paragraph IV Certification on March 14, 2013, claiming those patents were also invalid, unenforceable, or not infringed by Natco's generic lenalidomide. (Id. ¶ 231.) Almost three years after it instituted the patent infringement suit against Natco, Celgene listed two other patents in the Orange Book under Revlimid: Patent No. 8,404,717 (“the '717 Patent”) and Patent No. 8,431,509 (“the '598 Patent”). (Id. ¶ 232–33.) Through a series of amended complaints in its lawsuit against Natco, Celgene has, according to plaintiffs, pursued its goal of delaying generic entry into the Revlimid market. (Id. ¶ 238.)
D. Celgene's Overall Anti-Competitive Scheme

Plaintiffs allege that Celgene engaged in an anti-competitive scheme to “block[] and delay[] generic Thalomid and Revlimid competition, disrupt[] the normal channels, and the statutory and regulatory mechanisms, by which generic competition takes place ... , and exclude[] would-be generic competitors from the most efficient means of distributing their products.” (Id. ¶ 243.) Were it not for Celgene's anti-competitive conduct, plaintiffs claim that generic versions of Thalomid and Revlimid would have entered the market, thus “driving down the cost” of thalidomide and lenalidomide products and increasing consumer choice. (Providence Compl., ¶¶ 243, 244.) They assert that “[t]he enormous cost savings” that generic drugs would afford consumers “outweigh” any justification that Celgene could offer and that any reasons it does put forth are pretextual. (IUB Compl., ¶ 248.) Plaintiffs conclude that Celgene did not maintain its monopoly power through “meritorious competition” but did so through unlawful, willful exclusionary conduct violating federal and state laws. (Providence Compl., ¶ 247.)

E. Procedural History

IUB filed its five-count class action complaint against Celgene on November 7, 2014, on behalf of:

All persons or entities who purchased and/or paid for some or all of the purchase price for thalidomide or lenalidomide in any form, in the United States, and its territories for consumption by themselves, their families, or their members employees, insureds, participants, or beneficiaries at any time during the period of November 7, 2010 through and until the anticompetitive effects of [Celgene's] unlawful conduct cease.

(Providence Compl., ¶ 252.) Providence filed its five-count class action complaint on March 3, 2015, on behalf of a similarly defined class. (Providence Compl., ¶ 250.) IUB and Providence, in counts 1 and 2 of their complaints, allege that Celgene's scheme constituted unlawful monopolization and attempted monopolization under state law. (IUB Compl., ¶¶ 282–99; Providence Compl., ¶¶ 279–92.) IUB asserts that Celgene violated 27 state laws in count 1 and 30 in count 2 (IUB Compl., ¶¶ 289, 295), and Providence relies on 25 state laws in count 1 and count 2. (Providence Compl., ¶¶ 286, 292.) Count 3 of both complaints contends that Celgene engaged in unfair and deceptive trade practices under state law. (IUB Compl., ¶¶ 296–99; Providence Compl., ¶¶ 293–96.) Plaintiffs, in their respective fourth counts, request injunctive relief under the Clayton Act, 15 U.S.C. § 26, ordering Celgene to cease its alleged anti-competitive activities, asserting that they contravene Section 2 of the Sherman Antitrust Act (“the Sherman Act”), 15 U.S.C. § 2. (IUB Compl., ¶¶ 300–02; Providence Compl., ¶¶ 297–99.) The last claim contends that Celgene was unjustly enriched by its anti-competitive and unlawful acts in the form of the economic benefit conferred on it by plaintiffs and their prospective class when they purchased and/or provided reimbursement for the cost of Thalomid and/or Revlimid. (IUB Compl., ¶¶ 303–15; Providence Compl., ¶¶ 300–12.)

III. Discussion

A. Standard of Review

“Detailed factual allegations” are not required for a plaintiff to survive a motion to dismiss, but there must be more in the complaint than “the-defendant-unlawfully-harmed-me accusation[s]” and legal conclusions. Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). The plaintiff must set forth “ 'sufficient factual matter' to show that a claim is facially plausible” so as to permit “ 'the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.' ” Fowler v. UPMC Shadyside, 578 F.3d 203, 210 (3d Cir.2009) (quoting Iqbal, 556 U.S. at 678).
B. Sherman Act Claims – Plaintiffs’ Fourth Counts
Celgene first challenges the fourth counts in plaintiffs’ complaints, which bring claims under Section 2 of the Sherman Act and seek injunctive relief pursuant Section 16 of the Clayton Act. Section 2 of the Sherman Act makes it unlawful for any person to “monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States.” 15 U.S.C. § 2. Injunctive relief is available to prevent “against threatened loss or damage by a violation of the antitrust laws” pursuant to the Clayton Act. § 26. To state a plausible claim for relief under Section 2 of the Sherman Act, the plaintiff must show that the defendant (1) possessed “monopoly power in the relevant market” and (2) willfully acquired or maintained that power “as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.” Broadcom Corp. v. Qualcomm Inc., 501 F.3d 297, 307 (3d Cir.2007) (quoting United States v. Grinnell Corp., 384 U.S. 563 570–71 (1966)) (internal quotation marks omitted).

1. Antitrust Causation and Injury
Celgene contends that plaintiffs lack antitrust standing, having failed to show antitrust causation or injury. The requirements of antitrust injury and standing, although mutually exclusive, often overlap. See Animal Sci. Prods., Inc. v. Chin Minmetals Corp., 903 F.3d 465, 492 (D.N.J.2014) (McNulty, J.). To satisfy the requirements of injury, a plaintiff must show “(1) 'injury of the type the antitrust laws were intended to prevent,' and (2) injury that 'flows from that which makes the defendants' acts unlawful.’ ” Int'l Raw Materials, Ltd. v. Stauffer Chem. Co., 978 F.3d 1318, 1328 (3d Cir.1992) (quoting Brunswick Corp. v. Pueblo Bowl–O Mat, Inc., 429 U.S. 477, 489 (1977)). And while an injury may be “causally related to an antitrust violation,” it will not constitute antitrust injury “unless it is attributable to an anti-competitive aspect of the practice under scrutiny.” Atlantic Richfield Co. v. USA Petroleum Co., 495 U.S. 328, 334 (1990). Celgene's argument rests on two premises. First, it maintains that plaintiffs fail to plead causation and injury because the Noerr Pennington Doctrine immunizes it from antitrust liability for asserting its patents covering Thalomid and Revlimid against generic drug manufacturers. 9 Second, Celgene argues that its numerous patents covering Thalomid and Revlimid (“the Non–Distribution Patents”) operate as an independent bar to market entry for generic versions of those drugs. Celgene therefore concludes that “[n]o generic manufacturer could have brought generic versions of Revlimid and Thalomid to market in any event, for the wholly independent reason that, as a matter of law Celgene can assert (and has asserted) patents in its portfolio that [plaintiffs do] not, and could not legitimately, challenge as having been fraudulently procured or sham asserted.” (Celgene Br. at 2–3.)

a. The Noerr Pennington Doctrine

*10 Celgene contends that its conduct in asserting its patents is immune from antitrust liability under the Noerr Pennington Doctrine. Plaintiffs counter by asserting that Celgene engaged in sham litigation and obtained the Distribution Patents by committing fraud on the USPTO, stripping it of any immunity it could claim under Noerr Pennington.

“Whether conduct in procuring or enforcing a patent is sufficient to strip a patentee of its immunity from the antitrust laws” is resolved applying Federal Circuit law, while Third Circuit law applies “to issues involving other elements of antitrust law.” Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1068 (Fed.Cir.1998). The Noerr Pennington Doctrine stands for the proposition that “the Sherman Act does not prohibit ... persons from associating together in an attempt to persuade the legislature or the executive to take particular action with respect to a law that would produce a restraint or a monopoly.” Noerr, 365 U.S. at 136; accord Pennington, 381 U.S. at 670. This includes the use of “state and federal agencies to advocate their causes and points of view respecting resolution of their business and economic interests vis-à-vis their competitors.” Cal.

The Supreme Court has carved out two exceptions to Noerr Pennington immunity. The first, which relates solely to patents, is based on Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp., 382 U.S. 172 (1965). A plaintiff raising a Walker Process claim alleges that the defendant is “bringing a suit to enforce a patent with knowledge that the patent is invalid or not infringed, and the litigation is conducted for anti-competitive purposes.” C.R. Bard, Inc. v. MS Sys., Inc., 157 F.3d 1340, 1368 (Fed.Cir.1998). Noerr Pennington immunity does not attach, and a defendant is liable under antitrust laws, when it procures a patent “by knowing and willful fraud” and “enforced the patent with knowledge of the fraudulent manner in which it was obtained.” Ritz Camera & Image, LLC v. SanDisk Corp., 700 F.3d 503, 506 (Fed.Cir.2012); see also Walker Process, 382 U.S. at 179 (Harlan, J., concurring). The additional elements of a Section 2 claim, such as monopoly power, must also be shown. See Hydril Co. LP v. Grant Pridence LP, 474 F.3d 1344, 1349 (Fed.Cir.2007) (stating that the other elements of a claim under Section 2 of the Sherman Act must be present when an antitrust violation is premised on a fraudulently obtained patent).

The second exception applies to “petitions and lawsuits that are a 'mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor.' ” Chemiior Drugs, Ltd. v. Ethyl Corp., 168 F.3d 119, 122 (3d Cir.1999) (quoting Noerr, 365 U.S. at 144). In identifying sham litigation, a court must first assess whether the lawsuit is “objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits.” PRE, 508 U.S. at 60. If so, the inquiry then turns to “whether the baseless lawsuit conceals an attempt to interfere directly with the business relationships of a competitor through the use of the governmental process—as opposed to the outcome of that process—as an anticompetitive weapon.” Id. at 60–61 (citations and internal quotation marks omitted).

*11 A patent owner can be stripped of antitrust immunity under either exception. The sham litigation exception precludes a patent holder from Noerr Pennington immunity if the suit is “based on a theory of infringement or validity that is objectively baseless,” in that no reasonable person would believe that the patent was infringed or valid, and if it is “subjectively brought in bad faith.” Nobelpharma, 141 F.3d at 1072. “[I]f a suit is not objectively baseless, an antitrust defendant's subjective motivation is immaterial,” and the sham litigation exception does not apply. Id. For a Walker Process claim, in contrast, the mindset of the patent holder in enforcing a patent is irrelevant because, once it is shown that a patent was knowingly and willfully procured by fraud, the patent owner may not hide under shelter of Noerr Pennington irrespective of its reasons for bringing suit. See Dippin’ Dots, Inc. v. Mosey, 476 F.3d 1337, 1346 (Fed.Cir.2007) (“A party who asserts such a fraudulently obtained patent may be subject to an antitrust claim.”).

i. Walker Process Claim

Celgene argues that plaintiffs' allegations fall short of the heightened pleading standard of Fed.R.Civ.P. 9(b), which applies to Walker Process claims. “Rule 9(b) requires identification of the specific who, what, when, where, and how of the material misrepresentation or omission committed before the [USPTO].” Exergen Corp. v. Wal–Mart Stores, Inc., 575 F.3d 1312, 1327 (Fed.Cir.2009). A plaintiff alleging that a patent was procured through fraud under Walker Process must show:
(1) a false representation or deliberate omission of a fact material to patentability, (2) made with the intent to deceive the patent examiner, (3) on which the examiner justifiably relied in granting the patent, and (4) but for which misrepresentation or deliberate omission the patent would not have been granted.

_C.R. Bard_, 157 F.3d at 1364. But “[a] mere failure to cite a reference to the [USPTO] will not suffice” as a willful omission because “the applicant could have a good-faith belief that disclosure was not necessary, or simply have forgotten to make the disclosure.” _Dippin' Dots_, 476 F.3d at 1347 (citation and internal quotation marks omitted). “There must be evidence of intent separable from the simple fact of the omission.” _Id._

A patent applicant has a duty of candor to the USPTO, which includes disclosing all prior art, 37 C.F.R. § 1.56(a), and “[a] patent is invalid for anticipation if a single prior art reference discloses each and every limitation of the claimed invention.” _Schering Corp. v. Geneva Pharm._, 339 F.3d 1373, 1377 (Fed.Cir.2003). Among the classes of prior art, the one relevant to the present matter is that which precludes the issuing of a patent when “the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.” 35 U.S.C. § 102(a)(1).

Plaintiffs allege that Celgene fraudulently procured the six Distribution Patents, the earliest of which was obtained on April 4, 2000, by knowingly omitting ten references of anticipatory prior art material to their patentability. (IUB Compl., ¶ 135.) Celgene argues these allegations fail to meet the heightened pleading standard of Fed.R.Civ.P. 9(b) because they do not explain how the prior art “materially differ[s] from, and/or was not cumulative of, the prior art” it disclosed to the USPTO while prosecuting the Distribution Patents. Celgene also contends that the pleadings are insufficient to show fraud on the USPTO because plaintiffs failed to explain how the references of prior art “are materially similar to, and/or anticipatory of,” any of the Distribution Patents' claims.

According to plaintiffs, Celgene employees attended the CDER Meeting and NIH Meeting, easily raising the inference that Celgene was aware of those two references of prior art at all times before procuring the earliest Distribution Patent. (IUB Compl., ¶¶ 171, 172, 179, 180.) And plaintiffs assert that Williams, a named inventor of the Distribution Patents, gave presentations at both meetings about developing a restricted distribution program for thalidomide, extrapolating the methods used for Accutane and Clozaril. (Id. ¶¶ 174, 175, 179, 180.) Williams's knowledge of the Accutane and Clozaril programs raises the inference that he, and in turn Celgene, was aware of CPMS, PPP, and the PPP Package. This knowledge is further shown by the assertions that Williams and Zeldis were at the CDC Meeting during which PPP and CPMS were discussed. (Id. ¶¶ 159–61.) Plaintiffs also claim that the Zeldis Article, which Williams and other Celgene employees authored, cites to Honigfeld I and II, implying a knowledge of those two references of alleged prior art. (Id. ¶¶ 165–168.) Last, Celgene included the Guide as prior art in the '886 Patent's application. (Id. ¶ 197.)

*12* Plaintiffs note that Celgene included eight of the ten references of prior art in the 2010 application for the '886 Patent, the latest of the Distribution Patents. (IUB Compl, ¶¶ 197–98.) This raises the inference that Celgene believed those eight references of prior art were material to the '886 Patent's application and the others as well. Plaintiffs therefore plausibly allege that Celgene willfully omitted the prior art from the prior applications with the intent to deceive the USPTO. The issuance of the patents demonstrates justifiable reliance by the USPTO. See _Unitherm Food Sys., Inc. v. Swift–Eckrich, Inc._, 375 F.3d 1341, 1361 (Fed.Cir.2004) (finding that the USPTO justifiably relied on a patent application's omission because it issued the patent), rev'd on other grounds, 546 U.S. 394 (2006). Plaintiffs' allegations, taken as true, sufficiently allege, under the heightened pleading standard of Fed.R.Civ.P. 9(b), that Celgene obtained the Distribution Patents by committing fraud on the USPTO.10
Plaintiffs assert that Celgene sought to enforce the Distribution Patents in infringement suits brought against Barr and Natco in response to Paragraph IV Certifications they filed. (IUB Compl., ¶¶ 213, 214, 226, 229.) The litigation is not in dispute and the complaints sufficiently allege facts that support plaintiffs' theory that Celgene mounted the lawsuits to enforce illegally obtained patents, satisfying the second prong of a *Walker Process* claim. Celgene's motion to dismiss plaintiffs' Sherman Act claim on *Noerr Pennington* immunity grounds is denied.

### ii. Sham Litigation

A plaintiff contending that a defendant engaged in sham litigation must plead facts that show the lawsuit was “(1) 'objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits' (the objective element), and (2) motivated by a desire 'to interfere *directly* with the business relationships of a competitor' (the subjective element).” *Tyco Healthcare Grp. LP v. Mutual Pharm. Co., Inc.*, 762 F.3d 1338, 1343 (Fed.Cir.2014) (quoting *PRE*, 508 U.S. at 60–61).

Litigation is objectively baseless if it is brought without probable cause. *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, 682 F.3d 1003, 1007 (Fed.Cir.2012). But, “[n]either the bringing of an unsuccessful lawsuit to enforce patent rights, nor the effort to enforce a patent that falls to invalidity, subjects the suit to antitrust liability,” *C.R. Bard*, 157 F.3d at 1369, and “evidence of anticompetitive intent or purpose” alone will not transform an objectively reasonable lawsuit into a sham. *PRE*, 508 U.S. at 59. It must be shown “that plaintiff's case [had] no objective foundation, and the plaintiff must actually know this.” *iLOR, LLC v. Google, Inc.*, 631 F.3d 1372, 1377 (Fed.Cir.2011).

Plaintiffs argue that several of their allegations allow the Court to infer that Celgene's patent infringement suits were objectively baseless, which include those asserting Celgene obtained the Distribution Patents by fraud and that it entered into reverse payment agreements with Barr and Lannett because the settlements evince Celgene's knowledge that the Distribution Patents were unenforceable. Plaintiffs' factual allegations showing that Celgene procured the Distribution Patents by committing fraud plausibly show that the patent infringement suits were objectively baseless because a reasonable litigant would know that a lawsuit to enforce invalid patents is without probable cause. See *C.R. Bard*, 157 F.3d at 1368 (“Conduct prohibited under antitrust laws includes bringing suit to enforce a patent with knowledge that the patent is invalid or not infringed, and the litigation is conducted for anticompetitive purposes.”); *Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F.Supp.2d 408, 428 (D.Del.2006) (finding that plaintiffs sufficiently alleged that the defendant's patent infringement suits were objectively baseless because it knew that the patents were unenforceable).

*13* Plaintiffs argue they pleaded other facts that plausibly support that Celgene engaged in sham litigation—specifically that it entered into settlements with Barr and Lannett that were pay-for-delay agreements. They allege Celgene paid the two manufacturers either to delay or not to market their generic versions of *thalidomide* until a certain event or point in time. (IUB Compl., ¶¶ 213, 214, 217.) According to plaintiffs, Celgene also “may have agreed to sell Thalomid to Lannett under the terms of the settlement, because Lannett announced in late 2014 that its bioequivalence studies were going well, and it expected to submit an ANDA” in January 2014. (Id. ¶ 240.)

The Supreme Court recently addressed such pay-for-delay, or reverse payment agreements in *Actavis*, holding that under certain circumstances, such arrangements may violate the Sherman Act. *Actavis*, 133 S.Ct. 2237. Essentially, the Court found that for a reverse payment to raise possible antitrust implications and cast doubt on a patent's validity: (1) there must be a “reverse payment”; (2) that is “large and unjustified”; (3) that the payor is “unable to explain and to justify.” *Id.*
The Court recognizes that plaintiffs do not allege facts going to the amount of any “reverse payment” to Barr and Lannett. What remains troubling is Celgene’s insistence, in its reply to plaintiffs’ arguments on this point, that because of its large portfolio of patents covering Thalomid and Revlimid, competitors could not enter the market. This pushes aside the fact that the complaints here arise out of the particular nature of Hatch–Waxman. The plaintiffs allege that by various means that directly had an impact on the requirements for ANDAs, Celgene carefully blocked or delayed generic manufacturers’ entry into the market over which it had monopoly power. At this stage of the litigation, the Court is reluctant to dismiss claims of sham litigation when plaintiffs’ theory is clearly enunciated in the complaints and the facts in support connect the litigation to delay to the injury complained of.

The Court also finds that in context, the filing of the citizen petition may be seen as consistent with efforts to block entry into the thalidomide and lenalidomide markets. It is not determinative of the plausibility of the facts pled that the FDA did not take action on the citizen petition, as Celgene argues. Plaintiffs are asserting that Celgene’s litigation is causally connected to its overall anti-competitive scheme whereby it first blocked its competitors’ access to its drugs by refusing to providing samples for bioequivalency testing, and then sued the same competitors after they were able to obtain sufficient samples to conduct testing and file ANDAs.

b. The Non–Distribution Patents

Celgene’s second standing argument rests on the “almost three-dozen” patents that it owns, which cover Thalomid and Revlimid and are not challenged here as invalid (“the Non–Distribution Patents”). Even if its enforcement of the Distribution Patents were anti-competitive, Celgene argues, it could prevent generic drug manufacturers from entering the thalidomide and lenalidomide markets by raising the Non–Distribution Patents in an infringement action. In its moving brief, Celgene asserts that the Non–Distribution Patents “explain[s] the absence of generic competition of Revlimid and Thalomid,” and therefore, plaintiffs fail to allege antitrust injury and causation because their payment of supracompetitive prices is not solely attributable to its alleged anti-competitive conduct. (Celgene Br. at 16.)

As plaintiffs note in their opposition, this argument would essentially require them to discredit all possible intervening causes of an injury in their complaint to demonstrate standing. But the law does not demand that plaintiffs “allege all alternative theories of causation to survive a motion to dismiss.... Plaintiffs are simply required to allege facts showing that they suffered the type of injury or harm the antitrust laws were intended to prevent, and that their injury flows from [Celgene’s] anti-competitive conduct.” In re K–Dur Antitrust Litig., 338 F.Supp.2d 517, 535 (D.N.J.2004) (Greenaway, J.) (hereinafter “K–Dur (2004) ”); see also Zenith Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100, 114 n.9 (1969) (“[A] plaintiff need not exhaust all possible alternative sources of injury in fulfilling his burden of proving compensable [antitrust] injury....”). Therefore, at this stage of the litigation, whether Celgene owned other patents by which it could lawfully exclude generic competition from the thalidomide and lenalidomide markets is not the point. 11

11 These complaints allege how Celgene manipulated the FDA regulatory scheme, particularly the Hatch–Waxman Act, to “block[ ] and delay[ ] generic Thalomid and Revlimid competition.” (IUB Compl., ¶ 243.) Plaintiffs assert facts supporting their claims of anticompetitive conduct: that Celgene engaged in sham litigation, and that it used its restricted distribution programs as a pretext to withhold samples for bioequivalency testing in order to prevent generic competitors from entering the thalidomide and lenalidomide markets (IUB Compl., ¶ 243, 246.), which is the type of conduct antitrust laws were aimed to prevent because it “impairs the opportunity of rivals” without “further[ing] competition on the merits.” Broadcom Corp., 501 F.3d at 308. And plaintiffs allege this conduct resulted in them paying supracompetitive prices for Thalomid and Revlimid due to the lack of generic competition in thalidomide and lenalidomide markets—a quintessential antitrust injury. See Brantley v. NBC Universal, Inc., 675 F.3d 1192, 1202 n.11 (9th Cir.2012) (noting that reduced consumer choice and increased price constitute antitrust

*14
injury when caused by anti-competitive practices). The Court therefore finds that plaintiffs' factual allegations sufficiently plead antitrust injury and causation.

2. **Celgene's Refusal to Deal**

Celgene challenges the sufficiency of plaintiffs' allegations founded on its refusal to provide Thalomid and Revlimid samples to generic drug manufacturers for bioequivalency testing. It contends that, in order to state a Section 2 Sherman Act claim based on a refusal to deal, the plaintiff must show that the defendant terminated a prior course of dealing with a competitor and that it had no legitimate business justification for doing so. Implicit in plaintiffs' arguments is that a prior course of dealing is not a necessary element of a refusal-to-deal claim.

“As a general rule, businesses are free to choose the parties with whom they will deal....” *Pac. Bell Tel. Co. v. Linkline Commc'ns, Inc.*, 555 U.S. 438, 448 (2009); see also *King Drug*, 791 F.3d at 409 n.32. Requiring a business to cooperate with competitors “is in some tension with the underlying purpose of antitrust law, since it may lessen the incentive for the monopolist, rival, or both” to innovate. *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407–08 (2004). “Courts are ill suited 'to act as central planners, identifying the proper price, quantity, and other terms of dealing.' ” *Linkline*, 555 U.S. at 452 (quoting *Trinko*, 504 U.S. at 408). And of most concern is that forced cooperation and negotiation between competitors may facilitate “the supreme evil of antitrust: collusion.” *Trinko*, 540 U.S. at 408.

“The high value ... placed on the right to refuse to deal with other firms does not mean the right is unqualified,” however. *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 601 (1985). A business may freely choose with whom to deal except where its motivation is to obtain or maintain a monopoly. *United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919). However, a Sherman Act violation for a refusal to deal “is near the outer boundary of § 2.” *Trinko*, 540 U.S. at 409.

The parties dispute the validity of this claim based on competing interpretations of the Supreme Court's decision in *Aspen Skiing*, specifically whether, under that decision, the termination of a prior course of dealing between the defendant and a competitor is a necessary element of a Section 2 refusal-to-deal claim. In *Aspen Skiing*, the defendant, Ski Co., the owner of three of four ski areas in Aspen, Colorado, ceased cooperating with the owner of the fourth, Highlands, in selling a multi-mountain six-day pass for use at any of the four ski areas. Ski Co. replaced it with a six-day pass that was limited to its three ski mountains, and would only agree to reinstate the four-mountain pass if Highlands accepted a fixed percentage of the revenue, allocating Highlands far less than what it had been getting. Highlands responded by marketing its own four-mountain pass, but Ski Co. refused to sell Highlands passes to its three ski areas, even at retail value. Highlands' market share for downhill skiing in Aspen tumbled after Ski Co. unilaterally terminated the four-mountain ski pass program.

*15 The Supreme Court found these facts sufficient to conclude that Ski Co.'s refusal to deal violated the Sherman Act as being motivated by anti-competitive goals. The Supreme Court noted that the inquiry should be limited not just to the effect of Ski Co.'s conduct on its competitor, Highlands, but also on consumers, and “whether it has impaired competition in an unnecessarily restrictive way.” *Aspen Skiing*, 472 U.S. at 605. It found that “[i]f a firm has been attempting to exclude rivals on some basis other than efficiency, it is fair to characterize its behavior as predatory.” *Id.* The Court determined that the elimination of the four-area ticket adversely affected consumer choice as well as having a negative impact on Highlands' ability to compete. *Id.* at 606–08. Moreover, the Court reasoned that Ski Co.'s justifications for refusing to deal with Highlands were pretextual. *Id.* at 608–09. Ski Co. offered no efficiency justifications and an argument that it was too difficult to monitor skier mountain usage under the four-mountain pass was without merit because that had been done successfully in the past. *Id.* at 608–09. Ski Co. also claimed that Highlands' ski area's quality was inferior, and the Court dismissed that argument as pretextual because the four-area pass allowed the skiers to choose based on quality. *Id.* at 610.
The Court concluded that the evidence “support[ed] an inference that the monopolist made a deliberate effort to discourage its customers from doing business with its smaller rival” and that “Ski Co. was not motivated by efficiency concerns and ... was willing to sacrifice short-run benefits and consumer goodwill in exchange for the perceived long-run impact on its smaller rival.” *Id.* at 610–11. Thus, the Court looked at all the facts surrounding Ski Co.’s refusal to deal with Highlands as circumstantial evidence to support the inference that it acted with anticompetitive intent because, as the Court noted earlier in its opinion, “no monopolist monopolizes unconscious of what he is doing.” *Id.* at 602 (citation and internal quotation marks omitted).

The reasoning behind *Aspen Skiing* was revisited by the Supreme Court in *Trinko* where the plaintiffs alleged that the defendant, Verizon, violated Section 2 of the Sherman Act by refusing to provide its competitors with access to its communication network, conduct for which the government had penalized Verizon under the Telecommunications Act of 1996. The Court rejected the plaintiffs' claim, declining to extend *Aspen Skiing* to Verizon's conduct. *Trinko*, 540 U.S. at 409. The Court noted that in *Aspen Skiing* it found significant that Ski Co.'s “unilateral termination of a voluntary (and thus presumably profitable ) course of dealing suggested a willingness to forsake short-term profits to achieve an anti-competitive end, and also that the defendant's unwillingness to renew the ticket even if compensated at retail price revealed a distinctly anticompetitive bent.” *Id.* Verizon's prior conduct, unlike Ski Co.'s, “shed[ ] no light upon the motivation of its refusal to deal upon whether it[ ] ... [was] prompted not by competitive zeal but by anticompetitive malice.” *Id.* (emphasis added).

Celgene reads *Aspen Skiing* and *Trinko* too narrowly. The termination of the dealing between Ski Co. and Highlands was used as circumstantial evidence of Ski Co.'s demonstrated anti-competitive motivation, along with its lack of legitimate business justifications for doing so.

Both decisions indicate that motivation is central. The Court agrees with the plaintiffs that at this point it is too soon to measure motivation on Celgene's part. The facts asserted are that Celgene provided samples to researchers who were not seeking to enter the market, but not to competitors, who were. Plaintiffs specify that Mylan and Lannett gave Celgene letters from the FDA that stated that the agency would not take action should Celgene provide samples to them. Celgene continued to refuse to deal. This raises a plausible inference that Celgene's reliance on its distribution programs is pretextual. 12

*16* Celgene offers the additional justification that “certain states ... purport to hold branded manufacturers ... liable for the injuries caused by generic copies of their drugs,” relying on several cases where courts have held a brand name manufacturer liable for injuries caused by generic manufacturer's drug. (Celgene Br. at 35.) As plaintiffs argue in their opposition, Celgene overstates the basis on which liability is extended to a brand name manufacturer.

Those states holding brand name manufacturers liable do so on a failure-to-warn theory. See, e.g., *Kellogg v. Wyeth*, 762 F.Supp.2d 694, 708–09 (D.Vt.2010); *Conte v. Wyeth, Inc.*, 85 Cal.Rptr.3d 299, 318 (Cal.Ct.App.2008). These decisions rely on the laws regulating a generic drug's labeling, which require it to use the identical labeling that was approved for the brand name drug. 21 U.S.C. § 355(j)(2)(A)(v). These courts held that a brand name manufacturer owes a duty to a consumer injured by a generic manufacturer's drug when a risk of that drug is not adequately disclosed on the its labeling because the generic drug must use the same labeling as the brand name drug. *Kellogg*, 762 F.Supp.2d at 708–09. A brand name manufacturer would not be liable for defects in the generic drug's formulation or manufacture. *Conte*, 85 Cal.Rptr.3d at 317 n. 16. In fact, a failure-to-warn claim relies on the fact that the brand name and generic drugs are bioequivalents, having the same formulation. *See id.* at 307. The possibility that Celgene could be liable for a generic drug's harm is therefore not a legitimate justification that would support its refusal to supply generic manufacturers with samples of Thalomid and Revlimid.

Plaintiffs' allegations plausibly show that Celgene lacked a legitimate business justification for withholding samples of its drugs.
3. Celgene's Overall Anti–Competitive Scheme

Celgene moves to dismiss plaintiffs' fourth count in its entirety by arguing that plaintiffs fail to state claim under Section 2 of the Sherman Act because each individual act that they allege to be part of its overall anti-competitive scheme is not itself an antitrust violation. This argument, however, takes too narrow a view of what a plaintiff must plead to state claim under Section 2.

A court must look at allegations about a defendant's anti-competitive conduct as a whole, 

\textbf{LePage's, Inc. v. 3M, 324 F.3d 141, 162 (3d Cir.2003)}, and its legal analysis must not “tightly compartmentaliz[es] the various factual components” of a plaintiff's allegations, “wiping the slate clean after scrutiny of each.” \textbf{Cont'l Ore Co. v. Union Carbide & Carbon Corp., 370 U.S. 690, 699 (1962)}; see also \textbf{Abbott Labs., 432 F.Supp.2d at 428}. A court assessing the anti-competitive effect of a defendant's overall scheme must consider “the increase in the defendant's market share, the effects of foreclosure on the market, benefits to customers and the defendant, and the extent to which customers felt they were precluded from dealing with other manufacturers.” \textbf{LePage's, 324 F.3d at 162}.

Plaintiffs plausibly assert that Celgene procured the Distribution Patents by committing fraud on the USPTO and then sued potential generic competitors for infringement of those invalid patents such that its conduct is not protected by the \textit{Noerr Pennington} Doctrine. Plaintiffs also adequately claim that Celgene manipulated the Hatch–Waxman Act by listing the Distribution Patents in the Orange Book and by filing infringement lawsuits to prevent or delay the approval of any ANDAs filed by generic competitors. As IUB characterizes the allegations in its opposition brief, Celgene “first block[ed] competitors' access to its drug for bioequivalence testing, and then su[ed] those same competitors when they managed to obtain the drug and file an ANDA.” (D.E. 29 at 23.) These allegations allow the Court to infer that Celgene willfully sought to maintain its monopoly in violation of Section 2 of the Sherman Act in order to charge supracompetitive prices, not through business acumen or a superior product, but through a concerted effort to deny potential generic competitors access to the market.

\*17  For the above reasons, Celgene's motion to dismiss count 4 of plaintiffs' complaints is denied.

C. State Law Claims – Count 1, Count 2, Count 3, and Count 5

Celgene requests the dismissal of plaintiffs' state law claims in their respective first, second, third, and fifth counts and raises four arguments that are equally applicable to both IUB's and Providence's complaints. Celgene first contends that plaintiffs lack Article III standing to assert claims on behalf of putative class members under the laws of states in which they have not alleged an injury. It also maintains that, pursuant to New Jersey choice-of-law rules, plaintiffs may only bring claims under the laws of Connecticut and Rhode Island and that all other state law claims must be dismissed. Celgene's third argument asserts that plaintiffs' state law claims are preempted by federal patent law because they rely on its alleged inequitable conduct before the USPTO. It focuses its final assertion on plaintiffs' unjust enrichment claims in their fifth counts, arguing that those claims rest on the same allegations as their state antitrust claims and that unjust enrichment claims cannot be used as an end-run around state antitrust laws. Celgene further contends the individualized nature of the harm inherent in unjust enrichment claims precludes class certification.

1. Article III Standing for State Law Claims

Celgene argues that plaintiffs lack Article III standing to assert claims on behalf of putative class members under the laws of states in which they either have not alleged an injury or do not reside. Constitutional standing, under Article III, requires a plaintiff to show: (1) it suffered an injury-in-fact, that is “concrete and particularized” and “actual or imminent,” and not merely “conjectural or hypothetical”; (2) that the defendant's complained of conduct caused that injury; and (3) that it is likely, "as
opposed to merely speculative,” a favorable decision by the court will redress the injury. *Winer Family Trust v. Queen*, 503 F.3d 319, 325 (3d Cir.2007). “[N]amed plaintiffs who represent a class ‘must allege and show that they have been injured, not that injury has been suffered by other, unidentified members of the class to which they belong and which they purport to represent.’ * Lewis v. Casey*, 518 U.S 343, 357 (1996) (quoting *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 40 n.20 (1976)). “Once threshold individual standing by the class representative is met, a proper party to raise a particular issue is before the court, and there remains no further separate class standing requirement in the constitutional sense.” *In re Prudential Ins. Co. Am. Sales Practice Litig. Agent Actions*, 148 F.3d 283, 306–07 (3d Cir.1998) (citation and internal quotation marks omitted) (hereinafter “*In re Prudential*”). Celgene contends IUB has standing in only three states, Connecticut, Massachusetts, and Nebraska, and that Providence has standing in five, Rhode Island, Kansas, Massachusetts, New Jersey, North Carolina, and Pennsylvania.

Plaintiffs respond that Celgene conflates Article III standing with class certification issues under Fed.R.Civ.P. 23, and that for Article III standing purposes it is sufficient to show they have suffered a personal injury. They note Celgene concedes they satisfactorily alleged injury in certain states, and argue that whether they can raise claims on behalf of absent class members under the laws of states where they did not suffer an injury is a question appropriate for the class certification stage, which must follow the resolution of any Article III standing questions.

*18 The Third Circuit recently addressed the last point in *Neale v. Volvo Cars of North America*, 794 F.3d 353, 360 (2015), finding that “considerations under *Rule 23* are themselves procedural rules, and thus rarely can be antecedent to the question of whether a federal court has jurisdiction to hear a claim at all,” and so an Article III standing inquiry is a necessary prerequisite to Fed.R.Civ.P. 23 considerations. The court reasoned that delaying the standing analysis until after class certification could result in an advisory opinion—an act of “ultra vires.” Id. at 361 (internal quotation marks omitted) (quoting *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 102 (1998)).

IUB, which is located in Connecticut, alleges to have paid and/or reimbursed its members for the price of Thalomid and Revlimid in Massachusetts and Nebraska. (IUB Compl., ¶ 12.) Providence is based in Rhode Island, and it claims it paid or reimbursed its members for the price of the two brand name drugs in Florida, Kansas, Massachusetts, New Jersey, North Carolina, and Pennsylvania. (Providence Compl., ¶ 14.) Celgene, for purposes of its motions to dismiss, accepts that plaintiffs allege injuries in those states. The Court finds that the factual allegations discussed above support plaintiffs' standing to pursue state law claims because they show that Celgene's anti-competitive conduct caused their claimed injury in paying supracompetitive prices by unlawfully excluding generic competition. Further, plaintiffs seek damages for their state law claims, so a favorable decision will redress their injury. Plaintiffs therefore possess Article III standing to pursue their state law claims in those particular states.

The fact that plaintiffs have Article III standing, however, does not resolve the question of whether they can pursue state law claims on behalf of putative class members under the laws of states where they do not allege they suffered a personal injury. Celgene and plaintiffs point to cases that arrived at differing conclusions regarding this issue, but this authority offers little by way of legal analysis for their conclusions; the courts are either dismissing those state law claims or finding it premature to decide the issue. The Supreme Court, recently provided guidance in *Lexmark International, Inc. v. Static Control Components, Inc.*, 134 S.Ct. 1377, 1386 (2014) (citation and internal quotation marks omitted), where it stated that the limitation of a court's “power to resolve Cases or Controversies” flows from Article III, which sets out, along with the separation-of-powers principle, the “irreducible constitutional minimum of standing.” Once the three-part test of (1) injury, (2) causation, and (3) redressability is satisfied, the Court emphasized that “a federal court's obligation to hear and decide cases within its jurisdiction is virtually unflagging.” Id. (citation and internal quotation marks omitted). The Court differentiated the zone-of-interests test, which it found was unrelated to standing and strictly a matter of statutory construction. Id. at 1387. That test “requires [a court] to determine, using traditional tools of statutory interpretation, whether a legislatively conferred cause of action encompasses a particular plaintiff's claim.” Id. Unlike the question of Article III standing, the zone-of-interest test does not concern a court's subject matter jurisdiction—it's “power” to hear the case, but whether the plaintiff states a claim—a merits question. See id. at 1387 n.3, 1387 n.4; see also *Chabad Lubavitch of Litchfield Cnty., Inc. v. Litchfield Historic Dist. Comm'n*, 768 F.3d 183, 201

(2d Cir.2014) (elaborating that the zone-of-interests test does not involve a court's jurisdiction to hear a case or controversy under Article III).

*19 Celgene's attack on plaintiffs' standing to pursue state law claims on behalf of absent class members is not an Article III jurisdictional issue under Lexmark. Celgene argues that plaintiffs must allege an in-state injury, but Article III's injury-in-fact requirement "has nothing to do with the text of the statute relied upon." Steel Co., 523 U.S. at 97 n.2; see also Lexmark, 134 S.Ct. at 1386. Celgene's attempt "to inject the condition that [p]laintiffs must satisfy certain elements of the state antitrust claims into a constitutional standing analysis ... result[s] in an impermissible out-of-the-box merits inquiry." Processed Egg, 851 F.Supp.2d 867, 886 (E.D.Pa.2012); see also Nesbit v. Gears Unlimited, Inc., 347 F.3d 72, 80 (3d Cir.2003) ("The [Supreme] Court also criticized the implications of treating the validity of a cause of action as jurisdictional.").

In this opinion the Court has determined that there is a live case or controversy sufficient to invoke its subject matter jurisdiction under Article III. Plaintiffs correctly conclude that whether they may pursue these claims is better left for the class certification stage because "the issue now [becomes] one of compliance with the provisions of Rule 23, not one of Article III standing." In re Prudential, 148 F.3d at 307 (alteration in original) (citation and internal quotation marks omitted); see also Sosna v. Iowa, 419 U.S. 393, 403 (1975) (noting that, once Article III standing is established, the focus shifts to whether the plaintiff will adequately represent the interests of the proposed class under Fed.R.Civ.P. 23(a)). Celgene's motion to dismiss all of plaintiffs' claims under the laws of states in which they do not allege a personal injury in their first, second, third, and fifth counts is denied.

2. Choice of Law

Celgene also argues that all of plaintiffs' state law claims in their first, second, third, and fifth counts must be dismissed because New Jersey choice of law rules require the Court to apply Connecticut law to all of IUB's claims, which Celgene contends bars indirect purchasers, like IUB, from pursuing antitrust damages claims and prohibits IUB from raising unfair competition or unjust enrichment claims on the same facts as a way to plead around this prohibition. It makes a similar argument regarding Providence's claims. Plaintiffs contend that it is premature at the motion-to-dismiss stage to engage in a choice-of-law analysis before class certification.

A court's determination about "whether a choice-of-law issue is ripe or premature should be made on a case-by-case basis depending on the facts presented." Montich v. Miele USA, Inc., 849 F.Supp.2d 439, 445 (D.N.J.2012) (Wolfson, J.) While a court may resolve a choice-of-law question on a motion to dismiss, see Cooper v. Samsung Elecs. Am., Inc., 374 F. App'x 250, 255 (3d Cir.2010), it should defer engaging in such an analysis if the facts are, as of yet, under developed to decide the issue. See K–Dur 2004, 338 F.Supp.2d at 541 (declining to decide which state laws would apply because the class of plaintiffs had yet to be certified); see also In re Flonase Antitrust Litig., 692 F.Supp.2d 524, 534 (E.D.Pa.2010) ("[C]hoice-of-law issues may be determined at or after class certification."). A court should exercise caution prior to class certification when asked to resolve choice-of-law questions "in a nationwide class action where an array of factors beyond the residence of the class members must be considered, including ... the location of the parties and the purchased items." Sullivan v. DB Investments, Inc., 667 F.3d 273, 309 (3d Cir.2011).

Based on the above, the Court will defer its decision regarding the validity of any claims under particular state laws until the facts are further developed about the residence of putative class members or the state where they purchased or reimbursed their members for the price of Thalomid and Revlimid, and where the absent class members suffered an injury. The Court also does not address Celgene's motions to dismiss specific claims in plaintiffs' first, second, third, and fifth counts because it “is unwilling to predict which state law(s) would be applicable in the event the class is certified.” *K–Dur (2004)*, 338 F.Supp.2d at 541.

For the foregoing reasons, Celgene's motion to dismiss individual state law claims in the complaints is denied.

### 3. Federal Preemption

Celgene contends that all of plaintiffs' state law claims are preempted by federal patent law because they primarily rely on the allegations that it obtained the Distribution Patents through inequitable conduct on the USPTO. Plaintiffs maintain that their state law claims are not preempted by federal patent law because they rely on more than Celgene's alleged misconduct before the USPTO and also contain the element of bad faith misconduct in the market place.

“Federal Circuit law governs whether federal patent law preempts a state law claim,” *Ultra–Precision Mfg., Ltd. v. Ford Motor Co.*, 411 F.3d 1369, 1376 (Fed.Cir.2005), and it preempts any state law causes of action that are based on nothing more than misconduct before the USPTO. See *Semiconductor Energy Lab., Ltd. v. Samsung Elecs. Co., Ltd.*, 204 F.3d 1368, 1382 (Fed.Cir.2008). But a state law claim is not preempted “even if it requires the state court to adjudicate a question of federal patent law,” so long as it contains additional elements not part of a federal patent cause of action. *Dow Chem. Co. v. Exxon Corp.*, 139 F.3d 1470, 1473 (Fed.Cir.1998). These additional elements, as plaintiffs note, often include allegations regarding bad faith conduct in the marketplace committed by the patentee. See *Zenith Elecs. Corp. v. Exzec, Inc.*, 182 F.3d 1340, 1355 (Fed.Cir.1999) (finding that a state-law tortious interference claim was not preempted by federal patent law because the plaintiff must show the defendant acted in bad faith). For example, in *Dow* the court found that the plaintiffs' interference with contractual relations cause of action was not preempted by federal patent law because, although the tort claim relied, in part, on inequitable conduct before the USPTO, “but rather was premised upon bad faith misconduct in the marketplace.” *Dow*, 139 F.3d at 1477

Plaintiffs' claims, while alleging that Celgene committed fraud before the USPTO, are also premised on bad faith misconduct in the thalidomide and lenalidomide markets. They assert that Celgene obtained the Distribution Patents through fraud, enforced those patents knowing they were invalid, and manipulated the FDA regulations, all to foreclose generic competition so it could continue to charge supracompetitive prices for Thalomid and Revlimid. These allegations go beyond just claiming fraud on the USPTO and, rather, focus on Celgene's acts in the marketplace and form the foundation of all of plaintiffs' state law claims. The Court therefore agrees with plaintiffs that their state law claims are not preempted by federal patent law because they go beyond Celgene's alleged misconduct before the USPTO by claiming Celgene's acts also involved marketplace misconduct and denies Celgene's motion to dismiss plaintiffs' state law claims as preempted.

### 4. Count 5—Unjust Enrichment

Celgene contends that plaintiffs' unjust enrichment claims rely entirely on their allegations that Celgene violated antitrust laws and that a plaintiff cannot bring a corresponding unjust enrichment claim as a means to avoid a state's antitrust law's bar against damages claims by indirect purchasers. Celgene also maintains that the type of harm alleged when bringing an unjust
enrichment claim is too individualized to permit class certification. Plaintiffs' primary opposition is that it is premature to decide these issues prior to class certification.

Plaintiffs may plead alternative theories of recovery in their complaints, and it is too soon now, prior to discovery, to make the determination that plaintiffs' unjust enrichment claims are brought to evade a state's rule about the litigation rights of indirect purchasers. See In re Hypodermic Prods. Antitrust Litig., No. 05–1602, 2007 WL 1599225, at *16 (D.N.J.2007) (Linares, J.) (declining to dismiss unjust enrichment claims when the defendant argued they were redundant of plaintiffs' antitrust claims because it was premature to do so). And whether the individualized nature of the harm will preclude class certification is a question of predominance better left for class certification for when a more developed factual and legal record is before the Court so that it may conduct the “rigorous analysis” Fed.R.Civ.P. 23 requires. In re Hydrogen Peroxide Antitrust Litig., 552 F.3d 305, 309 (3d Cir.2008). The Court therefore denies Celgene's motion to dismiss unjust enrichment claims.

IV. Conclusion
For the foregoing reasons, Celgene's motion to dismiss all counts in plaintiffs' complaints is denied. An appropriate order will be entered.

All Citations
Not Reported in Fed. Supp., 2015 WL 9589217

Footnotes

1 The Court will refer to IUB and Providence collectively as plaintiffs.

2 Plaintiffs appear to indicate that following the settlement agreement Barr was purchased by Teva, but because the allegations are unclear in this regard, the Court will continue to refer to this entity as Barr.

3 In a reverse payment settlement, “Company A sues Company B for patent infringement. The two companies settle under terms that require (1) Company B, the claimed infringer, not to produce the patented product until the patent's term expires, and (2) Company A, the patentee, to pay B many millions of dollars.” F.T.C. v. Actavis, Inc., 133 S.Ct. 2223, 2227 (2013).

4 In count 1, both IUB and Providence allege Celgene's conduct violated the laws of Arizona, California, the District of Columbia, Florida, Illinois, Iowa, Maine, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, North Carolina, North Dakota, Oregon, Puerto Rico, South Dakota, Utah, Vermont, West Virginia, and Wisconsin. (IUB Compl., ¶ 289; Providence Compl., ¶ 286.) IUB also relies on the antitrust laws of Hawaii, Massachusetts, Missouri, and Tennessee. (IUB Compl., ¶ 289.) Providence claims that Celgene's acts also violated the antitrust laws of Kansas and Rhode Island. (Providence Compl., ¶ 286.)

5 As for count 2, both IUB and Providence rely on the same states' antitrust laws that they relied on in count 1, and IUB adds New York's statute. (IUB Compl., ¶ 289; Providence Compl., ¶ 292.)

6 IUB and Providence both rely on the laws of Arizona, Arkansas, California, the District of Columbia, Florida, Kansas, Idaho, Michigan, Minnesota, Missouri, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina,
Oregon, Pennsylvania, Rhode Island, South Dakota, Utah, and Virginia in count 3. (IUB Compl., ¶ 299; Providence Compl., ¶ 296.) IUB additionally brings claims in count 3 pursuant to Illinois, Maine, Massachusetts, Tennessee, and West Virginia statutes. (IUB Compl., ¶ 299.)

7 Plaintiffs limit their request to injunctive relief for Celgene's alleged violations of the Sherman Act recognizing the Supreme Court's ruling in Illinois Brick Co. v. Illinois, 431 U.S. 720, 747 (1977) that indirect purchasers may not obtain monetary relief for federal antitrust violations.

8 The plaintiffs bring their unjust enrichment claims “under the law of the District of Columbia and the laws of all states and territories in the United States, except Ohio and Indiana.” (IUB Compl., ¶ 311; Providence Compl., ¶ 308.)


10 The Court notes that Celgene neglected to provide the Distribution Patents' applications or prosecution history, further buttressing the plausibility of plaintiffs' allegations. See Hydril, 474 F.3d at 1349 (finding that, in the absence of the patent applications or prosecution history, that plaintiffs' allegations were sufficient to plead a claim of Walker Process fraud).

11 Celgene also argues that the Court may use Fed.R.Evid. 201(b) to take judicial notice of the Non–Distribution Patents and their validity based on their listings in the Orange Book. Fed.R.Evid. 201(b) permits a court to take judicial notice of an adjudicative fact “that is not subject to dispute because it is (1) generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.” The Court may take judicial notice of the fact that Celgene's Non–Distribution Patents are listed in the Orange Book as a matter of public record, see Schmidt v. Skolas, 770 F.3d 241, 249 (3d Cir.2014), but cannot deem the listings as proof of their validity when the FDA admits that it does not review the patent information submitted as part of an NDA. See King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp., 792 F.3d 388, 395 (3d Cir.2015); see also aaiPharma Inc. v. Thompson, 296 F.3d 227, 237 (4th Cir.2002) (“[The FDA] explain[s] that it lacks both the resources and the expertise to police the correctness of Orange Book listings.”). Furthermore, patents “should not be irrebuttably presumed valid” because of “the public interest support[ing] judicial testing and elimination of weak patents.” King Drug, 792 F.3d at 398 (alteration in original) (citation and internal quotation marks omitted).

12 Both parties brought to the Court's attention a recent decision in which a court dismissed a plaintiff's refusal-to-deal claim when a drug manufacturer cited a restricted distribution program as the reason for its refusal to sell the plaintiff drug samples for bioequivalency testing. Natco Pharma Ltd. v. Gilead Scis., Inc., 2015 WL 5718398, at *6 (D.Minn. Sept. 29, 2015). The primary difference between the present matter and that matter, however, is that the plaintiff never alleged that the FDA informed the defendant that its restricted distribution program could not be relied on in denying potential generic manufacturers access to samples.
Synopsis

Background: Advocacy groups and direct and indirect buyers of brand-name drug containing patented compound ciprofloxacin hydrochloride sued brand-name drug manufacturer and generic drug manufacturers, alleging, inter alia, that settlement agreements in patent litigation that involved reverse payments from brand-name manufacturer to generic manufacturers resulted in illegal market allocation in violation of Sherman Act and state antitrust and consumer protection laws. After cases were consolidated, the United States District Court for the Eastern District of New York, David G. Trager, Senior District Judge, 363 F.Supp.2d 514, granted defendants' motion for summary judgment and also dismissed state-law claims. Plaintiffs appealed.

Holdings: The Court of Appeals, Prost, Circuit Judge, held that:

- district court could decline to find settlement agreements to be per se unlawful under Sherman Act, and instead conduct rule of reason analysis;
- settlement agreements had no anti-competitive effects outside patent's exclusionary zone and thus were not unlawful restraints on trade; and
under settlement agreements, generic drug manufacturer did not retain its 180-day period of market exclusivity pursuant to Hatch-Waxman Act.

Affirmed.

Procedural Posture(s): On Appeal; Motion for Summary Judgment.

Attorneys and Law Firms

*1326 J. Douglas Richards, Pomerantz Haudek Block Grossman & Ross LLP, New York, NY, argued for all plaintiffs–appellants. With him on the brief were Christopher J. McDonald, Labaton Sucharow LLP, of New York, NY, and Patrick E. Cafferty, Cafferty Faucher LLP, of Ann Arbor, MI, Of counsel were Dan Drachler, Zwerling, Schachter & Zwerling, LLP, of Seattle, WA; Robert S. Schachter and Joseph Lipofsky, of New York, NY; Eric B. Fastiff and Joseph R. Saveri, Lieff Cabraser Heiman & Bernstein, LLP, of San Francisco, CA; and David Kalow and Scott D. Locke, Kalow & Springut LLP, of New York, NY.

Fred H. Bartlit, Jr., Bartlit Beck Herman Palenchar & Scott LLP, of Chicago, IL, argued for all defendants-appellees. With him on the brief were Peter B. Bensinger, Jr., Michael J. Valaik, and Paul J. Skiermont, for Bayer AG, et al. Of counsel on the brief were Phillip A. Proger, Kevin D. McDonald, and Lawrence D. Rosenberg, Jones Day, of Washington, DC.

Karen N. Walker, Kirkland & Ellis LLP, of Washington, DC, for defendant-appellee Barr Laboratories, Inc. With her on the brief were Edwin John U, Bridget K. O'Connor and Gregory L. Skidmore.

David E. Everson, Stinson Morrison Hecker LLP, of Kansas City, MO, for defendants-appellees Hoechst Marion Roussel, Inc., et al. With him on the brief were Heather S. Woodson and Victoria L. Smith.

Cheryl L. Johnson, Deputy Attorney General, Los Angeles, CA, for amici curiae The State of Alabama, et al. With her on the brief were Manuel Medeiros, Solicitor General; Janet Gaard, Chief Assistant Attorney General; Kathleen Foote, Senior Assistant Attorney General; and Edmund G. Brown, Jr., Attorney General, of The State of California, of Sacramento, CA.

Professor Mark A. Lemley, Stanford Law School, of Stanford, CA, for amici curiae, Law Professors John R. Allison, et al.

Imad D. Abyad, Attorney, Federal Trade Commission, of Washington, DC, for amicus curiae Federal Trade Commission. With him on the brief were William Blumenthal, General Counsel; John D. Graubert, Principal Deputy General Counsel, and John F. Daly, Deputy General Counsel for Litigation. Of counsel were Jefffrey Schmidt, Director, Suzanne T. Michel, Assistant Director; and Elizabeth R. Hilder, Attorney.

Bruce B. Vignery, AARP Foundation Litigation, of Washington, DC, for amici curiae AARP, et al.

Don L. Bell, II, National Association of Chain Drug Stores, of Alexandria, Virginia, for amicus curiae National Association of Chain Drug Stores.

Elizabeth M. Locke, Kirkland & Ellis LLP, of Washington, DC, for amicus curiae Generic Pharmaceutical Association. With her on the brief was Susan E. Engel.

Before SCHALL and PROST, Circuit Judges, and WARD, District Judge.*
Opinion

PROST, Circuit Judge.

This case under the Hatch–Waxman Act presents the issue of whether a settlement agreement between a patent holder and a generic manufacturer violates the antitrust laws. The agreements here involve a reverse payment from the patent holder to the generic manufacturer, but do not implicate the 180–day exclusivity period. Indirect purchasers of Cipro and several advocacy groups (“appellants”) appeal the grant of summary judgment of their federal antitrust claims and dismissal of their state antitrust claims against the patent holders and brand-name manufacturers, Bayer AG and Bayer Corp. (collectively “Bayer”), and the generic manufacturers, Barr Labs., Inc. (“Barr”), Hoechst Marion Roussel, Inc. (“HMR”), The Rugby Group, Inc. (“Rugby”), and Watson Pharmaceuticals, Inc. (“Watson”) (collectively “generic defendants”). The United States District Court for the Eastern District of New York granted Bayer's and the generic defendants' motion for summary judgment, holding that any anti-competitive effects caused by the settlement agreements between Bayer and the generic defendants were within the exclusionary zone of the patent, and thus could not be redressed by federal antitrust law. In re Ciprofloxacin Hydrochloride Antitrust Litigation, 363 F.Supp.2d 514 (E.D.N.Y.2005) (“Cipro II”). The court further granted Bayer's motion to dismiss the state antitrust claims. For the reasons set forth below, we affirm.

I

A

Bayer is the owner of U.S. Patent No. 4,670,444 (“the ′444 patent”). The patent relates to certain quinoline- and napthyridine-carboxylic acid compounds with antibacterial properties and methods of administering the compounds to combat bacterial illnesses. ′444 patent, col.1 ll.13–17, col.2 *1328 ll.28–32, claims 1, 21. More particularly, the patent is directed to ciprofloxacin hydrochloride, the compound that is the active ingredient in Cipro® (“Cipro”). Id., claim 12. The patent issued on June 2, 1987, and Bayer's predecessor obtained approval from the Food and Drug Administration (“FDA”) to market Cipro in October 1987. The FDA granted Bayer an additional six-month period of marketing exclusivity (pediatric exclusivity) following the expiration of the patent on December 9, 2003.

In October 1991, Barr filed an abbreviated new drug application (“ANDA”) for a generic version of Cipro. The ANDA included a Paragraph IV certification indicating that Barr sought to market its generic drug before expiration of the ′444 patent on the grounds that the patent was invalid and unenforceable. Specifically, Barr asserted that the patent was invalid based on obviousness under 35 U.S.C. § 103 and obviousness type double patenting under 35 U.S.C. § 101, and unenforceable due to inequitable conduct. Under the Hatch–Waxman Act, the first filer of a Paragraph IV ANDA is automatically entitled to a 180–day period of market exclusivity, which, in the version of the Act in effect at the time, begins to run either on the date that the first ANDA filer begins to market its drug or on the date of a final court decision finding the patent to be invalid or not infringed, whichever is earlier. 21 U.S.C. § 355(j)(4)(B)(iv) (1988). Thus, as the first Paragraph IV ANDA filer, Barr was entitled to the 180–day exclusivity period.

On January 16, 1992, Bayer sued Barr for patent infringement in the Southern District of New York. Barr answered and counterclaimed for a declaratory judgment that the ′444 patent is invalid and unenforceable and that its generic ciprofloxacin would not infringe the ′444 patent. In 1996, Rugby (a subsidiary of HMR) and Barr entered into the “Litigation Funding Agreement,” in which Rugby agreed to help Barr fund its litigation against Bayer in exchange for half of any profits realized from Barr's sale of ciprofloxacin. Also, in 1996, Bayer entered into settlement discussions with HMR and Barr.
In re Ciprofloxacin Hydrochloride Antitrust Litigation, 544 F.3d 1323 (2008)
2008-2 Trade Cases P 76,336, 88 U.S.P.Q.2d 1801

Just before trial, Bayer, Barr, HMR, and Rugby entered into the following agreements (collectively “the Agreements”): (1) the “Barr Settlement Agreement” between Bayer and Barr; (2) the “HMR/Rugby Settlement Agreement” among Bayer, HMR, and Rugby; (3) the “Apotex Settlement Agreement” among Bayer, Bernard Sherman (Barr’s principal shareholder), and Apotex (another company controlled by Sherman); and (4) the “Cipro Supply Agreement” among Bayer, Barr, and HMR.  

The first three agreements provided that Barr, HMR, Rugby, Apotex, and Bernard Sherman would not challenge the validity or enforceability of the ′444 patent. Pursuant to the Barr Settlement Agreement, Barr agreed to convert its Paragraph IV ANDA to a Paragraph III ANDA, thus certifying that it would not market its generic version of Cipro until after the ′444 patent expired. 4 See 21 U.S.C. § 355(j)(2)(A)(vii)(III). In exchange, Bayer agreed to make a settlement payment to Barr of $49.1 million.

Under the Cipro Supply Agreement, Bayer agreed to either supply Barr with Cipro for resale or make quarterly payments (referred to as “reverse payments” or “exclusion payments”) to Barr until December 31, 2003. 5 In return, Barr agreed not to manufacture, or have manufactured, a generic version of Cipro in the United States. Beginning at least six months before the ′444 patent expired, Bayer agreed to allow Barr to sell a competing ciprofloxacin product. Bayer and Barr then entered into a consent judgment, whereby Barr affirmed the validity and enforceability of the ′444 patent and admitted infringement.

On July 25, 1997, Bayer filed for reexamination. Bayer cancelled and amended certain claims, and the validity of the remaining claims of the ′444 patent was reaffirmed by the Patent and Trademark Office (“PTO”) in the reexamination certificate. In particular, the patentability of claim 12, directed to ciprofloxacin hydrochloride, was confirmed.

Thereafter, four other companies—Ranbaxy, Mylan, Schein, and Carlsbad—filed Paragraph IV ANDAs for a generic version of Cipro. Bayer sued each of them for infringement of the reexamined ′444 patent. The issue of inequitable conduct was not adjudicated in any of the actions. Bayer defeated Schein and Mylan's challenges to the validity of the ′444 patent on summary judgment. Bayer AG v. Schein Pharm., Inc., 129 F.Supp.2d 705 (D.N.J.2001), aff'd, 301 F.3d 1306 (Fed.Cir.2002). The validity of the ′444 patent was upheld after a bench trial in the Carlsbad case. Bayer AG v. Carlsbad Tech., Inc., No. 01 CV0867–B (S.D. Cal. June 7, 2002 & Aug. 7, 2002). The Ranbaxy case was dismissed after Ranbaxy withdrew its Paragraph IV certification.

B

In 2000 and 2001, direct and indirect purchasers of Cipro and advocacy groups filed several antitrust actions in federal courts challenging the Agreements. The cases were consolidated in the Eastern District of New York pursuant to 28 U.S.C. § 1407. In re Ciprofloxacin Hydrochloride Antitrust Litig., No. 1383, 2001 WL 253240 (J.P.M.L. Jan. 10, 2001). Thereafter, the plaintiffs filed a consolidated complaint containing Counts I–IV, which alleged that the Agreements constituted an illegal market allocation in violation of the prohibition on contracts in restraint of trade contained in sections 1 and 2 of the Sherman Act and in violation of various state antitrust and consumer protection laws.

On May 20, 2003, the district court denied the plaintiffs’ motion for partial summary judgment that the Agreements were per se unlawful under the Sherman Act and under the state antitrust and consumer protection laws. In re Ciprofloxacin Hydrochloride Antitrust Litig., 261 F.Supp.2d 188 (E.D.N.Y.2003) (“Cipro I”).

The plaintiffs then amended their complaint to add Count V, a state law Walker Process type antitrust claim, alleging that Bayer unlawfully monopolized the ciprofloxacin market in violation of state antitrust laws by enforcing a patent obtained...
by fraud. Specifically, they alleged that Bayer violated state antitrust and/or consumer protection laws through fraud on the PTO and sham litigation in enforcing the '444 patent against Barr.

The parties filed cross-motions for summary judgment regarding whether the Agreements had anti-competitive effects under section 1 of the Sherman Act. The district court denied the plaintiffs' motion and granted Bayer's and the generic defendants' motion. Cipro II, 363 F.Supp.2d at 548. Employing a rule of reason analysis, the district court first determined that the relevant market is ciprofloxacin and that Bayer had market power within that market. Id. at 520–23. The court then determined that any adverse effects on competition stemming from the Agreements were within the exclusionary zone of the '444 patent, and hence could not be redressed by antitrust law. Id. at 523–40. In so concluding, the court considered recent decisions by the Second Circuit, as well as other regional circuits, and rejected the plaintiffs' argument that the exclusionary power of the patent, for the purpose of the anticompetitive effects analysis, should be tempered by the patent's potential invalidity. Id. Given the absence of evidence that the Agreements created a bottleneck on challenges to the '444 patent or otherwise restrained competition beyond the scope of the patent, the court concluded that the plaintiffs had failed to show that the Agreements had any anti-competitive effects on the market for ciprofloxacin beyond that permitted under the patent. Id. at 540. Thus, the court found it unnecessary to address the second and third steps of the rule of reason analysis. Id. at 541.

Bayer also filed a motion to dismiss Count V as preempted by federal patent law and barred by the statute of limitations. The district court agreed that Count V is preempted by federal patent law because the plaintiffs alleged no theory for a Walker Process claim or sham litigation claim that does not depend on a showing of misconduct before the PTO. Id. at 542–46. The court noted that Count V does not allege any misconduct other than misconduct before the PTO, i.e., there is no allegation of marketplace misconduct. Id. Thus, the court concluded that Count V rests entirely on patent law.7 Id. The court also reasoned that Bayer's success in its litigation against Schein, Mylan and Carlsbad foreclosed any argument that its lawsuits were shams. Id. at 547. Because the court granted Bayer's motion to dismiss on preemption grounds, it did not reach whether Count V was barred by the statute of limitations. Id. at 547–48.

This appeal followed. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).8

II

This court reviews the district court's grant of summary judgment de novo, applying the same legal standards applied by the district court. *1331 Innogenetics, N.V. v. Abbott Labs., 512 F.3d 1363, 1378 (Fed.Cir.2008); U.S. Philips Corp. v. Iwasaki Elec. Co., 505 F.3d 1371, 1374 (Fed.Cir.2007). Summary judgment is appropriate where, after drawing all reasonable inferences in favor of the non-movant, there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. Fed.R.Civ.P. 56(c); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986); Rubens v. Mason, 527 F.3d 252, 254 (2d Cir.2008).

This court also reviews the district court's grant or denial of a motion to dismiss de novo. Adenta GmbH v. OrthoArm, Inc., 501 F.3d 1364, 1368 (Fed.Cir.2007); Univ. of W. Va. Bd. of Trs. v. VanVoorhes, 278 F.3d 1288, 1295 (Fed.Cir.2002). Whether federal patent law preempts a state law claim is a question of law which we review de novo. Ultra–Precision Mfg., Ltd. v. Ford Motor Co., 411 F.3d 1369, 1376 (Fed.Cir.2005).

III
The appellants allege that the district court erred in its determination that the Agreements did not constitute an unreasonable restraint of trade in violation of section 1 of the Sherman Act, and in its grant of Bayer's and the generic defendants' motions for summary judgment on Counts I–IV, as follows: (1) by not finding the Agreements to be per se unlawful, or at least applying a proper rule of reason analysis; (2) by finding the Agreements to be lawful because they fell within the “exclusionary zone” of the '444 patent; (3) by not considering the law of the regional circuits and government agencies in evaluating the Agreements; (4) by failing to appreciate the effects of the Agreements on other generic manufacturers; and (5) by not considering evidence showing that the Agreements preserved Barr's claim to the 180–day exclusivity period. We address each asserted error in turn.

A

According to the appellants, the Agreements allowed Bayer to exclude a horizontal competitor from the market not by enforcing its rights as a patentee, but instead by ceasing to enforce its rights and paying the competitor $398 million. The appellants contend that the district court should have concluded that the Agreements were per se unlawful or should have applied a proper rule of reason analysis. At a minimum, the appellants assert, the court should not have resolved the case on summary judgment, but instead should have presented it to a fact-finder to determine whether the Agreements constituted an unreasonable restraint on trade.

The Sherman Act provides that “[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal.” 15 U.S.C. § 1. Although by its terms, the Act prohibits any “restraint of trade,” the Supreme Court “has long recognized that Congress intended to outlaw only unreasonable restraints.” State Oil Co. v. Khan, 522 U.S. 3, 10, 118 S.Ct. 275, 139 L.Ed.2d 199 (1997). Courts will presumptively apply a “rule of reason” analysis to determine whether an agreement imposes an unreasonable restraint on competition. Texaco, Inc. v. Dagher, 547 U.S. 1, 5, 126 S.Ct. 1276, 164 L.Ed.2d 1 (2006). Only agreements that have a “predictable and pernicious anticompetitive effect, and ... limited potential for procompetitive benefit” are deemed to be per se unlawful under the Sherman Act. State Oil, 522 U.S. at 10, 118 S.Ct. 275. A finding of per se unlawfulness “is appropriate ‘[o]nce experience with a particular type of restraint enables the Court to predict with confidence that the rule of reason will condemn it.’ ” Id. (quoting Arizona v. Maricopa County Med. Soc’y, 457 U.S. 332, 344, 102 S.Ct. 2466, 73 L.Ed.2d 48 (1982)). The Supreme Court has expressed reluctance to adopt per se rules where the economic impact is not immediately obvious. Id.

Since there was no basis for the district court to confidently predict that the Agreements at issue here would be found to be unlawful under a rule of reason analysis, we find no error by the court in declining to find them to be per se unlawful. Instead, the court properly went through a rule of reason analysis to determine whether the Agreements were in fact an unreasonable restraint of trade.

Under the law of the Second Circuit, the rule of reason analysis is a three-step process:

First, the plaintiff bears the initial burden of showing that the challenged action has had an actual adverse effect on competition as a whole in the relevant market. Then, if the plaintiff succeeds, the burden shifts to the defendant to establish the pro-competitive redeeming virtues of the action. Should the defendant carry this burden, the plaintiff must then show that the same pro-competitive effect could be achieved through an alternative means that is less restrictive of competition.
In re Ciprofloxacin Hydrochloride Antitrust Litigation, 544 F.3d 1323 (2008)
2008-2 Trade Cases P 76,336, 88 U.S.P.Q.2d 1801

Clorox Co. v. Sterling Winthrop, Inc., 117 F.3d 50, 56 (2d Cir.1997) (citations and internal quotations omitted). Typically, the starting point is to define the relevant market, Geneva Pharmas. Tech. Corp. v. Barr Labs., Inc., 386 F.3d 485, 495–96 (2d Cir.2004), and to determine whether the defendants possess market power in the relevant market. United States v. Visa U.S.A., Inc., 344 F.3d 229, 238 (2d Cir.2003). Although the precise role that market power plays in the rule of reason analysis is unclear, it may be a highly relevant factor. Id. at 238 n. 4; Capital Imaging Assocs., P.C. v. Mohawk Valley Med. Assocs., 996 F.2d 537, 546 (2d Cir.1993).

Contrary to the contentions of the appellants, the court did undertake a full rule of reason analysis. It first determined that the relevant market is ciprofloxacin and that Bayer had market power within that market. Cipro II, 363 F.Supp.2d at 523. It then determined that there was no evidence that the Agreements created a bottleneck on challenges to the ′444 patent or otherwise restrained competition outside the “exclusionary zone” of the patent. Id. at 540. Thus, the court concluded that the plaintiffs had failed to demonstrate that the Agreements had an anti-competitive effect on the market for ciprofloxacin beyond that permitted by the patent. Id. Because the court concluded that the plaintiffs failed to meet their burden under the first step of the rule of reason analysis, it did not find it necessary to consider the second or third steps of the analysis. Id. at 541.

The appellants assert, however, that the district court erred in concluding that the Agreements were within the “exclusionary zone” of the ′444 patent, in essence treating them as per se legal. According to the appellants, the patentee's right to exclude competition is not defined by the facial scope of the patent, but rather is limited to the right to exclude others from profiting from the patented invention. Under the Agreements, the appellants argue, Bayer *1333 is seeking not simply to enforce its patent rights, but to insulate itself from competition and avoid the risk that the patent is held invalid.

The district court did not treat the Agreements as per se legal. Rather, the court simply recognized that any adverse anti-competitive effects within the scope of the ′444 patent could not be redressed by antitrust law. United States v. Gen. Elec. Co., 272 U.S. 476, 485, 47 S.Ct. 192, 71 L.Ed. 362 (1926); E. Bement & Sons v. Nat'l Harrow Co., 186 U.S. 70, 91, 22 S.Ct. 747, 46 L.Ed. 1058 (1902); see In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 201–02 (2d Cir.2006); Valley Drug Co. v. Geneva Pharmas., Inc., 344 F.3d 1294, 1312 (11th Cir.2003); United States v. Stud iengesellschaft Kohle, m.b.H., 670 F.2d 1122, 1127 (D.C.Cir.1981). This is because a patent by its very nature is anticompetitive; it is a grant to the inventor of “the right to exclude others from making, using, offering for sale, or selling the invention....” 35 U.S.C. § 154(a)(1); Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 215, 100 S.Ct. 2601, 65 L.Ed.2d 696 (1980) ( “[T]he essence of a patent grant is the right to exclude others from profiting by the patented invention.”). Thus, “a patent is an exception to the general rule against monopolies and to the right of access to a free and open market.” Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 816, 65 S.Ct. 993, 89 L.Ed. 1381 (1945). The district court appreciated this underlying tension between the antitrust laws and the patent laws when it compared the anti-competitive effects of the Agreements with the “zone of exclusion” provided by the claims of the patent. See In re Tamoxifen, 466 F.3d at 201–02; Andrx Pharmas., Inc. v. Elan Corp., 421 F.3d 1227, 1235 (11th Cir.2005); Schering–Plough Corp. v. FTC, 402 F.3d 1056, 1066 (11th Cir.2005); Valley Drug, 344 F.3d at 1312. Because the court found no anti-competitive effects outside the exclusionary zone of the patent, it concluded that the Agreements were not violative of section 1 of the Sherman Act. Cipro II, 363 F.Supp.2d at 540–41.

We find no error in the court's analysis. Pursuant to the Agreements, the generic defendants agreed not to market a generic version of Cipro until the ′444 patent expired 10 and not to challenge the validity of the ′444 patent, and Bayer agreed to make payments and optionally supply Cipro for resale. Thus, the essence of the Agreements was to exclude the defendants from profiting from the patented invention. This is well within Bayer's rights as the patentee. Furthermore, there is a long-standing policy in the law in favor of settlements, and this policy extends to patent infringement litigation. Flex–Foot, Inc. v. CRP, Inc.,
We disagree with the appellants that the fact that the generic defendants agreed *1334 not to challenge the validity of the ‘444 patent renders the Agreements violative of the antitrust laws. According to the appellants, there is a vital public interest in patent validity challenges to ensure that consumers are not burdened by unwarranted patent monopolies. Appellants assert that Congress underscored this public interest by providing in 35 U.S.C. § 282 that an issued patent carries only a rebuttable presumption of validity, which can be challenged in court. In fact, appellants argue, at the preliminary injunction stage, the patentee has the burden of establishing the likelihood of success on the merits of the patent's validity. Furthermore, the appellants contend, in the Hatch–Waxman Act, Congress provided the incentive of a 180–day exclusivity period to the first generic manufacturer to challenge a patent.

Settlements in patent cases, however, frequently provide that the alleged infringer will not challenge the validity of the patent. See, e.g., Flex–Foot, 238 F.3d at 1367, 1370; Diversey Lever, Inc. v. Ecolab, Inc., 191 F.3d 1350, 1351 (Fed.Cir.1999); Interspiro USA, Inc. v. Figgie Int'l, Inc., 18 F.3d 927, 932 (Fed.Cir.1994). Thus, the mere fact that the Agreements insulated Bayer from patent validity challenges by the generic defendants was not in itself an antitrust violation. Indeed, there is no evidence that the Agreements prevented challenges by other generic drug manufacturers to the validity of the ′444 patent. In fact, four other generic manufacturers—Ranbaxy, Mylan, Schein, and Carlsbad—filed Paragraph IV ANDAs and initiated challenges of the validity of the patent.

C

The appellants urge this court to consider the legal standards applied by the regional circuits and government agencies in addressing Agreements involving exclusion payments in the context of the Hatch–Waxman Act, all of which, they assert, encompass greater antitrust scrutiny than the standard adopted by the district court. In particular, the appellants point to the Sixth Circuit's decision in In re Cardizem CD Antitrust Litigation, 332 F.3d 896 (6th Cir.2003), upholding a summary judgment ruling by the district court that a reverse payment agreement is per se illegal. Further, the appellants assert that although the Eleventh Circuit in Valley Drug reversed the district court's ruling of per se illegality, it provided a more extensive analytical framework within which to review the settlement agreements on remand. And, in Schering–Plough, the appellants assert the Eleventh Circuit adhered to the standard in Valley Drug and recognized the need to evaluate the strength of the patent in determining whether reverse payments are unlawful. The appellants contend that the Federal Trade Commission (“FTC”) advocates a rule of reason inquiry focusing on the amount of the payment and several other factors, although not requiring consideration of the validity of the patent. Finally, the appellants note that the Solicitor General has suggested that a reverse payment should be evaluated using a rule of reason approach and that “the strength of the patent as it appeared at the time at which the parties settled” should be considered in the analysis, citing Brief for the United States as Amicus Curiae at *12, Joblove v. Barr Labs., 551 U.S. 1144, 127 S.Ct. 3001, 168 L.Ed.2d 726 (2007) (No. 06–830), 2007 WL 1511527. According to the appellants, only the Second Circuit in In re Tamoxifen, has concluded that a settlement between a patent holder and an alleged infringer in Hatch–Waxman litigation does not violate the antitrust laws provided the litigation is not baseless, although it recognized that such an approach shields settlement agreements involving “fatally weak” patents. Therefore, the appellants assert, the district court's treatment of the Agreements *1335 here was not in line with that of the other circuits, the FTC, and the Solicitor General, and we should reject the district court's approach in lieu of those other standards.
In re Ciprofloxacin Hydrochloride Antitrust Litigation, 544 F.3d 1323 (2008)

2008-2 Trade Cases P 76,336, 88 U.S.P.Q.2d 1801

We find, however, the district court's analysis to be sound. As noted above, the district court applied a rule of reason analysis in assessing the lawfulness of the Agreements. In that analysis, it considered whether there was evidence of sham litigation or fraud before the PTO, and whether any anticompetitive effects of the Agreements were outside the exclusionary zone of the patent. The application of a rule of reason analysis to a settlement agreement involving an exclusion payment in the Hatch–Waxman context has been embraced by the Second Circuit, and advocated by the FTC and the Solicitor General. And, although the Sixth Circuit found a per se violation of the antitrust laws in In re Cardizem, the facts of that case are distinguishable from this case and from the other circuit court decisions. In particular, the settlement in that case included, in addition to a reverse payment, an agreement by the generic manufacturer to not relinquish its 180–day exclusivity period, thereby delaying the entry of other generic manufacturers. In re Cardizem, 332 F.3d at 907. Furthermore, the agreement provided that the generic manufacturer would not market non-infringing versions of the generic drug. Id. at 908 n. 13. Thus, the agreement clearly had anticompetitive effects outside the exclusion zone of the patent. See Brief for the United States, 2007 WL 1511527 at *16 n. 7 (No. 06–830); Brief for the United States as Amicus Curiae at *17, FTC v. Schering–Plough Corp., (No. 05–273), 2006 WL 1358441. To the extent that the Sixth Circuit may have found a per se antitrust violation based solely on the reverse payments, we respectfully disagree.

The Eleventh Circuit in Valley Drug reversed a finding by the district court that settlement agreements constituted a per se violation of the antitrust laws because the court failed to consider the exclusionary power of the patent in its antitrust analysis. 344 F.3d at 1306, 1312. Although it rejected the court's condemnation of the agreements as a per se antitrust violation, it did not advocate application of a rule of reason analysis, finding such an analysis to be inappropriate given that the anticompetitive effects of the exclusionary zone of a patent are not subject to debate. Id. at 1312 n. 27. In so holding, it emphasized that the subsequent declaration of invalidity did not render the patent's potential exclusionary effects irrelevant to the antitrust analysis. Id. at 1309. It did leave open the possibility, however, that an antitrust violation could be found in the extreme situation where there was evidence of fraud on the PTO or sham litigation. Id. at 1309 & n. 21. On remand, it ordered the district court to consider the exclusionary potential of the patent, the extent to which provisions of the settlement agreement exceeded the scope of the patent, and the anticompetitive effects of those provisions. Id. at 1312.

This approach was followed by the Eleventh Circuit in Schering–Plough and Andrx Pharmaceuticals and by the Second Circuit in In re Tamoxifen. In re Tamoxifen, 466 F.3d at 212; Andrx Pharms., 421 F.3d at 1235; Schering–Plough, 402 F.3d at 1066. In Schering–Plough, the Eleventh Circuit set aside the decision by the FTC that the settlement agreements constituted an unreasonable restraint of trade. 402 F.3d at 1058. It noted that there was no evidence that the patent was invalid or that the litigation was a sham, and thus the proper analysis was whether the agreements restricted competition beyond the exclusionary effects of the patent. Id. at 1068. After reviewing the terms of the settlement agreements, it found that they were within *1336 the exclusionary zone of the patent and therefore protected by patent law. Id. at 1072. The Second Circuit, in In re Tamoxifen, similarly concluded that the validity of the patent need not be considered in the analysis of whether the settlement agreement violates the antitrust laws unless the infringement suit was objectively baseless. 466 F.3d at 213. In that case, the patent holder settled with the generic manufacturer after losing on validity before the district court and while on appeal to this court. Id. at 193. In so holding, the Second Circuit recognized that alleged Sherman Act violations are generally evaluated under a rule of reason analysis. Id. at 201 n. 13. It concluded that the presence of a reverse payment, or the size of a reverse payment, alone is not enough to render an agreement violative of the antitrust laws unless the anticompetitive effects of the agreement exceed the scope of the patent's protection. Id. at 212–13. Because the agreement did not extend to non-infringing products and did not create a bottleneck for other generic manufacturers, the court held that any anticompetitive effects were within the exclusionary power of the patent. Id. at 213–16.

We conclude that in cases such as this, wherein all anticompetitive effects of the settlement agreement are within the exclusionary power of the patent, the outcome is the same whether the court begins its analysis under antitrust law by applying a rule of reason approach to evaluate the anti-competitive effects, or under patent law by analyzing the right to exclude afforded by the patent. The essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent. This analysis has been adopted by the Second and the Eleventh Circuits and by the district court below and we find it to be
In re Ciprofloxacin Hydrochloride Antitrust Litigation, 544 F.3d 1323 (2008)

2008-2 Trade Cases P 76,336, 88 U.S.P.Q.2d 1801

completely consistent with Supreme Court precedent. See Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 175–77, 86 S.Ct. 347, 15 L.Ed.2d 247 (1965) (holding that there may be a violation of the Sherman Act when a patent is procured by fraud, but recognizing that a patent is an exception to the general rule against monopolies).

In addition, we agree with the Second and Eleventh Circuits and with the district court that, in the absence of evidence of fraud before the PTO or sham litigation, the court need not consider the validity of the patent in the antitrust analysis of a settlement agreement involving a reverse payment. The FTC has also rejected the application of a post hoc analysis of the validity of the patent as part of the antitrust analysis. In its decision that led to the Eleventh Circuit appeal in Schering–Plough, the FTC concluded that “it would not be necessary, practical, or particularly useful for the Commission to embark on an inquiry into the merits of the underlying patent dispute when resolving antitrust issues in patent settlements.” In re Schering–Plough Corp., No. 9297, 2003 WL 22989651, slip op. at 19 (F.T.C. Dec. 8, 2003). However, on petition for writ of certiorari, the FTC criticized the Eleventh Circuit’s approach to evaluating the exclusionary potential of the patent because it “ignore[d] the most salient factor that gives rise to patent litigation and settlements, the existence of uncertainty.” *1337 Regarding whether a patent is valid or... infringed by particular products.” Petitioner's Opening Brief at *15, Schering–Plough, (2006) (No. 05–273), 2005 WL 2105243. Similarly, here, the FTC argues that the district court erred by equating the exclusionary power of the patent with the scope of the patent claims without consideration of the uncertainty of patent validity. Corrected Br. of Amicus Curiae FTC in Supp. of Appellants 19. Apparently, the FTC, in recognizing the “probabilistic” nature of the patent interest, recommends that the “expected value” of the lawsuit at the time of the settlement be considered in the antitrust analysis. Petitioner's Opening Brief at *16, Schering–Plough, (No. 05–273), 2005 WL 2105243; Reply Brief for the Petitioner at *6, Schering–Plough, (No. 05–273), 2005 WL 2652617.

The Solicitor General advocates that an appropriate antitrust analysis “should take into account the relative likelihood of success of the parties' claims, viewed ex ante.” Brief for the United States at *12, Joblove, (No. 06–830), 2007 WL 1511527; Brief for the United States at *11, Schering–Plough, (No. 05–273), 2005 WL 2105243. Practically, the Solicitor General proposes that, while the court need not conduct a full trial, it could conduct a limited evaluation of the merits of the patent claims. Brief for the United States at *13, Joblove (No. 06–830), 2007 WL 1511527; Brief for the United States at *11 n. 1, Schering–Plough, (No. 05–273), 2005 WL 2105243. While the expected value of the lawsuit (considered in the approach advocated by the FTC) should relate directly to the relative strength of the claim (considered in the approach advocated by the Solicitor General), the distinction between the approaches advocated by the FTC and the Solicitor General may lie in the fact that the expected value of the lawsuit depends on the subjective views of the parties as opposed to objective evidence of validity. See Brief for the United States at *12, Schering–Plough, (No. 05–273), 2005 WL 2105243.

We disagree that analysis of patent validity is appropriate in the absence of fraud or sham litigation. Pursuant to statute, a patent is presumed to be valid, 35 U.S.C. § 282, and patent law bestows the patent holder with “the right to exclude others from profiting by the patented invention.” Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 215, 100 S.Ct. 2601, 65 L.Ed.2d 696 (1980). A settlement is not unlawful if it serves to protect that to which the patent holder is legally entitled—a monopoly over the manufacture and distribution of the patented invention. In re Tamoxifen, 466 F.3d at 208–09. Thus, the district court correctly concluded that there is no legal basis for restricting the right of a patentee to choose its preferred means of enforcement and no support for the notion that the Hatch–Waxman Act was intended to thwart settlements. Cipro II, 363 F.Supp.2d at 531–32. As Judge Posner remarked, if “there is nothing suspicious about the circumstances of a patent settlement, then to prevent a cloud from being cast over the settlement process a third party should not be permitted to haul the parties to the settlement over the hot coals of antitrust litigation.” Asahi Glass Co. v. Pentech Pharms., Inc., 289 F.Supp.2d 986, 992 (N.D.Ill. 2003).

Accordingly, we find the analysis by the district court to be fully supported in law and to demonstrate that it was cognizant of the legal standards applied by the regional circuits and government agencies in addressing agreements involving exclusion payments in the context of the Hatch–Waxman Act.
The appellants next contend that the district court erred in reasoning that even though Bayer settled with Barr, other generic companies could still challenge the ‘444 patent and their incentive to challenge the patent would grow with the chance that the patent would be held invalid, rendering any anticompetitive effects of the Agreements short-lived. According to the appellants, while that reasoning may make sense outside the Hatch–Waxman context, it does not apply under Hatch–Waxman, where they allege generic manufacturers are less motivated to initiate and vigorously challenge a patent. The appellants contend that the incentives are significantly reduced in the Hatch–Waxman context because any generic manufacturer that wishes to challenge the patent must first undertake the effort, time, and expense of filing a Paragraph IV ANDA. The appellants further assert that few generic manufacturers are capable of initiating such a challenge and any challenge would be significantly delayed. Thus, the appellants argue that the brand name manufacturer, by paying off the first Paragraph IV ANDA filer, can protect its monopoly from competition for years—particularly near the end of the patent term—even if its patent is “fatally weak.” It is that delay in challenge by generic manufacturers that is emphasized by the appellants here, since there is no dispute that four other generic manufacturers ultimately challenged the validity of the ’444 patent.

While we recognize that the Hatch–Waxman Act creates certain burdens for generic manufacturers, it also provides significant benefits. First, it streamlines the process of obtaining FDA approval to market a generic version of a drug without having to go through the rigorous new drug application (“NDA”) process that the patent holder is required to do. Compare 21 U.S.C. § 355(j)(2)(A) with 355(b)(1). See Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 676, 110 S.Ct. 2683, 110 L.Ed.2d 605 (1990). Thus, the generic drug manufacturers can piggyback on the safety and efficacy studies conducted by the patent holder. Second, it allows the generic manufacturers to challenge the validity of a patent simply by filing a Paragraph IV ANDA. 21 U.S.C. § 355(j)(2)(A)(vii), (5)(C)(i); see Eli Lilly, 496 U.S. at 677, 110 S.Ct. 2683. Thus, as explained by the Eleventh Circuit, the Hatch–Waxman Act redistributes the relative risks between the patent holder and generic manufacturers, allowing generic manufacturers to challenge the validity of the patent without incurring the costs of market entry or the risks of damages from infringement. Schering–Plough, 402 F.3d at 1074. Thus, the district court reasonably concluded that the incentive to mount a challenge would increase with the chance that the patent would be held invalid. Cipro II, 363 F.Supp.2d at 534. Further, the district court noted that there was no evidence that the Agreements created a bottleneck preventing generic challenges to the ’444 patent. Id. at 540. Indeed, the patent was subsequently challenged by four other generic manufacturers and was upheld as valid.

Finally, the appellants contend that the district court erred in not considering evidence showing that the Agreements preserved Barr’s claim to the 180–day exclusivity period, which served the defendants’ joint interest in protecting the Cipro monopoly from generic competition. According to the appellants, the district court refused to consider the evidence in Cipro II because it had earlier denied the plaintiffs’ motions for partial summary judgment in Cipro I. But, the appellants assert, the district court should have considered the evidence anew in Cipro II, because: (1) the plaintiffs were now the nonmoving parties and thus the evidence should have been considered in the light most favorable to the plaintiffs; and (2) at *1339 issue was whether the Agreements had an actual adverse effect on competition in the relevant market, whereas in Cipro I the issue was the per se illegality of the Agreements. The appellants aver that the evidence raised genuine issues of material fact regarding whether the Agreements preserved Barr’s claim to the 180–day exclusivity period, delayed and deterred other generic manufacturers from entering the ciprofloxacin market, and thus had an actual adverse effect on competition.
Again, we find no error in the district court's analysis. In addressing whether the Agreements restrained competition outside the scope of the '444 patent, the court observed that the only legitimate allegation by the plaintiffs was that the 180–day exclusivity period had been manipulated by Barr. Cipro II, 363 F.Supp.2d at 540. However, the court noted that that theory had already been addressed in Cipro I. Specifically, in Cipro I, the court determined that the Agreements did not create a “bottleneck” for future Paragraph IV ANDA filers because Barr had no right to the 180–day exclusivity period. 261 F.Supp.2d at 243. That was because at the time of the Agreements, the FDA regulation in effect conditioned the first Paragraph IV ANDA filer's right to the 180–day exclusivity period on a “successful defense” of its Paragraph IV ANDA against the patent holder. Id.: see 21 C.F.R. § 314.107(c)(1) (1998), revoked 63 Fed.Reg. 59710, 59711 (Nov. 5, 1998). However, Barr acknowledged in the consent judgment both its infringement and the validity of the '444 patent, thereby ending the underlying litigation. Cipro I, 261 F.Supp.2d at 243. More importantly, as part of the Agreements, Barr converted its Paragraph IV ANDA to a Paragraph III ANDA. Id. Thus, the court concluded that Barr had failed to satisfy the successful defense requirement necessary to be eligible for the 180–day exclusivity period. Id.

We do not know what evidence the plaintiffs believe would have created a genuine issue of material fact had it been considered by the district court in Cipro II. There appears to be no dispute about the contents of the consent judgment and the Agreements, and there does not appear to be a dispute about what was contained in the FDA regulation that was in effect at the time. Although the appellants make much of the uncertainty in the law regarding the validity of the “successful defense” requirement, we find no merit to that argument. The district court acknowledged that two circuit courts issued opinions in April 1998, more than a year after the Agreements were executed, striking down the FDA regulation. Cipro I, 261 F.Supp.2d at 243–44 (citing Mova Pharm. Corp. v. Shalala, 140 F.3d 1060 (D.C.Cir.1998); Granutech, Inc. v. Shalala, 139 F.3d 889 (4th Cir.1998)). The court further noted that the FDA ultimately removed the successful defense requirement from the regulation in November 1998. Cipro I, 261 F.Supp.2d at 244 (citing 63 Fed.Reg. 59710, 59711 (Nov. 5, 1998)). Nevertheless, the court correctly concluded that “the fact still remains that the requirement was in effect at the time of the [Agreements].” Cipro I, 261 F.Supp.2d at 244; see Tamoxifen, 466 F.3d at 218 (concluding that because the established law at the time of the settlement agreement required that a generic manufacturer must successfully defend an infringement lawsuit in order to obtain exclusivity, the generic manufacturer had no claim to the exclusivity period despite the terms of the agreement). Furthermore, the court appreciated that even without the successful defense requirement, there was still no support for the claim that Barr retained the 180–day exclusivity period after amending from a Paragraph IV ANDA to a Paragraph III ANDA. Cipro I, 261 F.Supp.2d at 247. Finally, the court recognized that since the Agreements were executed, Bayer has sued four other generic manufacturers that filed ANDAs and defended against invalidity counterclaims; thus, the Agreements did not prevent other generic manufacturers from challenging the '444 patent. Id. We find no error by the district court in declining to consider anew the evidence allegedly showing that the Agreements preserved Barr's claim to the 180–day exclusivity period, and in concluding that the Agreements did not create a “bottleneck” for other generic manufacturers.

Accordingly, we affirm the district court's grant of summary judgment on Counts I–IV, holding that the Agreements were not violative of section 1 of the Sherman Act since all anticompetitive effects were within the exclusionary power of the '444 patent.

IV

Count V alleges that Bayer violated state antitrust and consumer protection laws by fraudulently obtaining the '444 patent and enforcing it through sham litigation. The district court dismissed Count V as preempted by federal patent law. Cipro II, 363 F.Supp.2d at 547.

In re Ciprofloxacin Hydrochloride Antitrust Litigation, 544 F.3d 1323 (2008)

2008-2 Trade Cases P 76,336, 88 U.S.P.Q.2d 1801

err in concluding that their state law monopolization claims are preempted by federal patent law because preemption does not apply when the patent was procured by fraud. Further, the appellants contend that the district court erroneously concluded that no tortious conduct in the marketplace had been alleged, ignoring Bayer's lawsuit against Barr seeking to enforce a fraudulently procured patent. According to the appellants, the district court's reliance on Semiconductor Energy Laboratory Co. v. Samsung Electronics Co., 204 F.3d 1368 (Fed.Cir.2000), and Abbott Laboratories v. Brennan, 952 F.2d 1346 (Fed.Cir.1991), is misplaced because neither case involves a state law antitrust claim based on wrongful enforcement of a patent procured by fraud. The appellants assert that an antitrust claim under Walker Process is distinguishable from an inequitable conduct claim because it contains the additional elements of an antitrust claim, namely, market power and antitrust injury. The monopolization claims here, the appellants contend, like those in Dow Chemical Co. v. Exxon Corp., 139 F.3d 1470 (Fed.Cir.1998), have elements other than inequitable conduct before the PTO—and therefore are not preempted by federal patent law. The monopolization claims here, the appellants contend, like those in Dow Chemical Co. v. Exxon Corp., 139 F.3d 1470 (Fed.Cir.1998), have elements other than inequitable conduct before the PTO—and therefore are not preempted by federal patent law. Finally, the appellants argue that because antitrust is a field traditionally regulated by the states, there is a presumption against preemption of state law, and Congress has made no express legislative statement to overcome that presumption.

It is not clear that the district court considered the portions of Hunter Douglas and Nobelpharma that the appellants rely on in their brief. However, the result in this case would not change even if we were to adopt the appellants' interpretation of these cases because the district court determined, and we agree, that no fraud occurred. In light of this, the district court's disposition of Count V was not erroneous.

V

For the foregoing reasons, we affirm the grant of summary judgment by the District Court for the Eastern District of New York that the Agreements were not in violation of section 1 of the Sherman Act because any anti-competitive effects caused by the Agreements were within the exclusionary zone of the patent. We further affirm the court's dismissal of the state antitrust claims.

AFFIRMED

All Citations

544 F.3d 1323, 2008-2 Trade Cases P 76,336, 88 U.S.P.Q.2d 1801

Footnotes

* Honorable T. John Ward, District Judge, United States District Court for the Eastern District of Texas, sitting by designation.

1 The filer of a Paragraph IV ANDA certifies that the patent is invalid or will not be infringed by the generic drug. 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

2 Barr did not certify that its product did not infringe the ′444 patent.

3 Notably, the Agreements were entered into before the 2003 amendments to the Hatch-Waxman Act, requiring a patent holder and a first Paragraph IV ANDA filer who settle their patent litigation to file their agreement with the Federal Trade Commission and Department of Justice for review, and if the agreement is found to violate the antitrust laws,
In re Ciprofloxacin Hydrochloride Antitrust Litigation, 544 F.3d 1323 (2008)


Barr, however, preserved the option to reamend its ANDA to a Paragraph IV certification—in order to reclaim the 180–day exclusivity period—in the event a court declared the ′444 patent to be invalid or unenforceable.

Added to the $49.1 million initial payment, the payments from Bayer to Barr totaled $398.1 million. Barr shared the payments equally with HMR.

In Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp., 382 U.S. 172, 86 S.Ct. 347, 15 L.Ed.2d 247 (1965), the Supreme Court held that the enforcement of a patent procured by fraud on the patent office may be a violation of the Sherman Act provided that the other elements necessary to a Sherman Act claim are present. Id. at 177, 86 S.Ct. 347. Here, however, the plaintiffs alleged a violation of state antitrust laws.

The court further noted that there was a serious question whether the indirect purchasers even had standing to assert a Walker Process claim. Id. at 547.


Specifically, the appellants contend that there are genuine issues of material fact relating to whether the defendants received far more under the Agreements then they could have had Barr won the litigation against Bayer, invalidated the ′444 patent, and entered the market. Further, the appellants aver that the court needs to assess the apparent strength of the patent at the time of the Agreements.

Under the Cipro Supply Agreement, however, Barr was allowed to sell a competing ciprofloxacin product six months before the ′444 patent expired.

Indeed, a sizable exclusion payment from the patent holder to the generic manufacturer is not unexpected under the Hatch–Waxman Act, where the relative risks of litigation are redistributed. Schering–Plough, 402 F.3d at 1074; see infra pp. 23–24.

Although certain statements by the Eleventh Circuit have been interpreted to mean that it advocated consideration of the validity of the patent, Brief for the United States at *16, Joblove, 551 U.S. 1144, 127 S.Ct. 3001, 168 L.Ed.2d 726 (No. 06–830); Brief for the United States at *17–19, Schering–Plough 548 U.S. 919, 126 S.Ct. 2929, 165 L.Ed.2d 977 (No. 05–273), the district court correctly noted that the Eleventh Circuit did not consider or rely on evidence of patent invalidity in either Valley Drug or Schering–Plough. Cipro II, 363 F.Supp.2d at 525, 529.

At oral argument, the appellants emphasized that Mylan was delayed for two-and-a-half years in filing its ANDA and challenging the patents because it believed that Barr was entitled to the 180–day exclusivity period. Oral Arg. at 5:56–6:29, 6:49–7:02, available at http://www.cafc.uscourts.gov/oralarguments/mp3/2008–1097.mp3. They further asserted that because of the delay, none of the generic challengers raised the issue of inequitable conduct. Id. at 7:05–7:57.

Although the Agreements apparently did contain a provision preserving the option for Barr to reamend to a Paragraph IV ANDA (presumptively for the purpose of reclaiming the 180–day exclusivity period) if the ′444 patent was subsequently declared by a court to be invalid or unenforceable, that provision does not change the analysis. Under the FDA regulations in effect at the time of the Agreements, the first generic manufacturer was not entitled to the 180–day exclusivity period.
unless it had satisfied the successful defense requirement. Furthermore, since the option was never exercised, there was no evidence of an *actual* adverse effect on competition due to that provision. *See Clorox*, 117 F.3d at 56.
In re K-Dur Antitrust Litigation, 686 F.3d 197 (2012)
2012-2 Trade Cases P 77,971, 103 U.S.P.Q.2d 1497

686 F.3d 197
United States Court of Appeals, Third Circuit.

In re K–DUR ANTITRUST LITIGATION.
Louisiana Wholesale Drug Co., Inc., on behalf of itself and all others similarly situated, Appellants.
In re K–DUR Antitrust Litigation.
CVS Pharmacy, Inc.; Rite Aid Corporation, Appellants.
In re K–DUR Antitrust Litigation.
In re K–DUR Antitrust Litigation.

Nos. 10–2077, 10–2078, 10–2079, 10–4571

Argued Dec. 12, 2011.

Filed: July 16, 2012.

Synopsis
Background: Wholesalers and retailers that purchased name-brand patented drug directly from pharmaceutical company brought putative class actions against company and its competitors, alleging that defendants effected an unreasonable restraint of trade in violation of Sherman Act by settling company's patent-infringement cases against competitors, thereby delaying market entry of competitors' planned generic versions of drug. Actions were consolidated by the Judicial Panel on Multidistrict Litigation. Plaintiffs moved for class certification. The United States District Court for the District of New Jersey, Garrett E. Brown, Jr., J., adopted the opinion of Stephen M. Orlofsky, Special Master, 2008 WL 2699390, and certified class. Defendants moved for summary judgment. The District Court, Greenaway, Jr., Chief Judge, J., 2010 WL 1172995, adopted the opinion of Orlofsky, Special Master, 2009 WL 508869, and granted summary judgment to defendants. Plaintiffs appealed.

Holdings: The Court of Appeals, Sloviter, Circuit Judge, held that:

district court was required to apply a quick look rule of reason analysis, abrogating King Drug Co. of Florence, Inc. v. Cephalon, Inc., 702 F.Supp.2d 514;

issues common to proposed class predominated over individual issues; and

proposed class did not suffer from inherent conflict precluding adequacy of representation.

Affirmed in part, reversed in part, and remanded.
OPINION OF THE COURT

SLOVITER, Circuit Judge.
In re K-Dur Antitrust Litigation, 686 F.3d 197 (2012)

2012-2 Trade Cases P 77,971, 103 U.S.P.Q.2d 1497

In this appeal, we consider the antitrust implications of an agreement by a manufacturer of a generic drug that, in return for a payment by the patent holder, agrees to drop its challenge to the patent and refrain from entering the market for a specified period of time.

A secondary issue concerns the certification by the District Court of a class of antitrust plaintiffs. Specifically, we must determine whether the antitrust injury allegedly suffered by class members can be shown through common proof, i.e. proof applicable to all plaintiffs, and whether there are insurmountable conflicts preventing named plaintiffs from adequately representing the members of the class.

These appeals arise out of the settlement of two patent cases involving the drug K–Dur 20 (“K–Dur”), which is manufactured by Schering–Plough Corporation (“Schering”). Plaintiffs are Louisiana Wholesale Drug Company, Inc., on behalf of a class of wholesalers and retailers who purchased K–Dur directly from Schering and nine individual plaintiffs, including CVS Pharmacy, Inc., Rite Aid Corporation, and other pharmacies. Defendants are Schering and Upsher–Smith Laboratories (“Upsher Smith”).

*203 I. STATUTORY AND REGULATORY FRAMEWORK

K–Dur is Schering's brand-name sustained-release potassium chloride supplement. Sustained-release potassium chloride is used to treat potassium deficiencies, including those that arise as a side effect of the use of diuretic products to treat high blood pressure.

Schering did not hold a patent for the potassium chloride salt itself, as that compound is commonly known and not patentable. Instead, Schering held a formulation patent on the controlled release coating it applied to the potassium chloride crystals. Schering identified patent number 4,863,743 (“the ′743 patent”) as the patent that would be infringed by the production of a generic version of K–Dur. Schering assigned the ′743 patent to its subsidiary Key Pharmaceuticals, Inc. The ′743 patent was set to expire on September 5, 2006.

By statute, a pharmaceutical company must obtain from the Food and Drug Administration (“FDA”) approval before it may market a prescription drug. 21 U.S.C. § 355(a). For a new drug, the approval process requires submission of a New Drug Application (“NDA”), which includes exhaustive information about the drug, including safety and efficacy studies, the method of producing the drug, and any patents issued on the drug's composition or methods of use. Id. § 355(b)(1). The FDA publishes the patent information submitted in NDAs in the “Approved Drug Products with Therapeutic Equivalence Evaluations,” otherwise known as the “Orange Book.” See FDA Electronic Orange Book, http://www.fda.gov/cder/ob/.


When a generic manufacturer files an ANDA, it is also required to file a certification that, “in the opinion of the applicant and to the best of his knowledge,” the proposed generic drug does not infringe any patent listed with the FDA as covering the patented drug. Id. § 355(j)(2)(A)(vii). The generic manufacturer can satisfy this requirement by certifying one of the following four options with respect to the patent for the listed drug: “(I) that such patent information has not been filed, (II) that such patent has expired, (III) [by certifying] the date on which such patent will expire, or (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.” Id. § 355(j)(2)(A)(vii). The
generic manufacturers at issue here, Upsher and ESI, used the fourth of these certification options, the so-called “paragraph IV certification.” Id. § 355(j)(2)(A)(vii)(IV). When a would-be generic manufacturer submits a paragraph IV certification, it must consult the Orange Book and provide written *204 notice to each listed patent owner impacted by the ANDA. Id. § 355(j)(2)(B)(iii)(I). By statute, a paragraph IV certification constitutes a technical act of patent infringement. 35 U.S.C. § 271(e)(2)(A).

Upon receiving notice of a paragraph IV certification with respect to one of its pharmaceutical patents, the patent holder may initiate an infringement suit based on the filing of the paragraph IV certification alone within forty-five days after the generic applicant files its ANDA and paragraph IV certification. 21 U.S.C. § 355(j)(5)(B)(iii). Filing suit by the patent holder within that window effects an automatic stay that prevents the FDA from approving the generic drug until the earlier of (1) thirty months have run or (2) the court hearing the patent challenge finds that the patent is either invalid or not infringed. Id. § 355(j)(5)(B)(iii)(I).

Congress explained that the purpose of the Hatch–Waxman Act is “to make available more low cost generic drugs.” H.R.Rep. No. 98–857(I), at 14–15, reprinted in 1984 U.S.C.C.A.N. 2647, 2647–48. In order to encourage generic entry and challenges to drug patents, the Hatch–Waxman Act rewards the first generic manufacturer who submits an ANDA and a paragraph IV certification by providing it with a 180–day period during which the FDA will not approve subsequent ANDA applications. 21 U.S.C. § 355(j)(5)(B)(iv). The 180–day exclusivity period is triggered on the date on which the first ANDA applicant begins commercial marketing of its drug. Id. Notably, the 180–day exclusivity window is only available to the first filer of an ANDA with a paragraph IV certification, meaning that even if the first filer never becomes eligible to use its 180–day exclusivity period because it settles, loses, or withdraws the litigation, that potential benefit will not pass to subsequent filers. 21 U.S.C. § 355(j)(5)(D)(iii). It has been suggested that the first filer is usually the most motivated challenger to the patent holder's claimed intellectual property. See C. Scott Hemphill, Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem, 81 N.Y.U. L.Rev. 1553, 1583 (2006) (noting “a sharp difference in incentives ... between [the first paragraph IV] filer and all other generic firms”).


**II. FACTUAL AND PROCEDURAL BACKGROUND**

**A. Approval of the ′743 Patent**

The patented invention claims a controlled-release dispersible potassium chloride tablet. The ′743 patent was developed using a technique called “microencapsulation,” a process in which small particles of a drug are coated to *205 make them disperse over time. The research supporting the ′743 patent built on work that Schering had done for an earlier patent for a controlled-release aspirin tablet, Patent No. 4,555,399 (the ‘399 patent”). The application for what became the ′743 patent was initially rejected by the Patent and Trademark Office (“PTO”) as obvious in light of the ′399 patent and other prior art. In order to circumvent the prior art, Schering amended its application for what became the ′743 patent to clarify that the controlled release
coating in the invention contained ethylcellulose with a viscosity of greater than 40 cp, whereas the ‘399 patent called for the use of ethylcellulose with a viscosity of 9–11 cp. Schering argued that a coating containing ethylcellulose of greater than 40 cp was not obvious under the prior art. After this amendment, the PTO granted the ‘743 patent on September 5, 1989.

### B. The Schering–Upsher Litigation and Settlement

In August 1995, Upsher filed the first ANDA seeking approval to produce a generic version of K–Dur to be called Klor–Con M20. Upsher provided a paragraph IV certification to Schering in November 1995, certifying that its generic would not infringe Schering's ‘743 patent. On December 15, 1995, within the forty-five-day window provided by Hatch–Waxman, Schering sued Upsher in the District of New Jersey for patent infringement, triggering the 30–month automatic stay in FDA approval of Upsher's generic.

Upsher's defense against Schering's patent infringement suit was based on differences between the chemical composition of the controlled release coating in its generic product and that of the invention claimed in the ‘743 patent. Throughout the litigation, Upsher vigorously defended against Schering's infringement claims, at one point telling the court that Schering's claims of infringement “are baseless and could not have been made in good faith.” App. at 3610.

The parties began trying to settle the infringement case at least as early as May 1997. During settlement negotiations, Upsher requested both a cash payment and an early entry date for its generic product. However, Schering expressed concern about possible antitrust problems that might arise if it made a reverse payment.

In the early morning of June 18, 1997, just hours before the District Court was to rule on the pending cross motions for summary judgment and begin, if necessary, a patent trial, Upsher and Schering agreed to settle the case. The settlement was memorialized in an eleven-page short-form agreement dated June 17, 1997 (“the Schering–Upsher agreement”). That agreement provided that, while Upsher did not concede the validity, infringement, or enforceability of the ‘743 patent, it would refrain from marketing its generic potassium chloride supplement or any similar product until September 1, 2001, at which point it would receive a non-royalty non-exclusive license under the ‘743 patent to make and sell a generic form of Klor–Con. Additionally, Upsher granted Schering licenses to make and sell several pharmaceutical products Upsher had developed, including Niacor–SR, a sustained-release niacin product used to treat high cholesterol. In return, Schering promised to pay Upsher sixty million dollars ($60,000,000) over three years, plus additional smaller sums depending upon its sales of Niacor–SR in defined markets. While the parties to this litigation dispute whether the payment was solely for the licensing of Upsher products or instead formed part of the consideration for dropping the patent action, the agreement lists Upsher's promises to dismiss the patent infringement action and not to market any sustained-release microencapsulated potassium chloride tablet until September 1, 2001, as part of the consideration for the payment.

The settlement agreement and the acquisition of licenses from Upsher were ratified by Schering's board of directors on June 24, 1997. Subsequent to the settlement, Upsher and Schering abandoned plans to make and market Niacor–SR.

In this action, the parties dispute the facts related to the Niacor–SR license. Plaintiffs contend that the license was a sham and that the $60 million paid as royalties for Niacor–SR was actually compensation for Upsher's agreement to delay the entry of its generic extended-release potassium tablet. On the other hand, defendants contend that Schering's board valued the license deal separately and that $60 million was its good faith valuation of the licenses at the time.
C. The Schering–ESI Litigation and Settlement

In December 1995, ESI Lederle 4 ("ESI") filed an ANDA seeking FDA approval to make and sell a generic version of K–Dur along with a paragraph IV certification stating that its proposed generic did not infringe the ′743 patent. Within the forty-five-day period provided by the Hatch–Waxman Act, Schering sued ESI for patent infringement in the Eastern District of Pennsylvania. ESI defended on the ground that, unlike K–Dur, its generic equivalent did not employ a “coating material with two different ingredients” as specified by the ′743 patent, but rather was made by a “different technology which produces a multi-layered coating with each layer comprised of a separate material having only a single ingredient.” App. at 1696–97.

In the fall of 1996, Schering and ESI agreed to participate in court-supervised mediation before a magistrate judge. The settlement agreement the parties eventually reached (“the Schering–ESI agreement”) called for Schering to grant ESI a royalty-free license under the ′743 patent beginning on January 1, 2004. In exchange, Schering would pay ESI $5 million up front and a varying sum depending on when ESI's ANDA was approved by the FDA. Specifically, Schering agreed to pay ESI an amount ranging from a maximum of $10 million if ESI's ANDA was approved before July 1999 down to a minimum of $625,000 if the ANDA was not approved until 2002. As part of the settlement, ESI also represented that it was not developing and had no plans to develop any other potassium chloride product.

The FDA approved ESI's generic K–Dur product in May 1999, and Schering paid ESI the additional $10 million as required under the settlement agreement.

D. The FTC Action

In March 2001, the FTC filed a complaint against Schering, Upsher, and ESI alleging that Schering's settlements with Upsher and ESI unreasonably restrained commerce in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45. Specifically, the FTC alleged that the settlement payments from Schering to Upsher and ESI constituted reverse payments intended to delay generic entry and improperly preserve Schering's monopoly.

In June 2002, after a lengthy trial, the Administrative Law Judge ("ALJ") issued an initial decision dismissing the FTC's complaint and finding that neither agreement violated Section 5 of the FTC Act. In re Schering–Plough Corp., Initial Decision, 136 F.T.C. 1092, 1263 (2002). The ALJ found that there was no reverse payment in the Schering–Upsher agreement because the licensing deal included in that agreement was separately valued and was not a payment to Upsher to delay generic entry. Id. at 1243. The ALJ also found that the Schering–ESI agreement was not an attempt to unlawfully preserve Schering's monopoly power in the market. Id. at 1236, 1262–63.

In December 2003, the FTC unanimously reversed the ALJ's ruling, finding that there was a “direct nexus between Schering's payment and Upsher's agreement to delay its competitive entry” and that this agreement “unreasonably restrain[ed] commerce.” In re Schering–Plough Corp., Final Order, 136 F.T.C. 956, 1052 (2003). The FTC likewise found that the ESI settlement violated antitrust law, noting that Schering had not attempted to rebut the natural presumption that the payment to ESI was for delay in generic entry, except to argue unpersuasively that the parties felt judicial pressure to settle. Id. at 1056–57. In making these determinations, the FTC found that it was “neither necessary nor helpful to delve into the merits of the [underlying patent disputes].” Id. at 1055. Rather, the FTC determined that, where a name brand pharmaceutical maker pays a generic manufacturer as part of a settlement, “[a]bsent proof of other offsetting consideration, it is logical to conclude that the quid pro quo for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise.” Id. at 988. In applying the rule of reason, the FTC concluded that the possible existence of a reverse payment...
In re K-Dur Antitrust Litigation, 686 F.3d 197 (2012)

2012-2 Trade Cases P 77,971, 103 U.S.P.Q.2d 1497

raises a red flag and can give rise to a prima facie case that an agreement is anticompetitive. Id. at 991, 1000–01. The FTC concluded that the reverse payment at issue was illegal because the settling parties could show neither (1) that the payment was for something other than delay of generic entry nor (2) that the payment had pro-competitive effects. Id. at 988–89, 1061.

Schering appealed the FTC's ruling to the Eleventh Circuit, which reversed in Schering–Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir.2005). The Eleventh Circuit's ruling in Schering–Plough is discussed in Section III(C) infra.

E. The Instant Litigation

Separate from the FTC's challenge, various private parties filed antitrust suits attacking the settlements. Those suits, the matters giving rise to this appeal, were consolidated in the District of New Jersey by the Judicial Panel on Multidistrict Litigation. In 2006, by consent of the parties, the District Court appointed Stephen Orlofsky as Special Master with responsibility to handle all motions, including motions for class certification and summary judgment. 5

*208 On April 14, 2008, the Special Master certified a class of plaintiffs consisting of forty-four wholesalers and retailers who purchased K–Dur directly from Schering. The District Court adopted that decision on December 30, 2008. 6

In February 2009, the Special Master issued a Report and Recommendation granting defendants' motions for summary judgment and denying plaintiffs' motions for partial summary judgment. In his Report and Recommendation, the Special Master applied a presumption that Schering's '743 patent was valid and that it gave Schering the right to exclude infringing products until the end of its term, including through reverse payment settlements. Under this analysis, the settlements in this case would only be subject to antitrust scrutiny if (1) they exceeded the scope of the '743 patent or (2) the underlying patent infringement suits were objectively baseless. The Special Master determined that neither of these exceptions applied. The District Court subsequently adopted the Report and Recommendation in its entirety.

F. Economic Background and the History of Reverse Payment Settlements

Reverse payment settlements appear to be unique to the Hatch–Waxman context, and the FTC has made them a top enforcement priority in recent years. A 2010 analysis by the FTC found that reverse payment settlements cost consumers $3.5 billion annually. FTC, Pay–for–Delay: How Drug Company Pay–Offs Cost Consumers Billions 2 (2010), available at http://www.ftc.gov/os/2010/01/100112 payfordelayrpt.pdf. The FTC estimates that about one year after market entry an average generic pharmaceutical product takes over ninety percent of the patent holder's unit sales and sells for fifteen percent of the price of the name brand product. Id. at 8. This price differential means that consumers, rather than generic producers, are typically the biggest beneficiaries of generic entry.

III. THE ANTITRUST ISSUE (Appeals Nos. 10–2077, 10–2078, 10–2079)

A. Jurisdiction and Standard of Review

The District Court had jurisdiction pursuant to 15 U.S.C. § 15(a) and 28 U.S.C. §§ 1331 and 1337. This court has jurisdiction over the antitrust appeals pursuant to 28 U.S.C. § 1291.
This court exercises plenary review of the District Court's grant of summary judgment, applying the same summary judgment standard that guides the District Court. *Eichenlaub v. Twp. of Indiana*, 385 F.3d 274, 279 (3d Cir.2004).

**B. General Antitrust Standard**

The Sherman Act provides, in part, that “[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal.” 15 U.S.C. § 1. Under a literal reading, this provision would make illegal every agreement in restraint of trade. See *Arizona v. Maricopa Cnty. Med. Soc'y*, 457 U.S. 332, 342, 102 S.Ct. 2466, 73 L.Ed.2d 48 (1982). However, it has not been so interpreted. Rather the Supreme Court has long construed it to prohibit only unreasonable restraints. See *State Oil Co. v. Khan*, 522 U.S. 3, 10, 118 S.Ct. 275, 139 L.Ed.2d 199 (1997). Whether a restraint qualifies as unreasonable and therefore conflicts with the statute is normally evaluated under the “rule of reason.” *Id.* Applying this approach, “the finder of fact must decide whether the questioned practice imposes an unreasonable restraint on competition, taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect.” *Id.* This inquiry has been divided into three parts. First, the plaintiff must show that the challenged conduct has produced anti-competitive effects within the market. *United States v. Brown Univ.*, 5 F.3d 658, 668 (3d Cir.1993). If the plaintiff meets the initial burden, “the burden shifts to the defendant to show that the challenged conduct promotes a sufficiently pro-competitive objective.” *Id.* at 669. Finally, the plaintiff can rebut the defendant's purported pro-competitive justification by showing that the restraint is not reasonably necessary to achieve the pro-competitive objective. *Id.*

Courts have recognized, however, that “[s]ome types of restraints ... have such predictable and pernicious anticompetitive effect, and such limited potential for pro-competitive benefit, that they [should be] deemed unlawful *per se.*” *State Oil Co.*, 522 U.S. at 10, 118 S.Ct. 275. Examples of agreements that have been held unlawful pursuant to the *per se* rule include horizontal price fixing, output limitations, market allocation, and group boycotts. See *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 768, 104 S.Ct. 2731, 81 L.Ed.2d 628 (1984); *N. Pac. Ry. v. United States*, 356 U.S. 1, 5, 78 S.Ct. 514, 2 L.Ed.2d 545 (1958). The *per se* rule is applied where a “practice facially appears to be one that would always or almost always tend to restrict competition or decrease output.” *Broad. Music, Inc. v. CBS, Inc.*, 441 U.S. 1, 19–20, 99 S.Ct. 1551, 60 L.Ed.2d 1 (1979).

In some situations, courts apply an antitrust analysis that falls between the full rule of reason inquiry on the one hand and the rigid *per se* approach on the other. This so-called “quick look” or “truncated rule of reason” analysis applies where the plaintiff has shown that the defendant has engaged in practices similar to those subject to *per se* treatment. See *Brown Univ.*, 5 F.3d at 669. Having so shown, plaintiff is not required to make a full showing of anti-competitive effects within the market; rather defendant has the burden of demonstrating pro-competitive justifications. *Id.*

**C. Precedent from Other Circuits**

Neither this court nor the Supreme Court has yet weighed in on the legality of reverse payment settlements. However, five other circuits have addressed the question. Two of those courts—the first two to consider the question—concluded that such agreements should be subject to strict antitrust scrutiny, at least where the settling parties attempted to manipulate the 180-day exclusivity period to block all potential generic competition. The three courts to address the question of reverse payments more recently have reached a contrary result, ruling that such agreements are permissible so long as they do not exceed the potential exclusionary scope of the patent.

The D.C. Circuit considered a reverse payment in *Andrx Pharmaceuticals, Inc. v. Biovail Corp. International, 256 F.3d 799 (D.C.Cir.2001)*, cert. denied, 535 U.S. 931, 122 S.Ct. 1305, 152 L.Ed.2d 216 (2002). Unlike the instant case, that case did not involve a settlement resolving patent litigation. Rather, while allowing the patent litigation to continue, the name brand manufacturer agreed to compensate the would-be generic producer to delay marketing a generic product.

In September 1995, Andrx Pharmaceuticals (“Andrx”) filed an ANDA seeking to manufacture and sell a generic form of Cardizem CD, a heart drug for which Hoechst Marion Russell, Inc. (“HMRI”) held the patent. *Id.* at 803. Andrx filed a paragraph IV certification and was timely sued for patent infringement by HMRI. *Id.* The filing of the patent infringement suit triggered the thirty-month waiting period during which the FDA could not give final approval to Andrx or any subsequent ANDA applicants seeking to make a generic version of Cardizem CD. *Id.* (citing 21 U.S.C. § 355(j)(5)(B)(iii)). In June 1997, a second generic manufacturer, Biovail Corp. International (“Biovail”), filed an ANDA and a paragraph IV certification to produce generic Cardizem CD. Shortly thereafter, the FDA issued a tentative approval of Andrx's ANDA. *Id.*

Soon after the tentative approval was issued, HMRI and Andrx entered into an agreement pursuant to which HMRI would pay Andrx $40 million per year beginning on the date that Andrx received final approval from the FDA and ending on the date that Andrx either began selling generic Cardizem CD or was adjudged liable for patent infringement in the pending suit. *Id.* The apparent purpose of this agreement was to create a bottleneck by delaying the triggering of Andrx's 180–day period of exclusivity, and thereby delaying generic entry not only by Andrx but also by any other potential generic manufacturer. *Id.* at 804.

The D.C. Circuit reversed the district court's dismissal with prejudice of Biovail's antitrust claims, holding that the agreement between HMRI and Andrx could “reasonably be viewed as an attempt to allocate market share and preserve monopolistic conditions.” *Id.* at 811. The D.C. Circuit treated the payment from HMRI to Andrx as *prima facie* evidence of an illegal agreement not to compete, noting that “Andrx's argument that any rational actor would wait for resolution of the patent infringement suit [before triggering the 180–day exclusivity period] is belied by the *quid* of HMRI's *quo.*” *Id.* at 813.

2. Sixth Circuit—In re Cardizem CD Antitrust Litig., 332 F.3d 896 (6th Cir.2003)

The Sixth Circuit's decision of *In re Cardizem CD Antitrust Litigation* concerned the same agreement considered by the D.C. Circuit in *Andrx, 332 F.3d 896 (6th Cir.2003)*, cert. denied, 543 U.S. 939, 125 S.Ct. 307, 160 L.Ed.2d 248 (2004). The Sixth Circuit case was brought by direct and indirect purchasers of Cardizem CD who alleged that they suffered antitrust harm as a result of Andrx's agreement with HMRI to delay market entry. *Id.* at 903–04. The Sixth Circuit held that the Andrx–HMRI agreement was “a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a *per se* illegal restraint of trade.” *Id.* at 908.

While both *Cardizem* and *Andrx* concerned an agreement that caused a bottleneck by preventing other generic manufacturers from entering the market by delaying the triggering of the first filer's 180–day exclusivity period, much of the Sixth Circuit's reasoning in *Cardizem* is equally applicable to cases, like the instant one, that do not involve bottlenecking. Specifically, the Sixth Circuit emphasized its concern that, even setting aside the bar to subsequent generic applicants, HMRI had paid Andrx not to enter the market itself, stating, “it is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market.” *Id.* at 908.
3. Eleventh Circuit—Valley Drug Co. v. Geneva Pharmas., Inc., 344 F.3d 1294 (11th Cir.2003) and Schering–Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir.2005)

The Eleventh Circuit has also considered the question of reverse payments settlements in three significant cases. The first of these, Valley Drug Co. v. Geneva Pharmaceuticals, Inc., 344 F.3d 1294 (11th Cir.2003), cert. denied, 543 U.S. 939, 125 S.Ct. 308, 160 L.Ed.2d 248 (2004), concerned two agreements arising out of cases where a name brand drug manufacturer sued generic manufacturers for patent infringement and the generic manufacturers defended on the ground of patent invalidity.\(^7\) Id. at 1299–301. In the two agreements at issue, the name brand manufacturer agreed to pay the generic manufacturer substantial sums to refrain from entering the market until the end of the name brand manufacturer's patent term. Id. at 1300. The patent at issue was subsequently declared invalid in another case. Id. at 1306–07. The district court granted summary judgment to antitrust plaintiffs, holding that the settlements were per se violations of the Sherman Act. Id. at 1301. The Eleventh Circuit reversed on the ground that the name brand manufacturer held a patent that gave it the right to exclude competitors. Id. at 1306. In so ruling, the court emphasized the fact that the name brand manufacturer might have prevailed in the underlying patent litigation, id. at 1309, and highlighted policy considerations favoring the settlement of patent litigation, id. at 1308 n. 20. The court applied neither a per se nor rule of reason analysis to the agreements as a whole; rather, it directed the district court to first determine whether any part of the agreement went beyond the protections afforded by the name brand manufacturer's patent and, if so, to apply traditional antitrust scrutiny only to those portions of the agreement. Id. at 1311–1312.

A subsequent Eleventh Circuit case, Schering–Plough Corp. v. FTC, arose out of the same settlement agreement as the instant appeal.\(^8\) 402 F.3d 1056 (11th Cir.2005), cert. denied, 548 U.S. 919, 126 S.Ct. 2929, 165 L.Ed.2d 977 (2006). After the FTC found that both agreements violated antitrust laws, the defendants appealed to the Eleventh Circuit. Applying the test articulated in Valley Drug, the Eleventh Circuit set aside the ruling of the FTC. Id. at 1065–66, 1076. The court rejected the FTC’s conclusion that Schering’s $60 million payment to Upsher was for something other than the licenses it obtained, finding by “overwhelming evidence” that the payment was only for the licenses. Id. 1069–71. As such, the court found that there was no reverse payment from Schering to Upsher and thus necessarily no antitrust violation in that agreement. Id. With respect to the ESI settlement, the court acknowledged the presence of a reverse payment but concluded that the payment was acceptable in light of judicial policy favoring settlements and the court's finding that the settlement terms “reflect[ed] a reasonable implementation” of the protections afforded by patent law.” Id. at 1072 (quoting Valley Drug, 344 F.3d at 1312).\(^9\)

Plaintiffs construe Valley Drug and Schering–Plough as requiring courts to conduct an ex post evaluation of the strength of the underlying patent before determining whether the patent shields an agreement from antitrust scrutiny. However, following oral argument in this case, the Eleventh Circuit explicitly rejected that interpretation of its prior holdings. In FTC v. Watson Pharmaceuticals, Inc., the Eleventh Circuit clarified that its prior opinions did not call for an evaluation of the strength of the patent but rather only a determination whether, absent sham litigation or fraud in obtaining the patent, the settlement agreement exceeded the scope of the patent. FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1311–13 n. 8, 1313–14 (11th Cir.2012). Thus the standard applied by the Eleventh Circuit is identical to the scope of the patent test applied by the Second Circuit to which we now turn.

4. Second Circuit—In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187 (2d Cir.2006)

The Second Circuit's decision of In re Tamoxifen Citrate Antitrust Litigation arose out of an agreement settling a patent infringement suit over the drug tamoxifen, then the most widely prescribed drug for the treatment of breast cancer. 466 F.3d 187, 190 (2d Cir.2006), cert. denied, 551 U.S. 1144, 127 S.Ct. 3001, 168 L.Ed.2d 726 (2007). That settlement was reached while the patent case was on appeal after the district court had ruled the patent invalid. Id. The settlement called for the name
brand manufacturer to grant the generic manufacturer a license to sell an unbranded version of tamoxifen and make a reverse payment of $21 million to the generic manufacturer. The settlement was contingent on obtaining a vacatur of the district court's judgment holding the patent to be invalid, which was subsequently obtained. Id.

Affirming the district court's dismissal of antitrust plaintiffs' claims, the Second Circuit applied a presumption of patent validity and held that “there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent.” Id. at 213 (internal citations and quotation marks omitted). The only exceptions to this rule, the court held, occur where there is evidence that the patent was procured by fraud or that the enforcement *213 suit was objectively baseless. Id. This test is commonly referred to as the “scope of the patent test” or the “Tamoxifen test.” The Second Circuit conceded that there was a potentially troubling result of such a rule in that “[t]he less sound the patent or the less clear the infringement, and therefore the less justified the monopoly enjoyed by the patent holder, the more a rule permitting settlement is likely to benefit the patent holder by allowing it to retain the patent.” Id. at 211. The court determined, however, that this risk was counterbalanced by the judicial preference for settlement. Id.

In reaching this conclusion, the Second Circuit concluded that “the Hatch–Waxman Act created an environment that encourages [reverse payments]” because, unlike traditional infringement suits where the patent holder can negotiate by agreeing to forego the infringement damages it expects to recover, there usually are no infringement damages in Hatch–Waxman suits. Id. at 206. The Second Circuit thus reasoned that the “reverse payments” common in Hatch–Waxman suits are less troubling because they take the place of infringement damages that the patent holder might have otherwise waived in order to reach a settlement. Id.

Judge Pooler dissented from the decision in Tamoxifen, contending that the scope of the patent rule applied by the majority “is not soundly grounded in Supreme Court precedent and is insufficiently protective of the consumer interests safeguarded by the Hatch–Waxman Act and the antitrust laws.” Id. at 224 (Pooler, J., dissenting). Judge Pooler argued, inter alia, that judicial reevaluation of patent validity is a public good that reverse payment settlements undercut, id. at 225–26, and suggested that the proper antitrust standard is one of reasonableness considering all the circumstances affecting a restrictive agreement including (1) the strength of the patent as it appeared at the time of settlement, (2) the amount of the reverse payment, (3) the amount the generic manufacturer would have made during its 180–day exclusivity period, and (4) any ancillary anticompetitive effects of the agreement. Id. at 228.

In a subsequent reverse payment case, Arkansas Carpenters Health & Welfare Fund v. Bayer AG, the Second Circuit applied the Tamoxifen standard and rejected an antitrust challenge to a Hatch–Waxman settlement involving a reverse payment. 604 F.3d 98 (2d Cir.2010), cert. denied, — U.S. ——, 131 S.Ct. 1606, 179 L.Ed.2d 517 (2011). However, the judges on the Arkansas Carpenters panel made clear that they thought that Tamoxifen was wrongly decided and invited appellants to petition for rehearing en banc. Id. at 108–10. Among other things, the Arkansas Carpenters court noted its concern about evidence suggesting that the number of reverse payment settlements had increased dramatically in the wake of the Tamoxifen decision. Id. at 109. Rehearing en banc was subsequently denied over a dissent from Judge Pooler. Ark. Carpenters Health & Welfare Fund v. Bayer AG, 625 F.3d 779 (2d Cir.2010).

5. Federal Circuit—In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed.Cir.2008)

In In re Ciprofloxacin Hydrochloride Antitrust Litigation the Federal Circuit considered a case related to those confronted by the Second Circuit in Arkansas Carpenters. 544 F.3d 1323 (Fed.Cir.2008), cert. denied, 557 U.S. 920, 129 S.Ct. 2828, 174 L.Ed.2d 553 (2009). The Federal Circuit applied the scope of the patent test explicated in Tamoxifen and other cases, stating, “[t]he essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent.” Id. at 1336. The court further “agree[d] with the Second and Eleventh Circuits ... that, in the absence of evidence of fraud before the
PTO or sham litigation, the court need not consider the validity of the patent in the antitrust analysis of a settlement agreement involving a reverse payment.” *Id.*

**D. Analysis**

While the first two courts of appeal to address the issue of reverse payments subjected those agreements to antitrust scrutiny, later courts have gravitated toward the scope of the patent test under which reverse payments are permitted so long as (1) the exclusion does not exceed the patent's scope, (2) the patent holder's claim of infringement was not objectively baseless, and (3) the patent was not procured by fraud on the PTO. The scope of the patent test was applied by the Special Master in this case and has been applied by at least one other district court in this circuit. See *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 702 F.Supp.2d 514, 528–29, 533 (E.D.Pa.2010) (applying scope of the patent test but denying defendants' motion to dismiss where plaintiffs pleaded facts supporting their claim that the underlying patent suit was objectively baseless). As a practical matter, the scope of the patent test does not subject reverse payment agreements to any antitrust scrutiny. As the antitrust defendants concede, no court applying the scope of the patent test has ever permitted a reverse payment antitrust case to go to trial.

After consideration of the arguments of counsel, the conflicting decisions in the other circuits, the Report of the Special Master, and our own reading, we cannot agree with those courts that apply the scope of the patent test. In our view, that test improperly restricts the application of antitrust law and is contrary to the policies underlying the Hatch–Waxman Act and a long line of Supreme Court precedent on patent litigation and competition.

First, we take issue with the scope of the patent test's almost unrebuttable presumption of patent validity. This presumption assumes away the question being litigated in the underlying patent suit, enforcing a presumption that the patent holder would have prevailed. We can identify no significant support for such a policy. While persons challenging the validity of a patent in litigation bear the burden of defeating a presumption of validity, this presumption is intended merely as a procedural device and is not a substantive right of the patent holder. See *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed.Cir.1983) (“The presumption, like all legal presumptions, is a procedural device, not substantive law.”). Moreover, the effectively conclusive presumption that a patent holder is entitled to exclude competitors is particularly misguided with respect to agreements—like those here—where the underlying suit concerned patent infringement rather than patent validity: In infringement cases it is the patent holder who bears the burden of showing infringement. See *Egyptian Goddess, Inc. v. Swisa, Inc.*, 543 F.3d 665, 679 (Fed.Cir.2008).

Rather than adopt an unrebuttable presumption of patent validity, we believe *215* courts must be mindful of the fact that “[a] patent, in the last analysis, simply represents a legal conclusion reached by the Patent Office.” *Lear, Inc. v. Adkins*, 395 U.S. 653, 670, 89 S.Ct. 1902, 23 L.Ed.2d 610 (1969). Many patents issued by the PTO are later found to be invalid or not infringed, and a 2002 study conducted by the FTC concluded that, in Hatch–Waxman challenges made under paragraph IV, the generic challenger prevailed seventy-three percent of the time. See FTC, *Generic Drug Entry Prior to Patent Expiration* 16 (2002), available at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf; Kimberly A. Moore, *Judges, Juries, and Patent Cases—An Empirical Peek Inside the Black Box*, 99 Mich. L.Rev. 365, 385 (2000) (noting that between 1983 and 1999 the alleged infringer prevailed in forty-two percent of patent cases that reached trial). *11* These figures add force to the likelihood—conceded by the *Tamoxifen* majority—that reverse payments enable the holder of a patent that the holder knows is weak to buy its way out of both competition with the challenging competitor and possible invalidation of the patent. 466 F.3d at 211 (“The less sound the patent or the less clear the infringement, and therefore the less justified the monopoly enjoyed by the patent holder, the more a rule permitting settlement is likely to benefit the patent holder by allowing it to retain the patent.”).
Moreover, we question the assumption underlying the view of the Second Circuit and other courts that subsequent challenges by other generic manufacturers will suffice to eliminate weak patents preserved through a reverse payment to the initial challenger. Cf., e.g., id. at 211–12. We note that the initial generic challenger is necessarily the most motivated because, unlike all subsequent challengers, it stands to benefit from the 180–day exclusivity period of 21 U.S.C. § 355(j)(5)(B)(iv). Additionally, as the experience of at least one court in this Circuit confirms, the high profit margins of a monopolist drug manufacturer may enable it to pay off a whole series of challengers rather than suffer the possible loss of its patent through litigation. See King Drug Co. of Florence, Inc., 702 F.Supp.2d at 521–22 (drug manufacturer settled infringement suits by four generic firms, which agreed to delay market entry “in exchange for significant payments ... for various licensing agreements, supply agreements and research and development deals”).

This practical analysis is supported by a long line of Supreme Court cases recognizing that valid patents are a limited exception to a general rule of the free exploitation of ideas. It follows that the public interest supports judicial testing and elimination of weak patents. See Cardinal Chem. Co. v. Morton Int'l, Inc., 508 U.S. 83, 100–01, 113 S.Ct. 1967, 124 L.Ed.2d 1 (1993) (explaining the “importance to the public at large of resolving questions of patent validity” and noting the danger of “grant[ing] monopoly privileges to the holders of invalid patents”); Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 146, 109 S.Ct. 971, 103 L.Ed.2d 118 (1989) (noting that the patent laws embody “a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy”); United States v. Masonite Corp., 316 U.S. 265, 277, 62 S.Ct. 1070, 86 L.Ed. 1461 (1942) (a patent “affords no immunity for a monopoly not fairly or plainly within the grant”); id. at 280, 62 S.Ct. 1070 (patents are to be “strictly construed” because they are “privileges restrictive of a free economy”); Pope Mfg. Co. v. Gormully, 144 U.S. 224, 234, 12 S.Ct. 632, 36 L.Ed. 414 (1892) (“It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly.”).

That reasoning underlies the decision of the Supreme Court in Edward Katzinger Co. v. Chicago Metallic Manufacturing Co., where the Court considered whether a patent licensor could be contractually estopped from challenging the validity of the patent under a licensing agreement that also contained a price fixing term. 329 U.S. 394, 67 S.Ct. 416, 91 L.Ed. 374 (1947). The Court reasoned that if the patent was invalid, the price fixing provision would violate federal antitrust law and that, as such, the licensor could not be estopped from challenging the patent. Id. at 399, 401–02, 67 S.Ct. 416. In reaching this conclusion the Court emphasized “the broad public interest in freeing our competitive economy from the trade restraints which might be imposed by price-fixing agreements stemming from narrow or invalid patents.” Id. at 400, 67 S.Ct. 416 (citing Sola Elec. Co. v. Jefferson Elec. Co., 317 U.S. 173, 177, 63 S.Ct. 172, 87 L.Ed. 165 (1942)). The Court additionally stated: “It is the public interest which is dominant in the patent system and ... the right to challenge [a patent] is not only a private right to the individual, but it is founded on public policy which is promoted by his making the defence, and contravened by his refusal to make it.” Id. at 401, 67 S.Ct. 416 (internal citations and quotation marks omitted).

This logic is persuasive with respect to the situation at bar because reverse payments permit the sharing of monopoly rents between would-be competitors without any assurance that the underlying patent is valid. See also United States v. Studiengesellschaft Kohle, m.b.H., 670 F.2d 1122, 1136 (D.C.Cir.1981) (suggesting an agreement might be anticompetitive if it “give[s] potential competitors incentives to remain in cartels rather than turning to another product, inventing around the patent, or challenging its validity”). It appears that these aspects of the Supreme Court's general patent jurisprudence had been overlooked by the Special Master and others adopting the scope of the patent test.

We caution that our decision today is limited to reverse payments between patent holders and would be generic competitors in the pharmaceutical industry. As the Supreme Court has made clear, “antitrust analysis must sensitively recognize and reflect the distinctive economic and legal setting of the regulated industry to which it applies.” Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 411–12, 124 S.Ct. 872, 157 L.Ed.2d 823 (2004); see also IA Phillip E. Areeda & Herbert Hovenkamp Antitrust Law, ¶ 240d, 289 (3d ed. 2006) (“[T]he presence of regulation in some instances limits the antitrust...
The goal of the Hatch–Waxman Act is to increase the availability of low cost generic drugs. H.R.Rep. No. 98–857, pt. 1, at 14, reprinted in 1984 U.S.C.C.A.N. 2647 at 2647. One method Congress employed was to encourage litigated challenges by generic manufacturers against the holders of weak or narrow patents. See 21 U.S.C. § 355(j)(5)(B)(iv) (establishing 180–day exclusivity period as reward for successfully challenging a patent); S.Rep. No. 107–167, at 4 (2002) (“Under Hatch–Waxman, manufacturers of generic drugs are encouraged to challenge weak or invalid patents on brand name drugs so consumers can enjoy lower drug prices.”). That goal is undermined by application of the scope of the patent test which entitles the patent holder to pay its potential generic competitors not to compete. As one commentator has noted, this approach nominally protects the protection of intellectual property and the need for competition. Specifically, in passing the Hatch–Waxman Act, Congress drew a careful line between patent protection and the need to provide incentives for competition in the pharmaceutical industry. See 130 Cong. Rec. 24425 (Sept. 6, 1984) (statement of Rep. Waxman underscoring the “fundamental balance of the bill”); H.R.Rep. No. 98–857, pt. 2, at 30 (1984), 1984 U.S.C.C.A.N. 2686 at 2713 (emphasizing that the bill achieves “what the Congress has traditionally done in the area of intellectual property law[:] balance the need to stimulate innovation against the goal of furthering the public interest”), reprinted in 1984 U.S.C.C.A.N. 2686 at 2715. The line that Congress drew between competing objectives strongly supports the application of rule of reason scrutiny of reverse payment settlements in the pharmaceutical industry.

In rejecting the scope of the patent test, we are cognizant that such a test encourages settlement, an objective our decisions generally support. See, e.g., Ehrheart v. Verizon Wireless, 609 F.3d 590, 595 (3d Cir.2010) (“Settlement agreements are to be encouraged because they promote the amicable resolution of disputes and lighten the increasing load of litigation faced by the federal courts.”). However, the judicial preference for settlement, while generally laudable, should not displace countervailing public policy objectives or, in this case, Congress's determination—which is evident from the structure of the Hatch–Waxman Act and the statements in the legislative record—that litigated patent challenges are necessary to protect consumers from unjustified monopolies by name brand drug manufacturers. We also emphasize that nothing in the rule of reason test that we adopt here limits the ability of the parties to reach settlements based on a negotiated entry date for marketing of the generic drug: the only settlements subject to antitrust scrutiny are those involving a reverse payment from the name brand manufacturer to the generic challenger. Data analyzed by the FTC suggest that this will leave the vast majority of pharmaceutical patent settlements unaffected. See FTC, Bureau of Competition, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2010, 2 (2011) (showing that nearly seventy-five percent of Hatch–Waxman Act infringement suits that settled in 2010 did so without reverse payments), available at http://www.ftc.gov/os/2011/05/1105mm agreements.pdf.

For all of these reasons we reject the scope of the patent test. In its place we will direct the District Court to apply a quick look rule of reason analysis based on the economic realities of the reverse payment settlement rather than the labels applied by the settling parties. Specifically, the finder of fact must treat any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as prima facie evidence of an unreasonable restraint of trade, which could be rebutted by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit.
In holding that a reverse payment is pr**ima facie** evidence of an unreasonable restraint of trade, we follow the approach suggested by the DC Circuit in *Andrx* and embrace that court's common sense conclusion that “[a] payment flowing from the innovator to the challenging generic firm may suggest strongly the anticompetitive intent of the parties entering the agreement....” 256 F.3d at 809 (internal quotation marks and citation omitted).

We agree, moreover, with the FTC that there is no need to consider the merits of the underlying patent suit because “[a]bsent proof of other offsetting consideration, it is logical to conclude that the quid pro quo for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise.” In re Schering–Plough Corp., Final Order, 136 F.T.C. at 988. Of course, a patent holder may attempt to rebut plaintiff's pr**ima facie** case of an unreasonable restraint of trade by arguing that there is in fact no reverse payment because any money that changed hands was for something other than a delay in market entry. Alternatively, the patent holder may attempt to rebut the pr**ima facie** case by demonstrating that the reverse payment offers a competitive benefit that could not have been achieved in the absence of a reverse payment. This second possible defense attempts to account for the—probably rare—situations where a reverse payment increases competition. For example, a modest cash payment that enables a cash-starved generic manufacturer to avoid bankruptcy and begin marketing a generic drug might have an overall effect of increasing the amount of competition in the market. For the reasons set forth, we will reverse the judgment of the District Court and remand for further proceedings in accordance with the foregoing.

**IV. THE CLASS CERTIFICATION ISSUE (Appeal No. 10–4571)**

**A. Procedural Background**

The other issue before us on this appeal concerns plaintiffs' effort to certify a class of persons who purchased K–Dur directly from Schering between November 20, 1998 and September 1, 2001 and subsequently purchased a generic version of K–Dur. As identified by the parties' experts, the class consists of forty-four wholesalers and retailers. The Special Master recommended granting plaintiffs' motion to certify the class. The District Court adopted the Special Master's Report and Recommendation and formally certified the class.

Defendants sought interlocutory review of the District Court's order under Federal Rule of Civil Procedure 23(f). While that petition was pending, the District Court ruled on the cross motions for summary judgment and entered final judgment in defendants' favor. Plaintiffs filed a notice of appeal, and defendants filed a cross appeal, which this court dismissed as untimely. See Order, In re K–Dur Antitrust Litig., No. 10–2727 (3d Cir. Nov. 24, 2010). However, this court accepted defendants' Rule 23(f) petition, see Order, In re K–Dur Antitrust Litig., No. 09–8006 (3d Cir. Nov. 16, 2010), and we therefore have jurisdiction pursuant to 28 U.S.C. § 1292(e). 12

**B. Standard of Review**

This court reviews class certification orders “for abuse of discretion, which occurs if the district court's decision rests upon a clearly erroneous finding of fact, an errant conclusion of law or an improper application of law to fact.” In re Hydrogen Peroxide Antitrust Litig., 552 F.3d 305, 312 (3d Cir.2008) (internal quotation marks and citation omitted).
C. Defendants' Arguments

In order to certify a class under Rule 23(b)(3), a plaintiff must satisfy both the general class action prerequisites—numerosity, commonality, typicality, and adequacy of representation—and the additional requirements of predominance and superiority. Fed.R.Civ.P. 23(a), (b)(3). The Special Master, in a report adopted in full by the District Court, discussed the class requirements in detail; defendants challenge only a few of those findings. Defendants assert that (1) plaintiffs cannot use common evidence to prove that the class members suffered an actual injury from defendants' conduct because showing actual injury means demonstrating lost profits damages, which defendants argue necessarily requires individualized assessments, (2) even assuming that overcharges are an acceptable form of injury, the District Court erred in its conclusion that there was common evidence of injury to all class members, and (3) the class should not have been certified because of inherent conflicts between members. Defendants' first two arguments challenge the District Court's finding with respect to the predominance requirement, while the third goes to the adequacy requirement. We address these arguments in order.

1. Predominance Issues

In order for the predominance requirement to be satisfied “[i]ssues common to the class must predominate over individual issues.” In re Hydrogen Peroxide, 552 F.3d at 311 (internal citations and quotation marks omitted). Class certification calls for the district court to conduct a “rigorous assessment of the available evidence,” id. at 312, and is only appropriate in antitrust cases where plaintiffs can show, by a preponderance of the evidence, *220 that proof of the essential elements of the cause of action, including antitrust injury, do not require individual treatment. Id. at 307, 311.

It is plaintiffs' thesis that they will prove that class members paid more for K–Dur because of Schering's antitrust violations, and that this constitutes the required antitrust impact. The Special Master accepted this based on Third Circuit law, stating:

    The Third Circuit has held that “when an antitrust violation impacts upon a class of persons who do have standing, there is no reason in doctrine why proof of impact cannot be made on a common basis, so long as the common proof adequately demonstrates some damage to each individual.”

App. at 7980 (quoting Bogosian v. Gulf Oil Corp., 561 F.2d 434, 454 (3d Cir.1977)). Because all of the class members purchased some of the generic versions of K–Dur, plaintiffs have satisfactorily explained their theory of impact.

Plaintiffs proposed to prove antitrust injury through common proof consisting largely of the declarations and report of their expert, Dr. Leitzinger. Dr. Leitzinger offered statistical and economic analyses of the overall brand-name and generic drug market and of the specific entry of generic potassium chloride in the market to show that, but for the challenged reverse payment agreements, “all (or virtually all) members of the proposed class” would have purchased at least some less expensive generic potassium chloride earlier, and therefore suffered an antitrust injury as a result of the delay in generic entry. The Special Master considered Dr. Leitzinger's proposed methodology and the criticisms of it made by defendants' expert, Dr. Rubinfeld, in detail. After slightly narrowing the class definition to accommodate a criticism made by defendants' expert, 13 the Special Master found that plaintiffs had satisfied their burden of showing that antitrust impact may be proven by evidence common to all class members.

In December 2008, several months after the Special Master's Report and Recommendation, this court issued its decision in In re Hydrogen Peroxide Antitrust Litigation, which clarified the standard to be applied when certifying a class of plaintiffs in an antitrust action. 552 F.3d 305. In that case, we held that the preponderance requirement demands more than a mere threshold showing by a party seeking to certify a class and that, in considering a motion for class certification, a district court is required
In re K-Dur Antitrust Litigation, 686 F.3d 197 (2012)
2012-2 Trade Cases P 77,971, 103 U.S.P.Q.2d 1497

to resolve any factual or legal disputes necessary to determine whether a plaintiff will be able to show antitrust injury for all plaintiffs with common evidence. Id. at 316–18.

a. Whether Lost Profits Are the Relevant Antitrust Injury

Defendants argue first that the predominance requirement of Rule 23(b)(3) is not satisfied because, in order to prove actual injury from delayed generic entry, plaintiffs must produce evidence of lost profits, which necessarily requires an individual assessment for each class member. Defendants contend specifically that some of the wholesalers lost substantial sales volumes after generic entry, and that, for such wholesalers, generic entry caused a decrease in profits.

Defendants' lost profits argument is unavailing because it is simply a version of the so-called “passing-on defense” that was rejected by the Supreme Court in *221 Hanover Shoe, Inc. v. United Shoe Machinery Corporation, 392 U.S. 481, 88 S.Ct. 2224, 20 L.Ed.2d 1231 (1968). In that case, the Supreme Court held that demonstrating antitrust injury does not require a showing of lost profits. Id. at 494, 88 S.Ct. 2224. Rather, the Supreme Court ruled that a plaintiff suffers an antitrust injury where it is overcharged for a product, regardless of whether it can show lost profits. Id. at 492–95, 88 S.Ct. 2224. In reaching this conclusion, the Court noted that requiring plaintiffs to show lost profits was too burdensome on both courts and litigants and would undercut the effectiveness of private antitrust suits as an enforcement mechanism. Id. at 492–94, 88 S.Ct. 2224; see also Bogosian, 561 F.2d at 456 (noting that a lost-profits inquiry would be “enormously complicated, posing a tremendous burden on the presentation of plaintiffs' case” and that “it is precisely for this reason that the Supreme Court eliminated the ‘passing-on defense’ in Hanover Shoe ”).

Defendants argue that the Hanover Shoe rule should not apply here because that case involved an overcharge for an identical product whereas this one involves two different products, a name brand drug with a higher price and a lower priced generic drug. However, defendants cite no authority distinguishing Hanover Shoe on that basis, and their own expert conceded that the generic supplement that Schering began manufacturing after Upsher entered the market was made in the same plant as K–Dur and chemically identical to K–Dur. Moreover, in In re Warfarin Sodium Antitrust Litigation, this court affirmed class certification where plaintiffs sought overcharges—not lost profits—stemming from anti-competitive behavior that hindered their access to generic pharmaceuticals. 391 F.3d 516, 532 (3d Cir.2004).

In sum, defendants' contention that plaintiffs are required to show lost profits in order to demonstrate antitrust injury is without support in law or the facts of this case. As such, we reject it.

b. Whether There Was Common Evidence of Injury to All Class Members

Defendants argue that because of discrepancies in the pricing of K–Dur and variations in purchaser behavior, plaintiffs cannot prove injury to all class members by common evidence, even if lost profits are not required to show antitrust injury. They contend further that the District Court applied the wrong standard in evaluating plaintiffs' evidence that antitrust injury could be proven by common evidence.

In support of their argument that antitrust injury requires an individualized assessment for each class member, defendants point to two places where purportedly conflicting evidence demonstrates the need for individualized assessment of antitrust harm. Defendants point out that they did not sell K–Dur to all customers at a single list price; rather, the price paid varied considerably among class members. Additionally, defendants argue that, for certain customers at certain times, Schering offered rebates which caused further price variation among customers. Defendants contend that these pricing variations caused several class members to have zero or negative damages under the formula applied by plaintiffs' expert. Finally, defendants point out that not all class members purchased generic potassium chloride as soon as it became available and argue that, in light of this variation in
purchase timing, plaintiffs need to make an individualized showing that each plaintiff would have purchased a generic product earlier if one had been available.

*222 We do not read Hydrogen Peroxide as precluding a class because of variations in purchasing by a very small percentage of those who purchased K–Dur. As the Special Master recognized, defendants conceded “that 45 of the proposed Class members purchased some amount of generic K–Dur.” App. at 7984 (emphasis in original). He noted that defendants' arguments “relate to the quantum of damages, rather than the fact of injury.” Id. Indeed, in Hydrogen Peroxide itself, we focused on what was really at issue—that for certification plaintiff need not prove antitrust injury actually occurred.

Plaintiffs' burden at the class certification stage is not to prove the element of antitrust impact, although in order to prevail on the merits each class member must do so. Instead, the task for plaintiffs at class certification is to demonstrate that the element of antitrust impact is capable of proof at trial through evidence that is common to the class rather than individual to its members.

552 F.3d at 311–12. To the extent that there were minor variations, they can be handled at trial in the context of damages.

With regard to both the price-variation and purchase-timing issues, the Special Master conducted an exceedingly thorough review of plaintiffs' proposal for demonstrating antitrust impact through common evidence and determined that defendants' objections were without support. Critically, the Special Master recognized his obligation to “probe beyond the pleadings” and to conduct a “rigorous analysis” of the available evidence. App. at 7960 (internal citations and quotation marks omitted).

Our review confirms that the Special Master applied the appropriate standard. In contrast to Hydrogen Peroxide, where the court found that there was “no tendency for prices ... to move together,” 552 F.3d at 314 (internal quotation marks omitted), plaintiffs in this case presented evidence, credited by the Special Master, of significant, industry-wide price drops after generic entry. Such evidence of an industry-wide price drop after generic entry supports the Special Master's rejection of defendants' arguments about limited price variations and purchase-timing variations between plaintiffs.

First, concerning the price-variation argument, the Special Master carefully considered the conflicting opinions of plaintiffs' and defendants' experts and credited the theories of plaintiffs' expert over that of defendants. The Special Master concluded that “Plaintiffs have satisfied their burden of adducing sufficient evidence and a plausible theory to convince me that impact may be proven by evidence common to all class members.” App. at 7988 (internal citations and quotation marks omitted). Our review of the record confirms that plaintiffs presented a comprehensive and detailed means of proving impact through common means, notwithstanding some very limited pricing variation, and that the Special Master conducted an appropriately searching evaluation of this evidence.

With regard to defendants' argument about variations in the timing of the purchase of generic K–Dur, the Special Master explicitly rejected that argument and concluded that “[e]vidence that all (or virtually all) class members substituted a lower priced generic for some of their K–Dur 20 purchases gives rise to the inference that they would have similarly done in the but-for world.” App. at 7984. This, combined with plaintiffs' theory of damages, means that impact could be proven on a class-wide basis via common evidence. Here again, the Special Master conducted a thorough evaluation of the available evidence and resolved all significant disputes between conflicting evidence as required *223 under the standard set forth in Hydrogen Peroxide.
2. Adequacy Issue—Whether the Class Faces Inherent Conflicts

Defendants next contend that the District Court erred in certifying a class because the class faces inherent conflicts that preclude adequacy of representation. “The inquiry that a court should make regarding the adequacy of representation requisite of Rule 23(a)(4) is to determine that the putative named plaintiff has the ability and the incentive to represent the claims of the class vigorously, ... and that there is no conflict between the individual's claims and those asserted on behalf of the class.” In re Cmty. Bank of N. Va., 622 F.3d 275, 291 (3d Cir.2010) (quoting Hassine v. Jeffes, 846 F.2d 169, 179 (3d Cir.1988)). Only a fundamental conflict will defeat adequacy of representation. See, e.g., id. at 303 (adequacy defeated by “obvious and fundamental intra-class conflict of interest”); Ward v. Dixie Nat. Life Ins. Co., 595 F.3d 164, 180 (4th Cir.2010).

Defendants contend that three members of the class, all national wholesalers, were net beneficiaries of the absence of generic competition in the potassium chloride supplement market because once generics came on the market those class members saw decreased sales volumes and lower per-pill profits. Defendants argue that, because these three class members have financial incentives to delay generic entry, there is an inherent conflict between them and the rest of the class.

The case law on defendants' argument reveals a split in authority. A large number of district courts, including some in this Circuit, have rejected defendants' argument. See, e.g., Teva Pharms. USA, Inc. v. Abbott Labs., 252 F.R.D. 213, 226–27 (D.Del.2008) (Robinson, J.); Meijer, Inc. v. Abbott Labs., 251 F.R.D. 431, 435 (N.D.Cal.2008); but see Valley Drug Co. v. Geneva Pharms., Inc., 350 F.3d 1181, 1190 (11th Cir.2003).14

We reject the Valley Drug decision for two reasons. First, requiring plaintiffs to show that no class member benefitted from the challenged conduct in the form of greater profits is contrary to the Supreme Court's decision in Hanover Shoe. In Hanover Shoe, the Supreme Court permitted antitrust plaintiffs to seek overcharge damages rather than lost profits damages precisely because proving lost profits was too complicated and burdensome. 392 U.S. at 493, 88 S.Ct. 2224; Bogosian, 561 F.2d at 456. The same logic applies equally, if not more strongly, in the class certification setting because under defendants' proposed approach, plaintiffs would not only have to assess their own lost profits but also those of potential class members. Moreover, because Hanover Shoe sets the amount of the overcharge as plaintiffs' damages, all of the class members have the same financial incentive for purposes of the litigation—i.e. proving that they were overcharged and recovering damages based on that overcharge. See 7A Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, Federal Practice and Procedure § 1768 (3d ed. 2005) (“[A] potential conflict between the representatives and some class members should not preclude the use of the class-action device if the parties appear united in interest against an outsider at the beginning of the case.”). Defendants have not pointed to any plausible scenario in which the class members might seek conflicting forms of relief. For *224 these reasons, we conclude that defendants' conflict argument fails.

D. Conclusion—Class Certification Issues

In sum, with respect to the class certification issues, we reject defendants' arguments and will affirm the District Court's determination approving maintenance of the class action.

All Citations

686 F.3d 197, 2012-2 Trade Cases P 77,971, 103 U.S.P.Q.2d 1497
Footnotes

* Hon. Lawrence F. Stengel, United States District Court for the Eastern District of Pennsylvania, sitting by designation.

1 In appeals numbered 10–2077, 10–2078, and 10–2079, Appellants challenge the District Court's grant of summary judgment on behalf of defendants, relying on their patents. In No. 10–4571, defendants challenge the District Court's certification of a class of plaintiffs.

2 After the facts at issue in this case, Merck & Co. acquired Schering, the named defendant in these actions. However, in keeping with the practice of the parties and amici, the court will refer to Schering.


5 Because there was no objection to the appointment of a Special Master, we have no occasion to address the use of Special Master to prepare Reports and Recommendations on summary judgment motions. See In re Bituminous Coal Operators' Ass'n, Inc., 949 F.2d 1165, 1168 (D.C.Cir.1991) (“Rule 53 of the Federal Rules of Civil Procedure authorizes the appointment of special masters to assist, not to replace, the adjudicator, whether judge or jury, constitutionally indicated for federal court litigation.”) (emphasis in original) (citing La Buy v. Howes Leather Co., Inc., 352 U.S. 249, 256, 77 S.Ct. 309, 1 L.Ed.2d 290 (1957)).

6 The class certification decision is discussed in Section IV infra.

7 One of these agreements was a final settlement of certain claims, the other was structured, like the agreements in Andrx and Cardizem, to take effect even as the litigation continued. See Valley Drug, 344 F.3d at 1300.

8 Defendants argue in passing that this court should begin its analysis in this case with a strong presumption in favor of following the Eleventh Circuit's decision in Schering–Plough. However, none of the cases cited by defendants employs such a presumption; rather, they stand for the unsurprising proposition that this court will follow the decisions of its sister courts where it finds them persuasive. See, e.g., Ramadan v. Chase Manhattan Corp., 229 F.3d 194, 197–203 (3d Cir.2000) (following the rulings of other courts of appeal on similar facts but conducting an independent analysis). As explained below, we do not find the Eleventh Circuit's decision in Schering–Plough persuasive, and thus decline to follow it.

9 The Eleventh Circuit subsequently applied, without further significant explication, the scope of the patent test announced in Valley Drug and Schering–Plough in another case, Andrx Pharmaceuticals, Inc. v. Elan Corporation, PLC, 421 F.3d 1227 (11th Cir.2005).
In re K-Dur Antitrust Litigation, 686 F.3d 197 (2012)

That case was severed by the Second Circuit and transferred to the Federal Circuit because it involved a claim arising out of patent law. See Order, No. 05–2863 (2d Cir. Nov. 7, 2007).

The Pharmaceutical Research and Manufacturers of America points to a more recent study concluding that, in the years from 2000 to 2009, generics prevailed in slightly less than half of their challenges. RBC Capital Mkts., Pharmaceuticals: Analyzing Litigation Success Rates 4 (2010), available at http://www.amlawdaily.typepad.com/pharmareport.pdf. Even if the industry's own figures are accepted, they show that a substantial fraction of Hatch–Waxman patent challenges succeed on the merits. Moreover, the study cited by the industry further states that “when you take into account patent settlements and cases that were dropped, the success rate for generics jumps to 76%, substantially in favor of challenging patents.” Id.

Plaintiffs argue that because defendants' cross appeal was dismissed as untimely defendants' 23(f) petition should have been dismissed also. An appeals court has discretion to consider an interlocutory appeal even after the entry of final judgment. Cf. In re Coordinated Pretrial Proceedings in Petroleum Prods. Antitrust Litig., 788 F.2d 1571, 1573–74 (Temp.Emer.Ct.App.1986). Moreover, in granting defendants' 23(f) petition, this court has already considered the issue of the appropriateness of review, and we see no reason to reconsider the decision to hear this appeal.

Specifically, the Special Master excluded from the class direct purchasers who did not purchase a generic version of K–Dur after generic entry.

This is a different appeal than Valley Drug, 344 F.3d 1294 (11th Cir.2003), discussed supra.
Synopsis

Background: Consumers, providers of medical benefits, and consumer advocacy groups brought actions in multiple districts against owner of patent rights for cancer drug and maker of generic version of that drug, alleging that settlement between defendants monopolized and allocated the United States market for the drug. After centralization, 196 F.Supp.2d 1371, the United States District Court for the Eastern District of New York, I. Leo Glasser, J., 277 F.Supp.2d 121 dismissed the complaint, and plaintiffs appealed. Defendants moved to transfer the appeal to the Federal Circuit.

Holdings: The Court of Appeals, Sack, Circuit Judge, held that:

case did not “arise under” federal patent law, and therefore Federal Circuit did not have appellate jurisdiction, and

settlement agreement did not give rise to cause of action under Sherman Act.

Affirmed.

Pooler, Circuit Judge, filed dissenting opinion.

Procedural Posture(s): On Appeal; Motion to Dismiss; Motion to Dismiss for Failure to State a Claim.

Attorneys and Law Firms

*189 J. Douglas Richards, Milberg Weiss Bershad Hynes & Lerach LLP (Michael M. Buchman, Milberg Weiss Bershad & Schulman LLP, New York, NY; Patrick E. Cafferty, Miller Faucher and Cafferty LLP, Ann Arbor, MI; Bernard Persky, Barbara...
In re Tamoxifen Citrate Antitrust Litigation, 466 F.3d 187 (2006)

2006-2 Trade Cases P 75,382


Before: POOLER, SACK, and RAGGI, Circuit Judges. POOLER, Circuit Judge, dissents in a separate opinion.

Opinion

SACK, Circuit Judge.

This appeal, arising out of circumstances surrounding a lawsuit in which a drug manufacturer alleged that its patent for the drug tamoxifen citrate (“tamoxifen”) was about to be infringed, and the suit's subsequent settlement, requires us to address issues at the intersection of intellectual property law and antitrust law. Although the particular factual circumstances of this case are unlikely to recur, the issues presented have been much litigated and appear to retain their vitality.

The plaintiffs appeal from a judgment of the United States District Court for the Eastern District of New York (I. Leo Glasser, Judge) dismissing their complaint pursuant to Federal Rule of Civil Procedure 12(b)(6). The plaintiffs claim that the defendants conspired, under an agreement settling a patent infringement lawsuit among the defendants in 1993 while an appeal in that lawsuit was pending, to monopolize the market for tamoxifen—the most widely prescribed drug for the treatment of breast cancer—by suppressing competition from generic versions of the drug. The settlement agreement included, among other things, a so-called “reverse payment” of $21 million from the defendant patent-holders Zeneca, Inc., AstraZeneca Pharmaceuticals LP, and AstraZeneca PLC (collectively “Zeneca”) to the defendant generic manufacturer Barr Laboratories, Inc. (“Barr”), and a license from Zeneca to Barr allowing Barr to sell an unbranded version of Zeneca-manufactured tamoxifen. The settlement agreement was contingent on obtaining a vacatur of the judgment of the district court that had heard the infringement action holding the patent to be invalid.

The district court in the instant case concluded that the settlement did not restrain trade in violation of the antitrust laws, and that the plaintiffs suffered no antitrust injury from that settlement. Because we conclude that we have jurisdiction to hear the appeal and that the behavior of the defendants alleged in the complaint would not violate antitrust law, we affirm the judgment of the district court.

REGULATORY BACKGROUND

Before setting forth the salient facts of this case and addressing the merits of the plaintiffs' appeal, it may be helpful to outline the relevant regulatory background. 1

The Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (codified at scattered sections of title 21 of the United States Code), prohibits the introduction or delivery for introduction into interstate commerce of “any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of [21 U.S.C. § 355] is effective with respect to such drug.” 21

An ANDA filer must certify, with respect to each patent that claims the listed drug for the bioequivalent of which the ANDA filer is seeking approval, 3 either that no patent was filed for the listed drug (a “paragraph I” certification), that the patent has expired (a “paragraph II” certification), that the patent will expire on a specified date and the ANDA filer will not market the drug until that date (a “paragraph III” certification), or that the patent is invalid or would not be infringed by the manufacture, use, or sale of the new drug (a “paragraph IV” certification). 21 U.S.C. § 355(j)(2)(A)(vii).

An ANDA filer that elects a paragraph IV certification must notify each affected patent owner of the certification. Id. § 355(j)(2)(B)(i). The patent owner then has forty-five days after the date it receives such notice to bring suit against the ANDA filer for patent infringement. Id. § 355(j)(5)(B)(iii). If no patent owner brings such a lawsuit during this period, the FDA may immediately approve the ANDA. Id. If, however, the patent owner brings suit during this period, the FDA's final approval of the ANDA is stayed for thirty months after the date the patent owner received the requisite notice or until a district court 4 returns a decision as to *192 the validity of the patent or its infringement if it does so before the thirty-month period expires. Id.

Any approval letter sent by the FDA before the expiration of the prescribed stay and before a court ruling of patent invalidity or non-infringement is tentative. See 21 C.F.R. § 314.105(d). If before the thirty months expire a court rules that the patent is either invalid or not infringed, the tentative approval of the ANDA is made effective as of the date of judgment. 21 U.S.C. § 355(j)(5)(B)(i)(I)-(II). If after thirty months there has been no ruling on patent validity or infringement and the stay expires, the ANDA filer can distribute and market the drug but, depending on the court's later patent ruling, an ANDA filer that chooses to follow this course may thereafter become liable for infringement damages if infringement is found. See In re Ciprofloxacin Hydrochloride Antitrust Litig., 166 F.Supp.2d 740, 744 (E.D.N.Y.2001) (“Cipro I ”).

As an incentive for generic manufacturers to choose the paragraph IV certification route and, in the course of pursuing such applications, to challenge weak patents, the Hatch–Waxman Act offers the first ANDA filer with a paragraph IV certification, under certain conditions, the opportunity to market its generic drug exclusively for 180 days. To this end, the FDA may not approve the ANDA of a subsequent filer until 180 days after the earlier of the date (1) the first ANDA filer commercially markets the generic drug or (2) a court of competent jurisdiction concludes that the patent in question is invalid or not infringed. 5 21 U.S.C. § 355(j)(5)(B)(iv)(I)-(II).

Until 1998 (and, therefore, at the time of the settlement that is the subject of this appeal), the 180–day exclusivity period was available to the first ANDA filer to elect a paragraph IV certification, but only if the ANDA filer successfully defended against a lawsuit for infringement of the relevant patent. See 21 C.F.R. § 314.107(c)(1) (1995). This so-called “successful defense” requirement was challenged in 1997 in two separate lawsuits. In each, the circuit court rejected the requirement as inconsistent with the Hatch–Waxman Act. See Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1076 (D.C.Cir.1998); Granutec, Inc. v. Shalala, 139 F.3d 889, 1998 WL 153410, at *7 (4th Cir. Apr.3, 1998), 1998 U.S.App. LEXIS 6685, at *19–*21 (unpublished opinion).
In June 1998, in response to these decisions, the FDA published a “Guidance for Industry.” See Ctr. for Drug Evaluation & Research, Food & Drug Admin., U.S. Dep't of Health and Human Servs., Guidance for Industry: 180–Day Generic Drug Exclusivity Under the Hatch–Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (June 1998), available at http://www.fda.gov/cder/guidance/2576fnl. *193 pdf (last visited May 12, 2005). In the “Guidance,” the FDA expressed its intention to remove the “successful defense” requirement formally through rulemaking and made clear that thereafter even ANDA paragraph IV filers that are not the subject of lawsuits will be eligible for the 180–day exclusivity period. Id. at 4–5. “Until such time as the rulemaking process [was] complete, FDA ... regulate[d] directly from the statute, and ... ma[de] decisions on 180–day generic drug exclusivity on a case-by-case basis.” Id. at 4. Later that year, the FDA formally revoked the “successful defense” requirement. See Effective Date of Approval of an Abbreviated New Drug Application, 63 Fed.Reg. 59,710, 59,710 (Nov. 5, 1998), 21 C.F.R. § 314.107 (1999).

FACTUAL AND PROCEDURAL BACKGROUND

Tamoxifen, the patent for which was obtained by Imperial Chemical Industries, PLC, (“ICI”) on August 20, 1985, is sold by Zeneca (a former subsidiary of ICI which succeeded to the ownership rights of the tamoxifen patent) under the trade name Nolvadex®. Tamoxifen is the most widely prescribed drug for the treatment of breast cancer. Indeed, it is the most prescribed cancer drug in the world. In December 1985, four months after ICI was awarded the patent, Barr filed an ANDA with the FDA requesting the agency's approval for Barr to market a generic version of tamoxifen that it had developed. Barr amended its ANDA in September 1987 to include a paragraph IV certification.

In response, on November 2, 1987—within the required forty-five days of Barr's amendment of its ANDA to include a paragraph IV certification—ICI filed a patent infringement lawsuit against Barr and Barr's raw material supplier, Heumann Pharma GmbH & Co. (“Heumann”), in the United States District Court for the Southern District of New York. 7 See Imperial Chem. Indus., PLC v. Barr Labs., Inc., 126 F.R.D. 467, 469 (S.D.N.Y.1989). On April 20, 1992, the district court (Vincent L. Broderick, Judge ) declared ICI's tamoxifen patent invalid based on the court's conclusion that ICI had deliberately withheld “crucial information” from the Patent and Trademark Office regarding tests that it had conducted on laboratory animals with respect to the safety and effectiveness of the drug. See Imperial Chem. Indus., PLC v. Barr Labs., Inc., 795 F.Supp. 619, 626–27 (S.D.N.Y.1992) (“Tamoxifen I”). Those tests had revealed hormonal effects “opposite to those sought in humans,” which, the court found, could have “unpredictable and at times disastrous consequences.” Id. at 622.

ICl appealed the district court's judgment to the United States Court of Appeals for the Federal Circuit. In 1993, while the appeal was pending, the parties entered into a confidential settlement agreement (the “Settlement Agreement”) which is the principal subject of this appeal. In the Settlement Agreement, Zeneca (which had succeeded to the ownership rights of the patent) and Barr agreed that in return for $21 million and a non-exclusive license to sell Zeneca-manufactured tamoxifen in the United States under Barr's label, rather than Zeneca's trademark Nolvadex®, Barr would change its ANDA paragraph IV certification to a paragraph III certification, thereby agreeing *194 that it would not market its own generic version of tamoxifen until Zeneca's patent expired in 2002. See In re Tamoxifen Citrate Antitrust Litig., 277 F.Supp.2d 121, 125–26 (E.D.N.Y.2003) (“Tamoxifen II ”). Zeneca also agreed to pay Heumann $9.5 million immediately, and an additional $35.9 million over the following ten years. The parties further agreed that if the tamoxifen patents were to be subsequently declared invalid or unenforceable in a final and (in contrast to the district court judgment in Tamoxifen I ) unappealable judgment by a court of competent jurisdiction, Barr would be allowed to revert to a paragraph IV ANDA certification. Thus if, in another lawsuit, a generic marketer prevailed as Barr had prevailed in Tamoxifen I, and that judgment was either not appealed or was affirmed on appeal, Barr would have been allowed to place itself in the same position (but for the 180–day head start, if it was available) that it would have been in had it prevailed on appeal in Tamoxifen I, rather than settling while its appeal was pending in the Federal Circuit.
The plaintiffs allege that as a part of the Settlement Agreement, Barr “understood” that if another generic manufacturer attempted to market a version of tamoxifen, Barr would seek to prevent the manufacturer from doing so by attempting to invoke the 180-day exclusivity right possessed by the first “paragraph IV” filer. Compl. ¶ 58. According to the plaintiffs, this understanding among the defendants effectively forestalled the introduction of any generic version of tamoxifen, because, five years later—only a few weeks before other generic manufacturers were to be able to begin marketing their own versions of tamoxifen—Barr did in fact successfully claim entitlement to the exclusivity period. It thereby prevented those manufacturers from entering the tamoxifen market until 180 days after Barr triggered the period by commercially marketing its own generic version of the drug. In fact, Barr had not yet begun marketing its own generic version and had little incentive to do so because, pursuant to the Settlement Agreement, it was already able to market Zeneca's version of tamoxifen.

Meanwhile, pursuant to the Settlement Agreement which was contingent on the vacatur of the district court judgment in Tamoxifen I, Barr and Zeneca filed a “Joint Motion to Dismiss the Appeal as Moot and to Vacate the Judgment Below.” See Tamoxifen II, 277 F.Supp.2d at 125. The Federal Circuit granted the motion, thereby vacating the district court's judgment that the patent was invalid. See Imperial Chem. Indus., PLC v. Hewmann Pharma GmbH & Co., 991 F.2d 811, 1993 WL 118931, at *1 (Fed.Cir. Mar. 19, 1993), U.S.App. LEXIS 14872, at *1–*2 (unpublished opinion). Such a vacatur, while generally considered valid as a matter of appellate procedure by courts at the time of the Settlement Agreement, see U.S. Philips Corp. v. Windmere Corp., 971 F.2d 728, 731 (Fed.Cir.1992), was shortly thereafter held to be invalid in nearly all circumstances by the Supreme Court, see U.S. Bancorp Mortgage Co. v. Bonner Mall P'ship, 513 U.S. 18, 27–29, 115 S.Ct. 386, 130 L.Ed.2d 233 (1994). 8

In the years after the parties entered into the Settlement Agreement and the Federal Circuit vacated the district court's judgment,9 three other generic manufacturers *195 filed ANDAs with paragraph IV certifications to secure approval of their respective generic versions of tamoxifen: Novopharm Ltd., in June 1994, Mylan Pharmaceuticals, Inc., in January 1996, and Pharmachemie, B.V., in February 1996.10 See Tamoxifen II, 277 F.Supp.2d at 126–27. Zeneca responded to each of these certifications in the same manner that it had responded to Barr's: by filing a patent infringement lawsuit within the forty-five day time limit provided by 21 U.S.C. § 355(j)(5)(B)(iii). See id. In each case, the court rejected the generic manufacturer's attempt to rely on the vacated Tamoxifen I decision, and—contrary to the Tamoxifen I judgment—upheld the validity of Zeneca's tamoxifen patent. See Zeneca Ltd. v. Novopharm Ltd., 111 F.3d 144, 1997 WL 168318, at *2–*4 (Fed.Cir. Apr.10, 1997), 1997 U.S.App. LEXIS 6634, at *4–*11 (unpublished opinion) (affirming the judgment of the United States District Court for the District of Maryland declining to give Tamoxifen I collateral estoppel effect or to apply U.S. Bancorp retroactively and deciding that Zeneca's patent was valid); Zeneca Ltd. v. Pharmachemie B.V., No. 96–12413, 2000 WL 34335805, at *15 (D.Mass. Sept.11, 2000), 2000 U.S. Dist LEXIS 22631, at *51–*53 (concluding that Zeneca had not engaged in inequitable conduct and that the patent was valid); AstraZeneca UK Ltd. v. Mylan Pharmas., Inc., No. 00–2239, slip op. at 2–3 (W.D.Pa. Nov. 30, 2000) (entering stipulated consent order that FDA approval for Mylan would not be effective before the expiration of the tamoxifen patent).

While Mylan and Pharmachemie's lawsuits were pending in district court, the FDA's “successful defense” rule, requiring that a generic manufacturer seeking to market an allegedly patented drug “successfully defend” its patent infringement lawsuit in order to receive the 180-day exclusivity period—which at the time the Settlement Agreement was entered into would have excluded Barr from benefitting from the exclusivity period—was, as noted, held invalid. See Mova Pharm. Corp. v. Shalala, 955 F.Supp. 128, 130–32 (D.D.C.1997), aff'd in part and rev'd in part on other grounds, 140 F.3d 1060 (D.C.Cir.1998); Granutec, Inc. v. Shalala, 139 F.3d 889, 1998 WL 153410, at *7 (4th Cir. Apr.3, 1998), 1998 U.S.App. LEXIS 6685, at *19–*21 (unpublished opinion). In June 1998, at the time the FDA removed the requirement, Barr—armed with the new rule rendering the first ANDA paragraph IV filer eligible for the 180–day exclusivity period even if it had not successfully defended a patent infringement suit—attempted to block final FDA approval of other generic versions of tamoxifen by claiming entitlement to the 180–day exclusivity period. See Tamoxifen II, 277 F.Supp.2d at 127 (citing “Petition for Stay of Action” filed with the FDA on June 26, 1998).
At the time, Pharmachemie had received tentative approval from the FDA to distribute its version of the drug, Mylan was awaiting approval to do the same, and both Pharmachemie and Mylan's thirty-month stays under section 355(j)(5)(B)(iii), triggered by Zeneca's infringement lawsuits, were soon to expire. See Compl. ¶¶ 61–63 (stating that the 30–month stay for Mylan was scheduled to expire on July 10, 1998, and for Pharmachemie in August 1998); Pharmachemie B.V. v. Barr Labs., Inc., 276 F.3d 627, 630 (D.C.Cir.2002) (noting that Pharmachemie was granted tentative approval on April 3, 1997); Mylan Pharms. Inc. v. Henney, 94 F.Supp.2d 36, 44 (D.D.C.2000), vacated and dismissed as moot sub nom. Pharmachemie B.V. v. Barr Labs., Inc., 284 F.3d 125 (D.C.Cir.2002) (per curiam). Because of the rule change, however, the FDA was able to, and on March 2, 1999, did, grant Barr's petition to confirm its entitlement to the exclusivity period despite the fact that it had settled, rather than “successfully defended” against, Zeneca's lawsuit. See Tamoxifen II, 277 F.Supp.2d at 127. The FDA's action effectively delayed the marketing of other generic versions of tamoxifen unless and until Barr triggered and exhausted its 180–day exclusivity period by selling its own generic form of the drug, rather than the version manufactured by Zeneca. As noted, Barr had little incentive to do so because it was already distributing Zeneca's version of tamoxifen.

Pharmachemie and Mylan challenged the FDA's decision. On March 31, 2000, in Mylan Pharmaceuticals, the United States District Court for the District of Columbia ruled in Pharmachemie's and Mylan's favor. 94 F.Supp.2d at 54. It concluded that, although Judge Broderick's ruling of invalidity in Tamoxifen I had been vacated by the Settlement Agreement, that ruling was still a court decision sufficient to trigger Barr's 180–day exclusivity period, which therefore had already expired. See Mylan Pharms., 94 F.Supp.2d at 54. As a result, on June 26, 2000, the FDA revoked Barr's claim to the 180–day exclusivity period. See Tamoxifen II, 277 F.Supp.2d at 127.

On appeal, however, the District of Columbia Circuit vacated the district court's decision as moot. Pharmachemie, 276 F.3d at 634; Pharmachemie, 284 F.3d at 125. The court noted that subsequent to the FDA's decision to approve Barr's application, the district court had ruled against Pharmachemie in Zeneca's patent infringement lawsuit against it. See Pharmachemie, 276 F.3d at 629. Thus, even if, as the district court held in Mylan, Barr's 180–day exclusivity period had run, Pharmachemie and Mylan were prohibited by the judgments against them in the patent litigation from marketing their generic versions of tamoxifen until Zeneca's patent expired. Zeneca's patent on tamoxifen expired on August 20, 2002, and generic manufacturers began marketing their own versions of tamoxifen soon thereafter.

Proceedings in the District Court

While these generic manufacturers were litigating the validity of Zeneca's patent on tamoxifen, consumers and consumer groups in various parts of the United States filed some thirty lawsuits challenging the legality of the 1993 Settlement Agreement between Zeneca and Barr. See Tamoxifen II, 277 F.Supp.2d at 127. Those lawsuits were subsequently transferred by the Judicial Panel on Multidistrict Litigation to the United States District Court for the Eastern District of New York. Subsequently, a consolidated class action complaint embodying the claims was filed. In re Tamoxifen Citrate Antitrust Litig., 196 F.Supp.2d 1371 (2001); Tamoxifen II, 277 F.Supp.2d at 127. In the consolidated lawsuit, the plaintiffs alleged that the Settlement Agreement unlawfully (1) enabled Zeneca and Barr to resuscitate a patent that the district court had already held to be invalid and unenforceable; (2) facilitated Zeneca's continuing monopolization of the market for tamoxifen; (3) provided for the sharing of unlawful monopoly profits between Zeneca and Barr; (4) maintained an artificially high price for tamoxifen; and (5) prevented competition from other generic manufacturers of tamoxifen. See Tamoxifen II, 277 F.Supp.2d at 127–28. At the heart of the lawsuit was the contention that the Settlement Agreement enabled Zeneca and Barr effectively to circumvent the district court's invalidation of Zeneca's tamoxifen patent in Tamoxifen I, which, the plaintiffs asserted, would have been affirmed by the Federal Circuit. The result of such an affirmance, according to the plaintiffs, would have been that Barr would have received approval to market a generic version of tamoxifen; Barr would have begun marketing tamoxifen, thereby triggering the 180–day exclusivity period; other generic manufacturers would have introduced their own versions of tamoxifen upon the expiration of the exclusivity period, with Zeneca collaterally estopped from invoking its invalidated patent as a defense; and,
as a result, the price for tamoxifen would have declined substantially below the levels at which the Zeneca-manufactured drug in fact sold in the market shared by Zeneca and Barr through the Settlement Agreement. *Id.* at 128. The defendants moved to dismiss the class action complaint pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted.

On May 15, 2003, in a thorough and thoughtful opinion, the district court granted the defendants' motion to dismiss. *See id.* at 140. The court noted that although market-division agreements between a monopolist and a potential competitor ordinarily violate the Sherman Act, they are not necessarily unlawful when the monopolist is a patent holder. *Id.* at 128–29. Pursuant to a patent grant, the court reasoned, a patent holder may settle patent litigation by entering into a licensing agreement with the alleged infringer without running afoul of the Sherman Act. *Id.* at 129. Yet, the court continued, a patent holder is prohibited from acting in bad faith “beyond the limits of the patent monopoly” to restrain or monopolize trade. *Id.* (quoting *United States v. Line Material Co.*, 333 U.S. 287, 308, 68 S.Ct. 550, 92 L.Ed. 701 (1948) (internal quotation marks omitted)).

Analyzing the terms and impact of the Settlement Agreement, the district court concluded that the agreement permissibly terminated the litigation between the defendants, which “cleared the field for other generic manufacturers to challenge the patent.” *Id.* at 133. “Instead of leaving in place an additional barrier to subsequent ANDA filers, the Settlement Agreement in fact removed one possible barrier to final FDA approval—namely, the existence of ongoing litigation between an existing ANDA filer and a subsequent filer.” *Id.* To the court, this factor distinguished the case from similar cases in which other circuits had held settlement agreements to be unlawful, where the agreement in question did not conclude the underlying litigation and instead prolonged the period during which other generic manufacturers could not enter the market. *Id.* (distinguishing the Settlement Agreement from the agreements addressed in *In re Terazosin Hydrochloride Antitrust Litig.*, 164 F.Supp.2d 1340, 1346–47 (S.D.Fla.2000), rev’d sub nom. *Valley Drug Co. v. Geneva Pharms.*, Inc., 344 F.3d 1294 (11th Cir.2003), cert. denied, 125 S.Ct. 308 (2004), and *In re Cardizem CD Antitrust Litig.*, 105 F.Supp.2d 618, 632 (E.D.Mich.2000), aff’d, 332 F.3d 896 (6th Cir.2003), cert. denied sub nom. *Andrx Pharms.*, Inc. v. Kroger Co., 543 U.S. 939, 125 S.Ct. 307, 160 L.Ed.2d 248 (2004)).

The district court was also of the view that the defendants could not be held liable for Barr's FDA petition to preserve its 180–day exclusivity period even if this was a term of the defendants' negotiated Settlement Agreement. *Id.* at 135. It reasoned that at the time of settlement, Barr could not have successfully pursued its FDA application because the FDA continued to apply the “successful defense” rule until 1997. *Id.* at 134. It was only after 1997 that Barr petitioned the FDA to preserve its exclusivity period. The court concluded that Barr's petition was an attempt to petition a governmental body in order to protect an arguable interest in a statutory right based on recent developments in the court and at the FDA. As such, the FDA Petition was protected activity under the First Amendment, and long-settled law established that the Sherman Act, with limited exceptions, does not apply to petitioning administrative agencies.

*Id.* at 135. The court concluded that the plaintiffs' complaint therefore did not sufficiently allege a bad-faith settlement in violation of the Sherman Act. *Id.* at 136.

The district court also concluded that even if the plaintiffs had stated an antitrust violation, they did not suffer antitrust injury from either Barr's exclusivity period or the Settlement Agreement and the resulting *vacatur* of the district court's judgment in *Tamoxifen I* invalidating the tamoxifen patent. *Id.* at 136–38. The court noted that “[a]ntitrust injury ... must be caused by something other than the regulatory action limiting entry to the market.” *Id.* at 137. The court attributed “the lack of competition in the market” not to “the deployment of Barr's exclusivity period, but rather [to] the inability of the generic companies to
invalidate or design around” the tamoxifen patent, and their consequent loss of the patent litigation against Zeneca. *Id.* This was so, the district court concluded, even if Barr's petition to the FDA had delayed the approval of Mylan's ANDA. *Id.* at 137. Any “injury” suffered by the plaintiffs, said the court, “is thus not antitrust injury, but rather the result of the legal monopoly that a patent holder possesses.” *Id.* at 138.

The district court also rejected the plaintiffs' contention that “the settlement and *vacatur* deprived other generic manufacturers of the ability to make the legal argument that the [Tamoxifen I ] judgment (if affirmed) would collaterally estop Zeneca from claiming the [tamoxifen] patent was valid in future patent litigation with other ANDA filers.” *Id.* It reasoned that there is no basis for the assertion that “forcing other generic manufacturers to litigate the validity of the [tamoxifen] patent[ ] is an injury to competition.” *Id.* The court also referred to the other generic manufacturers' subsequent litigation against Zeneca over the validity of the tamoxifen patent, in which Zeneca prevailed, as additional reason to reject the plaintiffs' assertion that the Federal Circuit would have affirmed Judge Broderick's judgment invalidating the tamoxifen patent. *Id.*

The district court therefore dismissed the plaintiffs' Sherman Act claims. *Id.* It also dismissed the plaintiffs' state-law claims, which had alleged violations of the antitrust laws of seventeen states and violations of consumer protection and unfair competition laws of twenty-one states, because those claims were based on the same allegations as the plaintiffs' federal antitrust claims. *Id.* at 138–40. The plaintiffs appeal the dismissal of their claims.

On July 28, 2003, the defendants moved in this Court to transfer the appeal to the Federal Circuit on the ground that that court alone has jurisdiction to entertain this appeal. For the reasons stated below, we deny the defendants' motion and affirm *199* the district court's judgment dismissing the plaintiffs' complaint.

**DISCUSSION**

I. Jurisdiction

The defendants argue that this Court does not have jurisdiction to hear this appeal because the case arises under federal patent law and the Federal Circuit has exclusive appellate jurisdiction over such appeals. The plaintiffs respond that we, rather than the Federal Circuit, have appellate jurisdiction because this case does not, on the basis of their well-pleaded complaint, substantially turn on issues of federal patent law. We agree with the plaintiffs.

The United States Court of Appeals for the Federal Circuit has exclusive jurisdiction over an appeal from a federal district court “if the jurisdiction of that court was based, in whole or in part, on section 1338 of [title 28],” with exceptions not pertinent here. 28 U.S.C. § 1295(a)(1). Section 1338, in turn, provides that federal district courts shall have original and exclusive jurisdiction “of any civil action arising under any Act of Congress relating to patents.” Id. § 1338(a). Therefore, whether the Federal Circuit has jurisdiction over the instant case “turns on whether this is a case ‘arising under’ a federal patent statute.” Christianson v. Colt Indus. Operating Corp., 486 U.S. 800, 807, 108 S.Ct. 2166, 100 L.Ed.2d 811 (1988).

A case “arises under” federal patent law if “a well-pleaded complaint establishes either that federal patent law creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law, in that patent law is a necessary element of one of the well-pleaded claims.” *Id.* at 809, 108 S.Ct. 2166. 12 This is determined “from what necessarily appears in the plaintiff's statement of his own claim in the bill or declaration, unaided by anything alleged in anticipation or avoidance of defenses which it is thought the defendant may interpose.” *Id.* (internal quotation marks and citation omitted). “[A] case raising a federal patent-law defense does not, for that reason alone, arise under patent law, even if the defense is anticipated in the plaintiff's complaint, and even if both parties admit that the defense is the only question truly at issue in the case.” *Id.* (internal quotation marks and citation omitted).
Moreover, even if one theory supporting a claim essentially turns on an issue arising under patent law, as long as there is at least one alternative theory supporting the claim that does not rely on patent law, there is no “arising under” jurisdiction under 28 U.S.C. § 1338. In that case, as the Supreme Court concluded in Christianson: “Since there are reasons completely unrelated to the provisions and purposes of federal patent law why petitioners may or may not be entitled to the relief they seek under their monopolization claim, the claim does not arise under federal patent law.” Id. at 812, 108 S.Ct. 2166 (internal quotation marks, citation, and alterations omitted); see also id. at 810, 108 S.Ct. 2166 (“[A] claim supported by alternative theories in the complaint may not form the basis for § 1338(a) jurisdiction unless patent law is essential to each of those theories.”).

Applying these principles to the case at hand, we conclude that we have jurisdiction to entertain this appeal. As we explain below, the defendants’ contention that “all of [p]laintiffs’ claims arise under the patent law because each requires [p]laintiffs to establish that the [tamoxifen] patent was invalid or unenforceable,” Appellees’ Reply Mem. Supp. Mot. to Transfer Appeal at 2, is mistaken. The theories that would enable the plaintiffs to prevail do not require us to examine whether Judge Broderick’s invalidation of the tamoxifen patent would have been upheld on appeal or whether the tamoxifen patent was otherwise enforceable and infringed.

If the plaintiffs alleged facts that, if proved, would establish that the Settlement Agreement provided the defendants with benefits exceeding the scope of the tamoxifen patent, they would succeed in alleging an antitrust violation. And if the plaintiffs plausibly alleged that the defendants entered into an agreement to manipulate the 180-day exclusivity period to the defendants’ joint benefit, and if they were able to prove based on the facts alleged that they suffered antitrust injury as a result of that agreement, then that, too, would likely be sufficient to state an antitrust violation. Were they to allege and then prove facts sufficient to support either of these theories, the argument that the Settlement Agreement was unlawful “[e]ven if the [tamoxifen p]atent is presumed valid and enforceable,” Compl. ¶ 55, would, in our view, be persuasive.

Because we conclude that there are “reasons completely unrelated to the provisions and purposes of the patent laws why the plaintiff[s] may or may not be entitled to the relief [they] seek[ ]”, Christianson, 486 U.S. at 810, 108 S.Ct. 2166 (internal quotation marks, citation, and alterations omitted), we have jurisdiction to entertain this appeal.

II. Standard of Review
We review a decision on a motion to dismiss de novo. Gregory v. Daly, 243 F.3d 687, 691 (2d Cir.2001).

“A pleading which sets forth a claim for relief ... shall contain ... a short and plain statement of the claim showing that the pleader is entitled to relief.” Fed.R.Civ.P. 8(a)(2). “Given the Federal Rules' simplified standard for pleading, a court may dismiss a complaint only if it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations.” Swierkiewicz v. Sorema N.A., 534 U.S. 506, 514, 113 S.Ct. 1160, 122 L.Ed.2d 517 (1993) (internal quotation marks, citation, and alteration omitted). There is no heightened pleading requirement in antitrust cases. See Twombly v. Bell Atl. Corp., 550 U.S. 407, 125 S.Ct. 1121, 161 L.Ed.2d 116 (2005).

In reviewing a decision on a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), we “must accept as true all the factual allegations in the complaint,” Leatherman v. Tarrant County Narcotics Intelligence & Coordination Unit, 507 U.S. 163, 113 S.Ct. 1160, 122 L.Ed.2d 517 (1993), and “draw all reasonable inferences in plaintiffs’ favor,” Freedom Holdings Inc. v. Spitzer, 357 F.3d 205, 216 (2d Cir.2004). To survive a motion to dismiss, a plaintiff bringing suit under section 1 of the Sherman Act need not allege facts that exclude the possibility that the behavior of which complaint is made is legal. See Twombly, 550 U.S. at 111 (“[S]hort of the extremes of ‘bare bones’ and ‘implausibility,’ a complaint in an antitrust case need only contain the ‘short and plain statement of the claim showing that the pleader is entitled to relief’ that Rule 8(a) requires.” (citation omitted)). However, “bald assertions and conclusions of law are not adequate [to state a claim] and a complaint consisting only of naked
In re Tamoxifen Citrate Antitrust Litigation, 466 F.3d 187 (2006)

2006-2 Trade Cases P 75,382

assertions, and setting forth no facts upon which a court could find a violation of the [law], fails to state a claim under Rule 12(b)(6).” Gregory, 243 F.3d at 692 (internal quotation marks and citations omitted). And “[i]t is ... improper to assume that the plaintiff can prove facts that it has not alleged or that the defendants have violated the antitrust laws in ways that have not been alleged.” Todd v. Exxon Corp., 275 F.3d 191, 198 (2d Cir.2001) (internal quotation marks, citation, and alterations omitted). At the same time, in antitrust cases, “plaintiffs should be given the full benefit of their proof without tightly compartmentalizing the various factual components and wiping the slate clean after scrutiny of each.” Cont’l Ore Co. v. Union Carbide & Carbon Corp., 370 U.S. 690, 699, 82 S.Ct. 1404, 8 L.Ed.2d 777 (1962).

III. The Plaintiffs' Antitrust Claims

A. The Tension between Antitrust Law and Patent Law

With the ultimate goal of stimulating competition and innovation, the Sherman Act prohibits “[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States,” 13 15 U.S.C. § 1, and “monopoliz[ation], or attempt[s] to monopolize, or combin[ations] or conspir[acies] ... to monopolize any part of the trade or commerce among the several States,” id. § 2. 14 By contrast, also with the ultimate goal of stimulating competition and innovation, patent law grants an innovator “the right to exclude others *202 from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States” for a limited term of years. 35 U.S.C. § 154(a)(1)-(2); see also Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 215, 100 S.Ct. 2601, 65 L.Ed.2d 696 (1980) (“[T]he essence of a patent grant is the right to exclude others from profiting by the patented invention.”). It is the tension between restraints on anti-competitive behavior imposed by the Sherman Act and grants of patent monopolies under the patent laws, as complicated by the Hatch–Waxman Act, that underlies this appeal. See, e.g., United States v. Singer Mfg. Co., 374 U.S. 174, 196–97, 83 S.Ct. 1773, 10 L.Ed.2d 823 (1963) (“[T]he possession of a valid patent ... does not give the patentee any exemption from the provisions of the Sherman Act beyond the limits of the patent monopoly.”) (internal quotation marks and citation omitted); cf. Andrx Pharms., Inc. v. Biovail Corp. Int’l, 256 F.3d 799, 802 (D.C.Cir.2001) (“Although the Congress was interested in increasing the availability of generic drugs, it also wanted to protect the patent rights of the pioneer applicants.”), cert. denied, 535 U.S. 931, 122 S.Ct. 1305, 152 L.Ed.2d 216 (2002); Schering–Plough Corp. v. F.T.C., 402 F.3d 1056, 1067 (11th Cir.2005) (“Although the exclusionary power of a patent may seem incongruous with the goals of antitrust law, a delicate balance must be drawn between the two regulatory schemes.”).

B. The Plaintiffs' Allegations

1. Settlement of a Patent Validity Lawsuit. The plaintiffs contend that several factors—including that Tamoxifen I was settled after the tamoxifen patent had been held invalid by the district court, making the patent unenforceable at the time of settlement —indicate that if their allegations are proved, the defendants violated the antitrust laws. They argue that the district court in the case before us erred by treating the tamoxifen patent as valid and enforceable. Instead, they say, in accordance with the never-reviewed judgment in Tamoxifen I, the district court in this case should have treated the patent as presumptively invalid for purposes of assaying the sufficiency of the plaintiffs' complaint.

We begin our analysis against the backdrop of our longstanding adherence to the principle that “courts are bound to encourage” the settlement of litigation. Gambale v. Deutsche Bank AG, 377 F.3d 133, 143 (2d Cir.2004). “Where a case is complex and expensive, and resolution of the case will benefit the public, the public has a strong interest in settlement. The trial court must protect the public interest, as well as the interests of the parties, by encouraging the most fair and efficient resolution.” United States v. Glens Falls Newspapers, Inc., 160 F.3d 853, 856–57 (2d Cir.1998). As the Eleventh Circuit recently noted in drug patent litigation similar to the one before us, “There is no question that settlements provide a number of private and social benefits as opposed to the inveterate and costly effects of litigation.” Schering–Plough, 402 F.3d at 1075.
In re Tamoxifen Citrate Antitrust Litigation, 466 F.3d 187 (2006)

It is well settled that “[w]here there are legitimately conflicting [patent] claims ..., a settlement by agreement, rather than litigation, is not precluded by the [Sherman] Act,” although such a settlement may ultimately have an adverse effect on competition. Standard Oil Co. v. United States, 283 U.S. 163, 171, 51 S.Ct. 421, 75 L.Ed. 926 (1931); cf. Flex-Foot, Inc. v. CRP, Inc., 238 F.3d 1362, 1369 (Fed.Cir.2001) (“[W]hile the federal patent laws favor full and free competition in the use of ideas in the public domain over the technical requirements of contract doctrine, *203 settlement of litigation is more strongly favored by the law.”); Nestle Co. v. Chester's Mkt., Inc., 756 F.2d 280, 284 (2d Cir.1985) (“[T]he district court imposed the heavy burden on trademark defendants of having to continue to litigate when they would prefer to settle, a ruling without precedent.”), overruled on other grounds, U.S. Bancorp Mortgage Co. v. Bonner Mall P'ship, 513 U.S. 18, 27–29, 115 S.Ct. 386, 130 L.Ed.2d 233 (1994); Duplan Corp. v. Deering Milliken, Inc., 540 F.2d 1215, 1220 (4th Cir.1976) (“[T]he settlement of patent litigation, in and of itself, does not violate the antitrust laws.”); Asahi Glass Co. v. Pентech Pharmas., Inc., 289 F.Supp.2d 986, 991 (N.D.Ill.2003) (Posner, J., sitting by designation) (“The general policy of the law is to favor the settlement of litigation, and the policy extends to the settlement of patent infringement suits.”).

Rules severely restricting patent settlements might also be contrary to the goals of the patent laws because the increased number of continuing lawsuits that would result would heighten the uncertainty surrounding patents and might delay innovation. See Valley Drug, 344 F.3d at 1308; Daniel A. Crane, Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications, 54 Fla. L.Rev. 747, 749 (2002). Although forcing patent litigation to continue might benefit consumers in some instances, “patent settlements can ... promote efficiencies, resolving disputes that might otherwise block or delay the market entry of valuable inventions.” Joseph F. Brodley & Maureen A. O’Rourke, Preliminary Views: Patent Settlement Agreements, Antitrust, Summer 2002, at 53. As the Fourth Circuit has observed, “It is only when settlement agreements are entered into in bad faith and are utilized as part of a scheme to restrain or monopolize trade that antitrust violations may occur.” Duplan Corp., 540 F.2d at 1220.

We cannot judge this post-trial, pre-appeal settlement on the basis of the likelihood vel non of Zeneca's success had it not settled but rather pursued its appeal. As the Supreme Court noted in another context, “[i]t is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in his case.” Whitmore v. Arkansas, 495 U.S. 149, 159–60, 110 S.Ct. 1717, 109 L.Ed.2d 135 (1990). Similarly, “[n]o one can be certain that he will prevail in a patent suit.” Asahi Glass, 289 F.Supp.2d at 993 (emphasis in original). We cannot guess with any degree of assurance what the Federal Circuit would have done on an appeal from the district court's judgment in Tamoxifen I. Cf. In re Ciprofloxacin *204 Hydrochloride Antitrust Litig., 261 F.Supp.2d 188, 200–01 (E.D.N.Y.2003) (“Cipro II”) (noting that courts should not speculate about the outcome of litigation) (citing Boehm v. Comm’r, 146 F.2d 553 (2d Cir.), aff’d, 326 U.S. 287, 66 S.Ct. 120, 90 L.Ed. 78 (1945)); In re Ciprofloxacin Hydrochloride Antitrust Litig., 363 F.Supp.2d 514, 529 (E.D.N.Y.2005) (“Cipro III”) (“[M]aking the legality of a patent settlement agreement, on pain of treble damages, contingent on a later court's assessment of the patent's validity might chill patent settlements altogether.”). And because in this case any such guess is retrospective, it would in any event be of limited value in assessing the behavior of the defendants at the relevant time: when they were entering into the Settlement Agreement. See Valley Drug, 344 F.3d at 1306 (“[T]he reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into.”) (citing, inter alia, SCM Corp. v. Xerox Corp., 645 F.2d 1195, 1207 (2d Cir.1981), cert. denied, 455 U.S. 1016, 102 S.Ct. 1708, 72 L.Ed.2d 132 (1982)).

As the plaintiffs correctly point out, the Federal Circuit would have reviewed Judge Broderick's factual findings underlying his conclusion of invalidity with considerable deference, rather than engaging in a presumption of validity. See Shelcore, Inc. v. Durham Indus., Inc., 745 F.2d 621, 624–25 (Fed.Cir.1984) (“The presumption of validity does not guide our analysis on appeal. Rather, we review the findings and conclusions of a district court under the appropriate standards of review.”). But it takes no citation to authority to conclude that appellants prevail with some frequency in federal courts of appeals even when a high degree of deference is accorded the district courts from which the appeals are taken. Accordingly, it does not follow from the deference that was due by the Federal Circuit to the district court in Tamoxifen I that Zeneca would have been unsuccessful on
appeal. See Cipro III, 363 F.Supp.2d at 529 (noting that with few exceptions “courts assessing the legality of patent settlement agreements have not engaged in a post hoc determination of the potential validity of the underlying patent ... when deciding whether an agreement concerning the patent violates antitrust law”).

The facts of this case provide an additional reason for us to embrace the general rule that we will ordinarily refrain from guessing what a court will hold or would have held. As noted earlier, federal district courts in later lawsuits seeking to enforce the tamoxifen patent concluded, contrary to the court in Tamoxifen I, that the patent was, in fact, valid. While we do not think that these results enable us to estimate the chances that the Federal Circuit would have reversed the judgment of the district court in Tamoxifen I, they at least suggest the extent to which the outcome of such proceedings may be unpredictable. 17

*205 The fact that the settlement here occurred after the district court ruled against Zeneca seems to us to be of little moment. There is a risk of loss in all appeals that may give rise to a desire on the part of both the appellant and the appellee to settle before the appeal is decided. 18 Settlements of legitimate disputes, even antitrust and patent disputes of which an appeal is pending, in order to eliminate that risk, are not prohibited. That Zeneca had sufficient confidence in its patent to proceed to trial rather than find some means to settle the case first should hardly weigh against it.

We conclude, then, that without alleging something more than the fact that Zeneca settled after it lost to Barr in the district court that would tend to establish that the Settlement Agreement was unlawful, the assertion that there was a bar—antitrust or otherwise—to the defendants' settling the litigation at the time that they did is unpersuasive.

2. Reverse Payments. Payments pursuant to the settlement of a patent suit such as those required under the Settlement Agreement are referred to as “reverse” payments because, by contrast, “[t]ypically, in patent infringement cases the payment flows from the alleged infringer to the patent holder.” David A. Balto, Pharmaceutical Patent Settlements: The Antitrust Risks, 55 Food & Drug L.J. 321, 335 (2000). Here, the patent holder, which, if its patent is valid, has the right to prevent the alleged infringer from making commercial use of it, nonetheless pays that party not to do so. Seeking to supply the “something more” than the fact of settlement that would render the Settlement Agreement unlawful, the plaintiffs allege that the value of the reverse payments from Zeneca to Barr thereunder “greatly exceeded the value of Barr’s ‘best case scenario’ in winning the appeal ... and entering the market with its own generic product.” Appellants' Br. at 27.

It is the size, not the mere existence, of Zeneca's reverse payment that the plaintiffs point to in asserting that they have successfully pleaded a Sherman Act cause of action. In explaining our analysis, though, it is worth exploring the notion advanced by others that the very existence of reverse payments establishes unlawfulness. See Balto, supra, at 335 (“A payment flowing from the innovator to the challenging generic firm may suggest strongly the anticompetitive intent of the parties in entering the agreement and the rent-preserving effect of that agreement.”); Herbert Hovenkamp et al., Anticompetitive Settlement of Intellectual Property Disputes, 87 Minn. L.Rev. 1719, 1751 (2003) (“[T]he problem of exclusion payments can arise whenever the patentee has an incentive to postpone determination of the validity of its patent.”).

*206 Heeding the advice of several courts and commentators, we decline to conclude (and repeat that the plaintiffs do not ask us to conclude) that reverse payments are per se violations of the Sherman Act such that an allegation of an agreement to make reverse payments suffices to assert an antitrust violation. We do not think that the fact that the patent holder is paying to protect its patent monopoly, without more, establishes a Sherman Act violation. See Valley Drug, 344 F.3d at 1309 (concluding that the presence of a reverse payment, by itself, does not transform an otherwise lawful settlement into an unlawful one); Asahi Glass, 289 F.Supp.2d at 994 (asserting that “[a] ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive,” and observing that if the parties decided not to settle, and the patent holder ultimately prevailed in the infringement lawsuit, there would be the same level of competition as in the reverse payment case); Thomas F. Cotter, Refining the “Presumptive
Illegality” Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis & Lemley, 87 Minn. L.Rev. 1789, 1807 (2003) (noting that “the plaintiff often will have an incentive to pay the defendant not to enter the market, regardless of whether the former expects to win at trial,” which “suggests that reverse payments should not be per se illegal, since they are just as consistent with a high probability of validity and infringement as they are with a low probability. It also suggests that reverse payments should not be per se legal for the same reason.”). But see Cardizem, 332 F.3d at 911 (calling a forty-million-dollar reverse payment to a generic manufacturer “a naked, horizontal restraint of trade that is per se illegal because it is presumed to have the effect of reducing competition in the market for Cardizem CD and its generic equivalents to the detriment of consumers”).

As other courts have noted, moreover, reverse payments are particularly to be expected in the drug-patent context because the Hatch–Waxman Act created an environment that encourages them. See Cipro II, 261 F.Supp.2d at 252 (noting that the Hatch–Waxman Act “has the unintended consequence of altering the litigation risks of patent lawsuits” and concluding that “reverse payments are a natural by-product of the Hatch–Waxman process”); accord Schering–Plough, 402 F.3d at 1074.

In the typical patent infringement case, the alleged infringer enters the market with its drug after the investment of substantial sums of money for manufacturing, marketing, legal fees, and the like. The patent holder then brings suit against the alleged infringer seeking damages for, inter alia, its lost profits. If the patent holder wins, it receives protection for the patent and money damages for the infringement. And in that event, the infringer loses not only the opportunity to continue in the business of making and selling the infringing product, but also the investment it made to enter the market for that product in the first place. And it must pay damages to boot. It makes sense in such a circumstance for the alleged infringer to enter into a settlement in which it pays a significant amount to the patent holder to rid itself of the risk of losing the litigation.

By contrast, under the Hatch–Waxman Act, the patent holder ordinarily brings suit shortly after the paragraph IV ANDA has been filed—before the filer has spent substantial sums on the manufacturing, marketing, or distribution of the potentially infringing generic drug. The prospective generic manufacturer therefore has relatively little to lose in litigation precipitated by a paragraph IV certification beyond litigation costs and the opportunity for future profits from selling the generic drug. Conversely, there are no infringement damages for the patent holder to recover, and there is therefore little reason for it to pursue the litigation beyond the point at which it can assure itself that no infringement will occur in the first place.

Accordingly, a generic marketer has few disincentives to file an ANDA with a paragraph IV certification. The incentive, by contrast, may be immense: the profits it will likely garner in competing with the patent holder without having invested substantially in the development of the drug, and, in addition, possible entitlement to a 180–day period (to be triggered at its inclination) during which it would be the exclusive seller of the generic drug in the market. 19

The patent holder's risk if it loses the resulting patent suit is correspondingly large: It will be stripped of its patent monopoly. At the same time, it stands to gain little from winning other than the continued protection of its lawful monopoly over the manufacture and sale of the drug in question.

“Hatch–Waxman essentially redistributes the relative risk assessments and explains the flow of settlement funds and their magnitude. Because of the Hatch–Waxman scheme, [the generic challengers] gain[ ] considerable leverage in patent litigation: the exposure to liability amount[s] to litigation costs, but pale[s] in comparison to the immense volume of generic sales and profits.” Schering–Plough, 402 F.3d at 1074 (citation omitted).

Under these circumstances, we see no sound basis for categorically condemning reverse payments employed to lift the uncertainty surrounding the validity and scope of the holder's patent. 20
In re Tamoxifen Citrate Antitrust Litigation, 466 F.3d 187 (2006)

2006-2 Trade Cases P 75,382

*208 3. “Excessive” Reverse Payments. As we have noted, although there are those who contend that reverse payments are in and of themselves necessarily unlawful, the plaintiffs are not among them. They allege instead that “[t]he value of the consideration provided to keep Barr's product off the market ... greatly exceeded the value Barr could have realized by successfully defending its trial victory on appeal and entering the market with its own competitive generic product.” Appellants' Br. at 15. The plaintiffs assert that it is that excessiveness that renders the Settlement Agreement unlawful.21 We agree that even if “reverse payments are a natural by-product of the Hatch–Waxman process,” Cipro II, 261 F.Supp.2d at 252, it does not follow that they are necessarily lawful, see Hovenkamp et al., supra, at 1758 (“We do not think it follows that because it is rational for the patentee to agree to an exclusion payment, that payment cannot be anticompetitive. Far from it.”). But

[on]ly if a patent settlement is a device for circumventing antitrust law is it vulnerable to an antitrust suit. Suppose a seller obtains a patent that it knows is almost certainly invalid (that is, almost certain not to survive a judicial challenge), sues its competitors, and settles the suit by licensing them to use its patent in exchange for their agreeing not to sell the patented product for less than the price specified in the license. In such a case, the patent, the suit, and the settlement would be devices —masks—for fixing prices, in violation of antitrust law.

Asahi Glass, 289 F.Supp.2d at 991. “If, however, there is nothing suspicious about the circumstances of a patent settlement, then to prevent a cloud from being cast over the settlement process a third party should not be permitted to haul the parties to the settlement over the hot coals of antitrust litigation.” Id. at 992.

There is something on the face of it that does seem “suspicious” about a patent holder settling patent litigation against a potential generic manufacturer by paying that manufacturer more than either party anticipates the manufacturer would earn by winning the lawsuit and entering the newly competitive market in competition with the patent holder. Why, after all—viewing the settlement through an antitrust lens—should the potential competitor be permitted to receive such a windfall at the ultimate expense of drug purchasers? We think, however, that the suspicion abates upon reflection. In such a case, so long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly *209 over the manufacture and distribution of the patented product.22

If the patent holder loses its patent monopoly as a result of defeat in patent litigation against the generic manufacturer, it will likely lose some substantial portion of the market for the drug to that generic manufacturer and perhaps others. The patent holder might also (but will not necessarily)23 lower its price in response to the competition. The result will be, unsurprisingly, that (assuming that lower prices do not attract significant new purchasers for the drug) the total profits of the patent holder and the generic manufacturer on the drug in the competitive market will be lower than the total profits of the patent holder alone under a patent-conferred monopoly. In the words of the Federal Trade Commission: “The anticipated profits of the patent holder in the absence of generic competition are greater than the sum of its profits and the profits of the generic entrant when the two compete.” In re Schering–Plough Corp., slip op. at 27, 2003 WL 22989651 (Fed. Trade Comm’n Dec. 8, 2003), 2003 FTC LEXIS 187, vacated, 402 F.3d 1056 (11th Cir.2005). It might therefore make economic sense for the patent holder to pay some portion of that difference to the generic manufacturer to maintain the patent-monopoly market for itself. And, if that amount exceeds what the generic manufacturer sees as its likely profit from victory, it seems to make obvious economic sense for the generic manufacturer to accept such a payment if it is offered.24 We think *210 we can safely assume that the patent holder will seek to pay less if it can, but under the circumstances of a paragraph IV Hatch–Waxman filing, as we have discussed, the ANDA filer might well have the whip hand. Cf. Valley Drug, 344 F.3d at 1310 (“Given the asymmetries of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement.”).

Of course, the law could provide that the willingness of the patent holder to settle at a price above the generic manufacturer's projected profit betrays a fatal disbelief in the validity of the patent or the likelihood of infringement, and that the patent holder therefore ought not to be allowed to maintain its monopoly position. Perhaps it is unwise to protect patent monopolies that rest

© 2022 Thomson Reuters. No claim to original U.S. Government Works.
on such dubious patents. But even if large reverse payments indicate a patent holder's lack of confidence in its patent's strength or breadth, we doubt the wisdom of deeming a patent effectively invalid on the basis of a patent holder's fear of losing it.

[T]he private thoughts of a patentee, or of the alleged infringer who settles with him, about whether the patent is valid or whether it has been infringed is not the issue in an antitrust case. A firm that has received a patent from the patent office (and not by fraud ...), and thus enjoys the presumption of validity that attaches to an issued patent, 35 U.S.C. § 282, is entitled to defend the patent's validity in court, to sue alleged infringers, and to settle with them, whatever its private doubts, unless a neutral observer would reasonably think either that the patent was almost certain to be declared invalid, or the defendants were almost certain to be found not to have infringed it, if the suit went to judgment. It is not “bad faith” to assert patent rights that one is not certain will be upheld in a suit for infringement pressed to judgment and to settle the suit to avoid risking the loss of the rights. No one can be certain that he will prevail in a patent suit.

*Asahi Glass*, 289 F.Supp.2d at 992–93 (citation omitted) (emphasis in original).

Such a rule would also work to give sufficient consideration to the patent holder's incentive to settle the lawsuit without reference to the amount the generic manufacturer might earn in a competitive market, even when it is relatively confident of the validity of its patent—to insure against the possibility that its confidence is misplaced, or, put another way, that a reviewing court might (in its view) render an erroneous decision. *Cf. Schering–Plough*, 402 F.3d at 1075–76. Whatever the degree of the patent holder's certainty, there is always some risk of loss that the patent holder might wish to insure against by settling. This case is illustrative. It is understandable that however sure Zeneca was at the outset that its patent was valid, settlement might have seemed attractive once it lost in the district court, especially in light of the deferential standard the Federal Circuit was expected to apply on review. But its desire to settle does not necessarily belie Zeneca's confidence in the patent's validity. Indeed, Zeneca's pursuit of subsequent litigation seeking to establish the tamoxifen patent's validity, and the success of that litigation, strongly suggest that such confidence persisted and was not misplaced. Neither do we think that the settlement's entry after the district court rendered a judgment against Zeneca should counsel against the settlement's propriety. It would be odd to handicap the ability of Zeneca to settle after it had displayed sufficient confidence in its patent to risk a finding of invalidity by taking the case to trial.

We are unsure, too, what would be accomplished by a rule that would effectively outlaw payments by patent holders to generic manufacturers greater than what the latter would be able to earn in the market were they to defend successfully against an infringement claim. A patent holder might well prefer such a settlement limitation—it would make such a settlement cheaper —while a generic manufacturer might nonetheless agree to settle because it is less risky to accept in settlement all the profits it expects to make in a competitive market rather than first to defend and win a lawsuit, and then to enter the marketplace and earn the profits. If such a limitation had been in place here, Zeneca might have saved money by paying Barr the maximum such a rule might allow—what Barr was likely to earn if it entered the market—and Barr would have received less than it could have if it were free to negotiate the best deal available—as it did here. But the resulting level of competition, and its benefit to consumers, would have been the same. The monopoly would have nonetheless endured—but, to no apparent purpose, at less expense to Zeneca and less reward for Barr.
It strikes us, in other words, as pointless to permit parties to enter into an agreement settling the litigation between them, thereby protecting the patent holder's monopoly even though it may be based on a relatively weak patent, but to limit the amount of the settlement to the amount of the generic manufacturer's projected profits had it won the litigation.

We are not unaware of a troubling dynamic that is at work in these cases. The less sound the patent or the less clear the infringement, and therefore the less justified the monopoly enjoyed by the patent holder, the more a rule permitting settlement is likely to benefit the patent holder by allowing it to retain the patent. But the law allows the settlement even of suits involving weak patents with the presumption that the patent is valid and that settlement is merely an extension of the valid patent monopoly. So long as the law encourages settlement, weak patent cases will likely be settled even though such settlements will inevitably protect patent monopolies that are, perhaps, undeserved.

We also agree with the *Cipro III* court's observation that:

> If courts do not discount the exclusionary power of the patent by the probability of the patent's being held invalid, then the patents most likely to be the subject of exclusion payments would be precisely those patents that have the most questionable validity. This concern, on its face, is quite powerful. But the answer to this concern lies in the fact that, while the strategy of paying off a generic company to drop its patent challenge would work to exclude that particular competitor from the market, it would have no effect on other challengers of the patent, whose incentive to mount a challenge would also grow commensurately with the chance that the patent would be held invalid.

*Cipro III*, 363 F.Supp.2d at 534. There is, of course, the possibility that the patent holder will continue to buy out potential competition such that a settlement with one generic manufacturer protecting the patent holder's ill-gotten patent monopoly will be followed by other settlements with other generic manufacturers should a second, third, and fourth rise to challenge the patent. We doubt, however, that this scenario is realistic.

Every settlement payment to a generic manufacturer reduces the profitability of the patent monopoly. The point will come when there are simply no monopoly profits with which to pay the new generic challengers. “[I]t is unlikely that the holder of a weak patent could stave off all possible challengers with exclusion payments because the economics simply would not justify it.” *Cipro III*, 363 F.Supp.2d at 535 (emphasis supplied). We note in this regard that Zeneca settled its first tamoxifen lawsuit against the first generic manufacturer, Barr, but did not settle, and, as far as we know, did not attempt to settle, the litigation it brought against the subsequent challenging generics, Novopharm, Pharmachemie, and Mylan. (To be sure, the settlement with Barr came after a judgment *against* Zeneca, while the judgments in Novopharm, Pharmachemie, and Mylan's challenges were *for* Zeneca.)

An alternative rule is, of course, possible. As suggested above, the antitrust laws could be read to outlaw all, or nearly all, settlements of Hatch–Waxman infringement actions. Patent holders would be required to litigate each threatened patent to final, unappealable judgment. Only patents that the courts held were valid would be entitled to confer monopoly power on their proprietors. But such a requirement would be contrary to well-established principles of law. As we have rehearsed at some length above, settlement of patent litigation is not only suffered, it is encouraged for a variety of reasons even if it leads in some cases to the survival of monopolies created by what would otherwise be fatally weak patents. It is too late in the journey for us to alter course.
In re Tamoxifen Citrate Antitrust Litigation, 466 F.3d 187 (2006)

We further agree with the Schering–Plough, Andrx from marketing other bioequivalent or generic versions of Cardizem that were not at issue in the pending litigation, ...($1993). alleged, grant rights to Schering in excess of what is granted by the [relevant] patent alone.” (emphasis in original)).
alleged, grant rights to Schering in excess of what is granted by the [relevant] patent alone.” (emphasis in original)). Whatever damage is done to competition by settlement is done pursuant to *213 the monopoly extended to the patent holder by patent law unless the terms of the settlement enlarge the scope of that monopoly. “Unless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent.” Cipro III, 363 F.Supp.2d at 535.

We further agree with the Cipro III court that absent an extension of the monopoly beyond the patent's scope, an issue that we address in the next section of this opinion, and absent fraud, which is not alleged here, the question is whether the underlying infringement lawsuit was “objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits.” Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 60, 113 S.Ct. 1920, 123 L.Ed.2d 611 (1993). In this case, the plaintiffs do not contend that they can—and we conclude that in all likelihood they cannot—establish that Zeneca's patent litigation was baseless, particularly in light of the subsequent series of decisions upholding the validity of the same patent. Cf. id. at 60 n. 5, 113 S.Ct. 1920 (“A winning lawsuit is by definition a reasonable effort at petitioning for redress and therefore not a sham.”). Payments, even “excessive” payments, to settle the dispute were therefore not necessarily unlawful.

4. The Terms of the Settlement Agreement. Inasmuch as we conclude that neither the fact of settlement nor the amount of payments made pursuant thereto as alleged by the plaintiffs would render the Settlement Agreement unlawful, we must assess its other terms to determine whether they do. As we have explained in the previous section of this opinion, we think that the question is whether the “exclusionary effects of the agreement” exceed the “scope of the patent's protection.” Schering–Plough, 402 F.3d at 1076. Looking to other courts that have addressed similar cases for guidance, and accepting the plaintiffs' allegations as true, we conclude that the Settlement Agreement did not unlawfully extend the reach of Zeneca's tamoxifen patent.

First, the Settlement Agreement did not extend the patent monopoly by restraining the introduction or marketing of unrelated or non-infringing products. It is thus unlike the agreement the Sixth Circuit held per se illegal in Cardizem, 332 F.3d at 908, which included not only a substantial reverse *214 payment but also an agreement that the generic manufacturer would not market non-infringing products. See id. at 902, 908 & n.13 (quoting the court in Cipro II, 261 F.Supp.2d at 242, which observed that the Cardizem district court, in condemning the settlement agreement in that case, “ emphasized that the agreement [there] restrained Andrx from marketing other bioequivalent or generic versions of Cardizem that were not at issue in the pending litigation, ... Thus, the court found that the agreement's restrictions extended to noninfringing and/or potentially noninfringing versions of generic Cardizem.” (alterations in original)); see also Valley Drug, 344 F.3d at 1306 n. 18 (observing that if the agreement “also prohibited the marketing of non-infringing terazosin products, prohibited [the generic manufacturer] from marketing infringing products beyond the date a district court held the [relevant] patent invalid, and prohibited [the generic manufacturer] from waiving its 180–day exclusivity period” then the agreement “may be beyond the scope of [the patent holder's] lawful right to exclude and, if so, would expose appellants to antitrust liability”); In re K–Dur Antitrust Litig., 338 F.Supp.2d 517, 532 (D.N.J.2004) (noting, in connection with a private lawsuit involving the same settlement agreements challenged by the FTC in Schering–Plough, that the plaintiffs “alleged that [the generic manufacturer] not only agreed not to enter the market with the allegedly infringing generic drug at issue in the patent litigation, but agreed not to enter the market with any generic competitor drug, irrespective of whether it infringed the patent” and that another potential distributor of generic equivalents also agreed to delay marketing a generic competitor drug and “agreed not to conduct, sponsor, file or support any study of a generic drug's bioequivalence to [the patented drug] before the expiration of the [relevant] patent,” and concluding: “These agreements, as alleged, grant rights to Schering in excess of what is granted by the [relevant] patent alone.” (emphasis in original)).
In re Tamoxifen Citrate Antitrust Litigation, 466 F.3d 187 (2006)

2006-2 Trade Cases P 75,382

Like the patent for the compound ciprofloxacin hydrochloride, which was the subject of dispute in the Cipro cases, and unlike the patents at issue in Cardizem and Valley Drug, Zeneca's tamoxifen patent is not a formulation patent, which covers only specific formulations or delivery methods of compounds; rather, it is a patent on a compound that, by its nature, excludes all generic versions of the drug. See Appellees' Br. at 23; Cipro II, 261 F.Supp.2d at 249–50 (observing that the patent in that case covered all formulations and the generic manufacturer could not have avoided it). Because Zeneca's patent therefore precludes all generic versions of tamoxifen, so that any such competing version would, as we understand it, necessarily infringe the patent, the Settlement Agreement did not, by precluding the manufacture of a generic version of tamoxifen, restrain the marketing of any non-infringing products.

Second, the Settlement Agreement ended all litigation between Zeneca and Barr and thereby opened the tamoxifen patent to immediate challenge by other potential generic manufacturers, which did indeed follow—spurred by the additional incentive (at the time) of potentially securing the 180–day exclusivity period available upon a victory in a subsequent infringement lawsuit, since by vacating the district court judgment and amending its ANDA to remove its paragraph IV certification, Barr appeared to ensure (under procedures in effect at the time) that it was not eligible for the exclusivity period. See Cipro II, 261 F.Supp.2d at 242–43 (emphasizing that the settlement in that case extinguished the litigation between Barr and Bayer and *215 that Barr agreed to withdraw its paragraph IV certification, thus removing any “bottleneck” to future generic entrants). The Agreement thus avoided a “bottleneck” of the type created by the agreements in Valley Drug and Cardizem, which prevented other generic manufacturers from obtaining approval for their own generic versions from the FDA. Rather than resolve the litigation, the settlements in those cases prolong it by providing incentives to the defendant generic manufacturers not to pursue the litigation avidly. In Cardizem, for example, the settlement included periodic payments to the generic manufacturer during the pendency of the lawsuit in exchange for its promise not to market a generic drug for which it had already received FDA approval, thereby delaying the market entry of other generic manufacturers “who could not enter until the expiration of [the first-moving generic manufacturer's] 180–day period of marketing exclusivity, which [the generic] had agreed not to relinquish or transfer.” Cardizem, 332 F.3d at 907; see also Cipro II, 261 F.Supp.2d at 243 (noting that in Valley Drug, the generic manufacturer had obtained final FDA approval, yet the settlement agreement “delayed triggering [the generic manufacturer's] 180–day exclusivity period, effectively holding up FDA approval of other generic manufacturers' ANDA IVs.”).

The disadvantage purportedly suffered by the plaintiffs is not that Barr somehow prevented others from challenging the patent and obtaining FDA approval; nor is it that no other generic manufacturer tried to do so. It is instead that each of the subsequent challenges failed. While it is true that, had the district court's decision in Zeneca's patent infringement lawsuit against Barr been affirmed, other generic manufacturers would have been allowed to market their drugs, there is no legal requirement that parties litigate an issue fully for the benefit of others. See, e.g., Nestle, 756 F.2d at 284.

Thus the stated terms of the Settlement Agreement include nothing that would place it beyond the legitimate exclusionary scope of Zeneca's patent: The Settlement Agreement did not have an impact on the marketing of non-infringing or unrelated products, and the Agreement fully resolved the litigation between Zeneca and Barr, clearing the way for other generic manufacturers to seek to enter the market.

Finally, the Settlement Agreement did not entirely foreclose competition in the market for tamoxifen. It included a license from Zeneca to Barr that allowed Barr to begin marketing Zeneca's version of tamoxifen eight months after the Settlement Agreement became effective. The license ensured that money also flowed from Barr to Zeneca, decreasing the value of the reverse payment. By licensing tamoxifen to Barr, Zeneca added a competitor to the market, however limited the competition may have been. Unlike reverse payment settlements that leave the competitive situation as it was prior to the litigation, the reverse payment in this case was pursuant to an agreement that increased competition in the market for tamoxifen—even if only a little—almost nine years before the tamoxifen patent was to expire. Cf. Cipro II, 261 F.Supp.2d at 209 (noting that if the patent holder had not
agreed to pay the generic manufacturers “hundreds of millions of dollars,” then the patent holder “would have issued to [the generic manufacturers] a license for distribution of generic Cipro”).

*216 The Settlement Agreement almost certainly resulted in less price competition than if Barr had introduced its own generic version, of course. The plaintiffs allege that the Barr-distributed, Zeneca-manufactured tamoxifen sold at retail for just five percent less than the Zeneca-branded version, Compl. ¶ 75, compared with what the plaintiffs allege is a typical initial drop of sixteen percent or more, see Oral Argument Tr., July 12, 2004, at 5, and an eventual drop in a truly competitive market of thirty to eighty percent, Compl. ¶ 75. See also Congr. Budget Office, How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry 32 (July 1998), available at http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf (last visited May 12, 2005) (describing one study that estimated that the average price of a generic drug fell from sixty percent of the brand-name price to thirty-four percent of the brand-name price as the number of generic manufacturers increased from one to ten). This was competition nonetheless. It was certainly more competition than would have occurred had there been no settlement and had Zeneca prevailed on appeal. Cf. Nestle, 756 F.2d at 284 (noting that the district court erred by not placing more weight on the consequences of requiring the litigation to go forward, such as the fact that “the appellees will be forced to bear the costs and risks of further litigation, including the non-trivial risk of a reversal on the merits”).

We conclude that the facts as alleged in the plaintiffs' complaint, if proved, would not establish that the terms of the Settlement Agreement violated the antitrust laws. In the absence of any plausible allegation that the reverse payment provided benefits to Zeneca outside the scope of the tamoxifen patent, the plaintiffs have not stated a claim for relief with respect to the Settlement Agreement. See Twombly, 425 F.3d at 111.

5. Barr's 180–Day Exclusivity Period. The plaintiffs also advance allegations regarding actions that Barr took with respect to the 180–day exclusivity period to which the first paragraph IV filer is entitled under the Hatch–Waxman Act. We confess that it is not altogether clear to us what the import of those allegations is. The plaintiffs contend that Barr's attempt to assert its exclusivity period in 1998, five years after the date of the Settlement Agreement, should be viewed as “circumstantial evidence demonstrating the anticompetitive consequences of [the] agreement[ ]” among the defendants. Appellants' Reply Br. at 13. They allege that the Settlement Agreement was drafted “carefully to preserve Barr's” ability to “strategically deploy[ ]” its claim to the exclusivity period. Compl. ¶ 57. And they further allege the existence of an understanding among the defendants as to when and under what circumstances “Barr would assert its claimed exclusivity period rights to prevent ... FDA approval” of other generic manufacturers' ANDA applications, “even if Zeneca was unsuccessful in using patent litigation to keep another generic competitor off the market.” 29 Id. ¶ 58. They also contend that because they have alleged an unlawful conspiracy, the issue is only “whether Barr's conduct in blocking generic entry was in furtherance of that alleged conspiracy.” Appellants' Br. at 35 (emphasis omitted).

The defendants contend in response that any consequences of the 180–day exclusivity period resulted from Barr's petition to *217 the FDA, and that Barr's actions in claiming the 180–day exclusivity period were therefore immune from antitrust scrutiny under the Noerr–Pennington doctrine, which immunizes parties from antitrust liability for injuries resulting from government action prompted by the parties' petitioning activities. See E.R.R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 136, 81 S.Ct. 523, 5 L.Ed.2d 464 (1961) (stating that “the Sherman Act does not prohibit two or more persons from associating together in an attempt to persuade the legislature or the executive [or an agency or a court] to take particular action with respect to a law that would produce a restraint or a monopoly”); United Mine Workers of Am. v. Pennington, 381 U.S. 657, 670, 85 S.Ct. 1585, 14 L.Ed.2d 626 (1965) (“Joint efforts to influence public officials do not violate the antitrust laws even though intended to eliminate competition.”). Such immunity does not disappear even if the petitioning activity is intended to harm competitors. See Noerr, 365 U.S. at 138–39, 81 S.Ct. 523. In this case, the defendants assert, because Barr's petitioning activity was protected under Noerr–Pennington, it cannot be the basis for antitrust liability.
We are not so sure. Although Noerr–Pennington immunity may lend Barr's actions some protection, it does not immunize all actions with respect to the 180–day exclusivity period from antitrust scrutiny. The doctrine does not extend protection to the defendants “where the alleged conspiracy ‘is a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor.’ ” Cal. Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508, 511, 92 S.Ct. 609, 30 L.Ed.2d 642 (1972) (quoting Noerr, 365 U.S. at 144, 81 S.Ct. 523). And it “does not authorize anticompetitive action in advance of [the] government's adopting the industry's anticompetitive proposal. The doctrine applies when such action is the consequence of legislation or other governmental action, not when it is the means for obtaining such action.” In re Brand Name Prescription Drugs Antitrust Litig., 186 F.3d 781, 789 (7th Cir.1999) (emphasis in original); see also Juster Assocs. v. City of Rutland, 901 F.2d 266, 271–72 (2d Cir.1990) (stating that when a claimed restraint is the consequence of government action, it falls within the purview of Noerr–Pennington immunity, but when the restraint is the means by which the defendants seek to obtain favorable government action, it does not). Because we think that an agreement to time the deployment of the exclusivity period to extend a patent's monopoly power might well constitute anticompetitive action outside the scope of a valid patent, we decline to rest our conclusion on the ground of Noerr–Pennington immunity.

We nonetheless do not think that the facts as alleged with respect to Barr's *218 claim to the 180–day exclusivity period amount to an antitrust violation.

First, as we have explained, our review of the Settlement Agreement convinces us that, accepting the plaintiffs' allegations as true, the defendants did not violate the antitrust laws merely by entering into it. Therefore, even if we were to view Barr's actions with regard to the 180–day exclusivity period as somehow constituting “evidence”—“circumstantial” or otherwise—of the “anticompetitive consequences” of the Settlement Agreement, it would not affect our conclusion. The Agreement is no doubt “anticompetitive”—the plaintiffs need no additional proof of that. It limited competition between generic tamoxifen and Zeneca's branded product. But, as we have seen, because it did not exceed the scope of the tamoxifen patent, it was not an unlawful anticompetitive agreement.

Second, because we have concluded that the Settlement Agreement was not itself an unlawful conspiracy, Barr's “block[ing of] generic entry” would not be unlawful as “in furtherance of” an unlawful conspiracy. There would have to be an unlawful conspiracy before Barr's actions could contribute to it.

Third, [t]he factual predicate that is pleaded does need to include [an unlawful] conspiracy among the realm of plausible possibilities. Twombly, 425 F.3d at 111 (footnote omitted). Assuming that the plaintiffs intended to allege a separate agreement among the defendants relating to Barr's manipulation of its exclusivity period in order to protect the defendants from competition from other generic manufacturers, the pleaded conspiracy seems to us to be “implausible.”

At the time the Settlement Agreement was entered into, the established law was that a generic manufacturer must “successfully defend” a patent infringement lawsuit in order to obtain exclusivity. Accordingly, even if Barr might have suspected that the FDA would drop its “successful defense” requirement, it had, at the time, no claim to the exclusivity period. Although the Agreement in this case did include a provision allowing Barr to revert its paragraph III certification back to a paragraph IV certification in the event another generic manufacturer successfully invalidated the patent, it seems farfetched, in light of the law at the time, to construe that provision as a conscious and unlawful attempt to manipulate the exclusivity period.

Moreover, the fact that Barr acted as it did with respect to the deployment of the exclusionary period is easily explained by Barr's own interest in protecting itself from competition through a petition to the FDA for a statutorily prescribed benefit. Nothing that we can draw from the facts alleged in the complaint indicates how Barr's actions in this regard suggest that it was in league with Zeneca.
Fourth and last, we have grave doubt as to whether, even if the defendants agreed to deploy the exclusionary period to protect their shared monopoly power, the injury that the defendants allege they suffered in this regard constitutes “antitrust injury.”

To state a claim under the Sherman Act, a plaintiff, in addition to stating an antitrust violation, must allege facts sufficient to prove that it suffered “antitrust injury, which is to say injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful.” Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 97 S.Ct. 690, 50 L.Ed.2d 701 (1977) (emphasis omitted); see also George Haug Co., Inc. v. Rolls Royce Motor Cars Inc., 148 F.3d 136, 139 (2d Cir.1998). “The injury should reflect the anticompetitive effect either of the violation or of anticompetitive acts made possible by the violation.” Brunswick, 429 U.S. at 489, 97 S.Ct. 690. “Harm to the antitrust plaintiff is sufficient to satisfy the constitutional standing requirement of injury in fact.” Associated Gen. Contractors, Inc. v. Cal. State Council of Carpenters, 459 U.S. 519, 74 L.Ed.2d 723 (1983).

Accepting for the sake of argument that the plaintiffs have stated an antitrust violation by alleging an agreement or understanding between Barr and Zeneca to manipulate the 180–day exclusivity period, we are inclined to agree with the district court's conclusion that any injury that the plaintiffs suffered nonetheless resulted from Zeneca's valid patent and from the inability of other generic manufacturers to establish that the patent was either invalid or not infringed—and not from any agreement between Barr and Zeneca that Barr should employ its exclusivity powers to exclude competition. See Tamoxifen II, 277 F.Supp.2d at 136–38.

As we have noted, at the time that Zeneca and Barr entered into the Settlement Agreement and caused the district court's judgment of patent invalidity to be vacated, Barr was not entitled to the 180–day period of exclusivity. It was only after the FDA announced that it was abandoning the “successful defense” requirement that Barr asserted its claim to the exclusivity period. See Tamoxifen II, 277 F.Supp.2d at 135. As the district court noted:

Barr did not seek similar relief when Novopharm filed its ANDA and challenged the [tamoxifen] patent between 1994 and 1997. Only after the events in 1997 and 1998 ... did Barr attempt to assert its rights. If Barr intended to protect its exclusivity period on behalf of itself and Zeneca pursuant to the Settlement Agreement, Barr's inactivity during the pendency of the Novopharm litigation is inexplicable.

Id. at 134 n. 9 (emphasis in original).

Therefore, the plaintiffs could not have suffered any antitrust injury with regard to an exclusivity period for Barr from the time the defendants signed the Settlement Agreement until the time the regulations were changed in 1997–1998. During that period, as far as all parties were concerned, the Settlement Agreement had indeed “cleared the field” so that other generic challengers could enter the market. Accordingly, any injury suffered by the plaintiffs during that time period was the result of Zeneca's legitimate patent monopoly—which remained intact as a result of the lawful Settlement Agreement—and not the result of any steps that Barr took.

The plaintiffs also suffered no antitrust injury from the time the “successful defense” requirement was eliminated until, in 2000, the FDA rejected Barr's claim to the exclusivity period, because the other ANDA filers with a paragraph IV certification ultimately lost their infringement suits against Zeneca. Even if Barr had not successfully petitioned the FDA, other generic manufacturers would not have been able to enter the market with their generic versions without infringing the tamoxifen patent. As the district court rightly noted, this allegation of injury is “based on the lack of competition that could have only existed by
In re Tamoxifen Citrate Antitrust Litigation, 466 F.3d 187 (2006)

Illegally infringing on the tamoxifen patent.” Id. at 137–38. Thus, the plaintiffs did not suffer antitrust injury then either. See, e.g., Axis, S.p.A. v. Micafil, Inc., 870 F.2d 1105, 1111 (6th Cir.), cert. denied, 493 U.S. 823, 110 S.Ct. 83, 107 L.Ed.2d 49 (1989) (finding no antitrust injury where plaintiffs had stated an antitrust violation, but where the alleged injury would have resulted even in the absence of the antitrust violation, because of the existence of patents preventing market entry).

Finally, there is clearly no antitrust injury with regard to Barr's use of the exclusivity period after the FDA rejected Barr's claim to the exclusivity period in 2000. From that time on, no one could have thought that Barr had a claim to an exclusivity period. Any injury suffered by the plaintiffs arose from Zeneca's patent monopoly, which remained valid until its expiration in 2002, after which other generic manufacturers did, in fact, enter the market.

For the foregoing reasons, we conclude that the plaintiffs have not sufficiently stated an antitrust claim arising out of the defendants' actions with regard to Barr's 180–day exclusionary period.

IV. Leave To Amend

The plaintiffs contend that the district court erred in not addressing, and therefore in effectively denying, their request to amend their complaint to state a claim on which relief could be granted. The defendants reply that the district court acted within its discretion in effectively denying the plaintiffs' request—which appeared in a footnote in the middle of their brief opposing the defendants' motion to dismiss—because the request was buried and because it was, in any event, futile.

Federal Rule of Civil Procedure 15(a) provides that “a party may amend the party's pleading ... by leave of court ... and leave shall be freely given when justice so requires.” A district court has broad discretion to decide whether to grant leave to amend, a decision that we review for an abuse of discretion. Gurary v. Winehouse, 235 F.3d 792, 801 (2d Cir.2000). It is within the court's discretion to deny leave to amend implicitly by not addressing the request when leave is requested informally in a brief filed in opposition to a motion to dismiss. See id. Furthermore, where amendment would be futile, denial of leave to amend is proper. See Van Buskirk v. N.Y. Times Co., 325 F.3d 87, 91–92 (2d Cir.2003).

The plaintiffs' assertion that, if granted leave to amend, they “would be able to redress perceived deficiencies” in their complaint, Appellants' Br. at 56, does not persuade us. Even were plaintiffs to allege—as they now assert they are able to—that the defendants were concerned about the possibility that the Settlement Agreement might run afoul of antitrust law, or that the reverse payments were in excess of Zeneca's litigation costs but “less than the substantial losses Zeneca anticipated *221 upon generic competition,” or that the defendants “believed the Federal Circuit would likely affirm” the invalidation of the tamoxifen patent, id., in the absence of any plausible allegation that Zeneca's patent infringement lawsuit was baseless or that the Settlement Agreement otherwise restricted competition beyond the scope of the tamoxifen patent, their complaint would fail to state a claim on which relief can be granted.

“[I]t appears beyond doubt that the plaintiff[s] can prove no set of facts in support of [their] claim which would entitle [them] to relief.” Conley v. Gibson, 355 U.S. 41, 45–46, 78 S.Ct. 99, 2 L.Ed.2d 80 (1957). The district court therefore did not abuse its discretion in denying the plaintiffs' request for leave to amend.

CONCLUSION

For the foregoing reasons, the judgment of the district court is affirmed.
In re Tamoxifen Citrate Antitrust Litigation, 466 F.3d 187 (2006)
2006-2 Trade Cases P 75,382

POOLER, Circuit Judge.

I respectfully dissent. I believe that the opinion of the court, which dismisses plaintiffs' complaint at the Rule 12(b)(6) stage, shortcuts a process necessary to balance the interests at stake in this litigation. These interests include, on one side, the encouragement of innovation fostered by the patent laws, the public and private interest in amicable settlements, and judicial economy; and, on the other side, an interest in vigorous competition protected by the Sherman Act as well as the interest of consumers in having the validity of a patent litigated. I agree with the majority that balancing is required but differ from them as to (1) the proper balancing analysis, and (2) the ability to perform this analysis without further development of the factual record. In my view, plaintiffs' allegations were sufficient to allow discovery and, thereafter, a more fully informed balancing analysis.

BACKGROUND

I. Plaintiffs' relevant allegations.

Plaintiffs allege that the various agreements described in the majority opinion are a cover for an agreement to allow Zene
c1 and Barr to monopolize and allocate the tamoxifen market. In support of this proposition, plaintiffs further allege that (1) at the time the two drug manufacturers entered into their agreements, Zene
c1's patent had been declared invalid by a district court and Zene
c1's appeal was fully briefed before the Federal Circuit; (2) Zene
c1 agreed to pay Barr $21 million and Barr's supplier $45.4 million in return for Barr's agreement to withdraw its challenge to Zene
c1's patent and refrain from entering the generic market until Zene
c1's patent expired in 2002; (3) the amount paid to Barr exceeded the amount that Barr could have earned by successfully defending its judgment because the 180–day period during which Barr would have been the only generic manufacturer would have been followed immediately by a highly competitive generic market; (4) although the agreement required Barr to convert its paragraph IV certification to a paragraph III certification, it also provided that Barr could revert to a paragraph IV certification if Zene
c1's patent was later declared invalid, which would allow Barr and Zene
c1 to delay the entry of any subsequent generic challenger into the market; (5) in order to render the agreement effective, Barr was required to join Zene
c1 in moving for vacatur of the judgment, *222 which motion resulted in the vacatur of the district court's determination that the patent was not valid; (6) subsequent generic challengers faced a thirty-month stay before they could enter the market; (7) Barr did indeed employ its exclusivity period against another generic manufacturer, Mylan Pharmaceuticals, when the latter was poised to enter the market; and (8) the savings to end purchasers who bought the tamoxifen that Barr obtained from Zene
c1 was only about 5% as compared to the 30% to 80% discount typically available where there is true generic competition.

II. The majority's analysis.

The majority's resolution of this appeal rests on a series of premises. First, the majority states that the Sherman Act aims to encourage competition by prohibiting agreements that unreasonably restrain trade. Majority op. at 201–02 & n.13. The majority next states that the patent laws also ultimately aim to stimulate competition and innovation, but that they do so through a system that grants an inventor a time-limited exclusive right in her invention or formulation. Id. at 202. These contrasting goals, the majority posits, create a tension in cases where patent and antitrust overlap and require "a delicate balance." Id. at 202 (quoting Schering–Plough Corp. v. FTC, 402 F.3d 1056, 1067 (11th Cir.2005)).

After thus recognizing the inherent tension between antitrust and patent law, the majority goes on to articulate principles that it believes should be used to resolve this tension in the context of an antitrust challenge to a Hatch–Waxman settlement agreement. First, it notes the general principle that settlements, including patent settlements in the pharmaceutical area, are to be encouraged because they promote the public interest and the interests of the parties. Id. at 202–03. In addition, the majority relies on the Supreme Court's recognition that " ‘where there are legitimately conflicting [patent] claims ... a settlement by agreement rather
than litigation, is not precluded by the Sherman Act.’” Id. at 202 (quoting Standard Oil Co. v. United States, 283 U.S. 163, 171, 51 S.Ct. 421, 75 L.Ed. 926 (1931)).

The majority then suggests that rules that severely restrict patent settlements create undue uncertainty concerning patents and thus might delay the entry of innovative products into the market. It also reasons that, although forcing patent litigation to continue might be pro-competitive in some cases, resolving disputes may also allow the entry into the market of valuable inventions. Id. at 203–04.

Turning to the agreements at issue in this case, the majority states that it cannot find them unreasonable based on the likelihood that Barr would maintain its victory on appeal because courts are ill positioned to predict the outcome of litigation. Id. at 204. Puzzlingly, after noting that the validity of a settlement agreement must be judged from the viewpoint of the time in which it was made, id. at 204, the majority relies on the fact that other district courts reached a different conclusion from that of the Southern District of New York to show that it is difficult to assess Barr's likelihood of success on appeal, id. at 205. It finds “of little moment” the fact that the parties reached settlement “after the district court ruled against Zeneca” because all parties have a motivation to eliminate risk on appeal, but finds it significant “[t]hat Zeneca had sufficient confidence in its patent to proceed to trial rather than find some means to settle the case first.” Id. at 205.

The court concludes “that without alleging something more than the fact that Zeneca settled after it lost to Barr in the district court,” plaintiffs have not alleged an antitrust violation. Id. at 205. The first “something more” that the majority considers is the $21–million reverse payment Zeneca made to Barr in return for the latter's agreement to stay out of the generic market for tamoxifen and to cooperate in vacating its favorable judgment. It finds no per se bar to reverse payments, indicating that “the fact that the patent holder is paying to protect its patent monopoly [does not], without more, establish[ ] a Sherman Act violation.” Id. at 206. The majority also posits that reverse payments are to be expected in the drug patent context because Hatch–Waxman shifted the risk of a lawsuit from an infringer to a patent holder. Id. at 206–08.

Next, after conceding that reverse payments that, like the one alleged here, exceed the profits the generic might expect to make if it prevailed in the underlying litigation look suspicious, the majority holds that such excessive reverse payments are not unlawful, explaining that “so long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly over the manufacture and distribution of the patented product.” Id. at 208.

The court then articulates its standard for judging whether a Hatch–Waxman settlement agreement violates the antitrust laws: “[A]bsent an extension of the monopoly beyond the patent's scope ... and absent fraud ... the question is whether the underlying infringement lawsuit was ‘objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits.’” Id. at 213 (quoting Prof'l Real Estate Investors, Inc. v. Columbia Pictures, Inc., 508 U.S. 49, 60, 113 S.Ct. 1920, 123 L.Ed.2d 611 (1993)). The majority then holds that plaintiffs did not and cannot—in light of Zeneca's subsequent litigation victories-establish that Zeneca's infringement suit against Barr was objectively baseless. Id. at 213.

The majority next considers whether the exclusionary effects of the agreements exceed the patent's scope and concludes that they do not because (1) the agreements did not bar the introduction of any non-infringing products; (2) they ended all litigation between Zeneca and Barr, thus opening the field to other generic challengers; and (3) they did not entirely foreclose competition because they allowed Barr to market Zeneca's version of Tamoxifen. Id. at 213–16. Finally, the majority considers plaintiffs' allegations concerning Barr's manipulation of the exclusivity period. It concludes that although “an agreement to time the deployment of the exclusivity period to extend a patent's monopoly power might well constitute anticompetitive action outside the scope of a valid patent,” id. at 217, because the agreements themselves did not exceed the scope of Zeneca's lawful patent, Barr's actions could not be unlawful as in furtherance of an original conspiracy, id. at 217–18.
The court dismisses as speculative any claim by plaintiffs that Barr and Zeneca entered into a side agreement that Barr would use its exclusivity period in the way it did, claiming that “[a]lthough the Agreement in this case did include a provision allowing Barr to revert its paragraph III certification back to a paragraph IV certification in the event another generic manufacturer successfully invalidated the patent, it seems farfetched, in light of the law at the time, to construe the provision as a conscious and unlawful attempt to manipulate the exclusivity period.” *Id.* at 218. The law to which the majority refers is a former federal regulation requiring that in order to obtain an exclusivity period, the *224* generic manufacturer must successfully defend a patent infringement suit. See *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1065 (D.C.Cir.1998) (citing former 21 C.F.R. 314.107(c)(1)). The majority also argues that Barr's deployment of the exclusory period is adequately explained “by [its] own interest in protecting itself from competition through a petition to the FDA for a statutorily described benefit” and that nothing in the complaint suggests a conspiracy. *Id.* at 218. Alternatively, the majority suggests that it has grave doubts that the injury plaintiffs allege is antitrust injury because the injury stemmed from the scope of Zeneca's patent and from the inability of other generics to defeat Zeneca's patent. *Id.* at 219–20.

**DISCUSSION**

I differ with both the majority's standard for pleading a Hatch–Waxman–settlement antitrust violation and with several subsidiary holdings, conclusions, or assumptions. The requirement that-unless an antitrust plaintiff demonstrates that a settlement agreement exceeds the scope of the patent-it must show that the settled litigation was a sham, i.e., objectively baseless, before the settlement can be considered an antitrust violation is not soundly grounded in Supreme Court precedent and is insufficiently protective of the consumer interests safeguarded by the Hatch–Waxman Act and the antitrust laws. Beyond that overarching difference, the majority has, in my view, wrongly (1) accorded dispositive deference to Zeneca's patent rights when its patent had been declared invalid at the time of the settlement; (2) focused on subsequent litigation concerning patent validity rather than the litigation posture at the time of settlement; (3) held that the district court could not assess the likelihood that Zeneca would succeed on appeal; (4) held that plaintiffs insufficiently alleged a conspiracy between Barr and Zeneca to deploy Barr's paragraph IV certification when it would delay the market entry of another generic manufacturer; and (5) failed to recognize that whether plaintiffs' injuries stem from the alleged Barr/Zeneca conspiracy or from the failure of other generics to invalidate the patent cannot be resolved on the pleadings.

**I. The pleading standard.**

Relying principally on *Professional Real Estate Investors*, the majority concludes that, in order to attack a Hatch–Waxman settlement on antitrust grounds, plaintiffs must allege either that the agreement gave the patent holder benefits beyond the scope of the patent or that the agreement was a sham, that it was “objectively baseless in the sense that no reasonable litigant would realistically expect success on the merits.” Majority op. at 213 (quoting 508 U.S. at 60, 113 S.Ct. 1920). I agree that a settlement agreement that confers on the patent holder a greater monopoly benefit than does the patent itself is illegal. However, I do not agree that, absent a showing of benefits exceeding the scope of the patent, the antitrust plaintiff must show that the settled litigation was objectively baseless.

*Professional Real Estate Investors* is not apposite because it did not involve the settlement of Hatch–Waxman patent litigation. Rather, plaintiffs brought a copyright infringement case, and defendants countersued, alleging that the suit was a sham and a violation of §§ 1 and 2 of the Sherman Act. 508 U.S. at 52, 113 S.Ct. 1920. The district court held that while no infringement occurred, no antitrust violation occurred either because the plaintiffs were entitled to immunity under *225* Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 81 S.Ct. 523, 5 L.Ed.2d 464 (1961), as their litigation “was clearly a legitimate effort and therefore not a sham.” 508 U.S. at 53, 113 S.Ct. 1920 (quoting *Columbia Pictures Indus., Inc. v. Prof'l Real Estate Investors, Inc.*, 1990 WL 56166 at *1 (C.D.Cal.1990)). Both the Court of Appeals and the Supreme Court
agreed, and the Supreme Court defined “sham” for the purposes of defeating Noerr–Pennington immunity, as the majority does here. *Id.* at 60. The Court was not called upon to decide and did not decide the standard for pleading an antitrust violation; it simply defined “sham,” in a context in which it was already clear that the required standard was sham litigation. It is ill-advised, I think, to import the definition of “sham” used where a party must concededly establish that litigation was “sham” to avoid a well-established immunity from antitrust liability to a context in which we are defining antitrust liability in the first instance. Although Zeneca's original suit was likely protected under the standard set out in Professional Real Estate Investors, it does not necessarily follow that the settlement of that suit should be judged on the same grounds.

In fact, other leading cases cited in the majority opinion suggest, although I concede they do not mandate, a contrary conclusion. See Standard Oil, 283 U.S. at 180, 51 S.Ct. 421 (noting in the context of upholding cross-licensing agreements for patents against an antitrust challenge that a “master found, after an elaborate review of the entire art, that the presumption of validity attaching to the patents had not been negatived in any way; that they merited a broad interpretation; that they had been acquired in good faith; and that the scope of the several groups of patents overlapped sufficiently to justify the threats and fears of litigation.”); United States v. Singer Mfg Co., 374 U.S. 174, 197, 83 S.Ct. 1773, 10 L.Ed.2d 823 (1963) (White, Justice, concurring) (noting that the majority had not reached issue of whether “collusive termination of a Patent Office interference proceeding pursuant to an agreement between [certain parties] to help one another to secure as broad a patent monopoly as possible, invalidity considerations, notwithstanding” was sufficient, standing alone, to state an antitrust claim and indicating that he believed it was). Both the majority opinion in Standard Oil and the concurrence in Singer suggest that an antitrust court must go beyond deciding that a lawsuit was not a sham, that is objectively baseless, before it can dismiss an antitrust challenge to the lawsuit's settlement-as opposed to the initiation of the lawsuit-and, in fact, must consider the strength of the patent.

Holding that a Hatch–Waxman settlement agreement cannot violate antitrust laws unless the underlying litigation was a sham also ill serves the public interest in having the validity of patents litigated. See United States v. Glaxo Group Ltd., 410 U.S. 52, 57, 93 S.Ct. 861, 35 L.Ed.2d 104 (1973). This interest exists because “[i]t is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly.”

A Hatch–Waxman settlement, by definition, protects the parties' interests as they see them. Whether it also promotes the public's interest depends on the facts. If the validity of the patent is clear, and the generic company receives a license to market the patent holder's product, competition is increased. However, if, as in this case, the patent has already been shown to be vulnerable to attack and the generic manufacturer is paid to keep its generic product off the market, it is hard to see how the public benefits.

The Hatch–Waxman Act provides an incentive for the second kind of agreement that other patent laws do not provide. Patent litigation other than Hatch–Waxman patent litigation generally proceeds along familiar lines. A patent holder sues an alleged infringer, and the infringer either chooses to go to trial to vindicate its view that the patent is invalid or pays the patent holder money as compensation for damages the patent holder has suffered or as the price of a license. In this context, one can perhaps assume that the parties' relative views on the strength of a patent will result in a pro-competitive or neutral result. If the patent holder believes its patent is strong, it will proceed to trial, knowing that it can collect damages at the end. The generic manufacturer, if it believes the patent holder's patent is weak, may be willing to risk damages and market its product during the litigation, thereby promoting competition. And if the claims are in relative equipoise, a licensing arrangement may well result.

In contrast, a generic competitor subject to Hatch–Waxman cannot enter the market for the first thirty months after litigation is commenced against it. See 21 U.S.C. § 355(j)(5)(B)(iii). In addition, whether its attack against the patent is strong or weak, the benefit it will obtain by successfully litigating to the finish is not great. At best, it will obtain 180 days in which it will be the exclusive generic on the market. See 21 U.S.C. § 355(j)(5)(B)(iv). On the other hand, the benefits to the public from the
completion of litigation can be enormous if the generic challenger prevails as it did, at least initially, here. Once the 180–day exclusivity period is over, any generic that wishes to market a generic product and that can establish its product is bioequivalent to the patented product can enter the market, thus providing increased competition.

Moreover, the thirty-month stay provides an incentive to the patent holder to pay its generic competitor more than the generic company could have realized from winning the lawsuit. This is so because once the settlement is reached and the litigation dismissed, another generic manufacturer will have to wait at least thirty months after litigation is commenced against it to begin production. Thus, the patent holder will be protected against all generic competition for thirty months after the first lawsuit is terminated. This problem is aggravated when the agreement between the putative competitors provides that the generic company can deploy its exclusivity period after sitting on it until another ANDA applicant attempts to enter the market. These anti-competitive effects— and others not present in this case—have caused antitrust scholars to propose various analytical frameworks for determining whether an antitrust violation has occurred when a patent holder makes a reverse payment to settle patent litigation. The analytical frameworks proposed vary both as to burden of proof and as to the evidence necessary to find a reverse payment illegal.

For instance, Herbert Hovenkamp, Mark Janis, and Mark A. Lemly propose that a Hatch Waxman Act settlement that includes a reverse payment be presumed illegal with the patent holder being allowed to rebut this presumption “by showing both (1) that the ex ante likelihood of prevailing in its infringement lawsuit is significant, and (2) that the size of the payment is no more than the expected value of litigation and collateral costs attending the lawsuit.” Herbert Hovenkamp et al., Anticompetitive Settlement of Intellectual Property Disputes, 87 Minn. L.Rev. 1719, 1759 (2004).

Daniel A. Crane urges a standard somewhat more favorable to the settling parties. See Daniel A. Crane, Ease Over Acuracy in Assessing Patent Settlements, 88 Minn. L.Rev. 698, 709 (2004) (urging that the dispositive factor should be “the ex ante likelihood that the defendant would be excluded from the market if the case was finally adjudicated”). Id. at 709. Because the settling parties will typically have the most documentation relevant to the issue, he contends that “there is relatively little social cost in requiring the settling parties to retain documents going to the core issues in the patent infringement lawsuit.” Id. However, to avoid unduly chilling patent settlements, Crane, unlike Hovenkamp et al, would not shift the burden of proof to the settling parties. Id.

Thomas F. Cotter's approach occupies the middle ground. Cotter would leave on the antitrust defendants the burden of demonstrating the legality of a reverse-payment settlement, but he does not adopt Hovenkamp's position that the reverse payment must be limited to litigation costs. See Thomas F. Cotter, Refining the “Presumptive Illegality” Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis and Lemley, 87 Minn. L.Rev. 1789, 1795–97, 1802 (2003). Rather, he argues that “when the antitrust defendants can show that the payment is below the expected amount of the patent defendant's loss if an injunction were to issue, the burden of proving validity and infringement should be somewhat easier to satisfy than at a full-blown infringement trial.” Id. at 1814. Cotter rejects, and the other commentators implicitly reject, the approach adopted by the majority. See id. at 1811 (noting that requiring antitrust plaintiffs to show that patent litigation is a sham “would permit too many anticompetitive settlements to escape scrutiny. A suit with only a 25% chance of success may not be a sham, but a settlement based upon such a low probability estimate reduces consumer welfare for no apparent offsetting benefit.”) (footnote omitted).

Thus, commentators, precedent, and policy suggest the majority's requirement that an antitrust plaintiff show that a Hatch–Waxman lawsuit settled by agreement was a sham—assuming that the agreement did not convey benefits beyond the scope of the patent—is unjustified. A more searching inquiry and a less stringent standard are required to properly protect all interests. I see no reason why the general standard for evaluating an anti-competitive agreement, i.e., its reasonableness, should not govern in this context. See Clorox Co. v. Sterling Winthrop, Inc., 117 F.3d 50, 56 (2d Cir.1997). In assessing reasonableness, the fact-finder
must consider all the circumstances affecting a restrictive agreement. *Id.* Of course, the strength of the patent must be central to any antitrust analysis involving a patent. Thus, in assessing the reasonability of a Hatch–Waxman settlement, I would rely primarily on the strength of the patent as it appeared at the time at which the parties settled and secondarily on (a) the amount the patent holder paid to keep the generic manufacturer from marketing its product, (b) the amount the generic manufacturer stood to earn during its period of exclusivity, and (c) any ancillary anti-competitive effects of the agreement including the presence or absence of a provision allowing the parties to manipulate the generic's exclusivity period. Because plaintiffs allege that the district court's determination of patent invalidity would have been upheld on appeal; that Barr received more than it would have through a victory on appeal; and that Barr and Zeneca agreed that Barr would deploy its paragraph IV certification to defeat other potential generic entrants, I believe that their pleading is adequate.

II. Ancillary issues.

A. Capacity of the district court to evaluate Zeneca's likelihood of success on appeal.

It appears that the court may have been motivated to adopt the “sham” or objectively baseless standard because it overestimated the difficulty of estimating Zeneca's chance of prevailing on appeal. See Majority op. at 203 (citing principally *Whitmore v. Arkansas*, 495 U.S. 149, 159–60, 110 S.Ct. 1717, 109 L.Ed.2d 135 (1990), for the proposition that is impossible to predict the likelihood that Barr would have maintained its patent victory on appeal). *Whitmore* is inapposite; there the Court considered a challenge to one inmate's death sentence from a different inmate, *229* Whitmore, who also had been sentenced to death. 495 U.S. at 153, 110 S.Ct. 1717. Whitmore argued that he had standing because Arkansas's Supreme Court compared the circumstances of any capital case currently before it to prior capital cases to determine whether the death penalty had been arbitrarily applied. *Id.* at 156, 110 S.Ct. 1717. Whitmore claimed that if he obtained federal habeas relief in the future *and if* he were again convicted and sentenced to death *and appealed* to the Arkansas Supreme Court, the failure to include the first inmate's heinous crime in the data base the Arkansas Supreme Court considered would prejudice the review of his sentence. *Id.* at 156–57, 110 S.Ct. 1717. The Court dismissed as speculative the probability of Whitmore's obtaining federal habeas relief, the odds that he would be retried, convicted and sentenced to death once more, and the odds “that the addition of [the first inmate's] crimes to a comparative review ‘data base’ would lead the Supreme Court of Arkansas to set aside a death sentence for Whitmore.” *Id.* at 157, 110 S.Ct. 1717. To find that the sequence of events Whitmore alleged would actually occur indeed requires multiple layers of speculation. In contrast, by the time of the settlement, Barr had already prevailed at the district court level. The record in that case is presumably available, the standards of review the appellate court would have employed are well known, and it is not outside the bounds of the district court's competence to predict whether Barr would have prevailed on appeal. *6* Judges and juries routinely perform an analogous, but more difficult, task in legal malpractice cases in which they must estimate whether, absent attorney error, a party would have prevailed at trial. Estimating the possibility of success on appeal with the assistance of the full record and the parties' briefs is much simpler. Certainly the review would not be so difficult as to justify a sham litigation test.

B. The strength of Zeneca's patent.

As the majority states, the reasonableness of agreements under antitrust law must be judged by the circumstances existing at the time when the agreements were made. Majority op. at 204; cf. *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1207 (2d Cir.1981) ("Because the essence of a patent is the monopoly or exclusionary power it confers upon the holder; analyzing the lawfulness of the acquisition of the patent [within an antitrust analysis] necessitates *230* that we primarily focus upon the circumstances of the acquiring party and the status of the relevant product and geographic markets at the time of acquisition."). When the agreements here were reached, Judge Broderick had found by clear and convincing evidence that Zeneca's patent was invalid. Therefore, the patent could no longer be considered presumptively valid. See *Shelcore, Inc. v. Durham Indus., Inc.*, 745 F.2d 1171, 1177 (9th Cir.1984) ("... the court is required to consider the entire record on the issue of invalidity,").
The majority, citing Rosco, Inc. v. Mirror Lite Co., 304 F.3d 1373, 1377–78 (Fed. Cir.2002), appears to suggest that Shelcore is no longer good law and that patents are presumed valid on appeal even if they have been declared invalid by the district court. See majority op. at 209 n.22. I respectfully suggest that the majority places too much weight on Rosco. The Rosco court simply reiterated the statutory language indicating that patents are presumed valid. 304 F.3d at 1377. It then held that the district court had improperly found that plaintiffs produced clear and convincing evidence to overcome this presumption and thus reversed its finding of validity as to one patent. Id. at 1378–79. This analysis is a far cry from a statement that a patent must be presumed valid on appeal because the latter holding would imply—contrary to Shelcore and Federal Rule of Civil Procedure 52(a)—that the district court's factual findings in support of its ultimate conclusion of invalidity are entitled to no deference.

Alternatively the majority suggests that it is not important where the presumption of validity lay at the moment of appeal because the patent holder was still entitled to protect its monopoly. Majority op. at 209 n.22. However, even assuming, contrary to my view, that most patent settlements should be subject to the “sham litigation” standard, surely there are strong policy reasons for applying more searching scrutiny where a court of competent jurisdiction has found the patent to be invalid.

C. The majority's reliance on Zeneca's subsequent litigation victories.

The majority also focuses on the subsequent litigation between other generics and Zeneca to demonstrate that plaintiffs cannot support a claim that Zeneca's litigation against Barr was sham litigation. Of course, in my view, plaintiffs need not plead or prove sham or objectively baseless litigation. But, in addition, the majority's discussion of the later litigation appears to violate its own acknowledgment of the basic principle that “the reasonableness of agreements under the antitrust laws are to be judged at the time they are entered into.” Majority op. at 204 (quoting Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1306 (11th Cir.2003) (citing, inter alia, SCM Corp., 645 F.2d at 1207)). At the time Zeneca and Barr settled the appeal, the existing facts made it fairly likely, if not certain, that Barr would prevail. Judge Broderick had judged the credibility of the witnesses and found that Zeneca willfully withheld information from the FDA. That finding is quintessentially factual. Thus, the Federal Circuit could have set it aside only for clear error. Fed.R.Civ.P. 52(a). Without the record, I cannot say that the Federal Circuit would have been required to affirm, but, as I am sure the majority will concede, it is the rare case in which an appellate court sets aside a trial court's credibility findings. Had Barr prevailed, on appeal, as I expect it would have, Zeneca would have been estopped from asserting the validity of its patent in any subsequent litigation. Therefore, there is a certain unfairness in using the subsequent litigation, which would not have existed had Barr prevailed on appeal, to demonstrate that plaintiffs cannot establish that Barr would have prevailed on appeal.

D. Conspiracy to use Barr's paragraph IV certification in an anticompetitive manner.

I turn now to the majority's expressed belief that the complaint cannot be read to plausibly allege a conspiracy between Barr and Zeneca to deploy Barr's putative exclusivity period to their joint benefit and to the detriment of other potential competitors and consumers. A complaint need “include only ‘a short and plain statement of the claim showing the pleader is entitled to relief.’” Swierkiewicz v. Sorema, 534 U.S. 506, 512, 122 S.Ct. 992, 152 L.Ed.2d 1 (2002) (quoting Fed.R.Civ.P. 8(a)(2)). A simplified notice pleading standard is acceptable because “liberal discovery rules and summary judgment motions” allow the parties “to define disputed facts and issues and to dispose of unmeritorious claims.” Id. The majority requires more than Swierkiewicz mandates when it complains of plaintiffs' failure to plead evidentiary facts that create an inference of conspiracy.
In re Tamoxifen Citrate Antitrust Litigation, 466 F.3d 187 (2006)

2006-2 Trade Cases P 75,382

The court additionally attacks the plausibility of plaintiffs' allegations because, at the time Barr and Zeneca entered into their agreements, a generic enjoyed the benefit of the exclusivity period only if it had successfully defended an infringement lawsuit. See Mova Pharm., 140 F.3d at 1065 (citing former 21 C.F.R. § 314.107(c)(1)). This regulation was struck down after the agreements at issue. See id. at 1076. Because the regulation was in effect when Barr and Zeneca finalized their agreement, the majority finds it implausible that they could have envisioned any anti-competitive effect from the portion of the agreement allowing Barr to deploy its exclusivity period if another generic manufacturer succeeded in invalidated Zeneca's patent. That inference is certainly one that a reasonable fact finder could draw from the facts alleged to date. However, a reasonable fact-finder could also conclude that it is quite unlikely that sophisticated parties would include in their agreement a provision that had no potential benefit to either of them. Is it not at least as likely that the parties were conscious that the regulation was vulnerable to attack and that they wished to add another layer of protection against potential competitors in the event the regulation was invalidated? Discovery would presumably produce materials relevant to determining whether this provision was part of an antitrust conspiracy between Barr and Zeneca. Among other things, the parties may have had written communications concerning the purpose of the exclusionary-period clause. If not, the corporate employees who negotiated the agreement could be deposed. And, the parties could explore the state of legal discussion concerning the successful-defense requirement at the time of the agreement. Thus, it is premature to reject out of hand plaintiffs' *232 claim that Barr and Zeneca agreed to the exclusivity-period provision because they wanted to further restrict other generic manufacturers' ability to market Tamoxifen.

E. Antitrust injury.

In addition to affirming dismissal of the paragraph IV certification claim because plaintiffs did not adequately describe an antitrust violation, the majority states that it has “grave doubt as to whether, even if the defendants agreed to deploy the exclusionary period to protect their shared monopoly power, the injury that the defendants allege they suffered in this regard constitutes ‘antitrust injury.’ ” Majority op. at 219. The majority's doubt stems, in part, from Zeneca's victories in subsequent patent litigation. Id. at 219 Because these victories could not have existed if (1) the settlement agreement had not been signed and (2) Barr had prevailed on appeal, they are not finally determinative of causation. Therefore, it is necessary to assess the strength of Zeneca's patent in order to decide whether the injuries were really caused by the patent itself or by the agreements.

III. The inappropriateness of dismissal at the Rule 12(b)(6) stage.

Applying the reasonableness inquiry that I suggest requires a factual record not yet in existence. We have no sense of the value to Barr of the exclusivity period it gave up or the relationship of the value of this period to the reverse payment Zeneca made. Nor do we have any sense of the negotiations between the parties concerning the provision that allowed Barr to revivify its Paragraph IV certification. Finally no judge or appellate panel has attempted to discern whether Judge Broderick's findings of facts were clearly erroneous. Allowing the parties to develop a record and make summary judgment motions would give the district court information it needs to assess the reasonableness of the agreements.

However, even under the majority's newly articulated standard, I believe that it was wrong to affirm the dismissal. At a minimum, the plaintiffs should be allowed to develop a factual record to demonstrate that Zeneca's litigation was sham because they had no reason to anticipate the standard articulated here. I note that the courts that have finally rejected antitrust challenges to Hatch–Waxman settlements have done so after reviewing a full record. See Schering–Plough, 402 F.3d at 1058 (granting a petition for review of and reversing an agency decision made upon a full record that granted injunctive relief against certain Hatch–Waxman settlements); In re Ciprofloxacin Hydrochloride Antitrust Litig., 363 F.Supp.2d 514, 517 (E.D.N.Y.2005) (granting summary judgment motion).
CONCLUSION

Because I disagree with the majority's test for judging whether a Hatch–Waxman agreement violates antitrust law, and because I believe it was inappropriate to dismiss plaintiffs' complaint without allowing discovery, I respectfully dissent.

All Citations

466 F.3d 187, 2006-2 Trade Cases P 75,382

Footnotes


2 The ANDA process was intended to be available to manufacturers of generic versions of approved drugs. “A generic version ... contains the same active ingredients, but not necessarily the same inactive ingredients, as the pioneer drug. A generic drug, as the name implies, is ordinarily sold without a brand name and at a lower price.” Andrx Pharms., 256 F.3d at 801 n. 1. Filing an ANDA allows a generic drug manufacturer to avoid the costly and time-consuming process of demonstrating safety and efficacy, allowing the manufacturer to rely on the FDA's earlier findings concerning the brand-name drug's NDA, and thereby facilitates quicker market entry by generic manufacturers. See id. at 801.

3 The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.


4 At the time of the settlement in this case, the statute did not specify that a district court decision would end the 30–month stay, and the FDA interpreted the statute to require a court decision “from which no appeal can be or has been taken.” Ctr. for Drug Evaluation & Research (CDER), Food & Drug Admin., U.S. Dep't of Health & Human Servs., Guidance for Industry: Court Decisions, ANDA Approvals, and 180–Day Exclusivity Under the Hatch–Waxman Amendments to the Federal Food, Drug, and Cosmetic Act 2 (Mar.2000) (quoting 21 C.F.R. § 314.107(e)(1) (1999)) (hereinafter CDER, Court Decisions, supra, at 2 (quoting 21 C.F.R. § 314.107(e)(1) (1999)). In 2000, the FDA changed its interpretation to include any district court decision. See id. at 3–5.

5 Like its interpretation of the type of court decision sufficient to end the 30–month stay of final FDA approval described above, at the time of the settlement in this case and until 2000, the FDA interpreted a court decision required to trigger the 180–day period to mean only a court decision “from which no appeal can be or has been taken.” See CDER, Court Decisions, supra, at 2 (quoting 21 C.F.R. § 314.107(e)(1) (1999)). That interpretation was subsequently changed in
2000, when the FDA concluded that a patent invalidity decision by a district court would be sufficient to trigger the commencement of the 180-day period. See id. at 3–5.

6 In 2001, Zeneca's domestic sales of tamoxifen amounted to $442 million.

7 Soon thereafter, Heumann was dismissed as a defendant after it agreed to be bound by a determination in that case as to the validity of the tamoxifen patent. Compl. ¶ 40.


9 After the Settlement Agreement was entered into and the vacatur ordered, Barr began to market its licensed version of Zeneca's tamoxifen, selling its product to distributors and wholesalers at a 15 percent discount to the brand-name price, which translated into a price to consumers about five percent below Zeneca's otherwise identical Nolvadex® brand-name version. Barr soon captured about 80 percent of the tamoxifen market.

10 Pharmachemie initially filed a paragraph III certification in August 1994, but later amended it to include a paragraph IV certification. See Tamoxifen II, 277 F.Supp.2d at 126.

11 Mylan had agreed to follow the Pharmachemie court decision. See Tamoxifen II, 277 F.Supp.2d at 127; AstraZemeca UK Ltd., No. 00–2239, slip op. at 2–3.


13 “Although the Sherman Act, by its terms, prohibits every agreement ‘in restraint of trade,’ th[e Supreme] Court has long recognized that Congress intended to outlaw only unreasonable restraints.” State Oil Co. v. Khan, 522 U.S. 3, 10, 118 S.Ct. 275, 139 L.Ed.2d 199 (1997). Conduct may be deemed an unreasonable restraint of trade in two ways. Conduct may be considered per se unreasonable because it has “such predictable and pernicious anticompetitive effect, and such limited potential for procompetitive benefit.” Id.

In most cases, however, conduct will be evaluated under a “rule of reason” analysis, “according to which the finder of fact must decide whether the questioned practice imposes an unreasonable restraint on competition, taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect.” Id. (citation omitted).

The rule-of-reason analysis has been divided into three steps. First, a plaintiff must demonstrate “that the challenged action has had an actual adverse effect on competition as a whole in the relevant market.” Capital Imaging Assocs., P.C. v. Mohawk Valley Med. Assocs., 996 F.2d 537, 543 (2d Cir.) (emphasis in original), cert. denied, 510 U.S. 947, 114 S.Ct. 388, 126 L.Ed.2d 337 (1993). If the plaintiff succeeds in doing so, “the burden shifts to the defendant to establish the ‘pro-competitive “redeeming virtues” ’ of the action.” K.M.B. Warehouse Distribrs., Inc. v. Walker Mfg. Co., 61 F.3d 123, 127 (2d Cir.1995) (quoting Capital Imaging Assocs., 996 F.2d at 543). If the defendant succeeds in meeting its burden, the plaintiff then has the burden of “show[ing] that the same pro-competitive effect could be achieved through an alternative means that is less restrictive of competition.” Id.
“The offense of monopoly under § 2 of the Sherman Act has two elements: (1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.” United States v. Grinnell Corp., 384 U.S. 563, 570–71, 86 S.Ct. 1698, 16 L.Ed.2d 778 (1966).

It is true that had the defendants not settled the underlying patent litigation and had the district court's judgment been affirmed on appeal, Zeneca would have been estopped from asserting the validity of its patent against others seeking to enter the market. See Blonder–Tongue Labs., Inc. v. Univ. of Ill. Found., 402 U.S. 313, 350, 91 S.Ct. 1434, 28 L.Ed.2d 788 (1971). However, it is clearly a permissible byproduct of settlement that future hypothetical plaintiffs might be forced to relitigate the same issues involved in the settled case. Furthermore, before 1994, when district court judgments were vacated as a matter of course upon settlement, see U.S. Bancorp, 513 U.S. at 29, 115 S.Ct. 386 (virtually ending this practice), there was similarly and permissibly no collateral estoppel effect accorded these judgments for the benefit of future hypothetical plaintiffs. See Nestle, 756 F.2d at 284 (“Drumbeating about the need to protect other unknown users of the trademark [in question] will ring hollow indeed in the ears of the present defendants if the peril of a reversal is realized.... We see no justification to force these defendants, who wish only to settle the present litigation, to act as unwilling private attorneys general and to bear the various costs and risks of litigation.”).


We thus think that it was appropriate for the district court to take these decisions into account for the limited purpose of rebutting the plaintiffs' conclusory allegation that the Federal Circuit would have affirmed Judge Broderick's decision invalidating the tamoxifen patent. See Mason v. Am. Tobacco Co., 346 F.3d 36, 39 (2d Cir.2003) (“[L]egal conclusions, deductions or opinions couched as factual allegations are not given a presumption of truthfulness.” (internal quotation marks and citations omitted)), cert. denied, 541 U.S. 1057, 124 S.Ct. 2163, 158 L.Ed.2d 757 (2004); Smith v. Local 819 I.B.T. Pension Plan, 291 F.3d 236, 240 (2d Cir.2002) (“[C]onclusory allegations or legal conclusions masquerading as factual conclusions will not suffice to prevent a motion to dismiss.” (internal quotation marks and citation omitted)).

Indeed, our Circuit requires civil litigants to go through a pre-argument, Court-sponsored process called the Civil Appeals Management Plan (“CAMP”), see http://www.ca2.uscourts.gov/Docs/Forms/CAMP.pdf and http://www.ca2.uscourts.gov/Docs/Forms/Preargument.pdf, designed in part to facilitate just such post-judgment, pre-appellate argument settlements—which it accomplishes with significant success. See Gilbert J. Ginsburg, The Case for a Mediation Program in the Federal Circuit, 50 Am. U. L.Rev. 1379, 1383 (2001) (reporting estimate that forty-five to fifty percent of civil cases pending before the Second Circuit settle each year).

In this case, Barr could not at the time of the Settlement Agreement count on obtaining the 180–day exclusive period from the FDA because, as a settler rather than a “successful defender,” it at least appeared that it was unlikely to be entitled to the period of exclusivity—in other words, it appeared that, by settling, Barr was trading away its exclusivity period. It is noteworthy, nonetheless, that the 180–day period is of substantial benefit to the generic drug manufacturer who obtains it because it gives that manufacturer a significant head start over other manufacturers. See, e.g., Geneva Pharms. Tech. Corp. v. Barr Labs. Inc., 386 F.3d 485, 494, 510 (2d Cir.2004) (considering claim that defendant's first-mover status converted a transitory advantage into a permanent one, where plaintiffs provided testimony that “even though its offer price to the Eckerd and CVS drugstore chains was as much as 25 percent below [the first mover's price], neither chain was willing to leave [the first mover] after having devoted substantial time to switching patients and getting their pharmacists comfortable with the new product”); Mova Pharm., 955 F.Supp. at 131 (“All parties recognize that the earliest generic drug manufacturer in a specific market has a distinct advantage over later entrants.”).
It has been observed that even the typical settlement of the ordinary patent infringement suit appears to involve what may be characterized as a reverse payment. See Cipro II, 261 F.Supp.2d at 252 (“[E]ven in the traditional context, implicit consideration flows from the patent holder to the alleged infringer.”); cf. Asahi Glass, 289 F.Supp.2d at 994 (“[A]ny settlement agreement can be characterized as involving ‘compensation’ to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is thus to be classified as involving a forbidden ‘reverse payment,’ we shall have no more patent settlements.” (emphasis in original)); Daniel A. Crane, Ease Over Accuracy in Assessing Patent Settlements, 88 Minn. L.Rev. 698, 700 (2004) (“It makes no sense to single out exclusion payments for disfavor when the same potential for collusion arises in any settlement involving the defendant's exit.”). A blanket rule that all settlements involving reverse payments are unlawful could thus conceivably endanger many ordinary settlements of patent litigation.

The Federal Trade Commission and some commentators have proposed similar or even more stringent rules. See In re Schering–Plough Corp., No. 9297, final order at 4, 2003 WL 22989651 (Fed. Trade Comm'n Dec. 8, 2003), 2003 FTC LEXIS 187 (applying a rule under which generic manufacturers would not be permitted to receive reverse payments that exceeded “the lesser of the [patent] [h]older's expected future litigation costs to resolve the Patent Infringement Claim or $2 million”), vacated, 402 F.3d 1056 (11th Cir.2005); Hovenkamp et al., supra, at 1759 (proposing that “[i]n an antitrust challenge, a payment from a patentee to an infringement defendant for the latter's exit from the market is presumptively unlawful,” and that the “infringement plaintiff can defend by showing both (1) that the ex ante likelihood of prevailing in its infringement lawsuit is significant, and (2) that the size of the payment is no more than the expected value of litigation and collateral costs attending the lawsuit”).

The dissent questions what it sees as our reliance on the presumption of validity of the patent at the time of the settlement. Post at 227–28. Even after a district court holds a patent invalid, it is treated as presumptively valid under 35 U.S.C. § 282 on appeal. See Rosco, Inc. v. Mirror Lite Co., 304 F.3d 1373, 1377–78 (Fed.Cir.2002). But irrespective of whether there was a presumption or where any such presumption lay at the time of settlement, we think that Zeneca was then entitled to protect its tamoxifen patent monopoly through settlement. The question for this Court is whether the settlement extended the patent's scope. If the judgment of the district court against a patent's validity put an end to the patent monopoly that the patent holder was entitled to protect, then any settlement after judgment of the district court holding the patent invalid would extend the patent monopoly beyond the patent's scope and therefore be unlawful. We do not think that to be the law, a view which appears to be consistent with the plaintiffs'. See Appellants' Reply Br. at 4, Heading “B.” (“Hatch–Waxman Patent Infringement Litigation Can Be Settled, Even On Appeal, Without Violating The Antitrust Laws.”).


To illustrate using a vastly oversimplified hypothetical example (ignoring, for example, legal fees and costs): Suppose the patent holder is selling 1,000,000 pills per year at a $1 profit per pill (for a total profit of $1,000,000). The generic manufacturer files a paragraph IV ANDA, and the patent holder responds by bringing suit to protect its patent. If the patent holder projects that, should it lose the suit, it will thereafter sell only 250,000 pills per year at a $.90 profit per pill (for a total profit of $225,000) in the competitive market, and the generic will sell 750,000 pills per year at a profit of $.60 per pill (for a total profit of $450,000)—so that total market profits are now down from $1,000,000 to $675,000—it would make economic sense for the patent holder to pay the generic manufacturer something more than the $450,000 the generic manufacturer would make in a competitive market to settle the litigation. If it paid $500,000 a year to the generic manufacturer—$50,000 more than the generic manufacturer could earn in the market in a “best case scenario”—for example, it would thereby retain the ability to make $500,000 per year selling its branded pills ($1,000,000 profit less $500,000 per year paid to the generic), $275,000 more per year than it would earn if it paid nothing to the generic.
but lost the patent litigation and with it the patent monopoly. It might well be sensible for the patent holder to enter into this sort of settlement, depending in part on its perceived prospects for winning the litigation, and it would seem difficult for the generic manufacturer to refuse. The $325,000 of yearly monopoly profits which accrued to the patent holder before the litigation began would thereafter be divided between the patent holder and the generic manufacturer.

It seems to us odd for the dissent to urge, in the context of this case, that we have not given proper weight to “the public interest in having the validity of patents litigated.” Post at 224 The Settlement Agreement was a virtual invitation to other generic manufacturers to file paragraph IV certifications and thereby court litigation as to the validity of the tamoxifen patent. It was an invitation that was accepted three times leading to three lawsuits, two of them litigated to judgment, as to the validity of the tamoxifen patent. Accepting the value of litigating the validity of patents in these circumstances, it has hardly been undermined here.

The dissent “see[s] no reason why the general standard for evaluating an anti-competitive agreement, i.e., its reasonableness, should not govern in this context.” Post at 226. We think, such a rule, making every settlement of patent litigation, at least in the Hatch–Waxman Act context, subject to the inevitable, lengthy and expensive hindsight of a jury as to whether the settlement constituted a “reasonable” restraint (and, in this case, whether the Federal Circuit would have affirmed or reversed in a patent appeal), would place a huge damper on such settlements contrary to the law that we have discussed at some length that settlements are not only permitted, they are to be encouraged.

The reasoning of the dissent, which quotes an excerpt from this statement, post at 223, is, in our view, largely based on a repeated mis-characterization of our views in this regard. We do not, as the dissent states in one form or another many times, see post at 223, 223–24, 226, 227, and 228, think that there is a “requirement” that antitrust plaintiffs “must show that the settled litigation was a sham, i.e., objectively baseless, before the settlement can be considered an antitrust violation ...” id. at 191. There is no such requirement. The central criterion as to the legality of a patent settlement agreement is whether it “exceeds the ‘scope of the patent's protection.’ ” As we pointed out at the outset of this discussion, we think that “[i]f the plaintiffs alleged facts that, if proved, would establish that the Settlement Agreement provided the defendants with benefits exceeding the scope of the tamoxifen patent, they would succeed in alleging an antitrust violation.” Ante at 200; see also, e.g., post at 213 (“[T]he question is whether the ‘exclusionary effects of the agreement’ exceed the ‘scope of the patent's protection.' Schering–Plough, 402 F.3d at 1076.”). A plaintiff need not allege or prove sham litigation in order to succeed in establishing that a settlement has provided defendants “with benefits exceeding the scope of the tamoxifen patent.” Whether there is fraud or baseless litigation may be relevant to the inquiry, but it is hardly, we think, “the ... standard,” post at 227, as the dissent posits in order to take issue with it.

See Asahi Glass, 289 F.Supp.2d at 994 (noting that in the typical reverse-payment case, “the settlement leaves the competitive situation unchanged from before the defendant tried to enter the market.”).

Of course, as it turned out, Zeneca was successful in subsequently protecting its patent in the courts.

“The competitive concern is that the 180–day exclusivity provision can be used strategically by a patent holder to prolong its market power in ways that go beyond the intent of the patent laws and the Hatch–Waxman Act by delaying generic entry for a substantial period.” Balto, supra, at 331. An agreement that a “generic manufacturer would not relinquish its 180–day exclusivity ... prevent[s] other generic manufacturers from entering as well.” Id. at 335; see also Hovenkamp et al., supra, at 1755 (“It is widely understood that the 180–day exclusivity period offers the potential for collusive settlement arrangements between pioneers and generics. A pioneer could initiate a patent infringement suit against a first generic ANDA filer and settle the litigation with a ‘non-entry’ payment to the generic, under which the generic would delay commercialization of the generic product, thus postponing the commencement of the 180–day exclusivity period and locking other generics out of the market indefinitely.”).
In re Tamoxifen Citrate Antitrust Litigation, 466 F.3d 187 (2006)
2006-2 Trade Cases P 75,382

31 In \textit{Andrx}, the defendant attempted unsuccessfully to claim that it was unable to cause any delay in generic entry because the “successful defense” requirement would prevent it from doing so. \textit{Andrx Pharms.}, 256 F.3d at 810. The D.C. Circuit noted that the settlement agreement in that case was signed in September 1997—after the district court in \textit{Mova} issued, in January 1997, a preliminary injunction banning the enforcement of the successful defense requirement. \textit{Id.} (citing \textit{Mova Pharm.}, 955 F.Supp. at 131–32). Thus, “[t]he timing of the Agreement and of the demise of the successful defense requirement defeats Andrx's argument on this point.” \textit{Id.} In the instant case, however, the Settlement Agreement was executed long before \textit{Mova} struck down the successful defense requirement.

32 The dissent says that a reasonable fact-finder might conclude that sophisticated parties would not have included a provision that allowed Barr to re-file under paragraph IV absent an unlawfully anticompetitive purpose because it “had no potential benefit to either of them” apart from an anti-competitive one. \textit{Post} at 229. We disagree. If another generic manufacturer had been successful in having the tamoxifen patent held invalid, it was strongly and legitimately in Barr's interest to be able to re-file so that it could market tamoxifen without risking a violation of the Settlement Agreement.

Like the majority, I use “Zeneca” to refer collectively to defendants Zeneca, Inc., Astrazeneca Pharmaceuticals LP, and AstraZeneca, Inc. “Barr” refers to defendant Barr Labs, Inc.


The majority suggests, [majority op. at 212 n.25] that this interest was adequately protected through the subsequent suits by other generics. I disagree. This position ignores the time gap between the Barr–Zeneca litigation and the subsequent litigation. During this period, had Barr maintained its victory on appeal, which, as I explain below, was quite likely, very ill consumers would have had access to low cost generic tamoxifen. In addition, once Zeneca's patent protection was gone with respect to Zeneca, it was gone with respect to all generic manufacturers, which would have produced a very competitive market at the close of the 180–day exclusivity period. Thus, it was very important to the public interest that Barr and Zeneca allow the appeal to proceed. This does not mean, as the majority suggests at 212 n.25 that any settlement of patent litigation after the challenger prevails at trial is an antitrust violation. As I discuss at [194–95] below, a Hatch–Waxman settlement agreement, even on appeal from a judgment declaring the patent invalid, is not a per se antitrust violation. Rather, a reviewing court must assess the reasonability of the settlement by weighing various factors including the strength of the patent as it appeared at the time of settlement.

Of course, other generic challengers could file Paragraph IV certifications before the first litigation is resolved, but a second generic manufacturer has little incentive to incur the cost of litigation. Even if it wins, it will have to wait until after the first generic challenger's exclusivity period has expired to market its product.

The majority argues that applying the general rule of reasonableness would “mak[e] every settlement of patent litigation, at least in the Hatch–Waxman Act context, subject to the inevitable, lengthy and expensive hindsight of a jury as to whether the settlement constituted a ‘reasonable’ restraint (and, in this case, whether the Federal Circuit would have affirmed or reversed in a patent appeal)” and thus “place a huge damper on such settlements.” Majority op. at 212 n.26. I doubt that this doomsday scenario would, in fact, take place. Courts would eventually develop rules for judging the reasonableness of a settlement, and as with other litigation, the majority of cases would be resolved in motion practice. Moreover, the majority again emphasizes the acknowledged interest in settlements without acknowledging the absent party in Hatch Waxman litigation settlements, the consumer of medicines. Those consumers have no ability to affect the settlement, which, in some cases, may benefit both parties beyond any expectation they could have from the litigation itself while harming the consumer. There is a panglossian aspect to the majority's tacit assumption that the settling parties will not act to injure the consumer or competition.
The majority also relies on *Boehm v. Comm'r*, 146 F.2d 553 (2d Cir. 1945), aff'd, 326 U.S. 287, 66 S.Ct. 120, 90 L.Ed. 78 (1945). This case also is strikingly inapposite; the *Boehm* court held only that a taxpayer must claim a loss in the year it becomes obvious and cannot rely on the inherently speculative outcome of litigation seeking to recover some of that loss to justify claiming it in a later year. 146 F.2d at 555. The relevance of that principle to the case at hand is not immediately obvious to me. It is also interesting to note that the Supreme Court affirmed not on the impossibility of predicting litigation outcome but rather because the Tax Court had found that the suit had “no substantial value” and “[t]here was no evidence in the stipulation of the merits of the suit, the probability of recovery or any assurance of collection of an amount sufficient to pay the creditors' claim ... and to provide a sufficient surplus for stockholders.” 326 U.S. at 294, 66 S.Ct. 120. The majority's additional reliance on *Asahi Glass Co. v. Pentech Pharms*, 289 F.Supp.2d 986, 993 (N.D.II.2003), and *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F.Supp.2d. 188, 200–01 (E.D.N.Y.2003), requires little discussion. The statement quoted from *Asahi Glass* that “[n]o one can be certain that he will prevail in a patent suit”—is irrelevant to the capacity of skilled corporate counsel and district court judges to evaluate the likelihood that a determination of patent invalidity will be upheld, and the discussion in *Ciprofloxacin* relies primarily on *Whitmore* and *Boehm*, which I have already discussed.

I do not find persuasive the statistics the majority cites on the frequency of reversal in the Federal Circuit. These statistics would include decisions construing the patent and making other legal determinations. Therefore, they do nothing to show how frequently the Federal Circuit reverses credibility determinations on appeal.

I recognize that it makes more sense to use the subsequent litigation to argue that plaintiffs could not prove the Zeneca lawsuit was not a sham. However, as noted, I do not believe this is an appropriate test.
Schering-Plough Corp. v. F.T.C., 402 F.3d 1056 (2005)


402 F.3d 1056
United States Court of Appeals,
Eleventh Circuit.

SCHERING–PLOUGH CORPORATION, Upsher–Smith Laboratories, Inc., a
Minnesota corporation having its principal place of business in Minnesota, Petitioners,
v.

FEDERAL TRADE COMMISSION, Respondent.

No. 04–10688.

March 8, 2005.

Synopsis


The Court of Appeals, Fay, Circuit Judge, held that evidence did not support finding that settlement agreements unreasonably restrained competition beyond exclusionary effects of patent.

Order vacated.

Attorneys and Law Firms


Kenneth Winston Starr, Kirkland & Ellis, LLP, Washington, DC, for Generic Pharmaceutical Ass'n, Amicus Curiae.


*1058 Before DUBINA and FAY, Circuit Judges, and GOLDBERG * , Judge.

Opinion

FAY, Circuit Judge:

Pharmaceutical companies Schering–Plough Corp. and Upsher–Smith Laboratories, Inc. petition for review of an order of the Federal Trade Commission ("FTC") that they cease and desist from being parties to any agreement settling a patent infringement lawsuit, in which a generic manufacturer either (1) receives anything of value; and (2) agrees to suspend research, development, manufacture, marketing, or sales of its product for any period of time. The issue is whether substantial evidence supports the
Schering–Plough Corp. v. F.T.C., 402 F.3d 1056 (2005)

conclusion that the Schering–Plough settlements unreasonably restrain trade in violation of Section 1 of the Sherman Antitrust Act, 15 U.S.C. § 1, and Section 5 of the Federal Trade Commission Act (“FTC Act”), 15 U.S.C. § 45(a). We have jurisdiction pursuant to 15 U.S.C. § 45(c), and, for the reasons discussed below, we grant the petition for review and set aside and vacate the FTC’s order.

I. Factual Background

A. The Upsher Settlement

Schering–Plough (“Schering”) is a pharmaceutical corporation that develops, markets, and sells a variety of science-based medicines, including antihistamines, corticosteroids, antibiotics, anti-infectives and antiviral products. Schering manufactures and markets an extended-release microencapsulated potassium chloride product, K–Dur 20, which is a supplement generally taken in conjunction with prescription medicines for the treatment of high blood pressure or congestive heart disease. The active ingredient in K–Dur 20, potassium chloride, is commonly used and unpatentable. Schering, however, owns a formulation patent on the extended-release coating, which surrounds the potassium chloride in K–Dur 20, patent number 4,863,743 (the “’743 patent”). The ’743 patent expires on September 5, 2006. 

In late 1995, Upsher–Smith Laboratories (“Upsher”), one of Schering's competitors, sought Food and Drug Administration (“FDA”) approval to market Klor Con M20 (“Klor Con”), a generic version of K–Dur 20. 2 Asserting that Upsher's product was an infringing generic substitute, Schering sued for patent infringement. K–Dur 20 itself was the most frequently prescribed potassium supplement, and generic manufacturers such as Upsher could develop their own potassium-chloride supplement as long as the supplement's coating did not infringe on Schering's patent.

In 1997, prior to trial, Schering and Upsher entered settlement discussions. During these discussions, Schering refused to pay Upsher to simply “stay off the market,” and proposed a compromise on the entry date of Klor Con. Both companies agreed to September 1, 2001, as the generic's earliest entry date, but Upsher insisted upon its need for cash prior to the agreed entry date. Although still opposed to paying Upsher for holding Klor Con's release date, Schering agreed to a separate deal to license other Upsher products. Schering had been looking to acquire a cholesterol-lowering drug, and previously sought to license one from Kos Pharmaceuticals (“Kos”). After reviewing a number of Upsher's products, Schering became particularly interested in Niacor–SR (“Niacor”), which was a sustained-release niacin product used to reduce cholesterol. 3

Upsher offered to sell Schering an exclusive license to market Niacor worldwide, except for North America. The parties executed a confidentiality agreement in June 1997, and Schering received licenses to market five Upsher products, including Niacor. In relation to Niacor, Schering received a data package, containing the results of Niacor's clinical studies. The cardiovascular products unit of Schering's Global Marketing division, headed by James Audibert (“Audibert”) evaluated Niacor's profitability and effectiveness.

According to the National Institute of Health, niacin was the only product known to have a positive effect on the four lipids related to cholesterol management. Immediate-release niacin, however, created an annoying—but innocuous—side effect of “flushing,” which reduced patient compliance. On the other hand, previous versions of sustained-release niacin supplements, like Niacor, had been associated with substantial elevations in liver enzyme levels.

Schering knew of the effects associated with niacin supplements, but continued with its studies of Niacor because it had passed the FDA's medical review and determined that it would likely be approved. More important, the clinical trials studied by
Audibert demonstrated that Niacor reduced the flushing effect to one-fourth of the immediate-release niacin levels and only increased liver enzymes by four percent, which was generally consistent with other cholesterol inhibitors. Based on this data, Audibert constructed a sales and profitability forecast, and concluded that Niacor's net present value at that time would be between $245–265 million.

On June 17, 1997, the day before the patent trial was scheduled to begin, Schering and Upsher concluded the settlement. The companies negotiated a three-part license deal, which called for Schering to pay (1) $60 million in initial royalty fees; (2) $10 million in milestone royalty payments; and (3) 10% or 15% royalties on sales. Schering's board approved of the licensing transaction after determining the deal was valuable to Schering. This estimation corresponds to the independent valuation that Schering completed in relation to Kos' Niaspan, a substantially similar product to Niacor. That evaluation fixed Niaspan's net present value between $225–265 million. The sales projections for both the Kos and Upsher products are substantially similar. Raymond Russo (“Russo”) estimated Niaspan (Kos' supplement) sales to reach $174 million by 2005 for the U.S. market. Comparably, and more conservatively, Audibert predicted Niacor (Upsher's supplement) to reach $136 million for the global market outside the United States, Canada, and Mexico, which is either equal to or larger than U.S. market alone.

After acquiring the licensing rights to Niacor, Schering began to readied its documents for overseas filings. In late 1997, however, Kos released its first-quarter sales results for Niaspan, which indicated a poor performance and lagging sales. Following this announcement, Kos' stock price dramatically dropped from $30.94 to $16.56, and eventually bottomed out at less than $6.00. In 1998, with Niaspan's disappointing decline as a precursor, Upsher and Schering decided further investment in Niacor would be unwise.

B. The ESI Settlement

In 1995, ESI Lederle, Inc. (“ESI”), another pharmaceutical manufacturer, sought FDA approval to market its own generic version of K-Dur 20 called “Micro-K 20.” Schering sued ESI in United States District Court, and, as part of the pretrial process, the trial judge prompted the parties to engage a court-supervised mediation, pursuant to the Civil Justice Reform Act, 28 U.S.C. § 471 et seq. (1991). The trial court appointed U.S. Magistrate Judge Thomas Rueter (“Judge Rueter”) to mediate the fifteen-month process, which resulted in nothing more than an impasse.

Finally, in December 1997, Schering offered to divide the remaining patent life with ESI and allow Micro-K 20 to enter the market on January 1, 2004—almost three years ahead of the patent's September 2006 expiration date. ESI accepted this offer, but demanded on receiving some form of payment to settle the case. At Judge Rueter's suggestion, Schering offered to pay ESI $5 million, which was attributed to legal fees, however, ESI insisted upon another $10 million. Judge Rueter and Schering then devised an amicable settlement whereby Schering would pay ESI up to $10 million if ESI received FDA approval by a certain date. Schering doubted the likelihood of this contingency happening, and Judge Rueter intimated that if Schering's prediction proved true, it would not have to pay the $10 million. The settlement was signed in Judge Rueter's presence on January 23, 1998.

C. The FTC Complaint

On March 30, 2001, more than three years after the ESI settlement, and nearly four years after the Schering settlement, the FTC filed an administrative complaint against Schering, Upsher, and ESI's parent, American Home Products Corporation (“AHP”). The complaint alleged that Schering's settlements with Upsher and ESI were illegal agreements in restraint of trade, in violation
The Complaint was tried before an Administrative Law Judge (ALJ) from January 23, 2002 to March 28, 2002. Numerous exhibits were admitted in evidence, and the ALJ heard testimony from an array of expert witnesses presented by both sides. In his initial decision, the ALJ found that both agreements were lawful settlements of legitimate patent lawsuits, and dismissed the complaint. Specifically, the ALJ ruled that the theories advanced by the FTC, namely, that the agreements were anticompetitive, required either a presumption of (1) that Schering's '743 patent was invalid; or (2) that Upsher's or ESI's generic products did not infringe the '743 patent. The ALJ concluded that such presumptions had no basis in law or fact. Moreover, the ALJ noted that Schering's witnesses went unrebutted by FTC complaint counsel, and credibly established that the licensing agreement with Upsher was a “bona-fide arm's length transaction.”

The ALJ further found that the presence of payments did not make the settlement anticompetitive, per se. Rather, the strength of the patent itself and its exclusionary power needed to be assessed. The initial decision highlighted the FTC's failure to prove that, absent a payment, either better settlement agreements or litigation results would have effected an earlier entry date for the generics. Finally, the ALJ found no proof that Schering maintained an illegal monopoly within the relevant potassium chloride supplement market.

The FTC's complaint counsel appealed this decision to the full Commission. On December 8, 2003, the Commission issued its opinion, reversing the ALJ's initial decision, and agreeing with complaint counsel that Schering's settlements with ESI and Upsher had violated the FTC Act and the Sherman Act. Although it refrained from ruling that Schering's payments to Upsher and ESI made the settlements per se illegal, the Commission concluded that the quid pro quo for the payment was an agreement to defer the entry dates, and that such delay would injure competition and consumers.

In contrast to the ALJ's inquiry into the merits of the '743 patent litigation, the Commission turned instead to the entry dates that “might have been” agreed upon in the absence of payments as the determinative factor. Despite the Commission's assumption that the parties could have achieved earlier entry dates via litigation or non-monetary compromises, it also acknowledged that the settled entry dates were non-negotiable. Upon review of the settlement payments, the Commission determined that neither the $60 million to Upsher nor the $30 million to ESI represented legitimate consideration for the licenses granted by Upsher or ESI's ability to secure FDA approval of its generic. Consequently, the Commission prohibited settlements under which the generic receives anything of value and agrees to defer its own research, development, production or sales activities. Nevertheless, the Commission carved out one arbitrary exception for payments to the generic: beyond a “simple compromise” to the entry date, if payments can be linked to litigation costs (not to exceed $2 million), and the Commission is notified of the settlement, then the parties need not worry about a later antitrust attack. Neither of the Schering agreements fit this caveat, and Schering and Upsher timely petition for review.

We review the FTC's findings of fact and economic conclusions under the substantial evidence standard. 15 U.S.C. § 45(c); see Orkin Exterminating Co., Inc. v. FTC, 849 F.2d 1354 (11th Cir.1988); Olin Corp. v. FTC, 986 F.2d 1295 (9th Cir.1993). The FTC's findings of fact, “if supported by evidence, shall be conclusive.” 15 U.S.C. § 45(c). This standard applies regardless whether the FTC agrees with the ALJ. Thiret v. FTC, 512 F.2d 176, 179 (10th Cir.1975). We may, however, examine the FTC's
findings more closely where they differ from those of the ALJ. *1063 Id.; California Dental Association v. FTC, 128 F.3d 720, 725 (9th Cir.1997), rev’d on other grounds, 526 U.S. 756, 119 S.Ct. 1604, 143 L.Ed.2d 935 (1999); see also ITT Continental Baking Co. v. FTC, 532 F.2d 207, 219 (2d Cir.1976); American Cyanamid Co. v. FTC, 363 F.2d 757, 772–73 (6th Cir.1966). “Substantial evidence is more than a mere scintilla,” and we require “such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.” Consolidated Edison Co. v. NLRB, 305 U.S. 197, 229, 59 S.Ct. 1018, 1026, 16 L.Ed.2d 131 (1938); *1063 Consolo v. Federal Maritime Commission, 383 U.S. 607, 620, 86 S.Ct. 1018, 1026, 16 L.Ed.2d 131 (1966); see NLRB v. Gimrock Constr., Inc., 247 F.3d 1307, 1309 (11th Cir.2001). While we afford the FTC some deference as to its informed judgment that a particular commercial practice violates the FTC Act, we review issues of law de novo. See FTC v. Indiana Federation of Dentists, 476 U.S. 447, 454, 106 S.Ct. 2009, 2015–16, 90 L.Ed.2d 445 (1986).

In their arguments, the parties urge that Universal Camera provides the yardstick by which to measure the evidence at issue. Indeed, in 1951, the Supreme Court clarified the substantial evidence standard for reviewing an administrative agency's decision. Universal Camera Corp. v. NLRB, 340 U.S. 474, 487–88, 71 S.Ct. 456, 95 L.Ed. 456 (1951). In Universal Camera, the ALJ found an employee was lawfully discharged for insubordination rather than his appearance at an NLRB proceeding. The factual testimony directly conflicted, and the ALJ's finding clearly relied on a credibility determination. The Board reversed the holding. On judicial review, the court of appeals hesitated to consider the ALJ's initial ruling because the Administrative Procedure Act gave the Board “all the powers it would have had in making the initial decision.” 5 U.S.C. § 557(b). Thus, the Second Circuit affirmed the Board's decision. The Supreme Court disagreed, and held that the plain language of the statute required a review of the record as a whole, which included the ALJ's decision. Universal Camera, 340 U.S. at 493, 71 S.Ct. 456.

Although Universal Camera involved the NLRB, and not the FTC, the results are applicable here. When we review a jury verdict, we ignore all evidence contrary to the verdict and then draw every reasonable inference in favor of the verdict from the remaining evidence. In the administrative setting, however, Universal Camera dictates that “the substantiality of the evidence must take into account whatever in the record fairly detracts from its weight.” Id. at 488, 71 S.Ct. 456. We are mindful that we do not review the record to draw our own conclusions that we then measure against an administrative agency; rather, we must consider all of the evidence when drawing our conclusions about the reasonableness of an agency's findings of fact. The evidence must be such that it would be possible for a reviewing court to reach the same conclusions that the administrative fact-finder did. If this condition is not met, then the substantial evidence test requires that the administrative decision be reversed. Id.

IV. Discussion

The question remains whether the Commission's conclusions are legally sufficient to establish a violation of the Sherman Act and the FTC Act—that is, whether Schering's agreements with Upsher and ESI amount to an “unreasonable” restraint of trade. In Valley Drug, this Court stated that the “ultimate purpose of the antitrust inquiry is to form a judgment with respect to the competitive significance of the restraint at issue.” Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294, 1303–04 (11th Cir.2003) (citing NCAA v. Bd. of Regents Okla. Univ., 468 U.S. 85, 103, 104 S.Ct. 2948, 2962, 82 L.Ed.2d 70 (1984)). We wrote that the focus of antitrust analysis should be on “what conclusions regarding the competitive impact of a challenged restraint can confidently be drawn from the facts demonstrated by the parties.” Valley Drug, 344 F.3d at 1304.

Valley Drug involved an interim settlement agreement between a patent-holding pharmaceutical company and its potential generic competitor. Under the agreement, the patent holder paid the generic manufacturer $4.5 million per month to keep its product off the market until resolution of the underlying patent infringement suit. The lower court determined that the payments amounted to a per se violation of antitrust laws. See In re Terazosin Hydrochloride Antitrust Litig., 164 F.Supp.2d 1340 (S.D.Fla.2000). We reversed that decision, and concluded that monetary payments made to an alleged infringer as part of a patent litigation settlement did not constitute a per se violation of antitrust law. Valley Drug, 344 F.3d at 1309.
Although we acknowledged in *Valley Drug* that an agreement to allocate markets is “clearly anticompetitive,” resulting in reduced competition, increased prices, and a diminished output, we nonetheless reversed for a rather simple reason: one of the parties owned a patent. *Id.* at 1304. We recognized the effect of agreements that employ extortion-type tactics to keep competitors from entering the market. In the context of patent litigation, however, the anticompetitive effect may be no more broad than the patent's own exclusionary power. To expose those agreements to antitrust liability would “obviously chill such settlements.” *Id.* at 1309.

Both the ALJ and the Commission analyzed the Schering agreements according to the rule of reason analysis, albeit under two different methodologies. To the contrary, the district court in *Valley Drug* approached the agreements in that case from the perspective of whether they were a *per se* violation of antitrust laws. Under the Supreme Court's guidance, an alleged restraint may be found unreasonable either because it fits within a category of restraints that has been held to be “*per se*” unreasonable, or because it violates the so-called “Rule of Reason.” *Id.* at 1309.

The rule of reason tests “whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition.” *FTC v. Indiana Federation of Dentists*, 476 U.S. 447, 457, 106 S.Ct. 2009, 2017, 90 L.Ed.2d 445 (1986) (quoting *Board of Trade of City of Chicago v. United States*, 246 U.S. 231, 238, 38 S.Ct. 242, 244, 62 L.Ed. 683, (1918)).

Both the ALJ's initial decision and the Commission's opinion rejected the *per se* approach, and instead employed the rule of reason. The traditional rule of reason analysis requires the factfinder to “weigh all of the circumstances of a case in deciding whether a restrictive practice should be prohibited as imposing an unreasonable restraint on competition.” *Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 49, 97 S.Ct. 2549, 2557, 53 L.Ed.2d 568 (1977). The plaintiff bears an initial burden of demonstrating that the alleged agreement produced adverse, anti-competitive effects within the relevant product and geographic markets, i.e., market power. See *FTC v. Indiana Federation of Dentists*, 476 U.S. 447, 460–61, 106 S.Ct. 2009, 2019, 90 L.Ed.2d 445 (1986).

Once the plaintiff meets the burden of producing sufficient evidence of market power, the burden then shifts to the defendant to show that the challenged conduct promotes a sufficiently pro-competitive objective. A restraint on competition cannot be justified solely on the basis of social welfare concerns. *See, e.g., National Society of Professional Engineers v. United States*, 435 U.S. 679, 98 S.Ct. 1355, 55 L.Ed.2d 637 (1978); *Indiana Dentists*, 476 U.S. at 463, 106 S.Ct. at 2020. In rebuttal then, the plaintiff must demonstrate that the restraint is not reasonably necessary to achieve the stated objective. *Bhan v. NME Hospitals, Inc.*, 929 F.2d 1404, 1413 (9th Cir.), *cert. denied*, 502 U.S. 994, 112 S.Ct. 617, 116 L.Ed.2d 639 (1991).

In the present case, the Commission emphasized that its rule of reason standard required a methodology different from that set out by the ALJ's initial decision. The Commission chided the ALJ's approach—which evaluated the strength of the patent, defined the relevant geographic and product markets, calculated market shares, and then drew inferences from the shares and other industry characteristics—as an inappropriate manner of analyzing the competitive effects of the parties' activities. Instead, the Commission's rule of reason dictated application of the *Indiana Federation* exception, in that complaint counsel need not prove the relevant market. *See 476 U.S. at 460–61, 106 S.Ct. 2009.* Rather, the FTC was only required to show a detrimental market effect. Thus, under the Commission's standard, once the FTC met the low threshold of demonstrating the anticompetitive nature of the agreements, it found that Schering and Upsher did not sufficiently establish that the challenged activities were justified by procompetitive benefits. Despite the appearance that it openly considered Schering and Upsher's procompetitive affirmative defense, the Commission immediately condemned the settlements because of their absolute anti-competitive nature, and discounted the merits of the patent litigation. It would seem as though the Commission clearly made its decision before it considered any contrary conclusion.
We think that neither the rule of reason nor the *per se* analysis is appropriate in this context. We are bound by our decision in *Valley Drug* where we held both approaches to be ill-suited for an antitrust analysis of patent cases because they seek to determine whether the challenged conduct had an anticompetitive effect on the market. 344 F.3d 1294, 1311 n. 27. By their nature, patents create an *1066* environment of exclusion, and consequently, cripple competition. The anticompetitive effect is already present. “What is required here is an analysis of the extent to which antitrust liability might undermine the encouragement of innovation and disclosure, or the extent to which the patent laws prevent antitrust liability for such exclusionary effects.” *Id.* Therefore, in line with *Valley Drug*, we think the proper analysis of antitrust liability requires an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects. *Valley Drug*, 344 F.3d at 1312.15

A. The '743 Patent

“A patent shall be presumed valid.” 35 U.S.C. § 282. See e.g., *Doddridge v. Thompson*, 9 Wheat. 469, 22 U.S. 469, 483, 6 L.Ed. 137 (1824) (holding that a patent is presumed valid until the contrary is shown); *Sure Plus Mfg. Co. v. Kobrin*, 719 F.2d 1114, 1117 (11th Cir.1983) (“Congress recognized the expertise of the patent office on this matter when it provided for a legal presumption in favor of patent validity for any patent issued by the patent office.”). Engrafted into patent law is the notion that a patent grant bestows “the right to exclude others from profiting by the patented invention.” *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215, 100 S.Ct. 2601, 65 L.Ed.2d 696 (1980); see *Valley Drug*, 344 F.3d at 1304 (“A patent grants its owner the lawful right to exclude others.”). Thus, the Patent Act essentially provides the patent owner “with what amounts to a permissible monopoly over the patented work.” *Telecom Technical Services Inc. v. Rolm Co.*, 388 F.3d 820, 828 (11th Cir.2004) (citing *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 135, 89 S.Ct. 1562, 23 L.Ed.2d 129 (1969)). The Patent Act also explicitly allows for the assignability of a patent; providing the owner with a right to “grant or convey an exclusive right under his application for patent ... to the whole or any specified part of the United States.” 35 U.S.C. § 261.

By virtue of its '743 patent, Schering obtained the legal right to exclude Upsher and ESI from the market until they proved either that the '743 patent was invalid or that their products, Klor–Con and Micro–K 20, respectively, *1067* did not infringe Schering's patent. Although the exclusionary power of a patent may seem incongruous with the goals of antitrust law, a delicate balance must be drawn between the two regulatory schemes. Indeed, application of antitrust law to markets affected by the exclusionary statutes set forth in patent law cannot discount the rights of the patent holder. *Simpson v. Union Oil Co.*, 377 U.S. 13, 14, 84 S.Ct. 1051, 12 L.Ed.2d 98 (1964). (Patent laws “are in pari materia with the antitrust laws and modify them pro tanto (as far as the patent laws go).”). Therefore, a patent holder does not incur antitrust liability when it chooses to exclude others from producing its patented work. *Valley Drug*, 344 F.3d at 1305.

A patent gives its owner the right to grant licenses, if it so chooses, or it may ride its wave alone until the patent expires. *Ethyl Gasoline Corp. v. United States*, 309 U.S. 436, 456, 60 S.Ct. 618, 84 L.Ed. 852 (1940). What patent law does not do, however, is extend the patentee's monopoly beyond its statutory right to exclude. *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 708 (Fed.Cir.1992); see also, *United States v. Singer Mfg. Co.*, 374 U.S. 174, 196–197, 83 S.Ct. 1773, 10 L.Ed.2d 823 (1963) (“[B]eyond the limited monopoly which is granted, the arrangements by which the patent is utilized are subject to the general law.... [T]he possession of a valid patent or patents does not give the patentee any exemption from the provisions of the Sherman Act beyond the limits of the patent monopoly.”). If the challenged activity simply serves as a device to circumvent antitrust law, then that activity is susceptible to an antitrust suit. *Asahi Glass Co., Ltd. v. Pentech Pharmaceuticals, Inc.*, 289 F.Supp.2d 986, 991 (N.D.Ill.2003), In *Asahi*, Judge Posner gave an illustrative example of when certain conduct transcends the confines of the patent:
Suppose a seller obtains a patent that it knows is almost certainly invalid (that is, almost certain not to survive a judicial challenge), sues its competitors, and settles the suit by licensing them to use its patent in exchange for their agreeing not to sell the patented product for less than the price specified in the license. In such a case, the patent, the suit, and the settlement would be devices—masks—for fixing prices, in violation of antitrust law.

Id.

It is uncontested that potassium chloride is the unpatentable active ingredient in Schering’s brand-name drug K–Dur 20. Schering won FDA approval in 1986 to sell its K–Dur 20 tablets. Under the Hatch–Waxman scheme, in order for Upsher and ESI to obtain FDA approval to market their generic versions of an approved drug product like K–Dur 20, they simply needed to demonstrate that the drugs were bioequivalent, i.e., that the “active ingredient of the new drug is the same as that of the listed drug.” 21 U.S.C. § 355(j)(2)(A)(ii)(I). K–Dur 20’s uniqueness, and hence the reason for a patent, is the time-release capsule that surrounds the potassium chloride. Because the patent only covers the individualized delivery method (the sustained-release formula), and not the active ingredient itself, it is termed a “formulation” patent.

No one disputes that the ‘743 patent gave Schering the lawful right to exclude infringing products from the market until September 5, 2006. Nor is there any dispute that Schering's agreement with Upsher gave it a license under the ‘743 patent to sell a microencapsulated form of potassium chloride more than five years before the expiration of the ‘743 patent. Likewise, ESI gained a license under the ‘743 patent to sell its microencapsulated version more than two years before the ‘743 patent expired. Perhaps most important, and which the ALJ duly noted, is that FTC complaint counsel acknowledged that it could not prove that Upsher and ESI could have entered the market on their own prior to the ‘743 patent's expiration on September 5, 2006. This reinforces the validity and strength of the patent.

Although the FTC alleges that Schering's settlement agreements are veiled attempts to disguise a quid pro quo arrangement aimed at preserving Schering's monopoly in the potassium chloride supplement market, there has been no allegation that the ‘743 patent itself is invalid or that the resulting infringement suits against Upsher and ESI were “shams.” Additionally, without any evidence to the contrary, there is a presumption that the ‘743 patent is a valid one, which gives Schering the ability to exclude those who infringe on its product. Therefore, the proper analysis now turns to whether there is substantial evidence to support the Commission’s conclusion that the challenged agreements restrict competition beyond the exclusionary effects of the ‘743 patent. Valley Drug, 344 F.3d at 1306; see also In re Ciprofloxacin Hydrochloride Antitrust Litig., 261 F.Supp.2d 188, 196 (E.D.N.Y.2003).

B. The Scope of Schering's Agreements

1. The Upsher Settlement

The FTC's complaint characterized the agreements at the center of this contest as “horizontal market allocation agreements,” whereby Schering reserved its sales of K–Dur 20 for several years, while Upsher and ESI refrained from selling their generic versions of K–Dur 20 during that same time period. Adding to the FTC's ire is the presence of “reverse payments,” represented by settlement payments from the patent owner to the alleged infringer. The Commission ruled that the coupling of reverse
payments with an agreement by the generics not to enter the market before a particular date, “raise[d] a red flag that distinguishes this particular litigation settlement from most other patent settlements, and mandates a further inquiry.” Slip. Op. at 29.

In the context of Schering's settlement with Upsher, the FTC argues that the $60 million payment from Schering to Upsher was not a bona fide royalty payment under the licenses Schering obtained for Niacor and five other Upsher products. Instead, according to the FTC, the royalty payments constituted payoffs to delay the introduction of Upsher's generic. The FTC concedes that its position fails if it cannot prove a direct causal link between the payments and the delay.

The trial before the ALJ covered 8,629 pages of transcript, involved forty-one witnesses, and included thousands of exhibits. The trial revealed that Schering personnel evaluated Niacor, and forecast its profit stream with a net present value of $225–265 million. Upsher itself had invested significant time and financial resources in Niacor. Moreover, Schering had a long-documented and ongoing interest in licensing an extended-release niacin product, as evidenced by its efforts to acquire Niaspan from Kos Pharmaceuticals.

Evidence at trial also demonstrated that the personnel who evaluated Niaspan's potential were unaware of the ongoing litigation between Upsher and Schering, and had little, if any, incentive to inflate Niacor's value. Indeed, many of the estimates in conjunction with the Niacor evaluation traced the independent conclusions of the team that evaluated Niaspan. Schering's witnesses corroborated the documentary evidence, and the ALJ found the $60 million payment to Upsher to be a bona fide fair-value payment.

The Commission chose to align its opinion with the two witnesses presented by the FTC. One witness, Dr. Nelson Levy (“Levy”) was proffered as an expert in pharmaceutical licensing and valuation. He concluded that the $60 million payment was “grossly excessive,” and that Schering's due diligence in evaluating Niacor fell astonishingly short of industry standards. Levy cited Upsher and Schering's post-settlement behavior, as proof of the agreement's artificial nature. We are troubled by Levy's testimony. Interestingly, Levy arrived at his conclusions without performing a quantitative analysis of Niacor or any of the other Upsher products licensed by Schering. Additionally, Levy lacked expertise in the area of cholesterol-lowering drugs and niacin supplements. Finally, Levy's unpersuasive appraisal of the post-settlement behavior blatantly ignored the parties' ongoing communications and the fact that the niacin market essentially bottomed out. Although the Commission's opinion does not state that it in relying on Levy's testimony, it curiously mirrors each of Levy's conclusions.

The FTC also offered Professor Timothy Bresnahan (“Bresnahan”) to prove that Schering's payment was not for the Niacor license. While Bresnahan neither challenged Niacor's sales projections nor discounted its economic value, Bresnahan nonetheless opined that the payment was for Upsher's delayed entry, and not Niacor. Bresnahan based his conclusions on his interpretation of the parties' subjective incentives to trade a payment for delay. Bresnahan specifically pointed to Schering's failed transactions with Kos and the lack of other competitors vying for Niacor as evidence that the payment was not connected to the license.

Like the Levy testimony, the Commission did not expressly adopt Bresnahan's theories, but his rationale and the Commission's conclusions became one and the same. The Commission is quite comfortable with assenting to Bresnahan's rather amorphous “incentive” theory despite its lack of empirical foundation. Unfortunately, Bresnahan's so-called incentives do not rise to the level of legal conclusions. We understand that certain incentives may rank high in these transactions, but it also true that the possibility of an outside impetus often lays dormant. The simple presence of economic motive weighs little on the scale of probative value. See *Serfecz v. Jewel Food Stores, 67 F.3d 591, 600–01 (7th Cir.1995)* (“The mere existence of mutual economic advantage, by itself, does not tend to exclude the possibility of independent, legitimate action and supplies no basis for inferring a conspiracy.”).
Schering-Plough Corp. v. F.T.C., 402 F.3d 1056 (2005)


The ALJ rejected the FTC's experts, concluding that testimony from Schering's witnesses “provides direct evidence that the parties did not exchange money for delay.” The Commission disagreed, and determined that Niacor was not worth $60 million. To prove its point, the Commission relied on somewhat forced evidence: (1) the unconvincing fact that doctors gave Kos' niacin product mixed reviews, causing Schering to value those profits at an apparently contemptible $254 million; (2) the meretricious argument that Schering's personnel did not adequately assess Niacor's safety; 20 (3) the Commission's questionable non-expert opinion that Schering should have done more due diligence; 21 (4) the Commission's belief that the European market—where Schering held the Niacor license—for a niacin product was less desirable than the U.S. market; 22 and (5) Schering's post-settlement decision to discontinue its Niacor efforts in light of the poor sales effected by Kos' Niaspan. 23

To borrow from the Commission's own words, we think its conclusion that Niacor was not worth $60 million, and that settlement payment was to keep Upsher off the market is “not supported by law or logic.” Substantial evidence requires a review of the entire record at trial, and that most certainly includes the ALJ's credibility determinations and the overwhelming evidence that contradicts the Commission's conclusion. Universal Camera, 340 U.S. at 487–488, 496, 71 S.Ct. 456 (1951); see also Equifax Inc. v. FTC, 678 F.2d 1047, 1052 (11th Cir.1982).

The ALJ made credibility findings based upon his observations of the witnesses' demeanor and the testimony given at trial. The Commission rejected these findings, and instead relied on information that was not even in the record. The Supreme Court has noted the importance of an examiner's determination of credibility, and explained that evidence which supports an administrative agency's fact-finding “may be less substantial when an impartial, experienced examiner who has observed the witnesses and lived with the case has drawn conclusions different from the *1071 [agency's]...” Id. 24 Additionally, the Court instructs that “[t]he findings of the examiner are to be considered along with the consistency and inherent probability of testimony.” Id.

We think that this record consistently demonstrates the factors that Schering considered, and there is nothing to undermine the clear findings of the ALJ that this evidence was reliable. The Commission's finding that the “Upsher licenses were worth nothing to Schering” overlooks the very nature of the pharmaceutical industry where licenses are very often granted on drugs that never see the market. 25 Likewise, the essence of research and development is the need to encourage and foster new innovations, which necessarily involves exploring licensing options and selecting which products to pursue.

Finally, we note that the terms of the Schering–Upsher agreement expressly describes three payments totaling $60 million as “up-front royalty payments.” The surrounding negotiations, trial testimony, and the record all evidence that both parties intended “royalty” to denote its traditional meaning: that Schering would pay Upsher for the licenses and production rights of Upsher's products. See e.g., Sierra Club, Inc. v. C.I.R., 86 F.3d 1526, 1531 (9th Cir.1996) (noting that ‘‘royalty’ commonly refers to a payment made to the owner of property for permitting another to use the property”) (citing Black's Law Dictionary 1330–31 (6th ed.1979)). There is nothing to refute that these payments are a fair price for Niacor and the other Upsher products. Schering–Plough made a stand-alone determination that it was getting as much in return from these products as it was paying, and just because the agreement also includes Upsher's entry date into the potassium chloride supplement market, one cannot infer that the payments were solely for the delay rather than the licenses. See Valley Drug, 344 F.3d at 1309. Thus, the substantial and overwhelming evidence undercuts the Commission's conclusion that Schering's agreement with Upsher was illegal.

2. The ESI Settlement

The Commission separately addressed Schering's settlement with ESI. Although it purported to analyze this agreement under the same scheme as it did the Upsher settlement, there is far less development of the factual record to support the Commission's conclusion that the settlement was unreasonable. At trial, the FTC called no fact witnesses to testify about the ESI settlement,
and its economic expert offered only brief testimony. The Commission’s opinion itself spends little time on the ESI settlement, and begins with the recognition that the case is based on “relatively limited evidence.” On the other hand, Schering produced experts who posited that Schering would have won the patent case, and that the ESI’s January 1, 2004, entry date reasonably reflected the strength of Schering’s case. The FTC did not rebut this testimony, but rather ignored it.

It seems the sole indiscretion committed in the context of the ESI settlement is the inclusion of monetary payments. The Commission ignored the lengthy mediation process, and insisted that the parties could have reached an alternative settlement with an earlier entry date. We do not pretend to understand the Commission’s profound concern with this settlement, but it takes particular exception to the $10 million payment, which was contingent on FDA approval of the generic product. The Commission also subtly questions the validity of the $5 million for legal costs. We might only guess that if the legal fee tallied $2 million—the arbitrary cap the Commission would allow for such settlements—it would not garner the same scrutiny.

The Commission, however, refused to consider the underlying patent litigation, and its certainty to be a bitter and prolonged process. All of the evidence of record supports the conclusion of the ALJ that this is not the case of a “naked payment” aimed to delay the entry of product that is “legally ready and able to compete with Schering.” The litigation that unfolded between Schering and ESI was fierce and impassioned. Fifteen months of mediation demonstrates the doubt of a peaceful conclusion (or a simple compromise, as the Commission would characterize it).

That the parties to a patent dispute may exchange consideration to settle their litigation has been endorsed by the Supreme Court. See Standard Oil Co. v. United States, 283 U.S. 163, 170–71 n. 5, 51 S.Ct. 421, 75 L.Ed. 926 (1931) (noting that the interchange of rights and royalties in a settlement agreement “may promote rather than restrain competition”). Veritably, the Commission’s opinion would leave settlements, including those endorsed and facilitated by a federal court, with little confidence. The general policy of the law is to favor the settlement of litigation, and the policy extends to the settlement of patent infringement suits. Flex–Foot, Inc. v. CRP, Inc., 238 F.3d 1362, 1368 (Fed.Cir.2001); Foster v. Hallco Manufacturing Co., 947 F.2d 469, 477 (Fed.Cir.1991); Aro Corp. v. Allied Witan Co., 531 F.2d 1368, 1372 (6th Cir.1976). Patent owners should not be in a worse position, by virtue of the patent right, to negotiate and settle surrounding lawsuits. We find the terms of the settlement to be within the patent’s exclusionary power, and “reflect a reasonable implementation” of the protections afforded by patent law. Valley Drug, 344 F.3d at 1312.

C. The Anticompetitive Effects

Our final line of inquiry turns to whether these agreements were indeed an “unfair method of competition.” The FTC Act’s prohibition on such agreements encompasses violations of other antitrust laws, including the Sherman Act, which prohibits agreements in restraint of trade. 15 U.S.C. § 45(a); California Dental Ass’n., 526 U.S. at 763 n. 3, 119 S.Ct. 1604. In California Dental, the Supreme Court required that the anticompetitive effect cannot be hypothetical or presumed. Rather, the probe must turn to “whether the effects actually are anticompetitive.” Id. at 775 n. 12., 119 S.Ct. 1604

The restraints at issue here covered any “sustained release microencapsulated potassium chloride tablet.” Such a specific clause—an “ancillary restraint”—is routine to define the parameters of the agreement and to prevent future litigation over what may or may not infringe upon the patent. See Rothery Storage & Van Co. v. Atlas Van Lines, Inc., 792 F.2d 210, 224 (D.C.Cir.1986) (“The ancillary restraint is subordinate and collateral in the sense that it serves to make the main transaction more effective in accomplishing its purpose.”). Ancillary restraints are generally permitted if they are “reasonably necessary” toward the contract’s objective of utility and efficiency. See Law v. NCAA, 134 F.3d 1010, 1019 (10th Cir.1998).
The efficiency-enhancing objectives of a patent settlement are clear, and “[p]ublic policy strongly favors settlement of disputes without litigation.” *Aro Corp. v. Allied Witan Co.*, 531 F.2d 1368, 1372 (6th Cir.1976). See also *Schlegal Mfg. Co. v. U.S.M. Corp.*, 525 F.2d 775, 783 (6th Cir.1975) (“The importance of encouraging settlement of patent-infringement litigation ... cannot be overstated.”). In order for a condition to be ancillary, an agreement limiting competition must be secondary and collateral to an independent and legitimate transaction. *Rothery Storage*, 792 F.2d at 224. Naturally, the restraint imposed must relate to the ultimate objective, and cannot be so broad that some of the restraint extinguishes competition without creating efficiency. Even restraints ancillary in form can in substance be illegal if they are part of a general plan to gain monopoly control of a market. *United States v. Addyston Pipe & Steel Co.*, 85 F. 271, 282–83 (6th Cir.1898). Such a restraint, then, is not ancillary.

Under the Schering–Upsher agreement, the scope of the products subject to the September 1, 2001 entry date demonstrate an efficient narrowness. No other products were delayed by the ancillary restraints contained in the agreements. The '743 patent claims a “controlled release [microencapsulated] potassium chloride tablet.” The language in the Schering–Upsher agreement covers the identical reach of the '743 patent. There is no broad provision that detracts from the efficiency of settling the underlying patent litigation. Nevertheless, the Commission rejected the notion that the narrow restraints were legitimate and reasonable means of accomplishing the settlement, and refused to consider that this settlement preserved public and private resources, and that the resultant certainty ultimately led to more intense competition.

The Commission's opinion requires the conclusion that but for the payments, the parties would have fashioned different settlements with different entry dates. Although it claimed to apply a rule of reason analysis, which we disagree with on its own, the Commission pointedly states that it logically concluded that “*quid pro quo* for the payment was an agreement by the generic to defer entry date beyond the date that represents an otherwise reasonable litigation compromise.” We are not sure where this “logic” derives from, particularly given our holding in *Valley Drug*. “It is not obvious that competition was limited more than that lawful degree by paying potential competitors for their exit ... litigation is a much more costly mechanism to achieve exclusion, both to the parties and to the public, than is settlement.” *Id.* at 1309.

The Commission rationalizes its decision not to consider the exclusionary power of the patent by asserting that the parties could have attained an earlier entry without the role of payments. There is simply no evidence in the record, however, that supports this conclusion. The Commission even recognized that the January 1, 2004 entry date in the ESI settlement was “non-negotiable.” For its part, Schering presented experts who testified to the litigation truism that settlements are not always possible. Indeed, Schering's experts agreed that ancillary agreements may be the only avenue to settlement.

The proposition that the parties could have “simply compromised” on earlier entry dates is somewhat myopic, given the nature of patent litigation and the role that reverse payments play in settlements. It is uncontested that parties settle cases based on their perceived risk of prevailing in and losing the litigation. Pre–Hatch–Waxman, Upsher and ESI normally would have had to enter the market with their products, incurring the costs of clinical trials, manufacturing and marketing. This market entry would have driven down Schering's profits, as it took sales away. As a result, Schering would have sued ESI and Upsher, seeking damages for lost profits and willful infringement. Assuming the patent is reasonably strong, and the parties then settled under this scenario, the money most probably would flow from the infringers to Schering because the generics would have put their companies at risk by making infringing sales.

By contrast, the Hatch–Waxman Amendments grant generic manufacturers standing to mount a validity challenge without incurring the cost of entry or risking enormous damages flowing from any possible infringement. *See In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 261 F.Supp.2d 188, 251 (E.D.N.Y.2003). Hatch–Waxman essentially redistributes the relative risk assessments and explains the flow of settlement funds and their magnitude. *Id.* Because of the Hatch–Waxman scheme, ESI and Upsher gained considerable leverage in patent litigation: the exposure to liability amounted to litigation costs, but paled in comparison to the immense volume of generic sales and profits. This statutory scheme could then cost Schering its patent.
By entering into the settlement agreements, Schering realized the full potential of its infringement suit—a determination that the '743 patent was valid and that ESI and Upsher would not infringe the patent in the future. Furthermore, although ESI and Upsher obtained less than what they would have received from successfully defending the lawsuits (the ability to immediately market their generics), they gained more than if they had lost. A conceivable compromise, then, directs the consideration from the patent owner to the challengers. *Id.* Ultimately, the consideration paid to Upsher and ESI was arguably less than if Schering's patent had been invalidated, which would have resulted in the generic entry of potassium chloride supplements.

In fact, even in the pre-Hatch-Waxman context, “implicit consideration flows from the patent holder to the alleged infringer.” *Id.* If Schering had been able to prove damages from infringing sales, and settled before trial for a sum less than the damages, the result is a windfall to the generic manufacturers who essentially keep a portion of the profits. If this were true, then under the Commission's analysis, such a settlement would be a violation of antitrust law because the infringer reaped the benefit of the patent holder's partial surrender of damages. Like the reverse payments at issue here, “such a rule would discourage any rational party from settling a patent case because it would be an invitation to antitrust litigation.” *Id.*

The Commission's inflexible compromise-without-payment theory neglects to understand that “[r]everse payments are a natural by-product of the Hatch–Waxman process.” *Id.* Pure compromise ignores that patents, payments, and settlement are, in a sense, all symbiotic components that must work together in order for the larger abstract to succeed. As Judge Posner emphasized in *Asahi*, “[i]f any settlement agreement can be characterized as involving ‘compensation’ to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is thus classified as involving a forbidden ‘reverse payment,’ we shall have no more patent settlements.” *Asahi Glass Co.*, 289 F.Supp.2d at 994. We agree. If settlement negotiations fail and the patentee prevails in its suit, competition would be prevented to the same or an even greater extent because the generic could not enter the market prior to the expiration of the patent. *See* *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 261 F.Supp.2d 188, 250–52 (E.D.N.Y.2003). A prohibition on reverse-payment settlements would “reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive.” *Asahi Glass Co.*, 289 F.Supp.2d at 994.

There is no question that settlements provide a number of private and social benefits as opposed to the inveterate and costly effects of litigation. *See generally* D. Crane, “Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications,” 54 Fla. L.Rev. 747, 760 (2002). Patent litigation breeds a litany of direct and indirect costs, ranging from attorney and expert fees to the expenses associated with discovery compliance. Other costs accrue for a variety of reasons, be it the result of uncompromising legal positions, differing strategic objectives, heightened emotions, lawyer incompetence, or sheer moxie. *Id.; see also* S. Carlson, *Patent Pools and the Antitrust Dilemma*, 16 Yale. J. Reg. 359, 380 (1999) (U.S. patent litigation costs $1 billion annually).

Finally, the caustic environment of patent litigation may actually decrease product innovation by amplifying the period of uncertainty around the drug manufacturer's ability to research, develop, and market the patented product or allegedly infringing product. The intensified guesswork involved with lengthy litigation cuts against the benefits proposed by a rule that forecloses a patentee's ability to settle its infringement claim. *See In re Tamoxifen Citrate Antitrust Litig.*, 277 F.Supp.2d 121, 133 (E.D.N.Y.2003) (noting that the settlement resolved the parties' complex patent litigation, and in so doing, “cleared the field” for other ANDA filers). Similarly, Hatch–Waxman settlements, likes the ones at issue here, which result in the patentee's purchase of a license for some of the alleged infringer's other products may benefit the public by introducing a new rival into the market, facilitating competitive production, and encouraging further innovation. *See* H. Hovenkamp, *et al.*, *Anticompetitive Settlement of Intellectual Property Disputes* 87 Minn. L.Rev. at 1719, 1750–51 (2003); *see also* H. Hovenkamp *Antitrust Law: An Analysis of Antitrust Principles and Their Application*, ¶ 1780a (1999).
Despite the associated benefits of settlements—which include the avoidance of the burdensome costs and the resolution of uncertainty regarding the respective rights and obligations of party litigants—the Commission manufactured a rule that would make almost any settlement involving a payment illegal. 26 Furthermore, the Commission's minimal allowance for $2 million in litigation costs is rather naive. While we agree that a settlement cannot be more anticompetitive than litigation, see Valley Drug, 344 F.3d at 1312, we must recognize “[a] suitable accommodation between antitrust law's free competition requirement and the patent regime's incentive system.” 344 F.3d at 1307.

We have said before, and we say it again, that the size of the payment, or the mere presence of a payment, should not dictate the availability of a settlement remedy. Due to the “asymmetrics of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement.” Id. at 1310. An exception cannot lie, as the Commission might think, when the issue turns on validity (Valley Drug) as opposed to infringement (the Schering agreements). 27 The effect is the same: a generic's entry into the market is delayed. What we must focus on is the extent to which the exclusionary effects of the agreement fall within the scope of the patent's protection. Id. Here, we find that the agreements fell well within the protections of the '743 patent, and were therefore not illegal.

V. Conclusion

Valley Drug established the law in our Circuit. Simply because a brand-name pharmaceutical company holding a patent paid its generic competitor money cannot be the sole basis for a violation of antitrust law. This alone underscores the need to evaluate the strength of the patent. Our conclusion, to a degree, and we hope that the FTC is mindful of this, reflects policy. Given the costs of lawsuits to the parties, the public problems associated with overcrowded court dockets, and the correlative public and private benefits of settlements, we fear and reject a rule of law that would automatically invalidate any agreement where a patent-holding pharmaceutical manufacturer settles an infringement case by negotiating the generic's entry date, and, in an ancillary transaction, pays for other products licensed by the generic. Such a result does not represent the confluence of patent and antitrust law. Therefore, this Court grants the petition for review. Accordingly, we SET ASIDE the decision of the Federal Trade Commission and VACATE its cease and desist order.

All Citations


Footnotes

* Honorable Richard W. Goldberg, Judge, United States Court of International Trade, sitting by designation.

1 Schering also markets another version of this product, K–Dur 10, the coating of which is also covered by the '743 patent. The difference between the two is dosage: K–Dur 20 contains twice as much potassium as K–Dur 10. This lawsuit only involves K–Dur 20.

   The '743 patent claims a pharmaceutical dosage unit in tablet form for oral administration of potassium chloride. The tablet contains potassium chloride crystals coated with a cellulose-type material. The novel feature in the '743
The FDA must approve any new drug before it can be marketed or sold in the United States. Previously, applications for FDA approval proceeded under a new drug application (“NDA”). 21 U.S.C. § 355(b). This cumbersome and involved process required each applicant to submit safety and efficacy studies, even if it duplicated previous studies done on identical drugs with the same ingredients. In 1984, Congress passed Drug Price Competition and Patent Term Restoration Act (the “Hatch–Waxman Act”), Pub.L. No. 98–417, 98 Stat. 1585 (1984). The purpose of the Hatch–Waxman Act was threefold: (1) to reduce the average price paid by consumers; (2) preserve the technologies pioneered by the brand-name pharmaceutical companies; and (3) create an abbreviated new drug application (“ANDA”) to bring generic drugs to the market.

The ANDA process allows the manufacturers of generic drugs to gain early entry into the market. Hatch–Waxman's truncated procedure avoids the duplication of expensive safety and efficacy studies, so long as the generic manufacturer proves that its drug is bio-equivalent to the already-approved brand-name/pioneer drug. As part of the application process, the generic applicant must certify that the relevant patent(s) on the brand-name drug are either invalid or will not be infringed. This is commonly known as a “Paragraph IV certification.” The patent holder is then notified of the ANDA, and if the patent holder sues for infringement within forty-five days of receiving the notice, the FDA automatically institutes a thirty-month delay on the generic manufacturer's ANDA approval. See 21 U.S.C. 355(j)(5)(B)(iii).

As part of its ANDA, Upsher certified that Schering's patent was either invalid or that Upsher did not infringe on that patent. When Schering brought suit, the thirty-month delay was activated.

Schering's focus on Niacor is consistent with its previous attempt to purchase the rights to Niaspan, another sustained-release niacin product, which Kos was in the process of developing during this time. Negotiations between Kos and Schering broke down several months before Upsher offered Niacor to Schering.

Indeed, there is the indication of some internal independence between Schering's evaluation of Niaspan and Niacor, as two different teams examined the products and arrived at similar estimates.


There was also a side agreement in this settlement that provided for a payment of $15 million in return for the right to license generic enalpril and buspirone from ESI.

ESI provided Schering with information related to the Micro–K 20's current approval status. The summary noted the difficulties ESI had up to that point in trying to obtain FDA approval for its proposed generic version. The primary concern was ESI's bioequivalence study, which had been performed in 1989. The FDA found five different deficiencies with regard to that study, and ESI did not respond to those deficiencies until May 1997. ESI then began a new bioequivalence study in December 1997.

Under the final settlement agreement, dated June 19, 1998, Schering agreed to pay ESI a $5 million noncontingent payment, representing legal fees, and an additional $10 million contingent on ESI's FDA approval. Schering and ESI also entered into a contemporaneous license agreement whereby ESI granted Schering the licenses to enalpril and buspirone in exchange for $15 million.
On October 12, 2001, the Complaint against AHP was withdrawn to consider a proposed consent agreement. The FTC approved a final consent order on April 2, 2002. AHP was not a party to either the trial before the ALJ or any subsequent proceedings, and is not a party to this appeal. The legality of the Schering's settlement with ESI/AHP, however, remained at issue with respect to Schering.

The contradictory nature of the Commission's opinion is exemplified by its assessment of the ESI settlement. Although the Commission found the payment to be unjustified and in violation of the law, it simultaneously explained that “[a]s a matter of prosecutorial discretion, we might not have brought a stand-alone case based on such relatively limited evidence.”

The majority of antitrust claims are analyzed under the rule of reason. State Oil Co. v. Khan, 522 U.S. 3, 20, 118 S.Ct. 275, 139 L.Ed.2d 199 (1997). Courts generally determine the reasonableness of a particular agreement by reference to the surrounding facts and circumstances under the rule of reason. Generally, a per se analysis is applied only in limited circumstances, and after experience and pattern establish that a particular class of restraint is manifestly anticompetitive. Broadcast Music, Inc. v. Columbia Broad. Sys., Inc., 441 U.S. 1, 9, 99 S.Ct. 1551, 60 L.Ed.2d 1 (1979). Essentially, the per se rule should only be employed when the conduct has “pernicious effect on competition” and “lack[s] ... any redeeming virtue.” Continental T.V Inc. v. GTE Sylvania Inc., 433 U.S. 36, 9, 99 S.Ct. 2549, 53 L.Ed.2d 568 (1977).

By and large, the construction of the rule of reason inquiry has remained unaltered since the Supreme Court first articulated it in Board of Trade of City of Chicago v. United States, 246 U.S. 231, 238, 38 S.Ct. 242, 244, 62 L.Ed. 683 (1918):

[The] court must ordinarily consider the facts peculiar to the business to which the restraint is applied; its condition before and after the restraint was imposed; the nature of the restraint and its effect, actual or probable. The history of the restraint, the evil believed to exist, the reason for adopting the particular remedy, the purpose or end sought to be attained, are all relevant facts.

Indiana Dentists noted an exception to the burden of proving market power: “Since the purpose of the inquiries into market definition and market power is to determine whether an arrangement has the potential for genuine adverse effects on competition, ‘proof of actual detrimental effects, such as a reduction of output,’ can obviate the need for an inquiry into market power, which is but a ‘surrogate for detrimental effects.’ ” 476 U.S. at 460–61, 106 S.Ct. 2009 (citing P. Areeda, Antitrust Law ¶ 1511, p. 429 (1986)).

On remand, the district court in Valley Drug still applied a per se analysis, and found those agreements to be illegal. See In re Terazosin Hydrochloride Antitrust Litigation, 352 F.Supp.2d 1279 (S.D.Fla.2005). We note that the case at bar is wholly different from Valley Drug. The critical difference is that the agreements at issue in Valley Drug did not involve final settlements of patent litigation, and, moreover, the Valley Drug agreements did not permit the generic company to market its product before patent expiration. On remand, the district court emphasized that the “[a]greement did not resolve or even simplify Abbott's patent infringement action ... to the contrary, the Agreement tended to prolong that dispute to Abbott's advantage, delaying generic entry for a longer period of time than the patent or any reasonable interpretation of the patent's protections would have provided.” In re Terazosin Hydrochloride Antitrust Litigation, 352 F.Supp.2d 1279 (S.D.Fla.2005). Given these material distinctions, the same analysis cannot apply.

The Commission wrote that it would neither address the exclusionary power of Schering's patent nor compare the patent's scope to the exclusionary effect of the settlements. Rather, the Commission grounds its decision in the untenable supposition that without a payment there would have been different settlements with both ESI and Schering, resulting in earlier entry dates: “we cannot assume that Schering had a right to exclude Upsher's generic competition for the life of the patent any more than we can assume that Upsher had the right to enter earlier. In fact we make neither assumption,
but focus on the effect that Schering's payment to Upsher was likely to have on the generic entry date which the parties would otherwise have agreed to in a settlement.”

In fact, Upsher received final FDA approval to market its Klor–Con generic version in November 1998. ESI followed suit, gaining FDA approval for Micro–K 20 in June 1999.

Upsher began selling Klor Con M20 on September 1, 2001.

It is patently obvious that the Commission's opinion did not employ this analysis; preferring, instead, to proceed through its laborious rule of reason framework, eventually branding the challenged restraints to be illegal horizontal market allocation agreements. The Commission was ostensibly silent with regard to the '743 patent, yet it cavalierly dismissed our holding in Valley Drug, stating that a determination on the merits of the underlying patent disputes was “not supported by law or logic.”

While the Commission's opinion conspicuously notes that it does not “adopt his terminology,” it nonetheless endorses Bresnahan's incentive analysis: “We agree that there are strong monetary incentives for the pioneer and the generic to share the pioneer's substantial profits until the expiration of the patent, rather than compete head-to-head. The existence of these strong incentives, standing alone, obviously does not amount to proof of a law violation, but it may help to resolve conflicting inferences.”

In his testimony before the ALJ, Dr. Levy asserted that Niacor was toxic to the liver and criticized Schering for not taking liver biopsies on Upsher's clinical patients, who had long-since exited the trial program. Levy's later testimony revealed that he was not an expert in cholesterol-reducing drugs, and admitted that he “probably overstated” his opinion. The Commission's opinion emphasizes that it did not rely on Dr. Levy's testimony, yet again it arrives at the same conclusion, despite what we would presume to be a similar lack of knowledge in cholesterol-reducing drugs. It puzzles us that the Commission's opinion carefully traces Schering's due diligence and goes to great pains to highlight the intricate details, but still scolds Schering for not doing more.

The Commission's opinion cited no authority for this assumption, but it also rejects “any suggestion that a reasonably adequate product review must necessarily take months, because the opportunity may no longer be on the table.”

This opinion was offered by a Kos official, who saw the U.S. market as “more appealing than the European market.” Evidence shows, and even the FTC's experts agreed, that the worldwide market Schering had acquired rights to was at least as large as the U.S. market.

Niaspan's sales were in fact disappointing. Market analysts predicted its 1999 sales to reach $169.3 million, and Schering's more conservative estimate calculated $101 million for the same year. In actuality, the sales were only $37.9 million.

At the time of the opinion in Universal Camera, an “examiner” performed the same functions as an ALJ.

At trial, the FTC selected eight products that Schering had licensed from companies other than Upsher for comparative analysis. Five of those eight products were never marketed.

Directly contrary to our opinion in Valley Drug.

The Schering agreements would necessarily be stronger than those in Valley Drug, where the facts demonstrated the likelihood of an invalid patent, because a valid patent could operate to exclude all infringing products for the life of the patent.
SYNOPSIS

Dealer which sold calculators brought antitrust action against supplier, based upon supplier's termination of dealership at request of competing dealer. The United States District Court for the Southern District of Texas, Woodrow B. Seals, J., entered jury verdict in favor of retailer and supplier appealed. The Court of Appeals, Clark, Chief Judge, 780 F.2d 1212, reversed and remanded. The Supreme Court, Justice Scalia, held that vertical restraint of trade is not per se illegal under § 1 of the Sherman Act unless it includes some agreement of price or price levels.

Affirmed.

Justice Stevens filed dissenting opinion in which Justice White joined.

Justice Kennedy did not participate.

Procedural Posture(s): On Appeal.

**1516 Syllabus*

Petitioner and another retailer (Hartwell) were authorized by respondent manufacturer to sell its electronic calculators in the Houston area. In response to Hartwell's complaints about petitioner's prices, respondent terminated petitioner's dealership. Petitioner brought suit in Federal District Court, alleging that respondent and Hartwell had conspired to terminate petitioner and that such conspiracy was illegal per se under § 1 of the Sherman Act. The court submitted a liability interrogatory to the jury asking whether there was an agreement or understanding between respondent and Hartwell to terminate petitioner's dealership because of its price cutting, and instructed the jury that the Sherman Act is violated when a seller enters into such an agreement or understanding with one of its dealers. The jury answered the interrogatory affirmatively, awarding damages, and the court entered judgment for petitioner for treble damages. The Court of Appeals reversed and remanded for a new trial, holding that, to render illegal per se a vertical agreement between a manufacturer and a dealer to terminate a second dealer, the first dealer must expressly or impliedly agree to set its prices at some level.

Held: A vertical restraint of trade is not per se illegal under § 1 of the Sherman Act unless it includes some agreement on price or price levels. Pp. 1519–1525.
Ordinarily, whether particular concerted action violates § 1 is determined through case-by-case application of the rule of reason. Per se rules are appropriate only for conduct that is manifestly anticompetitive. Although vertical agreements on resale prices are illegal per se, extension of that treatment to other vertical restraints must be based on demonstrable economic effect rather than upon formalistic line drawing. Continental T.V., Inc. v. GTE Sylvania Inc., 433 U.S. 36, 97 S.Ct. 2549, 53 L.Ed.2d 568, which held that vertical nonprice restraints are not per se illegal, recognized that such restraints have real potential to stimulate interbrand competition; that a rule of per se illegality for such restraints is not needed or effective to protect intrabrand competition; and that **1517 such restraints do not significantly facilitate cartelizing. There has been no showing here that different characteristics attend an agreement between a manufacturer and a dealer to terminate a “price cutter,” without a further agreement on the *718 price or price levels to be charged by the remaining dealer. A quite plausible purpose of the vertical restriction here was to enable Hartwell to provide better services under its sales franchise agreement with respondent. There is also no merit to petitioner's contention that an agreement on the remaining dealer's price or price levels will so often follow from terminating another dealer because of its price cutting that prophylaxis against resale price maintenance warrants the District Court's per se rule. Pp. 1519–1523.

(b) The term “restraint of trade” in the Sherman Act, like the term at common law before the statute was adopted, refers not to a particular list of agreements, but to a particular economic consequence, which may be produced by quite different sorts of agreements in varying times and circumstances. Moreover, this Court's precedents do not indicate that the pre-Sherman Act common law prohibited as illegal per se an agreement of the sort made here. Nor is the District Court's rule of per se illegality compelled by precedents under the Sherman Act holding certain horizontal agreements to constitute price fixing and thus to be per se illegal even though they did not set prices or price levels. The notion of equivalence between the scope of horizontal per se illegality and that of vertical per se illegality was explicitly rejected in GTE Sylvania. Finally, earlier vertical price-fixing cases are consistent with the proposition that vertical per se illegality requires an agreement setting a price or a price level. Pp. 1523–1525.

780 F.2d 1212 (CA5 1986), affirmed.

SCALIA, J., delivered the opinion of the Court, in which REHNQUIST, C.J., and BRENNAN, MARSHALL, BLACKMUN, and O'CONNOR, JJ., joined. STEVENS, J., filed a dissenting opinion, in which WHITE, J., joined, post, p. ———. KENNEDY, J., took no part in the consideration or decision of the case.

Attorneys and Law Firms

Gary V. McGowan argued the cause and filed briefs for petitioner.

Harold R. Tyler, Jr. argued the cause for respondent. With him on the brief was Lance Gotthoffer.*


108 S.Ct. 1515, 99 L.Ed.2d 808, 56 USLW 4387, 1988-1 Trade Cases P 67,982


Briefs of amici curiae urging affirmance were filed for the Consumer Electronics Group of the Electronic Industries Association by Gary J. Shapiro; for the National Association of Manufacturers by Jan S. Amundson, Quentin Riegel, and Donald I. Baker; and for the National Office Machine Dealers Association by Samuel Schoenberg.

Opinion

*719 Justice SCALIA delivered the opinion of the Court.

Petitioner Business Electronics Corporation seeks review of a decision of the United States Court of Appeals for the Fifth Circuit holding that a vertical restraint is per se illegal under § 1 of the Sherman Act, 26 Stat. 209, as amended, 15 U.S.C. § 1, only if there is an express or implied agreement to set resale prices at some level. 780 F.2d 1212, 1215–1218 (1986). We granted certiorari, 482 U.S. 912, 107 S.Ct. 3182, 96 L.Ed.2d 671 (1987), to resolve a conflict in the Courts of Appeals regarding the proper dividing line between the rule that vertical price restraints are illegal per se and the rule that vertical nonprice restraints are to be judged under the rule of reason. 1

*720

In 1968, petitioner became the exclusive retailer in the Houston, Texas, area of electronic calculators manufactured by respondent Sharp Electronics Corporation. In 1972, respondent appointed Gilbert Hartwell as a second retailer in the Houston area. During the relevant period, electronic calculators were primarily sold to business customers for prices up to
$1,000. While much of the evidence in this case was conflicting—in particular, concerning whether petitioner was “free riding” on Hartwell's provision of presale educational and promotional services by providing inadequate services itself—a few facts are undisputed. Respondent published a list of suggested minimum retail prices, but its written dealership agreements with petitioner and Hartwell did not obligate either to observe them, or to charge any other specific price. Petitioner's retail prices were often below respondent's suggested retail prices and generally below Hartwell's retail prices, even though Hartwell too sometimes priced below respondent's suggested retail prices. Hartwell complained to respondent on a number of occasions about petitioner's prices. In June 1973, Hartwell gave respondent the ultimatum that Hartwell would terminate his dealership unless respondent ended its relationship with petitioner within 30 days. Respondent terminated petitioner's dealership in July 1973.

Petitioner brought suit in the United States District Court for the Southern District of Texas, alleging that respondent and Hartwell had conspired to terminate petitioner and that such conspiracy was illegal per se under § 1 of the Sherman Act. The case was tried to a jury. The District Court submitted a liability interrogatory to the jury that asked whether “there was an agreement or understanding between Sharp Electronics Corporation and Hartwell to terminate Business Electronics as a Sharp dealer because of Business Electronics' price cutting.” Record, Doc. No. 241. The District Court instructed the jury at length about this question:

*722 “The Sherman Act is violated when a seller enters into an agreement or understanding with one of its dealers to terminate another dealer because of the other dealer's price cutting. Plaintiff contends that Sharp terminated Business Electronics in furtherance of Hartwell's desire to eliminate Business Electronics as a price-cutting rival.

“If you find that there was an agreement between Sharp and Hartwell to terminate Business Electronics because of Business Electronics' price cutting, you should answer yes to Question Number 1.

“A combination, agreement or understanding to terminate a dealer because of his price cutting unreasonably restrains trade and cannot be justified for any reason. Therefore, even though the combination, agreement or understanding may have been formed or engaged in ... to eliminate any alleged evils of price cutting, it is still unlawful....

“If a dealer demands that a manufacturer terminate a price cutting dealer, and the manufacturer agrees to do so, the agreement is illegal if the manufacturer's purpose is to eliminate the price cutting.” App. 18–19.

The jury answered Question 1 affirmatively and awarded $600,000 in damages. The District Court rejected respondent's motion for judgment notwithstanding the verdict or a new trial, holding that the jury interrogatory and instructions had properly stated the law. It entered judgment for petitioner for treble damages plus attorney's fees.

The Fifth Circuit reversed, holding that the jury interrogatory and instructions were erroneous, and remanded for a new trial. It held that, to render illegal per se a vertical agreement between a manufacturer and a dealer to terminate a second dealer, the first dealer “must expressly or impliedly agree to set its prices at some level, though not a specific one.  *723 The distributor cannot retain complete freedom to set whatever price it chooses.” 780 F.2d, at 1218.
Section 1 of the Sherman Act provides that “[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal.” 15 U.S.C. § 1. Since the earliest decisions of this Court interpreting this provision, we have recognized that it was intended to prohibit only unreasonable restraints of trade. National Collegiate Athletic Assn. v. Board of Regents of University of Oklahoma, 468 U.S. 85, 98, 104 S.Ct. 2948, 2958–9, 82 L.Ed.2d 70 (1984); see, e.g., Standard Oil Co. v. United States, 221 U.S. 1, 60, 31 S.Ct. 502, 515–16, 55 L.Ed. 619 (1911). Ordinarily, whether particular concerted action violates § 1 of the Sherman Act is determined through case-by-case application of the so-called rule of reason—that is, “the factfinder weighs all of the circumstances of a case in deciding whether a restrictive practice should be prohibited as imposing an unreasonable restraint on competition.” Continental T.V., Inc. v. GTE Sylvania Inc., 433 U.S. 36, 49, 97 S.Ct. 2549, 2557, 53 L.Ed.2d 568 (1977). Certain categories of agreements, however, have been held to be per se illegal, dispensing with the need for case-by-case evaluation. We have said that per se rules are appropriate only for “conduct that is manifestly anticompetitive,” id., at 50, 97 S.Ct., at 2557, that is, conduct “‘that would always or almost always tend to restrict competition and decrease output,’” Northwest Wholesale Stationers, Inc. v. Pacific Stationery & Printing Co., 472 U.S. 284, 289–290, 105 S.Ct. 2613, 2617, 86 L.Ed.2d 202 (1985), quoting Broadcast Music, Inc. v. Columbia Broadcasting System, Inc., 441 U.S. 1, 19–20, 99 S.Ct. 1551, 1562, 60 L.Ed.2d 1 (1979). See also FTC v. Indiana Federation of Dentists, 476 U.S. 447, 458–459, 106 S.Ct. 2009, 2017–2018, 90 L.Ed.2d 445 (1986) (“[W]e have been slow to extend per se analysis to restraints imposed in the context of business relationships where the economic impact of certain practices is not immediately obvious”); National Collegiate *724 Athletic Assn. v. Board of Regents of University of Oklahoma, supra, 433 U.S., at 103–104, 104 S.Ct., at 2961 (“Per se rules are invoked when surrounding circumstances make the likelihood of anticompetitive conduct so great as to render unjustified further examination of the challenged conduct”); National Society of Professional Engineers v. United States, 435 U.S. 679, 692, 98 S.Ct. 1355, 1365, 55 L.Ed.2d 637 (1978) (agreements are per se illegal only if their “nature and necessary effect are so plainly anticompetitive that no elaborate study of the industry is needed to establish their illegality”).

Although vertical agreements on resale prices have been illegal per se since Dr. Miles Medical Co. v. John D. Park & Sons Co., 220 U.S. 373, 31 S.Ct. 376, 55 L.Ed. 502 (1911), we have recognized that the scope of per se illegality should be narrow in the context of vertical restraints. In Continental T.V., Inc. v. GTE Sylvania Inc., supra, we refused to extend per se illegality to vertical nonprice restraints, specifically to a manufacturer's termination of one dealer pursuant to an exclusive territory agreement with another. We noted that especially in the vertical restraint context “departure from the rule-of-reason standard must be based on demonstrable economic effect rather than ... upon formalistic line drawing.” Id., at 53, 97 S.Ct., at 2560. We concluded that vertical nonprice restraints had not been shown to have such a “‘pernicious effect on competition’” and to be so “‘lack[ing] [in] ... redeeming value’” as to justify per se illegality. Id., at 58, 97 S.Ct., at 2561, quoting Northern Pacific R. Co. v. United States, 356 U.S. 1, 5, 78 S.Ct. 514, 518, 2 L.Ed.2d 545 (1958). Rather, we found, they had real potential to stimulate interbrand competition, “the primary concern of antitrust law,” 433 U.S., at 52, n. 19, 97 S.Ct., at 2558 n. 19:

**1520 “[N]ew manufacturers and manufacturers entering new markets can use the restrictions in order to induce competent and aggressive retailers to make the kind of investment of capital and labor that is often required in the distribution of products unknown to the consumer. Established manufacturers can use them to induce retailers *725 to engage in promotional activities or to provide service and repair facilities necessary to the efficient marketing of their products. Service and repair are vital for many products.... The availability and quality of these services affect a manufacturer's goodwill and the competitiveness of his product. Because of market imperfections such as the so-called ‘free-rider’ effect, these services might not be provided by retailers in a purely competitive situation, despite the fact that each retailer's benefit would be greater if all provided the services than if none did.” Id., at 55, 97 S.Ct., at 2560.

Moreover, we observed that a rule of per se illegality for vertical nonprice restraints was not needed or effective to protect intra brand competition. First, so long as interbrand competition existed, that would provide a “significant check” on any attempt to exploit intrabrand market power. Id., at 52, n. 19, 97 S.Ct., at 2558, n. 19; see also id., at 54, 97 S.Ct., at 2559–60. In fact, in order to meet that interbrand competition, a manufacturer's dominant incentive is to lower resale prices. Id., at 56, and n. 24, 97
108 S.Ct. 1515, 99 L.Ed.2d 808, 56 USLW 4387, 1988-1 Trade Cases P 67,982
S.Ct., at 2560, and n. 24. Second, the *per se* illegality of vertical restraints would create a perverse incentive for manufacturers to integrate vertically into distribution, an outcome hardly conducive to fostering the creation and maintenance of small businesses. *Id.*, at 57, n. 26, 97 S.Ct., at 2561, n. 6.

Finally, our opinion in *GTE Sylvania* noted a significant distinction between vertical nonprice and vertical price restraints. That is, there was support for the proposition that vertical price restraints reduce *inter* brand price competition because they “facilitate cartelizing.’ *Id.*, at 51, n. 18, 97 S.Ct., at 2558, n. 18, quoting Posner, Antitrust Policy and the Supreme Court: An Analysis of the Restricted Distribution, Horizontal Merger and Potential Competition Decisions, 75 Colum.L.Rev. 282, 294 (1975). The authorities cited by the Court suggested how vertical price agreements might assist horizontal price fixing at the manufacturer level (by reducing the manufacturer's incentive to cheat on a cartel, since its retailers could not pass on lower prices to consumers) or might be used to *726* organize cartels at the retailer level. See R. Posner, Antitrust: Cases, Economic Notes and Other Materials 134 (1974); E. Gellhorn, Antitrust Law and Economics 252, 256 (1976); Note, Vertical Territorial and Customer Restrictions in the Franchising Industry, 10 Colum.J.L. & Soc.Prob. 497, 498, n. 12 (1974). Similar support for the cartel-facilitating effect of vertical nonprice restraints was and remains lacking.

We have been solicitous to assure that the market-freeing effect of our decision in *GTE Sylvania* is not frustrated by related legal rules. In *Monsanto Co. v. Spray–Rite Service Corp.*, 465 U.S. 752, 763, 104 S.Ct. 1464, 1470, 79 L.Ed.2d 775 (1984), which addressed the evidentiary showing necessary to establish vertical concerted action, we expressed concern that “[i]f an inference of such an agreement may be drawn from highly ambiguous evidence, there is considerable danger that the doctrine enunciated in *Sylvania* ... will be seriously eroded.” See also *id.*, at 761, n. 6, 104 S.Ct., at 1469, n. 6. We eschewed adoption of an evidentiary standard that “could deter or penalize perfectly legitimate conduct” or “would create an irrational dislocation in the market” by preventing legitimate communication between a manufacturer and its distributors. *Id.*, at 763, 764, 104 S.Ct., at 1470.

Our approach to the question presented in the present case is guided by the premises of *GTE Sylvania* and *Monsanto*: that there is a presumption in favor of a rule-of-reason standard; that departure **1521** from that standard must be justified by demonstrable economic effect, such as the facilitation of cartelizing, rather than formalistic distinctions; that interbrand competition is the primary concern of the antitrust laws; and that rules in this area should be formulated with a view towards protecting the doctrine of *GTE Sylvania*. These premises lead us to conclude that the line drawn by the Fifth Circuit is the most appropriate one.

There has been no showing here that an agreement between a manufacturer and a dealer to terminate a “price cutter,” without a further agreement on the price or price levels to be charged by the remaining dealer, almost always tends *727* to restrict competition and reduce output. Any assistance to cartelizing that such an agreement might provide cannot be distinguished from the sort of minimal assistance that might be provided by vertical nonprice agreements like the exclusive territory agreement in *GTE Sylvania*, and is insufficient to justify a *per se* rule. Cartels are neither easy to form nor easy to maintain. Uncertainty over the terms of the cartel, particularly the prices to be charged in the future, obstructs both formation and adherence by making cheating easier. Cf. *Maple Flooring Mfrs. Assn. v. United States*, 268 U.S. 563, 45 S.Ct. 578, 69 L.Ed. 1093 (1925); *Cement Mfrs. Protective Assn. v. United States*, 268 U.S. 588, 45 S.Ct. 586, 69 L.Ed. 1104 (1925); see generally *Matsushita Electric Industrial Co. v. Zenith Radio Corp.*, 475 U.S. 574, 590, 106 S.Ct. 1348, 1358, 89 L.Ed.2d 538 (1986). Without an agreement with the remaining dealer on price, the manufacturer both retains its incentive to cheat on any manufacturer-level cartel (since lower prices can still be passed on to consumers) and cannot as easily be used to organize and hold together a retailer-level cartel.  

The District Court's rule on the scope of *per se* illegality for vertical restraints would threaten to dismantle the doctrine of *GTE Sylvania*. Any agreement between a manufacturer and a dealer to terminate another dealer who happens to have charged lower prices can be alleged to have been directed against the terminated dealer's “price cutting.” In the vast majority of cases, it will be extremely difficult for the manufacturer to convince a jury that its motivation was to ensure adequate services, since price cutting and *728* some measure of service cutting usually go hand in hand. Accordingly, a manufacturer that agrees to
give one dealer an exclusive territory and terminates another dealer pursuant to that agreement, or even a manufacturer that agrees with one dealer to terminate another for failure to provide contractually obligated services, exposes itself to the highly plausible claim that its real motivation was to terminate a price cutter. Moreover, even vertical restraints that do not result in dealer termination, such as the initial granting of an exclusive territory or the requirement that certain services be provided, can be attacked as designed to allow existing dealers to charge higher prices. Manufacturers would be likely to forgo legitimate and competitively useful conduct rather than risk treble damages and perhaps even criminal penalties.

We cannot avoid this difficulty by invalidating as illegal per se only those agreements imposing vertical restraints that contain the word “price,” or that affect the “prices” charged by dealers. Such formalism was explicitly rejected in GTE Sylvania. As the above discussion indicates, all vertical restraints, including the exclusive territory agreement held not to be per se illegal in GTE Sylvania, have the potential to allow dealers to increase “prices” and can be characterized as intended to achieve just that. In fact, vertical nonprice restraints only accomplish the benefits identified in GTE Sylvania because they reduce intrabrand price competition to the point where the dealer's profit margin permits provision of the desired services. As we described it in Monsanto: “The manufacturer often will want to ensure that its distributors earn sufficient profit to pay for programs such as hiring and training additional salesmen or demonstrating the technical features of the product, and will want to see that ‘free-riders’ do not interfere.” 465 U.S., at 762–763, 104 S.Ct., at 1470. See also GTE Sylvania, 433 U.S., at 55, 97 S.Ct., at 2560.

The dissent erects a much more complex analytic structure, which ultimately rests, however, upon the same discredited premise that the only function this nonprice vertical restriction can serve is restraint of dealer-level competition. Specifically, the dissent's reasoning hinges upon its perception that the agreement between Sharp and Hartwell was a “naked” restraint—that is, it was not “ancillary” to any other agreement between Sharp and Hartwell. Post, at 1526–1528, 1530–1531. But that is not true, unless one assumes, contrary to GTE Sylvania and Monsanto, and contrary to our earlier discussion, that it is not a quite plausible purpose of the restriction to enable Hartwell to provide better services under the sales franchise agreement. 3 From its faulty conclusion that what we have before us is a “naked” restraint, the dissent proceeds, by reasoning we do not entirely follow, to the further conclusion that it is therefore a horizontal rather than a vertical restraint. We pause over this only to note that in addition to producing what we think the wrong result in the present case, it introduces needless confusion into antitrust terminology. Restraints imposed by agreement between competitors have traditionally been denominated as horizontal restraints, and those imposed by agreement between firms at different levels of distribution as vertical restraints. 4

Finally, we do not agree with petitioner's contention that an agreement on the remaining dealer's price or price levels will so often follow from terminating another dealer “because of [its] price cutting” that prophylaxis against resale price maintenance warrants the District Court's per se rule. Petitioner has provided no support for the proposition that vertical price agreements generally underlie agreements to terminate a price cutter. That proposition is simply incompatible with the conclusion of GTE Sylvania and Monsanto that manufacturers are often motivated by a legitimate desire to have dealers provide services, combined with the reality that price cutting is frequently made possible by “free riding” on the services provided by other dealers. The District Court's per se rule would therefore discourage conduct recognized by GTE Sylvania and Monsanto as beneficial to consumers.

In resting our decision upon the foregoing economic analysis, we do not ignore common-law precedent concerning what constituted “restraint of trade” at the time the Sherman Act was adopted. But neither do we give that pre–1890 precedent the dispositive effect some would. The term “restraint of trade” in the statute, like the term at common law, refers not to a particular list of agreements, but to a particular economic consequence, which may be produced by quite different sorts of agreements.

B
108 S.Ct. 1515, 99 L.Ed.2d 808, 56 USLW 4387, 1988-1 Trade Cases P 67,982

in varying times and circumstances. The changing content of the term “restraint of trade” was well recognized at the time the Sherman Act was enacted. See Gibbs v. Consolidated Gas Co., 130 U.S. 396, 409, 9 S.Ct. 553, 557, 2 L.Ed. 979 (1889) (noting that English case laying down the common-law rule *732 that contracts in restraint of trade are invalid “was made under a condition of things, and a state of society, different from those which now prevail, [and therefore] the rule laid down is not regarded as inflexible, and has been considerably modified”); see also Dr. Miles Medical Co. v. John D. Park & Sons Co., 220 U.S., at 406, 31 S.Ct., at 384 (“With respect to contracts in restraint of trade, the earlier doctrine of the common law has been substantially modified in adaptation to modern conditions”); B. Cardozo, The Nature of the Judicial Process 94–96 (1921).

The Sherman Act adopted the term “restraint of trade” along with its dynamic potential. It invokes the common law itself, and not merely the static content that the common law had assigned to the term in 1890. See GTE Sylvania, 433 U.S., at 53, n. 21, 97 S.Ct., at 2559, n. 21; Standard Oil Co. v. United States, 221 U.S., at 51–60, 31 S.Ct., at 512–16; see also McNally v. United States, 483 U.S. 350, 372–373, 107 S.Ct. 2875, 2888–2889, 97 L.Ed.2d 292 (1987) (STEVENS, J., joined by O’CONNOR J., dissenting); Associated General Contractors of California, Inc. v. Carpenters, 459 U.S. 519, 533, n. 28, 539–540, and n. 43, 103 S.Ct. 897, 906, n. 28, 909, and n. 43 (1983); Bork 37. If it were otherwise, not only would the line of per se illegality have to be drawn today precisely where it was in 1890, but also case-by-case evaluation of legality (conducted where per se rules do not apply) would have to be governed by 19th-century notions of reasonableness. It would make no sense to create out of the single term “restraint of trade” a chronologically schizoid statute, in which a “rule of reason” evolves with new circumstances and new wisdom, but a line of per se illegality remains forever fixed where it was.

Of course the common law, both in general and as embodied in the Sherman Act, does not lightly assume that the economic realities underlying earlier decisions have changed, or that earlier judicial perceptions of those realities were in error. It is relevant, therefore, whether the common law of *733 restraint of trade ever prohibited as illegal per se an agreement of the sort made here, and whether our decisions under § 1 of the Sherman Act have ever expressed or necessarily implied such a prohibition.

With respect to this Court's understanding of pre-Sherman Act common law, petitioner refers to our decision in Dr. Miles Medical Co. v. John D. Park & Sons Co., supra. Though that was an early Sherman Act case, its holding that a resale price maintenance agreement was per se illegal was based largely on the perception that such an agreement was categorically impermissible at common law. Id., 220 U.S., at 404–408, 31 S.Ct., at 383–85. As the opinion made plain, however, the basis for that common-law judgment was that the resale restriction was an unlawful restraint on alienation. See ibid. As we explained in Boston Store of Chicago v. American Graphophone Co., 246 U.S. 8, 21–22, 38 S.Ct. 257, 259, 62 L.Ed. 551 (1918), “Dr. Miles ... decided that under the general law the owner of movables ... could not sell the movables and lawfully by contract fix a price at which the product should afterwards be sold, because to do so would be at one and the same time to sell and retain, to part with and yet to hold, to project the will of the seller so as to cause it to control the movable parted with when it was not subject to his will because owned by another.” In the present case, of course, no agreement on resale price or price level, and hence no restraint on alienation, was found by the jury, so the common-law rationale of Dr. Miles does not apply. Cf. United States v. General Electric Co., 272 U.S. 476, 486–488, 47 S.Ct. 192, 195–96, 71 L.Ed. 362 (1926) (Dr. Miles does not apply to restrictions on price to be charged by one who is in reality an agent of, not a buyer from, the manufacturer).

Petitioner’s principal contention has been that the District Court’s rule on per se illegality is compelled not by the old common law, but by our more recent Sherman Act precedents. First, petitioner contends that since certain horizontal agreements have been held to constitute price fixing (and *734 thus to be per se illegal) though they did not set prices or price levels, see, e.g., Catalano, Inc. v. Target Sales, Inc., 446 U.S. 643, 647–650, 100 S.Ct. 1925, 1927–29, 64 L.Ed.2d 580 (1980) (per curiam), it is improper to require that a vertical agreement set prices or price levels before it can suffer the same fate. This notion of equivalence between the scope of horizontal per se illegality and that of vertical per se illegality was explicitly rejected in GTE Sylvania, supra, 433 U.S., at 57, n. 27, 97 S.Ct., at 2561, n. 27—as it had to be, since a horizontal agreement to divide territories is per se illegal, see United States v. Topco Associates, Inc., 405 U.S. 596, 608, 92 S.Ct. 1126, 1133–34, 31 L.Ed.2d 515 (1972),
Second, petitioner contends that \textit{per se} illegality here follows from our two cases holding \textit{per se} illegal a group boycott of a dealer because of its price cutting. See \textit{United States v. General Motors Corp.}, 384 U.S. 127, 86 S.Ct. 1321, 16 L.Ed.2d 415 (1966); \textit{Klor's, Inc. v. Broadway–Hale Stores, Inc.}, 359 U.S. 207, 79 S.Ct. 705, 3 L.Ed.2d 741 (1959). This second contention is merely a restatement of the first, since both cases involved horizontal combinations—\textit{General Motors, supra}, 384 U.S., at 140, 143–145, 86 S.Ct., at 1327–28, 1329–31, at the dealer level,\textsuperscript{5} and \textit{Klor's, supra}, 359 U.S., at 213, 79 S.Ct., at 710, at the manufacturer and wholesaler levels. Accord, \textit{GTE Sylvania, supra}, at 58, n. 28; \textit{United States v. Arnold, Schwinn & Co.}, 388 U.S., at 373, 378, 87 S.Ct., at 1862, 1865; \textit{id.}, 388 U.S., at 390, 87 S.Ct., at 1871, (Stewart, J., joined by Harlan, J., concurring in part and dissenting in part); \textit{White Motor Co. v. United States, supra}, 372 U.S., at 263, 83 S.Ct., at 702.

\textsuperscript{*735} Third, petitioner contends, relying on \textit{Albrecht v. Herald Co.}, 390 U.S. 145, 88 S.Ct. 869, 19 L.Ed.2d 998 (1968), and \textit{United States v. Parke, Davis & Co.}, 362 U.S. 29, 80 S.Ct. 503, 4 L.Ed.2d 505 (1960), that our vertical price-fixing cases have already rejected the proposition that \textit{per se} illegality requires setting a price or a price level. We disagree. In \textit{Albrecht}, the maker of the product formed a combination to force a retailer to charge the maker's advertised retail price. See 390 U.S., at 149, 88 S.Ct., at 871. This combination had two aspects. Initially, the maker hired a third party to solicit customers away from the noncomplying retailer. This solicitor “was aware that the aim of the solicitation campaign was to force [the noncomplying retailer] to lower his price” to the suggested retail price. \textit{Id.}, at 150, 88 S.Ct., at 872. Next, the maker engaged another retailer who “undertook to deliver [products] at the suggested price” to the noncomplying retailer's customers obtained by the solicitor. \textit{Ibid.} This combination of maker, solicitor, and new retailer was held to be \textit{per se} illegal. \textit{Id.}, at 150, 153, 88 S.Ct., at 872, 873. It is plain that the combination involved both an explicit agreement on resale price and an agreement to force another to adhere to the specified price.

In \textit{Parke, Davis}, a manufacturer combined first with wholesalers and then with retailers in order to gain the “retailers' adherence to its suggested minimum retail prices.” 362 U.S., at 45–46, and n. 6, 80 S.Ct., at 512–13 and n. 6. The manufacturer also brokered an agreement among its retailers not to advertise prices below its suggested retail prices, which agreement was held to be part of the \textit{per se} illegal combination. This holding also does not support a rule that an agreement on price or price level is not required for a vertical restraint to be \textit{per se} illegal—first, because the agreement not to advertise prices was part and parcel of the combination that contained the price agreement, \textit{id.}, at 35–36, 80 S.Ct., at 507, and second because the agreement among retailers that the manufacturer organized was a \textit{horizontal} conspiracy among competitors. \textit{Id.}, at 46–47, 80 S.Ct., at 513.

In sum, economic analysis supports the view, and no precedent opposes it, that a vertical restraint is not illegal \textit{per se} \textsuperscript{*736} unless it includes some agreement on price or price levels. Accordingly, the judgment of the Fifth Circuit is

\textit{Affirmed}.

Justice KENNEDY took no part in the consideration or decision of this case.

\textsuperscript{**1526} Justice STEVENS, with whom Justice WHITE joins, dissenting.

In its opinion the majority assumes, without analysis, that the question presented by this case concerns the legality of a “vertical nonprice restraint.” As I shall demonstrate, the restraint that results when one or more dealers threaten to boycott a manufacturer unless it terminates its relationship with a price-cutting retailer is more properly viewed as a “horizontal restraint.” Moreover,

108 S.Ct. 1515, 99 L.Ed.2d 808, 56 USLW 4387, 1988-1 Trade Cases P 67,982

An agreement to terminate a dealer because of its price cutting is most certainly not a “nonprice restraint.” The distinction between “vertical nonprice restraints” and “vertical price restraints,” on which the majority focuses its attention, is therefore quite irrelevant to the outcome of this case. Of much greater importance is the distinction between “naked restraints” and “ancillary restraints” that has been a part of our law since the landmark opinion written by Judge (later Chief Justice) Taft in United States v. Addyston Pipe & Steel Co., 85 F. 271 (CA6 1898), aff’d, 175 U.S. 211, 20 S.Ct. 96, 44 L.Ed. 136 (1899).

I

The plain language of § 1 of the Sherman Act prohibits “every” contract that restrains trade. Because such a literal reading of the statute would outlaw the entire body of private contract law, and because Congress plainly intended *737 the Act to be interpreted in the light of its common-law background, the Court has long held that certain “ancillary” restraints of trade may be defended as reasonable. As we recently explained without dissent:

“The Rule of Reason suggested by Mitchel v. Reynolds [1 P. Wms. 181, 24 Eng.Rep. 347 (1711) ] has been regarded as a standard for testing the enforceability of covenants in restraint of trade which are ancillary to a legitimate transaction, such as an employment contract or the sale of a going business. Judge (later Mr. Chief Justice) Taft so interpreted the Rule in his classic rejection of the argument that competitors may lawfully agree to sell their goods at the same price as long as the agreed-upon price is reasonable. United States v. Addyston Pipe & Steel Co....” National Society of Professional Engineers v. United States, 435 U.S. 679, 689, 98 S.Ct. 1355, 1364, 55 L.Ed.2d 637 (1978).

Judge Taft’s rejection of an argument that a price-fixing agreement could be defended as reasonable was based on a detailed examination of common-law precedents. He explained in England there had been two types of objection to voluntary restraints on one’s ability to transact business. “One was that by such contracts a man disabled himself from earning a livelihood with the risk of becoming a public charge, and deprived the community of the benefit of his labor. The other was that such restraints tended to give to the covenantee, the beneficiary of such restraints, a monopoly of the trade, from which he had thus excluded one competitor, and by the same means might exclude others.” 85 F., at 279. Certain contracts, however, such as covenants not to compete in a particular business, for a certain period of time, within a defined geographical area, had always been considered reasonable when necessary to carry out otherwise procompetitive contracts, such as the sale of a business. Id., at 280–282. The difference between ancillary covenants that *738 may be justified as reasonable and those that are “void” because there is “nothing to justify or excuse the restraint,” id., at 282–283, was described in the opinion’s seminal discussion:

“[T]he contract must be one in which there is a main purpose, to which the **1527 covenant in restraint of trade is merely ancillary. The covenant is inserted only to protect one of the parties from the injury which, in the execution of the contract or enjoyment of its fruits, he may suffer from the unrestrained competition of the other. The main purpose of the contract suggests the measure of protection needed, and furnishes a sufficiently uniform standard by which the validity of such restraints may be judicially determined. In such a case, if the restraint exceeds the necessity presented by the main purpose of the contract, it is void for two reasons: First, because it oppresses the covenator, without any corresponding benefit to the covenantee; and, second, because it tends to a monopoly. But where the sole object of both parties in making the contract as expressed therein is merely to restrain competition, and enhance or maintain prices, it would seem that there was nothing to justify or excuse the restraint, that it would necessarily have a tendency to monopoly, and therefore would be void. In such a case there is no measure of what is necessary to the protection of either party, except the vague and varying opinion of judges as to how much, on principles of political economy, men ought to be allowed to restrain competition. There is in such contracts no main lawful purpose, to subserve which partial restraint is permitted, and by which its reasonableness is measured, but the sole object is to restrain trade in order to avoid the competition which it has always been the policy of the common law to foster.” Ibid.
Although Judge Taft was writing as a Circuit Judge, his opinion is universally accepted as authoritative. We affirmed his decision without dissent, we have repeatedly cited it with approval, and it is praised by a respected scholar as “one of the greatest, if not the greatest, antitrust opinions in the history of the law.” R. Bork, The Antitrust Paradox 26 (1978). In accordance with the teaching in that opinion, it is therefore appropriate to look more closely at the character of the restraint of trade found by the jury in this case.

II

It may be helpful to begin by explaining why the agreement in this case does not fit into certain categories of agreement that are frequently found in antitrust litigation. First, despite the contrary implications in the majority opinion, this is not a case in which the manufacturer is alleged to have imposed any vertical nonprice restraints on any of its dealers. The term “vertical nonprice restraint,” as used in Continental T.V., Inc. v. GTE Sylvania Inc., 433 U.S. 36, 97 S.Ct. 2549, 53 L.Ed.2d 568 (1977), and similar cases, refers to a contractual term that a dealer must accept in order to qualify for a franchise. Typically, the dealer must agree to meet certain standards in its advertising, promotion, product display, and provision of repair and maintenance services in order to protect the goodwill of the manufacturer's product. Sometimes a dealer must agree to sell only to certain classes of customers—for example, wholesalers generally may only sell to retailers and may be required not to sell directly to consumers. In Sylvania, to take another example, we examined agreements between a manufacturer and its dealers that included “provisions barring the retailers from selling franchised products from locations other than those specified in agreements.” Id., 433 U.S., at 37, 97 S.Ct., at 2551. Restrictions of that kind, which are a part of, or ancillary to, the basic franchise agreement, are perfectly lawful unless the “rule of reason” is violated. Although vertical nonprice restraints may have some adverse effect on competition, as long as they serve the main purpose of a procompetitive distribution agreement, the ancillary restraints may be defended under the rule of reason. And, of course, a dealer who violates such a restraint may properly be terminated by the manufacturer.

In this case, it does not appear that respondent imposed any vertical nonprice restraints upon either petitioner or Hartwell. Specifically, respondent did not enter into any “exclusive” agreement, as did the defendant in Sylvania. It is true that before Hartwell was appointed and after petitioner was terminated, the manufacturer was represented by only one retailer in the Houston market, but there is no evidence that respondent ever made any contractual commitment to give either of them any exclusive rights. This therefore is not a case in which a manufacturer's right to grant exclusive territories, or to change the identity of the dealer in an established exclusive territory, is implicated. The case is one in which one of two competing dealers entered into an agreement with the manufacturer to terminate a particular competitor without making any promise to provide better or more efficient services and without receiving any guarantee of exclusivity in the future. The contractual relationship between respondent and Hartwell was exactly the same after petitioner's termination as it had been before that termination.

Second, this case does not involve a typical vertical price restraint. As the Court of Appeals noted, there is some evidence in the record that may support the conclusion that respondent and Hartwell implicitly agreed that Hartwell's prices would be maintained at a level somewhat higher than petitioner had been charging before petitioner was terminated. 780 F.2d 1212, 1219 (CA5 1986). The illegality of the agreement found by the jury does not, however, depend on such evidence. For purposes of analysis, we should assume that no such agreement existed and that respondent was perfectly willing to allow its dealers to set prices at levels that would maximize their profits. That seems to have been the situation during the period when petitioner was the only dealer in Houston. Moreover, after respondent appointed Hartwell as its second dealer, it was Hartwell, rather than respondent, who objected to petitioner's pricing policies.

Third, this is not a case in which the manufacturer acted independently. Indeed, given the jury's verdict, it is not even a case in which the termination can be explained as having been based on the violation of any distribution policy adopted by respondent.
The termination was motivated by the ultimatum that respondent received from Hartwell and that ultimatum, in turn, was the culmination of Hartwell's complaints about petitioner's competitive price cutting. The termination was plainly the product of coercion by the stronger of two dealers rather than an attempt to maintain an orderly and efficient system of distribution. ⁴

*742 **1529 In sum, this case does not involve the reasonableness of any vertical restraint imposed on one or more dealers by a manufacturer in its basic franchise agreement. What the jury found was a simple and naked “‘agreement between Sharp and Hartwell to terminate Business Electronics because of Business Electronics' price cutting.’” Ante, at 1518.

III

Because naked agreements to restrain the trade of third parties are seldom identified with such stark clarity as in this case, there appears to be no exact precedent that determines the outcome here. There are, however, perfectly clear rules that would be decisive if the facts were changed only slightly.

Thus, on the one hand, if it were clear that respondent had acted independently and decided to terminate petitioner because respondent, for reasons of its own, objected to petitioner's pricing policies, the termination would be lawful. See United States v. Parke, Davis & Co., 362 U.S. 29, 43–45, 80 S.Ct. 503, 511–12, 4 L.Ed.2d 505 (1960). On the other hand, it is equally clear that if respondent had been represented by three dealers in the Houston market instead of only two, and if two of them had threatened to terminate their dealerships “unless respondent ended its relationship with petitioner within 30 days,” ante, at 1518, an agreement to comply with the ultimatum would be an obvious violation of the Sherman Act. See, e.g., United States v. General Motors Corp., 384 U.S. 127, 86 S.Ct. 1321, 16 L.Ed.2d 415 (1966); Klor's, Inc. v. Broadway–Hale Stores, Inc., 359 U.S. 207, 79 S.Ct. 705, 3 L.Ed.2d 741 (1959). ⁵ The *743 question then is whether the two-party agreement involved in this case is more like an illegal three-party agreement or a legal independent decision. For me, the answer is plain.

The distinction between independent action and joint action is fundamental in antitrust jurisprudence. ⁶ Any attempt *744 to define **1530 the boundaries of per se illegality by the number of parties to different agreements with the same anticompetitive consequences can only breed uncertainty in the law and confusion for the businessman.

More importantly, if instead of speculating about irrelevant vertical nonprice restraints, we focus on the precise character of the agreement before us, we can readily identify its anticompetitive nature. Before the agreement was made, there was price competition in the Houston retail market for respondent's products. The stronger of the two competitors was unhappy about that competition; it wanted to have the power to set the price level in the market and therefore it “complained to respondent on a number of occasions about petitioner's prices.” Ante, at 1518. Quite obviously, if petitioner had agreed with either Hartwell or respondent to discontinue its competitive pricing, there would have been no ultimatum from Hartwell and no termination by respondent. It is equally obvious that either of those agreements would have been illegal per se. ⁷ Moreover, it is also reasonable to assume that if respondent were to replace petitioner with another price-cutting dealer, there would soon be more complaints and another ultimatum from Hartwell. Although respondent has not granted Hartwell an exclusive dealership—it retains the right to appoint multiple dealers—its *745 agreement has protected Hartwell from price competition. Indeed, given the jury's finding and the evidence in the record, that is the sole function of the agreement found by the jury in this case. It therefore fits squarely within the category of “naked restraints of trade with no purpose except stifling of competition.” White Motor Co. v. United States, 372 U.S. 253, 263, 83 S.Ct. 696, 702, 9 L.Ed.2d 738 (1963).

This is the sort of agreement that scholars readily characterize as “inherently suspect.” ⁸ When a manufacturer responds to coercion from a dealer, instead of making an independent decision to enforce a predetermined distribution policy, the
anticompetitive character of the response is evident. 9 As Professor Areeda has correctly noted, the fact that the agreement is between only one complaining dealer and the manufacturer does not prevent it from imposing a “horizontal” restraint. 10 If two critical facts are present—a *746 naked purpose **1531 to eliminate price competition as such and coercion of the manufacturer 11—the conflict with antitrust policy is manifest. 12

*747 Indeed, since the economic consequences of Hartwell's ultimatum to respondent are identical to those that would result from a comparable ultimatum by two of three dealers in a market—and since a two-party price-fixing agreement is just as unlawful as a three-party price-fixing agreement **1532—it is appropriate to employ the term “boycott” to characterize this agreement. In my judgment the case is therefore controlled by our decision in United States v. General Motors Corp., 384 U.S. 127, 86 S.Ct. 1321, 16 L.Ed.2d 415 (1966).

The majority disposes quickly of both General Motors and Klor's, Inc. v. Broadway–Hale Stores, Inc., 359 U.S. 207, 79 S.Ct. 705, 3 L.Ed.2d 741 (1959), by concluding that “both cases involved horizontal combinations.” Ante, at 1525. But this distinction plainly will *748 not suffice. In General Motors, a group of Chevrolet dealers conspired with General Motors to eliminate sales from the manufacturer to discounting dealers. We held that “[e]limination, by joint collaborative action, of discounters from access to the market is a per se violation of the Act,” 384 U.S., at 145, 86 S.Ct., at 1330, and explained that “inherent in the success of the combination in this case was a substantial restraint upon price competition—a goal unlawful per se when sought to be effected by combination or conspiracy.” Id., at 147, 86 S.Ct., at 1331. Precisely the same goal was sought and effected in this case—the elimination of price competition at the dealer level. Moreover, the method of achieving that goal was precisely the same in both cases—the manufacturer's refusal to sell to discounting dealers. The difference between the two cases is not a difference between horizontal and vertical agreements—in both cases the critical agreement was between market actors at the retail level on the one hand and the manufacturer level on the other. Rather, the difference is simply a difference in the number of conspirators. Hartwell's coercion of respondent in order to eliminate petitioner because of its same-level price competition is not different in kind from the Chevrolet dealers' coercion of General Motors in order to eliminate other, price-cutting dealers; the only difference between the two cases—one dealer seeking a naked price-based restraint in today's case, many dealers seeking the same end in General Motors—is merely a difference in degree. Both boycotts lack any efficiency justification—they are simply naked restraints on price competition, rather than integral, or ancillary, parts of the manufacturers' predetermined distribution policies.

IV

What is most troubling about the majority's opinion is its failure to attach any weight to the value of intrabrand competition. In *749 Continental T.V., Inc. v. GTE Sylvania Inc., 433 U.S. 36, 97 S.Ct. 2549, 53 L.Ed.2d 568 (1977), we correctly held that a demonstrable benefit to interbrand competition will outweigh the harm to intrabrand competition that is caused by the imposition of vertical nonprice restrictions on dealers. But we also expressly reaffirmed earlier cases in which the illegal conspiracy affected only intrabrand competition. 13 Not a word in the Sylvania opinion implied that the elimination of intrabrand competition could be justified as reasonable without any evidence of a purpose to improve interbrand competition.

In the case before us today, the relevant economic market was the sale at retail in the Houston area of calculators manufactured by respondent. 14 There is no dispute **1533 that an agreement *750 to fix prices in that market, either horizontally between petitioner and Hartwell or vertically between respondent and either or both of the two dealers, would violate the Sherman Act. The “quite plausible” assumption, see ante, at 1522, that such an agreement might enable the retailers to provide better services to their customers would not have avoided the strict rule against price fixing that this Court has consistently enforced in the past.
*751 Under petitioner's theory of the case, an agreement between respondent and Hartwell to terminate petitioner because of its price cutting was just as indefensible as any of those price-fixing agreements. At trial the jury found the existence of such an agreement to eliminate petitioner's price competition. Respondent had denied that any agreement had been made and asked the jury to find that it had independently decided to terminate petitioner because of its poor sales performance, but after hearing several days of testimony, the jury concluded that this defense was pretextual.

Neither the Court of Appeals nor the majority questions the accuracy of the jury's resolution of the factual issues in this case. Nevertheless, the rule the majority fashions today is based largely on its concern that in other cases juries will be unable to tell the difference between truthful and pretextual defenses. Thus, it opines that "even a manufacturer that agrees with one dealer to terminate another for failure to provide contractually obligated services, exposes itself to the highly plausible claim that its real motivation was to terminate a price cutter." Ante, at 9. But such a "plausible" concern in a hypothetical case that is so different from this one should not be given greater weight than facts that can be established by hard evidence. If a dealer has, in fact, failed to provide contractually obligated services, and if the manufacturer has, in fact, terminated the dealer for that reason, both of those objective facts should be provable by admissible evidence. Both in its disposition of this case and in its attempt to justify a new approach to agreements to eliminate price competition, the majority exhibits little confidence in the judicial process as a means of ascertaining the truth.

*753 The majority fails to consider that manufacturers such as respondent will only be held liable in the rare case in which the following can be proved: First, the terminated dealer must overcome the high hurdle of Monsanto Co. v. Spray–Rite Service Corp., 465 U.S. 752, 104 S.Ct. 1464, 79 L.Ed.2d 775 (1984). A terminated dealer must introduce "evidence that tends to exclude the possibility that the manufacturer and nonterminated distributors were acting independently." Id., at 764, 104 S.Ct., at 1471. Requiring judges to adhere to the strict test for agreement laid down in Monsanto, in their jury instructions or own findings of fact, goes a long way toward ensuring that many legitimate dealer termination decisions do not succumb improperly to antitrust liability.

**1535 Second, the terminated dealer must prove that the agreement was based on a purpose to terminate it because of its price cutting. Proof of motivation is another commonplace in antitrust litigation of which the majority appears apprehensive, but as we have explained or demonstrated many times, see, e.g., Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585, 610–611, 105 S.Ct. 2847, 2861–62, 86 L.Ed.2d 467 (1985); McLain v. Real Estate Board of New Orleans, Inc., 444 U.S. 232, 243, 100 S.Ct. 502, 509–510, 62 L.Ed.2d 441 (1980); United States v. Socony–Vacuum Oil Co., 310 U.S. 150, 224–226, n. 59, 60 S.Ct. 811, 845–46, n. 59 (1940); Chicago Board of Trade v. United States, 246 U.S. 231, 238, 38 S.Ct. 242, 62 L.Ed. 683 (1918); see also Piraino, The Case for Presuming the Legality of Quality Motivated Restrictions on Distribution, 63 Notre Dame L.Rev. 1, 4, 16–19 (1988), in antitrust, as in many other areas of the law, motivation matters and factfinders are able to distinguish bad from good intent.

Third, the manufacturer may rebut the evidence tending to prove that the sole purpose of the agreement was to eliminate a price cutter by offering evidence that it entered the agreement for legitimate, nonprice-related reasons.

Although in this case the jury found a naked agreement to terminate a dealer because of its price cutting, ante, at 1518–1519, the majority boldly characterizes the same agreement as "this nonprice vertical restriction." Ante, at 1522. That characterization is surely an oxymoron when applied to the agreement the jury actually found. Nevertheless, the majority proceeds to justify it as "ancillary" to a "quite plausible purpose ... to enable Hartwell to provide better services under the sales franchise agreement." Ibid. There are two significant reasons why that justification is unacceptable.

First, it is not supported by the jury's verdict. Although it did not do so with precision, the District Court did instruct the jury that in order to hold respondent liable it had to find that the agreement's purpose was to eliminate petitioner because of its
price cutting and that no valid vertical nonprice restriction existed to which the motivation to eliminate price competition at the dealership level was merely ancillary. 19

**755** **1536** Second, the “quite plausible purpose” the majority hypothesizes as salvation for the otherwise anticompetitive elimination of price competition—“to enable Hartwell to provide better services under the sales franchise agreement,” *ibid.* is simply not the type of concern we sought to protect in *Continental T.V. Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 97 S.Ct. 2549, 53 L.Ed.2d 568 (1977). I have emphasized in this dissent the difference between restrictions imposed in pursuit of a manufacturer’s structuring of its product distribution, and those imposed at the behest of retailers who care less about the general efficiency of a product’s promotion than their own profit margins. *Sylvania* stressed the importance of the former, not the latter; we referred to the use that manufacturers can *756 make of vertical nonprice restraints, see *id.*, at 54–57, 97 S.Ct., at 2559–61, and nowhere did we discuss the benefits of permitting dealers to structure intrabrand competition at the retail level by coercing manufacturers into essentially anticompetitive agreements. Thus, while Hartwell may indeed be able to provide better services under the sales franchise agreement with petitioner out of the way, one would not have thought, until today, that the mere possibility of such a result—at the expense of the elimination of price competition and absent the salutary overlay of a manufacturer’s distribution decision with the entire product line in mind—would be sufficient to legitimate an otherwise purely anticompetitive restraint. See n. 14, *supra*. In fact, given the majority’s total reliance on “economic analysis,” see *ante*, at 1525, it is hard to understand why, if such a purpose were sufficient to avoid the application of a *per se* rule in this context, the same purpose should not also be sufficient to trump the *per se* rule in all other price-fixing cases that arguably permit cartel members to “provide better services.”

If, however, we continue to accept the premise that competition in the relevant market is worthy of legal protection—that we should not rely on competitive pressures exerted by sellers in other areas and purveyors of similar but not identical products—and if we are faithful to the competitive philosophy that has animated our antitrust jurisprudence since Judge Taft’s opinion in *Addyston Pipe*, we can agree that the elimination of price competition will produce wider gross profit margins for retailers, but we may not assume that the retailer’s self-interest will result in a better marketplace for consumers.

“The Sherman Act reflects a legislative judgment that ultimately competition will produce not only lower prices, but also better goods and services. ‘The heart of our national economic policy long has been faith in the value of competition.’ *Standard Oil Co. v. FTC*, 340 U.S. 231, 248, 71 S.Ct. 240, 249, 95 L.Ed. 239. The assumption that competition is the best *757 method of allocating resources in a free market recognizes that all elements of a bargain—quality, service, safety, and durability—and not just the immediate cost, are favorably affected by the free opportunity to select among alternative offers. Even assuming occasional exceptions to the presumed consequences of competition, the statutory policy precludes inquiry into the question whether competition is good or bad.” *National Society of Professional Engineers v. United States*, 435 U.S., at 695, 98 S.Ct., at 1367.

The “plausible purpose” posited by the majority as its sole justification for this mischaracterized “nonprice vertical restriction” is inconsistent with the legislative judgment that underlies the Sherman Act itself. Under the facts as found by the jury in this case, the agreement before us is one whose “sole object is to restrain trade in order to avoid the competition *1537 which it has always been the policy of the common law to foster.” *United States v. Addyston Pipe & Steel Co.*, 85 F., at 283.

**V**

In sum, this simply is not a case in which procompetitive vertical nonprice restraints have been imposed; in fact, it is not a case in which *any* procompetitive agreement is at issue. 20 The sole purpose of the agreement between respondent *758* and Hartwell was to eliminate price competition at Hartwell’s level. As Judge Bork has aptly explained:
“Since the naked boycott is a form of predatory behavior, there is little doubt that it should be a per se violation of the Sherman Act.” Bork, The Antitrust Paradox, at 334.

I respectfully dissent.

All Citations

Footnotes

* The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See United States v. Detroit Lumber Co., 200 U.S. 321, 337, 26 S.Ct. 282, 287, 50 L.Ed. 499.


2 The dissent's principal fear appears to be not cartelization at either level, but Hartwell's assertion of dominant retail power. This fear does not possibly justify adopting a rule of per se illegality. Retail market power is rare, because of the usual presence of interbrand competition and other dealers, see Continental T.V., Inc. v. GTE Sylvania Inc., 433 U.S. 36, 54, 97 S.Ct. 2549, 2559–60, 53 L.Ed.2d 568 (1977), and it should therefore not be assumed but rather must be proved. Cf. Baxter, The Viability of Vertical Restraints Doctrine, 75 Calif.L.Rev. 933, 948–949 (1987). Of course this case was not prosecuted on the theory, and therefore the jury was not asked to find, that Hartwell possessed such market power.

3 The conclusion of “naked” restraint could also be sustained on another assumption, namely, that an agreement is not “ancillary” unless it is designed to enforce a contractual obligation of one of the parties to the contract. The dissent appears to accept this assumption. See post, at 1527–1528, and n. 3, 1530–1531. It is plainly wrong. The classic “ancillary” restraint is an agreement by the seller of a business not to compete within the market. See Mitchell v. Reynolds, 1 P. Wms. 181, 24 Eng.Rep. 347 (1711); Restatement (Second) of Contracts § 188(2)(a) (1981). That is not ancillary to any other contractual obligation, but, like the restraint here, merely enhances the value of the contract, or permits the “enjoyment of [its] fruits.” United States v. Addyston Pipe & Steel Co., 85 F. 271, 282 (CA6 1898), aff'd, 175 U.S. 211, 20 S.Ct. 96, 44 L.Ed. 136 (1899); cf. Restatement (Second) of Contracts §§ 187, 188 (1981) (restraint may be ancillary to a “transaction or relationship ”) (emphasis added); R. Bork, The Antitrust Paradox 29 (1978) (hereinafter Bork) (vertical arrangements are ancillary to the “transaction of supplying and purchasing”).

More important than the erroneousness of the dissent's common-law analysis of “naked” and “ancillary” restraints are the perverse economic consequences of permitting nonprice vertical restraints to avoid per se invalidity only through attachment to an express contractual obligation. Such an approach is contrary to the express views of the principal scholar on whom the dissent relies. See 7 P. Areeda, Antitrust Law § 1457c, p. 170 (1986) (hereinafter Areeda) (legality of terminating price cutter should not depend upon formal adoption of service obligations that termination is assertedly
designed to protect). In the precise case of a vertical agreement to terminate other dealers, for example, there is no conceivable reason why the existence of an exclusivity commitment by the manufacturer to the one remaining dealer would render anticompetitive effects less likely, or the procompetitive effects on services more likely—so that the dissent's line for per se illegality fails to meet the requirement of Continental T.V., Inc. v. GTE Sylvania Inc., supra, 433 U.S., at 59, 97 S.Ct., at 2562, that it be based on “demonstrable economic effect.” If anything, the economic effect of the dissent's approach is perverse, encouraging manufacturers to agree to otherwise inefficient contractual provisions for the sole purpose of attaching to them efficient nonprice vertical restraints which, only by reason of such attachment, can avoid per se invalidity as “naked” restraints. The dissent's approach would therefore create precisely the kind of “irrational dislocation in the market” that legal rules in this area should be designed to avoid. Monsanto Co. v. Spray–Rite Service Corp., 465 U.S. 752, 764, 104 S.Ct. 1464, 1470–71, 79 L.Ed.2d 775 (1984).

4 The dissent apparently believes that whether a restraint is horizontal depends upon whether its anticompetitive effects are horizontal, and not upon whether it is the product of a horizontal agreement. Post, at 1530–1531, and n. 10. That is of course a conceivable way of talking, but if it were the language of antitrust analysis there would be no such thing as an unlawful vertical restraint, since all anticompetitive effects are by definition horizontal effects. The dissent quotes a statement of Professor Areeda as supposed adoption of its definition of horizontal restraint. Post, at 1530, n. 10, quoting Areeda § 1457d, p. 174. That statement seems to us to be, to the contrary, Professor Areeda's attempt to explain a peculiar usage of the term “horizontal” in Cernuto, Inc. v. United Cabinet Corp., 595 F.2d, at 168, noting that (even though Cernuto did not involve a horizontal restraint) the use of the term “horizontal” was “appropriate to capture the fact that dealer interests opposed to those of the manufacturer were being served.” Areeda § 1457d, p. 174. The dissent also seeks to associate Judge Bork with its terminological confusion. See post, at 1531, n. 10, quoting Bork 288. What the quoted passage says, however, is that a facially vertical restraint imposed by a manufacturer only because it has been coerced by a “horizontal carte[I]” agreement among his distributors is in reality a horizontal restraint. That says precisely what we say: that a restraint is horizontal not because it has horizontal effects, but because it is the product of a horizontal agreement.

5 Contrary to the dissent, post, at 1529, 1531, General Motors does not differ from the present case merely in that it involved a three-party rather than a two-party agreement. The agreement was among competitors in General Motors; it was between noncompetitors here. Cf. Bork 330 (defining “boycotts” as “agreements among competitors to refuse to deal”).

1 Section 1 of the Sherman Act, as set forth in 15 U.S.C. § 1, provides:

“Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal.”


3 Thus, in Morrison v. Murray Biscuit Co., 797 F.2d 1430 (CA7 1986), cited ante, at 1526, n. 1, the plaintiff had been terminated because he violated a lawful restriction on the customers to whom he could sell. As the court correctly explained:
“As long as the supplier's motive is not to keep his established dealers' prices up but only to maintain his system of lawful nonprice restrictions, he can terminate noncomplying dealers without fear of antitrust liability even if he learns about the violation from dealers whose principal or perhaps only concern is with protecting their prices.” 797 F.2d, at 1440.

There was no such justification for the termination in this case.

4 “When a manufacturer acts on its own, in pursuing its own market strategy, it is seeking to compete with other manufacturers by imposing what may be defended as reasonable vertical restraints. This would appear to be the rationale of the GTE Sylvania decision. However, if the action of a manufacturer or other supplier is taken at the direction of its customer, the restraint becomes primarily horizontal in nature in that one customer is seeking to suppress its competition by utilizing the power of a common supplier. Therefore, although the termination in such a situation is, itself, a vertical restraint, the desired impact is horizontal and on the dealer, not the manufacturer, level.” Cernuto, Inc. v. United Cabinet Corp., 595 F.2d 164, 168 (CA3 1979).

5 Thus, a boycott “is not to be tolerated merely because the victim is just one merchant whose business is so small that his destruction makes little difference to the economy. Monopoly can as surely thrive by the elimination of such small businessmen, one at a time, as it can by driving them out in large groups.” Klor's, Inc. v. Broadway–Hale Stores, Inc., 359 U.S., at 213, 79 S.Ct., at 710 (footnote omitted). Again, Judge Adams' analysis in the Cernuto opinion, n. 4, supra, is relevant:

“The importance of the horizontal nature of this arrangement is illustrated by United States v. General Motors Corp., 384 U.S. 127, 86 S.Ct. 1321, 16 L.Ed.2d 415 ... (1966). Although General Motors, the manufacturer, was seemingly imposing vertical restraints when it pressured recalcitrant automobile dealers not to deal with discounters, the Supreme Court noted that in fact these restraints were induced by the dealers seeking to choke off aggressive competitors at their level, and found a per se violation, rejecting the suggestion that only unilateral restraints were at issue. So here, if [the manufacturer and the sales representative acted at the nonterminated dealer's] direction, both the purpose and effect of the termination was to eliminate competition at the retail level, and not, as in GTE Sylvania, to promote competition at the manufacturer level. Accordingly, the pro-competitive redeeming virtues so critical in GTE Sylvania may not be present here.” 595 F.2d, at 168 (footnote omitted).

As we said in General Motors:

“The protection of price competition from conspiratorial restraint is an object of special solicitude under the antitrust laws. We cannot respect that solicitude by closing our eyes to the effect upon price competition of the removal from the market, by combination or conspiracy, of a class of traders. Nor do we propose to construe the Sherman Act to prohibit conspiracies to fix prices at which competitors may sell, but to allow conspiracies or combinations to put competitors out of business entirely.” 384 U.S., at 148, 86 S.Ct., at 1332.

6 See United States v. Colgate & Co., 250 U.S. 300, 307–308, 39 S.Ct. 465, 468, 63 L.Ed. 992 (1919). In Monsanto Co. v. Spray–Rite Service Corp., 465 U.S. 752, 761, 104 S.Ct. 1464, 1469, 79 L.Ed.2d 775 (1984), we noted that “the basic distinction between concerted and independent action” was “not always clearly drawn by parties and courts.” In its opinion today the majority virtually ignores that basic distinction. Thus, ante, at 1521, the majority discusses the manufacturer's risks arising out of its agreement “with one dealer to terminate another for failure to provide contractually obligated services.” But if such a breach of contract has occurred, the manufacturer should have an independent motivation for acting and need not enter into any agreement with a dealer to do so. As we held in Monsanto, the mere fact that the breach of contract may have been called to the manufacturer's attention by another dealer does not make the manufacturer's independent decision to terminate a price-cutting dealer unlawful.
“We have not wavered in our enforcement of the per se rule against price fixing.” Arizona v. Maricopa County Medical Society, 457 U.S., at 347, 102 S.Ct., at 2475. Thus, in Dr. Miles Medical Co. v. John D. Park & Sons Co., 220 U.S. 373, 31 S.Ct. 376, 55 L.Ed. 502 (1911), the Court determined that vertical price fixing is per se invalid because resale price maintenance plans serve the profit motives of the dealers, not the manufacturers, and are thereby similar to plans pursuant to which the dealers themselves conspire to fix prices. Id., at 407–408, 31 S.Ct. at 384. There is no doubt that horizontal intrabrand price fixing is per se illegal, even if the conspirators lack the market power to affect interbrand competition in a manner that would violate the rule of reason.

“[S]cenarios that involve a firm or firms at one level of activity using vertical restraints deliberately to confer market power on firms at an adjacent level are inherently suspect. To do so is, typically, to inflict self-injury, just as it would be for consumers to confer market power on the retailers from whom they buy.” Baxter, The Viability of Vertical Restraints Doctrine, 75 Calif.L.Rev. 933, 938 (1987).

“Termination responses reflecting the manufacturer's own distribution policy differ greatly from those imposed upon him by a complaining dealer. In the latter case, the manufacturer's compliance with the complainer's demand is more likely to be anticompetitive. There is a superficial resemblance to Parke Davis in that three parties are involved, but my earlier analysis suggested that the key to that case was ‘complex enforcement,’ which is absent where a complaining dealer simply threatens to abandon the manufacturer who continues selling to discounting dealers.” 7 P. Areeda, Antitrust Law § 1457, p. 166 (1986).

Commenting on Judge Adams' opinion in Cernuto, see nn. 4 and 5, supra, Professor Areeda wrote:

“That the complainer was a single firm did not weaken the ‘horizontal’ characterization. Because the elimination of price competition was the purpose of the complaint and the termination, the court declared that per se illegality would be appropriate. However, the court made clear that no illegal agreement would be found if United was implementing its own unilaterally chosen distribution policy. Thus, the court's implicit theory was that an agreement arose when the manufacturer bowed to the complainer's will. In that situation, the ‘horizontal’ characterization is appropriate to capture the fact that dealer interests opposed to those of the manufacturer were being served.” Areeda, supra, at 174 (footnotes omitted).

See also R. Bork, The Antitrust Paradox 288 (1978):

“A restraint—whether on price, territory, or any other term—is vertical, according to the usage employed here, when a firm operating at one level of an industry places restraints upon rivalry at another level for its own benefit. (This definition excludes restraints, vertical in form only, that are actually imposed by horizontal cartels at any level of the industry, e.g., resale price maintenance that is compelled not by the manufacturer but by the pressure of organized retailers.)”

The two critical facts that had not yet been determined by a jury in the Cernuto case are perfectly plain in this case. As Professor Areeda explained:

“The Cernuto case was decided on summary judgment which accepted the plaintiff's view of the facts. But two facts critical for the court will often be obscure. First, was it the manufacturer's purpose to eliminate price competition as such? Let us assume that termination was not based on such completely independent grounds as non-payment of bills. Even so, the existence of an inevitable price effect does not establish a purpose to control prices in a forbidden way. A purpose to facilitate point-of-sale services or to protect minimum economies of scale could induce a manufacturer to
limit intrabrand competition. Notwithstanding price effects, such limitations are lawful when reasonable and not subject to automatic condemnation. Indeed, termination of one dealer in order to grant another exclusive distribution rights in an area is generally lawful. Nevertheless, so long as the manufacturer is not implementing his own interest but that of the complainant, the vice of eliminating “horizontal” competition with the complainant's rivals seems equally present when the complainant thereby succeeds in eliminating horizontal competition with respect to customers or territories. Second, was the manufacturer coerced or was he indulging his own preferences? As we have seen, this question cannot be answered in the abstract. The court correctly acknowledged that the manufacturer might also be implementing his own unilateral vision of optimal distribution without regard to the complainant's desires and held that no illegal agreement would arise if that were the case.” Areeda, supra, at 174–175 (footnotes omitted).

“Let us defer for the moment problems of proof and assume that a manufacturer does not wish to terminate the plaintiff dealer but does so to placate the complaining dealer, who would otherwise cease handling the product. This manufacturer would rather keep both dealers but, when forced to choose between them, concludes that terminating the plaintiff hurts him less (considering sales lost, transaction costs in finding and perhaps training a replacement, and any spillover effects upon his relations with other dealers) than losing the complainant's patronage.

“The present situation is Colgate in reverse. In Colgate, it was the supplier who was controlling the dealer's behavior. Here a dealer is conditioning his patronage in a way that controls the manufacturer's behavior. The agreement concept seems parallel. But the economic effects can be very different. From the policy viewpoint, it can matter greatly whether manufacturer or dealer interests are being served. The former is more likely to seek efficient distribution, which stimulates interbrand competition; the latter is more likely to seek excess profits, which dampen interbrand competition. Accordingly, antitrust policy can be more hospitable toward manufacturer efforts to control dealer prices, customers, or territories than toward the efforts of dealers to control their competitors through the manufacturer.

“Of course, manufacturer and dealer interests are not necessarily antagonistic. Like the manufacturer, dealers might also believe that restricted distribution increases dealer services and sales and thus strengthens interbrand competition. However, this objective seems unlikely when the manufacturer is forced to violate the distribution policy he thinks best. Although he might be mistaken about what his optimal distribution policy ought to be, he should be presumed a better judge of that than coercing dealers who always desire excess profits unnecessary for efficient distribution.” Areeda, supra, at 167–168 (footnotes omitted).


It might be helpful to note at this point that although the majority mentions only the reduction of interbrand competition as a justification for a per se rule against vertical price restraints, see ante, at 1520, 1521, our opinion in Sylvania was quite different. As we stated then:

“The market impact of vertical restrictions is complex because of their potential for a simultaneous reduction of intrabrand competition and stimulation of interbrand competition. Significantly, the Court in Schwinn did not distinguish among the challenged restrictions on the basis of their individual potential for intrabrand harm or interbrand benefit. Restrictions that completely eliminated intrabrand competition among Schwinn distributors were analyzed no differently from those that merely moderated intrabrand competition among retailers.” 433 U.S., at 51–52, 97 S.Ct., at 2558 (footnotes omitted).

In the following pages, we pointed out that because vertical nonprice restrictions imposed by manufacturers may serve to advance interbrand competition, the restriction on intrabrand competition should be subject only to a rule of reason analysis. Along these same lines, we explained that “[e]conomists also have argued that manufacturers have an economic interest in maintaining as much intrabrand competition as is consistent with the efficient distribution of their products.”
“Intrabrand competition can benefit the consumer, and it is therefore important to insure that a manufacturer's motive for a vertical restriction is not simply to acquiesce in his distributors' desires to limit competition among themselves. The Supreme Court has recognized that restrictions on intrabrand competition can only be tolerated because of the countervailing positive impact on interbrand competition.” Piraino, The Case for Presuming the Legality of Quality Motivated Restrictions on Distribution, 63 Notre Dame L.Rev. 1, 17 (1988) (footnotes omitted).

See also H.R.Rep. No. 100–421, pp. 23, 38 (1987) (accompanying bill H.R. 585, the Freedom from Vertical Price Fixing Act of 1987, passed by the House and currently pending before the Senate; criticizing the Fifth Circuit's decision in this case, and restating “plainly and unequivocally that all forms of resale price maintenance are illegal per se under the antitrust laws,” including “where a conspiracy exists between a supplier and distributor to terminate or cut off supply to a second distributor because of the second distributor's pricing policies”) (emphasis in original); Departments of Commerce, Justice, and State, the Judiciary and Related Agencies Appropriation Act, 1986, Pub.L. 99–180, 99 Stat. 1169–1170 (congressional resolution that Department of Justice Vertical Restraints Guidelines “are inconsistent with established antitrust law, ... in maintaining that such policy guidelines do not treat vertical price fixing when, in fact, some provisions of such policy guidelines suggest that certain price fixing conspiracies are legal if such conspiracies are ‘limited’ to restricting intrabrand competition; ... in stating that vertical restraints that have an impact upon prices are subject to the per se rule of illegality only if there is an ‘explicit agreement as to the specific prices’ ”); Report of Attorney General's National Committee to Study the Antitrust Laws 149–155 (1955) (criticizing laws that permit resale price maintenance as a "throttling of price competition in the process of distribution").

15 The court instructed the jury:

“Sharp, on the other hand, contends that it terminated Business Electronics unilaterally, not as a result of any agreement or understanding with Hartwell, but because of Business Electronics' sales performance. If you find that Sharp did not terminate Business Electronics pursuant to an agreement or understanding with Hartwell to eliminate price cutting by Business Electronics, then you should answer ‘no’ to question number 1.” 22 Record 1587.

See also nn. 18–19, infra.

16 In *Morrison v. Murray Biscuit Co.*, 797 F.2d 1430 (CA7 1986), cited ante, at 1517, n. 1, Morrison, a wholesale distributor, sued Murray Biscuit, a producer of cookies and crackers, charging a conspiracy between Murray Biscuit and Feldman, a food broker, to suppress price competition between Feldman and Morrison. 797 F.2d 1431. But it was quite clear that Murray Biscuit “had assigned particular customers to particular middlemen, whether brokers [like Feldman] or warehouse distributors [like Morrison].” *Id.*, at 1435. Judge Posner's opinion explained:

“Suppose that after *Sylvania* was decided, a seller that had a price-fixing agreement (illegal per se) with its dealers adopted a lawful customer allocation agreement pursuant to which it terminated a dealer. That dealer could not sue for price fixing, even if the price-fixing agreement had never been rescinded, unless he could show that his breach of the customer allocation agreement was not the real reason for his termination; maybe the agreement was a mask behind which the illegal price fixing continued. The reason for Morrison's termination was that he tried to take away a customer who had been assigned to Feldman; there is no indication that the assignment was a mask for resale price
maintenance. Since Feldman had the exclusive right to sell Murray Biscuit's products to the Certified account, Morrison had no business selling to Certified at any price.” Id., at 1439 (emphasis added).

Judge Posner thus made it clear that although Morrison had been terminated pursuant to a valid vertical nonprice restraint, a terminated dealer might prevail if it could prove that the nonprice agreement was “a mask behind which the illegal price fixing continued.” Ibid.

“When faced with conflicting evidence, the jury must determine whether the nonprice justifications for the termination advanced by the defendant are legitimate, or are mere pretext to disguise a per se illegal agreement with the nonterminated dealer to maintain resale prices. It is the Court's duty under Monsanto to decide whether sufficient evidence was presented for a jury to make that determination.” McCabe's Furniture, Inc. v. La–Z–Boy Chair Co., 798 F.2d 323, 329 (CA8 1986), cited ante, at 1517, n. 1.

See also L. Sullivan, Law of Antitrust 202 (1977) (“A shorthand method which may help to identify a restraint affecting price as naked is to examine the arguments which are being pressed in justification of the practice”).

Although at trial respondent had asked the jury to find that it had acted independently, see n. 15, supra, and accompanying text, respondent has not disputed, either in the Court of Appeals or here, the jury's finding of an agreement. (Respondent has, of course, contended that no agreement was reached requiring some level of resale price maintenance. As I have argued, though, such an agreement is not needed to invoke the per se rule in a case such as this.) Respondent did argue before the District Court for an instruction explaining that “it must be shown that the manufacturer agreed with the complaining dealer to terminate the existing dealer and that, in so agreeing, the manufacturer shared with the complaining dealer the same desire of eliminating price competition for the complaining dealer.” 1 Record 151. Respondent later objected to the court's decision not to give this instruction, id., at 54, 22 Record 1599, but the court in fact had quite carefully explained to the jury that “[w]hat a preponderance ... of the evidence in the case must show in order to establish the existence of the required combination, agreement, or understanding is that Sharp and Hartwell knowingly came to a common and mutual understanding to accomplish or to attempt to accomplish an unlawful purpose.” Id., at 1584–1585.

The Court instructed the jury:

“The Sherman Act is violated when a seller enters into an agreement or understanding with one of its dealers to terminate another dealer because of the other dealer's price cutting. Plaintiff contends that Sharp terminated Business Electronics in furtherance of Hartwell's desire to eliminate Business Electronics as a price-cutting rival.

“If you find that there was an agreement between Sharp and Hartwell to terminate Business Electronics because of Business Electronics' price cutting, you should answer 'yes' to question number 1.

“Sharp, on the other hand, contends that it terminated Business Electronics unilaterally, not as a result of any agreement or understanding with Hartwell, but because of Business Electronics' sales performance. If you find that Sharp did not terminate Business Electronics pursuant to an agreement or understanding with Hartwell to eliminate price cutting by Business Electronics, then you should answer 'no' to question number 1.” 22 Record 1587.

Respondent had asked for an instruction requiring the jury to consider circumstantial evidence as proof of a motivation to eliminate price competition only if such evidence could not “equally be interpreted to show that Sharp terminated Business Electronics Corporation for other business reasons and not pursuant to any agreement with Mr. Hartwell to fix resale prices of calculators.” 1 Record 148. Respondent objected to the failure to give this instruction, id., at 54, and also objected, more specifically, to the instruction that was given on the ground that “it allows the jury to find against the defendant even if they do not believe that Sharp cared about [Business Electronics'] price cutting or if they believe...
that Sharp had a dual motive in making the termination.” 22 Record 1599. The instruction quoted above, though, makes it highly unlikely that the jury would have found for petitioner although finding respondent's motives to be mixed ones.

Thus, the Courts of Appeals decisions cited by the majority as supporting its view, see ante, at 1517, n. 1, are, in fact, consistent with the rule that a naked intent to eliminate price competition is per se invalid. Each of the opinions contains a discussion that distinguishes between, on the one hand, an agreement between manufacturer and dealer to eliminate a price-cutting competitor based solely on an intent to eliminate price competition, and, on the other hand, an agreement between manufacturer and dealer to eliminate a price-cutting competitor that is grounded not only in an antipathy to price competition, but also in a purpose to implement a procompetitive system of vertical nonprice restraints. See McCabe's Furniture, Inc. v. La–Z–Boy Chair Co., 798 F.2d, at 329–330; Morrison v. Murray Biscuit Co., 797 F.2d, at 1439–1440; Westman Commission Co. v. Hobart Int'l, Inc., 796 F.2d 1216, 1223 (CA10 1986). Moreover, none of these opinions proposes the rule that the majority sanctions today: that an agreement as to some level of resale price maintenance is necessary for invocation of the per se rule in these situations.

104 S.Ct. 2731, 81 L.Ed.2d 628, 1984-2 Trade Cases P 66,065

104 S.Ct. 2731
Supreme Court of the United States

COPPERWELD CORPORATION, et al., Petitioners
v.
INDEPENDENCE TUBE CORPORATION.

No. 82-1260


Synopsis

Tubing company sued another tubing company and its parent corporation as well as tubing mill manufacturer and others for, Sherman Act conspiracy. The United States District Court for the Northern District of Illinois, Eastern Division, Hubert L. Will, J., found that the parent subsidiary had conspired to violate section 1 of the Act and awarded treble damages. The Court of Appeals for the Seventh Circuit affirmed, 691 F.2d 310. Certiorari was granted. The Supreme Court, Chief Justice Burger, held that a parent corporation and its wholly owned subsidiary were not legally capable of conspiring with each other under section 1 of the Sherman Act.

Judgment of Court of Appeals reversed.

Justice Stevens, with whom Justice Brennan and Justice Marshall joined, filed a dissenting opinion.

Syllabus

Petitioner Copperweld Corp. purchased petitioner Regal Tube Co., a manufacturer of steel tubing, from Lear Siegler, Inc., which had operated Regal as an unincorporated division, and which under the sale agreement was bound not to compete with Regal for five years. Copperweld then transferred Regal's assets to a newly formed, wholly owned subsidiary. Shortly before Copperweld acquired Regal, David Grohne, who previously had been an officer of Regal, became an officer of Lear Siegler, and, while continuing to work for Lear Siegler, formed respondent corporation to compete with Regal. Respondent then gave Yoder Co. a purchase order for a tubing mill, but Yoder voided the order when it received a letter from Copperweld warning that Copperweld would be greatly concerned if Grohne contemplated competing with Regal and promising to take the necessary steps to protect Copperweld's rights under the noncompetition agreement with Lear Siegler. Respondent then arranged to have a mill supplied by another company. Thereafter, respondent filed an action in Federal District Court against petitioners and Yoder. The jury found, inter alia, that petitioners had conspired to violate § 1 of the Sherman Act but that Yoder was not part of the conspiracy, and awarded treble damages against petitioners. The **2733 Court of Appeals affirmed. Noting that the exoneration of Yoder from antitrust liability left a parent corporation and its wholly owned subsidiary as the only parties to the § 1 conspiracy, the court questioned the wisdom of subjecting an “intra-enterprise” conspiracy to antitrust liability, but held that such liability was appropriate “when there is enough separation between the two entities to make treating them as two independent actors sensible,” and that there was sufficient evidence for the jury to conclude that Regal was more like a separate corporate entity than a mere service arm of the parent.
Held: Petitioner Copperweld and its wholly owned subsidiary, petitioner Regal, are incapable of conspiring with each other for purposes of § 1 of the Sherman Act. Pp. 2736–2745.

(a) While this Court has previously seemed to acquiesce in the “intra-enterprise conspiracy” doctrine, which provides that § 1 liability is not *foreclosed* merely because a parent and its subsidiary are subject to common ownership, the Court has never explored or analyzed in detail the justifications for such a rule. Pp. 2736–2739.

(b) Section 1 of the Sherman Act, in contrast to § 2, reaches unreasonable restraints of trade effected by a “contract, combination ... or conspiracy” between separate entities, and does not reach conduct that is “wholly unilateral.” Pp. 2740–2741.

(c) The coordinated activity of a parent and its wholly owned subsidiary must be viewed as that of a single enterprise for purposes of § 1 of the Sherman Act. A parent and its wholly owned subsidiary have a complete unity of interest. Their objectives are common, not disparate, and their general corporate objectives are guided or determined not by two separate corporate consciousnesses, but one. With or without a formal “agreement,” the subsidiary acts for the parent's benefit. If the parent and subsidiary “agree” to a course of action, there is no sudden joining of economic resources that had previously served different interests, and there is no justification for § 1 scrutiny. In reality, the parent and subsidiary always have a “unity of purpose or a common design.” The “intra-enterprise conspiracy” doctrine relies on artificial distinctions, looking to the form of an enterprise's structure and ignoring the reality. Antitrust liability should not depend on whether a corporate subunit is organized as an unincorporated division or a wholly owned subsidiary. Here, nothing in the record indicates any meaningful difference between Regal's operations as an unincorporated division of Lear Siegler and its later operations as a wholly owned subsidiary of Copperweld. Pp. 2742–2744.

(d) The appropriate inquiry in this case is not whether the coordinated conduct of a parent and its wholly owned subsidiary may ever have anticompetitive effects or whether the term “conspiracy” will bear a literal construction that includes a parent and its subsidiaries, but rather whether the logic underlying Congress' decision to exempt unilateral conduct from scrutiny under § 1 of the Sherman Act similarly excludes the conduct of a parent and subsidiary. It can only be concluded that the coordinated behavior of a parent and subsidiary falls outside the reach of § 1. Any anticompetitive activities of corporations and their wholly owned subsidiaries meriting antitrust remedies may be policed adequately without resort to an “intra-enterprise conspiracy” doctrine. A corporation's initial acquisition of control is always subject to scrutiny under § 1 of the Sherman Act and § 7 of the Clayton Act, and thereafter the enterprise is subject to § 2 of the Sherman Act and § 5 of the Federal Trade Commission Act. Pp. 2744–2745.

691 F.2d 310 (CA7 1982), reversed.

Attorneys and Law Firms

* Erwin N. Griswold argued the cause for petitioners. With him on the briefs were William R. Jentes, Sidney N. Herman, Robert E. Shapiro, and Donald I. Baker.

Deputy Solicitor General Wallace argued the cause for the United States as amicus curiae urging reversal. With him on the brief were Solicitor General Lee, Assistant Attorney General Baxter, Deputy Assistant Attorney General Collins, Carolyn F. Corwin, Barry Grossman, and Nancy C. Garrison.

Victor E. Grimm argued the cause for respondent. With him on the brief were John R. Myers and Scott M. Mendel.*

* J. Randolf Wilson, Russell H. Carpenter, Jr., Stephen A. Bokat, Cynthia Wicker, William E. Blasier, and Quentin Riegel filed a brief for the Chamber of Commerce of the United States et al. as amici curiae urging reversal.
We granted certiorari to determine whether a parent corporation and its wholly owned subsidiary are legally capable of conspiring with each other under § 1 of the Sherman Act.

I

A

The predecessor to petitioner Regal Tube Co. was established in Chicago in 1955 to manufacture structural steel tubing used in heavy equipment, cargo vehicles, and construction. From 1955 to 1968 it remained a wholly owned subsidiary of C.E. Robinson Co. In 1968 Lear Siegler, Inc., purchased Regal Tube Co. and operated it as an unincorporated division. David Grohne, who had previously served as vice president and general manager of Regal, became president of the division after the acquisition.
In 1972 petitioner Copperweld Corp. purchased the Regal division from Lear Siegler; the sale agreement bound Lear Siegler and its subsidiaries not to compete with Regal in the United States for five years. Copperweld then transferred Regal's assets to a newly formed, wholly owned Pennsylvania corporation, petitioner Regal Tube Co. The new subsidiary continued to conduct its manufacturing operations in Chicago but shared Copperweld's corporate headquarters in Pittsburgh.

Shortly before Copperweld acquired Regal, David Grohne accepted a job as a corporate officer of Lear Siegler. After the acquisition, while continuing to work for Lear Siegler, Grohne set out to establish his own steel tubing business to compete in the same market as Regal. In May 1972 he formed respondent Independence Tube Corp., which soon secured an offer from the Yoder Co. to supply a tubing mill. In December 1972 respondent gave Yoder a purchase order to have a mill ready by the end of December 1973.

When executives at Regal and Copperweld learned of Grohne's plans, they initially hoped that Lear Siegler's noncompetition agreement would thwart the new competitor. Although their lawyer advised them that Grohne was not bound by the agreement, he did suggest that petitioners might obtain an injunction against Grohne's activities if he made use of any technical information or trade secrets belonging to Regal. The legal opinion was given to Regal and Copperweld along with a letter to be sent to anyone with whom Grohne attempted to deal. The letter warned that Copperweld would be “greatly concerned if [Grohne] contemplates *757 entering the structural tube market ... in competition with Regal Tube” and promised to take “any and all steps which are necessary to protect our rights under the terms of our purchase agreement and to protect the know-how, trade secrets, etc., which we purchased from Lear Siegler.” Petitioners later asserted that the letter was intended only to prevent third parties from developing reliance interests that might later make a court reluctant to enjoin Grohne's operations.

When Yoder accepted respondent's order for a tubing mill on February 19, 1973, Copperweld sent Yoder one of these letters; two days later Yoder voided its acceptance. After respondent's efforts to resurrect the deal failed, respondent arranged to have a mill supplied by another company, which performed its agreement even though it too received a warning letter from Copperweld. Respondent began operations on September 13, 1974, nine months later than it could have if Yoder had supplied the mill when originally agreed.

Although the letter to Yoder was petitioners' most successful effort to discourage those contemplating doing business with respondent, it was not their only one. Copperweld repeatedly contacted banks that were considering financing respondent's operations. One or both petitioners also approached real estate firms that were considering providing plant space to respondent and contacted prospective suppliers and customers of the new company.

In 1976 respondent filed this action in the District Court against petitioners and Yoder. 1 The jury found that Copperweld and Regal had conspired to violate § 1 of the Sherman Act, 26 Stat. 209, as amended, 15 U.S.C. § 1, but that Yoder was not part of the conspiracy. It also found that Copperweld, but not Regal, had interfered with respondent's contractual relationship with Yoder; that Regal, but not Copperweld, had interfered with respondent's contractual relationship with a potential customer of respondent, Deere Plow & Planter Works, and had slandered respondent to Deere; and that Yoder had breached its contract to supply a tubing mill.

At a separate damages phase, the judge instructed the jury that the damages for the antitrust violation and for the inducement of the Yoder contract breach should be identical and not double counted. The jury then awarded $2,499,009 against petitioners on the antitrust claim, which was trebled to $7,497,027. It awarded $15,000 against Regal alone on the contractual interference and slander counts pertaining to Deere. The court also awarded attorney's fees and costs after denying petitioners' motions for judgment n.o.v. and for a new trial.
104 S.Ct. 2731, 81 L.Ed.2d 628, 1984-2 Trade Cases P 66,065

C

The United States Court of Appeals for the Seventh Circuit affirmed. 691 F.2d 310 (1982). It noted that the exoneration of Yoder from antitrust liability left a parent corporation and its wholly owned subsidiary as the only parties to the § 1 conspiracy. The court questioned the wisdom of subjecting an “intra-enterprise” conspiracy to antitrust liability, when the same conduct by a corporation and an unincorporated division would escape liability for lack of the requisite two legal persons. However, relying on its decision in Photovest Corp. v. Fotomat Corp., 606 F.2d 704 (1979), cert. denied, 445 U.S. 917, 100 S.Ct. 1278, 63 L.Ed.2d 601 (1980), the Court of Appeals held that liability was appropriate “when there is enough separation between the two entities to make treating them as two independent actors sensible.” 691 F.2d, at 318. It held that the jury instructions took account of the proper factors for determining how much separation Copperweld and Regal in fact maintained in the conduct of their businesses. 2 It also held that there was sufficient evidence for the jury to conclude that Regal was more like a separate corporate entity than a mere service arm of the parent.

We granted certiorari to reexamine the intra-enterprise conspiracy doctrine, 462 U.S. 1131, 103 S.Ct. 3109, 77 L.Ed.2d 1365 (1983), and we reverse.

II

Review of this case calls directly into question whether the coordinated acts of a parent and its wholly owned subsidiary can, in the legal sense contemplated by § 1 of the Sherman Act, constitute a combination or conspiracy. 3 The so-called “intra-enterprise conspiracy” doctrine provides that § 1 liability is not foreclosed merely because a parent and its subsidiary are subject to common ownership. The doctrine derives from declarations in several of this Court's opinions.

In no case has the Court considered the merits of the intra-enterprise conspiracy doctrine in depth. Indeed, the concept arose from a far narrower rule. Although the Court has expressed approval of the doctrine on a number of occasions, a finding of intra-enterprise conspiracy was in all but perhaps one instance unnecessary to the result.

The problem began with United States v. Yellow Cab Co., 332 U.S. 218, 67 S.Ct. 1560, 91 L.Ed. 2010 (1947). The controlling shareholder of the Checker Cab Manufacturing Corp., Morris Markin, also controlled numerous companies operating taxicabs in four cities. With few exceptions, the operating companies had once been independent and had come under Markin's control by acquisition or merger. The complaint alleged conspiracies under §§ 1 and 2 of the Sherman Act among Markin, Checker, and five corporations in the operating system. The Court stated that even restraints in a vertically integrated enterprise were not “necessarily” outside of the Sherman Act, observing that an unreasonable restraint “may result as readily from a conspiracy among those who are affiliated or integrated under common ownership as from a conspiracy among those who are otherwise independent. Similarly, any affiliation or integration flowing from an illegal conspiracy cannot insulate the conspirators from the sanctions which Congress has imposed. The corporate interrelationships of the conspirators, in other words, are not determinative of the applicability of the Sherman Act. That statute is aimed at substance rather than form. See Appalachian Coals, Inc. v. United States, 288 U.S. 344, 360–361, 376–377 [53 S.Ct. 471, 474–475, 480, 77 L.Ed. 825].

“And so in this case, the common ownership and control of the various corporate appellees are impotent to liberate the alleged combination and conspiracy from the impact of the Act. The complaint charges that the restraint of interstate trade was not only effected by the combination of the appellees but was the primary object of the combination. The theory of the complaint ... is that ‘dominating power’ over the cab operating companies ‘was not obtained by normal expansion ... but by deliberate, calculated purchase for control.’ ” Id., at 227–228, 67 S.Ct., at 1565–1566 (emphasis added) (quoting United States v. Reading Co., 253 U.S. 26, 57, 40 S.Ct. 425, 432, 64 L.Ed. 760 (1920)).
It is the underscored language that later breathed life into the intra-enterprise conspiracy doctrine. The passage as a whole, however, more accurately stands for a quite different proposition. It has long been clear that a pattern of acquisitions may itself create a combination illegal under § 1, especially when an original anti-competitive purpose is evident from the affiliated corporations' subsequent conduct. The Yellow Cab passage is most fairly read in light of this settled rule. In Yellow Cab, the affiliation of the defendants was irrelevant because the original acquisitions were themselves illegal. An affiliation “flowing from an illegal conspiracy” would not avert sanctions. Common ownership and control were irrelevant because restraint of trade was “the primary object of the combination,” which was created in a “‘deliberate, calculated’” manner.

Other language in the opinion is to the same effect.

The Court's opinion relies on Appalachian Coals, Inc. v. United States, 288 U.S. 344, 53 S.Ct. 471, 77 L.Ed. 825 (1933); however, examination of that case reveals that it gives very little support for the broad doctrine Yellow Cab has been thought to announce. On the contrary, the language of Chief Justice Hughes speaking for the Court in Appalachian Coals supports a contrary conclusion. After observing that “[t]he restrictions the Act imposes are not mechanical or artificial,” 288 U.S., at 360, 53 S.Ct., at 474, he went on to state: "The argument that integration may be considered a normal expansion of business, while a combination of independent producers in a common selling agency should be treated as abnormal—that one is a legitimate enterprise and the other is not—makes but an artificial distinction. The Anti–Trust Act aims at substance.” Id., at 377, 53 S.Ct., at 480.

As we shall see, infra, at 2742–2744, it is the intra-enterprise conspiracy doctrine itself that “makes but an artificial distinction” at the expense of substance.

The ambiguity of the Yellow Cab holding yielded the one case giving support to the intra-enterprise conspiracy doctrine. In Kiefer–Stewart Co. v. Joseph E. Seagram & Sons, Inc., 340 U.S. 211, 71 S.Ct. 259, 95 L.Ed. 219 (1951), the Court held that two wholly owned subsidiaries of a liquor distiller were guilty under § 1 of the Sherman Act for jointly refusing to supply a wholesaler who declined to abide by a maximum resale pricing scheme. The Court offhandedly dismissed the defendants' argument that "their status as ‘mere instrumentalities of a single manufacturing-merchandizing unit’ makes it impossible for them to have conspired in a manner forbidden by the Sherman Act.” Id., at 215, 71 S.Ct., at 261. With only a citation to Yellow Cab and no further analysis, the Court stated that the “suggestion runs counter to our past decisions that common ownership and control does not liberate corporations from the impact of the antitrust laws” and stated that this rule was “especially applicable” when defendants ‘hold themselves out as competitors.” 340 U.S., at 215, 71 S.Ct., at 261.

Unlike the Yellow Cab passage, this language does not pertain to corporations whose initial affiliation was itself unlawful. In straying beyond Yellow Cab, the Kiefer–Stewart Court failed to confront the anomalies an intra-enterprise doctrine entails. It is relevant nonetheless that, were the case decided today, the same result probably could be justified on the ground that the subsidiaries conspired with wholesalers other than the plaintiff. An intra-enterprise conspiracy doctrine thus would no longer be necessary to a finding of liability on the facts of Kiefer–Stewart.

Later cases invoking the intra-enterprise conspiracy doctrine do little more than cite Yellow Cab or Kiefer–Stewart, and in none of the cases was the doctrine necessary to the result reached. Timken Roller Bearing Co. v. United States, 341 U.S. 593, 71 S.Ct. 971, 95 L.Ed. 1199 (1951), involved restrictive horizontal agreements between an American corporation and two
foreign corporations in which it owned 30 and 50 percent interests respectively. The Timken Court cited Kiefer–Stewart to show that “[t]he fact that there is common ownership or control of the contracting corporations does not liberate them from the impact of the antitrust laws.” 341 U.S., at 598, 71 S.Ct., at 974. But the relevance of this statement is unclear. The American defendant in Timken did not own a majority interest in either of the foreign corporate conspirators and, as the District Court found, it did not control them. Moreover, as in Yellow Cab, there was evidence that the stock acquisitions were themselves designed to effectuate restrictive practices.

The Court's reliance on the intra-enterprise conspiracy doctrine was in no way necessary to the result.

The same is true of Perma Life Mufflers, Inc. v. International Parts Corp., 392 U.S. 134, 88 S.Ct. 1981, 20 L.Ed.2d 982 (1968), which involved a conspiracy among a parent corporation and three subsidiaries to impose various illegal restrictions on plaintiff franchisees. The Court did suggest that, because the defendants “availed themselves of the privilege of doing business through separate corporations, the fact of common ownership *766 could not save them from any of the obligations that the law imposes on separate entities [citing Yellow Cab and Timken].” Id., at 141–142, 88 S.Ct., at 1985–1986.

But the Court noted immediately thereafter that “[i]n any event” each plaintiff could “clearly” charge a combination between itself and the defendants or between the defendants and other franchise dealers. Ibid. Thus, for the same reason that a finding of liability in Kiefer–Stewart could today be justified without reference to the intra-enterprise conspiracy doctrine, see n. 9, supra, the doctrine was at most only an alternative holding in Perma Life Mufflers.

In short, while this Court has previously seemed to acquiesce in the intra-enterprise conspiracy doctrine, it has never explored or analyzed in detail the justifications for such a rule; the doctrine has played only a relatively minor role in the Court's Sherman Act holdings.

III

Petitioners, joined by the United States as amicus curiae, urge us to repudiate the intra-enterprise conspiracy doctrine. The central criticism is that the doctrine gives undue significance to the fact that a subsidiary is separately incorporated and thereby treats as the concerted activity of two *767 entities what is really unilateral behavior flowing from decisions of a single enterprise.

We limit our inquiry to the narrow issue squarely presented: whether a parent and its wholly owned subsidiary are capable of conspiring in violation of § 1 of the Sherman Act. We do not consider under what circumstances, if any, a parent may be liable for conspiring with an affiliated corporation it does not completely own.

A

The Sherman Act contains a “basic distinction between concerted and independent action.” Monsanto Co. v. Spray–Rite Service Corp., 465 U.S. 752, 761, 104 S.Ct. 1464, 1469, 79 L.Ed.2d 775 (1984). The conduct of a single firm is governed by § 2 alone and is unlawful only when it threatens actual monopolization. It is not enough that a single firm appears to “restrain trade” unreasonably, for even a vigorous competitor may leave that impression. For instance, an efficient firm may capture unsatisfied customers from an inefficient rival, whose own ability to compete may suffer as a result. This is the rule of the marketplace and is precisely the sort of competition that promotes the consumer interests that the Sherman Act aims to foster. In part because it is sometimes difficult to distinguish robust competition from conduct with long-run anti-competitive effects, Congress authorized Sherman Act scrutiny of single firms only when they pose a danger of monopolization. Judging
unilateral conduct in this manner reduces the risk that the antitrust laws will dampen the competitive zeal of a single aggressive entrepreneur.

Section 1 of the Sherman Act, in contrast, reaches unreasonable restraints of trade effected by a “contract, combination ... or conspiracy” between separate entities. It does not reach conduct that is “wholly unilateral.” Albrecht v. Herald Co., 390 U.S. 145, 149, 88 S.Ct. 869, 871, 19 L.Ed.2d 998 (1968); accord, Monsanto Co. v. Spray–Rite Corp., supra, at 761, 104 S.Ct., at 1469. Concerted activity subject to § 1 is judged more sternly than unilateral activity under § 2. Certain agreements, such as horizontal price fixing and market allocation, are thought so inherently anticompetitive that each is illegal per se without inquiry into the harm it has actually caused. See generally Northern Pacific R. Co. v. United States, 356 U.S. 1, 5, 78 S.Ct. 514, 518, 2 L.Ed.2d 545 (1958). Other combinations, such as mergers, joint ventures, and various vertical agreements, hold the promise of increasing a firm's efficiency and enabling it to compete more effectively. Accordingly, such combinations are judged under a rule of reason, an inquiry into market power and market structure designed to assess the combination's actual effect. See, e.g., Continental T.V., Inc. v. GTE Sylvania Inc., 433 U.S. 36, 97 S.Ct. 2549, 53 L.Ed.2d 568 (1977); Chicago Board of Trade v. United States, 246 U.S. 231, 38 S.Ct. 242, 62 L.Ed. 683 (1918). Whatever form the inquiry takes, however, it is not necessary to prove that concerted activity threatens monopolization.

The reason Congress treated concerted behavior more strictly than unilateral behavior is readily appreciated. Concerted activity inherently is fraught with anticompetitive risk. It deprives the marketplace of the independent centers of decisionmaking that competition assumes and demands. In any conspiracy, two or more entities that previously pursued their own interests separately are combining to act as one for their common benefit. This not only reduces the diverse directions in which economic power is aimed but suddenly increases the economic power moving in one particular direction. Of course, such mergings of resources may well lead to efficiencies that benefit consumers, but their anticompetitive potential is sufficient to warrant scrutiny even in the absence of incipient monopoly.

The distinction between unilateral and concerted conduct is necessary for a proper understanding of the terms “contract, combination ... or conspiracy” in § 1. Nothing in the literal meaning of those terms excludes coordinated conduct among officers or employees of the same company. But it is perfectly plain that an internal “agreement” to implement a single, unitary firm's policies does not raise the antitrust dangers that § 1 was designed to police. The officers of a single firm are not separate economic actors pursuing separate economic interests, so agreements among them do not suddenly bring together economic power that was previously pursuing divergent goals. Coordination within a firm is as likely to result from an effort to compete as from an effort to stifle competition. In the marketplace, such coordination may be necessary if a business enterprise is to compete effectively. For these reasons, officers or employees of the same firm do not provide the plurality of actors imperative for a § 1 conspiracy. 15

*769 There is also general agreement that § 1 is not violated by the internally coordinated conduct of a corporation and one of its unincorporated divisions. 16 Although this Court has not previously addressed the question, 17 there can be little doubt that the operations of a corporate enterprise organized into divisions must be judged as the conduct of a single actor. The existence of an unincorporated division reflects no more than a firm's decision to adopt an organizational division of labor. A division within a corporate structure pursues the common interests of the whole rather than interests separate from those of the corporation itself; a business enterprise establishes divisions to further its own interests in the most efficient manner. Because coordination between a corporation and its division does not represent a sudden joining of two independent sources of economic power previously pursuing separate interests, it is not an activity that warrants § 1 scrutiny. 18
Indeed, a rule that punished coordinated conduct simply because a corporation delegated certain responsibilities to autonomous units might well discourage corporations from creating divisions with their presumed benefits. This would serve no useful antitrust purpose but could well deprive consumers of the efficiencies that decentralized management may bring.

C

For similar reasons, the coordinated activity of a parent and its wholly owned subsidiary must be viewed as that of a single enterprise for purposes of § 1 of the Sherman Act. A parent and its wholly owned subsidiary have a complete unity of interest. Their objectives are common, not disparate; their general corporate actions are guided or determined not by two separate corporate consciousnesses, but one. They are not unlike a multiple team of horses drawing a vehicle under the control of a single driver. With or without a formal “agreement,” the subsidiary acts for the benefit of the parent, its sole shareholder. If a parent and a wholly owned subsidiary do “agree” to a course of action, there is no sudden joining of economic resources that had previously served different interests, and there is no justification for § 1 scrutiny.

Indeed, the very notion of an “agreement” in Sherman Act terms between a parent and a wholly owned subsidiary lacks meaning. A § 1 agreement may be found when “the conspirators had a unity of purpose or a common design and understanding, or a meeting of minds in an unlawful arrangement.” American Tobacco Co. v. United States, 328 U.S. 781, 810, 66 S.Ct. 1125, 1139, 90 L.Ed. 1575 (1946). But in reality a parent and a wholly owned subsidiary always have a “unity of purpose or a common design.” They share a common purpose whether or not the parent keeps a tight rein over the subsidiary; the parent may assert full control at any moment if the subsidiary fails to act in the parent's best interests. 18

The intra-enterprise conspiracy doctrine looks to the form of an enterprise's structure and ignores the reality. Antitrust liability should not depend on whether a corporate subunit is organized as an unincorporated division or a wholly owned subsidiary. A corporation has complete power to maintain a wholly owned subsidiary in either form. The economic, legal, or other considerations that lead corporate management to choose one structure over the other are not relevant to whether the enterprise's conduct seriously threatens competition. 19 Rather, a corporation may adopt the subsidiary form of organization for valid management and related purposes. Separate incorporation may improve management, avoid special tax problems arising from multistate operations, or serve other legitimate interests. 20 Especially in view of the increasing complexity of corporate operations, a business enterprise should be free to structure itself in ways that serve efficiency of control, economy of operations, and other factors dictated by business judgment without increasing its exposure to antitrust liability. Because there is nothing inherently anticompetitive about a corporation's decision to create a subsidiary, the intra-enterprise conspiracy doctrine “impose[s] grave legal consequences upon organizational distinctions that are of de minimis meaning and effect.” Sunkist Growers, Inc. v. Winckler & Smith Citrus Products Co., 370 U.S. 19, 29, 82 S.Ct. 1130, 1136, 8 L.Ed.2d 305 (1962). 21

If antitrust liability turned on the garb in which a corporate subunit was clothed, parent corporations would be encouraged to convert subsidiaries into unincorporated divisions. Indeed, this is precisely what the Seagram company did after this Court's decision in Kiefer–Stewart Co. v. Joseph E. Seagram & Sons, Inc., 340 U.S. 211, 71 S.Ct. 259, 95 L.Ed. 219 (1951). 22 Such an incentive serves no valid antitrust goals but merely deprives consumers and producers of the benefits that the subsidiary form may yield.

The error of treating a corporate division differently from a wholly owned subsidiary is readily seen from the facts of this case. Regal was operated as an unincorporated division of Lear Siegler for four years before it became a wholly owned subsidiary of Copperweld. Nothing in this record indicates any meaningful difference between Regal's operations as a division and its later operations as a separate corporation. Certainly nothing suggests that Regal was a greater threat to competition as a subsidiary of Copperweld than as a division of Lear Siegler. Under either arrangement, Regal might have acted to bar a new competitor from entering the market. In one case it could have relied on economic power from other quarters of the Lear Siegler corporation;
instead it drew on the strength of its separately incorporated parent, Copperweld. From the standpoint of the antitrust laws, there is no reason to treat one more harshly than the other. As Chief Justice Hughes cautioned, “[r]ealities must dominate the judgment.” Appalachian Coals, Inc. v. United States, 288 U.S., at 360, 53 S.Ct., at 474. 23

Any reading of the Sherman Act that remains true to the Act's distinction between unilateral and concerted conduct will necessarily disappoint those who find that distinction arbitrary. It cannot be denied that § 1's focus on concerted *775 behavior leaves a “gap” in the Act's proscription against unreasonable restraints of trade. See post, at 2751. An unreasonable restraint of trade may be effected not only by two independent firms acting in concert; a single firm may restrain trade to precisely the same extent if it alone possesses the combined market power of those same two firms. Because the Sherman Act does not prohibit unreasonable restraints of trade as such—but only restraints effected by a contract, combination, or conspiracy—it leaves untouched a single firm's anticompetitive **2744 conduct (short of threatened monopolization) that may be indistinguishable in economic effect from the conduct of two firms subject to § 1 liability.

We have already noted that Congress left this “gap” for eminently sound reasons. Subjecting a single firm's every action to judicial scrutiny for reasonableness would threaten to discourage the competitive enthusiasm that the antitrust laws seek to promote. See supra, at 2741–2742. Moreover, whatever the wisdom of the distinction, the Act's plain language leaves no doubt that Congress made a purposeful choice to accord different treatment to unilateral and concerted conduct. Had Congress intended to outlaw unreasonable restraints of trade as such, § 1's requirement of a contract, combination, or conspiracy would be superfluous, as would the entirety of § 2. 24 Indeed, this Court has recognized *776 that § 1 is limited to concerted conduct at least since the days of United States v. Colgate & Co., 250 U.S. 300, 39 S.Ct. 465, 63 L.Ed. 992 (1919). Accord, post, at 2751.

The appropriate inquiry in this case, therefore, is not whether the coordinated conduct of a parent and its wholly owned subsidiary may ever have anticompetitive effects, as the dissent suggests. Nor is it whether the term “conspiracy” will bear a literal construction that includes parent corporations and their wholly owned subsidiaries. For if these were the proper inquiries, a single firm's conduct would be subject to § 1 scrutiny whenever the coordination of two employees was involved. Such a rule would obliterate the Act's distinction between unilateral and concerted conduct, contrary to the clear intent of Congress as interpreted by the weight of judicial authority. See n. 15, supra. Rather, the appropriate inquiry requires us to explain the logic underlying Congress' decision to exempt unilateral conduct from § 1 scrutiny, and to assess whether that logic similarly excludes the conduct of a parent and its wholly owned subsidiary. Unless we second-guess the judgment of Congress to limit § 1 to concerted conduct, we can only conclude that the coordinated behavior of a parent and its wholly owned subsidiary falls outside the reach of that provision.

Although we recognize that any “gap” the Sherman Act leaves is the sensible result of a purposeful policy decision by Congress, we also note that the size of any such gap is open *777 to serious question. Any anticompetitive activities of corporations and their wholly owned subsidiaries meriting antitrust remedies may be policed adequately without resort to an intra-enterprise conspiracy doctrine. A corporation's initial acquisition of control will always be subject to scrutiny under § 1 of the Sherman Act and § 7 of the Clayton Act, 38 Stat. 731, 15 U.S.C. § 18. Thereafter, the enterprise is fully subject to § 2 of the Sherman Act and § 5 of the Federal Trade Commission Act, 38 Stat. 719, **2745 15 U.S.C. § 45. That these statutes are adequate to control dangerous anticompetitive conduct is suggested by the fact that not a single holding of antitrust liability by this Court would today be different in the absence of an intra-enterprise conspiracy doctrine. It is further suggested by the fact that the Federal Government, in its administration of the antitrust laws, no longer accepts the concept that a corporation and its wholly owned subsidiaries can “combine” or “conspire” under § 1. 25 Elimination of the intra-enterprise conspiracy doctrine with respect to corporations and their wholly owned subsidiaries will therefore not cripple antitrust enforcement. It will simply eliminate treble damages from private state tort suits masquerading as antitrust actions.
IV

We hold that Copperweld and its wholly owned subsidiary Regal are incapable of conspiring with each other for purposes of § 1 of the Sherman Act. To the extent that prior decisions of this Court are to the contrary, they are disapproved and overruled. Accordingly, the judgment of the Court of Appeals is reversed.

It is so ordered.

*778 Justice WHITE took no part in the consideration or decision of this case.

Justice STEVENS, with whom Justice BRENNAN and Justice MARSHALL join, dissenting.

It is safe to assume that corporate affiliates do not vigorously compete with one another. A price-fixing or market-alLOCATION agreement between two or more such corporate entities does not, therefore, eliminate any competition that would otherwise exist. It makes no difference whether such an agreement is labeled a “contract,” a “conspiracy,” or merely a policy decision, because it surely does not unreasonably restrain competition within the meaning of the Sherman Act. The Rule of Reason has always given the courts adequate latitude to examine the substance rather than the form of an arrangement when answering the question whether collective action has restrained competition within the meaning of § 1.

Today the Court announces a new per se rule: a wholly owned subsidiary is incapable of conspiring with its parent under § 1 of the Sherman Act. Instead of redefining the word “conspiracy,” the Court would be better advised to continue to rely on the Rule of Reason. Precisely because they do not eliminate competition that would otherwise exist but rather enhance the ability to compete, restraints which enable effective integration between a corporate parent and its subsidiary—the type of arrangement the Court is properly concerned with protecting—are not prohibited by § 1. Thus, the Court's desire to shield such arrangements from antitrust liability provides no justification for the Court's new rule.

In contrast, the case before us today presents the type of restraint that has precious little to do with effective integration between parent and subsidiary corporations. Rather, the purpose of the challenged conduct was to exclude a potential competitor of the subsidiary from the market. The jury apparently concluded that the two defendant corporations—Copperweld *779 and its subsidiary Regal—had successfully delayed Independence's entry into the steel tubing business by applying a form of economic coercion to potential suppliers of financing and capital equipment, as well as to potential customers. Everyone seems to agree that this conduct was tortious as a matter of state law. This type of exclusionary conduct is plainly distinguishable from vertical integration designed to achieve competitive efficiencies. If, as seems to be the case, the challenged conduct was manifestly anticompetitive, it should not be immunized from scrutiny under § 1 of the Sherman Act.

**2746 I

Repudiation of prior cases is not a step that should be taken lightly. As the Court wrote only days ago: “[A]ny departure from the doctrine of stare decisis demands special justification.” Arizona v. Rumsey, 467 U.S. 203, 212, 104 S.Ct. 2305, 2311, 81 L.Ed.2d 164 (1984). It is therefore appropriate to begin with an examination of the precedents.

In United States v. Yellow Cab Co., 332 U.S. 218, 67 S.Ct. 1560, 91 L.Ed. 2010 (1947), the Court explicitly stated that a corporate subsidiary could conspire with its parent:

“The fact that these restraints occur in a setting described by the appellees as a vertically integrated enterprise does not necessarily remove the ban of the Sherman Act. The test of illegality under the Act is the presence or absence of an unreasonable restraint on interstate commerce. Such a restraint may result as readily from a conspiracy among those who are affiliated or
The majority attempts to explain Yellow Cab by suggesting that it dealt only with unlawful acquisition of subsidiaries. Ante, at 2737. But the Court mentioned acquisitions only as an additional consideration separate from the passage *780 quoted above, 1 and more important, the Court explicitly held that restraints imposed by the corporate parent on the affiliates that it already owned in themselves violated § 1. 2

At least three cases involving the motion picture industry also recognize that affiliated corporations may combine or conspire within the meaning of § 1. In United States v. Crescent Amusement Co., 323 U.S. 173, 65 S.Ct. 254, 89 L.Ed. 160 (1944), as the Court recognizes, ante, at 2737, n. 6, the only conspirators were affiliated corporations. The majority's claim that the case involved only unlawful acquisitions because of the Court's comments concerning divestiture of the affiliates cannot be squared with the passage immediately following that cited by the majority, which states that there had been unlawful conduct going beyond the acquisition of subsidiaries:

“That principle is adequate here to justify divestiture of all interest in some of the affiliates since their acquisition was part of the fruits of the conspiracy. But the relief need not, and under these facts should not, be so restricted [to divestiture]. The fact that the companies were affiliated induced joint action and agreement. Common control was one of the instruments in bringing about unity of purpose and unity of action and in making the conspiracy effective. If that affiliation continues, *781 there will be tempting opportunity for these exhibitors to continue to act in combination against the independents.” 323 U.S., at 189–190, 65 S.Ct., at 262–263 (emphasis supplied).

Similarly, in Schine Chain Theatres, Inc. v. United States, 334 U.S. 110, 68 S.Ct. 947, 92 L.Ed. 1245 (1948), the Court held that concerted action by parents and subsidiaries constituted an unlawful conspiracy. 3 **2747 That was also the holding in United States v. Griffith, 334 U.S. 100, 109, 68 S.Ct. 941, 946, 92 L.Ed. 1236 (1948). The majority's observation that in these cases there were alternative grounds that could have been used to reach the same result, ante, at 2738, n. 8, disguises neither the fact that the holding that actually appears in these opinions rests on conspiracy between affiliated entities, nor that today's holding is inconsistent with what was actually held in these cases.

In Kiefer–Stewart Co. v. Joseph E. Seagram & Sons, Inc., 340 U.S. 211, 71 S.Ct. 259, 95 L.Ed. 219 (1951), the Court's holding was plain and unequivocal:

“Respondents next suggest that their status as ‘mere instrumentalities of a single manufacturing-merchandizing unit’ makes it impossible for them to have conspired in a manner forbidden by the Sherman Act. But this suggestion runs counter to our past decisions that common ownership and control does not liberate corporations from the impact of the antitrust laws. E.g. United States v. Yellow Cab Co., 332 U.S. 218, 67 S.Ct. 1560, 91 L.Ed. 2010. The rule is especially applicable where, as here, respondents hold themselves out as competitors.” Id., at 215, 71 S.Ct., at 261.

*782 This holding is so clear that even the Court, which is not wanting for inventiveness in its reading of the prior cases, cannot explain it away. The Court suggests only that today Kiefer–Stewart might be decided on alternative grounds, ante, at 2738, ignoring the fact that today's holding is inconsistent with the ground on which the case actually was decided. 4

A construction of the statute that reaches agreements between corporate parents and subsidiaries was again embraced by the Court in Timken Roller Bearing Co. v. United States, 341 U.S. 593, 71 S.Ct. 971, 95 L.Ed. 1199 (1951), 5 and Perma Life Mufflers, Inc. v. United States, 392 U.S. 134, 88 S.Ct. 1881, 20 L.Ed.2d 982 (1968). 6 The majority only notes that there
might have been other grounds for decision available in these cases, ante, at 2739, but again it cannot deny that its new rule is inconsistent with what the Court actually did write in these cases.

*783 Thus, the rule announced today is inconsistent with what this Court has held on at least seven previous occasions. 7 Perhaps **2748 most illuminating is the fact that until today, whether they favored the doctrine or not, it had been the universal conclusion of both the lower courts 8 and the commentators 9 that this Court's cases establish that a parent *784 and a wholly owned subsidiary corporation are capable of conspiring in violation of § 1. In this very case the Court of Appeals observed:

“[T]he salient factor is that the Supreme Court's decisions, while they need not be read with complete literalism, of course they cannot be ignored. It is no accident that every Court of Appeals to consider the question has concluded that a parent and its subsidiary have the same capacity to conspire, whether or not they can be found to have done so in a particular case.” 691 F.2d 310, 317 (CA7 1982) (footnotes omitted).

Thus, we are not writing on a clean slate. “[W]e must bear in mind that considerations of stare decisis weigh heavily in the area of statutory construction, where Congress is free to change this Court's interpretation of its legislation.” Illinois Brick Co. v. Illinois, 431 U.S. 720, 736, 97 S.Ct. 2061, 2069, 52 L.Ed.2d 707 (1977). 10 There can be no doubt that the Court today changes what has been taken to be the long-settled rule: a rule that Congress did not revise at any point in the last four decades. At a minimum there should be a strong presumption against the approach taken today by the Court. It is to the merits of that approach that I now turn.

II

The language of § 1 of the Sherman Act is sweeping in its breadth: “Every contract, combination in the form of trust or *785 otherwise, or conspiracy, in restraint of trade or commerce among the several States, ... is declared to be illegal.” **2749 15 U.S.C. § 1. This Court has long recognized that Congress intended this language to have a broad sweep, reaching any form of combination:

“[I]n view of the many new forms of contracts and combinations which were being evolved from existing economic conditions, it was deemed essential by an all-embracing enumeration to make sure that no form of contract or combination by which an undue restraint of interstate or foreign commerce was brought about could save such restraint from condemnation. The statute under this view evidenced the intent not to restrain the right to make and enforce contracts, whether resulting from combination or otherwise, which did not unduly restrain interstate or foreign commerce, but to protect that commerce from being restrained by methods, whether old or new, which would constitute an interference that is an undue restraint.” Standard Oil Co. v. United States, 221 U.S. 1, 59–60, 31 S.Ct. 502, 515–516, 55 L.Ed. 619 (1911).

This broad construction is illustrated by the Court's refusal to limit the statute to actual agreements. Even mere acquiescence in an anticompetitive scheme has been held sufficient to satisfy the statutory language. 11

Since the statute was written against the background of the common law, 12 reference to the common law is particularly enlightening in construing the statutory requirement of a “contract, combination in the form of trust or otherwise, or conspiracy.” Under the common law, the question whether *786 affiliated corporations constitute a plurality of actors within the meaning of the statute is easily answered. The well-settled rule is that a corporation is a separate legal entity; the separate corporate form cannot be disregarded. 13 The Congress that passed the Sherman Act was well acquainted with this rule. See 21 Cong.Rec. 2571 (1890) (remarks of Sen. Teller) (“Each corporation is a creature by itself”). Thus it has long been the law of criminal conspiracy that the officers of even a single corporation are capable of conspiring with each other or the corporation. 14 This Court has
held that a corporation can conspire with its employee,\(^{15}\) and \(^{2750}\) that a labor union can “combine” with its business agent within the meaning of § 1.\(^{16}\) This concept explains the Timken Court's statement that the affiliated corporations in that case made \(^{787}\) “agreements between legally separate persons,” 341 U.S., at 598, 71 S.Ct., at 975. Thus, today's holding that agreements between parent and subsidiary corporations involve merely unilateral conduct is at odds with the way that this Court has traditionally understood the concept of a combination or conspiracy, and also at odds with the way in which the Congress that enacted the Sherman Act surely understood it.

Holding that affiliated corporations cannot constitute a plurality of actors is also inconsistent with the objectives of the Sherman Act. Congress was particularly concerned with “trusts,” hence it named them in § 1 as a specific form of “combination” at which the statute was directed. Yet “trusts” consisted of affiliated corporations. As Senator Sherman explained:

“Because these combinations are always in many States and, as the Senator from Missouri says, it will be very easy for them to make a corporation within a State. So they can; but that is only one corporation of the combination. The combination is always of two or more, and in one case of forty-odd corporations, all bound together by a link which holds them under the name of trustees, who are themselves incorporated under the laws of one of the States.” 21 Cong.Rec. 2569 (1890).

The activities of these “combinations” of affiliated corporations were of special concern:

 “[A]ssociated enterprise and capital are not satisfied with partnerships and corporations competing with each other, and have invented a new form of combination commonly called trusts, that seeks to avoid competition by combining the controlling corporations, partnerships, and individuals engaged in the same business, and placing the power and property of the combination under the government of a few individuals, and often under the control of a single man called a trustee, a chairman, or a president.

\(^{788}\) “The sole object of such a combination is to make competition impossible. It can control the market, raise or lower prices, as will best promote its selfish interests, reduce prices in a particular locality and break down competition and advance prices at will where competition does not exist. Its governing motive is to increase the profits of the parties composing it. The law of selfishness, uncontrolled by competition, compels it to disregard the interest of the consumer. It dictates terms to transportation companies, it commands the price of labor without fear of strikes, for in its field it allows no competitors.... It is this kind of a combination we have to deal with now.” Id., at 2457.\(^{17}\)

Thus, the corporate subsidiary, when used as a device to eliminate competition, was one of the chief evils to which the Sherman Act was addressed.\(^{18}\) The anomaly \(^{2751}\) in today's holding is that the corporate devices most similar to the original “trusts” are now those which free an enterprise from antitrust scrutiny.

\(^{789}\) III

The Court's reason for rejecting the concept of a combination or conspiracy among a parent corporation and its wholly owned subsidiary is that it elevates form over substance—while in form the two corporations are separate legal entities, in substance they are a single integrated enterprise and hence cannot comprise the plurality of actors necessary to satisfy § 1. Ante, at 2742–2744. In many situations the Court's reasoning is perfectly sensible, for the affiliation of corporate entities often is procompetitive precisely because, as the Court explains, it enhances efficiency. A challenge to conduct that is merely an incident of the desirable integration that accompanies such affiliation should fail. However, the protection of such conduct provides no justification for the Court's new rule, precisely because such conduct cannot be characterized as an unreasonable restraint of trade violative of § 1. Conversely, the problem with the Court's new rule is that it leaves a significant gap in the enforcement of § 1 with respect to anticompetitive conduct that is entirely unrelated to the efficiencies associated with integration.
Since at least United States v. Colgate & Co., 250 U.S. 300, 39 S.Ct. 465, 63 L.Ed. 992 (1919), § 1 has been construed to require a plurality of actors. This requirement, however, is a consequence of the plain statutory language, not of any economic principle. As an economic matter, what is critical is the presence of market power, rather than a plurality of actors. \textsuperscript{19} From a competitive standpoint, a decision of a single firm possessing power to reduce output and raise prices above competitive levels has the same consequence as a decision by two firms acting together who have acquired an equivalent amount of market power through an agreement not to compete. \textsuperscript{20} Unilateral conduct by a firm with market power has no less anticompetitive potential than conduct by a plurality of actors which generates or exploits the same power, \textsuperscript{21} and probably more, since the unilateral actor avoids the policing problems faced by cartels.

The rule of Yellow Cab thus has an economic justification. It addresses a gap in antitrust enforcement by reaching anticompetitive agreements between affiliated corporations which \textsuperscript{791} have sufficient market power to restrain marketwide competition, but not sufficient power to be considered monopolists within the ambit of § 2 of the Act. \textsuperscript{22} The doctrine is also useful when a third party declines to join a conspiracy to restrain trade among affiliated corporations, and is harmed as a result through a boycott or similar tactics designed to penalize the refusal. In such cases, since there has been no agreement with the third party, only an agreement between the affiliated corporations can be the basis for § 1 inquiry. \textsuperscript{23} Finally, it must be remembered that not all persons who restrain trade wear grey flannel suits. Businesses controlled by organized crime often attempt to gain control of an industry through violence or intimidation of competitors; in such cases § 1 can be applied to separately incorporated businesses which benefit from such tactics, but which may be ultimately controlled by a single criminal enterprise. \textsuperscript{24}

\textsuperscript{792} The rule of Yellow Cab and its progeny is not one that condemns every parent-subsidiary relationship. A single firm, no matter what its corporate structure may be, is not expected to compete with itself. \textsuperscript{25} Functional integration by its very nature requires unified action; hence in itself it has never been sufficient to establish the existence of an unreasonable restraint of trade: “In discussing the charge in the Yellow Cab case, we said that the fact that the conspirators were integrated did not insulate them from the act, not that corporate integration violated the act.” United States v. Columbia Steel Co., 334 U.S. 495, 522, 68 S.Ct. 1107, 1121, 92 L.Ed. 1533 (1948). Restraints that act only on the parent or its subsidiary as a consequence of an otherwise lawful integration do not violate § 1 of the Sherman Act. \textsuperscript{26} But if the behavior at issue is unrelated to any functional integration between the affiliated corporations and \textsuperscript{793} imposes a restraint on third parties of sufficient magnitude to restrain marketwide competition, as a matter of economic substance, as well as form, it is appropriate to characterize the conduct as a “combination or conspiracy in restraint of trade.”\textsuperscript{27}

For example, in Yellow Cab the Court read the complaint as alleging that integration had assisted the parent in excluding competing manufacturers from the marketplace, 332 U.S., at 226–227, 67 S.Ct., at 1564–1565, leading the Court to conclude that “restraint of interstate trade was not only effected by the combination of the appellees but was the primary object of the combination.” Id., at 227, 67 S.Ct., at 1565. Similarly, in Crescent Amusement the Court noted that corporate affiliation between exhibitors enhanced their buying power and “was one of the instruments in ... making the conspiracy effective” in excluding independents from the market. 323 U.S., at 189–190, 65 S.Ct., at 262–263. Thus, in both cases the Court found that the affiliation enhanced the ability of the parent corporation to exclude the competition of third parties, and hence raised entry barriers faced by actual and potential competitors. When conduct restrains trade not merely by integrating affiliated corporations but rather by restraining the ability of others to compete, that conduct has competitive significance drastically different from procompetitive integration. \textsuperscript{28} In these cases, the affiliation assisted exclusionary conduct; it was not the competitive equivalent of unilateral integration but instead generated power to restrain marketwide competition.

There are other ways in which corporate affiliation can operate to restrain competition. A wholly owned subsidiary might market a “fighting brand” or engage in other predatory behavior that would be more effective if its ownership were concealed than
if it was known that only one firm was involved. A predator might be willing to accept the risk of bankrupting a subsidiary when it could not afford to let a division incur similar risks. Affiliated corporations might enhance their power over suppliers by agreeing to refuse to deal with those who deal with an actual or potential competitor of one of them; such a threat might be more potent coming from both corporations than from only one.  

In this case, it may be that notices to potential suppliers of respondent emanating from Copperweld carried more weight than would notices coming only from Regal. There was evidence suggesting that Regal and Copperweld were not integrated, and that the challenged agreement had little to do with achieving procompetitive efficiencies and much to do with protecting Regal's market position. The Court does not even try to explain why their common ownership meant that Copperweld and Regal were merely obtaining benefits associated with the efficiencies of integration. Both the District Court and the Court of Appeals thought that their agreement had a very different result—that it raised barriers to entry and imposed an appreciable marketwide restraint. The Court's discussion of the justifications for corporate affiliation is therefore entirely abstract—while it dutifully lists the procompetitive justifications for corporate affiliation, ante, at 2743, it fails to explain how any of them relate to the conduct at issue in this case. What is challenged here is not the fact of integration between Regal and Copperweld, but their specific agreement with respect to Independence. That agreement concerned the exclusion of Independence from the market, and not any efficiency resulting from integration. The facts of this very case belie the conclusion that affiliated corporations are incapable of engaging in the kind of conduct that threatens marketwide competition. The Court does not even attempt to assess the competitive significance of the conduct under challenge here—it never tests its economic assumptions against the concrete facts before it. Use of economic theory without reference to the competitive impact of the particular economic arrangement at issue is properly criticized when it produces overly broad per se rules of antitrust liability; criticism is no less warranted when a per se rule of antitrust immunity is adopted in the same way.

In sum, the question that the Court should ask is not why a wholly owned subsidiary should be treated differently from a corporate division, since the immunity accorded that type of arrangement is a necessary consequence of Colgate. Rather the question should be why two corporations that engage in a predatory course of conduct which produces a marketwide restraint on competition and which, as separate legal entities, can be easily fit within the language of § 1, should be immunized from liability because they are controlled by the same godfather. That is a question the Court simply fails to confront. I respectfully dissent.

All Citations

467 U.S. 752, 104 S.Ct. 2731, 81 L.Ed.2d 628, 1984-2 Trade Cases P 66,065

Footnotes

a1 The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See United States v. Detroit Lumber Co., 200 U.S. 321, 337, 26 S.Ct. 282, 287, 50 L.Ed. 499.

1 The chairman of the board and chief executive officer of both Copperweld and Regal, Phillip H. Smith, was also named as a defendant. In addition, respondents originally charged petitioners and Smith with an attempt to monopolize the market for structural steel tubing in violation of § 2 of the Sherman Act, 26 Stat. 209, as amended, 15 U.S.C. § 2. Before trial respondent dismissed Smith as a defendant and dismissed its § 2 monopolization count.

Petitioners counterclaimed on the ground that respondent and Grohne had used proprietary information belonging to Regal, had competed unfairly by hiring away key Regal personnel, and had interfered with prospective business relationships by filing the lawsuit on the eve of a large Copperweld debenture offering. At the close of the evidence,

the court directed a verdict against petitioners on their counterclaims. The disposition of these claims is not at issue before this Court.

2 The jury was instructed to consider many different factors: for instance, whether Copperweld and Regal had separate management staffs, separate corporate officers, separate clients, separate records and bank accounts, separate corporate offices, autonomy in setting policy, and so on. The jury also was instructed to consider “any other facts that you find are relevant to a determination of whether or not Copperweld and Regal are separate and distinct companies.” App. to Pet. for Cert. B–9.

3 Section 1 of the Sherman Act provides in pertinent part:

“Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal. Every person who shall make any contract or engage in any combination or conspiracy hereby declared to be illegal shall be deemed guilty of a felony.” 26 Stat. 209, as amended, 15 U.S.C. § 1.

4 Under the arrangements condemned in Northern Securities Co. v. United States, 193 U.S. 197, 354, 24 S.Ct. 436, 463, 48 L.Ed. 679 (1904) (plurality opinion), “all the stock [a railroad holding company] held or acquired in the constituent companies was acquired and held to be used in suppressing competition between those companies. It came into existence only for that purpose.” In Standard Oil Co. v. United States, 221 U.S. 1, 31 S.Ct. 502, 55 L.Ed. 619 (1911), and United States v. American Tobacco Co., 221 U.S. 106, 31 S.Ct. 632, 55 L.Ed. 663 (1911), the trust or holding company device brought together previously independent firms to lessen competition and achieve monopoly power. Although the Court in the latter case suggested that the contracts between affiliated companies, and not merely the original combination, could be viewed as the conspiracy, id., at 184, 31 S.Ct., at 650, the Court left no doubt that “the combination in and of itself” was a restraint of trade and a monopolization, id., at 187, 31 S.Ct., at 651.

5 Contrary to the dissent's suggestion, post, at 2746–2751, n. 18, our point is not that Yellow Cab found only the initial acquisition illegal; our point is that the illegality of the initial acquisition was a predicate for its holding that any post-acquisition conduct violated the Act.

6 When discussing the fact that some of the affiliated Chicago operating companies did not compete to obtain exclusive transportation contracts held by another of the affiliated companies, the Court stated:

“[T]he fact that the competition restrained is that between affiliated corporations cannot serve to negative the statutory violation where, as here, the affiliation is assertedly one of the means of effectuating the illegal conspiracy not to compete.” 332 U.S., at 229, 67 S.Ct., at 1566 (emphasis added).

The passage quoted in text is soon followed by a cite to United States v. Crescent Amusement Co., 323 U.S. 173, 189, 65 S.Ct. 254, 262, 89 L.Ed. 160 (1944). Crescent Amusement found violations of §§ 1 and 2 by film exhibitors affiliated (in most cases) by 50 percent ownership. The exhibitors used the monopoly power they possessed in certain towns to force film distributors to give them favorable terms in other towns. The Court found it unnecessary to view the distributors as part of the conspiracy, id., at 183, 65 S.Ct., at 259, so the Court plainly viewed the affiliated entities themselves as the conspirators. The Crescent Amusement Court, however, in affirming an order of divestiture, noted that such a remedy was appropriate when “creation of the combination is itself the violation.” Id., at 189, 65 S.Ct., at 262. This suggests that both Crescent Amusement and Yellow Cab, which cited the very page on which this passage appears, stand for a narrow rule based on the original illegality of the affiliation.

The dissent misconstrues a later passage in Crescent Amusement stating that divestiture need not be limited to those affiliates whose “acquisition was part of the fruits of the conspiracy,” 323 U.S., at 189, 65 S.Ct., at 262. See post, at 2747.
Hong, Kenneth 7/11/2022  
For Educational Use Only

104 S.Ct. 2731, 81 L.Ed.2d 628, 1984-2 Trade Cases P 66,065

This meant only that divestiture could apply to affiliates other than those who were driven out of business by the practices of the original conspirators and who were then acquired illegally to increase the combination's monopoly power. See 323 U.S., at 181, 65 S.Ct., at 258. It did not mean that affiliates acquired for lawful purposes were subject to divestiture.

7 Appalachian Coals does state that the key question is whether there is an unreasonable restraint of trade or an attempt to monopolize. “If there is, the combination cannot escape because it has chosen corporate form; and, if there is not, it is not to be condemned because of the absence of corporate integration.” 288 U.S., at 377, 53 S.Ct., at 480. Appalachian Coals, however, validated a cooperative selling arrangement among independent entities. The statement that intracorporate relationships would be subject to liability under § 1 is thus dictum. The statement may also envision merely the limited rule in Yellow Cab pertaining to acquisitions that are themselves anticompetitive.

8 In two cases decided soon after Yellow Cab on facts similar to Crescent Amusement, see n. 6, supra, affiliated film exhibitors were found to have conspired in violation of § 1. Schine Chain Theatres, Inc. v. United States, 334 U.S. 110, 68 S.Ct. 947, 92 L.Ed. 1245 (1948); United States v. Griffith, 334 U.S. 100, 68 S.Ct. 941, 92 L.Ed. 1236 (1948). Griffith simply assumed that the companies were capable of conspiring with each other; Schine cited Yellow Cab and Crescent Amusement for the proposition, 334 U.S., at 116, 68 S.Ct., at 951. In both cases, however, an intra-enterprise conspiracy holding was unnecessary not only because the Court found a § 2 violation, but also because the affiliated exhibitors had conspired with independent film distributors. See ibid.; Griffith, supra, at 103, n. 6, 109, 68 S.Ct., at 943, n. 6, 946.

9 Although the plaintiff apparently never acquiesced in the resale price maintenance scheme, Kiefer–Stewart Co. v. Joseph E. Seagram & Sons, Inc., 182 F.2d 228, 231 (CA7 1950), rev'd, 340 U.S. 211, 71 S.Ct. 259, 95 L.Ed. 219 (1951), one of the subsidiaries did gain the compliance of other wholesalers after once terminating them for refusing to abide by the pricing scheme. See 182 F.2d, at 231; 340 U.S., at 213, 71 S.Ct., at 260. A theory of combination between the subsidiaries and the wholesalers could now support § 1 relief, whether or not it could have when Kiefer–Stewart was decided. See Albrecht v. Herald Co., 390 U.S. 145, 149–150, and n. 6, 88 S.Ct. 869, 871–872, and n. 6, 19 L.Ed.2d 998 (1968); United States v. Parke, Davis & Co., 362 U.S. 29, 80 S.Ct. 503, 4 L.Ed.2d 505 (1960).

10 See United States v. Timken Roller Bearing Co., 83 F.Supp. 284, 11–312 (ND Ohio 1949), aff'd as modified, 341 U.S. 593, 71 S.Ct. 971, 95 L.Ed. 1199 (1951). The agreement of an individual named Dewar, who owned 24 and 50 percent of the foreign corporations respectively, was apparently required for the American defendant to have its way.

11 For almost 20 years before they became affiliated by stock ownership, two of the corporations had been party to the sort of restrictive agreements the Timken Court condemned. Three Justices upholding antitrust liability were of the view that Timken's “interests in the [foreign] companies were obtained as part of a plan to promote the illegal trade restraints” and that the “intercorporate relationship” was “the core of the conspiracy.” Id., at 600–601, 71 S.Ct., at 975–976. Because two Justices found no antitrust violation at all, see id., at 605, 71 S.Ct., at 978 (Frankfurter, J., dissenting); id., at 606, 71 S.Ct., at 978 (Jackson, J., dissenting), and two Justices did not take part, apparently only Chief Justice Vinson and Justice Reed were prepared to hold that there was a violation even if the initial acquisition itself was not illegal. See id., at 601–602, 71 S.Ct., at 976–977 (Reed, J., joined by Vinson, C.J., concurring).

Section 2 of the Sherman Act provides in pertinent part:

“Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony.” 26 Stat. 209, as amended, 15 U.S.C. § 2.

By making a conspiracy to monopolize unlawful, § 2 does reach both concerted and unilateral behavior. The point remains, however, that purely unilateral conduct is illegal only under § 2 and not under § 1. Monopolization without conspiracy is unlawful under § 2, but restraint of trade without a conspiracy or combination is not unlawful under § 1.

For example, the Court has declared that § 2 does not forbid market power to be acquired “as a consequence of a superior product, [or] business acumen.” United States v. Grinnell Corp., 384 U.S. 563, 571, 86 S.Ct. 1698, 1704, 16 L.Ed.2d 778 (1966). We have also made clear that the “antitrust laws ... were enacted for ‘the protection of competition, not competitors.’ ” Brunswick Corp. v. Pueblo Bowl–O–Mat, Inc., 429 U.S. 477, 488, 97 S.Ct. 690, 697, 50 L.Ed.2d 701 (1977) (damages for violation of Clayton Act § 7) (quoting Brown Shoe Co. v. United States, 370 U.S. 294, 320, 82 S.Ct. 1502, 1521, 8 L.Ed.2d 510 (1962)).

Nothing in the language of the Sherman Act is inconsistent with the view that corporations cannot conspire with their own officers. It is true that a “person” under the Act includes both an individual and a corporation. 15 U.S.C. § 7. But § 1 does not declare every combination between two “persons” to be illegal. Instead it makes liable every “person” engaging in a combination or conspiracy “hereby declared to be illegal.” As we note, the principles governing § 1 liability plainly exclude from unlawful combinations or conspiracies the activities of a single firm.

As applied to a wholly owned subsidiary, the so-called “single entity” test is thus inadequate to preserve the Sherman Act’s distinction between unilateral and concerted conduct. Followed by the Seventh Circuit below as well as by other Courts of Appeals, this test sets forth various criteria for evaluating whether a given parent and subsidiary are capable
of conspiring with each other. See n. 2, supra; see generally Ogilvie v. Fotomat Corp., 641 F.2d 581 (CA8 1981); Las Vegas Sun, Inc. v. Summa Corp., 610 F.2d 614 (CA9 1979), cert. denied, 447 U.S. 906, 100 S.Ct. 2988, 64 L.Ed.2d 855 (1980); Photovest Corp. v. Fotomat Corp., 606 F.2d 704 (CA7 1979), cert. denied, 445 U.S. 917, 100 S.Ct. 1278, 63 L.Ed.2d 601 (1980). These criteria measure the “separateness” of the subsidiary: whether it has separate control of its day-to-day operations, separate officers, separate corporate headquarters, and so forth. At least when a subsidiary is wholly owned, however, these factors are not sufficient to describe a separate economic entity for purposes of the Sherman Act. The factors simply describe the manner in which the parent chooses to structure a subunit of itself. They cannot overcome the basic fact that the ultimate interests of the subsidiary and the parent are identical, so the parent and the subsidiary must be viewed as a single economic unit.

Because an “agreement” between a parent and its wholly owned subsidiary is no more likely to be anticompetitive than an agreement between two divisions of a single corporation, it does not matter that the parent “availed [itself] of the privilege of doing business through separate corporations,” Perma Life Mufflers, Inc. v. International Parts Corp., 392 U.S. 134, 141, 88 S.Ct. 1981, 1985, 20 L.Ed.2d 982 (1968). The purposeful choice of a parent corporation to organize a subunit as a subsidiary is not itself a reason to heighten antitrust scrutiny, because it is not laden with anticompetitive risk.

Separate incorporation may reduce federal or state taxes or facilitate compliance with regulatory or reporting laws. Local incorporation may also improve local identification. Investors or lenders may prefer to specialize in a particular aspect of a conglomerate’s business. Different parts of the business may require different pension or profit-sharing plans or different accounting practices.” Areeda, 97 Harv.L.Rev., at 453.

Sunkist Growers provides strong support for the notion that separate incorporation does not necessarily imply a capacity to conspire. The defendants in that case were an agricultural cooperative, its wholly owned subsidiary, and a second cooperative comprising only members of the first. The Court refused to find a § 1 or § 2 conspiracy among them because they were “one ‘organization’ or ‘association’ even though they have formally organized themselves into three separate legal entities.” 370 U.S., at 29, 82 S.Ct., at 1136. Although this holding derived from statutory immunities granted to agricultural organizations, the reasoning of Sunkist Growers supports the broader principle that substance, not form, should determine whether a separately incorporated entity is capable of conspiring under § 1.


The dissent argues that references in the legislative history to “trusts” suggest that Congress intended § 1 to govern the conduct of all affiliated corporations. See post, at 2750–2751. But those passages explicitly refer to combinations created for the very purpose of restraining trade. None of the cited debates refers to the postacquisition conduct of corporations whose initial affiliation was lawful. Indeed, Senator Sherman stated:

“It is the unlawful combination, tested by the rules of common law and human experience, that is aimed at by this bill, and not the lawful and useful combination.” 121 Cong.Rec. 2457 (1890).

Even if common-law intracorporate conspiracies were firmly established when Congress passed the Sherman Act, the obvious incompatibility of an intracorporate conspiracy with § 1 is sufficient to refute the dissent’s suggestion that Congress intended to incorporate such a definition. See post, at 2749–2750. Moreover, it is far from clear that intracorporate conspiracies were recognized at common law in 1890. Even today courts disagree whether corporate employees can conspire with themselves or with the corporation for purposes of certain statutes, such as 42 U.S.C. § 1985(3). Compare, e.g., Novotny v. Great Am. Fed. Sav. & Loan Assn., 584 F.2d 1235 (CA3 1978) (en banc), vacated and remanded on other grounds, 442 U.S. 366, 99 S.Ct. 2345, 60 L.Ed.2d 957 (1979), with Dombrowski v. Dowling, 459 F.2d 190 (CA7 1972). And in 1890 it was disputed whether a corporation could itself be guilty of a crime that required criminal intent, such as conspiracy. Commentators appear to agree that courts began finding corporate liability for such
crimes only around the turn of the century. See generally Edgerton, Corporate Criminal Responsibility, 36 Yale L.J. 827, 828, and n. 11 (1927); Miller, Corporate Criminal Liability: A Principle Extended to Its Limits, 38 Fed. Bar J. 49 (1979); Note, 60 Harv.L.Rev. 283, 284, and n. 9 (1946). Of course, Congress changed that common-law rule when it explicitly provided that a corporation could be guilty of a § 1 conspiracy. But the point remains that the Sherman Act did not import a pre-existing common-law tradition recognizing conspiracies between corporations and their own employees.

25 “[T]he [intra-enterprise conspiracy] doctrine has played a relatively minor role in government enforcement actions, and the government has not relied on the doctrine in recent years.” Brief for United States as Amicus Curiae 26, n. 42.

1 The language I have quoted, most of which is overlooked by the majority, makes it clear that the Court's adoption of the concept of conspiracy between affiliated corporations was unqualified. As the first word of the sentence indicates, the Court's following statement: “Similarly, any affiliation or integration flowing from an illegal conspiracy cannot insulate the conspirators from the sanctions which Congress has imposed,” 332 U.S., at 227, 67 S.Ct., at 1565, expresses a separate if related point.

2 “[B]y preventing the cab operating companies under their control from purchasing cabs from manufacturers other than CCM, the appellees deny those companies the opportunity to purchase cabs in a free, competitive market. The Sherman Act has never been thought to sanction such a conspiracy to restrain the free purchase of goods in interstate commerce.” Id., at 226–227, 67 S.Ct., at 1564–1565 (footnote omitted).

3 “[T]he combining of the open and closed towns for the negotiation of films for the circuit was a restraint of trade and the use of monopoly power in violation of § 1 and § 2 of the Act. The concerted action of the parent company, its subsidiaries, and the named officers and directors in that endeavor was a conspiracy which was not immunized by reason of the fact that the members were closely affiliated rather than independent. See United States v. Yellow Cab Co., 332 U.S. 218, 227 [67 S.Ct. 1560, 1565, 91 L.Ed. 2010]; United States v. Crescent Amusement Co., 323 U.S. 173 [65 S.Ct. 254, 89 L.Ed. 160].” 334 U.S., at 116, 68 S.Ct., at 951.

4 In Kiefer–Stewart, Seagram unsuccessfully argued that Yellow Cab was confined to cases concerning unlawful acquisitions, see Brief for Respondents, O.T.1950, No. 297, p. 21. Thus the Kiefer–Stewart Court considered and rejected exactly the same argument embraced by today's majority.

5 “The fact that there is common ownership or control of the contracting corporations does not liberate them from the impact of the antitrust laws. E.g., Kiefer–Stewart Co. v. Seagram & Sons, [340 U.S.,] at 215 [71 S.Ct., at 261]. Nor do we find any support in reason or authority for the proposition that agreements between legally separate persons and companies to suppress competition among themselves and others can be justified by labeling the project a 'joint venture.' Perhaps every agreement and combination to restrain trade could be so labeled.” 341 U.S., at 598, 71 S.Ct., at 974.

6 “There remains for consideration only the Court of Appeals' alternative holding that the Sherman Act claim should be dismissed because respondents were all part of a single business entity and were therefore entitled to cooperate without creating an illegal conspiracy. But since respondents Midas and International availed themselves of the privilege of doing business through separate corporations, the fact of common ownership could not save them from any of the obligations that the law imposes on separate entities. See Timken Co. v. United States, 341 U.S. 593, 598 [71 S.Ct. 971, 974, 95 L.Ed. 1199] (1951); United States v. Yellow Cab Co., 332 U.S. 218, 227 [67 S.Ct. 1560, 1565, 91 L.Ed. 2010] (1947).” 392 U.S., at 141–142, 88 S.Ct., at 1985–1986.

7 Also pertinent is United States v. Citizens & Southern National Bank, 422 U.S. 86, 95 S.Ct. 2099, 45 L.Ed.2d 41 (1975), in which the Court wrote:

104 S.Ct. 2731, 81 L.Ed.2d 628, 1984-2 Trade Cases P 66,065


Attorney General’s Committee Report, supra n. 9, at 30–31 (citing Barron v. United States, 5 F.2d 799 (CA1 1925); Mininsohn v. United States, 101 F.2d 477 (CA3 1939); Egan v. United States, 137 F.2d 369 (CA8), cert. denied, 320...

104 S.Ct. 2731, 81 L.Ed.2d 628, 1984-2 Trade Cases P 66,065


17 See also 21 Cong.Rec. 2562 (1890) (remarks of Sen. Teller); id., at 2570 (remarks of Sen. Sherman); id., at 2609 (remarks of Sen. Morgan).

18 This legislative history thus demonstrates the error in the majority's conclusion that only acquisitions of corporate affiliates fall within § 1. See ante, at 2737. The conduct of the trusts that Senator Sherman and others objected to went much further than mere acquisitions. Indeed, the irony of the Court's approach is that, had it been adopted in 1890, it would have meant that § 1 would have no application to trust combinations which had already been formed—the very trusts to which Senator Sherman was referring.

I cannot believe that the Court really intends to express doubt as to whether the Congress that passed the Sherman Act thought conspiracy doctrine could apply to corporations. Ante, at 2744, n. 24. If that were not the case, then the Sherman Act would have no application to corporations. Since, as is clear and as the Court concedes, the Sherman Act does apply to corporations, there can be no doubt that Congress intended to apply the law of conspiracy to agreements between corporations.


20 Significantly, the Court never suggests that the plurality-of-actors requirement has any intrinsic economic significance. Rather, it suggests that the requirement has evidentiary significance: combinations are more likely to signal anticompetitive conduct than is unilateral activity: “In any conspiracy, two or more entities that previously pursued their own interests separately are combining to act as one for their common benefit. This not only reduces the diverse directions in which economic power is aimed but suddenly increases the economic power moving in one particular direction.” Ante, at 2741. That is true, but it is also true of any ordinary commercial contract between separate entities, as can be seen if one substitutes the word “contract” for “conspiracy” in the passage I have quoted. The language of the Sherman Act indicates that it treats “contracts” and “conspiracies” as equivalent concepts—both satisfy the multiplicity-of-actors requirement—and yet one of the most fundamental points in antitrust jurisprudence, dating at least to Standard Oil, is that there is nothing inherently anticompetitive about a contract. Similarly, an agreement to act “for common benefit” in itself is unremarkable—all agreements are in some sense a restraint of trade be they contracts or conspiracies. It is only when trade is unreasonably restrained that § 1 is implicated. The Court's evidentiary concern lacks merit.
We made this point in the context of resale price maintenance in United States v. Parke, Davis & Co., 362 U.S. 29, 80 S.Ct. 503, 4 L.Ed.2d 505 (1960):

“The Sherman Act forbids combinations of traders to suppress competition. True, there results the same economic effect as is accomplished by a prohibited combination to suppress price competition if each customer, although induced to do so solely by a manufacturer's announced policy, independently decides to observe specified resale prices. So long as Colgate is not overruled, this result is tolerated but only when it is the consequence of a mere refusal to sell in the exercise of a manufacturer's right ‘freely to exercise his own independent discretion as to parties with whom he will deal.’” Id., at 44, 80 S.Ct., at 512 (quoting Colgate, 250 U.S., at 307, 39 S.Ct., at 468).

“[I]t is the potential which this conspiracy concept holds for the development of a rational enforcement policy which, if anything, will ultimately attract the courts. If conduct of a single corporation which restrains trade were to violate Section 1, a forceful weapon would be available to the government with which to challenge conduct which in oligopolistic industries creates or reinforces entry barriers. Excessive advertising in the cereal, drug, or detergent industries, annual style changes in the auto industry, and other such practices could be reached as soon as they threatened to inhibit competition; there would be no need to wait until a ‘dangerous probability’ of monopoly had been reached, the requirement under Section 2 ‘attempt’ doctrine. Nor would a single firm restraint of trade rule be overbroad. It would in no way threaten single firm activity—setting a price, deciding what market it would deal in, or the like—which did not threaten competitive conditions.” L. Sullivan supra, n. 9, § 114, at 324 (footnotes omitted).

This was the case in Kiefer–Stewart, for example. Seagram had refused to sell liquor to Kiefer–Stewart unless it agreed to an illegal resale price maintenance scheme. Kiefer–Stewart refused to agree, and as a result was injured by losing access to Seagram's products. See 340 U.S., at 213, 71 S.Ct., at 260.


See Comment, Decisionmaking, supra n. 9, at 1753–1757; Note, Suggested Standard, supra n. 9, at 735–738. Professor Sullivan elaborates:

“Picture, at one end of the spectrum, a family business which operates one retail store in each of three or four adjacent communities. All of the stores are managed as a unit by one individual, the founder of the business who sets policy, does all the buying, decides on all the advertising, sets prices, and hires and fires all employees other than family members. The fact that each store is operated by a separate corporation should not convert a family business into a cartel.... If there is, as a practical matter, an integrated ownership and management, this small business is a single firm. And a single firm cannot compete with itself. Hence it cannot restrain price competition with itself, or divide markets with itself, or act as a common purchasing agent for itself or otherwise restrain competition with itself, regardless of how many separate corporations the single firm may, for reasons unrelated to the act, be divided into.” L. Sullivan, supra n. 9, § 114, at 326–327.

Thus, the Court is wrong to suggest, ante, at 2742, 2744–2745, and n. 24, that Yellow Cab could reach truly unilateral conduct involving only the employees of a single firm.

If the rule of Yellow Cab and its progeny could be easily circumvented through, for example, use of unincorporated divisions instead of subsidiaries, then there would be reason to question its efficacy as a tool for rational antitrust enforcement. However, the Court is incorrect when it asserts, ante, at 2742, 2743, that there is no economic substance in a
distinction between unincorporated divisions, which cannot provide a plurality of actors, and wholly owned subsidiaries, which under Yellow Cab can. If that were the case, incorporated subsidiaries would never be used to achieve integration — the ready availability of an unincorporated alternative would always be employed in order to avoid antitrust liability. The answer is provided by the Court itself—the use of subsidiaries often makes possible operating efficiencies that are unavailable through the use of unincorporated divisions. Ante, at 2743. We may confidently assume that any corporate parent whose contingent antitrust liability exceeds the savings it realizes through the use of subsidiaries already utilizes unincorporated divisions instead of corporate subsidiaries. Thus, it is more than merely a question of form when a decision is made to use corporate subsidiaries instead of unincorporated divisions, and the rule is not that easily circumvented.

28 See L. Sullivan, supra n. 9, § 114, at 328 (“To have two competitors acting concertedly two separate firms, not just persons, are needed. Thus ‘concerted action’ by two ‘legal persons’ which is limited solely to the internal management of a single firm does not restrain competition; but ‘concerted action’ by two ‘legal persons’ which erects barriers to entry by another separate firm, a competitor or potential competitor, can be a restraint of trade”); see also Willis & Pitofsky, supra n. 9, at 38–41. The Attorney General's National Committee to Study the Antitrust Laws made the same point in 1955:

“The substance of the Supreme Court decisions is that concerted action between a parent and subsidiary or between subsidiaries which has for its purpose or effect coercion or unreasonable restraint on the trade of strangers to those acting in concert is prohibited by Section 1. Nothing in these opinions should be interpreted as justifying the conclusion that concerted action solely between a parent and subsidiary or subsidiaries, the purpose and effect of which is not coercive restraint of the trade of strangers to the corporate family, violates Section 1. Where such concerted action restrains no trade and is designed to restrain no trade other than that of the parent and its subsidiaries, Section 1 is not violated.” Attorney General's Committee Report, supra n. 9, at 34.

29 Professor Sullivan provides another example: “[P]icture a parent corporation and its wholly owned subsidiary (or two corporations wholly owned by the same parent or stockholder group) which operate, respectively, a newspaper and a radio station in the same city. If the radio station, which has no local competitors, were to deny advertising to a local business because the latter advertised in a rival newspaper, the integration between the two corporations, however close in terms of ownership or management or both, would not protect them from a charge of conspiracy to restrain trade.... [T]he concerted action here involved is not merely carrying on the business of a single integrated firm, it is action which is aimed at restraining trade by utilizing such market power as is possessed by the firm because of its radio station in order to erect a competitive barrier in front of a competitor of the firm's newspaper.” L. Sullivan, supra n. 9, § 114, at 327 (footnote omitted).

201 L.Ed.2d 678, 86 USLW 4561, 2018-1 Trade Cases P 80,427...

138 S.Ct. 2274
Supreme Court of the United States

OHIO, et al., Petitioners
v.
AMERICAN EXPRESS COMPANY, et al.

No. 16–1454


Synopsis

Background: United States brought action against credit card company, alleging it engaged in restraint of trade by including antisteering provisions in its contracts with merchants that prevented merchants from discouraging customers from using company's cards. Following a bench trial, the United States District Court for the Eastern District of New York, Garaufis, J., 88 F.Supp.3d 143, entered judgment against company, and imposed a permanent injunction, 2015 WL 1966362. Credit card company appealed. The United States Court of Appeals for the Second Circuit, Wesley, Circuit Judge, 838 F.3d 179, reversed and remanded. Certiorari was granted.

Holdings: The Supreme Court, Justice Thomas, held that:

it would analyze two-sided market for credit card transactions as a whole, and

United States failed to carry its burden of proving that antisteering provisions had anticompetitive effects.

Affirmed.

Justice Breyer filed a dissenting opinion, in which Justices Ginsburg, Sotomayor, and Kagan joined.

*Syllabus*

Respondent credit-card companies American Express Company and American Express Travel Related Services Company (collectively, Amex) operate what economists call a “two-sided platform,” *2277 providing services to two different groups (cardholders and merchants) who depend on the platform to intermediate between them. Because the interaction between the two groups is a transaction, credit-card networks are a special type of two-sided platform known as a “transaction” platform. The key feature of transaction platforms is that they cannot make a sale to one side of the platform without simultaneously making a sale to the other. Unlike traditional markets, two-sided platforms exhibit “indirect network effects,” which exist where the value of the platform to one group depends on how many members of another group participate. Two-sided platforms must take these effects into account before making a change in price on either side, or they risk creating a feedback loop of declining...

201 L.Ed.2d 678, 86 USLW 4561, 2018-1 Trade Cases P 80,427...

...demand. Thus, striking the optimal balance of the prices charged on each side of the platform is essential for two-sided platforms to maximize the value of their services and to compete with their rivals.

Visa and MasterCard—two of the major players in the credit-card market—have significant structural advantages over Amex. Amex competes with them by using a different business model, which focuses on cardholder spending rather than cardholder lending. To encourage cardholder spending, Amex provides better rewards than the other credit-card companies. Amex must continually invest in its cardholder rewards program to maintain its cardholders' loyalty. But to fund those investments, it must charge merchants higher fees than its rivals. Although this business model has stimulated competitive innovations in the credit-card market, it sometimes causes friction with merchants. To avoid higher fees, merchants sometimes attempt to dissuade cardholders from using Amex cards at the point of sale—a practice known as “steering.” Amex places antisteering provisions in its contracts with merchants to combat this.

In this case, the United States and several States (collectively, plaintiffs) sued Amex, claiming that its antisteering provisions violate § 1 of the Sherman Antitrust Act. The District Court agreed, finding that the credit-card market should be treated as two separate markets—one for merchants and one for cardholders—and that Amex's antisteering provisions are anticompetitive because they result in higher merchant fees. The Second Circuit reversed. It determined that the credit-card market is one market, not two. And it concluded that Amex's antisteering provisions did not violate § 1.


(a) Section 1 of the Sherman Act prohibits “unreasonable restraints” of trade. State Oil Co. v. Khan, 522 U.S. 3, 10, 118 S.Ct. 275, 139 L.Ed.2d 199. Restraints may be unreasonable in one of two ways—unreasonable per se or unreasonable as judged under the “rule of reason.” Business Electronics Corp. v. Sharp Electronics Corp., 485 U.S. 717, 723, 108 S.Ct. 1515, 99 L.Ed.2d 808. The parties agree that Amex's antisteering provisions should be judged under the rule of reason using a three-step burden-shifting framework. They ask this Court to decide whether the plaintiffs have satisfied the first step in that framework—i.e., whether they have proved that Amex's antisteering provisions have a substantial anticompetitive effect that harms consumers in the relevant market. Pp. 2283 - 2285.

(b) Applying the rule of reason generally requires an accurate definition of the relevant market. In this case, both sides of the two-sided credit-card market—cardholders and merchants—must be considered. Only a company with both cardholders and merchants willing to use its network could sell transactions and compete in the credit-card market. And because credit-card networks cannot make a sale unless both sides of the platform simultaneously agree to use their services, they exhibit more pronounced indirect network effects and interconnected pricing and demand. Indeed, credit-card networks are best understood as supplying only one product—the transaction—that is jointly consumed by a cardholder and a merchant. Accordingly, the two-sided market for credit-card transactions should be analyzed as a whole. Pp. 2285 – 2288.

(c) The plaintiffs have not carried their burden to show anticompetitive effects. Their argument—that Amex's antisteering provisions increase merchant fees—wrongly focuses on just one side of the market. Evidence of a price increase on one side of a two-sided transaction platform cannot, by itself, demonstrate an anticompetitive exercise of market power. Instead, plaintiffs must prove that Amex's antisteering provisions increased the cost of credit-card transactions above a competitive level, reduced the number of credit-card transactions, or otherwise stifled competition in the two-sided credit-card market. They failed to do so. Pp. 2287 – 2290.

(1) The plaintiffs offered no evidence that the price of credit-card transactions was higher than the price one would expect to find in a competitive market. Amex's increased merchant fees reflect increases in the value of its services and the cost of its transactions, not an ability to charge above a competitive price. It uses higher merchant fees to offer its cardholders a more robust rewards program, which is necessary to maintain cardholder loyalty and encourage the level of spending that makes it valuable...
201 L.Ed.2d 678, 86 USLW 4561, 2018-1 Trade Cases P 80,427...

to merchants. In addition, the evidence that does exist cuts against the plaintiffs' view that Amex's antisteering provisions are the cause of any increases in merchant fees: Visa and MasterCard's merchant fees have continued to increase, even at merchant locations where Amex is not accepted. Pp. 2288 – 2289.

(2) The plaintiffs' evidence that Amex's merchant-fee increases between 2005 and 2010 were not entirely spent on cardholder rewards does not prove that Amex's antisteering provisions gave it the power to charge anticompetitive prices. This Court will "not infer competitive injury from price and output data absent some evidence that tends to prove that output was restricted or prices were above a competitive level." *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 237, 113 S.Ct. 2578, 125 L.Ed.2d 168. There is no such evidence here. Output of credit-card transactions increased during the relevant period, and the plaintiffs did not show that Amex charged more than its competitors. Pp. 2288 – 2289.

(3) The plaintiffs also failed to prove that Amex's antisteering provisions have stifled competition among credit-card companies. To the contrary, while they have been in place, the market experienced expanding output and improved quality. Nor have Amex's antisteering provisions ended competition between credit-card networks with respect to merchant fees. Amex's competitors have exploited its higher merchant fees to their advantage. Lastly, there is nothing inherently anticompetitive about the provisions. They actually stem negative externalities in the credit-card market and promote interbrand competition. And they do not prevent competing credit-card networks from offering lower merchant fees or promoting their broader merchant acceptance. Pp. 2289 – 2290.

838 F.3d 179, affirmed.

*2279* THOMAS, J., delivered the opinion of the Court, in which ROBERTS, C.J., and KENNEDY, ALITO, and GORSUCH, JJ., joined. BREYER, J., filed a dissenting opinion, in which GINSBURG, SOTOMAYOR, and KAGAN, JJ., joined.

**Attorneys and Law Firms**

Eric E. Murphy, Solicitor, Columbus, OH, supporting the Petitioners and state Respondents.

Malcolm L. Stewart, Washington, DC, for Respondent United States in support of Petitioners.

Evan R. Chesler, New York, NY, for Respondents.

Michael Dewine, Attorney General of Ohio, Eric E. Murphy, State Solicitor, Counsel of Record, Michael J. Hendershot, Chief Deputy Solicitor, Hannah C. Wilson, Deputy Solicitor, Columbus, OH, for Petitioner State of Ohio.


Lawrence G. Wasden, Attorney General, State of Idaho.

Lisa Madigan, Attorney General, State of Illinois.

Tom Miller, Attorney General, State of Iowa.

Brian E. Frosh, Attorney General, State of Maryland.

Bill Schuette, Attorney General, State of Michigan.

Tim Fox, Attorney General, State of Montana.
201 L.Ed.2d 678, 86 USLW 4561, 2018-1 Trade Cases P 80,427...

Douglas J. Peterson, Attorney General, State of Nebraska.

Peter Kilmartin, Attorney General, State of Rhode Island.


Ken Paxton, Attorney General, State of Texas.

Sean D. Reyes, Attorney General, State of Utah.

Thomas J. Donovan, Jr., Attorney General, State of Vermont.


**Opinion**

Justice THOMAS delivered the opinion of the Court.

American Express Company and American Express Travel Related Services Company (collectively, Amex) provide credit-card services to both merchants and cardholders. When a cardholder buys something from a merchant who accepts Amex credit cards, Amex processes the transaction through its network, promptly pays the merchant, and subtracts a fee. If a merchant wants to accept Amex credit cards—and attract Amex cardholders to its business—Amex requires the merchant to agree to an antisteering contractual provision. The antisteering provision prohibits merchants from discouraging customers from using their Amex card after they have already entered the store and are about to buy something, thereby avoiding Amex's fee. In this case, we must decide whether Amex's antisteering provisions violate federal antitrust law. We conclude they do not.

I

A

Credit cards have become a primary way that consumers in the United States purchase goods and services. When a cardholder uses a credit card to buy something from a merchant, the transaction is facilitated by a credit-card network. The network provides separate but interrelated services to both cardholders and merchants. For cardholders, the network extends them credit, which allows them to make purchases without cash and to defer payment until later. Cardholders also can receive rewards based on the amount of money they spend, such as airline miles, points for travel, or cash back. For merchants, the network allows them to avoid the cost of processing transactions and offers them quick, guaranteed payment. This saves merchants the trouble and risk of extending credit to customers, and it increases the number and value of sales that they can make.
By providing these services to cardholders and merchants, credit-card companies bring these parties together, and therefore operate what economists call a “two-sided platform.” As the name implies, a two-sided platform offers different products or services to two different groups who both depend on the platform to intermediate between them. See Evans & Schmalensee, Markets With Two–Sided Platforms When Firms Operate Two–Sided Platforms, 1 Issues in Competition L. & Pol’y 667 (2008) (Evans & Schmalensee); Evans & Noel, Defining Antitrust Markets When Firms Operate Two–Sided Platforms, 2005 Colum. Bus. L. Rev. 667, 668 (Evans & Noel); Filistrucchi, Geradin, Van Damme, & Affeldt, Market Definition in Two–Sided Markets: Theory and Practice, 10 J. Competition L. & Econ. 293, 296 (2014) (Filistrucchi). For credit cards, that interaction is a transaction. Thus, credit-card networks are a special type of two-sided platform known as a “transaction” platform. See id., at 301, 304, 307; Evans & Noel 676–678. The key feature of transaction platforms is that they cannot make a sale to one side of the platform without simultaneously making a sale to the other. See Klein, Lerner, Murphy, & Plache, Competition in Two–Sided Markets: The Antitrust Economics of Payment Card Interchange Fees, 73 Antitrust L.J. 571, 580, 583 (2006) (Klein). For example, no credit-card transaction can occur unless both the merchant and the cardholder simultaneously agree to use the same credit-card network. See Filistrucchi 301.

Two-sided platforms differ from traditional markets in important ways. Most relevant here, two-sided platforms often exhibit what economists call “indirect network effects.” Evans & Schmalensee 667. Indirect network effects exist where the value of the two-sided platform to one group of participants depends on how many members of a different group participate. D. Evans & R. Schmalensee, Matchmakers: The New Economics of *2281 Multisided Platforms 25 (2016). In other words, the value of the services that a two-sided platform provides increases as the number of participants on both sides of the platform increases. A credit card, for example, is more valuable to cardholders when more merchants accept it, and is more valuable to merchants when more cardholders use it. See Evans & Noel 686–687; Klein 580, 584. To ensure sufficient participation, two-sided platforms must be sensitive to the prices that they charge each side. See Evans & Schmalensee 675; Evans & Noel 680; Muris, Payment Card Regulation and the (Mis)Application of the Economics of Two–Sided Markets, 2005 Colum. Bus. L. Rev. 515, 532–533 (Muris); Rochet & Tirole, Platform Competition in Two–Sided Markets, 1 J. Eur. Econ. Assn. 990, 1013 (2003). Raising the price on side A risks losing participation on that side, which decreases the value of the platform to side B. If participants on side B leave due to this loss in value, then the platform has even less value to side A—risking a feedback loop of declining demand. See Evans & Schmalensee 675; Evans & Noel 680–681. Two-sided platforms therefore must take these indirect network effects into account before making a change in price on either side. See Evans & Schmalensee 675; Evans & Noel 680–681. 1

Sometimes indirect network effects require two-sided platforms to charge one side much more than the other. See Evans & Schmalensee 667, 675, 681, 690–691; Evans & Noel 668, 691; Klein 585; Filistrucchi 300. For two-sided platforms, “‘the [relative] price structure matters, and platforms must design it so as to bring both sides on board.’” Evans & Schmalensee 669 (quoting Rochet & Tirole, Two–Sided Markets: A Progress Report, 37 RAND J. Econ. 645, 646 (2006)). The optimal price might require charging the side with more elastic demand a below-cost (or even negative) price. See Muris 519, 550; Klein 579; Evans & Schmalensee 675; Evans & Noel 681. With credit cards, for example, networks often charge cardholders a lower fee than merchants because cardholders are more price sensitive. 2 See Muris 522; Klein 573–574, 585, 595. In fact, the network might well lose money on the cardholder side by offering rewards such as cash back, airline miles, or gift cards. See Klein 587; Evans & Schmalensee 672. The network can do this because increasing the number of cardholders increases the value of accepting the card to merchants and, thus, increases the number of merchants who accept it. Muris 522; Evans & Schmalensee 692. Networks can then charge those merchants a fee for every transaction (typically a percentage of the purchase price). Striking the optimal balance of the prices charged on each side of the platform is essential for two-sided platforms to maximize the value of their services and to compete with their rivals.

*2282 B
Amex, Visa, MasterCard, and Discover are the four dominant participants in the credit-card market. Visa, which is by far the largest, has 45% of the market as measured by transaction volume. Amex and MasterCard trail with 26.4% and 23.3%, respectively, while Discover has just 5.3% of the market.

Visa and MasterCard have significant structural advantages over Amex. Visa and MasterCard began as bank cooperatives and thus almost every bank that offers credit cards is in the Visa or MasterCard network. This makes it very likely that the average consumer carries, and the average merchant accepts, Visa or MasterCard. As a result, the vast majority of Amex cardholders have a Visa or MasterCard, but only a small number of Visa and MasterCard cardholders have an Amex. Indeed, Visa and MasterCard account for more than 432 million cards in circulation in the United States, while Amex has only 53 million. And while 3.4 million merchants at 6.4 million locations accept Amex, nearly three million more locations accept Visa, MasterCard, and Discover.

Amex competes with Visa and MasterCard by using a different business model. While Visa and MasterCard earn half of their revenue by collecting interest from their cardholders, Amex does not. Amex instead earns most of its revenue from merchant fees. Amex's business model thus focuses on cardholder spending rather than cardholder lending. To encourage cardholder spending, Amex provides better rewards than other networks. Due to its superior rewards, Amex tends to attract cardholders who are wealthier and spend more money. Merchants place a higher value on these cardholders, and Amex uses this advantage to recruit merchants.

Amex's business model has significantly influenced the credit-card market. To compete for the valuable cardholders that Amex attracts, both Visa and MasterCard have introduced premium cards that, like Amex, charge merchants higher fees and offer cardholders better rewards. To maintain their lower merchant fees, Visa and MasterCard have created a sliding scale for their various cards—charging merchants less for low-reward cards and more for high-reward cards. This differs from Amex's strategy, which is to charge merchants the same fee no matter the rewards that its card offers. Another way that Amex has influenced the credit-card market is by making banking and card-payment services available to low-income individuals, who otherwise could not qualify for a credit card and could not afford the fees that traditional banks charge. See 2 Record 3835–3837, 4527–4529. In sum, Amex's business model has stimulated competitive innovations in the credit-card market, increasing the volume of transactions and improving the quality of the services.

Despite these improvements, Amex's business model sometimes causes friction with merchants. To maintain the loyalty of its cardholders, Amex must continually invest in its rewards program. But, to fund those investments, Amex must charge merchants higher fees than its rivals. Even though Amex's investments benefit merchants by encouraging cardholders to spend more money, merchants would prefer not to pay the higher fees. One way that merchants try to avoid them, while still enticing Amex's cardholders to shop at their stores, is by dissuading cardholders from using Amex at the point of sale. This practice is known as “steering.”

Amex has prohibited steering since the 1950s by placing antisteering provisions in its contracts with merchants. These antisteering provisions prohibit merchants from implying a preference for non-Amex cards; dissuading customers from using Amex cards; persuading customers to use other cards; imposing any special restrictions, conditions, disadvantages, or fees on Amex cards; or promoting other cards more than Amex. The antisteering provisions do not, however, prevent merchants from steering customers toward debit cards, checks, or cash.
In October 2010, the United States and several States (collectively, plaintiffs) sued Amex, claiming that its antisteering provisions violate § 1 of the Sherman Act, 26 Stat. 209, as amended, 15 U.S.C. § 1. After a 7–week trial, the District Court agreed that Amex’s antisteering provisions violate § 1. *United States v. American Express Co.*, 88 F.Supp.3d 143, 151–152 (E.D.N.Y.2015). It found that the credit-card market should be treated as two separate markets—one for merchants and one for cardholders. See *id.*, at 171–175. Evaluating the effects on the merchant side of the market, the District Court found that Amex’s antisteering provisions are anticompetitive because they result in higher merchant fees. See *id.*, at 195–224.

The Court of Appeals for the Second Circuit reversed. *United States v. American Express Co.*, 838 F.3d 179, 184 (2016). It concluded that the credit-card market is one market, not two. *Id.*, at 196–200. Evaluating the credit-card market as a whole, the Second Circuit concluded that Amex's antisteering provisions were not anticompetitive and did not violate § 1. See *id.*, at 200–206.

We granted certiorari, 583 U.S. ———, 138 S.Ct. 355, 199 L.Ed.2d 261 (2017), and now affirm.

II

Section 1 of the Sherman Act prohibits “[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States.” 15 U.S.C. § 1. This Court has long recognized that, “[i]n view of the common law and the law in this country” when the Sherman Act was passed, the phrase “restraint of trade” is best read to mean “undue restraint.” *Standard Oil Co. of N.J. v. United States*, 221 U.S. 1, 59–60, 31 S.Ct. 502, 55 L.Ed. 619 (1911). This Court's precedents have thus understood § 1 “to outlaw only unreasonable restraints.” *State Oil Co. v. Khan*, 522 U.S. 3, 10, 118 S.Ct. 275, 139 L.Ed.2d 199 (1997) (emphasis added).

Restraints can be unreasonable in one of two ways. A small group of restraints are unreasonable *per se* because they “‘always or almost always tend to restrict competition and decrease output.’” *Business Electronics Corp. v. Sharp Electronics Corp.*, 485 U.S. 717, 723, 108 S.Ct. 1515, 99 L.Ed.2d 808 (1988). Typically only “horizontal” restraints—restraints “imposed by agreement between *2284* competitors”—qualify as unreasonable *per se*. *Id.*, at 730, 108 S.Ct. 1515. Restraints that are not unreasonable *per se* are judged under the “rule of reason.” *Id.*, at 723, 108 S.Ct. 1515. The rule of reason requires courts to conduct a fact-specific assessment of “market power and market structure ... to assess the [restraint]' s actual effect” on competition. *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 768, 104 S.Ct. 2731, 81 L.Ed.2d 628 (1984). The goal is to “distinguish between restraints with anticompetitive effect that are harmful to the consumer and restraints stimulating competition that are in the consumer's best interest.” *Leegin Creative Leather Products, Inc. v. PSKS, Inc.*, 551 U.S. 877, 886, 127 S.Ct. 2705, 168 L.Ed.2d 623 (2007).

In this case, both sides correctly acknowledge that Amex's antisteering provisions are vertical restraints—*i.e.*, restraints “imposed by agreement between firms at different levels of distribution.” *Business Electronics, supra*, at 730, 108 S.Ct. 1515. The parties also correctly acknowledge that, like nearly every other vertical restraint, the antisteering provisions should be assessed under the rule of reason. See *Leegin, supra*, at 882, 127 S.Ct. 2705; *State Oil, supra*, at 19, 118 S.Ct. 275; *Business Electronics, supra*, at 726, 108 S.Ct. 1515; *Continental T. V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 57, 97 S.Ct. 2549, 53 L.Ed.2d 568 (1977).

To determine whether a restraint violates the rule of reason, the parties agree that a three-step, burden-shifting framework applies. Under this framework, the plaintiff has the initial burden to prove that the challenged restraint has a substantial anticompetitive effect that harms consumers in the relevant market. See 1 J. Kalinowski, Antitrust Laws and Trade Regulation § 12.02[1] (2d ed. 2017) (Kalinowski); P. Areeda & H. Hovenkamp, Fundamentals of Antitrust Law § 15.02[B] (4th ed. 2017).

201 L.Ed.2d 678, 86 USLW 4561, 2018-1 Trade Cases P 80,427...

(Areeda & Hovenkamp); Capital Imaging Assoc., P.C. v. Mohawk Valley Medical Associates, Inc., 996 F.2d 537, 543 (C.A.2 1993). If the plaintiff carries its burden, then the burden shifts to the defendant to show a procompetitive rationale for the restraint. See 1 Kalinowski § 12.02[1]; Areeda & Hovenkamp § 15.02[B]; Capital Imaging Assoc., supra, at 543. If the defendant makes this showing, then the burden shifts back to the plaintiff to demonstrate that the procompetitive efficiencies could be reasonably achieved through less anticompetitive means. See 1 Kalinowski § 12.02[1]; Capital Imaging Assoc., supra, at 543.

Here, the parties ask us to decide whether the plaintiffs have carried their initial burden of proving that Amex's antisteering provisions have an anticompetitive effect. The plaintiffs can make this showing directly or indirectly. Direct evidence of anticompetitive effects would be "'proof of actual detrimental effects [on competition],' " FTC v. Indiana Federation of Dentists, 476 U.S. 447, 460, 106 S.Ct. 2009, 90 L.Ed.2d 445 (1986), such as reduced output, increased prices, or decreased quality in the relevant market, see 1 Kalinowski § 12.02[2]; Craftsman Limousine, Inc. v. Ford Motor Co., 491 F.3d 380, 390 (C.A.8 2007); Virgin Atlantic Airways Ltd. v. British Airways PLC, 257 F.3d 256, 264 (C.A.2 2001). Indirect evidence would be proof of market power plus some evidence that the challenged restraint harms competition. See 1 Kalinowski § 12.02[2]; Tops Markets, Inc. v. Quality Markets, Inc., 142 F.3d 90, 97 (C.A.2 1998); Spanish Broadcasting System of Fla. v. Clear Channel Communications, Inc., 376 F.3d 1065, 1073 (C.A.11 2004).

Here, the plaintiffs rely exclusively on direct evidence to prove that Amex's antisteering provisions have caused anticompetitive effects in the credit-card market. 6 To assess this evidence, we must first define the relevant market. Once defined, it becomes clear that the plaintiffs' evidence is insufficient to carry their burden.

A

Because “[l]egal presumptions that rest on formalistic distinctions rather than actual market realities are generally disfavored in antitrust law,” Eastman Kodak Co. v. Image Technical Services, Inc., 504 U.S. 451, 466–467, 112 S.Ct. 2072, 119 L.Ed.2d 265 (1992), courts usually cannot properly apply the rule of reason without an accurate definition of the relevant market. 7 “Without a definition of [the] market there is no way to measure [the defendant's] ability to lessen or destroy competition.” Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp., 382 U.S. 172, 177, 86 S.Ct. 347, 15 L.Ed.2d 247 (1966); accord, 2 Kalinowski § 24.01[4][a]. Thus, the relevant market is defined as “the area of effective competition.” Ibid. Typically this is the “arena within which significant substitution in consumption or production occurs.” Areeda & Hovenkamp § 5.02[a]; accord, 2 Kalinowski § 24.02[1]; United States v. Grinnell Corp., 384 U.S. 563, 571, 86 S.Ct. 1698, 16 L.Ed.2d 778 (1966). But courts should “combin[e]” different products or services into “a single market” when “that combination reflects commercial realities.” Id., at 572, 86 S.Ct. 1698; see also Brown Shoe Co. v. United States, 370 U.S. 294, 336–337, 82 S.Ct. 1502, 8 L.Ed.2d 510 (1962) (pointing out that “the definition of the relevant market” must “‘correspond to the commercial realities of the industry’”).

As explained, credit-card networks are two-sided platforms. Due to indirect network effects, two-sided platforms cannot raise prices on one side without risking a feedback loop of declining demand. See Evans & Schmalensee 674–675; Evans & Noel 680–681. And the fact that two-sided platforms charge one side a *2286 price that is below or above cost reflects differences in the two sides' demand elasticity, not market power or anticompetitive pricing. See Klein 574, 595, 598, 626. Price increases on one side of the platform likewise do not suggest anticompetitive effects without some evidence that they have increased the overall cost of the platform's services. See id., at 575, 594, 626. Thus, courts must include both sides of the platform—merchants and cardholders—when defining the credit-card market.

To be sure, it is not always necessary to consider both sides of a two-sided platform. A market should be treated as one sided when the impacts of indirect network effects and relative pricing in that market are minor. See Filistrucchi 321–322. Newspapers that sell advertisements, for example, arguably operate a two-sided platform because the value of an advertisement increases as

201 L.Ed.2d 678, 86 USLW 4561, 2018-1 Trade Cases P 80,427...

more people read the newspaper. *Id.*, at 297, 315; Klein 579. But in the newspaper-advertisement market, the indirect networks effects operate in only one direction; newspaper readers are largely indifferent to the amount of advertising that a newspaper contains. See Filistrucchi 321, 322, and n. 99; Klein 583. Because of these weak indirect network effects, the market for newspaper advertising behaves much like a one-sided market and should be analyzed as such. See Filistrucchi 321; *Times–Picayune Publishing Co. v. United States*, 345 U.S. 594, 610, 73 S.Ct. 872, 97 L.Ed. 1277 (1953).

But two-sided transaction platforms, like the credit-card market, are different. These platforms facilitate a single, simultaneous transaction between participants. For credit cards, the network can sell its services only if a merchant and cardholder both simultaneously choose to use the network. Thus, whenever a credit-card network sells one transaction's worth of card-acceptance services to a merchant it also must sell one transaction's worth of card-payment services to a cardholder. It cannot sell transaction services to either cardholders or merchants individually. See Klein 583 (“Because cardholders and merchants jointly consume a single product, payment card transactions, their consumption of payment card transactions must be directly proportional”). To optimize sales, the network must find the balance of pricing that encourages the greatest number of matches between cardholders and merchants.

Because they cannot make a sale unless both sides of the platform simultaneously agree to use their services, two-sided transaction platforms exhibit more pronounced indirect network effects and interconnected pricing and demand. Transaction platforms are thus better understood as “supply[ing] only one product”—transactions. Klein 580. In the credit-card market, these transactions “are jointly consumed by a cardholder, who uses the payment card to make a transaction, and a merchant, who accepts the payment card as a method of payment.” *Ibid.* Tellingly, credit cards determine their market share by measuring the volume of transactions they have sold. 8

*2287* Evaluating both sides of a two-sided transaction platform is also necessary to accurately assess competition. Only other two-sided platforms can compete with a two-sided platform for transactions. See Filistrucchi 301. A credit-card company that processed transactions for merchants, but that had no cardholders willing to use its card, could not compete with Amex. See *ibid.* Only a company that had both cardholders and merchants willing to use its network could sell transactions and compete in the credit-card market. Similarly, if a merchant accepts the four major credit cards, but a cardholder only uses Visa or Amex, only those two cards can compete for the particular transaction. Thus, competition cannot be accurately assessed by looking at only one side of the platform in isolation. 9

For all these reasons, “[i]n two-sided transaction markets, only one market should be defined.” *Id.*, at 302; see also Evans & Noel 671 (“[F]ocusing on one dimension of ... competition tends to distort the competition that actually exists among [two-sided platforms]”). Any other analysis would lead to “ ‘ “mistaken inferences” ’ ” of the kind that could “ ‘ ‘chill the very conduct the antitrust laws are designed to protect.’ ” *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 226, 113 S.Ct. 2578, 125 L.Ed.2d 168 (1993); see also *Matsushita Elec. Industrial Co. v. Zenith Radio Corp.*, 475 U.S. 574, 594, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986) (“ ‘[W]e must be concerned lest a rule or precedent that authorizes a search for a particular type of undesirable pricing behavior end up by discouraging legitimate price competition’ ”); *Leegin*, 551 U.S., at 895, 127 S.Ct. 2705 (noting that courts should avoid “increas[ing] the total cost of the antitrust system by prohibiting procompetitive conduct the antitrust laws should encourage”). Accordingly, we will analyze the two-sided market for credit-card transactions as a whole to determine whether the plaintiffs have shown that Amex's antisteering provisions have anticompetitive effects.

B

The plaintiffs have not carried their burden to prove anticompetitive effects in the relevant market. The plaintiffs stake their entire case on proving that Amex's agreements increase merchant fees. We find this argument unpersuasive.
As an initial matter, the plaintiffs' argument about merchant fees wrongly focuses on only one side of the two-sided credit-card market. As explained, the credit-card market must be defined to include both merchants and cardholders. Focusing on merchant fees alone misses the mark because the product that credit-card companies sell is transactions, not services to merchants, and the competitive effects of a restraint on transactions cannot be judged by looking at merchants alone. Evidence of a price increase on one side of a two-sided transaction platform cannot by itself demonstrate an anticompetitive exercise of market power. To demonstrate anticompetitive effects on the two-sided credit-card market as a whole, the plaintiffs must prove that Amex's antisteering provisions increased the cost of credit-card transactions above a competitive level, reduced the number of credit-card transactions, or otherwise stifled competition in the credit-card market. See 1 Kalinowski § 12.02[2]; *2288 Craftsman Limousine, Inc., 491 F.3d, at 390; Virgin Atlantic Airways Ltd., 257 F.3d, at 264. They failed to do so.

The plaintiffs did not offer any evidence that the price of credit-card transactions was higher than the price one would expect to find in a competitive market. As the District Court found, the plaintiffs failed to offer any reliable measure of Amex's transaction price or profit margins. 88 F.Supp.3d, at 198, 215. And the evidence about whether Amex charges more than its competitors was ultimately inconclusive. *Id.*, at 199, 202, 215.

Amex's increased merchant fees reflect increases in the value of its services and the cost of its transactions, not an ability to charge above a competitive price. Amex began raising its merchant fees in 2005 after Visa and MasterCard raised their fees in the early 2000s. *Id.*, at 195, 199–200. As explained, Amex has historically charged higher merchant fees than these competitors because it delivers wealthier cardholders who spend more money. *Id.*, at 200–201. Amex's higher merchant fees are based on a careful study of how much additional value its cardholders offer merchants. See *id.*, at 192–193. On the other side of the market, Amex uses its higher merchant fees to offer its cardholders a more robust rewards program, which is necessary to maintain cardholder loyalty and encourage the level of spending that makes Amex valuable to merchants. *Id.*, at 160, 191–195. That Amex allocates prices between merchants and cardholders differently from Visa and MasterCard is simply not evidence that it wields market power to achieve anticompetitive ends. See Evans & Noel 670–671; Klein 574–575, 594–595, 598, 626.

In addition, the evidence that does exist cuts against the plaintiffs' view that Amex's antisteering provisions are the cause of any increases in merchant fees. Visa and MasterCard's merchant fees have continued to increase, even at merchant locations where Amex is not accepted and, thus, Amex's antisteering provisions do not apply. See 88 F.Supp.3d, at 222. This suggests that the cause of increased merchant fees is not Amex's antisteering provisions, but rather increased competition for cardholders and a corresponding marketwide adjustment in the relative price charged to merchants. See Klein 575, 609.

The plaintiffs did offer evidence that Amex increased the percentage of the purchase price that it charges merchants by an average of 0.09% between 2005 and 2010 and that this increase was not entirely spent on cardholder rewards. See 88 F.Supp.3d, at 195–197, 215. The plaintiffs believe that this evidence shows that the price of Amex's transactions increased.

Even assuming the plaintiffs are correct, this evidence does not prove that Amex's antisteering provisions gave it the power to charge anticompetitive prices. “Market power is the ability to raise price profitably by restricting output.” Areeda & Hovenkamp § 5.01 (emphasis added); accord, Kodak, 504 U.S., at 464, 112 S.Ct. 2072; Business Electronics, 485 U.S., at 723, 108 S.Ct. 1515. This Court will “not infer competitive injury from price and output data absent some evidence that tends to prove that
output was restricted or prices were above a competitive level.” *2289 Brooke Group Ltd., supra, at 237, 113 S.Ct. 2578. And, as previously explained, the plaintiffs did not show that Amex charged more than its competitors.

The plaintiffs also failed to prove that Amex's antisteering provisions have stifled competition among credit-card companies. To the contrary, while these agreements have been in place, the credit-card market experienced expanding output and improved quality. Amex's business model spurred Visa and MasterCard to offer new premium card categories with higher rewards. And it has increased the availability of card services, including free banking and card-payment services for low-income customers who otherwise would not be served. Indeed, between 1970 and 2001, the percentage of households with credit cards more than quadrupled, and the proportion of households in the bottom-income quintile with credit cards grew from just 2% to over 38%. See D. Evans & R. Schmalensee, Paying With Plastic: The Digital Revolution in Buying and Borrowing 88–89 (2d ed. 2005) (Paying With Plastic).

Nor have Amex's antisteering provisions ended competition between credit-card networks with respect to merchant fees. Instead, fierce competition between networks has constrained Amex's ability to raise these fees and has, at times, forced Amex to lower them. For instance, when Amex raised its merchant prices between 2005 and 2010, some merchants chose to leave its network. 88 F.Supp.3d, at 197. And when its remaining merchants complained, Amex stopped raising its merchant prices. Id., at 198. In another instance in the late 1980s and early 1990s, competition forced Amex to offer lower merchant fees to “everyday spend” merchants—supermarkets, gas stations, pharmacies, and the like—to persuade them to accept Amex. See id., at 160–161, 202.

In addition, Amex's competitors have exploited its higher merchant fees to their advantage. By charging lower merchant fees, Visa, MasterCard, and Discover have achieved broader merchant acceptance—approximately 3 million more locations than Amex. Id., at 204. This broader merchant acceptance is a major advantage for these networks and a significant challenge for Amex, since consumers prefer cards that will be accepted everywhere. Ibid. And to compete even further with Amex, Visa and MasterCard charge different merchant fees for different types of cards to maintain their comparatively lower merchant fees and broader acceptance. Over the long run, this competition has created a trend of declining merchant fees in the credit-card market. In fact, since the first credit card was introduced in the 1950s, merchant fees—including Amex's merchant fees—have decreased by more than half. See id., at 202–203; Paying With Plastic 54, 126, 152.

Lastly, there is nothing inherently anticompetitive about Amex's antisteering provisions. These agreements actually stem negative externalities in the credit-card market and promote interbrand competition. When merchants steer cardholders away from Amex at the point of sale, it undermines the cardholder's expectation of “welcome acceptance”—the promise of a frictionless transaction. 88 F.Supp.3d, at 156. A lack of welcome acceptance at one merchant makes a cardholder less likely to use Amex at all other merchants. This externality endangers the viability of the entire Amex network. And it undermines the investments that Amex has made to encourage increased cardholder spending, which discourages investments in rewards and ultimately harms both cardholders and merchants. Cf. *2290 Leegin, 551 U.S., at 890–891, 127 S.Ct. 2705 (recognizing that vertical restraints can prevent retailers from free riding and thus increase the availability of “tangible or intangible services or promotional efforts” that enhance competition and consumer welfare). Perhaps most importantly, antisteering provisions do not prevent Visa, MasterCard, or Discover from competing against Amex by offering lower merchant fees or promoting their broader merchant acceptance. 10
201 L.Ed.2d 678, 86 USLW 4561, 2018-1 Trade Cases P 80,427...

In sum, the plaintiffs have not satisfied the first step of the rule of reason. They have not carried their burden of proving that Amex's antisteering provisions have anticompetitive effects. Amex's business model has spurred robust interbrand competition and has increased the quality and quantity of credit-card transactions. And it is “[t]he promotion of interbrand competition,” after all, that “is ... ‘the primary purpose of the antitrust laws.’ ” Id., at 890, 127 S.Ct. 2705.

* * *

Because Amex's antisteering provisions do not unreasonably restrain trade, we affirm the judgment of the Court of Appeals.

It is so ordered.

Justice BREYER, with whom Justice GINSBURG, Justice SOTOMAYOR, and Justice KAGAN join, dissenting.

For more than 120 years, the American economy has prospered by charting a middle path between pure laissez-faire and state capitalism, governed by an antitrust law “dedicated to the principle that markets, not individual firms and certainly not political power, produce the optimal mixture of goods and services.” 1 P. Areeda & H. Hovenkamp, Antitrust Law ¶ 100b, p. 4 (4th ed. 2013) (Areeda & Hovenkamp). By means of a strong antitrust law, the United States has sought to avoid the danger of monopoly capitalism. Long gone, we hope, are the days when the great trusts presided unfettered by competition over the American economy.

This lawsuit is emblematic of the American approach. Many governments around the world have responded to concerns about the high fees that credit-card companies often charge merchants by regulating such fees directly. See GAO, Credit and Debit Cards: Federal Entities Are Taking Actions to Limit Their Interchange Fees, but Additional Revenue Collection Cost Savings May Exist 31–35 (GAO–08–558, 2008). The United States has not followed that approach. The Government instead filed this lawsuit, which seeks to restore market competition over credit-card merchant fees by eliminating a contractual barrier with anticompetitive effects. The majority rejects that effort. But because the challenged contractual term clearly has serious anticompetitive effects, I dissent.

I agree with the majority and the parties that this case is properly evaluated under the three-step “rule of reason” that governs many antitrust lawsuits. *2291 Ante, at 2284 – 2285. Under that approach, a court looks first at the agreement or restraint at issue to assess whether it has had, or is likely to have, anticompetitive effects. FTC v. Indiana Federation of Dentists, 476 U.S. 447, 459, 106 S.Ct. 2009, 90 L.Ed.2d 445 (1986). In doing so, the court normally asks whether the restraint may tend to impede competition and, if so, whether those who have entered into that restraint have sufficient economic or commercial power for the agreement to make a negative difference. See id., at 459–461, 106 S.Ct. 2009. Sometimes, but not always, a court will try to determine the appropriate market (the market that the agreement affects) and determine whether those entering into that agreement have the power to raise prices above the competitive level in that market. See ibid.

It is important here to understand that in cases under § 1 of the Sherman Act (unlike in cases challenging a merger under § 7 of the Clayton Act, 15 U.S.C. § 18), it may well be unnecessary to undertake a sometimes complex, market power inquiry:

“Since the purpose [in a Sherman Act § 1 case] of the inquiries into ... market power is [simply] to determine whether an arrangement has the potential for genuine adverse effects on competition, ‘proof of actual detrimental effects, such as a reduction in output,’ can obviate the need for an inquiry into market power, which is but a ‘surrogate for detrimental effects.’
201 L.Ed.2d 678, 86 USLW 4561, 2018-1 Trade Cases P 80,427...


Second (as treatise writers summarize the case law), if an antitrust plaintiff meets the initial burden of showing that an agreement will likely have anticompetitive effects, normally the “burden shifts to the defendant to show that the restraint in fact serves a legitimate objective.” 7 Areeda & Hovenkamp ¶ 1504b, at 415; see California Dental Assn. v. FTC, 526 U.S. 756, 771, 119 S.Ct. 1604, 143 L.Ed.2d 935 (1999); id., at 788, 119 S.Ct. 1604 (BREYER, J., dissenting).

Third, if the defendant successfully bears this burden, the antitrust plaintiff may still carry the day by showing that it is possible to meet the legitimate objective in less restrictive ways, or, perhaps by showing that the legitimate objective does not outweigh the harm that competition will suffer, i.e., that the agreement “on balance” remains unreasonable. 7 Areeda & Hovenkamp ¶ 1507a, at 442.

Like the Court of Appeals and the parties, the majority addresses only the first step of that three-step framework. Ante, at 2284–2285.

II

A

This case concerns the credit-card business. As the majority explains, ante, at 2280–2281, that business involves the selling of two different but related card services. First, when a shopper uses a credit card to buy something from a participating merchant, the credit-card company pays the merchant the amount of money that the merchant's customer has charged to his card and charges the merchant a fee, say 5%, for that speedy-payment service. I shall refer to that kind of transaction as a merchant-related card service. Second, the credit-card company then sends a bill to the merchant's customer, the shopper who holds the card; and the shopper pays the card company the sum that merchant charged the shopper for the goods or services he or she bought. The cardholder also often pays the card company a fee, such as an annual fee for the card or an interest charge for delayed payment. I *2292 shall call that kind of transaction a shopper-related card service. The credit-card company can earn revenue from the sale (directly or indirectly) of each of these services: (1) speedy payment for merchants, and (2) credit for shoppers. (I say “indirectly” to reflect the fact that card companies often create or use networks of banks as part of the process—but I have found nothing here suggesting that that fact makes a significant difference to my analysis.)

Sales of the two basic card services are related. A shopper can pay for a purchase with a particular credit card only if the merchant has signed up for merchant-related card services with the company that issued the credit card that the shopper wishes to use. A firm in the credit-card business is therefore unlikely to make money unless quite a few merchants agree to accept that firm's card and quite a few shoppers agree to carry and use it. In general, the more merchants that sign up with a particular card company, the more useful that card is likely to prove to shoppers and so the more shoppers will sign up; so too, the more shoppers that carry a particular card, the more useful that card is likely to prove to merchants (as it obviously helps them obtain the shoppers' business) and so the more merchants will sign up. Moreover, as a rough rule of thumb (and assuming constant charges), the larger the networks of paying merchants and paying shoppers that a card firm maintains, the larger the revenues that the firm will likely receive, since more payments will be processed using its cards. Thus, it is not surprising that a card company may offer shoppers incentives (say, points redeemable for merchandise or travel) for using its card or that a firm might want merchants to accept its card exclusively.
This case focuses upon a practice called “steering.” American Express has historically charged higher merchant fees than its competitors. App. to Pet. for Cert. 173a–176a. Hence, fewer merchants accept American Express' cards than its competitors'. Id., at 184a–187a. But, perhaps because American Express cardholders are, on average, wealthier, higher-spending, or more loyal to American Express than other cardholders, vast numbers of merchants still accept American Express cards. See id., at 156a, 176a–177a, 184a–187a. Those who do, however, would (in order to avoid the higher American Express fee) often prefer that their customers use a different card to charge a purchase. Thus, the merchant has a monetary incentive to “steer” the customer towards the use of a different card. A merchant might tell the customer, for example, “American Express costs us more,” or “please use Visa if you can,” or “free shipping if you use Discover.” See id., at 100a–102a.

Steering makes a difference, because without it, the shopper does not care whether the merchant pays more to American Express than it would pay to a different card company—the shopper pays the same price either way. But if steering works, then American Express will find it more difficult to charge more than its competitors for merchant-related services, because merchants will respond by steering their customers, encouraging them to use other cards. Thus, American Express dislikes steering; the merchants like it; and the shoppers may benefit from it, whether because merchants will offer them incentives to use less expensive cards or in the form of lower retail prices overall. See id., at 92a, 97a–104a.

In response to its competitors' efforts to convince merchants to steer shoppers to use less expensive cards, American Express tried to stop, or at least to limit, steering by placing antisteering provisions in most of its contracts with merchants. It *2293 called those provisions “nondiscrimination provisions.” They prohibited steering of the forms I have described above (and others as well). See id., at 95a–96a, 100a–101a. After placing them in its agreements, American Express found it could maintain, or even raise, its higher merchant prices without losing too many transactions to other firms. Id., at 195a–198a. These agreements—the “nondiscrimination provisions”—led to this lawsuit.

In 2010 the United States and 17 States brought this antitrust case against American Express. They claimed that the “nondiscrimination provisions” in its contracts with merchants created an unreasonable restraint of trade. (Initially Visa and MasterCard were also defendants, but they entered into consent judgments, dropping similar provisions from their contracts with merchants). After a 7–week bench trial, the District Court entered judgment for the Government, setting forth its findings of fact and conclusions of law in a 97–page opinion. 88 F.Supp.3d 143 (E.D.N.Y.2015).

Because the majority devotes little attention to the District Court's detailed factual findings, I will summarize some of the more significant ones here. Among other things, the District Court found that beginning in 2005 and during the next five years, American Express raised the prices it charged merchants on 20 separate occasions. See id., at 195–196. In doing so, American Express did not take account of the possibility that large merchants would respond to the price increases by encouraging shoppers to use a different credit card because the nondiscrimination provisions prohibited any such steering. Id., at 215. The District Court pointed to merchants' testimony stating that, had it not been for those provisions, the large merchants would have responded to the price increases by encouraging customers to use other, less-expensive cards. Ibid.

The District Court also found that even though American Express raised its merchant prices 20 times in this 5–year period, it did not lose the business of any large merchant. Id., at 197. Nor did American Express increase benefits (or cut credit-card prices) to American Express cardholders in tandem with the merchant price increases. Id., at 196. Even had there been no direct
201 L.Ed.2d 678, 86 USLW 4561, 2018-1 Trade Cases P 80,427...

evidence of injury to competition, American Express' ability to raise merchant prices without losing any meaningful market share, in the District Court's view, showed that American Express possessed power in the relevant market. See id., at 195.

The District Court also found that, in the absence of the provisions, prices to merchants would likely have been lower. Ibid. It wrote that in the late 1990's, Discover, one of American Express' competitors, had tried to develop a business model that involved charging lower prices to merchants than the other companies charged. Id., at 213. Discover then invited each “merchant to save money by shifting volume to Discover,” while simultaneously offering merchants additional discounts “if they would steer customers to Discover.” Ibid. The court determined that these efforts failed because of American Express' (and the other card companies') “nondiscrimination provisions.” These provisions, the court found, “denied merchants the ability to express a preference for Discover or to employ any other tool by which they might steer share to Discover's lower-priced network.” Id., at 214. Because the provisions eliminated any advantage that lower prices might produce, Discover *2294 “abandoned its low-price business model” and raised its merchant fees to match those of its competitors. Ibid. This series of events, the court concluded was “emblematic of the harm done to the competitive process” by the “nondiscrimination provisions.” Ibid.

The District Court added that it found no offsetting pro-competitive benefit to shoppers. Id., at 225–238. Indeed, it found no offsetting benefit of any kind. See ibid.

American Express appealed, and the U.S. Court of Appeals for the Second Circuit held in its favor. 838 F.3d 179 (2016). The Court of Appeals did not reject any fact found by the District Court as “clearly erroneous.” See Fed. Rule Civ. Proc. 52(a)(6). Rather, it concluded that the District Court had erred in step 1 of its rule-of-reason analysis by failing to account for what the Second Circuit called the credit-card business's “two-sided market” (or “two-sided platform”). 838 F.3d, at 185–186, 196–200.

III

The majority, like the Court of Appeals, reaches only step 1 in its “rule of reason” analysis. Ante, at 2284 – 2285. To repeat, that step consists of determining whether the challenged “nondiscrimination provisions” have had, or are likely to have, anticompetitive effects. See Indiana Federation of Dentists, 476 U.S., at 459, 106 S.Ct. 2009. Do those provisions tend to impede competition? And if so, does American Express, which imposed that restraint as a condition of doing business with its merchant customers, have sufficient economic or commercial power for the provision to make a negative difference? See id., at 460–461, 106 S.Ct. 2009.

A

Here the District Court found that the challenged provisions have had significant anticompetitive effects. In particular, it found that the provisions have limited or prevented price competition among credit-card firms for the business of merchants. 88 F.Supp.3d, at 209. That conclusion makes sense: In the provisions, American Express required the merchants to agree not to encourage customers to use American Express' competitors' credit cards, even cards from those competitors, such as Discover, that intended to charge the merchants lower prices. See id., at 214. By doing so, American Express has “disrupt[ed] the normal price-setting mechanism” in the market. Id., at 209. As a result of the provisions, the District Court found, American Express was able to raise merchant prices repeatedly without any significant loss of business, because merchants were unable to respond to such price increases by encouraging shoppers to pay with other cards. Id., at 215. The provisions also meant that competitors like Discover had little incentive to lower their merchant prices, because doing so did not lead to any additional market share. Id., at 214. The provisions thereby “suppress[ed] [American Express'] ... competitors' incentives to offer lower prices ... resulting in higher profit-maximizing prices across the network services market.” Id., at 209. Consumers throughout the economy paid...
higher retail prices as a result, and they were denied the opportunity to accept incentives that merchants might otherwise have offered to use less-expensive cards. \textit{Id.}, at 216, 220. I should think that, considering step 1 alone, there is little more that need be said.

The majority, like the Court of Appeals, says that the District Court should have looked not only at the market for the card companies' merchant-related services but also at the market for the card companies' shopper-related services, and that it should *2295 have combined them, treating them as a single market. \textit{Ante}, at 2287 – 2288; 838 F.3d, at 197. But I am not aware of any support for that view in antitrust law. Indeed, this Court has held to the contrary.

In \textit{Times–Picayune Publishing Co. v. United States}, 345 U.S. 594, 610, 73 S.Ct. 872, 97 L.Ed. 1277 (1953), the Court held that an antitrust court should begin its definition of a relevant market by focusing narrowly on the good or service directly affected by a challenged restraint. The Government in that case claimed that a newspaper's advertising policy violated the Sherman Act's “rule of reason.” See \textit{ibid.} In support of that argument, the Government pointed out, and the District Court had held, that the newspaper dominated the market for the sales of newspapers to readers in New Orleans, where it was the sole morning daily newspaper. \textit{Ibid.} But this Court reversed. We explained that “every newspaper is a dual trader in separate though interdependent markets; it sells the paper's news and advertising content to its readers; in effect that readership is in turn sold to the buyers of advertising space.” \textit{Ibid.} We then added:

“This case concerns solely one of those markets. The Publishing Company stands accused not of tying sales to its readers but only to buyers of general and classified space in its papers. For this reason, dominance in the advertising market, not in readership, must be decisive in gauging the legality of the Company's unit plan.” \textit{Ibid.}

Here, American Express stands accused not of limiting or harming competition for shopper-related card services, but only of merchant-related card services, because the challenged contract provisions appear only in American Express' contracts with merchants. That is why the District Court was correct in considering, at step 1, simply whether the agreement had diminished competition in merchant-related services.

B

The District Court did refer to market definition, and the majority does the same. \textit{Ante}, at 2285 – 2287. And I recognize that properly defining a market is often a complex business. Once a court has identified the good or service directly restrained, as \textit{Times–Picayune Publishing Co.} requires, it will sometimes add to the relevant market what economists call “substitutes”: other goods or services that are reasonably substitutable for that good or service. See, e.g., \textit{United States v. E.I. du Pont de Nemours & Co.}, 351 U.S. 377, 395–396, 76 S.Ct. 994, 100 L.Ed. 1264 (1956) (explaining that cellophane market includes other, substitutable flexible wrapping materials as well). The reason that substitutes are included in the relevant market is that they restrain a firm's ability to profitably raise prices, because customers will switch to the substitutes rather than pay the higher prices. See 2B Areeda & Hovenkamp ¶ 561, at 378.

But while the market includes substitutes, it does not include what economists call complements: goods or services that are used together with the restrained product, but that cannot be substituted for that product. See id., ¶ 565a, at 429; \textit{Eastman Kodak Co. v. Image Technical Services, Inc.}, 504 U.S. 451, 463, 112 S.Ct. 2072, 119 L.Ed.2d 265 (1992). An example of complements is gasoline and tires. A driver needs both gasoline and tires to drive, but they are not substitutes for each other, and so the sale price of tires does not check the ability of a gasoline firm (say a gasoline monopolist) to raise the price of gasoline above competitive levels. As a treatise on the subject states: “Grouping complementary goods into the same market” is “economic nonsense,” and would “undermin[e] the rationale for the policy *2296 against monopolization or collusion in the first place.” 2B Areeda & Hovenkamp ¶ 565a, at 431.
Here, the relationship between merchant-related card services and shopper-related card services is primarily that of complements, not substitutes. Like gasoline and tires, both must be purchased for either to have value. Merchants upset about a price increase for merchant-related services cannot avoid that price increase by becoming cardholders, in the way that, say, a buyer of newspaper advertising can switch to television advertising or direct mail in response to a newspaper's advertising price increase. The two categories of services serve fundamentally different purposes. And so, also like gasoline and tires, it is difficult to see any way in which the price of shopper-related services could act as a check on the card firm's sale price of merchant-related services. If anything, a lower price of shopper-related card services is likely to cause more shoppers to use the card, and increased shopper popularity should make it easier for a card firm to raise prices to merchants, not harder, as would be the case if the services were substitutes. Thus, unless there is something unusual about this case—a possibility I discuss below, see infra, at 2297 – 2301—there is no justification for treating shopper-related services and merchant-related services as if they were part of a single market, at least not at step 1 of the “rule of reason.”

C

Regardless, a discussion of market definition was legally unnecessary at step 1. That is because the District Court found strong direct evidence of anticompetitive effects flowing from the challenged restraint. 88 F.Supp.3d, at 207–224. As I said, supra, at 2293 – 2294, this evidence included Discover's efforts to break into the credit-card business by charging lower prices for merchant-related services, only to find that the “nondiscrimination provisions,” by preventing merchants from encouraging shoppers to use Discover cards, meant that lower merchant prices did not result in any additional transactions using Discover credit cards. 88 F.Supp.3d, at 213–214. The direct evidence also included the fact that American Express raised its merchant prices 20 times in five years without losing any appreciable market share. Id., at 195–198, 208–212. It also included the testimony of numerous merchants that they would have steered shoppers away from American Express cards in response to merchant price increases (thereby checking the ability of American Express to raise prices) had it not been for the nondiscrimination provisions. See id., at 221–222. It included the factual finding that American Express “did not even account for the possibility that [large] merchants would respond to its price increases by attempting to shift share to a competitor's network” because the nondiscrimination provisions prohibited steering. Id., at 215. It included the District Court's ultimate finding of fact, not overturned by the Court of Appeals, that the challenged provisions “were integral to” American Express' “[price] increases and thereby caused merchants to pay higher prices.” Ibid.

As I explained above, this Court has stated that “[s]ince the purpose of the inquiries into market definition and market power is to determine whether an arrangement has the potential for genuine adverse effects on competition, proof of actual detrimental effects ... can obviate the need for” those inquiries. Indiana Federation of Dentists, 476 U.S., at 460–461, 106 S.Ct. 2009 (internal quotation marks omitted). That statement is fully applicable here. Doubts about the District Court's market-definition analysis are beside *2297 the point in the face of the District Court's findings of actual anticompetitive harm.

The majority disagrees that market definition is irrelevant. See ante, at 2285 – 2287, and n. 7. The majority explains that market definition is necessary because the nondiscrimination provisions are “vertical restraints” and “[v]ertical restraints often pose no risk to competition unless the entity imposing them has market power, which cannot be evaluated unless the Court first determines the relevant market.” Ante, at 2285, n. 7. The majority thus, in a footnote, seems categorically to exempt vertical restraints from the ordinary “rule of reason” analysis that has applied to them since the Sherman Act's enactment in 1890. The majority's only support for this novel exemption is Leegin Creative Leather Products, Inc. v. PSKS, Inc., 551 U.S. 877, 127 S.Ct. 2705, 168 L.Ed.2d 623 (2007). But Leegin held that the “rule of reason” applied to the vertical restraint at issue in that case. See id., at 898–899, 127 S.Ct. 2705. It said nothing to suggest that vertical restraints are not subject to the usual “rule of reason” analysis. See also infra, at 2303 – 2304.
One critical point that the majority's argument ignores is that proof of actual adverse effects on competition is, a fortiori, proof of market power. Without such power, the restraints could not have brought about the anticompetitive effects that the plaintiff proved. See Indiana Federation of Dentists, supra, at 460, 106 S.Ct. 2009 (“[T]he purpose of the inquiries into market definition and market power is to determine whether an arrangement has the potential for genuine adverse effects on competition” (emphasis added)). The District Court's findings of actual anticompetitive harm from the nondiscrimination provisions thus showed that, whatever the relevant market might be, American Express had enough power in that market to cause that harm. There is no reason to require a separate showing of market definition and market power under such circumstances. And so the majority's extensive discussion of market definition is legally unnecessary.

D

The majority's discussion of market definition is also wrong. Without raising any objection in general with the longstanding approach I describe above, supra, at 2295 – 2296, the majority agrees with the Court of Appeals that the market for American Express' card services is special because it is a “two-sided transaction platform.” Ante, at 2280 – 2282, 2285 – 2287. The majority explains that credit-card firms connect two distinct groups of customers: First, merchants who accept credit cards, and second, shoppers who use the cards. Ante, at 2280 – 2281; accord, 838 F.3d, at 186. The majority adds that “no credit-card transaction can occur unless both the merchant and the cardholder simultaneously agree to use to the same credit-card network.” Ante, at 2280. And it explains that the credit-card market involves “indirect network effects,” by which it means that shoppers want a card that many merchants will accept and merchants want to accept those cards that many customers have and use. Ibid. From this, the majority concludes that “courts must include both sides of the platform—merchants and cardholders—when defining the credit-card market.” Ante, at 2286; accord, 838 F.3d, at 197.

1

Missing from the majority's analysis is any explanation as to why, given the purposes that market definition serves in antitrust law, the fact that a credit-card firm can be said to operate a “two-sided transaction platform” means that its merchant-related and shopper-related services should be combined into a single market. The phrase “two-sided transaction platform” is not one of antitrust art—I can find no case from this Court using those words. The majority defines the phrase as covering a business that “offers different products or services to two different groups who both depend on the platform to intermediate between them,” where the business “cannot make a sale to one side of the platform without simultaneously making a sale to the other” side of the platform. Ante, at 2280. I take from that definition that there are four relevant features of such businesses on the majority's account: they (1) offer different products or services, (2) to different groups of customers, (3) whom the “platform” connects, (4) in simultaneous transactions. See ibid.

What is it about businesses with those four features that the majority thinks justifies a special market-definition approach for them? It cannot be the first two features—that the company sells different products to different groups of customers. Companies that sell multiple products to multiple types of customers are commonplace. A firm might mine for gold, which it refines and sells both to dentists in the form of fillings and to investors in the form of ingots. Or, a firm might drill for both oil and natural gas. Or a firm might make both ignition switches inserted into auto bodies and tires used for cars. I have already explained that, ordinarily, antitrust law will not group the two nonsubstitutable products together for step 1 purposes. Supra, at 2295 – 2296.

Neither should it normally matter whether a company sells related, or complementary, products, i.e., products which must both be purchased to have any function, such as ignition switches and tires, or cameras and film. It is well established that an antitrust
court in such cases looks at the product where the attacked restraint has an anticompetitive effect. *Supra*, at 2294 – 2295; see *Eastman Kodak*, 504 U.S., at 463, 112 S.Ct. 2072. The court does not combine the customers for the separate, nonsubstitutable goods and see if “overall” the restraint has a negative effect. See *ibid.*; 2B Areeda & Hovenkamp ¶ 565a. That is because, as I have explained, the complementary relationship between the products is irrelevant to the purposes of market-definition. See *supra*, at 2295 – 2296.

The majority disputes my characterization of merchant-related and shopper-related services as “complements.” See *ante*, at 2286 – 2287, n. 8. The majority relies on an academic article which devotes one sentence to the question, saying that “a two-sided market [is] different from markets for complementary products [e.g., tires and gas], in which both products are bought by the same buyers, who, in their buying decisions, can therefore be expected to take into account both prices.” Filistrucchi, Geradin, Van Damme, & Affeldt, Market Definition in Two–Sided Markets: Theory and Practice, 10 J. Competition L. & Econ. 293, 297 (2014) (Filistrucchi). I agree that two-sided platforms—at least as some academics define them, but see *infra*, at 2289 – 2290—may be distinct from some types of complements in the respect the majority mentions (even though the services resemble complements because they must be used together for either to have value). But the distinction the majority mentions has nothing to do with the relevant question. The relevant question is whether merchant-related and shopper-related services are substitutes, one for the other, so that customers can respond to a price increase for one service by switching to the other service. As I have explained, the two types of services are not substitutes in this way. *Supra*, at 2295 – 2296. And so the question remains, just as before: *2299* What is it about the economic relationship between merchant-related and shopper-related services that would justify the majority's novel approach to market definition?

What about the last two features—that the company connects the two groups of customers to each other, in simultaneous transactions? That, too, is commonplace. Consider a farmers' market. It brings local farmers and local shoppers together, and transactions will occur only if a farmer and a shopper simultaneously agree to engage in one. Should courts abandon their ordinary step 1 inquiry if several competing farmers' markets in a city agree that only certain kinds of farmers can participate, or if a farmers' market charges a higher fee than its competitors do and prohibits participating farmers from raising their prices to cover it? Why? If farmers' markets are special, what about travel agents that connect airlines and passengers? What about internet retailers, who, in addition to selling their own goods, allow (for a fee) other goods-producers to sell over their networks? Each of those businesses seems to meet the majority's four-prong definition.

 Apparently as its justification for applying a special market-definition rule to “two-sided transaction platforms,” the majority explains that such platforms “often exhibit” what it calls “indirect network effects.” *Ante*, at 2280. By this, the majority means that sales of merchant-related card services and (different) shopper-related card services are interconnected, in that increased merchant-buyers mean increased shopper-buyers (the more stores in the card's network, the more customers likely to use the card), and vice versa. See *ibid.* But this, too, is commonplace. Consider, again, a farmers' market. The more farmers that participate (within physical and esthetic limits), the more customers the market will likely attract, and vice versa. So too with travel agents: the more airlines whose tickets a travel agent sells, the more potential passengers will likely use that travel agent, and the more potential passengers that use the travel agent, the easier it will likely be to convince airlines to sell through the travel agent. And so forth. Nothing in antitrust law, to my knowledge, suggests that a court, when presented with an agreement that restricts competition in any one of the markets my examples suggest, should abandon traditional market-definition approaches and include in the relevant market services that are complements, not substitutes, of the restrained good. See *supra*, at 2295 – 2296.
To justify special treatment for “two-sided transaction platforms,” the majority relies on the Court's decision in \textit{United States v. Grinnell Corp.}, 384 U.S. 563, 571–572, 86 S.Ct. 1698, 16 L.Ed.2d 778 (1966). In \textit{Grinnell}, the Court treated as a single market several different “central station services,” including burglar alarm services and fire alarm services. \textit{Id.}, at 571, 86 S.Ct. 1698. It did so even though, for consumers, “burglar alarm services are not interchangeable with fire alarm services.” \textit{Id.}, at 572, 86 S.Ct. 1698. But that is because, for producers, the services were indeed interchangeable: A company that offered one could easily offer the other, because they all involve “a single basic service—the protection of property through use of a central service station.” \textit{Ibid.} Thus, the “commercial realit[y]” that the \textit{Grinnell} Court relied on, \textit{ibid.}, was that the services being grouped were what economists call “producer substitutes.” See 2B Areeda & Hovenkamp ¶ 561, at 378. And the law is clear that “two products produced interchangeably from the same production facilities are presumptively *2300 in the same market,” even if they are not “close substitutes for each other on the demand side.” \textit{Ibid.} That is because a firm that produces one such product can, in response to a price increase in the other, easily shift its production and thereby limit its competitor's power to impose the higher price. See \textit{id.}, ¶ 561a, at 379.

Unlike the various types of central station services at issue in \textit{Grinnell Corp.}, however, the shopper-related and merchant-related services that American Express provides are not “producer substitutes” any more than they are traditional substitutes. For producers as for consumers, the services are instead complements. Credit card companies must sell them together for them to be useful. As a result, the credit-card companies cannot respond to, say, merchant-related price increases by shifting production away from shopper-related services to merchant-related services. The relevant “commercial realities” in this case are thus completely different from those in \textit{Grinnell Corp.} (The majority also cites \textit{Brown Shoe Co. v. United States}, 370 U.S. 294, 336–337, 82 S.Ct. 1502, 8 L.Ed.2d 510 (1962), for this point, but the “commercial realities” considered in that case were that “shoe stores in the outskirts of cities compete effectively with stores in central downtown areas,” and thus are part of the same market. \textit{Id.}, at 338–339, 82 S.Ct. 1502. Here, merchant-related services do not, as I have said, compete with shopper-related services, and so \textit{Brown Shoe Co.} does not support the majority's position.) Thus, our precedent provides no support for the majority's special approach to defining markets involving “two-sided transaction platforms.”

What about the academic articles the majority cites? The first thing to note is that the majority defines “two-sided transaction platforms” much more broadly than the economists do. As the economists who coined the term explain, if a “two-sided market” meant simply that a firm connects two different groups of customers via a platform, then “pretty much any market would be two-sided, since buyers and sellers need to be brought together for markets to exist and gains from trade to be realized.” Rochet & Tirole, Two–Sided Markets: A Progress Report, 37 RAND J. Econ. 645, 646 (2006). The defining feature of a “two-sided market,” according to these economists, is that “the platform can affect the volume of transactions by charging more to one side of the market and reducing the price paid by the other side by an equal amount.” \textit{Id.}, at 664–665; accord, Filistrucchi 299. That requirement appears nowhere in the majority's definition. By failing to limit its definition to platforms that economists would recognize as “two sided” in the relevant respect, the majority carves out a much broader exception to the ordinary antitrust rules than the academic articles it relies on could possibly support.

Even as limited to the narrower definition that economists use, however, the academic articles the majority cites do not support the majority's flat rule that firms operating “two-sided transaction platforms” should always be treated as part of a single market for all antitrust purposes. \textit{Ante}, at 2286 – 2287. Rather, the academics explain that for market-definition purposes, “[i]n some cases, the fact that a business can be thought of as two-sided may be irrelevant,” including because “nothing in the analysis of the practices [at issue] really hinges on the linkages between the demands of participating groups.” Evans & Schmalensee, Markets With Two–Sided Platforms, 1 Issues in Competition L. & Pol'y 667, 689 (2008). “In other cases, the fact that a business is two-sided will prove important both by *2301 identifying the real dimensions of competition and focusing on sources of
201 L.Ed.2d 678, 86 USLW 4561, 2018-1 Trade Cases P 80,427...

constraints.” Ibid. That flexible approach, however, is precisely the one the District Court followed in this case, by considering the effects of “[t]he two-sided nature of the ... card industry” throughout its analysis. 88 F.Supp.3d, at 155.

Neither the majority nor the academic articles it cites offer any explanation for why the features of a “two-sided transaction platform” justify always treating it as a single antitrust market, rather than accounting for its economic features in other ways, as the District Court did. The article that the majority repeatedly quotes as saying that “‘[i]n two-sided transaction markets, only one market should be defined.’ “ ante, at 2287 (quoting Filistrucchi 302), justifies that conclusion only for purposes of assessing the effects of a merger. In such a case, the article explains, “[e]veryone would probably agree that a payment card company such as American Express is either in the relevant market on both sides or on neither side.... The analysis of a merger between two payment card platforms should thus consider ... both sides of the market.” Id., at 301. In a merger case this makes sense, but is also meaningless, because, whether there is one market or two, a reviewing court will consider both sides, because it must examine the effects of the merger in each affected market and submarket. See Brown Shoe Co., 370 U.S., at 325, 82 S.Ct. 1502. As for a nonmerger case, the article offers only United States v. Grinnell as a justification, see Filistrucchi 303, and as I have already explained, supra, at 2298 – 2299, Grinnell does not support this proposition.

Put all of those substantial problems with the majority's reasoning aside, though. Even if the majority were right to say that market definition was relevant, and even if the majority were right to further say that the District Court should have defined the market in this case to include shopper-related services as well as merchant-related services, that still would not justify the majority in affirming the Court of Appeals. That is because, as the majority is forced to admit, the plaintiffs made the factual showing that the majority thinks is required. See ante, at 2288 – 2289.

Recall why it is that the majority says that market definition matters: because if the relevant market includes both merchant-related services and card-related services, then the plaintiffs had the burden to show that as a result of the nondiscrimination provisions, “the price of credit-card transactions”—considering both fees charged to merchants and rewards paid to cardholders—“was higher than the price one would expect to find in a competitive market.” Ante, at 2288. This mirrors the Court of Appeals' holding that the Government had to show that the “nondiscrimination provisions” had “made all [American Express] customers on both sides of the platform— i.e., both merchants and cardholders—worse off overall.” 838 F.3d, at 205.

The problem with this reasoning, aside from it being wrong, is that the majority admits that the plaintiffs did show this: they “offer[ed] evidence” that American Express “increased the percentage of the purchase price that it charges merchants ... and that this increase was not entirely spent on cardholder rewards.” Ante, 2288 (citing 88 F.Supp.3d, at 195–197, 215). Indeed, the plaintiffs did not merely “offer evidence” of this—they persuaded the District Court, which made an unchallenged factual finding that the merchant price increases that resulted from the nondiscrimination provisions “were not wholly offset by additional rewards expenditures or otherwise passed through to cardholders, and resulted in a higher net price.” 838 F.3d, at 205 (emphasis added).

In the face of this problem, the majority retreats to saying that even net price increases do not matter after all, absent a showing of lower output, because if output is increasing, “‘rising prices are equally consistent with growing product demand.' “ Ante, at 2288 (quoting Brooke Group Ltd. v. Brown & Williamson Tobacco Corp., 509 U.S. 209, 237, 113 S.Ct. 2578, 125 L.Ed.2d 168 (1993)). This argument, unlike the price argument, has nothing to do with the credit-card market being a “two-sided transaction platform,” so if this is the basis for the majority's holding, then nearly all of the opinion is dicta. The argument is also wrong. It is true as an economic matter that a firm exercises market power by restricting output in order to raise prices. But the relevant restriction of output is as compared with a hypothetical world in which the restraint was not present and prices were lower. The

fact that credit-card use in general has grown over the last decade, as the majority says, see ante, at 2288 – 2289, says nothing about whether such use would have grown more or less without the nondiscrimination provisions. And because the relevant question is a comparison between reality and a hypothetical state of affairs, to require actual proof of reduced output is often to require the impossible—tantamount to saying that the Sherman Act does not apply at all.

In any event, there are features of the credit-card market that may tend to limit the usual relationship between price and output. In particular, merchants generally spread the costs of credit-card acceptance across all their customers (whatever payment method they may use), while the benefits of card use go only to the cardholders. See, e.g., 88 F.Supp.3d, at 216; Brief for John M. Connor et al. as Amici Curiae 34–35. Thus, higher credit-card merchant fees may have only a limited effect on credit-card transaction volume, even as they disrupt the marketplace by extracting anticompetitive profits.

IV

A

For the reasons I have stated, the Second Circuit was wrong to lump together the two different services sold, at step 1. But I recognize that the Court of Appeals has not yet considered whether the relationship between the two services might make a difference at steps 2 and 3. That is to say, American Express might wish to argue that the nondiscrimination provisions, while anticompetitive in respect to merchant-related services, nonetheless have an adequate offsetting procompetitive benefit in respect to its shopper-related services. I believe that American Express should have an opportunity to ask the Court of Appeals to consider that matter.

American Express might face an uphill battle. A Sherman Act § 1 defendant can rarely, if ever, show that a pro-competitive benefit in the market for one product offsets an anticompetitive harm in the market for another. In United States v. Topco Associates, Inc., 405 U.S. 596, 611, 92 S.Ct. 1126, 31 L.Ed.2d 515 (1972), this Court wrote:

“If a decision is to be made to sacrifice competition in one portion of the economy for greater competition in another portion, this ... is a decision that must be made by Congress and not by private forces or by the courts. Private forces are too keenly aware of their own interests in making such decisions and courts are ill-equipped and ill-situated for such decisionmaking.”

*2303 American Express, pointing to vertical price-fixing cases like our decision in Leegin, argues that comparing competition-related pros and cons is more common than I have just suggested. See 551 U.S., at 889–892, 127 S.Ct. 2705. But Leegin held only that vertical price fixing is subject to the “rule of reason” instead of being per se unlawful; the “rule of reason” still applies to vertical agreements just as it applies to horizontal agreements. See id., at 898–899, 127 S.Ct. 2705.

Moreover, the procompetitive justifications for vertical price-fixing agreements are not apparently applicable to the distinct types of restraints at issue in this case. A vertically imposed price-fixing agreement typically involves a manufacturer controlling the terms of sale for its own product. A television-set manufacturer, for example, will insist that its dealers not cut prices for the manufacturer's own televisions below a particular level. Why might a manufacturer want its dealers to refrain from price competition in the manufacturer's own products? Perhaps because, for example, the manufacturer wants to encourage the dealers to develop the market for the manufacturer's brand, thereby increasing interbrand competition for the same ultimate product, namely a television set. This type of reasoning does not appear to apply to American Express' nondiscrimination provisions, which seek to control the terms on which merchants accept other brands' cards, not merely American Express' own.

Regardless, I would not now hold that an agreement such as the one before us can never be justified by procompetitive benefits of some kind. But the Court of Appeals would properly consider procompetitive justifications not at step 1, but at steps 2 and 3.
201 L.Ed.2d 678, 86 USLW 4561, 2018-1 Trade Cases P 80,427...

of the “rule of reason” inquiry. American Express would need to show just how this particular anticompetitive merchant-related agreement has procompetitive benefits in the shopper-related market. In doing so, American Express would need to overcome the District Court's factual findings that the agreement had no such effects. See 88 F.Supp.3d, at 224–238.

B

The majority charts a different path. Notwithstanding its purported acceptance of the three-step, burden-shifting framework I have described, ante, at 2284 – 2285, the majority addresses American Express' procompetitive justifications now, at step 1 of the analysis, see ante, at 2289 – 2290. And in doing so, the majority inexplicably ignores the District Court's factual findings on the subject.

The majority reasons that the challenged nondiscrimination provisions “stem negative externalities in the credit-card market and promote interbrand competition.” Ante, at 2289. The “negative externality” the majority has in mind is this: If one merchant persuades a shopper not to use his American Express card at that merchant's store, that shopper becomes less likely to use his American Express card at other merchants' stores. Ibid. The majority worries that this “endangers the viability of the entire [American Express] network,” ibid., but if so that is simply a consequence of American Express' merchant fees being higher than a competitive market will support. “The antitrust laws were enacted for ‘the protection of competition, not competitors.’ ” Atlantic Richfield Co. v. USA Petroleum Co., 495 U.S. 328, 338, 110 S.Ct. 1884, 109 L.Ed.2d 333 (1990). If American Express' merchant fees are so high that merchants successfully induce their customers to use other cards, American Express can remedy that problem by lowering those fees or by spending more on cardholder rewards so *2304 that cardholders decline such requests. What it may not do is demand contractual protection from price competition.

In any event, the majority ignores the fact that the District Court, in addition to saying what I have just said, also rejected this argument on independent factual grounds. It explained that American Express “presented no expert testimony, financial analysis, or other direct evidence establishing that without its [nondiscrimination provisions] it will, in fact, be unable to adapt its business to a more competitive market.” 88 F.Supp.3d, at 231. It further explained that the testimony that was provided on the topic “was notably inconsistent,” with some of American Express' witnesses saying only that invalidation of the provisions “would require American Express to adapt its current business model.” Ibid. After an extensive discussion of the record, the District Court found that “American Express possesses the flexibility and expertise necessary to adapt its business model to suit a market in which it is required to compete on both the cardholder and merchant sides of the [credit-card] platform.” Id., at 231–232. The majority evidently rejects these factual findings, even though no one has challenged them as clearly erroneous.

Similarly, the majority refers to the nondiscrimination provisions as preventing “free riding” on American Express' “investments in rewards” for cardholders. Ante, at 2289 – 2290; see also ante, at 2282 – 2283 (describing steering in terms suggestive of free riding). But as the District Court explained, “[p]lainly ... investments tied to card use (such as Membership Rewards points, purchase protection, and the like) are not subject to free-riding, since the network does not incur any cost if the cardholder is successfully steered away from using his or her American Express card.” 88 F.Supp.3d, at 237. This, I should think, is an unassailable conclusion: American Express pays rewards to cardholders only for transactions in which cardholders use their American Express cards, so if a steering effort succeeds, no rewards are paid. As for concerns about free riding on American Express' fixed expenses, including its investments in its brand, the District Court acknowledged that free-riding was in theory possible, but explained that American Express “ma[de] no effort to identify the fixed expenses to which its experts referred or to explain how they are subject to free riding.” Ibid.; see also id., at 238 (American Express' own data showed “that the network's ability to confer a credentialing benefit trails that of its competitors, casting doubt on whether there is in fact any particular benefit associated with accepting [American Express] that is subject to free riding”). The majority does not even acknowledge, much less reject, these factual findings, despite coming to the contrary conclusion.
Finally, the majority reasons that the nondiscrimination provisions “do not prevent Visa, MasterCard, or Discover from competing against [American Express] by offering lower merchant fees or promoting their broader merchant acceptance.” *Ante,* at 2289. But again, the District Court's factual findings were to the contrary. As I laid out above, the District Court found that the nondiscrimination provisions *in fact did prevent* Discover from pursuing a low-merchant-fee business model, by “den[y]ing merchants the ability to express a preference for Discover or to employ any other tool by which they might steer share to Discover's lower-priced network.” 88 F.Supp.3d, at 214; see *supra,* at 2293. The majority's statements that the nondiscrimination provisions are procompetitive are directly contradicted by this and other factual findings.

***

*2305* For the reasons I have explained, the majority's decision in this case is contrary to basic principles of antitrust law, and it ignores and contradicts the District Court's detailed factual findings, which were based on an extensive trial record. I respectfully dissent.

All Citations


Footnotes

* The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States v. Detroit Timber & Lumber Co.*, 200 U.S. 321, 337, 26 S.Ct. 282, 50 L.Ed. 499.

1 In a competitive market, indirect network effects also encourage companies to take increased profits from a price increase on side A and spend them on side B to ensure more robust participation on that side and to stem the impact of indirect network effects. See Evans & Schmalensee 688; Evans & Noel 670–671, 695. Indirect network effects thus limit the platform's ability to raise overall prices and impose a check on its market power. See Evans & Schmalensee 688; Evans & Noel 695.

2 “Cardholders are more price-sensitive because many consumers have multiple payment methods, including alternative payment cards. Most merchants, by contrast, cannot accept just one major card because they are likely to lose profitable incremental sales if they do not take [all] the major payment cards. Because most consumers do not carry all of the major payment cards, refusing to accept a major card may cost the merchant substantial sales.” Muris 522.

3 All figures are accurate as of 2013.

4 Discover entered the credit-card market several years after Amex, Visa, and MasterCard. It nonetheless managed to gain a foothold because Sears marketed Discover to its already significant base of private-label cardholders. Discover's business model shares certain features with Amex, Visa, and MasterCard. Like Amex, Discover interacts directly with its cardholders. But like Visa and MasterCard, Discover uses banks that cooperate with its network to interact with merchants.
201 L.Ed.2d 678, 86 USLW 4561, 2018-1 Trade Cases P 80,427...

5 Plaintiffs also sued Visa and MasterCard, claiming that their anti-steering provisions violated § 1. But Visa and MasterCard voluntarily revoked their antisteering provisions and are no longer parties to this case.

6 Although the plaintiffs relied on indirect evidence below, they have abandoned that argument in this Court. See Brief for United States 23, n. 4 (citing Pet. for Cert. i, 18–25).

7 The plaintiffs argue that we need not define the relevant market in this case because they have offered actual evidence of adverse effects on competition—namely, increased merchant fees. See Brief for United States 40–41 (citing FTC v. Indiana Federation of Dentists, 766 U.S. 447, 106 S.Ct. 2009, 90 L.Ed.2d 445 (1986), and Catalano, Inc. v. Target Sales, Inc., 446 U.S. 643, 100 S.Ct. 1925, 64 L.Ed.2d 580 (1980) (per curiam)). We disagree. The cases that the plaintiffs cite for this proposition evaluated whether horizontal restraints had an adverse effect on competition. See Indiana Federation of Dentists, supra, at 450–451, 459, 106 S.Ct. 2009 (agreement between competing dentists not to share X rays with insurance companies); Catalano, supra, at 644–645, 650, 100 S.Ct. 1925 (agreement among competing wholesalers not to compete on extending credit to retailers). Given that horizontal restraints involve agreements between competitors not to compete in some way, this Court concluded that it did not need to precisely define the relevant market to conclude that these agreements were anticompetitive. See Indiana Federation of Dentists, supra, at 460–461, 106 S.Ct. 2009; Catalano, supra, at 648–649, 100 S.Ct. 1925. But vertical restraints are different. See Arizona v. Maricopa County Medical Soc., 457 U.S. 332, 348, n. 18, 102 S.Ct. 2466, 73 L.Ed.2d 48 (1982); Leegin Creative Leather Products, Inc. v. PSKS, Inc., 551 U.S. 877, 888, 127 S.Ct. 2705, 168 L.Ed.2d 623 (2007). Vertical restraints often pose no risk to competition unless the entity imposing them has market power, which cannot be evaluated unless the Court first defines the relevant market. See id., at 898, 127 S.Ct. 2705 (noting that a vertical restraint “may not be a serious concern unless the relevant entity has market power”); Easterbrook, Vertical Arrangements and the Rule of Reason, 53 Antitrust L.J. 135, 160 (1984) (“[T]he possibly anticompetitive manifestations of vertical arrangements can occur only if there is market power”).

8 Contrary to the dissent’s assertion, post, at 2298, merchant services and cardholder services are not complements. See Filistrucchi 297 (“[A] two-sided market [is] different from markets for complementary products, in which both products are bought by the same buyers, who, in their buying decisions, can therefore be expected to take into account both prices”). As already explained, credit-card companies are best understood as supplying only one product—transactions—which is jointly consumed by a cardholder and a merchant. See Klein 580. Merchant services and cardholder services are both inputs to this single product. See ibid.

9 Nontransaction platforms, by contrast, often do compete with companies that do not operate on both sides of their platform. A newspaper that sells advertising, for example, might have to compete with a television network, even though the two do not meaningfully compete for viewers. See Filistrucchi 301.

10 The plaintiffs argue that United States v. Topco Associates, Inc., 405 U.S. 596, 610, 92 S.Ct. 1126, 31 L.Ed.2d 515 (1972), forbids any restraint that would restrict competition in part of the market—here, for example, merchant steering. See Brief for Petitioners and Respondents Nebraska, Tennessee, and Texas 30, 42. Topco does not stand for such a broad proposition. Topco concluded that a horizontal agreement between competitors was unreasonable per se, even though the agreement did not extend to every competitor in the market. See 405 U.S., at 599, 608, 92 S.Ct. 1126. A horizontal agreement between competitors is markedly different from a vertical agreement that incidentally affects one particular method of competition. See Leegin, 551 U.S., at 888, 127 S.Ct. 2705; Maricopa County Medical Soc., 457 U.S., at 348, n. 18, 102 S.Ct. 2466.

86 S.Ct. 1698, 16 L.Ed.2d 778

86 S.Ct. 1698
Supreme Court of the United States

UNITED STATES, Appellant,
v.
GRINNELL CORPORATION et al.
GRINNELL CORPORATION, Appellant,
v.
UNITED STATES.
AMERICAN DISTRICT TELEGRAPH CO., Appellant,
v.
UNITED STATES.
HOLMES ELECTRIC PROTECTIVE CO., Appellant,
v.
UNITED STATES.
AUTOMATIC FIRE ALARM CO., Appellant,
v.
UNITED STATES.

Nos. 73—77

Argued March 28 and 29, 1966.


Synopsis
Civil antitrust suit. The United States District Court for the District of Rhode Island, entered a decree for the government, 236 F.Supp. 244, and all parties appealed. The Supreme Court, Mr. Justice Douglas, held that the entire accredited central station service business, including such services as automatic burglar alarms, automatic fire alarms, sprinkler supervisory service, and watch signal service, was properly treated as a single ‘relevant market’ in determining existence of monopolization, warranting judgment against defendants who exercised monopoly power over 87% of the business.

Affirmed in part, and remanded for further hearing on nature of the relief to be awarded.

Mr. Justice Harlan dissented, Mr. Justice Fortas and Mr. Justice Stewart dissented in part.

Attorneys and Law Firms

**1701 *565** Daniel M. Friedman, Washington, D.C., for appellant in No. 73 and appellee in Nos. 74—77.

John F. Sonnett, New York City, for appellant in No. 74 and appellees in No. 73.

Macdonald Flinn, New York City, for appellant in No. 75 and appellees in No. 73.

John W. Drye, Jr., New York City, for appellant in No. 76 and appellees in No. 73.
Mr. Justice DOUGLAS delivered the opinion of the Court.

This case presents an important question under s 2 of the Sherman Act, \(^1\) which makes it an offense for any person to ‘monopolize ** * * any part of the trade or commerce among the several States.’ This is a civil suit brought by the United States against Grinnell Corporation (Grinnell), American District Telegraph Co. (ADT), Holmes Electric Protective Co. (Holmes) and Automatic Fire Alarm Co. of Delaware (AFA). The District Court held for the Government and entered a decree. All parties appeal, \(^2\) the United States because it deems the relief inadequate and the defendants both on the merits and on the relief and on the ground that the District Court denied them a fair trial. We noted probable jurisdiction. 381 U.S. 910, 85 S.Ct. 1538, 14 L.Ed.2d 432.

Grinnell manufactures plumbing supplies and fire sprinkler systems. It also owns 76% of the stock of ADT, 89% of the stock of AFA, and 100% of the stock of Holmes. \(^3\) ADT provides both burglary and fire protection services; Holmes \(^*1702\) provides burglary services alone; AFA supplies only fire protection service. Each offers a central station service under which hazard-detecting devices installed on the protected premises automatically \(^*567\) transmit an electric signal to a central station. \(^4\) The central station is manned 24 hours a day. Upon receipt of a signal, the central station, where appropriate, dispatches guards to the protected premises and notifies the police or fire department direct. There are other forms of protective services. But the record shows that subscribers to accredited central station service (i.e., that approved by the insurance underwriters) receive reductions in their insurance premiums that are substantially greater than the reduction received by the users of other kinds of protection service. In 1961 accredited companies in the central station service business grossed $65,000,000. ADT, Holmes, and AFA are the three largest companies in the business in terms of revenue: ADT (with 121 central stations in 115 cities) has 73% of the business; Holmes (with 12 central stations in three large cities) has 12.5%; AFA (with three central stations in three large cities) has 2%. Thus the three companies that Grinnell controls have over 87% of the business.

Over the years ADT purchased the stock or assets of 27 companies engaged in the business of providing burglar or fire alarm services. Holmes acquired the stock or assets of three burglar alarm companies in New York City using a central station. Of these 30, the officials \(^*568\) of seven agreed not to engage in the protective service business in the area for periods ranging from five years to permanently. After Grinnell acquired control of the other defendants, the latter continued in their attempts to acquire central station companies—offers being made to at least eight companies between the years 1955 and 1961, including four of the five largest nondefendant companies in the business. When the present suit was filed, each of those defendants had outstanding an offer to purchase one of the four largest nondefendant companies.

In 1906, prior to the affiliation of ADT and Holmes, they made a written agreement whereby ADT transferred to Holmes its burglar alarm business in a major part of the Middle Atlantic States and agreed to refrain forever from engaging in that business in that area, while Holmes transferred to ADT its watch signal business and agreed to limit its activities to burglar alarm service and night watch service for financial institutions. While this agreement was modified several times and terminated in 1947, in 1961 Holmes still restricted its business to burglar alarm service and operated only in those areas which had been allocated to it under the 1906 agreement. Similarly, ADT continued to refrain from supplying burglar alarm service in those areas earlier allocated to Holmes.

In 1907 Grinnell entered into a series of agreements with the other defendant companies and with Automatic Fire Protection Co. to the following effect:
AFA received the exclusive right to provide central station sprinkler supervisory and waterflow alarm and automatic fire alarm service in New York City, Boston and Philadelphia, and agreed not to provide burglar alarm service in those cities or central station service elsewhere in the United States.

Automatic Fire Protection Co. obtained the exclusive right to provide central station sprinkler supervisory and waterflow alarm service everywhere else in the United States except for the three cities in which AFA received that exclusive right, and agreed not to engage in burglar alarm service.

ADT received the exclusive right to render burglar alarm and nightwatch service throughout the United States. (Under ADT’s 1906 agreement with Holmes, however, it could not provide burglar alarm services in the areas for which it had given Holmes the exclusive right to do so.) It agreed not to furnish sprinkler supervisory and waterflow alarm service anywhere in the country and not to furnish automatic fire alarm service in New York City, Boston or Philadelphia (the three cities allocated to AFA). ADT agreed to connect to its central stations the systems installed by AFA and Automatic.

Grinnell agreed to furnish and install all sprinkler supervisory and waterflow alarm actuating devices used in systems that AFA and Automatic would install, and otherwise not to engage in the central station protection business.

AFA and Automatic received 25% of the revenue produced by the sprinkler supervisory waterflow alarm service which they provided in their respective territories; ADT and Grinnell received 50% and 25%, respectively, of the revenue which resulted from such service. The agreements were to continue until February 1954.

The agreements remained substantially unchanged until 1949 when ADT purchased all of Automatic Fire Protection Co.’s rights under it for $13,500,000. After these 1907 agreements expired in 1954, AFA continued to honor the prior division of territories; and ADT and AFA entered into a new contract providing for the continued sharing of revenues on substantially the same basis as before. In 1954 Grinnell and ADT renewed an agreement with a Rhode Island company which received the exclusive right to render central station service within Rhode Island at prices no lower than those of ADT and which agreed to use certain equipment supplied by Grinnell and ADT and to share its revenues with those companies. ADT had an informal agreement with a competing central station company in Washington, D.C., ‘that we would not solicit each other's accounts.’

ADT over the years reduced its minimum basic rates to meet competition and renewed contracts at substantially increased rates in cities where it had a monopoly of accredited central station service. ADT threatened retaliation against firms that contemplated inauguring central station service. And the record indicates that, in contemplating opening a new central station, ADT officials frequently stressed that such action would deter their competitors from opening a new station in that area.

The District Court found that the defendant companies had committed per se violations of § 1 of the Sherman Act as well as § 2 and entered a decree. 236 F.Supp. 244.

The offense of monopoly under § 2 of the Sherman Act has two elements: (1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident. We shall see that this second ingredient presents no major problem here, as what was done in building the empire was done plainly and explicitly for a single purpose. In United States v. E. I. du Pont De Nemours & Co., 351 U.S. 377, 391, 76 S.Ct. 994, 1005, 100 L.Ed. 1264, we defined monopoly power as ‘the power to control prices or exclude competition.’ The existence of such power ordinarily may be inferred from the predominant share of the market. In American Tobacco Co. v. United States, 328 U.S. 781, 797, 66 S.Ct. 1125, 1133, 90 L.Ed. 1575, we said that ‘over two-thirds of the entire domestic field of cigarettes, and * * * over 80% of the field of comparable
cigarettes' constituted 'a substantial monopoly.' In United States v. Aluminum Co. of America, 2 Cir., 148 F.2d 416, 429, 90% of the market constituted monopoly power. In the present case, 87% of the accredited central station service business leaves no doubt that the congeries of these defendants have monopoly power—power which, as our discussion of the record indicates, they did not hesitate to wield—if that business is the relevant market. The only remaining question therefore is, what is the relevant market?

In case of a product it may be of such a character that substitute products must also be considered, as customers may turn to them if there is a slight increase in the price of the main product. That is the teaching of the du Pont case (supra, 351 U.S. at 395, 404, 76 S.Ct. at 1007, 1012), viz., that commodities reasonably interchangeable make up that ‘part’ of trade or commerce which § 2 protects against monopoly power.

The District Court treated the entire accredited central station service business as a single market and we think it was justified in so doing. Defendants argue that the different central station services offered are so diverse that they cannot under du Pont be lumped together to §572 make up the relevant market. For example, burglar alarm services are not interchangeable with fire alarm services. They further urge that du Pont requires that protective services other than those of the central station variety be included in the market definition.

But there is here a single use, i.e., the protection of property, through a central station that receives signals. It is that service, accredited, that is unique and that competes with all the other forms of property protection. We see no barrier to combining in a single market a number of different products or services where that combination reflects commercial realities. To repeat, there is here a single basic service—the protection of property through use of a central service station—that must be compared with all other forms of property protection.

In §2 cases under the Sherman Act, as in §7 cases under the Clayton Act (Brown Shoe Co. v. United States, 370 U.S. 294, 325, 82 S.Ct. 1502, 1523, 8 L.Ed.2d 510) there may be submarkets that are separate economic entities. We do not pursue that question here. First, we deal with services, not with products; and second, we conclude that the accredited central station is a type of service that makes up a relevant market and that domination or control of it makes out a monopoly of a ‘part’ of trade or commerce within the meaning of §2 of the Sherman Act. The defendants have not made out a case for fragmentizing the types of services into lesser units.

**1705 Burglar alarm service is in a sense different from fire alarm service; from waterflow alarms; and so on. But it would be unrealistic on this record to break down the market into the various kinds of central station protective services that are available. Central station companies recognize that to compete effectively, they must offer all or nearly all types of service. The different §573 forms of accredited central station service are provided from a single office and customers utilize different services in combination. We held in United States v. Philadelphia Nat. Bank, 374 U.S. 321, 356, 83 S.Ct. 1715, 1737, 10 L.Ed.2d 915, that ‘the cluster’ of services denoted by the term ‘commercial banking’ is ‘a distinct line of commerce.’ There is, in our view, a comparable cluster of services here. That bank case arose under §7 of the Clayton Act where the question was whether the effect of a merger ‘in any line of commerce’ may be ‘substantially to lessen competition.’ We see no reason to differentiate between ‘line’ of commerce in the context of the Clayton Act and ‘part’ of commerce for purposes of the Sherman Act. See United States v. First Nat. Bank & Trust Co., 376 U.S. 665, 667—668, 84 S.Ct. 1033, 1034, 12 L.Ed.2d 1. In the §7 national bank case just mentioned, services, not products in the mercantile sense, were involved. In our view the lumping together of various kinds of services makes for the appropriate market here as it did in the §7 case.

There are, to be sure, substitutes for the accredited central station service. But none of them appears to operate on the same level as the central station service so as to meet the interchangeability test of the du Pont case. Nonautomatic and automatic local
alarm systems appear on this record to have marked differences, not the low degree of differentiation required of substitute services as well as substitute articles.

*574 Watchman service is far more costly and less reliable. Systems that set off an audible alarm at the site of a fire or burglary are cheaper but often less reliable. They may be inoperative without anyone's knowing it. Moreover, there is a risk that the local ringing of an alarm will not attract the needed attention and help. Proprietary systems that a customer purchases and operates are available; but they can be used only by a very large business or by government and are not realistic alternatives for most concerns. There are also protective services connected directly to a municipal police or fire department. But most cities with an accredited central station do not permit direct, connected service for private businesses. These alternate services and devices differ, we are told, in utility, efficiency, reliability, responsiveness, and continuity, and the record sustains that position. And, as noted, insurance companies generally allow a greater reduction in premiums for accredited central station service than for other types of protection.

Defendants earnestly urge that despite these differences, they face competition from these other modes of protection. They seem to us seriously to overstate the degree of competition, but we recognize that (as the District Court found) they 'do not have unfettered power to **1706 control the price of their services * * * due to the fringe competition of other alarm or watchmen services.' 236 F.Supp., at 254. What defendants overlook is that the high degree of differentiation between central station protection and the other forms means that for many customers, only central station protection will do. Though some customers may be willing to accept higher insurance rates in favor of cheaper forms of protection, others will not be willing or able to risk serious interruption to their businesses, even though covered by insurance, and will thus be unwilling to consider anything but central station protection.

*575 The accredited, as distinguished from nonaccredited service, is a relevant part of commerce. Virtually the only central station companies in the status of the nonaccredited are those that have not yet been able to meet the standards of the rating bureau. The accredited ones are indeed those that have achieved, in the eyes of underwriters, superiorities that other central stations do not have. The accredited central station is located in a building of approved design, provided with an emergency lighting system and two alternate main power sources, manned constantly by at least a required minimum of operators, provided with a direct line to fire headquarters and, where possible, a direct line to a police station; and equipped with all the devices, circuits and equipment meeting the requirements of the underwriters. These standards are important as insurance carriers often require accredited central station service as a condition to writing insurance. There is indeed evidence that customers consider the unaccredited service as inferior.

We also agree with the District Court that the geographic market for the accredited central station service is national. The activities of an individual station are in a sense local as it serves, ordinarily, only that area which is within a radius of 25 miles. But the record amply supports the conclusion that the business of providing such a service is operated on a national level. There is national planning. The agreements we have discussed covered activities in many States. The inspection, certification and rate-making is largely by national insurers. The appellant ADT has a national schedule of prices, rates, and terms, though the rates may be varied to meet local conditions. It deals with multistate businesses on the basis of nationwide contracts. The manufacturing business of ADT is interstate. The fact that Holmes is more nearly local than the others does not **576 save it, for it is part and parcel of the combine presided over and controlled by Grinnell.

As the District Court found, the relevant market for determining whether the defendants have monopoly power is not the several local areas which the individual stations serve, but the broader national market that reflects the reality of the way in which they built and conduct their business.

We have said enough about the great hold that the defendants have on this market. The percentage is so high as to justify the finding of monopoly. And, as the facts already related indicate, this monopoly was achieved in large part by unlawful and exclusionary practices. The restrictive agreements that pre-empted for each company a segment of the market where it was
free of competition of the others were one device. Pricing practices that contained competitors were another. The acquisitions by Grinnell of ADT, AFA, and Holmes were still another. Grinnell long faced a problem of competing with ADT. That was one reason it acquired AFA and Holmes. Prior to settlement of its dispute and controversy with ADT, Grinnell prepared to go into the central station service business. By acquiring ADT in 1953, Grinnell eliminated that alternative. Its control of the three other defendants eliminated any possibility of an outbreak of competition that might have occurred when the 1907 agreements terminated. By those acquisitions it perfected the monopoly power to exclude competitors and fix prices.  

*577 II.

The final decree enjoins the defendants in general terms from restraining trade or attempting or conspiring to restrain trade in this particular market, from further monopolizing, and attempting or conspiring to monopolize. The court ordered the alarm companies to file with the Department of Justice standard lists of prices and terms and every quotation to customers that deviated from those lists and enjoined the defendants from acquiring stock, assets, or business of any enterprise in the market. Grinnell was ordered to file, not later than April 1, 1966, a plan of divestiture of its stock in each of the other defendant companies. It was given the option either to sell the stock or distribute it to its stockholders or combine or vary those methods. The court further enjoined any of the defendants from employing in any capacity the President and Chairman of the Board of Grinnell, James D. Fleming. Both the Government and the defendants challenge aspects of the decree.

We start from the premise that adequate relief in a monopolization case should put an end to the combination and deprive the defendants of any of the benefits of the illegal conduct, and break up or render impotent the monopoly power found to be in violation of the Act. That is the teaching of our cases, notably Schine Chain Theatres v. United States, 334 U.S. 110, 128—129, 68 S.Ct. 947, 957, 92 L.Ed. 1245.

We largely agree with the Government's views on the relief aspect of the case. We start with ADT, which presently does 73% of the business done by accredited central stations throughout the country. It is indeed the keystone of the defendants' monopoly power. The mere dissolution of the combination through the divestiture by Grinnell of its interests in the other companies does not reach the root of the evil. In 92 of the 115 cities in which ADT operates there are no other accredited central stations. Perhaps some cities could not support more than one. Defendants recognized prior to trial that at least 13 cities can; the Government urged divestiture in 48 cities. That there should be some divestiture on the part of ADT seems clear; but the details of such divestiture must be determined by the District Court as the matter cannot be resolved on this record.

Two of the means by which ADT acquired and maintained its large share of the market are the requirement that subscribers sign five-year contracts and the retention by ADT of title to the protective services equipment installed on a subscriber's premises. On this record it appears that these practices constitute substantial barriers to competition and that relief against them is appropriate. The pros and cons are argued with considerable vehemence here.  

We 1708 Again, we cannot resolve them on this record. The various aspects of this controversy must be explored by the District Court and suitable protective provisions included in the decree that deprive these two devices of the coercive power that they apparently have had towards restraining competition and creating a monopoly.

*579 The Government proposed that the defendants be required to sell, on nondiscriminatory terms, any devices manufactured by them for use in furnishing central station service. It seems clear that if the competitors are to be able to compete effectively for the existing customers of the defendants when the present service contracts expire, they must be assured of replacement parts to maintain those systems.
The Government urges visitation rights, that is, requiring reports, examining documents, and interviewing company personnel, a relief commonly granted for the purpose of determining whether a defendant has complied with an antitrust decree. See United States v. United States Gypsum Co., 340 U.S. 76, 95, 71 S.Ct. 160, 172, 95 L.Ed. 89. The District Court gave no explanation for its refusal to grant this relief. It is so important and customary a provision that the District Court should reconsider it.

Defendants urge and the Government concedes that the barring of Mr. Fleming from the employment of any of the defendants is unduly harsh and quite unnecessary on this record. While relief of that kind may be appropriate where the predatory conduct is conspicuous, we cannot see that any such case was made out on this record.

The Government objects, as do the defendants, to the broad and generalized terms of the restraining order. They properly point out, as we emphasized in Schine Chain Theatres v. United States, supra, 334 U.S. at 125—126, 68 S.Ct. at 955—956, that the precise practices found to have violated the Act should be specifically enjoined. On remand we suggest that that course be taken.

The defendants object to the requirements that Grinnell divest itself of its holdings in the three alarm company defendants, but we think that provision is wholly justified. Dissolution of the combination is essential as indicated by many of our cases, starting with Standard Oil Co. of New Jersey v. United States, 221 U.S. 1, 78, 31 S.Ct. 502, 523, 55 L.Ed. 619. The defendants object to that portion of the decree that bars them from acquiring interests in firms in the accredited central station business. But since acquisition was one of the methods by which the defendants acquired their market power and was the method by which Grinnell put the combination together, an injunction against the repetition of the practice seems fully warranted. The defendants further object to the requirement in the decree that the alarm company defendants report to the Department of Justice any deviation they make from their list prices. We make no comment on that because in view of the other extensive changes necessary in the decree, the District Court might well deem it to be unnecessary in the fashioning of the new decree. In other words, we leave that matter open, to rest finally in the discretion of the District Court.

The defendants contend that Judge Wyzanski, who tried the case, was personally biased and prejudiced and should have been disqualified from sitting in the case, and that he denied them a fair trial. We think this point is without merit.

The complaint was filed in April 1961, the answers in July 1961. Shortly thereafter extensive taking of depositions began. The District Court in January 1963 directed that no depositions be taken after September 1, 1963. In response to an inquiry from the court both sides suggested that the trial be set no earlier than January 1964.

At a pretrial conference in December 1963, government counsel told the court that the parties had been trying to reach agreement on a consent decree but were far apart and asked how the court would like to handle the presentation of the evidence in the event a settlement was not reached. Grinnell's lawyer suggested that the next appropriate procedure would be a pretrial on the question of relief—a suggestion that the District Court construed as an invitation to the court to discuss the relief apart from the merits. The Government objected. The court then asked for a brief from each side setting forth its views on relief if the Government prevailed on the merits. In response to the court's statement that 'as I understand it, you want to find out what kind of relief I would be likely to allow if the government's case stood virtually uncontradicted,' Grinnell's counsel replied: 'That is what I had in mind, your Honor, yes.'

Thereupon the court set a day for such a hearing. At the next pretrial conference Grinnell's counsel stated that 'if your Honor would indicate the relief that might be appropriate in this case that would help both sides to come to a better understanding.'
Then the following colloquy occurred:

‘THE COURT. I don't think it would help very much.

‘MR. MCINERNEY. Well, your Honor, I think it would help both the plaintiff and the defendants to know what is really at stake here in this trial.

‘THE COURT. I assure you that you would not be helped by anything I would say. You would do better to get together with the government rather than run the risk of what I would say from what I have seen. Let me just assure you of that. * * *’

The case was then set for trial on June 15, 1964. When Grinnell's counsel sought to argue further, the court stated: ‘There is no use in discussing it with me. I have read enough to know that if I have to decide this case on what I have seen from the government you will not be in a position at this stage to agree to it.’

On June 3, 1964, defendants argued for a postponement of the trial, saying they needed more time. The court denied the motion. Then they argued that the relief issues to be tried be limited to those raised by the pleadings so as to eliminate what they considered to be extraneous issues raised by the Government. To that the court replied:

‘I can't understand frankly why you don't realize that you have forced me to look at the documents in this case, which I dislike doing in advance of trial. You have invited me, therefore, into what I regard as, from your point of view, a rather undesirable situation. I think I made that clear at the beginning. I have told you that, forced by you to look, my views are more extreme than those of the government; and I have also made you realize that if I am required to make Findings and reach Conclusions I am opening up third-party suits that will make, in view of the size of the industry, the percentage of people involved higher than in the electrical cases.’

Shortly thereafter defendants filed a motion for the disqualification of Judge Wyzanski on the grounds of personal bias and prejudice. The alleged bias and prejudice to be disqualifying must stem from an extrajudicial source and result in an opinion on the merits on some basis other than what the judge learned from his participation in the case. Berger v. United States, 255 U.S. 22, 31, 41 S.Ct. 230, 232, 65 L.Ed. 481. Any adverse attitudes that Judge Wyzanski evinced toward the defendants were based on his study of the depositions and briefs which the parties had requested him to make. What he said reflected no more than his view that, if the facts were as the Government alleged, stringent relief was called for.

During the trial he repeatedly stated that he had not made up his mind on the merits. During the trial he ruled certain evidence to be irrelevant to the issues and when the lawyer persisted in offering it Judge Wyzanski said, ‘Maybe you will persuade somebody else. And if you think so, all right. I just assure you it is a great ceremonial act, as far as I am concerned.’ We do not read this statement as manifesting a closed mind on the merits of the case but consider it merely a terse way of repeating the previously stated ruling that this particular evidence was irrelevant.

We have examined all the other claims of the defendants made against Judge Wyzanski and find that the claim of bias and prejudice is not made out. Our discussion of the relief which he granted shows indeed that he was in several critical respects, too lenient with those who now charge him with bias and prejudice.

The judgment below is affirmed except as to the decree. We remand for further hearings on the nature of the relief consistent with the views expressed herein. It is so ordered.
Affirmed in part and remanded.

Mr. Justice HARLAN, dissenting in Nos. 73—77.

I cannot agree with the Court that the relevant market has been adequately proved. I do not dispute that a national market may be found even though immediate competition takes place only within individual communities, some of which are themselves natural monopolies. For a national monopoly of such local enterprises may still have serious long-term impact on competition and be vulnerable on its own plane to the antitrust laws. In the product market also the Court seems to me to make out a good enough case for lumping together the different kinds of central station protective service (CSPS). But I cannot agree that the facts so far developed warrant restricting the product market to accredited CSPS.

Because the ultimate issue is the effective power to control price and competition, this Court has always recognized that the market must include products or services ‘reasonably interchangeable’ with those of the alleged monopolist. United States v. E. I. du Pont De Nemours & Co., 351 U.S. 377, 395, 76 S.Ct. 994, 1007, 100 L.Ed. 1264. In this instance, there is no doubt that the accredited CSPS business does compete in some measure with many other forms of hazard protection: watchmen, local alarms, proprietary systems, telephone-connected services, unaccredited CSPS, direct-connected (to police and fire stations) systems, and so forth. The critical question, then, is the extent of competition from these rivals.

The Government and the majority have stressed that differences in cost, reliability and insurance discounts may disqualify a competing form of protection for a particular customer. For example, it is said that proprietary systems are too expensive for any but large companies and local alarms may go unanswered in some neighborhoods. But if in general a CSPS customer has a feasible alternative to CSPS, it does not much matter that other ones are foreclosed to him, nor that other CSPS customers have different second choices. From this record, it may well be that other forms of protection are each competitive enough with segments of the CSPS market so that in sum CSPS rarely has a monopoly position.

From the defense standpoint, there is substantial evidence showing that the defendants do feel themselves under pressure from other forms of protection, that they do compete for customers, and that they do lower prices even in areas where no CSPS competition is present. This concrete evidence of market behavior seems to me to rank higher than the kind of inference proof heavily relied on by the Government—physical differences between competing forms of protection, self-advertising claims of CSPS companies that they represent a superior service and varying insurance discounts. Given that the burden of proof rests upon the Government, the record leaves me with such misgivings as to the validity of the District Court's findings on this score that I am not prepared to agree that the Government has made the showing of market domination that the law demands before a business is sundered.

At the same time the case must be recognized as a close one, and I am not ready to say at this stage that the findings and conclusions of the District Court might not be supportable. All things considered, I join with my Brothers Fortas and Stewart to the extent of voting to remand the case for further proceedings so that new findings can be made as to the relevant product market. This course seems to me the more appropriate in light of the fact that because of the Expediting Act, 15 U.S.C. s 29 (1964 ed.), we have not had the benefit of any intermediate appellate sifting of this record. In view of the disposition I propose, I do not consider any of the other questions in the case.

Mr. Justice FORTAS, with whom Mr. Justice STEWART joins, dissenting in Nos. 73 and 77.

I agree that the judgment below should be remanded, but I do not agree that the remand should be limited to reshaping the decree. Because I believe that the definition of the relevant market here cannot be sustained, I would reverse and remand for a new determination of this basic issue, subject to proper standards.
We have here a case under both s 1 and s 2 of the Sherman Act, which proscribe combinations in restraint of trade, and monopolies and attempts to monopolize. The judicial task is not difficult to state: Does the record show a combination in restraint of trade or a monopoly or attempt to monopolize? If so, what are its characteristics, scope and effect? And, finally, what is the appropriate remedy for a court of equity to decree?

Each of these inquiries depends upon two basic referents: definition of the geographical area of trade or commerce restrained or monopolized, and of the products or services involved. In s 1 cases this problem ordinarily presents little difficulty because the combination in restraint of trade itself delineates the ‘market’ with sufficient clarity to support the usual injunctive form of relief in those cases. See, e.g., United States v. Griffith, 334 U.S. 100, 68 S.Ct. 941, 92 L.Ed. 1236. In the present case, however, the essence of the offense is monopolization, achieved or attempted, and the major relief is divestiture. For these purposes, ‘market’ definition is of the essence, just as in s 7 cases the kindred definition of the ‘line of commerce’ is fundamental. We must define the area of commerce that is allegedly engrossed before we can determine its engrossment; and we must define it before a decree can be shaped to deal with the consequences of the monopoly, and to restore or produce competition. See United States v. E. I. du Pont De Nemours & Co. (the Cellophane Case), 351 U.S. 377, 389—396, 76 S.Ct. 994, 1003—1008, 100 L.Ed. 1264; United States v. Aluminum Co. of America, 148 F.2d 416 (C.A.2d Cir. 1945).

In s 2 cases, the search for ‘the relevant market’ must be undertaken and pursued with relentless clarity. It is, in essence, an economic task put to the uses of the law. Unless this task is well done, the results will be distorted in terms of the conclusion as to whether the law has been violated and what the decree should contain.

In this case, the relevant geographical and product markets have not been defined on the basis of the economic facts of the industry concerned. They have been tailored precisely to fit defendants' business. The Government proposed and the trial court concluded that the relevant market is not the business of fire protection, or burglary protection, or protection against waterflow, etc., or all of these together. It is not even the business of furnishing these from a central location. It is the business, viewed nationally, of supplying ‘insurance accredited central station protection services.’ (CSPS)—that is, fire, burglary and other kinds of protection furnished from a central station which is accredited by insurance companies. The business of defendants fits neatly into the product and geographic market so defined. In fact, it comes close to filling the market so defined. This Court has now approved this Procrustean definition.

The geographical market is defined as nationwide. But the need and the service are intensely local—more local by far, for example, than the market which this Court found to be local in United States v. Philadelphia Nat. Bank, 374 U.S. 321, 357—362, 83 S.Ct. 1715, 1738—1740, 10 L.Ed.2d 915. The premises protected do not travel. They are fixed locations. They must be protected where they are. Protection must be provided on the spot. It must be furnished by local personnel able to bring help to the scene within minutes. Even the central stations can provide service only within a 25-mile radius. Where the tenants of the premises turn to central stations for this service, they must make their contracts locally with the central station and purchase their services from it on the basis of local conditions.

But because these defendants, the trial court found, are connected by stock ownership, interlocking management and some degree of national corporate direction, and because there is some national participation in selling as well as national financing, advertising, purchasing of equipment, and the like, the court concluded that the competitive area to be considered is national. This Court now affirms that conclusion.

This is a non sequitur. It is not permissible to seize upon the nationwide scope of defendants’ operation and to bootstrap a geographical definition of the market from this. The purpose of the search for the relevant geographical market is to find the area or areas to which a potential buyer may rationally look for the goods or services that he seeks. The test, as this Court said in United States v. Philadelphia Nat. Bank, is ‘the geographic structure of supplier-customer relations,’ 374 U.S. 321, 357, 83 S.Ct. 1715, 1738, quoting Kaysen & Turner, Antitrust Policy 102 (1959). And, as Mr. Justice Clark put it in Tampa Electric Co.
The definition of the relevant market requires *589 CAREFUL SELECTION OF THE MARKET AREA IN which the seller operates, and to which the purchaser can practicably turn for supplies. *589 The central issue is where does a potential buyer look for potential suppliers of the service—what is the geographical area in which the buyer has, or, in the absence of monopoly, would have, a real choice as to price and alternative facilities? This depends upon the facts of the market place, taking into account such economic factors as the distance over which supplies and services may be feasibly furnished, consistently with cost and functional efficiency.

The incidental aspects of defendants' business which the court uses cannot control the outcome of this inquiry. They do not measure the market area in which buyer and sellers meet. They have little impact upon the ascertainment of the geographical areas in which the economic and legal questions must be answered: have defendants ‘monopolized’ or ‘restrained’ trade; have they eliminated or can they eliminate competitors or prevent or obstruct new entries into the business; have they controlled or can they control price for the services? These are the issues; and, in defendants' business, a finding that the ‘relevant market’ is national is nothing less than a studied failure to assess the effect of defendants' position and practices in the light of the competition which exists, or could exist, in economically defined areas—in the real world.

Here, there can be no doubt that the correct geographic market is local. The services at issue are intensely local: they can be furnished only locally. The business as it is done is local—not nationwide. If, as might well be the case on this record, defendants were found to have violated the Sherman Act in a number of these local areas, a proper decree, directed to those markets, as well as to *590 general corporate features relevant to the condemned practices, could be fashioned. On the other hand, a gross definition of the market as nationwide leads to a gross, nationwide decree which does not address itself to the realities of the market place. That is what happened here: The District Court's finding that the market was nationwide logically led it to a decree which operated on the only national aspect of the situation, the parent company nexus, instead of on the economically realistic areas—the local situations. This **1714 Court now directs the trial court to require ‘some (unspecified) divestiture’ locally by the alarm companies. This is a recognition of the economic reality that the relevant competitive areas are local. In plain terms, the Court's direction to the trial court means a 'market-by-market' analysis for the purpose of breaking up defendants' monopoly position and creating competitors and competition wherever feasible in particular cities. In my view, however, by so directing, the Court implies that which it does not command: that the case should be reconsidered at the trial court level because of the improper standard it used to define the relevant geographic markets.

The trial court's definition of the ‘product’ market even more dramatically demonstrates that its action has been Procrustean—that it has tailored the market to the dimensions of the defendants. It recognizes that a person seeking protective services has many alternative sources. It lists ‘watchmen, watchdogs, automatic proprietary systems confined to one site, (often, but not always), alarm systems connected with some local police or fire station, often unaccredited CSPS (central station protective services), and often accredited CSPS.’ The court finds that even in the same city a single customer seeking protection for several premises may ‘exercise its option’ differently for different locations. It may choose *591 accredited CSPS for one of its locations and a different type of service for another.

But the court isolates from all of these alternatives only those services in which defendants engage. It eliminates all of the alternative sources despite its conscientious enumeration of them. Its definition of the ‘relevant market’ is not merely confined to ‘central station’ protective services, but to those central station protective services which are ‘accredited’ by insurance companies.

There is no pretense that these furnish peculiar services for which there is no alternative in the market place, on either a price or a functional basis. The court relies solely upon its finding that the services offered by accredited central stations are of better quality, and upon its conclusion that the insurance companies tend to give ‘noticeably larger’ discounts to policyholders who use accredited central station protective services. This Court now approves this strange red-haired, bearded, one-eyed man-with-a-limp classification.
The unreality of the trial court's market definition may best be illustrated by an example. Consider the situation of a retail merchant in Pittsburgh who wishes to protect his store against burglary. The Holmes Electric Protective Company, a subsidiary of Grinnell, operates an accredited central station service in Pittsburgh. It provides only burglary protection.

The gerrymandered market definition approved today totally excludes from the market consideration of the availability in Pittsburgh of cheaper but somewhat less reliable local alarm systems, or of more expensive (although the expense is reduced by greater insurance discounts) watchman service, or even of unaccredited central station service which virtually duplicates the Holmes service.

Instead, and in the name of ‘commercial realities,’ we are instructed that the ‘relevant market’—which totally excludes these locally available alternatives—requires us to look only to accredited central station service, and that we are to include in the ‘market’ central stations which do not furnish burglary protection and even those which serve such places as Boston and Honolulu.  

Moreover, we are told that the ‘relevant market’ must assume this strange and curious configuration despite evidence in the record and a finding of the trial court that ‘fringe competition’ from such locally available alternatives as watchmen, local alarm systems, proprietary systems, and unaccredited central stations has, in at least 20 cities, forced the defendants to operate at a ‘loss’ even though defendants have a total monopoly in these cities of the ‘market’—namely, the ‘accredited central station protective services.’ And we are led to this odd result even though there is in the record abundant evidence that customers switch from one form of property protection to another, and not always in the direction of accredited central station service.

I believe this approach has no justification in economics, reason or law. It might be supportable if it were found that the accredited central stations offer services which are unique in the sense that potential buyers—or at least a substantial, identifiable part of the trade—look only to them for the services in question, and that neither cost, type, quality of service nor other factors bring competing services into the market. The findings here and the record do not permit this conclusion.

The Government's market definition, accepted by the trial court, is a distortion which inevitably leads to a superficial and distorted results even in the hands of a highly skilled judge. As this Court held in Brown Shoe, supra, the ‘reasonable interchangeability of use or the *593 cross-elasticity of demand,’ determines the boundaries of a product market. 370 U.S., at 325, 82 S.Ct., at 1523. See also the Cellophane Case, 351 U.S., at 380, 76 S.Ct., at 998. In plain language, this means that the court should have defined the relevant market here to include all services which, in light of geographic availability, price and use characteristics, are in realistic rivalry for all or some part of the business of furnishing protective services to premises. In the present situation, however, the court's own findings show that practical alternatives are available to potential users—although they vary from market to market and possibly from user to user. These have been arbitrarily excluded from the court's definition.

I do not suggest that wide disparities in quality, price and customer appeal could never affect the definition of the market. But this follows only where the disparities are so great that they create separate and distinct categories of buyers and sellers. The record here and the findings do not approach this standard. They fall far short of justifying the narrowing of the market as practiced here. I need refer only to the exclusion of non-accredited central stations, which the court seeks to justify by reference to differentials in insurance discounts. These differentials may indeed affect the relative cost to the consumer of the competing modes of protection. But, in the absence of proof that they result in eliminating the competing services from the category of those to which the purchaser ‘can practicably turn’ for supplies, they do not justify such total exclusion. This sort of exclusion of the supposedly not-quite-so-attractive service from the basic definition of the kinds of business and service against which defendants' activity will be measured, is entirely unjustified on this record.

**1716  *594 The importance of this kind of truncated market definition vividly appears if we are to say, as the trial court here held, that if defendant has so large a fraction of the market as to constitute a ‘predominant’ share, a rebuttable presumption
of monopolization follows. The fraction depends upon the denominator (the ‘market’) as well as the numerator (the defendants' volume). Clearly, this ‘presumption’ is unwarranted unless the ‘market’ is defined to include all competitors. The contrary is not supported by this Court's decisions in either the Cellophane Case, supra, or United States v. E. I. du Pont De Nemours & Co. (General Motors), 353 U.S. 586, 77 S.Ct. 872, 1 L.Ed.2d 1057. The latter case defined the market in terms of the total products which could be used for the defined purposes: automobile fabrics and finishes. This embraces the total range of options for customers seeking these products. On the contrary, as the record here shows and as the findings, candidly read, imply, substantial options exist for services other than through accredited central stations providing protective services. Those options, whether for all or a part of the services in issue, must be included in the assessment of the market.

In the opinion which this Court hands down today, there is considerable discussion of defendants' argument that the market should be ‘broken down’ by different type of service: e.g., Burglar protection, fire protection, etc. The Court rejects this on the ground that it is appropriate to evaluate a ‘cluster’ of services as such. It points to Philadelphia Nat. Bank, supra, for support for its approach. In that case, Mr. Justice Brennan's opinion for the Court carefully set out the distinctive characteristics of banking services: that some of these services (e.g., checking accounts) are virtually free of competition from other types of institutions, and that other services are distinctive in cost or other characteristics. 374 U.S., at 356—357, 83 S.Ct., at 1737—1738. See also United States v. First Nat. Bank, 376 U.S. 665, 668, 84 S.Ct. 1033, 1034, 12 L.Ed.2d 1 (per Douglas, J.). Similarly, in United States v. Paramount Pictures, 334 U.S. 131, 68 S.Ct. 915, 92 L.Ed. 1260, and International Boxing Club of N.Y. v. United States, 358 U.S. 242, 249—252, 79 S.Ct. 245, 249—251, 3 L.Ed.2d 270, ‘first-run’ moving pictures and championship boxing matches were held sufficiently distinctive in terms of demand in the market place to warrant consideration as separate markets.

But no such distinctiveness exists here. As I have discussed, neither this record nor the trial court's findings show either a distinctive demand or a separable market for ‘insurance accredited central station protective services.’ The contrary is evident. None of the services furnished by accredited central stations is unique, as I have discussed. Nor is there even a common or predominant ‘cluster’ of services offered by the central stations. One of the defendants, Holmes, is engaged only in the burglary alarm business. Another, AFA, furnishes only fire and waterflow service. Only ADT among the defendants makes available to its customers the full ‘cluster.’

I do not mean to suggest that the Government must prove its case, service by service. But in defining the market, individual services, even if furnished in isolation, ought to be specified and here, as distinguished from the conclusion impelled by the circumstances in Philadelphia Nat. Bank, supra, competitors for individual services ought to be taken into account.

I do not intend by any of the foregoing to suggest that, on this record, the relief granted by the trial court and the substantially more drastic relief ordered by this Court would necessarily be unjustified. It is entirely possible that monopoly or attempt to monopolize may be found—and perhaps found with greater force—in local situations. Relief on a pervasive, system-wide, national basis might follow, as decreed by the trial court, as well as divestiture in appropriate local situations, as directed by this Court. It is impossible, I submit, to make these judgments on the findings before us because of the distortion due to an incorrect and unreal definition of the ‘relevant market.’ Now, because of this Court's mandate, the market-by-market inquiry must begin for purposes of the decree. But this should have been the foundation of judgment, not its superimposed conclusion. This inquiry should—in my opinion, it must—take into account the total economic situation—all of the options available to one seeking protection services. It should not be limited to central stations, and certainly not to ‘insurance accredited central station protective services’ which this Court sanctions as the relevant market. Since I am of the opinion that defendants and the courts are entitled to a reappraisal of the liability consequences as well as the appropriate provisions of the decree on the basis of a sound definition of the market, I would reverse and remand for these purposes.

All Citations

384 U.S. 563, 86 S.Ct. 1698, 16 L.Ed.2d 778
Footnotes


3. These are the record figures. Since the time of the trial, Grinnell's holdings have increased. Counsel for Grinnell has advised this Court that Grinnell now holds 80% of ADT's stock and 90% of the stock of AFA.

4. Among the various central station services offered are the following:

   (1) automatic burglar alarms;

   (2) automatic fire alarms;

   (3) sprinkler supervisory service (any malfunctions in the fire sprinkler system—e.g., changes in water pressure, dangerously low water temperatures, etc.—are reported to the central station); and

   (4) watch signal service (night watchmen, by operating a key-triggered device on the protected premises, indicate to the central station that they are making their rounds and that all is well; the failure of a watchman to make his electrical report alerts the central station that something may be amiss).

5. In 1959, ADT complained that AFA's share of the revenues was excessive. AFA replied, in a letter to the president of Grinnell (which by that time controlled both ADT and AFA), that its share was just compensation for its continued observance of the service and territorial restrictions: 'The geographic restrictions placed upon us plus the requirement that we confine our activities to sprinkler and fire alarm services exclusively, since 1907 and presumably into the future, has definitely retarded our expansion in the past to the benefit of ADT growth. * * * (AFA's) contribution must also include the many things that helped make ADT big.' (Emphasis added.)

6. Thus, of the 38 nondefendant firms operating a central service station protective service in the United States in 1961, 24 offered all of the following services: automatic fire alarm; waterflow alarm and sprinkler supervision; watchman's reporting and manual fire alarm; and burglar alarm. Of the other firms, 11 provided no watchman's reporting and manual fire alarm service; six provided no automatic fire alarm service; and two offered no sprinkler supervisory and waterflow alarm service. Moreover, of the 14 firms not providing the full panoply of services, 10 lacked only one of the above-described services. Appellant ADT's assertion that 'very few accredited central stations furnish the full variety of services' is flatly contradicted by the record.

7. Since the record clearly shows that this monopoly power was consciously acquired, we have no reason to reach the further position of the District Court that once monopoly power is shown to exist, the burden is on the defendants to show that their dominance is due to skill, acumen, and the like.

8. Although the Government originally urged that the decree was inadequate as to divestiture in that it permitted Grinnell to distribute the stock of the other companies to Grinnell's shareholders, it has abandoned that point in this Court.

9. Specifically, the areas of disagreement are: (1) Defendants urge that barring them from offering five-year contracts would put them at a competitive disadvantage vis-a-vis nondefendant firms; the Government responds that since they violated
the law, they may properly be subjected to restrictions not borne by others. See United States v. Bausch & Lomb Optical Co., 321 U.S. 707, 723—724, 64 S.Ct. 805, 813—814, 88 L.Ed. 1024. (2) Some customers of defendants may wish to have long-term contracts; the Government responds that this may be explored on remand. (3) There is some dispute as to whether, if the central station company cannot retain title to the equipment it installs, the insurance companies will accredit the system. This, too, is a proper subject for inquiry on remand.

Prior to trial, the defendants agreed that this would be an appropriate provision in a decree were the Government to prevail in all its claims of antitrust violations. Although defendants now maintain that this pretrial discussion was ‘settlement talk,’ that earlier concession is a relevant factor that the District Judge can properly take into account on remand.

This provision, too, gained pretrial acceptance. See n. 10, supra.

28 U.S.C. s 144 (1964 ed.) provides in relevant part:

‘Whenever a party to any proceeding in a district court makes and files a timely and sufficient affidavit that the judge before whom the matter is pending has a personal bias or prejudice either against him or in favor of any adverse party, such judge shall proceed no further therein, but another judge shall be assigned to hear such proceeding.’

Judge Wyzanski referred the question of his disqualification to Chief Judge Woodbury of the Court of Appeals for the First Circuit who after hearing oral argument held that no case of bias and prejudice had been made out under s 144.

The defendants constitute 87% of the market as defined. One of the defendants alone, ADT, has 73%.


There is a danger that this Court's opinion, ante, at 1706, will be read as somewhat overstating the case. There is neither finding nor record to support the implication that rates are to any substantial extent fixed on a nationwide basis, or that there are nationwide contracts with multi-state businesses in any significant degree, or that insurers inspect or certify central stations on a nationwide basis.

None of the stations operated by defendant Automatic Fire Alarm Company offers burglary protection, just as none of Holmes' stations protects against the risk of fire.

The example used by the court in its findings is illuminating and disturbing. In explanation of its narrow market definition, the court says that the difference between the accredited central station protective services and all others ‘could
be compared’ to the difference between a compact six-cylinder car and a chauffeur-driven sedan. It is probably true that the degree of direct competition between luxury automobiles and compacts is slight, but it is by no means as clear-cut as the trial court seems to suggest. The question would require careful analysis in light of the total facts and issues. For example, if the antitrust problem at hand involved an acquisition of the business of a manufacturer of compacts by a maker of luxury cars, it is by no means inconceivable that sufficient competitive overlap would be found to place both products in the ‘relevant market.’
2020-2 Trade Cases P 81,393

976 F.3d 327
United States Court of Appeals, Third Circuit.

FEDERAL TRADE COMMISSION, Appellant
v.
ABBVIE INC; Abbott Laboratories; Unimed Pharmaceuticals, LLC; Besins Healthcare, Inc.; *Teva Pharmaceuticals USA, Inc
(*Dismissed Pursuant to Court's 3/12/19 Order.)
Federal Trade Commission,
v.
AbbVie Inc.; Abbott Laboratories; Unimed Pharmaceuticals, LLC; Besins Healthcare, Inc.; *Teva Pharmaceuticals USA, Inc.
AbbVie Inc.; Abbott Laboratories; Unimed Pharmaceuticals, LLC, Appellants
(*Dismissed Pursuant to Court's 3/12/19 Order.)
Federal Trade Commission,
v.
AbbVie Inc.; Abbott Laboratories; Unimed Pharmaceuticals, LLC; Besins Healthcare, Inc.; *Teva Pharmaceuticals USA, Inc.
Besins Healthcare, Inc., Appellant
(*Dismissed Pursuant to Court's 3/12/19 Order.)

No. 18-2621, No. 18-2748, No. 18-2758
Argued on January 15, 2020
Filed September 30, 2020

Synopsis

Background: Federal Trade Commission (FTC) brought action against pharmaceutical companies, alleging willful maintenance of a monopoly through a course of anticompetitive conduct including sham patent litigation and restraint of trade by entering into an anticompetitive reverse-payment agreement. The United States District Court for the Eastern District of Pennsylvania, Harvey Bartle, Senior District Judge, granted motions to partially dismiss counts, 107 F.Supp.3d 428, denied FTC's motion for reconsideration, 2015 WL 5025438, granted FTC's motion for partial summary judgment, 2017 WL 4098688, and, after a bench trial, found for FTC but declined to enter an injunction, 329 F.Supp.3d 98. Parties cross appealed.

Holdings: The Court of Appeals, Hardiman, Circuit Judge, held that:

the Court of Appeals for the Federal Circuit did not have exclusive jurisdiction of appeal;

FTC plausibly alleged an anticompetitive reverse payment;

companies' lawsuit against one alleged patent infringer did not meet sham-litigation exception to Noerr-Pennington immunity;
companies' lawsuit against another alleged infringer met sham-litigation exception to *Noerr-Pennington* immunity; companies had monopoly power in relevant market; district courts lack the power to order disgorgement under injunction provision of the FTC Act; and FTC was not entitled to an injunction.

Affirmed in part, reversed in part, and remanded.

**Procedural Posture(s):** On Appeal; Motion to Dismiss; Motion for Summary Judgment; Motion for Preliminary Injunction.

*336* On Appeal from the United States District Court for the Eastern District of Pennsylvania (D.C. No. 2-14-cv-05151), District Judge: Honorable Harvey Bartle, III

**Attorneys and Law Firms**

**Mark S. Hegedus**, Federal Trade Commission, MS-582, 600 Pennsylvania Avenue, N.W., Washington, DC 20580, **Matthew M. Hoffman [Argued]**, Joel R. Marcus, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, DC 20580, Attorneys for Federal Trade Commission

**Brittany Amadi, Catherine M.A. Carroll, Leon B. Greenfield, Seth P. Waxman [Argued]**, WilmerHale, 1875 Pennsylvania Avenue, N.W., DC 20006, **Elaine J. Goldenberg**, Munger Tolles & Olson, 1155 F Street, N.W., 7th Floor, Washington, DC 20004, **Adam R. Lawton, Stuart N. Senator, Jeffrey I. Weinberger**, Munger Tolles & Olson, 350 South Grand Avenue, 50th Floor, Los Angeles, CA 90071, **William F. Lee**, WilmerHale, 60 State Street, Boston, MA 02109, **Paul H. Saint-Antoine, John S. Yi**, Faegre Drinker Biddle & Reath, One Logan Square, Suite 2000, Philadelphia, PA 19103, Attorneys for AbbVie Inc, Abbott Laboratories, and Unimed Pharmaceuticals LLC


**William A. Rivera**, AARP Foundation Litigation, B4-230, 601 E Street, N.W., Washington, DC 20049, Attorney for Amici AARP and AARP Foundation

**Ilana H. Eisenstein**, DLA Piper, 1650 Market Street, One Liberty Place, Suite 5000, Philadelphia, PA 19103, Attorney for Amicus Chamber of Commerce of the United States of America

**Bradford J. Badke**, Sidley Austin, 787 Seventh Avenue, New York, NY 10019, Attorney for Amicus Amgen Inc

**Andrew D. Lazerow**, Covington & Burling, 850 10th Street, N.W., One City Center, Washington, DC 20001, Attorney for Amicus Pharmaceutical Research and Manufacturers of America

**Richard M. Brunell**, Hilliard & Shadowen, 1135 West 6th Street, Suite 125, Austin, TX 78703, Attorney for Amici American Antitrust Institute, Public Citizen Inc, and Public Knowledge

OPINION OF THE COURT

HARDIMAN, Circuit Judge.

*337 TABLE OF CONTENTS

I. FACTUAL BACKGROUND...338
   A. FDA Approval under the Hatch-Waxman Act...338
   B. Patent disputes under the Hatch-Waxman Act...339
   C. Therapeutic equivalence ratings...340
   D. Hypogonadism and testosterone replacement therapies...340
   E. AndroGel...341
   F. The '894 patent’s prosecution history...341
   G. AndroGel's competitors...342
   H. The lawsuits against Teva and Perrigo...342
   I. The settlements with Perrigo and Teva...344
   J. Teva and Perrigo's generic versions of AndroGel...345

II. PROCEDURAL HISTORY...345

III. JURISDICTION...346

IV. LIABILITY...351
   A. The District Court erred by rejecting the reverse-payment theory...351
   B. The District Court erred in concluding AbbVie and Besins's litigation against Teva was a sham; it did not err in concluding the Perrigo litigation was a sham...359
   C. The District Court did not err in concluding AbbVie and Besins had monopoly power in the relevant market...371

V. REMEDIES...374
   A. The District Court erred in ordering disgorgement...374
   B. The District Court did not abuse its discretion in denying injunctive relief...379
I. FACTUAL BACKGROUND

A. FDA Approval under the Hatch-Waxman Act

The Food, Drug, and Cosmetic Act (the FDC Act), 21 U.S.C. § 301 et seq., empowers the Food and Drug Administration (FDA) to regulate the manufacture and sale of drugs in the United States. Before a pharmaceutical company can market a drug, it must obtain FDA approval. Id. § 355(a). Under the FDC Act, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act), 21 U.S.C. § 355 and 35 U.S.C. § 271, a company can apply for FDA approval in one of three ways:

1. Section 505(b)(1) New Drug Application (NDA). This is a “full-length” application. FTC v. AbbVie Inc., 329 F. Supp. 3d 98, 107 (E.D. Pa. 2018). The “gauntlet of procedures” associated with it is “long, comprehensive, and costly.” In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class, 868 F.3d 132, 143 (3d Cir. 2017) (citation omitted). It includes “full reports of investigations” into whether the drug is safe and effective, a “full list of ... [the drug's] components,” “full detail of the methods used in ... the manufacture, processing, and packing” of the drug, samples of the drug, and specimens of the labeling the company proposes to use. 21 U.S.C. § 355(b)(1). A company must also list any relevant patents. See *339 Wellbutrin, 868 F.3d at 144 (citation omitted). We refer to drugs approved through this process as “brand-name” drugs.

2. Section 505(j) Abbreviated New Drug Application (ANDA). This streamlined application is appropriate for a company seeking to market a generic version of a brand-name drug. The company need not produce its own safety and efficacy data. 21 U.S.C. § 355(j)(2)(A)(vi). But it must show that the generic drug is “the same” as the brand-name drug in certain relevant respects. Id. § 355(j)(2)(A). It also must “assure the FDA that its proposed generic drug will not infringe the brand's patents.” Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 566 U.S. 399, 406, 132 S.Ct. 1670, 182 L.Ed.2d 678 (2012). It can do so by certifying that the manufacture, use, or sale of the generic will not infringe patents relating to the...
brand-name drug, or that those patents are invalid. 21 U.S.C. § 355 (j)(2)(A)(vii)(IV). This certification is known as a “paragraph IV notice.” AbbVie, 329 F. Supp. 3d at 108.

The first company to seek FDA approval in this way enjoys “a period of 180 days of exclusivity,” during which “no other generic can compete with the brand-name drug.” FTC v. Actavis, Inc., 570 U.S. 136, 143–44, 133 S.Ct. 2223, 186 L.Ed.2d 343 (2013) (citing 21 U.S.C. § 355 (j)(5)(B)(iv)). “[T]his 180-day period ... can prove valuable, possibly worth several hundred million dollars.” Id. at 144, 133 S.Ct. 2223 (internal quotation marks and citation omitted). One exception is that during the 180-day exclusivity period, the brand-name company can produce a generic version of its own drug or license a third party to do so. See Mylan Pharm., Inc. v. FDA, 454 F.3d 270, 276–77 (4th Cir. 2006). These “authorized generics” can decrease the value an applicant receives from the 180-day exclusivity period to the extent they share the generic drug market and depress prices. See id. at 273.

3. Section 505(b)(2) New Drug Application (hybrid NDA). This application is appropriate for a company seeking to modify another company's brand-name drug. For example, a company might seek FDA approval of “a new indication or new dosage form.” 21 C.F.R. § 314.54(a). This application is like an ANDA because the company need not produce all safety and efficacy data about the drug and because it must assure the FDA that its generic drug will not infringe the brand's patents. See 21 U.S.C. § 355(b)(2)(A)(iv). But it differs from an ANDA because the company must produce some data, including whatever “information [is] needed to support the modification(s).” 21 C.F.R. § 314.54(a).

The latter two pathways “speed the introduction of low-cost generic drugs to market” and promote competition in the pharmaceutical industry. Actavis, 570 U.S. at 142, 133 S.Ct. 2223 (internal citation omitted).

B. Patent disputes under the Hatch-Waxman Act

The Hatch-Waxman Act also has provisions that encourage the quick resolution of patent disputes. See Wellbutrin, 868 F.3d at 144. A paragraph IV notice “automatically counts as patent infringement.” Id. (quoting Actavis, 570 U.S. at 143, 133 S.Ct. 2223 (citing *340 35 U.S.C. § 271(e)(2)(A))). After receiving this notice, a patentee has 45 days to decide whether to sue. 21 U.S.C. § 355(j)(5)(B)(i).ii.

To help a patentee make that decision, the company seeking approval of a generic drug often allows the patentee's outside counsel to review the company's application in secret. If the patentee sues within the time limit, the FDA cannot approve the company's application for a generic drug until one of three things happens: (1) a court holds that the patent is invalid or has not been infringed; (2) the patent expires; or (3) 30 months elapse, as measured from the date the patentee received the paragraph IV notice. 21 U.S.C. § 355(j)(5)(B)(ii).

The automatic, 30-month stay creates tension with the Hatch-Waxman Act's procompetitive goals. Simply by suing, a patentee can delay the introduction of low-cost generic drugs to market and impede competition in the pharmaceutical industry. Cf. Actavis, 570 U.S. at 142, 133 S.Ct. 2223.

C. Therapeutic equivalence ratings

After the FDA approves a company's generic drug, the company can seek a therapeutic equivalence (TE) rating. “Products that are determined to be therapeutically equivalent [to the brand] are assigned an ‘A’ or ‘AB’ rating. Generic products for which therapeutic equivalence cannot be determined are assigned a ‘B’ or ‘BX’ rating.” AbbVie, 329 F. Supp. 3d at 107. Generic drug companies usually prefer A or AB ratings because every state's law “either permit[s] or require[s] pharmacists to dispense a therapeutically equivalent, lower-cost generic drug in place of a brand drug.” Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd., 838 F.3d 421, 428 (3d Cir. 2016) (internal quotation marks and citations omitted).
D. Hypogonadism and testosterone replacement therapies

Hypogonadism is a clinical syndrome resulting from low testosterone in the human body. See AbbVie, 329 F. Supp. 3d at 108. It affects an estimated 2-6 percent of the adult male population in the United States and causes “decreases in energy and libido, erectile dysfunction, and changes in body composition.” Id.

Doctors treat hypogonadism with testosterone replacement therapies (TRTs). TRTs include injectables, topical/transdermals (TTRTs), and other therapies. Companies first marketed injectables in the 1950s. Because generic injectables have been available for decades, they are the least expensive. They involve dissolving testosterone in a liquid and injecting it into the patient's body every one to three weeks. Some patients administer injections to themselves at home, while others receive injections at their doctor's office or a specialized testosterone clinic. By contrast, TTRTs first appeared in the 1990s and are more expensive. They deliver testosterone to the patient's body through a patch or gel applied to the patient's skin. Gels are applied daily.

TRTs have different benefits and drawbacks. Some patients dislike injectables because the injection is painful, or because the “peak in testosterone level” after the injection causes “swings in mood, libido, and energy.” Id. at 109. Many of these patients prefer TTRTs because they release testosterone steadily. Other patients dislike TTRT gels. Common complaints include skin irritation and the inconvenience of having to apply the gel daily. And patients sometimes transfer the testosterone gel to others inadvertently through skin-to-skin contact. Finally, some patients dislike TTRT patches, which can irritate the skin and are visible to other people, depending on where the patch is applied.

*341 E. AndroGel

In the 1990s, Laboratoires Besins International S.A.S. (LBI)—a corporate affiliate of Besins's parent company—developed the TTRT gel that became AndroGel. In 1995, LBI licensed to Unimed certain intellectual property relating to the gel, and Unimed assumed responsibility for marketing the gel in the United States. In exchange, Unimed agreed to pay LBI a royalty on the gel's net sales. Unimed secured FDA approval for the gel in 2000. That same year, Unimed and Besins filed a joint U.S. patent application, and, in 2003, U.S. Patent No. 6,503,894 (the '894 patent) issued.

Today, Besins and AbbVie co-own the '894 patent. AbbVie acquired Unimed's interest in the patent as follows: in 1999, Unimed was acquired by Solvay; in 2010, Solvay was acquired by Abbott; in 2013, Abbott separated into two companies—Abbott and AbbVie—with AbbVie assuming all of Abbott's propriety pharmaceutical business, including its interest in AndroGel.

Solvay brought AndroGel to market in 2000. At the time, AndroGel was available only in a sachet form at 1% strength. From 2004-2013, Solvay and its successors marketed AndroGel in a metered-dose pump form. And in 2011, Abbott started marketing AndroGel at 1.62% strength. Sales of AndroGel 1.62% grew more slowly than anticipated, but by June 2012, they comprised most of AndroGel's total sales.

AndroGel has been a huge commercial success. Its annual net sales sometimes surpassed a billion dollars and remained strong even after generic versions of AndroGel entered the market in 2015. From 2009-2015, it generated a high profit margin of about 65 percent.

F. The '894 patent’s prosecution history

TTRT gels use “penetration enhancers” to accelerate the delivery of testosterone through a patient's skin. AndroGel's penetration enhancer is isopropyl myristate.
Unimed and Besins’s joint patent application was U.S. Patent Application Serial No. 09/651,777. As originally drafted, claim 1 of the patent application claimed *all* penetration enhancers:

A pharmaceutical composition useful for the percutaneous delivery of an active pharmaceutical ingredient, comprising:

(a) a C1-C4 alcohol;

(b) *a penetration enhancer*;

(c) the active pharmaceutical ingredient; and

(d) water.

App. 909 (emphasis added). The penetration enhancers then in existence numbered in the tens of millions.

In June 2001, the patent examiner rejected this claim as obvious over two prior art references—Mak in view of Allen. Mak disclosed the penetration enhancer oleic acid used in a transdermal *testosterone* gel. Allen disclosed isopropyl myristate, isopropyl palmitate, and three other penetration enhancers used in a *nitroglycerin* cream. The examiner explained that “since all composition components herein are known to be useful for the percutaneous delivery of pharmaceuticals, it is considered prima facie obvious to combine them into a single composition useful for the very same purpose.” App. 1014–16.

In October 2001, Unimed and Besins amended the patent application’s claim 1 to recite at least one of 24 penetration enhancers, including isopropyl myristate and isostearic acid. Isopropyl palmitate was not among the 24. Unimed and Besins also added several new claims. Claim 47 recited “a penetration enhancer selected from the group consisting of isopropyl myristate and lauryl alcohol.” App. 1022. And claims 61 and 62 recited only isopropyl myristate as a penetration enhancer.

Unimed and Besins sought “reconsideration and withdrawal of the [obviousness] rejections and allowance of the[se] claims.” App. 1039. In support, they cited *AndroGel*’s commercial success. See id.; see generally *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966) (holding commercial success is a “secondary consideration” suggesting nonobviousness). They also argued “[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.” App. 1030–31 (citations omitted). For three reasons, they said, the prior art did not suggest combining Mak and Allen. First, Mak “[taught] away from using the presently claimed penetration enhancers by focusing on the superiority of oleic acid.” App. 1032. Second, the claimed penetration enhancers had an “unexpected and unique pharmacokinetic and pharmacodynamic profile.” *Id.* And third, “the prior art recognize[d] the chemical and physiologic/functional differences of penetration enhancers, including the differences between oleic acid and the claimed enhancers, such as isopropyl myristate.” App. 1037–38.

Attorneys for Unimed and Besins then met with the examiner for an interview. The examiner opined that “claims 61-62 are ... allowable over the prior art.” App. 1084. She also noted that the attorneys “argued claim 47 is novel [and] nonobvious over the prior art because the prior art does not teach the composition with particular concentrations [of isopropyl myristate and lauryl alcohol].” *Id.*

In December 2001 and February 2002, Unimed and Besins twice more amended the patent application. They cancelled claims 1 and 62, amended claim 47 to cover only a composition comprising isopropyl myristate, and modified the concentration ranges for isopropyl myristate in claim 61. With each amendment, they sought “reconsideration and withdrawal of the [obviousness] rejections and allowance of the[se] claims.” App. 1095, 1129.
The examiner issued a notice of allowability. She wrote that “[t]he claimed pharmaceutical composition consisting essentially of the particular ingredients herein in the specific amounts, is not seen to be taught or fairly suggested by the prior art.” App. 1152. She clarified that she considered the amendments “all together,” and they sufficed to “remove the prior art rejection ... over [Mak in view of Allen].” *Id.*

In January 2003, the ’894 patent issued. It expired on August 30, 2020.

**G. AndroGel's competitors**

When Solvay brought AndroGel to market in 2000, its only competitors were injectables and two TTRT patches (*i.e.*, Testoderm and Androderm). Since then, companies have marketed four other TTRT gels (*i.e.*, Testim, Axiron, Fortesta, and Vogelxo). Companies have also developed other TRTs, including Striant (a buccal tablet applied twice daily to a patient's gums), Testopel (a pellet surgically inserted into a patient's body every three to six months), and Natesto (a nasal spray administered three times a day).

**H. The lawsuits against Teva and Perrigo**

In December 2008, Perrigo filed two ANDAs for a generic 1% testosterone gel in sachet and pump forms, and in June 2009 it served paragraph IV notices on *343* Unimed and Besins. It asserted that because its gel used the penetration enhancer isostearic acid instead of isopropyl myristate, the gel would not literally infringe the ’894 patent. It also argued the gel would not infringe the patent under the doctrine of equivalents, which provides that “[t]he scope of a patent ... embraces all equivalents to the claims described.” *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. (“Festo VIII”),* 535 U.S. 722, 732, 122 S.Ct. 1831, 152 L.Ed.2d 944 (2002). Perrigo explained the ’894 patent’s prosecution history would estop Unimed and Besins from claiming equivalency between isostearic acid and isopropyl myristate, because they originally claimed isostearic acid before excluding it in response to a rejection. This limitation on the doctrine of equivalents is known as prosecution history estoppel. *Id.* at 733–34, 122 S.Ct. 1831.

Solvay, Unimed, and Besins retained outside counsel to review Perrigo's ANDAs. In July 2009, Solvay and Unimed issued a press release stating that they had carefully evaluated the ANDAs and decided not to sue Perrigo, in part because Perrigo's gel “contains a different formulation than the formulation protected by the AndroGel patent.” *AbbVie*, 329 F. Supp. 3d at 111. Besins also decided not to sue.

That same year, the FDA learned that patients were accidentally transferring TTRT gels to children through skin-to-skin contact. AndroGel's new owner Abbott petitioned the FDA to require Perrigo to resubmit its 2009 ANDAs as hybrid NDAs. See 21 C.F.R. § 10.30 (FDA citizen petition form). That would require Perrigo to investigate whether isostearic acid poses a higher risk of accidental transfer than isopropyl myristate. Abbott also asked the FDA to require Perrigo to serve new paragraph IV notices on Abbott and Besins, thereby reopening the 45-day window for them to decide whether to sue. The FDA granted Abbott's petition in relevant part.

In January 2011, Teva filed a hybrid NDA for a generic 1% testosterone gel in sachet and pump forms, and in March 2011 it served paragraph IV notices on Abbott, Solvay, Unimed, and Besins. Teva asserted its gel would not literally infringe the ’894 patent because it used isopropyl palmitate instead of isopropyl myristate. It also explained that the ’894 patent’s prosecution history would estop Abbott and Besins from claiming infringement on the ground that isopropyl palmitate is equivalent to isopropyl myristate. Abbott and Besins retained outside counsel to review Teva's hybrid NDA.

On April 29, 2011, Abbott, Unimed, and Besins sued Teva for patent infringement in the United States District Court for the District of Delaware. They argued that isopropyl myristate and isopropyl palmitate were equivalent. The lawsuit triggered
the Hatch-Waxman Act's automatic, 30-month stay on FDA approval for Teva's gel. Teva responded that prosecution history estoppel applied because Unimed and Besins's October 2001 amendment—which narrowed the application's claim 1 from all penetration enhancers to a list of 24—surrendered isopropyl palmitate. Abbott, Unimed, and Besins disagreed. They cited an exception to prosecution history estoppel—known as “tangentiality”—that applies if “the rationale underlying the amendment [bore] no more than a tangential relation to the equivalent in question.” Festo VIII, 535 U.S. at 740, 122 S.Ct. 1831. Abbott, Unimed, and Besins argued the October 2001 amendment sought to overcome Mak's use of oleic acid and was thus tangential to isopropyl palmitate, which Allen disclosed. The Court set trial for May 2012.

In July 2011, Perrigo filed a hybrid NDA for generic 1% testosterone gel, and in September 2001, it served new paragraph IV notices on Abbott, Unimed, and Besins. It again asserted its gel would not infringe the '894 patent. And it added that “a lawsuit asserting the '894 patent against Perrigo would be objectively baseless and a sham, brought in bad faith for the improper purpose of, inter alia, delaying Perrigo's NDA approval.” AbbVie, 329 F. Supp. 3d at 114. A bad faith motive for suing would be “particularly apparent,” Perrigo said, in light of Solvay's July 2009 press release. Id. Abbott, Unimed, and Besins retained outside counsel to review Perrigo's hybrid NDA.

In August 2011, Abbott petitioned the FDA not to grant therapeutic equivalence ratings to hybrid NDAs referencing AndroGel. Alternatively, it asked the FDA to assign such products BX ratings.


Four in-house patent attorneys in AbbVie's intellectual property group and AbbVie's general counsel decided to sue Teva and Perrigo. Those attorneys had “extensive experience in patent law and with AbbVie.” See id. at 113. However, “[n]o business persons at AbbVie were involved in the decision to sue.” Id. As for Besins, its in-house counsel Thomas MacAllister decided to sue. MacAllister is an experienced intellectual property attorney and a former patent examiner.

I. The settlements with Perrigo and Teva

In December 2011, Abbott and Perrigo settled. They agreed to dismiss all claims and counterclaims with prejudice; Abbott agreed to pay Perrigo $2 million as reasonable litigation expenses; and Abbott agreed to license Perrigo to market its generic 1% testosterone gel on either January 1, 2015 or when another generic version came to market, whichever was sooner. (The last provision is known as an acceleration clause). Perrigo unsuccessfully pushed for an earlier market entry date in settlement negotiations. Its assistant general counsel Andrew Solomon later said he predicted the acceleration clause would provide Perrigo with an earlier entry date, because he saw “a very good probability Teva could prevail” against Abbott and Besins at trial in the other lawsuit. AbbVie, 329 F. Supp. 3d at 115. He also said he advised Perrigo that it had a 75 percent chance of success, had the litigation proceeded to trial. He explained this figure meant Perrigo felt “very, very strongly about [its] chances for success, recognizing that there is [an] inherent uncertainty ... any time a case gets in front of an arbiter.” App. 4071.

Abbott and Teva also settled in December 2011, soon after the court set a trial date. Abbott agreed to license Teva to market its generic 1% testosterone gel on December 27, 2014—almost six years before the '894 patent expired. Teva pushed unsuccessfully for an earlier market–entry date in settlement negotiations.

On the same day Abbott and Teva settled the infringement suit, they also made a deal involving a popular brand-name cholesterol drug named TriCor. A previous settlement between Abbott and Teva had set Teva's entry in the TriCor market for July 2012. And because Teva was the first generic challenger to TriCor, Teva was entitled to 180 days of marketing exclusivity. Teva was struggling to capitalize on the exclusivity period, though, because it could not secure FDA approval. In the December 2011 deal, Abbott agreed to grant Teva a license to sell a generic version of TriCor, which Abbott would supply to Teva at
Teva's option, for a four-year term beginning in November 2012. This supply agreement provided for Teva to pay Abbott the costs of production, an additional percentage of that cost, and a royalty.

According to the FTC, the December 2011 settlement agreement and TriCor deal were an illegal reverse payment. A reverse payment occurs when a patentee, as plaintiff, pays an alleged infringer, as defendant, to end a lawsuit. See Wellbutrin, 868 F.3d at 142 n.3 (citing Actavis, 570 U.S. at 140–41, 133 S.Ct. 2223). Such agreements can be anticompetitive if they allow a brand-name company to split its monopoly profits with a generic company in exchange for the generic agreeing to delay market entry. As applied here, the FTC alleges Abbott calculated that it would sacrifice about $100 million in TriCor sales, but that was a small fraction of the billions of dollars in AndroGel revenue it protected by deferring competition in the TTRT market for three years. Deferring competition also gave Abbott time to shift sales to AndroGel 1.62%, for which there were no generic competitors. As for Teva, it “concluded that it would be better off by sharing in AbbVie’s monopoly profits from the sale of AndroGel than by competing.” App. 4418.

Teva's settlement triggered the acceleration clause in Perrigo's settlement agreement, so Perrigo's licensed entry date became December 27, 2014.

J. Teva and Perrigo's generic versions of AndroGel

In February 2012, the FDA approved Teva's hybrid NDA for the sachet form of its generic 1% testosterone gel. Teva withdrew the pump form from its application after the FDA identified a safety concern with the packaging. But the FDA allowed Teva to resubmit the pump form as a postapproval amendment.

In January 2013, the FDA approved Perrigo's hybrid NDA for generic 1% testosterone gel. It then considered the gel's therapeutic equivalence rating. Perrigo sent the FDA three letters to expedite the FDA's consideration. AbbVie petitioned the FDA to issue Perrigo's product a BX rating.

In March 2014, Perrigo sued the FDA, accusing it of unreasonable delay. The FDA responded that “Perrigo has itself obviated the need for a prompt decision by reaching an agreement with [Abbott] not to market until December 2014.” AbbVie, 329 F. Supp. 3d at 116. It said it expected to rate Perrigo's gel “by July 31, 2014—some five months before Perrigo's planned product launch.” Id. On July 23, 2014, the FDA issued the gel an AB rating, and Perrigo dismissed its lawsuit against the FDA. See id. at 116, 116 n.9. Perrigo brought its gel to market on December 27, 2014, its licensed entry date.

Also on July 23, 2014, the FDA issued Teva's gel a BX rating. Teva never marketed the product.

II. PROCEDURAL HISTORY

The FTC sued AbbVie, Abbott, Unimed, Besins, and Teva under Section 13(b) of the FTC Act in the United States District Court for the Eastern District of Pennsylvania. 15 U.S.C. § 53(b). We refer to AbbVie, Abbott, Unimed, and Solvay as “AbbVie” for simplicity.

In Count I of the complaint, the FTC alleged AbbVie and Besins willfully maintained a monopoly through a course of anticompetitive conduct, including sham patent litigation against Teva and Perrigo. In Count II, the FTC alleged AbbVie restrained trade by entering into an anticompetitive reverse-payment agreement with Teva. The FTC requested that the Court enjoin AbbVie and Besins “from engaging in similar and related conduct in the future,” and that the Court “grant such other equitable [monetary] relief as [it] finds necessary, including restitution or disgorgement.” App. 4454.
AbbVie and Besins moved to dismiss “Count I to the extent it [was] premised on the” alleged reverse payments, under Rule 12(b)(6) of the Federal Rules of Civil Procedure. Dkt. 2:14-cv-05151, ECF No. 38 at 1. AbbVie also moved to dismiss Count II in its entirety, as it was based only on the reverse-payment theory. The District Court granted both motions.

The FTC moved for reconsideration after our decision in *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388 (3d Cir. 2015). But the District Court distinguished *King Drug* and denied the motion.

The FTC then moved for partial summary judgment on the sham-litigation theory supporting Count I. AbbVie and Besins sought summary judgment as well.

The sham-litigation theory required the FTC to prove (1) that AbbVie had monopoly power in the relevant market and (2) that AbbVie willfully acquired or maintained that power through sham litigation. See *Mylan*, 838 F.3d at 433. Sham litigation has two prongs. “First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits.” *Prof'l Real Estate Invs., Inc. v. Columbia Pictures Indus., Inc.* (“PRE”), 508 U.S. 49, 60, 113 S.Ct. 1920, 123 L.Ed.2d 611 (1993). And second, the lawsuit must conceal an attempt to interfere directly with the business relationships of a competitor through the use of the governmental process as an anticompetitive weapon. See id. at 60–61, 113 S.Ct. 1920. The FTC sought summary judgment only on the objective baselessness prong.

The District Court granted the FTC partial summary judgment and denied AbbVie and Besins's motions. The Court held a sixteen-day bench trial on sham litigation's subjective prong and monopoly power, and it found for the FTC on both. See *AbbVie*, 329 F. Supp. 3d at 146. The Court awarded “equitable monetary relief in favor of the FTC and against [AbbVie and Besins] in the amount of $448 million, which represent[ed] disgorgement of [their] ill-gotten profits.” *Id.* It declined to enter an injunction. The FTC, AbbVie, and Besins now appeal.

The FTC argues the District Court erred in dismissing its claims to the extent they relied on a reverse-payment theory; abused its discretion in calculating the amount of disgorgement; and abused its discretion in denying the FTC injunctive relief.

AbbVie and Besins argue the District Court erred in concluding the infringement suits against Teva and Perrigo met either prong of the sham-litigation standard, and that AbbVie had monopoly power in the relevant market. They also argue the Court erred in ordering disgorgement because Section 13(b) of the FTC Act does not authorize disgorgement, the disgorgement is a penalty rather than an equitable remedy, and the FTC failed to prove statutory preconditions for injunctive relief. Finally, they argue the Court abused its discretion in calculating the amount of disgorgement.

III. JURISDICTION

The District Court had jurisdiction under 28 U.S.C. § 1331. The parties to this appeal agree that we have jurisdiction. Yet we have a “continuing obligation to ... raise the issue of subject matter jurisdiction if it is in question.” *Bracken v. Matgouranis*, 296 F.3d 160, 162 (3d Cir. 2002) (citations omitted).

*347* Our jurisdiction under 28 U.S.C. § 1291 extends to “appeals from all final decisions of the district courts of the United States.” But there is an exception. The United States Court of Appeals for the Federal Circuit has “exclusive jurisdiction ... of an appeal from a final decision of a district court of the United States ... in any civil action arising under ... any Act of Congress relating to patents.” 28 U.S.C. § 1295(a)(1) (emphasis added).
A civil action “aris[es] under” federal patent law if “a well-pleaded complaint” shows either that “federal patent law creates the cause of action,” or “the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law, in that patent law is a necessary element of one of the well-pleaded claims.” Christianson v. Colt Indus. Operating Corp., 486 U.S. 800, 809, 108 S.Ct. 2166, 100 L.Ed.2d 811 (1988) (emphasis added). In this appeal, the former basis for the Federal Circuit's jurisdiction does not apply because “[f]ederal ... antitrust law, not federal patent law, creates [the FTC's] claims.” In re Lipitor Antitrust Litig., 855 F.3d 126, 145 (3d Cir. 2017) (emphasis omitted). So “[t]his case ... turns on the [latter basis]” for the Federal Circuit's exclusive jurisdiction. Id.

The latter basis applies only if two requirements are met. First, federal patent law must be a “necessary” element of one of the plaintiff's well-pleaded claims. Here, the word “necessary” takes its strict, logical meaning: “a claim supported by alternative theories in the complaint may not form the basis for [the Federal Circuit's exclusive jurisdiction] unless patent law is essential to each of those theories.” Christianson, 486 U.S. at 810, 108 S.Ct. 2166 (emphasis added). And the patent-law issues must be “substantial.” Id. at 809, 108 S.Ct. 2166.

The Supreme Court has yet to interpret the substantiality requirement in a case involving 28 U.S.C. § 1295(a)(1) in its current form. But it has addressed the requirement in cases involving 28 U.S.C. § 1338(a), which is analogous because it gives district courts exclusive jurisdiction over “any civil action arising under any Act of Congress relating to patents.” (emphasis added). In Gunn v. Minton, 568 U.S. 251, 133 S.Ct. 1059, 185 L.Ed.2d 72 (2013), the Court held a state legal malpractice claim arising out of a patent infringement proceeding did not present a “substantial” federal issue vesting federal district courts with exclusive jurisdiction. Id. at 261, 133 S.Ct. 1059. The Court first clarified that whether a question is “substantial” turns not on the “importance of the issue to the plaintiff's case and to the parties,” but instead on “the importance of the issue to the federal system as a whole.” Id. at 260, 133 S.Ct. 1059. Applying that standard, it emphasized that because the legal malpractice claim was “backward-looking” and the issue it raised was “hypothetical,” the state court could not change the patent's invalidity as determined by the prior federal patent litigation. Id. at 261, 133 S.Ct. 1059. Nor could the state court undermine the uniformity of federal patent law going forward, because federal courts “are of course not bound by state court ... patent rulings” and “state courts can be expected to hew closely to the pertinent federal precedents.” Id. at 261–62, 133 S.Ct. 1059 (citations omitted). Moreover, any preclusive effect the state court's ruling might have “would be limited to the parties and patents that had been before the state court.” Id. at 263, 133 S.Ct. 1059. Finally, the mere possibility that the state court might misunderstand patent law and incorrectly resolve a state claim was not “enough to trigger the federal courts’ exclusive patent jurisdiction.” Id.

This appeal meets neither of the requirements for the latter basis of the Federal Circuit's exclusive jurisdiction. Thus, the Federal Circuit does not have exclusive jurisdiction here. First, federal patent law is not a “necessary” element of one of the FTC's well-pleaded claims. In its complaint, the FTC “challenges a course of anticompetitive conduct,” which the complaint defines to include AbbVie and Besins’s “sham patent infringement litigation” and “[AbbVie's] ... illegal [reverse-payment] agreement.” App. 4416. The complaint then asserts two counts. Count II (Restraint of Trade) claims AbbVie violated federal antitrust law by entering into an anticompetitive reverse-payment agreement with Teva. App. 4453–54. We have held that “reverse-payment antitrust claims do not present a question of patent law.” Lipitor, 855 F.3d at 146 (citing Actavis, 570 U.S. at 158, 133 S.Ct. 2223 (“[T]he size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself.”) (citation omitted)). Thus, patent law is not a necessary element of Count II.

The same reasoning applies to Count I (Monopolization). It first “reall[e]g[e] and incorporate[s] by reference” all of the complaint's allegations. App. 4453. It then asserts that AbbVie and Besins willfully maintained a monopoly “through a course of anticompetitive conduct, including filing sham patent litigation against Teva and Perrigo.” Id. By its terms, Count I challenges a “course of anticompetitive conduct,” which the complaint earlier defines to include not only sham litigation, but also the reverse-payment agreement. Because reverse-payment theories do not present a question of patent law, patent law is not a necessary element of Count I either.
Our reasoning is consistent with the Supreme Court's decision in *Christianson* and our decision in *Lipitor*. In both cases, the presence of “non-patent-law theories of liability supporting the ... plaintiffs’ monopolization claims vest[ed] jurisdiction over their appeals” in the regional circuit, “not the Federal Circuit.” *Lipitor*, 855 F.3d at 146 (citing *Christianson*, 486 U.S. at 812, 108 S.Ct. 2166).

The parties’ conduct before the District Court also supports our interpretation. AbbVie and Besins moved to dismiss “Count I to the extent it [wa]s premised on the” alleged reverse payments. Dkt. 2:14-cv-05151, ECF No. 38 at 1. The District Court granted that motion. Because Count I is premised, at least in part, on this non-patent-law theory, the Federal Circuit does not have exclusive jurisdiction over this action.

It is true that the FTC pleads in Count I that the course of conduct “includ[es]” sham patent litigation. App. 4453. And a sham-litigation theory does present patent-law questions because it requires us to review the objective reasonableness of AbbVie and Besins's patent-infringement litigation against Teva and Perrigo. See *PRE*, 508 U.S. at 60, 113 S.Ct. 1920. But that fact does not undermine our jurisdiction because the sham-litigation theory is one of two theories supporting Count I. And the other theory —the reverse-payment theory—does not present a question of patent law. See *Christianson*, 486 U.S. at 810, 108 S.Ct. 2166.

We also note that the FTC has not contended that Besins and Teva entered into an independent reverse-payment agreement. Thus, it might be argued the FTC's right to relief as against Besins necessarily depends on resolution of patent-law questions. ¹ We disagree because the FTC's complaint may be read to allege that Besins participated in AbbVie's settlement with Teva. The complaint notes “[t]he sham lawsuits did not eliminate the threat of Teva's and Perrigo's products to AbbVie Defendants and Besins's monopoly.” App. 4441. It then asserts “AbbVie ... and Besins ... turned to other ways to preserve their monopoly,” including AbbVie's settlement with Teva. App. 4442. As mentioned above, the parties’ conduct before the District Court supports our reading because both AbbVie and Besins moved to dismiss “Count I to the extent it [wa]s premised on the” alleged reverse payments.

Thus, patent law is not a “necessary” element of one of the FTC's well-pleaded claims, so the latter basis for the Federal Circuit's exclusive jurisdiction does not apply.

Second, the patent-law issues that the FTC's sham-litigation theory presents are not “substantial,” in the sense that they are important to the “federal system as a whole.” *Gunn*, 568 U.S. at 260, 133 S.Ct. 1059. So even if federal patent law were a “necessary” element of one of the FTC's well-pleaded claims, the latter basis for the Federal Circuit's exclusive jurisdiction still would not apply. Like the state legal malpractice claim in *Gunn*, the sham-litigation theory here is purely backward looking: just as the state court's adjudication of the legal malpractice claim could not change the result of the prior federal patent litigation, our adjudication of the FTC's sham-litigation theory cannot change the settlement that resulted from AbbVie and Besins's infringement suits against Teva and Perrigo. See *id.* at 261, 133 S.Ct. 1059.²

Nor would adjudicating the sham-litigation theory undermine the uniformity of federal patent law. See *id.* at 261–62, 133 S.Ct. 1059. The reasons for this are general and case specific. Generally, much like the state court's decision in *Gunn* could not bind federal courts, the parts of our decision in this appeal that interpret patent law cannot bind the Federal Circuit or district courts outside the Third Circuit. See *id.* And like the state court in *Gunn*, we must hew closely to the Federal Circuit's precedents. See *id.* If the patent-law issues we decide arise frequently, they “will soon be resolved within [the Federal Circuit], laying to rest any contrary ... precedent.” *Id.* at 262, 133 S.Ct. 1059. Otherwise, they are “unlikely to implicate substantial federal interests.” *Id.*

There are two additional, case-specific reasons that adjudicating the sham-litigation theory would not undermine the uniformity of federal patent law. First, litigation is a sham only if it is objectively baseless, meaning “no reasonable litigant could realistically...

2020-2 Trade Cases P 81,393

expect success on the merits.” PRE, 508 U.S. at 60, 113 S.Ct. 1920. Our application of this standard poses no threat to the uniformity of federal *350 patent law. Consider our choices in this appeal: AbbVie and Besins's lawsuits were or were not shams. If the former, it must be true that the patent law we apply is so clear that AbbVie and Besins were unreasonable in suing Teva or Perrigo for infringement and expecting to succeed. Such a holding would effectively adjudicate the merits of an infringement claim but at no cost to uniformity. And the latter holding would mean only that AbbVie and Besins were not unreasonable in expecting success in their infringement suits. That conclusion would not undermine uniformity because it would not adjudicate the merits of the infringement claims.

Moreover, whether AbbVie and Besins's infringement lawsuits were shams depends on whether the tangentiality exception to prosecution history estoppel applies. But the Federal Circuit has cautioned against applying analogical reasoning in determining tangentiality. See Eli Lilly & Co. v. Hospira, Inc., 933 F.3d 1320, 1332 n.5 (Fed. Cir. 2019) (“[W]e find the analogies to other cases less helpful than a direct consideration of the specific record of this case and what it shows about the reason for amendment and the relation of that reason to the asserted equivalent.”). Because the Federal Circuit limits reliance on its own precedents in determining tangentiality, it follows that our decision in this appeal will have limited effect on the uniformity of patent law. Even setting Eli Lilly aside, however, the rarity of the patent-law issues these appeals present counsels in favor of our jurisdiction: the issues are not ones whose resolution will control numerous other cases. See Gunn, 568 U.S. at 262, 133 S.Ct. 1059 (quoting Empire Healthchoice Assurance, Inc. v. McVeigh, 547 U.S. 677, 700, 126 S.Ct. 2121, 165 L.Ed.2d 131 (2006)).

Finally, here, as in Gunn, the preclusive effect of our ruling “would be limited to the parties and patents” before us. See 568 U.S. at 263, 133 S.Ct. 1059. And the mere possibility that we might misunderstand patent law is not dispositive. See id. So the patent-law issues that the FTC's sham-litigation theory presents are not “substantial.” Even if federal patent law were a “necessary” element of one of the FTC's well-pleaded claims, the latter basis for the Federal Circuit's exclusive jurisdiction still would not apply.

Before concluding, we note a prudential consideration supporting our jurisdiction: “u]nder the Federal Circuit's choice-of-law rules, it would apply Third Circuit antitrust jurisprudence ... when reviewing whether [the FTC] states[s a] plausible claim[ ] for relief under” a reverse-payment theory. Lipitor, 855 F.3d at 148 (citing Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1068 (Fed. Cir. 1998)) (the Federal Circuit “appl[ies] the law of the appropriate regional circuit to issues involving other elements of antitrust law such as relevant market, market power, damages, etc., as those issues are not unique to patent law”). The Federal Circuit would also apply our precedent when reviewing the District Court's judgment on the sham-litigation theory, except when the judgment raised issues unique to patent law. See id. Needless to say, we are as capable of applying our own law as the Federal Circuit. And it makes eminent sense for this Court to develop our own law in this area.

In summary, neither basis for the Federal Circuit's exclusive jurisdiction applies: federal patent law does not create the FTC's cause of action, and the FTC's right to relief does not necessarily depend on resolution of a substantial question of federal patent law. So this civil action does not “aris[e] under” federal patent law within the meaning of *351 28 U.S.C. § 1295(a)(1). We have jurisdiction under 28 U.S.C. § 1291.

IV. LIABILITY

Having assured ourselves of our jurisdiction, we turn to the merits of these cross-appeals. We hold the District Court erred by rejecting the reverse-payment theory and in concluding AbbVie and Besins's litigation against Teva was a sham. The Court did not err, however, in concluding the Perrigo litigation was a sham and that AbbVie and Besins had monopoly power in the relevant market.
A. The District Court erred by rejecting the reverse-payment theory.

We review the District Court's dismissal order de novo. Phillips v. Cnty. of Allegheny, 515 F.3d 224, 230 (3d Cir. 2008) (citation omitted). We must "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." Id. at 231 (internal citation and quotation marks omitted). A plaintiff relying on a reverse-payment theory must "allege facts sufficient to support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment under Actavis." In re Lipitor Antitrust Litig., 868 F.3d 231, 252 (3d Cir. 2017) (citation omitted).

1. Actavis

A reverse payment occurs when a patentee pays an alleged infringer to end a lawsuit. See Wellbutrin, 868 F.3d at 142 n.3 (citing Actavis, 570 U.S. at 140–41, 133 S.Ct. 2223). A typical reverse payment happens this way: “Company A sues Company B for patent infringement. The two companies settle under terms that require (1) Company B, the claimed infringer, not to produce the patented product until the patent's term expires, and (2) Company A, the patentee, to pay B many millions of dollars.” Actavis, 570 U.S. at 140, 133 S.Ct. 2223.

Reverse payments can be anticompetitive in violation of the antitrust laws. Absent the reverse payment in the previous example, Company B might have prevailed by proving Company A's patent invalid. Even if the patent were valid, Company B might prevail by showing it did not infringe. In either case, generic drugs would have entered the market before Company A's patent was set to expire, and consumers would have benefited from lower drug prices.

In Actavis, the Supreme Court held reverse payments “can sometimes unreasonably diminish competition in violation of the antitrust laws.” Id. at 141, 133 S.Ct. 2223. That case, like this one, involved AndroGel. See id. at 144, 133 S.Ct. 2223. Solvay sued Actavis, Inc., a company seeking to market a generic version of the gel. See id. at 145, 133 S.Ct. 2223. Solvay and Actavis settled under the following terms: (1) “Actavis agreed that it would not bring its generic to market until ... 65 months before Solvay's patent expired (unless someone else marketed a generic sooner)”; (2) “Actavis also agreed to promote AndroGel to urologists”; and (3) “Solvay agreed to pay ... an estimated $19–$30 million annually, for nine years, to Actavis.” Id. “The companies described these payments as compensation for other services [Actavis] promised to perform.” Id. at 145, 133 S.Ct. 2223. The FTC was unpersuaded. It sued Solvay and Actavis, contending the services had little value and the payments actually compensated the generics for delaying their market entry. See id.

The district court dismissed the FTC's complaint, and the United States Court of Appeals for the Eleventh Circuit affirmed. *352 See id. at 145–46, 133 S.Ct. 2223. Both courts applied the “scope of the patent” test, which provides that “absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.” Id. at 146, 133 S.Ct. 2223 (citation omitted). This “categorical rule ... relied on the premise that, because a patentee possesses a lawful right to keep others out of its market, the patentee may also enter into settlement agreements excluding potential patent challengers from entering that market.” Lipitor, 868 F.3d at 250 (citing Actavis, 570 U.S. at 146, 133 S.Ct. 2223). The Eleventh Circuit was also concerned that antitrust review of reverse payments would undermine the general policy in favor of settlements and “require the parties to litigate the validity of the patent in order to demonstrate what would have happened to competition in the absence of the settlement.” Actavis, 570 U.S. at 153, 133 S.Ct. 2223.

The Supreme Court reversed. It first rejected the scope of the patent test. The infringement suit Solvay and Actavis settled “put the patent's validity at issue, as well as its actual preclusive scope.” Actavis, 570 U.S. at 147, 133 S.Ct. 2223. And the parties' settlement was both “unusual” and potentially anticompetitive, because the FTC alleged Solvay “agreed to pay [Actavis] many millions of dollars to stay out of its market, even though [Actavis] did not have any claim that [Solvay] was liable ... for
damages.” *Id.* at 147–48, 133 S.Ct. 2223. These factors persuaded the Court it would be “incongruous to determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent law policy, rather than measuring them against procompetitive antitrust policies as well.” *Id.* at 148, 133 S.Ct. 2223.

The Court then held that for five reasons, the district court erred by dismissing the FTC's complaint. See *id.* at 153, 133 S.Ct. 2223. First, reverse payments can be anticompetitive because they allow a brand-name company to split its monopoly profits with a generic company willing to delay market entry. See *id.* at 153–56, 133 S.Ct. 2223. Second, reverse payments’ “anticompetitive consequences will at least sometimes prove unjustified.” *Id.* at 156, 133 S.Ct. 2223. A defendant might show that “traditional settlement considerations, such as avoided litigation costs or fair value for services” justified the reverse payment. *Id.* Alternatively, antitrust review could reveal “a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement,” in which case the payment is not justified. *Id.* Third and fourth, the “size of [an] unexplained reverse payment can provide a workable surrogate for a patent's weakness” and a patentee's market power, “all without forcing a court to conduct a detailed exploration of the patent itself.” *Id.* at 157–58, 133 S.Ct. 2223 (citation omitted).

Fifth, subjecting reverse payments to antitrust review does not violate the general legal policy in favor of settlements, because companies can settle in other ways. See *id.* at 158, 133 S.Ct. 2223. For example, a brand-name company may “allow[] the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point.” *Id.* Thus, the Court concluded, “a reverse payment, where large and unjustified,” can violate the antitrust laws. *Id.* at 158–60, 133 S.Ct. 2223 (emphasis added).

2. *King Drug* and *Lipitor*

Since the Supreme Court decided *Actavis*, we have applied its teachings on three occasions. See *King Drug*, 791 F.3d at 393; *Lipitor*, 868 F.3d at 239; *Wellbutrin*, 868 F.3d at 158. The parties to this appeal rely on *King Drug* and *Lipitor*.

In *King Drug*, we reinstated a complaint challenging a settlement agreement in which the alleged reverse payment took a form other than cash. See 791 F.3d at 393. There, direct purchasers of the brand-name drug *Lamictal* sued its producer (GlaxoSmithKline (GSK)) and generic applicant (Teva) over their settlement of Teva's challenge to the validity and enforceability of GSK's patents on *Lamictal'*s active ingredient (lamotrigine). See *id.* Teva agreed to “end its challenge to GSK's patent in exchange for early entry into the $50 million annual lamotrigine chewables market and GSK's commitment not to produce its own, 'authorized generic' version of *Lamictal* tablets for the market alleged to be worth $2 billion annually.” *Id.* at 393–94. The purchasers claimed this “no-AG agreement” was a reverse payment under *Actavis* because it “was designed to induce Teva to abandon the patent fight and thereby agree to eliminate the risk of competition in the $2 billion lamotrigine tablet market.” *Id.* at 394.

Reversing the district court, we held the no-AG agreement was actionable under *Actavis*. See *id.* The district court had reasoned that “when the Supreme Court said ‘payment’ it meant a payment of money.” *Id.* at 405 (quotation marks and citation omitted). We doubted “the Court intended to draw such a formal line.” *Id.* at 405–06. We explained that even though GSK did not pay Teva cash under the agreement, it was “likely to present the same types of problems as reverse payments of cash.” *Id.* at 404. The no-AG agreement could have been worth millions of dollars, if not hundreds of millions of dollars, to Teva. See *id.* Conversely, GSK's commitment not to produce an authorized generic transferred to Teva “the profits [GSK] would have made from its authorized generic.” *Id.* at 405. Thus, the agreement may have been “something more than just an agreed-upon early entry”—it may have been “pay-for-delay.” *Id.*

We also rejected the defendants' counterargument that the purchasers' “allegations [were] far too speculative to satisfy their burden of plausibly alleging that the settlement was anticompetitive.” *Id.* at 409 (quotations and citation omitted). Specifically, the defendants argued the purchasers needed to plead that without the reverse payment: GSK and Teva would have negotiated
an alternative, more competitive agreement; continued litigation ending in settlement would have yielded a more competitive result; and Teva would have launched its generics. See id.

We held the purchasers stated a claim. They alleged: GSK agreed not to launch an authorized generic during Teva's 180-day exclusivity period; the agreement was worth “many millions of dollars of additional revenue”; GSK would otherwise be incentivized to launch an authorized generic; Teva likely would have launched alongside GSK; and GSK's patent was likely to be invalidated. See id. at 409–10. “And although [the purchasers] concede[d] that Teva entered the lamotrigine chewables market about 37 months early ... the chewables market, allegedly worth only $50 million annually, was orders of magnitude smaller than the alleged $2 billion tablet market the agreement [was] said to have protected.” Id. at 410. Because the purchasers had plausibly alleged that “any procompetitive aspects of the chewables arrangement were outweighed by the anticompetitive harm from the no-AG agreement,” they were entitled to discovery. Id.

We also rejected the district court's alternative holding that “the settlement ... would survive Actavis scrutiny and [was] reasonable.” Id. at 410–11. The purchasers were entitled to discovery because they plausibly alleged the settlement was anticompetitive. See id. at 411. And “[i]f genuine issues of material fact remain[ed] after discovery, the rule-of-reason analysis [would be] for the finder of fact, not the court as a matter of law.” Id.

Next, in Lipitor, we addressed consolidated appeals concerning two drugs: Lipitor and Effexor XR. See 868 F.3d at 239. In the Lipitor litigation, we reinstated a complaint alleging a generic applicant delayed entry into the market in exchange for the brand-name producer settling a damages claim for much less than the claim was really worth. See id. at 253–54. There, the plaintiffs were a putative class of direct purchasers, a putative class of end payors, and several individual retailers. See id. at 241. They sued Lipitor's brand-name producer (Pfizer Inc.) and its generic applicant (Ranbaxy Inc.) over a “near-global” litigation settlement addressing “scores of patent litigations [between Pfizer and Ranbaxy] around the world.” Id. at 244. One part of that settlement resolved Ranbaxy's challenge to the validity and enforceability of Pfizer's patents on Lipitor. See id. at 242. It provided Ranbaxy would delay its entry, “thus extending Pfizer's exclusivity in the Lipitor market” past the expiration of its patents. Id. at 244–45. Another part of the settlement resolved Pfizer's claim against Ranbaxy for allegedly infringing Pfizer's patents on Accupril, a different drug. Id. at 243–44. Before settling, Pfizer had reason to believe its claim was worth hundreds of millions of dollars: Accupril's annual sales were “over $500 million”; Ranbaxy's generic entry “decimated” those sales; Pfizer sought treble damages for willful infringement; and the district court granted Pfizer a preliminary injunction and Pfizer posted a $200 million bond. Id. Pfizer had also “expressed confidence that it would succeed in obtaining a substantial monetary judgment from Ranbaxy.” Id. at 244. Nevertheless, Pfizer agreed to settle this claim for a mere $1 million. See id.

Reversing the district court, we held these two, otherwise-unrelated parts of the global settlement agreement were actionable under Actavis. See id. at 248, 253. The court had required the plaintiffs to plead a “reliable” monetary estimate of the dropped Accupril claims so it could determine whether the reverse payment was large and unjustified. See id. at 254. We rejected that requirement, explaining it “heightened [the] pleading standard contrary to Bell Atlantic v. Twombly, [550 U.S. 544, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007)], and Ashcroft v. Iqbal, [556 U.S. 662, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009)].” Id. Moreover, we said neither Actavis nor King Drug “demanded [that] level of detail.” Id. at 254.

In fact, the plaintiffs’ allegations “easily match[ed], if not exceed[ed], the level of specificity and detail of those in Actavis and King Drug.” Id. at 253, 255. As relevant here, the plaintiffs alleged:

Ranbaxy launched a generic version of Pfizer's brand drug Accupril “at risk” [of infringement] ...; Pfizer had annual Accupril sales over $500 million prior to Ranbaxy's launch ...; Pfizer brought suit and sought to enjoin Ranbaxy's generic sales ...; the District Court granted the injunction halting Ranbaxy's sales of generic Accupril, which the Federal Circuit affirmed ...; Pfizer posted 'a $200 million bond in conjunction with' the injunction and informed the Court that Ranbaxy's generic sales
The defendants countered that the plaintiffs did not address other parts of the global litigation settlement that might well have justified the alleged reverse payment. But because the defendants had the burden of justifying a reverse payment, *Actavis* did not “require antitrust plaintiffs to come up with possible explanations for the reverse payment and then rebut those explanations.” *Id.* at 256. The defendants also countered that because Ranbaxy paid Pfizer $1 million, it was a commonplace settlement to which *Actavis* does not apply. *Id.* at 257. We said this argument “[could not] be squared with *Actavis*” because “[i]f parties could shield their settlements from antitrust review by simply including a token payment by the purportedly infringing generic manufacturer, then otherwise unlawful reverse payment settlement agreements attempting to eliminate the risk of competition would escape review.” *Id.* at 258.

Similarly, in the *Effexor* XR litigation, we reinstated a complaint alleging a generic applicant delayed entry into the *Effexor* market in exchange for the brand-name producer's agreement not to market an authorized generic—even though the generic agreed to pay some royalties to the brand. See *id.* at 254, 247. There, the plaintiffs were a putative class of end payors, two third-party payors, and several retailers. See *id.* at 246. They sued *Effexor's* generic applicant (Teva) and brand-name producer (Wyeth, Inc.) over their settlement of Teva's challenge to the validity and enforceability of Wyeth's patents on *Effexor*. See *id.* at 247. Under the settlement, Teva and Wyeth agreed to vacate a district court ruling construing the patent claims unfavorably to Wyeth. See *id.* They further agreed that Teva could market the extended-release version of its generic nearly seven years before Wyeth's patent expired, and its instant-release version at some point before the patent expired. See *id.* In exchange, Wyeth agreed it would not market authorized generics during Teva's 180-day exclusivity period. See *id.* In return, Teva agreed to pay Wyeth royalties. See *id.*

Reversing the district court, we held the no-AG agreement was actionable under *Actavis*. Given the similarities between *King Drug* and the *Effexor* litigation, we will not repeat the *Effexor* plaintiffs’ allegations here. See *id.* at 258–59. We mention the *Effexor* litigation only to highlight two counterarguments the defendants made. First, the defendants argued “the reverse payment was not large because the complaints failed to sufficiently allege that Wyeth would have released an authorized generic but for its settlement agreement with Teva.” *Id.* They explained that “Wyeth has rarely introduced authorized generics in response to the entry of a generic into one of their branded drugs’ markets.” *Id.* at 260. We rejected this argument because the mere fact that “Wyeth does not typically introduce authorized generics into the market” did not “render[ ] [the plaintiffs’] allegations about the value of the no-AG agreement implausible.” *Id.* at 260–61. Second, the defendants argued the royalties Teva agreed to pay Wyeth justified the reverse payment. See *id.* We responded that “[a]lthough the royalty licensing provisions will perhaps be a valid defense, they require factual assessments, economic calculations, and expert analysis that are inappropriate at the pleading *356* stage.” *Id.* at 261. In sum, we said, “*Effexor* plaintiffs need not have valued the no-AG agreement beyond their allegations summarized above ... Nor were they required to counter potential defenses at the pleading stage.” *Id.* at 262 (citation omitted).

3. Application

Two principles emerge from *King Drug* and *Lipitor*. First, a reverse payment's legality depends mainly on its economic substance, not its form. The alleged reverse payment in *Actavis* was made in cash. Yet the alleged reverse payments in *King Drug* and *Lipitor* included two no-AG agreements and the settlement of a valuable damages claim. The reverse payment in *Actavis* was part of a single settlement agreement addressing one drug (AndroGel). Yet the reverse payment in the *Lipitor* litigation
spanned two parts of a “near-global” litigation settlement addressing two different drugs (Lipitor and Accupril); and in *King Drug*, the challenged settlement addressed a drug in two different forms (chewable and tablet). Finally, the settlement in *Actavis* did not provide for cash to flow from the generic entrant to the brand-name producer. Yet the settlements in *Lipitor* provided for Ranbaxy to pay Pfizer $1 million and for Teva to pay Wyeth royalties.

However meaningful these formalisms may be in other areas of the law, they are disfavored in antitrust. The purpose of antitrust law is “to protect consumers from arrangements that prevent competition in the marketplace.” *King Drug*, 791 F.3d at 406 (citations omitted). Because of that unique purpose, “economic realities rather than a formalistic approach must govern.” *United States v. Dentsply, Inc.*, 399 F.3d 181, 189 (3d Cir. 2005). Accordingly, in *King Drug* and *Lipitor*, we read *Actavis* practically; we read it to apply to potentially anticompetitive reverse payments regardless of their form.

The second principle emerging from *King Drug* and *Lipitor* is that the law of pleading applies to reverse-payment theories. To survive a motion to dismiss, a plaintiff must “allege facts sufficient to support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment under *Actavis*.” *Lipitor*, 868 F.3d at 252 (citation omitted). A plaintiff can meet this pleading standard without describing in perfect detail the world without the reverse payment, calculating reliably the payment's exact size, or preempting every possible explanation for it. Moreover, a district court must accept a plaintiff's well-pleaded allegations as true. If a plaintiff plausibly alleges that an agreement's anticompetitive effects outweigh its procompetitive virtues, the district court must accept that allegation and allow the plaintiff to take discovery. If genuine issues of material fact remain, the rule-of-reason analysis is for the factfinder, not the court.

Applying these precedents here, the District Court erred by dismissing the FTC's claims to the extent they relied on a reverse payment theory. The FTC plausibly alleged an anticompetitive reverse payment. It alleged AbbVie and Besins filed sham lawsuits against Teva and Perrigo in order to trigger the automatic, 30-month stay of FDA approval on its generic version of *AndroGel*. App. 4440 ¶ 99. But those suits “did not eliminate the threat of Teva's ... products to [AbbVie] and Besins's monopoly,” because AbbVie and Teva both expected Teva would win the infringement suit against it and would introduce its generic in 2012—before 30 months had passed. App. 4441 ¶¶ 107–09. So “[AbbVie] and Besins ... turned to other ways to preserve their monopoly.” App. 4442 ¶ 111. Specifically, AbbVie “approached Teva to discuss a potential settlement” that would give “[AbbVie] time to shift sales to its reformulated product, *AndroGel* 1.62%.” Id. ¶ 112. Teva agreed to “drop its patent challenge and refrain from competing with [*AndroGel*] until December 2014.” App. 4443 ¶ 115. In exchange, it asked AbbVie to sell it a “supply of ... *TriCor*.” Id. ¶ 113. AbbVie agreed. It authorized Teva to sell a generic version of *TriCor*, which AbbVie would supply to Teva at Teva's option, for a four-year term beginning in November 2012. Id. ¶ 117. The supply agreement provided for Teva to pay AbbVie the costs of production, an additional percentage of that cost, and a royalty. *See id.*

The payment was plausibly “large.” The FTC alleges the supply of *TriCor* was “extremely valuable” to Teva. App. 4444 ¶ 120. A previous settlement between AbbVie and Teva had set Teva's entry in the *TriCor* market for July 2012. App. 4442 ¶ 114. And because Teva was the first generic challenger to *TriCor*, Teva was entitled to 180 days of marketing exclusivity. *See id.* Teva was struggling to capitalize on the exclusivity period, though, because it could not secure FDA approval for its generic drug. *See id.* The *TriCor* deal enabled Teva “to secure generic *TriCor* revenues in 2012 and its first mover advantage.” App. 4444–45 ¶¶ 121, 124. Teva expected its “net sales of authorized generic *TriCor* sales would be nearly $175 million over a four-year period.” App. 4444 ¶ 120. In fact, Teva's actual sales were much higher. *Id.* They “far exceed[ed]” the litigation costs that AbbVie, Besins, or Teva saved by settling. App. 4445 ¶ 122. And they exceeded what Teva had projected it was likely to earn by winning the infringement suit and marketing its generic version of *AndroGel*. *Id.* ¶ 123.

The payment was also plausibly “unjustified.” The FTC alleges the *TriCor* deal “cannot be explained as an independent business deal from Abbott's perspective.” App. 4445 ¶ 125. AbbVie “had no incentive to increase ... generic competition from Teva on another of its blockbuster products.” App. 4443 ¶ 115. And the *TriCor* deal was “highly unusual” in other respects. App. 4445 ¶ 126. For example, it did not condition Teva's launch on the launch of an independent generic. App. 4445–46 ¶ 126.
It actually accelerated generic entry, because “Teva's launch triggered provisions in [AbbVie's] agreements with other generic TriCor ANDA filers allowing them to launch their own generic versions.” App. 446–47 ¶ 129. Moreover, the royalty terms were “significantly worse for [AbbVie]” than is usual in authorized-generic agreements, including contemporaneous agreements that AbbVie entered. App. 4447 ¶ 130. AbbVie expected to lose roughly $100 million in TriCor revenues as a result of the deal, and its “modest income from the ... deal did not come close to making up this significant loss of revenue.” Id. ¶ 132.

Finally, it is plausible that the anticompetitive effects of AbbVie's settlement with Teva outweighed any procompetitive virtues of the TriCor deal. The FTC alleges AbbVie calculated that it would sacrifice $100 million in TriCor sales, but that was a small fraction of the billions of dollars in AndroGel revenue it protected by deferring competition in the TTRT market for three years. See id.; cf. King Drug, 791 F.3d at 410 (purchasers were entitled to discovery because they plausibly alleged that “any procompetitive aspects of the chewables arrangement were outweighed by the anticompetitive harm from the no-AG agreement”). These allegations, if true, would “support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment.” *358 Lipitor, 868 F.3d at 252. So the District Court erred by dismissing the FTC's claims to the extent they relied on a reverse-payment theory.

The District Court ruled that “when two agreements are involved ... the court must determine separately whether each promotes competition.” *AbbVie, 107 F. Supp. 3d at 437 (citing Pac. Bell Tel. Co. v. *linkLine* Commc'ns, Inc., 555 U.S. 438, 129 S.Ct. 1109, 172 L.Ed.2d 836 (2009)). The Court then reasoned AbbVie's settlement with Teva promoted competition and was distinguishable from the settlement in *Actavis*. In *Actavis*, the patentee paid the alleged infringer. But here, the Court said, AbbVie and Besins “did not make any payment, reverse or otherwise, to ... Teva.” *Id. at 436*. Instead, they “simply allow[ed] Teva to enter the AndroGel market almost six years prior to the expiration of the ’894 patent.” *Id.* It further stated that because “*Actavis* specifically states that such an agreement does not run afoul of the antitrust laws,” the settlement was procompetitive and unactionable. *Id.* (citation omitted).

The District Court next reasoned the TriCor deal promoted competition because “[i]t allow[ed] Teva to enter the cholesterol drug market with a generic product to compete with Abbott's product and thus advantage[d] the purchasers of cholesterol drugs.” *Id.* The Court stressed that while “something of large value passed from [AbbVie] to Teva, it was not a reverse payment under *Actavis*” because AbbVie was “not making any payments to Teva.” *Id.* Rather, Teva was “paying [AbbVie] for the supply of TriCor.” *Id.* And even though the FTC alleged AbbVie was “charging a price that is well below what is customary in such situations,” it did not allege AbbVie “agreed to sell TriCor ... for less than its cost.” *Id.* Thus, the Court held the deal was procompetitive. *Id.*

The District Court's reasoning is unpersuasive. The Court cited *linkLine* for the proposition that if a settlement involves two agreements, a court must determine separately whether each promotes competition. But *Linkline* held “two antitrust theories cannot be combined to form a new theory of antitrust liability.” *ZF* Meritor, LLC v. Eaton Corp., 696 F.3d 254, 280 (3d Cir. 2012) (emphasis added) (citing *linkLine*, 555 U.S. at 457, 129 S.Ct. 1109). The FTC's complaint does not allege such a combination, so *linkLine* does not apply.

Nor do our precedents support the rule that “when two agreements are involved ... [a] court must determine separately whether each promotes competition.” *AbbVie*, 107 F. Supp. 3d at 437 (citation omitted). That rule violates two principles from our precedents. It elevates form over substance because companies could avoid liability for anticompetitive reverse payments simply by structuring them as two separate agreements—one in which the generic company agrees to delay entry until patent expiration, and the other in which the brand-name company agrees to split monopoly profits. In effect, *Actavis* would become a penalty for bad corporate lawyering instead of anticompetitive conduct. The rule also contradicts pleading law. Here, the FTC plausibly
alleged that AbbVie's settlement with Teva and the TriCor deal were linked. The Court had to accept that allegation as true. See Phillips, 515 F.3d at 230–31.

We are also unpersuaded by the District Court's economic analyses of the TriCor deal and AbbVie's settlement with Teva. As to the TriCor deal, the Court acknowledged that “something of large value passed from [AbbVie] to Teva.” AbbVie, 107 F. Supp. 3d at 436. Yet it said that transfer could not be a reverse payment under Actavis because AbbVie was not “making any payments to Teva.” Id. This reasoning cannot be reconciled with King Drug, where we held a plaintiff may base a reverse-payment theory on any “unexplained *359 large transfer of value from the patent holder to the alleged infringer.” King Drug, 791 F.3d at 403 (emphasis added).

Moreover, the Court emphasized that Teva paid AbbVie for the supply of TriCor. But in Lipitor, we held that parties cannot “shield their settlements from antitrust review by simply including a token payment by the purportedly infringing generic manufacturer.” 868 F.3d at 258. Although Teva's payments “will perhaps be a valid defense, they require factual assessments, economic calculations, and expert analysis that are inappropriate at the pleading stage.” Id. at 261. Finally, the Court intimated the result might be different if the FTC had alleged AbbVie agreed to sell TriCor below-cost. But the FTC did not have to allege the TriCor deal would appear as a loss on AbbVie's balance sheets; it needed only to allege that through the deal, AbbVie unjustifiably transferred to Teva an opportunity, and the profits associated with the opportunity were large. See King Drug, 791 F.3d at 405 (GSK's commitment not to produce an authorized generic transferred to Teva “the profits [GSK] would have made from its authorized generic”) (emphasis added). So without expressing an opinion whether the District Court correctly concluded the TriCor deal was procompetitive, we think it analyzed incorrectly the deal's economic substance.

As to AbbVie's settlement with Teva, the District Court erred in concluding it was procompetitive as a matter of law. Granted, the District Court was right that under Actavis, “an agreement does not run afoul of the antitrust laws” if it simply allows a generic company to enter a market before patent expiration. AbbVie, 107 F. Supp. 3d at 436 (citing Actavis, 570 U.S. at 158, 133 S.Ct. 2223 (“[Parties] may, as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point.”) (emphasis added)). And it was reasonable for the Court to think this exception reflects the Supreme Court's view that such agreements are so often procompetitive they should be legal per se. Still, the exception applies only if a patentee does not “pay[ ] the challenger to stay out [before patent expiration],” and the District Court erred in concluding this condition was met here. Actavis, 570 U.S. at 158, 133 S.Ct. 2223. The Court said AbbVie “did not make any payment, reverse or otherwise, to ... Teva.” AbbVie, 107 F. Supp. 3d at 436. But that finding rested on the Court's erroneous ruling that it had to analyze the settlement separately from the TriCor deal, which even the Court acknowledged involved a transfer of value from AbbVie to Teva. Because the FTC plausibly alleged the TriCor deal was a reverse payment, the settlement may have been “something more than just an agreed-upon early entry”—it may have been “pay-for-delay.” King Drug, 791 F.3d at 405. And pay-for-delay is anticompetitive even if the delay does not continue past patent expiration. It was this same anticompetitive potential that led the Supreme Court to reject the scope of the patent test in Actavis. See 570 U.S. at 147–48, 133 S.Ct. 2223.

For these reasons, the District Court erred by dismissing the FTC's claims to the extent they relied on a reverse-payment theory.

B. The District Court erred in concluding AbbVie and Besins's litigation against Teva was a sham; it did not err in concluding the Perrigo litigation was a sham.

1. Noerr-Pennington immunity


2020-2 Trade Cases P 81,393


Noerr-Pennington immunity is not absolute. Wellbutrin, 868 F.3d at 148. An exception arises if a lawsuit is “a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor.” E. R.R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 144, 81 S.Ct. 523, 5 L.Ed.2d 464 (1961). In PRE, the Supreme Court held this exception has two prongs:

First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits. If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is immunized under Noerr, and an antitrust claim premised on the sham exception must fail. Only if challenged litigation is objectively meritless may a court examine the litigant's subjective motivation. Under this second part of our definition of sham, the court should focus on whether the baseless lawsuit conceals an attempt to interfere directly with the business relationships of a competitor through the use of the governmental process—as opposed to the outcome of that process—as an anticompetitive weapon. This two-tiered process requires the plaintiff to disprove the challenged lawsuit's legal viability before the court will entertain evidence of the suit's economic viability.

508 U.S. at 60–61, 113 S.Ct. 1920 (internal quotation marks, citations, alteration, and footnote omitted). Under the objective baselessness prong, a “probable cause determination irrefutably demonstrates” a defendant's immunity. Id. at 63, 113 S.Ct. 1920. Probable cause is a “reasonable belief that there is a chance that a claim may be held valid upon adjudication.” Id. at 62–63, 113 S.Ct. 1920 (internal quotation marks, citations, and alterations omitted); see also id. at 65, 113 S.Ct. 1920 (defendant was immune because “[a]ny reasonable [litigant] in [its] position could have believed that it had some chance of winning”). In determining reasonableness, a court should consider the state of the law at the time of a defendant's suit. See id. at 65, 113 S.Ct. 1920; see also Wellbutrin, 868 F.3d at 150. Generally, the more “unsettled” the law is, the more reasonable is a belief that a claim will be held valid. PRE, 508 U.S. at 64–65, 113 S.Ct. 1920 (probable cause supports a claim if it is “arguably ‘warranted by existing law’”) (quoting FED. R. CIV. P. 11). Even if the law was settled against the defendant, however, that is not dispositive. Then, a court should ask whether the defendant's claim “at the very least was based on an objectively ‘good faith argument for the extension, modification, or reversal of existing law.’ ” Id. at 65, 113 S.Ct. 1920 (quoting FED. R. CIV. P. 11).

Under the subjective motivation prong, a plaintiff must show the defendant “brought baseless claims in an attempt to thwart competition (i.e., in bad faith).” Octane Fitness, LLC v. ICON Health & Fitness, Inc., 572 U.S. 545, 556, 134 S.Ct. 1749, 188 L.Ed.2d 816 (2014). Some factors relating to a defendant's “economic motivations” in bringing suit include whether the defendant was “indifferent to the outcome on the merits of the ... suit, whether any damages for infringement would be too low to justify ... investment in the suit, or whether [the defendant] *361 had decided to sue primarily for the benefit of collateral injuries inflicted through the use of legal process.” PRE, 508 U.S. at 65–66, 113 S.Ct. 1920 (citation omitted).

Generally, a plaintiff seeking to show the sham litigation exception faces “an uphill battle.” Wellbutrin, 868 F.3d at 147. And in some respects, the hill is steeper “in the context of an ANDA case.” Id. at 149. “Since the submission of an ANDA is, by statutory definition, an infringing act, an infringement suit filed in response to an ANDA with a paragraph IV certification could only be objectively baseless if no reasonable person could disagree with the assertions of noninfringement or invalidity in the certification.” Id. (citation omitted). Moreover, the number of lawsuits a brand-name drug manufacturer files will sometimes reveal little about its subjective motivation for suing, because the Hatch-Waxman Act “incentivizes [brands] to promptly file patent infringement suits by rewarding them with a stay of up to 30 months if they do so.” Id. at 157–58 (citing 21 U.S.C. § 355(j)
Yet in other respects, the ANDA context may help a plaintiff. The automatic, 30-month stay is a collateral injury the defendant's mere use of legal process invariably inflicts. And though the stay ends if a court holds the defendant's patent is invalid or has not been infringed, it does not otherwise depend on a suit's outcome. Thus, a plaintiff may be able to show a defendant was indifferent to the outcome of its infringement suit, and the automatic, 30-month stay was an anticompetitive weapon the defendant tried to wield.

In sum, applying the sham-litigation standard is a delicate task. The defendant's First Amendment right “to petition the Government for a redress of grievances” is at stake. U.S. Const. amend. I. So too is congressional policy, as expressed in both the Hatch-Waxman Act and the antitrust laws. We must not “penalize a brand-name manufacturer whose 'litigiousness was a product of Hatch-Waxman.’ ” *Wellbutrin*, 868 F.3d at 158 (citing *Kaiser Found. Health Plan, Inc. v. Abbott Labs., Inc.*, 552 F.3d 1033, 1047 (9th Cir. 2009)). “Doing so would punish behavior that Congress sought to encourage.” *Id.* (citation omitted). At the same time, we must not immunize a brand-name manufacturer who uses the Hatch-Waxman Act's automatic, 30-month stay to thwart competition. Doing so would excuse behavior that Congress proscribed in the antitrust laws.

2. Objective Baselessness
The District Court granted the FTC summary judgment on sham litigation's objective baselessness prong. We review that judgment de novo. See *Morgan v. Covington Twp.*, 648 F.3d 172, 177 (3d Cir. 2011).

   a. Patent law's doctrine of equivalents, prosecution history estoppel, and tangentiality

Under the doctrine of equivalents, “[t]he scope of a patent is not limited to its literal terms but instead embraces all equivalents to the claims described.” *Festo VIII*, 535 U.S. at 732, 122 S.Ct. 1831. There are at least two reasons for this doctrine. First, because “the nature of language makes it impossible to capture the essence of a thing in a patent application,” it is unrealistic to expect a patentee to “capture every nuance of [his or her] invention or describe with complete precision the range of its novelty.” *Festo VIII*, 535 U.S. at 731, 122 S.Ct. 1831. Second, “[i]f patents were always interpreted by their literal terms,” rival inventors might “defeat the patent” simply by making “unimportant and insubstantial” changes. *Id.* This would diminish the scientific and artistic progress that the patent system seeks to foster. See *id.*

Although the doctrine of equivalents counters the threat that literal interpretation of patents poses to scientific and artistic progress, it creates another problem. One function of patents is to notify would-be inventors about the scope of the patentee's property right. See *id.* (“A patent holder should know what he owns, and the public should know what he does not.”). Notice allows inventors to innovate without fear that the patentee will sue them for infringement. See *id.* at 732, 122 S.Ct. 1831. But because the doctrine of equivalents untethers a patentee's property right from a patent's literal terms, it tends to undermine notice. See *id.* So the doctrine risks dampening inventors' innovative spirit.

Thus, patent law must balance “the needs of patentees for adequate protection of their inventions” on the one hand, and “the needs of would-be competitors for adequate notice of the scope of that protection” on the other. *Festo Corp. v. Shoketsu Kinzoku Kabushiki Co. (“Festo IX”), 344 F.3d 1359, 1385 (Fed. Cir. 2003)* (Newman, J., concurring in part, dissenting in part).

Recognizing the need for balance, the Supreme Court has limited the doctrine of equivalents. One limitation—known as prosecution history estoppel—applies when “the patentee originally claimed the subject matter alleged to infringe but then narrowed the claim in response to a rejection.” *Festo VIII*, 535 U.S. at 733, 122 S.Ct. 1831. The patentee “may not argue that the
surrendered territory comprised unforeseen subject matter that should be deemed equivalent to the literal claims of the issued patent.” *Id.* at 733–34, 122 S.Ct. 1831.

Prosecution history estoppel “ensures that the doctrine of equivalents remains tied to its underlying purpose.” *Id.* at 734, 122 S.Ct. 1831. “The doctrine of equivalents is premised on language's inability to capture the essence of innovation.” *Id.* But that premise is unsound if a patent's prosecution history shows that the patentee “turned his attention to the subject matter in question, knew the words for both the broader and narrower claim, and affirmatively chose the latter.” *Id.* at 734–35, 122 S.Ct. 1831. In that case, the patentee's competitors could reasonably infer the patentee's property right extended only so far as the narrower claim.

Courts use a three-part test to determine whether prosecution history estoppel applies:

1. The first question in a prosecution history estoppel inquiry is whether an amendment filed in the Patent and Trademark Office (PTO) has narrowed the literal scope of a claim. ... If the amendment was not narrowing, then prosecution history estoppel does not apply.

2. If the accused infringer establishes that the amendment was a narrowing one, then the second question is whether the reason for that amendment was a substantial one relating to patentability. ... When the prosecution history record reveals no reason for the narrowing amendment, [the Supreme Court's decision in] *Warner–Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997)*] presuming that the patentee had a substantial reason relating to patentability; consequently, the patentee *must show that the reason for the amendment was not one relating to patentability if it is to rebut that presumption. ... In this regard, ... a patentee's rebuttal of the *Warner–Jenkinson* presumption is restricted to the evidence in the prosecution history record. ... If the patentee successfully establishes that the amendment was not for a reason of patentability, then prosecution history estoppel does not apply.

3. If, however, the court determines that a narrowing amendment has been made for a substantial reason relating to patentability ... then the third question in a prosecution history estoppel analysis addresses the scope of the subject matter surrendered by the narrowing amendment. ... At that point *Festo VIII* imposes the presumption that the patentee has surrendered all territory between the original claim limitation and the amended claim limitation. ... *The patentee may rebut that presumption* of total surrender by demonstrating that it did not surrender the particular equivalent in question ... Finally, if the patentee fails to rebut the *Festo* presumption, then prosecution history estoppel bars the patentee from relying on the doctrine of equivalents for the accused element. If the patentee successfully rebuts the presumption, then prosecution history estoppel does not apply and the question whether the accused element is in fact equivalent to the limitation at issue is reached on the merits.

*Festo IX, 344 F.3d at 1366–67* (internal citations omitted) (emphasis added). To rebut the presumption of total surrender, a patentee “must show that at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent.” *Festo VIII, 535 U.S. at 741, 122 S.Ct. 1831.*

One way a patentee can meet this high standard is by showing “the rationale underlying the narrowing amendment [bore] no more than a tangential relation to the equivalent in question.” *Festo IX, 344 F.3d at 1369* (internal citation omitted). This is the tangentiality exception to prosecution history estoppel. In determining whether an amendment was tangential to an equivalent, a court does not consider the patentee's subjective motivation for narrowing his claims. That approach would overlook “the public notice function of a patent and its prosecution history.” *Id.* (citations omitted). Instead, the court considers the “objectively apparent” motivation as suggested by the prosecution history. *Id.* Although the tangentiality exception generally cannot be reduced to hard-and-fast rules, see *id. at 1368*, one rule is clear: “an amendment made to avoid prior art that contains the equivalent in question is not tangential,” *id. at 1369* (citation omitted).
Like prosecution history estoppel, the tangentiality exception balances the needs of patentees and would-be competitors. It also ensures the doctrine of equivalents remains tied to its underlying purpose. If the rationale for an amendment is tangential to the alleged equivalent, “one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent.” *Festo VIII*, 535 U.S. at 741, 122 S.Ct. 1831. Thus, a patentee's competitors could not infer the patentee “turned his attention to the subject matter in question, knew the words for both the broader and narrower claim, and affirmatively chose the latter.” *Id.* at 734–35, 122 S.Ct. 1831. By the same token, however, the tangentiality exception does not apply if the rationale *364* for an amendment is to avoid prior art that contains the alleged equivalent. Then the prior art itself teaches the patentee how to draft a claim that literally encompasses the equivalent. And because the patentee turned his attention to the prior art in order to avoid it, the patentee's competitors could infer the patentee affirmatively chose the narrower claim.

b. The District Court erred in concluding AbbVie and Besins's suit against Teva was objectively baseless.

Teva's paragraph IV notice asserted that because its gel used the penetration enhancer isopropyl palmitate instead of isopropyl myristate, the gel did not literally infringe the '894 patent. It also argued the '894 patent's prosecution history estopped AbbVie and Besins from claiming infringement on the ground that isopropyl palmitate is equivalent to isopropyl myristate.

On appeal, AbbVie and Besins concede the October 2001 amendment—which narrowed the patent application's claim 1 from all penetration enhancers to a list of 24 not including isopropyl palmitate—was narrowing and was made for a substantial reason related to patentability. *See Festo IX*, 344 F.3d at 1366 (citation omitted). Thus, we presume AbbVie and Besins “surrendered all territory between the original claim limitation and the amended claim limitation,” which includes isopropyl palmitate. *Id.* at 1367 (citing *Festo VIII*, 535 U.S. at 740, 122 S.Ct. 1831). To rebut this presumption, AbbVie and Besins would have had to show that “at the time of the [October 2001] amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed [isopropyl palmitate].” *Festo VIII*, 535 U.S. at 741, 122 S.Ct. 1831. AbbVie and Besins argue they could make this showing. They contend the reason for the October 2001 amendment was to overcome Mak's use of oleic acid—not Allen's disclosure of isopropyl palmitate or other penetration enhancers. So, they claim, the rationale for the amendment was tangential to isopropyl palmitate. *See Festo IX*, 344 F.3d at 1369 (internal citation omitted).

The FTC has not shown that no reasonable litigant in AbbVie and Besins's position would believe it had a chance of winning. *See PRE*, 508 U.S. at 65, 113 S.Ct. 1920. AbbVie and Besins's argument has support in the prosecution history record. Allen disclosed isopropyl myristate—the penetration enhancer used in AndroGel—and yet the October 2001 amendment retained isopropyl myristate. Moreover, AbbVie and Besins gave three reasons why the prior art did not suggest combining Mak and Allen. Every one of those reasons distinguished the claimed penetration enhancers from oleic acid, the penetration enhancer Mak used. Finally, expert testimony could have supported AbbVie and Besins's interpretation of the prosecution history. *See Festo IX*, 344 F.3d at 1369–70. The District Court heard testimony from Dr. Jonathan Hadgraft, Emeritus Professor of Biophysical Chemistry at University College London School of Pharmacy. He testified the “chemical and functional differences identified by the patent applicants in their rationale for distinguishing the penetration enhancers listed in the claims in the [October 2001] amendment ... from oleic acid would apply equally to isopropyl palmitate.” App. 4511. For these reasons, AbbVie and Besins could reasonably have argued that at the time of the October 2001 amendment, one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed isopropyl palmitate. *See Festo VIII*, 535 U.S. at 741, 122 S.Ct. 1831. In that case, prosecution history estoppel would not apply. *See id.*

*365* The FTC presents three main counterarguments.

First, the District Court concluded the rationale for the October 2001 amendment was not tangential to isopropyl palmitate because “[i]f AbbVie and Besins merely sought to relinquish oleic acid and no other penetration enhancer in October 2001, they
Hong, Kenneth 7/11/2022
For Educational Use Only


2020-2 Trade Cases P 81,393

easily could have said so.” FTC v. AbbVie, 2017 WL 4098688, at *8 (E.D. Pa., Sept. 15, 2017). Relatedly, the FTC argues that because AbbVie's "oleic acid rationale does not explain the entire [October 2001] amendment," the rationale for the amendment was not tangential to isopropyl palmitate as a matter of law. FTC Resp. Br. 39–40 (citing Felix v. Am. Honda Motor Co., 562 F.3d 1167, 1184 (Fed. Cir. 2009) and Amgen Inc. v. Hoechst Marion Roussel, Inc., 457 F.3d 1293, 1315 (Fed. Cir. 2006)). But negative claim limitations of the sort the Court mentioned are usually impermissible. See In re Schechter, 205 F.2d 185, 188 (C.C.P.A. 1953). Put differently, AbbVie and Besins probably could not have claimed all penetration enhancers “except oleic acid.” And the law is not as well-settled as the FTC suggests. Granted, in the cases the FTC cites, the Federal Circuit held the tangentiality exception did not apply in part because the patentee's rationale failed to explain the entire amendment. But because the Federal Circuit has refused to reduce the tangentiality exception to hard-and-fast rules, see Festo IX, 344 F.3d at 1368, a reasonable litigant in AbbVie and Besins's position would not necessarily see those decisions as foreclosing its claim.

More persuasive is the District Court's reasoning that the October 2001 amendment sought to overcome the Allen prior art, which “listed isopropyl palmitate as one of five penetration enhancers.” AbbVie, 2017 WL 4098688, at *8. The FTC also argues Allen's disclosure of isopropyl palmitate “precludes a tangentiality finding,” because “an amendment made to avoid prior art that contains the equivalent in question is not tangential.” FTC Resp. Br. 38 (quoting Festo IX, 344 F.3d at 1369 (Pioneer Magnetics, Inc. v. Micro Linear Corp., 330 F.3d 1352, 1357 (Fed. Cir. 2003))). This argument is more persuasive because the rule the FTC cites is a well-settled exception to the Federal Circuit's case-by-case approach to the tangentiality exception. See id. But the argument is not so strong as to make the suits objectively unreasonable. AbbVie and Besins could reasonably have argued the rule did not apply or should be modified, because even though Allen disclosed isopropyl palmitate, AbbVie and Besins made the October 2001 amendment “to avoid” Mak's use of oleic acid, not Allen's disclosure of isopropyl palmitate or other penetration enhancers. PRE, 508 U.S. at 65, 113 S.Ct. 1920 (quoting FED. R. CIV. P. 11). Thus, a reasonable litigant in AbbVie and Besins's position would not necessarily see this rule as foreclosing its claim.

Finally, the District Court reasoned that the “entire prosecution history”—not just the October 2001 amendment—is relevant to determine whether estoppel applies. AbbVie, 2017 WL 4098688, at *6 (citing Wang Labs., Inc. v. Toshiba Corp., 993 F.2d 858, 867 (Fed. Cir. 1993) and Tex. Instruments, Inc. v. U.S. Int'l Trade Comm'n, 988 F.2d 1165, 1174 (Fed. Cir. 1993)). Likewise, the FTC argues that “[e]ven if the October 2001 amendment had not excluded isopropyl palmitate, the later amendments would have.” FTC Resp. Br. 41. And those amendments “plainly could not have been intended to distinguish oleic acid, which (as AbbVie concedes) had already been excluded by the October 2001 amendment.” FTC Resp. Br. 42. Again, the law is not as well-settled as the FTC would have us believe. AbbVie and Besins could reasonably have argued *366 only the October 2001 amendment was relevant under existing law. See Festo IX, 344 F.3d at 1369 (tangentiality “focuses on the patentee's objectively apparent reason for the narrowing amendment”) (emphasis added); see also Felix, 562 F.3d at 1182–83; PRE, 508 U.S. at 64–65, 113 S.Ct. 1920 (probable cause supports a claim if it is “arguably ’warranted by existing law’”) (quoting FED. R. CIV. P. 11).

Thus, the District Court erred in concluding AbbVie and Besins's suit against Teva was objectively baseless. Accordingly, we will not consider the subjective motivation prong as to Teva. See PRE, 508 U.S. at 60–61, 113 S.Ct. 1920.

c. The District Court did not err in concluding AbbVie and Besins's suit against Perrigo was objectively baseless.

Perrigo's first paragraph IV notice asserted that because its gel used the penetration enhancer isostearic acid instead of isopropyl myristate, the gel did not literally infringe the '894 patent. It also explained that the '894 patent's prosecution history estopped AbbVie and Besins from claiming infringement on the ground that isostearic acid is equivalent to isopropyl myristate.
AbbVie and Besins concede the December 2001 amendment narrowed the patent application's claims from 24 penetration enhancers including isostearic acid to isopropyl myristate. But they argue it was not for a substantial reason relating to patentability and, if it was, the rationale for the amendment was tangential to isostearic acid.

No reasonable litigant in AbbVie and Besins's position would believe it had a chance of winning on these arguments. First, AbbVie and Besins argue the December 2001 amendment was not for a substantial reason relating to patentability, both because “the claims pending at the time of the December 2001 amendment ... were never rejected or threatened with rejection,” and because they “amended the claims in December 2001 to expedite the timing of patent protection.” AbbVie Br. 47–48. This argument is untenable. “[A] voluntary amendment may give rise to prosecution history estoppel.” Festo IX, 344 F.3d at 1366 (internal quotations and citation omitted). And expediting prosecution is not a legitimate basis on which to avoid prosecution history estoppel. See Biogen, Inc. v. Berlex Labs., Inc., 318 F.3d 1132, 1142 (Fed. Cir. 2003) (“[C]laims that were deliberately limited in order to expedite prosecution by avoiding examination cannot regain that scope for infringement purposes.”) (citing Genentech, Inc. v. Wellcome Found., Ltd., 29 F.3d 1555, 1564 (Fed. Cir. 1994)). Regardless, no court would hold the December 2001 amendment's purpose was to expedite prosecution. “[A] patentee's rebuttal of the Warner–Jenkinson presumption” that a narrowing amendment was made for a substantial reason relating to patentability “is restricted to the evidence in the prosecution history record.” Festo IX, 344 F.3d at 1367 (citations omitted). But nothing in the prosecution history supports AbbVie and Besins's claim that the December 2001 amendment's purpose was to expedite prosecution. AbbVie and Besins cite the amendment's concluding sentence, which reads: “The Examiner is urged to call the undersigned with any questions or to otherwise expedite prosecution.” App. 1095 (emphasis added). But that boilerplate statement reveals nothing about the amendment's purpose. AbbVie and Besins also argue that even if the purpose to expedite prosecution did not appear in the prosecution history, it was clear “as a matter of law.” AbbVie Br. 48 n.3. This argument fails even as an argument “for the extension, modification, or reversal of existing *367 law.” PRE, 508 U.S. at 65, 113 S.Ct. 1920 (quoting FED. R. CIV. P. 11). As we have explained, the rule that a patentee's rebuttal of the Warner–Jenkinson presumption is restricted to the prosecution history is fundamental; it balances “the needs of patentees for adequate protection of their inventions” on the one hand, and “the needs of would-be competitors for adequate notice of the scope of that protection” on the other. Festo IX, 344 F.3d at 1385 (Newman, J., concurring in part, dissenting in part).

To the extent the prosecution history reveals the December 2001 amendment's purpose, it shows the amendment related to patentability. In June 2001, the patent examiner rejected the application's claim 1. In October 2001, AbbVie and Besins unsuccessfully tried to overcome the rejection by amending the application. Their attorneys then had an interview with the patent examiner in which she opined that the application's claims to isopropyl myristate were allowable over the prior art. As the District Court found, these facts were “a telling signal to any reasonable person that patentability required the narrowing of any claim so that it disclosed isopropyl myristate at a particular concentration as the sole penetration enhancer.” AbbVie, 2017 WL 4098688, at *11. AbbVie and Besins followed that signal in their December 2001 amendment: in the amendment's conclusion—immediately before the boilerplate discussed above—they sought “reconsideration and withdrawal of the outstanding rejections and allowance of the ... claims.” App. 1095. (emphasis added).

AbbVie and Besins also argue the rationale for the December 2001 amendment was to overcome Mak's use of oleic acid, so it was tangential to isostearic acid. That argument contradicts the prosecution history. AbbVie and Besins narrowed their claims to exclude oleic acid in October 2001, so that could not have been the purpose of the December 2001 amendment.

AbbVie and Besins counter that the District Court erred by “assessing ... whether [they] had a winning case against Perrigo” instead of whether a reasonable litigant would believe it had a chance of winning. AbbVie Br. 50. We disagree. While the Court did assess whether they had a winning case, it also assessed whether a reasonable litigant would believe it had a chance of winning. See AbbVie, 2017 WL 4098688, at *9 (“[A]ny reasonable person who reads the prosecution history of the `894 patent can reach no other conclusion than that the defendants have purposefully and not tangentially excluded ... isostearic acid.”).
Finally, AbbVie and Besins argue “[t]he favorable settlements [they] obtained in both suits foreclose the proposition that no reasonable person could have perceived a chance of success for the infringement claims.” AbbVie Br. 50–51. They note Perrigo agreed to “continued market exclusivity for AndroGel until late 2014—‘far beyond the maximum 30-month Hatch-Waxman stay[ ]’ that would have applied had the lawsuits continued.” Id. at 51. We think that, ordinarily, settlement on terms favorable to a plaintiff suggests a suit is not objectively baseless. See, e.g., Theme Promotions, Inc. v. News Am. Mktg. FSI, 546 F.3d 991, 1008 (9th Cir. 2008); New W., L.P. v. City of Joliet, 491 F.3d 717, 722 (7th Cir. 2007). But that is not the situation here. To start, the settlement with Perrigo was not especially favorable to AbbVie and Besins. AbbVie paid Perrigo $2 million as reasonable litigation expenses and agreed to let Perrigo enter the market for AndroGel at the same time as Teva—almost six years before the ’894 patent expired. Even if the settlement was favorable, however, that is not dispositive, *368 since the record is clear that Perrigo did not settle because it doubted its litigation position. In Perrigo’s paragraph IV notice, it opined that “a lawsuit asserting the ’894 patent ... would be objectively baseless and a sham, brought in bad faith for the improper purpose of, inter alia, delaying Perrigo’s NDA approval.” AbbVie, 329 F. Supp. 3d at 114. And Perrigo’s assistant general counsel estimated it had a 75 percent chance of victory, which, given the uncertainties inherent in litigation, is a strong probability. Thus, as the District Court found, Perrigo settled for reasons “independent of the merits of [AbbVie and Besins’s] claims,” including especially the cost of litigating. Id. at 123.

Thus, the District Court did not err in concluding AbbVie and Besins’s suit against Perrigo was objectively baseless.

3. The District Court did not err in concluding AbbVie and Besins's suit against Perrigo met sham litigation's subjective motivation prong.

The District Court’s evaluation of the subjective motivation prong of the sham litigation test required it to make findings of fact. We review those factual findings under the deferential clear-error standard. See VICI Racing, LLC v. T-Mobile USA, Inc., 763 F.3d 273, 282–83 (3d Cir. 2014). A finding is clearly erroneous when “although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed.” United States v. U.S. Gypsum Co., 333 U.S. 364, 395, 68 S.Ct. 525, 92 L.Ed. 746 (1948). “Where there are two permissible views of the evidence, the factfinder’s choice between them cannot be clearly erroneous.” Anderson v. City of Bessemer City, N.C., 470 U.S. 564, 574, 105 S.Ct. 1504, 84 L.Ed.2d 518 (1985) (citations omitted). Clear error review exists to prevent a reviewing court from “overstep[ping] the bounds of its duty ... [by] duplicat[ing] the role of the lower court.” Id. at 573, 105 S.Ct. 1504 (citing FED. R. CIV. P. 52(a)).

The District Court ruled the FTC “must prove [by clear and convincing evidence] that defendants had actual knowledge that the patent infringement suits here were baseless.” AbbVie, 329 F. Supp. 3d at 120.3 In support, it cited City of Columbia v. Omni Outdoor Advertising, Inc., 499 U.S. 365, 111 S.Ct. 1344, 113 L.Ed.2d 382 (1991), in which the Supreme Court said “[a] classic example [of sham litigation] is the filing of frivolous objections to the license application of a competitor, with no expectation of achieving denial of the license but simply in order to impose expense and delay.” Id. at 380, 111 S.Ct. 1344 (emphasis added).

The District Court then determined certain evidence submitted to show AbbVie and Besins's knowledge was not probative. This evidence included: (1) Solvay's 2009 press release, because “[n]one of the in-house AbbVie attorneys identified as the decision-makers regarding the 2011 suit[ ] *369 against ... Perrigo was previously employed by Solvay or Unimed,” AbbVie, 329 F. Supp. 3d at 121; (2) business planning documents, because “none of the[ ] documents ... was created by or influenced anyone who played a role in the decision[ ] to sue ... Perrigo,” id. at 122; (3) the settlement agreements, because “[p]arties often settle litigation for a variety of reasons independent of the merits of the claims,” id. at 123; and (4) AbbVie’s citizen petitions, because the petitions “were [all] found to be at least partially meritorious,” id. 4
Finally, the Court “zoom[ed] in on the individuals at AbbVie and Besins who made the decision[ ] to file the infringement action[ ] against ... Perrigo [to] discern what these individuals knew.” Id. at 123–24. Because AbbVie and Besins invoked attorney-client privilege and the attorney work product doctrine, the trial produced “no direct evidence of [these individuals’] subjective intent.” Id. at 125. The Court refused to draw any negative inference as a result. See id. Instead, it considered “the surrounding circumstances and the natural and probable consequences of [AbbVie and Besins's] knowing acts.” Id. The Court considered two pieces of circumstantial evidence. First, because AbbVie and Besins's decisionmakers were all “very experienced patent attorneys” who had reviewed Perrigo's paragraph IV notices and consulted outside counsel, they knew the lawsuit against Perrigo was objectively baseless. Id. at 126. And second, the decisionmakers—some of whom were long-time employees—“knew the extensive financial benefits to [AbbVie and Besins] if generic versions of AndroGel were kept or delayed from entry into the market.” Id. The Court concluded “[t]he only reason for the filing of these lawsuits was to impose expense and delay on ... Perrigo so as to block [its] entry into the TTRT market.” Id.

AbbVie and Besins argue the District Court erred by merging sham litigation's objective baselessness and subjective motivation prongs. They claim “the relevant inquiry under the subjective element [is] whether [the] decisionmakers actually believed the lawsuits had no possibility of success” and were therefore “subjective[ly] baseless[ ].” AbbVie Br. 56.

The FTC counters that the District Court required it to prove more than was necessary, because the subjective inquiry “has nothing to do with what a litigant knew or should have known regarding the merits of its claims.” FTC Resp. Br. 57 (quoting Kilopass Tech., Inc. v. Sidense Corp., 738 F.3d 1302, 1313 (Fed. Cir. 2013)). Instead, the FTC argues, what matters is the intent to “thwart competition.” Id. (citing Octane Fitness, 572 U.S. at 556, 134 S.Ct. 1749).

We agree with the FTC that the District Court applied an improper legal standard. The ultimate inquiry under sham litigation's subjective prong is a defendant's subjective motivation, not its subjective belief about the merits of its claims. See PRE, 508 U.S. at 60–61, 113 S.Ct. 1920; Octane Fitness, 572 U.S. at 556, 134 S.Ct. 1749. Thus, the term “subjective baselessness” is a misnomer. That said, we disagree that the inquiry into a defendant's motivation has “nothing to do” with a defendant's belief about the merits of its claims. But cf. Kilopass, 738 F.3d at 1313. Evidence that a defendant knew its claims were meritless may help a plaintiff *370 to show a defendant was “indifferent to the outcome on the merits of the ... suit” and “decided to sue primarily for the benefit of collateral injuries inflicted through the use of legal process.” PRE, 508 U.S. at 65, 113 S.Ct. 1920 (citation omitted). It is therefore unsurprising that evidence of a defendant's belief about the merits of its claims appears in a “classic example” of sham litigation, Omni, 499 U.S. at 380, 111 S.Ct. 1344, or that it appeared in this case. So while evidence of a defendant's belief about the merits of its claims may be relevant to determining a defendant's motivation, it is not required in every case. In short, a defendant can be ambivalent about the merits while filing litigation for an improper purpose (i.e., in bad faith).

We also reject AbbVie and Besins's argument that the District Court improperly merged sham litigation's objective baselessness and subjective motivation prongs. That argument assumes the two prongs are distinct, but they are interrelated. To see how, consider the following syllogism: (1) A lawsuit is objectively baseless if “no reasonable litigant could realistically expect success on the merits,” PRE, 508 U.S. at 60, 113 S.Ct. 1920; (2) and a litigant who files an objectively baseless lawsuit must have had some subjective motivation for suing; (3) but because the lawsuit was objectively baseless, the litigant's subjective motivation could not have been success on the merits, unless the litigant was unreasonable; (4) thus, a reasonable litigant's subjective motivation for filing an objectively baseless lawsuit must be something besides success on the merits. The District Court merely applied this syllogism. It first held that AbbVie and Besins's lawsuits were objectively baseless. It then reasoned that because AbbVie and Besins's decisionmakers were all very experienced patent attorneys who had reviewed Perrigo's paragraph IV notices and consulted outside counsel, they knew the lawsuits were baseless. Finally, it reasoned that because the decisionmakers knew the lawsuits were baseless, they must have been motivated by something other than success on the merits. The District Court's logic is valid.
AbbVie and Besins respond that, under the District Court's analysis, “in virtually every Hatch-Waxman suit in which a court finds objective baselessness, a finding of subjective baselessness would necessarily follow.” AbbVie Br. 57. Not so. The syllogism the Court applied establishes only that a reasonable litigant's subjective motivation must have been something besides success on the merits. It does not necessarily follow that the motivation was to thwart competition. For example, a company might file an objectively baseless lawsuit because it subjectively (though unreasonably) expected the lawsuit to succeed. In that case, a finding of “subjective baselessness” would not necessarily follow from a finding of objective baselessness.

AbbVie and Besins next argue that the circumstantial evidence the Court considered was insufficient to establish the subjective motivation prong by clear and convincing evidence, especially given the presumption that “the assertion of a duly granted patent is made in good faith.” AbbVie Br. 56 (quoting *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1369 (Fed. Cir. 1998)).

We disagree. Because AbbVie and Besins invoked attorney-client privilege and the attorney work product doctrine, the Court properly considered the surrounding circumstances and the natural and probable consequences of AbbVie and Besins' intentional acts to make its findings. *Cf. Howard Hess Dental Labs. Inc. v. Dentsply Intern., Inc.*, 602 F.3d 237, 257–58 (3d Cir. 2010) (“Specific intent in the antitrust context may be inferred from a defendant's unlawful conduct.”) (citing *Advo, Inc. v. Phila. Newspapers, Inc.*, 51 F.3d 1191, 1199 (3d Cir. 1995)). The Court noted that AbbVie and Besins' decisionmakers were all experienced patent attorneys who had reviewed Perrigo's paragraph IV notices and consulted outside counsel. They also knew the extensive financial benefits AbbVie and Besins would receive if generic versions of AndroGel were kept or delayed from entry into the market. Especially given the collateral injury the Hatch-Waxman Act's 30-month stay invariably inflicts, the Court was permitted to conclude from this evidence that in filing an objectively baseless lawsuit against Perrigo, the decisionmakers were motivated not to assert a patent in good faith, but to impose expense and delay on Perrigo to delay its entry into the TTRT market. *Anderson*, 470 U.S. at 574, 105 S.Ct. 1504.

Besins lastly argues the District Court clearly erred because the FTC presented “no evidence” about “who in 2011 were the decisionmakers at Besins ... and what those people knew.” Besins Br. 14. It also argues the trial testimony “neither addressed nor established who made the 2011 decisions to sue. Nor did the FTC ask [Besin's in-house counsel] MacAllister who at Besins made those decisions.” *Id.* at 15.

The District Court did not clearly err. MacAllister testified at trial that: he is a former patent examiner; he was “the highest ranking attorney in-house at Besins,” App. 3672; he “oversaw the global intellectual property group,” *id.*; and he “advised on litigations concerning Besins’ patents,” App. 3673. An attorney for the FTC asked MacAllister whether he was “involved in the decision to file patent litigation against Perrigo in 2011.” App. 3690. He responded that he conferred with AbbVie's in-house counsel “related to the decision whether or not to proceed with the lawsuit,” and that Besins's outside counsel provided him and others with advice that “informed our decision as to whether or not to proceed with the lawsuit.” *Id.* It was “permissible” for the Court to conclude from this testimony that MacAllister decided to sue on Besins's behalf. *Anderson*, 470 U.S. at 574, 105 S.Ct. 1504.

Thus, the District Court did not err in concluding AbbVie and Besins' suit against Perrigo concealed an attempt to interfere directly with its business relationships, through the use of the governmental process—as opposed to the outcome of that process—as an anticompetitive weapon.

C. The District Court did not err in concluding AbbVie and Besins had monopoly power in the relevant market.

To prove monopolization, a plaintiff must establish that the defendant had monopoly power in the relevant market. *See Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 306–07 (3d Cir. 2007). Monopoly power is “the ability to control prices and exclude competition in a given market.” *Id.*

2020-2 Trade Cases P 81,393

The FTC relied on indirect evidence to establish AbbVie's monopoly power. “To support a claim of monopoly power through indirect evidence, [a plaintiff] must show that (1) [d]efendants had market power in the relevant market and (2) that there were barriers to entry into the market.” Mylan, 838 F.3d at 435. Market power is “the ability to raise prices above those that would otherwise prevail in a competitive market.” Gordon v. Lewistown Hosp., 423 F.3d 184, 210 (3d Cir. 2005) (citation omitted). A court can infer market power from a market share significantly greater than 55 percent. See Dentsply, 399 F.3d at 187. “Other germane factors include the size and strength of competing firms, freedom of entry, pricing *372 trends and practices in the industry, ability of consumers to substitute comparable goods, and consumer demand.” Id. A defendant's ability to maintain market share is also relevant. See id. at 188–89 (citing United States v. Syufy Enters., 903 F.2d 659, 665–66 (9th Cir. 1990)). Barriers to entry include “regulatory requirements, high capital costs, or technological obstacles, that prevent new competition from entering a market in response to a monopolist's supracompetitive prices.” Broadcom Corp., 501 F.3d at 307.

The parties agreed that the relevant geographic market is the United States, so the District Court had to define only the product market.

To determine if two products are in the same market, we ask if they are readily substitutable for one another, an inquiry that requires us to assess the reasonable interchangeability of use between a product and its substitute. We also look to their cross-elasticity of demand, which is defined as a relationship between two products, usually substitutes for each other, in which a price change for one product affects the price of the other.

Mylan, 838 F.3d at 435–36 (internal quotation marks, citations, and alterations omitted); see also SmithKline Corp. v. Eli Lilly & Co., 575 F.2d 1056, 1064 (3d Cir. 1978) (requiring “significant” cross-elasticity of demand).

The District Court defined the product market as “the market for all TTRTs, that is all transdermal testosterone replacement therapies within the United States.” AbbVie, 329 F. Supp. 3d at 134. It found that all TTRTs were “reasonably interchangeable” and exhibited cross-elasticity of demand. See id. at 131–32. By contrast, in considering the market for TTRTs and injectables, the Court found that while TTRTs were reasonably interchangeable with injectables, they exhibited “little cross-elasticity of demand.” Id. at 133. It relied on the following evidence:

• Injectables are much cheaper than AndroGel, yet AbbVie has “consistently raised AndroGel's wholesale acquisition cost.”

• AbbVie executive James Hynd testified that AbbVie does not price AndroGel against injectables and did not offer rebates to match the price of injectables.

• AndroGel's Director of Marketing Frank Jaeger testified that AbbVie did not consider injectables to be competition. He identified other TTRTs “such as Axiron, Fortesta, and Testim as AndroGel's competitors.”

Id. The Court discounted an internal AbbVie document stating that a rise in AndroGel's copay was correlated with an increase in injectables’ sales. It explained that factors besides price drove the correlation, including “patient preference, the existence of specialized testosterone clinics, and the disproportionate negative publicity testosterone gels received after reports associating TTRTs with heightened cardiovascular risk.” Id. For the same reason, the Court also discounted a “patient switching study” that AbbVie and Besins's expert conducted. See id.
The District Court also found that AbbVie and Besins had “a dominant share of the TTRT market in the relevant period and that significant barriers existed for entry into that market.” *Id.* at 136. It relied on the following evidence in finding that AbbVie and Besins had a dominant share:

- “In the TTRT market, AndroGel was by far the most-prescribed product and was widely-recognized as the ‘market leader’ from before 2011 through 2014.”

- In April 2011 (when AbbVie and Besins sued Teva), AndroGel's share of the TTRT market was 71.5 percent. In October 2011 (when they sued Perrigo), AndroGel's share was 63.6 percent. AndroGel's share “remained above 60[ percent] until the end of 2014, when Perrigo's generic 1% testosterone product entered the market.”

- No other TTRT product ever held 10 percent or more of the market during this period, and AndroGel's market share was always more than three times larger than the market share of any of its brand-name competitors.

- “AbbVie was able to maintain its share of the TTRT market with a profit margin of over 65[ percent]” during this period, “even with huge rebates.”

- AbbVie increased the wholesale acquisition cost for AndroGel during this period.

*Id.* at 134–35. Finally, the Court found significant barriers to entry because “a generic drug has significant capital, technical, regulatory, and legal barriers to overcome.” *Id.* at 135–36. It explained that, although three brand-name TTRT products (i.e., Fortesta, Axiron, and Vogelxo) entered the market between 2011 and 2014, “they did not pose significant competition to [AbbVie and Besins's] monopolistic conduct” because they held a low market share. *Id.* at 136.

AbbVie and Besins claim the District Court clearly erred by excluding injectables from the product market for two reasons. First, the record contained “voluminous evidence, including expert testimony, showing substantial cross-elasticity between topical TRTs and injectables.” *AbbVie* Br. 64. And second, the FTC's expert conceded “some cross-elasticity ... between AndroGel and injectables” and “presented no cross-elasticity study to support” the market the Court defined. *Id.* at 64–65, 113 S.Ct. 1920 (citation omitted). In sum, AbbVie and Besins argue that the Court “defined the relevant antitrust market in terms no expert had endorsed.” *Id.* at 29, 117 S.Ct. 1040.

We disagree for several reasons. First, the mere fact that the record contained evidence tending to show substantial cross-elasticity between topical TRTs and injectables does not mean the Court clearly erred. AbbVie employees conceded at trial that AndroGel does not compete against injectables, so it was at least “permissible” for the Court to exclude injectables from the product market. *Anderson*, 470 U.S. at 574, 105 S.Ct. 1504. Second, while the FTC's expert conceded *some* cross-elasticity between AndroGel and injectables, he did not concede *significant* cross-elasticity, which is required to find clear error. *See SmithKline Corp.*, 575 F.2d at 1064. Finally, the FTC's expert did study whether AndroGel and injectables exhibited cross-elasticity of demand. App. 3862 (“I looked at the data on what happened over time to a number of injectable prescriptions and looked to see whether significant changes in the price of the transdermal products, whether we could see an effect on injectables ... [The data] indicates a low cross-elasticity of demand between AndroGel and injectables ....”). While the expert did not “endorse” the market the Court ultimately defined, his testimony supported the Court's market definition, and the FTC argued for that definition in the alternative. App. 3491 (“[E]ven if the relevant market included all other TRT products except injections, the market share has established that AndroGel still possessed monopoly power.”).

*AbbVie* and Besins also contend the District Court committed legal error by misapplying the legal standard as to the existence of market power and barriers to entry. They argue the Court gave dispositive weight to market share data and Hatch-Waxman's technical and regulatory requirements while ignoring real-world evidence. They emphasize that three new competing brand-name TTRTs entered the market between 2011 and 2014. We are unpersuaded.
The Court did not give dispositive weight to market share data; it also considered consumer demand for AndroGel, the durability of AndroGel's market share, the size and strength of AndroGel's competitors, and AndroGel's pricing trends and practices. See Dentsply, 399 F.3d at 187–89 (explaining these are relevant factors). And the Court did not ignore new entrants; it explained the three brand-name TTRT products that entered the market between 2011 and 2014 were not meaningful competitors to AndroGel because of their modest market shares. So the District Court did not err in concluding AbbVie and Besins had monopoly power in the relevant market.

For all the reasons stated, we hold the District Court erred by rejecting the reverse-payment theory and in concluding AbbVie and Besins's litigation against Teva was a sham. We also hold that the Court did not err when it concluded the Perrigo litigation was a sham and that AbbVie and Besins had monopoly power in the relevant market.

V. REMEDIES

We turn finally to remedial issues. The District Court erred in requiring AbbVie and Besins to disgorge $448 million because district courts lack the power to order disgorgement under Section 13(b) of the FTC Act. But it did not abuse its discretion in denying injunctive relief. Nor is it futile to remand the reverse-payment theory.

A. The District Court erred in ordering disgorgement.

The District Court ordered AbbVie and Besins to disgorge $448 million in ill-gotten profits. It reasoned “[t]he weight of authority ... supports the conclusion that the grant of authority in section 13(b) to provide injunctive relief includes the full range of equitable remedies, including the power to order a defendant to disgorge illegally obtained funds.” AbbVie, 329 F. Supp. 3d at 137 (citation omitted). It also said a contrary interpretation would “eviscerate the FTC Act” because a monopolist would “be able to retain its ill-gotten gains and simply face an injunction against future wrongdoing.” Id.

Reviewing the District Court's interpretation de novo, see Kaufman v. Allstate N.J. Ins. Co., 561 F.3d 144, 151 (3d Cir. 2009), we conclude it erred in ordering disgorgement because district courts lack the power to do so under Section 13(b).

“The FTC has multiple instruments in its toolbox to combat unfair methods of competition” and unfair or deceptive acts or practices. FTC v. Shire ViroPharma, Inc., 917 F.3d 147, 155 (3d Cir. 2019). First is the FTC's “traditional enforcement tool,” Section 5 of the FTC Act. Id. (citing 15 U.S.C. § 45(b)). That section allows the FTC to initiate an administrative proceeding to obtain a cease-and-desist order against an unfair method of competition or an unfair or deceptive act or practice. See 15 U.S.C. § 45(b). The FTC can then sue in federal district court to get “limited monetary remedies” for violations of the order. Shire, 917 F.3d at 155. A respondent who violates an order is liable for no more than $10,000 per violation. See 15 U.S.C. § 45(l). The FTC can also seek “mandatory injunctions” and “such other and further equitable relief” as the court deems appropriate. Id. Violators other than the respondent are also liable for up to $10,000 per violation, but only if they violate the order knowingly. See id. § 45(m)(1)(A).

Second, under Section 19 of the FTC Act, the FTC can promulgate “rules which define with specificity acts or practices which are unfair or deceptive.” Id. § 57a(a)(1)(B). Alternatively, it can initiate an administrative proceeding to obtain a cease-and-desist order. Id. § 57a(a)(2). In either case, it can sue violators in federal district court. See id. § 57a(a)(1)–(2). If the FTC promulgated a rule, the court can “grant such relief as the court finds necessary to redress injury,” including but not limited to “the refund of money or return of property” and “the payment of damages.” Id. § 57b(b). Otherwise, the FTC can obtain such relief only if it shows “a reasonable man would have known under the circumstances” his conduct was “dishonest or fraudulent.” Id. § 57b(a)(2).
A third enforcement tool is Section 13(b) of the FTC Act. “Unlike Section 5, Section 13 was not part of the original FTC Act.” *Shire*, 917 F.3d at 155. “Rather, [it] was added later [in 1973] in an effort to solve one of the main problems of the FTC’s relatively slow-moving administrative regime—the need to quickly enjoin ongoing or imminent illegal conduct.” *Id.*

The question presented in this appeal is whether a district court has the power to order disgorgement under Section 13(b). We start with the text, for where “the words of the statute are unambiguous, the judicial inquiry is complete.” *Desert Palace, Inc. v. Costa*, 539 U.S. 90, 91, 123 S.Ct. 2148, 156 L.Ed.2d 84 (2003) (internal quotation marks and citation omitted). Section 13(b) states:

> Whenever the Commission has reason to believe—

(1) that any person, partnership, or corporation is violating, or is about to violate, any provision of law enforced by the Federal Trade Commission, and

(2) that the enjoining thereof pending the issuance of a complaint by the Commission and until such complaint is dismissed by the Commission or set aside by the court on review, or until the order of the Commission made thereon has become final, would be in the interest of the public—

the Commission by any of its attorneys designated by it for such purpose may bring suit in a district court of the United States to enjoin any such act or practice. Upon a proper showing that, weighing the equities and considering the Commission’s likelihood of ultimate success, such action would be in the public interest, and after notice to the defendant, a temporary restraining order or a preliminary injunction may be granted without bond: *Provided, however,* That if a complaint is not filed within such period (not exceeding 20 days) as may be specified by the court after issuance of the temporary restraining order or preliminary injunction, the order or injunction shall be dissolved by the court and be of no further force and effect: *Provided further,* That in proper cases the Commission may seek, and after proper proof, the court may issue, a permanent injunction.

15 U.S.C. § 53(b). Section 13(b) authorizes a court to “enjoin” antitrust violations. It says nothing about disgorgement, which is a form of restitution, see *Liu v. SEC*, --- U.S. ----, 140 S. Ct. 1936, 1940–41, 207 L.Ed.2d 401 (2020), not injunctive relief, see, e.g., *Meghrig v. KFC W., Inc.*, 516 U.S. 479, 484, 116 S.Ct. 1251, 134 L.Ed.2d 121 (1996) (“[N]either a mandatory nor prohibitory injunction] contemplates the award of ... ‘damages’ or ‘equitable restitution.’” *376*); *Owner-Operator Indep. Drivers Ass’n v. Landstar Sys., Inc.*, 622 F.3d 1307, 1324 (11th Cir. 2010) (“Injunctive relief constitutes a distinct type of equitable relief; it is not an umbrella term that encompasses restitution or disgorgement.”). Thus, Section 13(b) does not explicitly empower district courts to order disgorgement.

This interpretation is even stronger in context. Section 13(b) says that, in order to sue, the FTC must have reason to believe an antitrust violation is imminent or ongoing. See *Shire*, 917 F.3d at 156 (holding requirement applies to request for permanent injunction). This requirement makes perfect sense as applied to injunctive relief, which prevents or mandates a future action. See *Injunction*, BLACK’S LAW DICTIONARY (rev. 4th ed. 1968). So if a violator's conduct is neither imminent nor ongoing, there is nothing to enjoin, and the FTC cannot sue under Section 13(b). By contrast, the requirement makes little sense as applied to a disgorgement remedy. Disgorgement deprives a wrongdoer of past gains, see *Liu*, 140 S. Ct. at 1940–41, meaning that even if a wrongdoer's conduct is not imminent or ongoing, he may have gains to disgorge. If Congress contemplated the FTC could sue for disgorgement under Section 13(b), it probably would not have required the FTC to show an imminent or ongoing violation. That requirement suggests Section 13(b) does not empower district courts to order disgorgement.

The FTC’s other enforcement powers also support our interpretation. Both distinguish between injunctions and other forms of equitable relief. See 15 U.S.C. § 45(l) (FTC can seek “mandatory injunctions” and “such other and further equitable relief” as the court deems appropriate); *Id.* § 57b(b) (court can “grant such relief as the court finds necessary to redress injury,” including
but not limited to “the refund of money or return of property” and “the payment of damages”). The timing of the enactment of these powers is also instructive. Congress amended Section 5 to allow “such other and further equitable relief” at the same time it enacted Section 13(b). See Trans-Alaska Pipeline Authorization Act, Pub. L. No. 93-153, § 408, 87 Stat. 576, 591 (1973). And it enacted Section 19—which allows disgorgement only under certain conditions—after Section 13(b). See Magnuson-Moss Warranty Act, Pub. L. No. 93-637, § 206, 88 Stat. 2183, 2201–02 (1975). Thus, Sections 5 and 19 both show that when Congress wants to empower a district court to order more expansive equitable relief than injunctions, it does so. Yet Congress did not do so in Section 13(b).

A contrary conclusion would undermine the FTC Act's statutory scheme. Section 13(b) was added in 1973 because the FTC’s administrative regime moved slowly. See Shire, 917 F.3d at 155. But it is slow-moving for a reason: it affords defendants valuable procedural protections. For example, Section 5 conditions relief to defendants on an administrative proceeding and a cease-and-desist order. See 15 U.S.C. § 45(b). It also limits the monetary relief the FTC can obtain. See 15 U.S.C. § 45(l); see also id. § 45(m)(1)(A). Section 19 likewise requires the FTC to promulgate “rules which define with specificity acts or practices which are unfair,” or initiate an administrative proceeding to obtain a cease-and-desist order. Id. § 57a(a)(1)(B)–(2). By contrast, Section 13(b) does not incorporate these same protections: it grants the FTC a cause of action to seek a preliminary injunction in federal court without first pursuing administrative adjudication or rulemaking; and it imposes no limits on the amount of any monetary relief the FTC may be able to obtain. Thus, our interpretation does not “eviscerate” the FTC Act; it harmonizes its provisions.

The FTC counters that Section 19 has a savings clause. That clause states: “Remedies provided in this section are in addition to, and not in lieu of, any other remedy or right of action provided by State or Federal law. Nothing in this section shall be construed to affect any authority of the Commission under any other provision of law.” 15 U.S.C. § 57b(e). But “[t]he saving clause preserves only those remedies that exist. It does not inform the question whether section 13(b) contains an implied power to award restitution.” FTC v. Credit Bureau Ctr., LLC, 937 F.3d 764, 775 (7th Cir. 2019).

The FTC argues the interpretation we adopt goes against the weight of precedent. It notes that seven of our sister courts have held courts may order disgorgement under Section 13(b), and we acknowledged as much in the footnote of a not-precedential decision. FTC Reply Br. 88 (quoting FTC v. Magazine Sols., LLC, 432 F. App'x 155, 158 n.2 (3d Cir. 2011)). That is true, but until recently, “[n]o circuit ha[d] examined whether reading a restitution remedy into section 13(b) comports with the FTCA’s text and structure.” Credit Bureau, 937 F.3d at 785 (describing the precedents); see also id. (quoting United States v. Hill, 48 F.3d 228, 232 (7th Cir. 1995) (“We are not merely to count noses. The parties are entitled to our independent judgment.”)). Moreover, today’s result is consistent with the recent ruling of the United States Court of Appeals for the Seventh Circuit, which, in a thorough and well-reasoned opinion, overturned its precedent authorizing restitution under Section 13(b). Credit Bureau Center, 937 F.3d at 764; see also FTC v. AMG Capital Mgmt., LLC, 910 F.3d 417, 429 (9th Cir. 2018) (O’Scannlain, J., specially concurring). Finally, our decision in Magazine Solutions does not bind us. See I.O.P. 5.7. Even if it did, the part of the footnote on which the FTC relies was dictum because the litigant forfeited the issue by failing to raise it in the district court. See 432 F. App’x at 158 n.2.

Next, the FTC argues Congress has “twice ratified the consistent understanding of the courts of appeals”—first in 1994, when Congress expanded the venue and service-of-process provisions of Section 13(b), see FTC Act Amendments of 1994, Pub. L. No. 103-312, § 10, 108 Stat. 1691, 1695–96 (1994); and second in 2006, when Congress made “[a]ll remedies available to the Commission ... including restitution to domestic or foreign victims” available for certain unfair practices abroad, see U.S. Safe Web Act of 2006, Pub. L. No. 109-455, § 3, 120 Stat. 3372, 3372 (2006) (amending 15 U.S.C. § 45(a)(4)(B)) (emphasis added). FTC Reply Br. 93. We disagree. The 1994 amendment did not change the remedies available to the Commission. So it can hardly be seen as ratifying our sister courts’ precedents on that issue. And the 2006 amendment’s reference to restitution does not mean restitution is available under Section 13(b); the availability of restitution under Sections 5 and 19 is well-settled, and the amendment could have referred to those sections instead.
The crux of the FTC's counterargument is a pair of Supreme Court decisions on which our sister courts and the District Court relied—Porter v. Warner Holding Co., 328 U.S. 395, 398, 66 S.Ct. 1086, 90 L.Ed. 1332 (1946), and Mitchell v. Robert DeMario Jewelry, Inc., 361 U.S. 288, 80 S.Ct. 332, 4 L.Ed.2d 323 (1960). According to the FTC, these decisions mean Section 13(b)’s use of the word “injunction” impliedly empowers district courts to order equitable relief in addition to injunctions. Once again, we disagree.

*378 In Porter, the Supreme Court held a district court could order restitution under the Emergency Price Control Act of 1942, which authorized the Administrator of the Office of Price Administration to seek “a permanent or temporary injunction, restraining order, or other order” in court. 328 U.S. at 397, 66 S.Ct. 1086 (emphasis added). The Court reasoned:

Unless otherwise provided by statute, all the inherent equitable powers of the District Court are available for the proper and complete exercise of that jurisdiction. And since the public interest is involved ..., those equitable powers assume an even broader and more flexible character than when only a private controversy is at stake. Power is thereby resident in the District Court, in exercising this jurisdiction to do equity and to mould each decree to the necessities of the particular case. It may act so as ... to accord full justice to all the real parties in interest .... In addition, the court may ... give whatever other relief may be necessary under the circumstances. Only in that way can equity do complete rather than truncated justice.

Moreover, the comprehensiveness of this equitable jurisdiction is not to be denied or limited in the absence of a clear and valid legislative command. Unless a statute in so many words, or by a necessary and inescapable inference, restricts the court's jurisdiction in equity, the full scope of that jurisdiction is to be recognized and applied.

Id. at 398, 66 S.Ct. 1086 (internal citations and quotations omitted). The Court concluded that “the term ‘other order’ contemplates a remedy other than that of an injunction or restraining order, a remedy entered in the exercise of the District Court's equitable discretion.” Id. at 399, 66 S.Ct. 1086. It noted that no “other provision of the Act ... expressly or impliedly precludes a court from ordering restitution.” Id. at 403, 66 S.Ct. 1086.

In Mitchell, the Supreme Court extended Porter. The Court held a district court could order wage reimbursement under the Fair Labor Standards Act, which gave courts jurisdiction “to restrain violations” of the Act. Mitchell, 361 U.S. at 289, 80 S.Ct. 332. The Court said:

When Congress entrusts to an equity court the enforcement of prohibitions contained in a regulatory enactment, it must be taken to have acted cognizant of the historic power of equity to provide complete relief in light of the statutory purposes. As this Court long ago recognized, there is inherent in the Courts of Equity a jurisdiction to ... give effect to the policy of the legislature.

Id. at 291–92, 80 S.Ct. 332 (alteration in original) (citation and internal quotations omitted). It was immaterial that the Act lacked language, like “other order” in Porter, that confirmed the court's power to order reimbursement. See id. at 291, 80 S.Ct. 332 (citations omitted).

We interpreted Porter and Mitchell in United States v. Lane Labs-USA Inc., 427 F.3d 219 (3d Cir. 2005). There, we held a court could order restitution under the FDC Act in part because the Act empowered district courts to “restrain violations.” See id. at 223; 21 U.S.C. § 332(a). We explained Porter and Mitchell “charted an analytical course that seems fairly easy to follow: (1) a district court sitting in equity may order restitution unless there is a clear statutory limitation on the district court's equitable jurisdiction and powers; and (2) restitution is permitted only where it furthers the purposes of the statute.” Id. at 225.
We noted “[n]umerous courts have followed this approach in opining about a court's power to order ... disgorgement under several different statutes.” *Id.* In support, we cited, among other authorities, *a decision holding disgorgement is available under Section 13(b).* See *id.* (citing FTC v. Gem Merch. Corp., 87 F.3d 466, 470 (11th Cir. 1996)).

Following the analytical course that *Lane Labs* described, we conclude Section 13(b) does not implicitly empower district courts to order disgorgement. Unlike the statutes at issue in *Porter, Mitchell*, and *Lane Labs*, Section 13(b) limits the district court's equitable jurisdiction and powers because it specifies the form of equitable relief a court may order. *Compare Porter, 328 U.S. at 397–98, 66 S.Ct. 1086 (“a permanent or temporary injunction, restraining order, or other order” in court), Mitchell, 361 U.S. at 289, 80 S.Ct. 332 (“restrain violations”), and Lane Labs, 427 F.3d at 223 (same) with 15 U.S.C. § 53(b) (“enjoin”). Moreover, as we have explained, the context of Section 13(b) and the FTC Act's broader statutory scheme both support “a necessary and inescapable inference” that a district court's jurisdiction in equity under Section 13(b) is limited to ordering injunctive relief. *Porter, 328 U.S. at 398, 66 S.Ct. 1086.* So our interpretation is consistent with *Lane Labs* and faithful to *Porter* and *Mitchell*.

The FTC counters that in *Lane Labs*, we cited *Gem Merchandising*, which held disgorgement is available under Section 13(b). But we cited that case solely to support our approach to applying *Porter* and *Mitchell*, and the other cases we cited involved three different statutes. *Lane Labs, 427 F.3d at 225.* We were not interpreting statutes en masse.

For these reasons, we hold district courts lack the power to order disgorgement under Section 13(b) of the FTC Act. So the District Court erred in requiring AbbVie and Besins to disgorge $448 million.

**B. The District Court did not abuse its discretion in denying injunctive relief.**

To obtain an injunction, the FTC must show there is a “cognizable danger of recurrent violation, something more than the mere possibility which serves to keep the case alive.” *United States v. W.T. Grant Co.*, 345 U.S. 629, 633, 73 S.Ct. 894, 97 L.Ed. 1303 (1953). An injunction that implicates a defendant's First Amendment rights must “burden no more speech than necessary to serve a significant government interest.” *Madsen v. Women's Health Ctr., Inc.*, 512 U.S. 753, 765, 114 S.Ct. 2516, 129 L.Ed.2d 593 (1994) (citations omitted).

The FTC sought an injunction:

(1) to prohibit the filing of any claims of patent infringement based on the '894 patent by a product that does not include about 0.1% to about 5% isopropyl myristate; (2) to prohibit defendants from filing any other sham litigation; (3) to prohibit defendants from engaging in any action that misuses government processes for anticompetitive purposes; and (4) to require defendants to certify that any patent infringement litigation or other use of governmental processes has an objectively reasonable basis.

*AbbVie, 329 F. Supp. 3d at 144.* It also sought an injunction to “restore competitive market conditions” by compelling AbbVie and Besins to license AndroGel 1.62% to one or more generic competitors, and to sell them a supply of the gel until they could manufacture it themselves. *Id. at 145.* At oral argument on appeal, the FTC stated that because the '894 patent would soon expire, on remand it would not seek to prohibit the filing of patent infringement claims based on the '894 patent, Oral Argument January 15, 2020 at 19:15–35; however, it reaffirmed its interest *a certification requirement, id. at 15:05–17:55.*

The District Court found no basis on which to conclude AbbVie and Besins's sham litigations were likely to recur. It explained the FTC proved only “that defendants filed two sham infringement lawsuits,” which do not establish a “pattern or practice.” *Id.* And though the FTC advised the Court that since suing Teva and Perrigo in 2011, AbbVie and Besins have filed “numerous
other patent infringement suits against competitors, including seven lawsuits related to the '894 patent," the FTC presented no evidence those lawsuits were shams. See id. at 145 n.31. Moreover, the Court noted generic versions of AndroGel had been on the market for over three years. See id. at 145. Finally, the Court held that because the proposed injunction would have limited AbbVie and Besins's ability to file patent infringement suits with respect to any patent, it was so “overbroad and punitive” that it would violate their First Amendment rights. See id. (citing Madsen, 512 U.S. at 765, 114 S.Ct. 2516).

On appeal, the FTC argues the District Court abused its discretion because, under the likelihood-of-recurrence test that governs SEC cases, AbbVie and Besins are likely to engage in further sham litigation. FTC Br. 48–49 (citing SEC v. Bonastia, 614 F.2d 908, 912 (3d Cir. 1980)). The FTC also argues the Court's First Amendment concerns rested on a mischaracterization of the injunctive relief it requested. Although its “pretrial brief used broader language,” its proposed order did not seek to prohibit AbbVie and Besins from engaging in any action that misuses government processes. FTC Br. 52 n.13. In any event, the FTC argues its injunction is constitutional because the certification requirement and prohibition on sham litigation implicate no First Amendment rights. Id.

We disagree. Under Grant, the District Court had to determine whether the likelihood of AbbVie and Besins engaging in sham litigation was a cognizable danger or merely possible. See 345 U.S. at 633, 73 S.Ct. 894. Even resolving doubts in the FTC's favor, for the reasons the Court stated it was well within its discretion to conclude the FTC had shown a mere possibility.

Nor did the District Court abuse its discretion by failing to apply the Bonastia factors, which we have never applied in FTC Act cases. See 614 F.2d at 908. And we are disinclined to extend Bonastia here for two reasons. First, our review of the voluminous record on appeal did not uncover any indication the FTC argued the District Court should extend Bonastia outside the SEC context. To the contrary, the FTC's proposed findings of fact and conclusions of law relied solely on Grant, which the District Court applied. To the extent the FTC did not timely raise this argument in the District Court, it is forfeited on appeal. See In Re: J & S Props., LLC, 872 F.3d 138, 146 (3d Cir. 2017) (citing United States v. Joseph, 730 F.3d 336, 341–42 (3d Cir. 2013)).

Second, we would not find an abuse of discretion even if Bonastia applied. Under that decision, courts look to:


Bonastia, 614 F.2d at 912 (citation omitted). Although the Court did not recite these factors mechanically, its rationale accounted for the substance of all but the third and fourth. And the antitrust laws afford no relief on the basis of those factors alone. Cf. Howard Hess, 602 F.3d at 251 (citing Bonastia, 614 F.2d at 912).

Thus, the District Court did not abuse its discretion in denying injunctive relief.

C. Remand on the reverse-payment theory is not futile.

AbbVie and Besins argue that remand to allow the FTC to proceed on the reverse-payment theory would be futile for several reasons. None is persuasive.
2020-2 Trade Cases P 81,393

First, AbbVie and Besins argue the FTC will not be able to show they “[are] violating, or [are] about to violate” the antitrust laws. AbbVie Br. 91 (quoting 15 U.S.C. § 53(b)). But in Shire, we held that whereas Section 13(b) of the FTC Act requires a plaintiff to plead the defendant “is violating” or is “about to violate” the antitrust laws, the likelihood-of-recurrence standard “applies when a court is considering whether to grant or deny injunctive relief.” 917 F.3d at 158. Second, AbbVie and Besins argue disgorgement would be inappropriate, both because Section 13(b) does not authorize it and because the District Court found, in calculating the amount of disgorgement, that Teva would not have marketed its generic gel even without the sham litigation. See AbbVie, 329 F. Supp. 3d at 140 (“[T]he FTC has not established that, but for defendants’ sham litigation, Teva would have launched its product on June 2012 or at any time thereafter.”). We agree that disgorgement is inappropriate because Section 13(b) does not authorize it. But because we cannot say, based on the pleadings alone, that the Court would abuse its discretion by granting the FTC injunctive relief, remand is not futile. Consistent with our holding in Shire, the District Court should apply the likelihood-of-recurrence standard. See 917 F.3d at 158. Apart from that instruction, the District Court retains discretion to determine whether the FTC is entitled to an injunction if it ultimately succeeds on the reverse-payment theory.

Finally, at oral argument before our Court, counsel for AbbVie argued for the first time that the District Court's finding that Teva would not have marketed its generic gel without the sham litigation means that, on remand, the FTC will be unable to show antitrust injury, which is an element of every antitrust claim. See generally Wellbutrin, 868 F.3d at 164–65; Oral Arg. 29:10–36:25. Arguments not briefed are forfeited on appeal. See Griswold v. Coventry First LLC, 762 F.3d 264, 274 n.8 (3d Cir. 2014) (citation omitted). Regardless, we think that on remand, the Court must consider anew its finding that Teva would not have marketed its generic gel without the sham litigation. The FTC plausibly alleged AbbVie paid Teva a large, unjustified reverse payment to delay its entry into the market for AndroGel.

* * *

For the reasons stated, we will reverse the District Court's order granting the motion to dismiss Count I in part and to dismiss Count II. We will also affirm the Court's order adjudging AbbVie and Besins liable for monopolization under Count I based upon its holding that the suit against Perrigo was a sham. Finally, we will affirm the Court's order denying injunctive relief, reverse the Court's disgorgement order, and remand for further proceedings consistent with this opinion.

All Citations
976 F.3d 327, 2020-2 Trade Cases P 81,393

Footnotes
1 Judge Phipps would have accepted this argument and held we have jurisdiction because the patent-law issues the FTC's sham-litigation theory presents are not substantial.

2 It might be argued the patent-law issues Gunn presented are less substantial than the ones we face here because the patent litigation in Gunn led to the patent's invalidation, see id. at 255, 133 S.Ct. 1059, whereas the '894 patent has not been invalidated. Indeed, while the '894 patent expired on August 30, 2020, AbbVie and Besins may sue for infringement for up to six years after that date. See 35 U.S.C. § 286. We think this distinction is immaterial under Gunn, which emphasized that state-court adjudication of the legal malpractice claim would not change the result of the prior federal patent litigation, rather than emphasizing the result itself. See 568 U.S. at 261, 133 S.Ct. 1059.
In a footnote in its response brief, the FTC challenges the District Court's requirement of proof by clear-and-convincing evidence. We have not decided what standard of proof applies to sham litigation's subjective motivation prong. Cf. Wellbutrin, 868 F.3d at 148 n.18 (referencing the objective baselessness prong). But in discussing Noerr-Pennington cases involving Section 1983 claims, we have explained that a higher standard of proof is needed in Noerr-Pennington cases involving patent disputes. See Campbell v. Pa. Sch. Bd. Ass'n, 2020 WL 5049051, at *7 (3d Cir. 2020). We need not adopt that dicta today because “arguments raised in passing (such as, in a footnote), but not squarely argued,” are forfeited on appeal. John Wyeth & Bro. Ltd. v. CIGNA Intern. Corp., 119 F.3d 1070, 1076 n.6 (3d Cir. 1997).

AbbVie and Besins argue the District Court erred by not considering the business planning documents and settlement agreements. The FTC argues the Court erred by not considering Solvay's 2009 press release. The Court correctly concluded that none of this evidence is probative of the decisionmakers' subjective motivations.
Professional Real Estate Investors, Inc. v. Columbia Pictures..., 508 U.S. 49 (1993)
113 S.Ct. 1920, 123 L.Ed.2d 611, 61 USLW 4450, 1993-1 Trade Cases P 70,207...

113 S.Ct. 1920
Supreme Court of the United States

PROFESSIONAL REAL ESTATE INVESTORS, INC., et al., Petitioners

v.

COLUMBIA PICTURES INDUSTRIES, INC., et al.

No. 91–1043.


Synopsis
Movie studios brought copyright infringement action against hotel operators, challenging rental of videodiscs to hotel guests, and operators filed antitrust counterclaims. After grant of summary judgment for operators on infringement claim was affirmed on appeal, 866 F.2d 278, the United States District Court for the Central of California, William P. Gray, J., granted summary judgment for studios on counterclaim, and operators appealed. The Court of Appeals, 944 F.2d 1525, affirmed, and certiorari review was sought. The Supreme Court, Justice Thomas, held that objectively reasonable effort to litigate cannot be “sham,” within meaning of exception to Noerr doctrine immunity from antitrust liability, regardless of plaintiff's subjective intent.

Affirmed.

Justice Souter, concurred and filed opinion.

Justice Stevens, concurred in judgment and filed opinion in which Justice O'Connor, joined.

Procedural Posture(s): On Appeal; Motion for Summary Judgment.

Although those who petition government for redress are generally immune from antitrust liability, Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 81 S.Ct. 523, 5 L.Ed.2d 464, such immunity is withheld when petitioning activity “ostensibly directed toward influencing governmental action, is a mere sham to cover ... an attempt to interfere directly” with a competitor's business relationships, id., at 144, 81 S.Ct., at 533. Petitioner resort hotel operators (collectively, PRE) rented videodiscs to guests for use with videodisc players located in each guest's room and sought to develop a market for the sale of such players to other hotels. Respondent major motion picture studios (collectively, Columbia), which held copyrights to the motion pictures recorded on PRE's videodiscs and licensed the transmission of those motion pictures to hotel rooms, sued PRE for alleged copyright infringement. PRE counterclaimed, alleging that Columbia's copyright action was a mere sham that cloaked underlying acts of monopolization and conspiracy to restrain trade in violation of §§ 1 and 2 of the Sherman Act. The District Court granted summary judgment to PRE on the copyright claim, and the Court of Appeals affirmed. On remand, the District Court granted Columbia's motion for summary judgment on PRE's antitrust claims. Because Columbia had probable cause to bring the infringement action, the court reasoned, the action was no sham and was entitled to Noerr immunity. The District Court also denied PRE's request for further discovery on Columbia's intent in bringing its action. The Court of Appeals affirmed. Noting that PRE's sole argument was that the lawsuit was a sham because Columbia did not honestly believe its
infringement claim was meritorious, the court found that the existence of probable cause precluded the application of the sham exception as a matter of law and rendered irrelevant any evidence of Columbia's subjective intent in bringing suit.

Held:

1. Litigation cannot be deprived of immunity as a sham unless it is objectively baseless. This Court's decisions establish that the legality of objectively reasonable petitioning “directed toward obtaining governmental action” is “not at all affected by any anticompetitive purpose [the actor] may have had.” *50 Id., at 140, 81 S.Ct., at 531. Thus, neither Noerr immunity nor its sham exception turns on subjective intent alone. See, e.g., Allied Tube & Conduit Corp. v. Indian Head, Inc., 486 U.S. 492, 503, 108 S.Ct. 1931, 1938, 100 L.Ed.2d 497. Rather, to be a “sham,” litigation must meet a two-part definition. First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits. Only if challenged litigation is objectively meritless may a court examine the litigant's subjective motivation. Under this second part of the definition a court should focus on whether the baseless suit conceals “an attempt to interfere directly” with a competitor's business relationships, Noerr, supra, 365 U.S., at 144, 81 S.Ct., at 533, through the “use [of] the governmental process—as opposed to the outcome of that process—as an anticompetitive weapon,” Columbia v. Omni Outdoor Advertising, Inc., 499 U.S. 365, 380, 111 S.Ct. 1344, 1354, 113 L.Ed.2d 382. This two-tiered process requires a plaintiff to disprove the challenged lawsuit's legal viability before the court will entertain evidence of the suit's economic viability. Pp. 1925–1929.

2. Because PRE failed to establish the objective prong of Noerr's sham exception, summary judgment was properly granted to Columbia. A finding that an antitrust defendant claiming Noerr immunity had probable cause to sue compels the conclusion that a reasonable litigant in the defendant's position could realistically expect success on the merits of the challenged lawsuit. Here, the lower courts correctly found probable cause for Columbia's suit. Since there was no dispute over the predicate facts of the underlying legal proceedings—Columbia had the exclusive right to show its copyrighted motion pictures publicly—the court could decide probable cause as a matter of law. A court could reasonably conclude that Columbia's action was an objectively plausible effort to enforce rights, since, at the time the District Court entered summary judgment, there was no clear copyright law on videodisc rental activities; since Columbia might have won its copyright suit in two other Circuits; and since Columbia would have been entitled to press a novel claim, even in the absence of supporting authority, if a similarly situated reasonable litigant could have perceived some likelihood of success. Pp. 1929–1931.

3. The Court of Appeals properly refused PRE's request for further discovery on the economic circumstances of the underlying copyright litigation, because such matters were rendered irrelevant by the objective legal reasonableness of Columbia's infringement suit. P. 1931.

944 F.2d 1525 (CA 9 1991), affirmed.

THOMAS, J., delivered the opinion of the Court, in which REHNQUIST, C.J., and WHITE, BLACKMUN, SCALIA, KENNEDY, and SOUTER, JJ., joined. *51 SOUTER, J., filed a concurring opinion, post, p. ———. STEVENS, J., filed an opinion concurring in the judgment, in which O'CONNOR, J., joined, post, p. ———.

Attorneys and Law Firms

Patrick J. Coyne, Washington, DC, for petitioners.

Andrew J. Pincus, Washington, DC, for respondents.
Opinion

Justice THOMAS delivered the opinion of the Court.

This case requires us to define the “sham” exception to the doctrine of antitrust immunity first identified in Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 81 S.Ct. 523, 5 L.Ed.2d 464 (1961), as that doctrine applies in the litigation context. Under the sham exception, activity “ostensibly directed toward influencing governmental action” does not qualify for Noerr immunity if it “is a mere sham to cover ... an attempt to interfere directly with the business relationships of a competitor.” Id., at 144, 81 S.Ct., at 533. We hold that litigation cannot be deprived of immunity as a sham unless the litigation is objectively baseless. The Court of Appeals for the Ninth Circuit refused to characterize as sham a lawsuit that the antitrust defendant admittedly had probable cause to institute. We affirm.

I

Petitioners Professional Real Estate Investors, Inc., and Kenneth F. Irwin (collectively, PRE) operated La Mancha Private Club and Villas, a resort hotel in Palm Springs, California. Having installed videodisc players in the resort’s hotel rooms and assembled a library of more than 200 motion picture titles, PRE rented videodiscs to guests for in-room viewing. PRE also sought to develop a market for the sale of videodisc players to other hotels wishing to offer in-room viewing of prerecorded material. Respondents, Columbia Pictures Industries, Inc., and seven other major motion picture studios (collectively, Columbia), held copyrights to the motion pictures recorded on the videodiscs that PRE purchased. Columbia also licensed the transmission of copyrighted motion pictures to hotel rooms through a wired cable system called Spectradyne. PRE therefore competed with Columbia not only for the viewing market at La Mancha but also for the broader market for in-room entertainment services in hotels.

In 1983, Columbia sued PRE for alleged copyright infringement through the rental of videodiscs for viewing in hotel rooms. PRE counterclaimed, charging Columbia with violations of §§ 1 and 2 of the Sherman Act, 26 Stat. 209, as amended, 15 U.S.C. §§ 1–2, and various state-law infractions. In particular, PRE alleged that Columbia's copyright action was a mere sham that cloaked underlying acts of monopolization and conspiracy to restrain trade.

The parties filed cross-motions for summary judgment on Columbia's copyright claim and postponed further discovery on PRE's antitrust counterclaims. Columbia did not dispute that PRE could freely sell or lease lawfully purchased videodiscs under the Copyright Act's “first sale” doctrine, see 17 U.S.C. § 109(a), and PRE conceded that the playing of videodiscs constituted “performance” of motion pictures, see 17 U.S.C. § 101 (1988 ed. and Supp. III). As a result, summary judgment depended solely on whether rental of videodiscs for in-room viewing infringed Columbia's exclusive right to perform the copyrighted work[s] publicly. § 106(4). Ruling that such rental did not constitute public performance, the District Court entered summary judgment for PRE. 228 USPQ 743, 1986 WL 32729 (CD Cal.1986). The Court of Appeals affirmed on the grounds that a hotel room was not a “public place” and that PRE did not “transmit or otherwise communicate” Columbia's motion pictures. 866 F.2d 278 (CA9 1989). See 17 U.S.C. § 101 (1988 ed. and Supp. III).

On remand, Columbia sought summary judgment on PRE's antitrust claims, arguing that the original copyright infringement action was no sham and was therefore entitled to immunity under Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc., supra. Reasoning that the infringement action “was clearly a legitimate effort and therefore not a sham,” 1990–1 Trade Cases ¶ 68,971, p. 63,242, 1990 WL 56166 (CD Cal.1990), the District Court granted the motion:
“It was clear from the manner in which the case was presented that [Columbia was] seeking and expecting a favorable judgment. Although I decided against [Columbia], the case was far from easy to resolve, and it was evident from the opinion affirming my order that the Court of Appeals had trouble with it as well. I find that there was probable cause for bringing the action, regardless of whether the issue was considered a question of fact or of law.” *Id.*, at 63,243.

The court then denied PRE's request for further discovery on Columbia's intent in bringing the copyright action and dismissed PRE's state-law counterclaims without prejudice.

The Court of Appeals affirmed. 944 F.2d 1525 (CA9 1991). After rejecting PRE's other allegations of anticompetitive conduct, see *Id.*, at 1528–1529, 2 the court focused on PRE's contention that the copyright action was indeed sham and that Columbia could not claim Noerr immunity. The Court of Appeals characterized “sham” litigation as one of two types of “abuse of judicial processes”: either “misrepresentations ... in the adjudicatory process” or the pursuit of “a pattern of baseless, repetitive claims” instituted “without probable cause, and regardless of the merits.” 944 F.2d, at 1529 (quoting *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508, 513, 512, 92 S.Ct. 609, 613, 612, 30 L.Ed.2d 642 (1972)). PRE neither “allege[d] that the [copyright] lawsuit involved misrepresentations” nor “challenge[d] the district court's finding that the infringement action was brought with probable cause, i.e., that the suit was not baseless.” *Id.*, at 1530. Rather, PRE opposed summary judgment solely by arguing that “the copyright infringement lawsuit [was] a sham because [Columbia] did not honestly believe that the infringement claim was meritorious.” *Ibid.*

The courts of appeals have defined “sham” in inconsistent and contradictory ways. 3 We once observed that “sham” might become “no more than a label courts could apply to activity they deem unworthy of antitrust immunity.” *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 508, n. 10, 108 S.Ct. 1931, 1941, n. 10, 100 L.Ed.2d 497 (1988). The array of definitions adopted by lower courts demonstrates that this observation was prescient.

*PRE contends that “the Ninth Circuit erred in holding that an antitrust plaintiff must, as a threshold prerequisite, establish that a sham lawsuit is baseless as a matter of law.” Brief for Petitioners 14. It invites us to adopt an approach under which either “indifference to ... outcome,” *Ibid.*, or failure to prove that a petition for redress of grievances “would ... have been brought but for [a] predatory motive,” Tr. of Oral Arg. 10, would expose a defendant to antitrust liability under the sham exception. We decline PRE's invitation.*

Those who petition government for redress are generally immune from antitrust liability. We first recognized in *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 81 S.Ct. 523, 5 L.Ed.2d 464 (1961), that “the Sherman Act does not prohibit ... persons from associating together in an attempt to persuade the legislature or the executive to take particular action with respect to a law that would produce a restraint or a monopoly.” *Ibid.*, at 136, 81 S.Ct., at 529. Accord, *Mine Workers v. Pennington*, 381 U.S. 657, 669, 85 S.Ct. 1585, 1593, 14 L.Ed.2d 626 (1965). In light of the government's “power to act in [its]
Noerr; however, withheld immunity from “sham” activities because “application of the Sherman Act would be justified” when petitioning activity, “ostensibly directed toward influencing governmental action, is a mere sham to cover ... an attempt to interfere directly with the business relationships of a competitor.” Id., at 144, 81 S.Ct., at 533. In Noerr itself, we found that a publicity campaign by railroads seeking legislation harmful to truckers was no sham in that the “effort to influence legislation” was “not only genuine but also highly successful.” Ibid.

In California Motor Transport Co. v. Trucking Unlimited, 404 U.S. 508, 92 S.Ct. 609, 30 L.Ed.2d 642 (1972), we elaborated on Noerr in two relevant respects. First, we extended Noerr to “the approach of citizens ... to administrative agencies ... and to courts.” 404 U.S., at 510, 92 S.Ct., at 611. Second, we held that the complaint showed a sham not entitled to immunity when it contained allegations that one group of highway carriers “sought to bar ... competitors from meaningful access to adjudicatory tribunals and so to usurp that decisionmaking process” by “institut[ing] ... proceedings and actions ... with or without probable cause, and regardless of the merits of the cases.” Id., at 512, 92 S.Ct., at 612 (internal quotation marks omitted). We left unresolved the question presented by this case—whether litigation may be sham merely because a subjective expectation of success does not motivate the litigant. We now answer this question in the negative and hold that an objectively reasonable effort to litigate cannot be sham regardless of subjective intent. 4

Our original formulation of antitrust petitioning immunity required that unprotected activity lack objective reasonableness. Noerr rejected the contention that an attempt “to influence the passage and enforcement of laws” might lose immunity merely because the lobbyists’ “sole purpose ... was to destroy [their] competitors.” 365 U.S., at 138, 81 S.Ct., at 530. Nor were we persuaded by a showing that a publicity campaign “was intended to and did in fact injure [competitors] in their relationships with the public and with their customers,” since such “direct injury” was merely “an incidental effect of the ... campaign to influence governmental action.” Id., at 143, 81 S.Ct., at 532. *58 We reasoned that “[t]he right of the people to **1927 inform their representatives in government of their desires with respect to the passage or enforcement of laws cannot properly be made to depend upon their intent in doing so.” Id., at 139, 81 S.Ct., at 530. In short, “Noerr shields from the Sherman Act a concerted effort to influence public officials regardless of intent or purpose.” Pennington, 381 U.S., at 670, 85 S.Ct., at 1593.

Nothing in California Motor Transport retreated from these principles. Indeed, we recognized that recourse to agencies and courts should not be condemned as sham until a reviewing court has “discern[ed] and draw[n]” the “difficult line” separating objectively reasonable claims from “a pattern of baseless, repetitive claims ... which leads the factfinder to conclude that the administrative and judicial processes have been abused.” 404 U.S., at 513, 92 S.Ct., at 613. Our recognition of a sham in that case signifies that the institution of legal proceedings “without probable cause” will give rise to a sham if such activity effectively “bar[s] ... competitors from meaningful access to adjudicatory tribunals and so ... usurp[s] th[e] decisionmaking process.” Id., at 512, 92 S.Ct., at 612.

Since California Motor Transport, we have consistently assumed that the sham exception contains an indispensable objective component. We have described a sham as “evidenced by repetitive lawsuits carrying the hallmark of insubstantial claims.” Otter Tail Power Co. v. United States, 410 U.S. 368, 93 S.Ct. 1022, 1031, 35 L.Ed.2d 359 (1973) (emphasis added). We regard as sham “private action that is not genuinely aimed at procuring favorable government action,” as opposed to “a valid effort to influence government action.” Allied Tube & Conduit Corp. v. Indian Head, Inc., 486 U.S., at 500, n. 4, 108 S.Ct., at 1937, n. 4. And we have explicitly observed that a successful “effort to influence governmental action ... certainly cannot be characterized as a sham.” Id., at 502, 108 S.Ct., at 1938. See also Vendo Co. v. Lektro–Vend Corp., 433 U.S. 623, 645, 97 S.Ct. 2881, 2894, 53 L.Ed.2d 1009 (1977) (BLACKMUN, J., concurring in result) (describing a successful lawsuit as a “genuine attempt[to] use
Unlawful, but does not necessarily render it a ‘sham.’” (internal quotation marks omitted). We reasoned that such inimical intent “may render the manner of lobbying improper or even to deny it a meaningful access to the appropriate ... administrative and legislative fora.”

prove a sham merely by showing that its competitor’s “purposes were to delay [the petitioning activity must be resolved according to objective criteria. We dispelled the notion that an antitrust plaintiff could ... action” is “not at all affected by any anticompetitive purpose [the actor] may have had.” Noerr, 365 U.S., at 140, 81 S.Ct., at 531, quoted in Pennington, supra, 381 U.S., at 669, 85 S.Ct., at 1593.

Our most recent applications of Noerr immuniy further demonstrate that neither Noerr immunity nor its sham exception turns on subjective intent alone. In Allied Tube, supra, 486 U.S., at 503, 108 S.Ct., at 1938, and FTC v. Trial Lawyers, supra, 493 U.S., at 424, 427, and n. 11, 110 S.Ct., at 775, 777, and n. 11, we refused to let antitrust defendants immunize otherwise unlawful restraints of trade by pleading a subjective intent to seek favorable legislation or to influence governmental action. Cf. National Collegiate Athletic Assn. v. Board of Regents of Univ. of Okla., 468 U.S. 85, 101, n. 23, 104 S.Ct. 2948, 2960, n. 23, 82 L.Ed.2d 70 (1984) (“Good motives will not validate an otherwise anticompetitive practice”). In Columbia v: Omni Outdoor Advertising, Inc., 499 U.S. 375, 111 S.Ct. 1344, 113 L.Ed.2d 382 (1991), we similarly held that challenges to allegedly sham petitioning activity must be resolved according to objective criteria. We dispelled the notion that an antitrust plaintiff could prove a sham merely by showing that its competitor’s “purposes were to delay [the plaintiff's] entry into the market and even to deny it a meaningful access to the appropriate ... administrative and legislative fora.” Id., at 381, 111 S.Ct., at 1354 (internal quotation mark omitted). We reasoned that such iminical intent “may render the manner of lobbying improper or even unlawful, but does not necessarily render it a ‘sham.’” Ibid. Accord, id., at 398, 111 S.Ct., at 1363 (STEVENS, J., dissenting).

In sum, fidelity to precedent compels us to reject a purely subjective definition of “sham.” The sham exception so construed would undermine, if not vitiate, Noerr. And despite whatever “superficial certainty” it might provide, a subjective standard would utterly fail to supply “real ‘intelligible guidance.’” Allied Tube, supra, 486 U.S., at 508, n. 10, 108 S.Ct., at 1941, n. 10.

III

We now outline a two-part definition of “sham” litigation. First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits. If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is immunized under Noerr, and an antitrust claim premised on the sham exception must fail. Only if challenged litigation is objectively meritless may a court examine the litigant's subjective motivation. Under this second part of our definition of sham, the court should focus on whether the baseless lawsuit conceals “an attempt to interfere directly with the business relationships of a competitor,” Noerr, supra, 365 U.S., at 141 81 S.Ct., at 533 (emphasis added), through the “use [of] the governmental process—as opposed to the outcome of that process—as an anticompetitive weapon,” Omni, 499 U.S., at 380, 111 S.Ct., at 1354 (emphasis in original). This two-tiered process requires the plaintiff to disprove the challenged lawsuit's legal viability before the court will entertain evidence of the suit's economic viability. Of course, even a plaintiff who defeats the defendant's claim to Noerr immunity by demonstrating both the objective and the subjective components of a sham must still prove a substantive antitrust violation. Proof of a sham merely deprives the defendant of immunity; it does not relieve the plaintiff of the obligation to establish all other elements of his claim.
Professional Real Estate Investors, Inc. v. Columbia Pictures..., 508 U.S. 49 (1993)

113 S.Ct. 1920, 123 L.Ed.2d 611, 61 USLW 4450, 1993-1 Trade Cases P 70,207...

Some of the apparent confusion over the meaning of “sham” may stem from our use of the word “genuine” to denote the opposite of “sham.” See *Omní, supra*, at 382, 111 S.Ct., at 1355; *Allied Tube*, 486 U.S., at 500, n. 4, 108 S.Ct., at 1937, n. 4; *Noerr, supra*, 365 U.S., at 144, 81 S.Ct., at 533; *Vendo Co. v. Lektro–Vend Corp., supra*, 433 U.S., at 645, 97 S.Ct., at 2894 (BLACkMUN, J., concurring in result). The word “genuine” has both objective and subjective connotations. On **1929** one hand, “genuine” means “actually having the reputed or apparent qualities or character.” Webster’s Third New International Dictionary 948 (1986). “Genuine” in this sense governs Federal Rule of Civil Procedure 56, under which a “genuine issue” is one “that properly can be resolved only by a finder of fact because [it] may reasonably be resolved in favor of either party.” *Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 250, 106 S.Ct. 2505, 2511, 91 L.Ed.2d 202 (1986)* (emphasis added). On the other hand, “genuine” also means “sincerely and honestly felt or experienced.” Webster’s Dictionary, *supra*, at 948. To be sham, therefore, litigation must fail to be “genuine” in both senses of the word. 6

*62 IV

We conclude that the Court of Appeals properly affirmed summary judgment for Columbia on PRE’s antitrust counterclaim. Under the objective prong of the sham exception, the Court of Appeals correctly held that sham litigation must constitute the pursuit of claims so baseless that no reasonable litigant could realistically expect to secure favorable relief. See 944 F.2d, at 1529.

The existence of probable cause to institute legal proceedings precludes a finding that an antitrust defendant has engaged in sham litigation. The notion of probable cause, as understood and applied in the commonlaw tort of wrongful civil proceedings, 7 requires the plaintiff to prove that the defendant lacked probable cause to institute an unsuccessful civil lawsuit and that the defendant pressed the action for an improper, malicious purpose. *Stewart v. Sonneborn*, 98 U.S. 187, 194, 25 L.Ed. 116 (1879); *Wyatt v. Cole*, 504 U.S. 158, 176, 112 S.Ct. 1827, 1837–1838, 118 L.Ed.2d 504 (1992) (REHNQUIST, C.J., dissenting); T. Cooley, Law of Torts *181. Cf. *Wheeler v. Nesbitt*, 24 How. 544, 549–550, 16 L.Ed. 765 (1861) (related tort for malicious prosecution of criminal charges). Probable cause to institute civil proceedings requires no more than a “reasonable[ly belief] that there is a chance that [a] claim *63 may be held valid upon adjudication” (internal quotation marks omitted). *Hubbard v. Beatty & Hyde, Inc.*, 343 Mass. 258, 262, 178 N.E.2d 485, 488 (1961); Restatement (Second) of Torts § 675, Comment e, pp. 454–455 (1977). Because the absence of probable cause is an essential element of the tort, the existence of probable cause is an absolute defense. See *Crescent City Live Stock Co. v. Butchers’ Union Slaughter–House Co.*, 120 U.S. 141, 149, 7 S.Ct. 472, 476, 30 L.Ed. 614 (1887); *Wheeler, supra*, 24 How., at 551; *Liberty Loan Corp. of Gadsden v. Mizell*, 410 So.2d 45, 48 (Ala.1982). Just as evidence of anticompetitive intent cannot affect the objective prong of *Noerr’s* sham exception, a showing of 66 malice alone will neither entitle the wrongful civil proceedings plaintiff to prevail nor permit the factfinder to infer the absence of probable cause. *Stewart, supra*, 98 U.S., at 194; *Wheeler, supra*, 24 How., at 551; 2 C. **1930** Addison, Law of Torts § 1, ¶ 853, pp. 67–68 (1876); T. Cooley, *supra*, at *184. When a court has found that an antitrust defendant claiming *Noerr’s* immunity had probable cause to sue, that finding compels the conclusion that a reasonable litigant in the defendant's position could realistically expect success on the merits of the challenged lawsuit. Under our decision today, therefore, a proper probable cause determination irrefutably demonstrates that an antitrust plaintiff has not proved the objective prong of the sham exception and that the defendant is accordingly entitled to *Noerr’s* immunity.

The District Court and the Court of Appeals correctly found that Columbia had probable cause to sue PRE for copyright infringement. Where, as here, there is no dispute over the predicate facts of the underlying legal proceeding, a court may decide probable cause as a matter of law. *Crescent, supra*, 120 U.S., at 149, 7 S.Ct., at 476; *Stewart, supra*, 98 U.S., at 194; *Nelson v. Miller*, 227 Kan. 271, 277, 607 P.2d 438, 444 (1980); *Stone v. Crocker*, 41 Mass. 81, 84–85 (1831); I. Bishop, Commentaries on Non–Contract Law § 240, p. 96 (1889). See also *Director General of Railroads v. Kastenbaum*, 263 U.S. 25, 28, 44 S.Ct. 52, 53, 68 L.Ed. 146 (1923) (“The question is not whether [the defendant] thought the facts to constitute probable cause, but whether the court thinks they did”). Columbia enjoyed the “exclusive righ[t] ... to perform [its] copyrighted” motion pictures
“publicly.” 17 U.S.C. § 106(4). Regardless of whether it intended any monopolistic or predatory use, Columbia acquired this statutory right for motion pictures as “original” audiovisual “works of authorship fixed” in a “tangible medium of expression.” § 102(a)(6). Indeed, to condition a copyright upon a demonstrated lack of anticompetitive intent would upset the notion of copyright as a “limited grant” of “monopoly privileges” intended simultaneously “to motivate the creative activity of authors” and “to give the public appropriate access to their work product.” Sony Corp. of America v. Universal City Studios, Inc., 464 U.S. 417, 429, 104 S.Ct. 774, 782, 78 L.Ed.2d 574 (1984).

When the District Court entered summary judgment for PRE on Columbia's copyright claim in 1986, it was by no means clear whether PRE's videodisc rental activities intruded on Columbia's copyrights. At that time, the Third Circuit and a District Court within the Third Circuit had held that the rental of video cassettes for viewing in on-site, private screening rooms infringed on the copyright owner's right of public performance. Columbia Pictures Industries, Inc. v. Redd Horne, Inc., 749 F.2d 154 (1984); Columbia Pictures Industries, Inc. v. Aveco, Inc., 612 F.Supp. 315 (MD Pa.1985), aff'd, 800 F.2d 59 (CA3 1986). Although the District Court and the Ninth Circuit distinguished these decisions by reasoning that hotel rooms offered a degree of privacy more akin to the home than to a video rental store, see 228 USPQ, at 746; 866 F.2d at 280–281, copyright scholars criticized both the reasoning and the outcome of the Ninth Circuit's decision, see 1 P. Goldstein, Copyright: Principles, Law and Practice § 5.7.2.2, pp. 616–619 (1989); 2 M. Nimmer & D. Nimmer, Nimmer on Copyright § 8.14[C][3], pp. 8–168 to 8–173 (1992). The Seventh Circuit expressly “declin[e]d to follow” the Ninth Circuit and adopted instead the Third Circuit's definition of a “public place.” Video *65 Views, Inc. v. Studio 21, Ltd., 925 F.2d 1010, 1020, cert. denied, 502 U.S. 861, 112 S.Ct. 181, 116 L.Ed.2d 143 (1991). In light of the unsettled condition of the law, Columbia plainly had probable cause to sue.

Any reasonable copyright owner in Columbia's position could have believed that it had some chance of winning an infringement suit against PRE. Even though it did not survive PRE's motion for summary judgment, Columbia's copyright action was arguably “warranted by existing law” or at the very least was based on an objectively “good faith argument for the extension, modification, or **1931 reversal of existing law.” Fed. Rule Civ. Proc. 11. By the time the Ninth Circuit had reviewed all claims in this litigation, it became apparent that Columbia might have won its copyright suit in either the Third or the Seventh Circuit. Even in the absence of supporting authority, Columbia would have been entitled to press a novel copyright claim as long as a similarly situated reasonable litigant could have perceived some likelihood of success. A court could reasonably conclude that Columbia's infringement action was an objectively plausible effort to enforce rights. Accordingly, we conclude that PRE failed to establish the objective prong of Noerr's sham exception.

Finally, the Court of Appeals properly refused PRE's request for further discovery on the economic circumstances of the underlying copyright litigation. As we have held, PRE could not pierce Columbia's Noerr immunity without proof that Columbia's infringement action was objectively baseless or frivolous. Thus, the District Court had no occasion to inquire whether Columbia was indifferent to the outcome on the merits of the copyright suit, whether any damages for infringement would be too low to justify Columbia's investment in the suit, or whether Columbia had decided to sue primarily for the benefit of collateral injuries inflicted through the use of legal process. Contra, Grip–Pak, Inc. v. Illinois Tool Works, Inc., 694 F.2d 466, 472 (CA7 1982), cert. denied, 461 U.S. 958, 103 S.Ct. 2430, 77 L.Ed.2d 1317 (1983). Such matters concern Columbia's *66 economic motivations in bringing suit, which were rendered irrelevant by the objective legal reasonableness of the litigation. The existence of probable cause eliminated any “genuine issue as to any material fact,” Fed.Rule Civ.Proc. 56(e), and summary judgment properly issued.

We affirm the judgment of the Court of Appeals.

So ordered.

Justice SOUTER, concurring.
The Court holds today that a person cannot incur antitrust liability merely by bringing a lawsuit as long as the suit is not “objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits.” Ante, at 1928. The Court assumes that the District Court and the Court of Appeals were finding this very test satisfied when they concluded that Columbia's suit against PRE for copyright infringement was supported by “probable cause,” a standard which, as the Court explains it in this case, requires a “reasonable belief that there is a chance that a claim may be held valid upon adjudication.” Ante, at 1929 (internal quotation marks omitted). I agree that this term, so defined, is rightly read as expressing the same test that the Court announces today; the expectation of a reasonable litigant can be dubbed a “reasonable belief,” and realistic expectation of success on the merits can be paraphrased as “a chance of being held valid upon adjudication.”

Having established this identity of meaning, however, the Court proceeds to discuss the particular facts of this case, not in terms of its own formulation of objective baselessness, but in terms of “probable cause.” Up to a point, this is understandable; the Court of Appeals used the term “probable cause” to represent objective reasonableness, and it seems natural to use the same term when reviewing the court's conclusions. Yet as the Court acknowledges, ante, at 1930, since there is no dispute over the facts underlying the suit *67 at issue here, the question whether that suit was objectively baseless is purely one of law, which we are obliged to consider de novo. There is therefore no need to frame the question in the Court of Appeals's terms. Accordingly, I would prefer to put the question in our own terms, and to conclude simply that, on the undisputed facts and the law as it stood when Columbia filed its suit, a reasonable litigant could realistically have expected success on the merits.

My preference stems from a concern that other courts could read today's opinion as transplanting every substantive nuance and procedural quirk of the common-law tort of wrongful civil proceedings into federal antitrust law. I do not understand the Court to mean anything of the sort, however, any more than I understand its citation of Rule 11 of the Federal Rules of Civil Procedure, see ante, at 1931, to signal the importation of every jot and tittle of the law of attorney sanctions. Rather, I take the Court's use of the term “probable cause” merely as shorthand for a reasonable litigant's realistic expectation of success on the merits, and on that understanding, I join the Court's opinion.

Justice STEVENS, with whom Justice O'CONNOR joins, concurring in the judgment.

While I agree with the Court's disposition of this case and with its holding that “an objectively reasonable effort to litigate cannot be sham regardless of subjective intent,” ante, at 1926, I write separately to disassociate myself from some of the unnecessarily broad dicta in the Court's opinion. Specifically, I disagree with the Court's equation of “objectively baseless” with the answer to the question whether any “reasonable litigant could realistically expect success on the merits.” There might well be lawsuits that fit the latter definition but can be shown to be objectively unreasonable, and thus shams. It might not be objectively reasonable to bring a lawsuit just because some form of success on the merits—no matter how insignificant—could be expected. With that possibility in mind, the Court should avoid an unnecessarily broad holding that it might regret when confronted with a more complicated case.

As the Court recently explained, a “sham” is the use of “the governmental process—as opposed to the outcome of that process—as an anticompetitive weapon.” Columbia v. Omni Outdoor Advertising, Inc., 499 U.S. 365, 380, 111 S.Ct. 1344, 1354, 113 L.Ed.2d 382 (1991). The distinction between abusing the judicial process to restrain competition and prosecuting a lawsuit that, if successful, will restrain competition must guide any court's decision whether a particular filing, or series of filings, is a sham. The label “sham” is appropriately applied to a case, or series of cases, in which the plaintiff is indifferent to the outcome of the litigation itself, but has nevertheless sought to impose a collateral harm on the defendant by, for example, impairing his credit, abusing the discovery process, or interfering with his access to governmental agencies. It might also apply to a plaintiff who had some reason to expect success on the merits but because of its tremendous cost would not bother to achieve that result without the benefit of collateral injuries imposed on its competitor by the legal process alone. Litigation filed or pursued for such collateral purposes is fundamentally different from a case in which the relief sought in the litigation itself would give...
**1933** The case before us today is in the latter, obviously legitimate, category. There was no unethical or other improper use of the judicial system; instead, respondents invoked the federal court's jurisdiction to determine whether they could lawfully restrain competition with petitioners. The relief they sought in their original action, if granted, would have had the anticompetitive consequences authorized by federal copyright law. Given that the original copyright infringement action was objectively reasonable—and the District Court, the Court of Appeals, and this Court all agree that it was—neither the respondents' own measure of their chances of success nor an alleged goal of harming petitioners provides a sufficient basis for treating it as a sham. We may presume that every litigant intends harm to his adversary; moreover, uncertainty about the possible resolution of unsettled questions of law is characteristic of the adversary process. Access to the courts is far too precious a right for us to infer wrongdoing from nothing more than using the judicial process to seek a competitive advantage in a doubtful case. Thus, the Court's disposition of this case is unquestionably correct.

I am persuaded, however, that all, or virtually all, of the Courts of Appeals that have reviewed similar claims (involving a single action seeking to enforce a property right) would have reached the same conclusion. To an unnecessary degree, therefore, the Court has set up a straw man to justify its elaboration of a two-part test describing all potential shams. Of the 10 cases cited by the Court as evidence of widespread confusion about the scope of the "sham" exception to the doctrine of *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 81 S.Ct. 523, 5 L.Ed.2d 646 (1961), and *Mine Workers v. Pennington*, 381 U.S. 657, 85 S.Ct. 1585, 14 L.Ed.2d 626 (1965), see ante, at 1925, n. 3, 5 share three important characteristics with this case: The alleged injury to competition was defined by the prayer for relief in the antitrust defendant's original action; there was no unethical conduct or collateral harm "external to the litigation or to the result reached in the litigation"; and there had been no series of repetitive claims. Each of those courts concluded, as this Court does today, that allegations of subjective anticompetitive motivation do not make an otherwise reasonable lawsuit a sham.

In each of the five other cases cited by the Court, the plaintiff alleged antitrust violations more extensive than the filing of a single anticompetitive lawsuit. In three of those cases the core of the alleged antitrust violation lay in the act of petitioning the government for relief: One involved the repetitive filing of baseless administrative claims, another involved extensive evidence of anticompetitive motivation behind the lawsuit that followed an elaborate and unsuccessful lobbying effort, and in the third a collateral lawsuit was only one of the many ways in which the antitrust defendant had allegedly tried to put the plaintiff out of business. In each of these cases the court showed appropriate deference to our opinions in *Noerr* and *Pennington*, in which we held that the act of petitioning the government (usually in the form of lobbying) deserves especially broad protection from antitrust liability. The Court can point to nothing in these three opinions that would require a different result here. The two remaining cases—in which the Courts of Appeals did state that a successful lawsuit could be a sham—did not involve lobbying, but did contain much broader and more complicated allegations than petitioners presented below. Like the three opinions described above, these decisions should not be expected to offer guidance, nor be blamed for spawning confusion, in a case alleging that the filing of a single lawsuit violated the Sherman Act.

Even in this Court, more complicated cases, in which, for example, the alleged competitive injury has involved something more than the threat of an adverse outcome in a single lawsuit, have produced less definite rules. Repetitive filings, some of which are successful and some unsuccessful, may support an inference that the process is being misused. *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508, 92 S.Ct. 609, 30 L.Ed.2d 642 (1972). In such a case, a rule that a single meritorious action can never constitute a sham cannot be dispositive. Moreover, a simple rule may be hard to apply when there is evidence that the judicial process has been used as part of a larger program to control a market and to interfere with a potential competitor's financing without any interest in the outcome of the lawsuit itself, see *Otter Tail Power Co. v. United
In one such case Judge Posner made the following observations about the subtle distinction between suing a competitor to get damages and filing a lawsuit only in the hope that the expense and burden of defending it will make the defendant abandon its competitive behavior:

“But we are not prepared to rule that the difficulty of distinguishing lawful from unlawful purpose in litigation between competitors is so acute that such litigation can never be considered an actionable restraint of trade, provided it has some, though perhaps only threadbare, basis in law. Many claims not wholly groundless would never be sued on for their own sake; the stakes, discounted by the probability of winning, would be too low to repay the investment in litigation. Suppose a monopolist brought a tort action against its single, tiny competitor; the action had a colorable basis in law; but in fact the monopolist would never have brought the suit—its chances of winning, or the damages it could hope to get if it did win, were too small compared to what it would have to spend on the litigation—except that it wanted to use pretrial discovery to discover its competitor's trade secrets; or hoped that the competitor would be required to make public disclosure of its potential liability in the suit and that this disclosure would increase the interest rate that the competitor had to pay for bank financing; or just wanted to impose heavy legal costs on the competitor in the hope of deterring entry by other firms. In these examples the plaintiff wants to hurt a competitor not by getting a judgment against him, which would be a proper objective, but just by the maintenance of the suit, regardless of its outcome. See City of Gainesville v. Florida Power & Light Co., 488 F. Supp. 1258, 1265–66 (S.D. Fla. 1980).

“It is important to remember that the distinction between “sham” litigation and genuine litigation is not always, or only, the difference between lawful and unlawful conduct; objectively reasonable lawsuits may still break the law. For example, a manufacturer's successful action enforcing resale price maintenance agreements, restrictive provisions in a license to use a patent or a trademark, or an equipment lease, may evidence, or even constitute, violations of the antitrust laws. On the other hand, just because a sham lawsuit has grievously harmed a competitor does not necessarily mean that it has violated the Sherman Act. See Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 455–459, 113 S.Ct. 884, 891, 122 L.Ed.2d 247 (1993). The rare plaintiff who successfully proves a sham must still satisfy the exacting elements of an antitrust demand. See ante, at 1928.
In sum, in this case I agree with the Court's explanation of why respondents' copyright infringement action was not "objectively baseless," and why allegations of improper subjective *76 motivation do not make such a lawsuit a "sham." I would not, however, use this easy case as a vehicle for announcing a rule that may govern the decision of difficult cases, some of which may involve abuse of the judicial process. Accordingly, I concur in the Court's judgment but not in its opinion.

All Citations


Footnotes

* The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See United States v. Detroit Lumber Co., 200 U.S. 321, 337, 26 S.Ct. 282, 287, 50 L.Ed. 499.

Section 1 of the Sherman Act prohibits "[e]very contract, combination ..., or conspiracy, in restraint of trade or commerce among the several States." 15 U.S.C. § 1. Section 2 punishes "[e]very person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States."

The Court of Appeals held that Columbia's alleged refusal to grant copyright licenses was not "separate and distinct" from the prosecution of its infringement suit. 944 F.2d, at 1528. The court also held that PRE had failed to establish how it could have suffered antitrust injury from Columbia's other allegedly anticompetitive acts. Id., at 1529. Thus, whatever antitrust injury Columbia inflicted must have stemmed from the attempted enforcement of copyrights, and we do not consider whether Columbia could have made a valid claim of immunity for anticompetitive conduct independent of petitioning activity. Cf. Continental Ore Co. v. Union Carbide & Carbon Corp., 370 U.S. 690, 707–708, 82 S.Ct. 1404, 1414–1415, 8 L.Ed.2d 777 (1962).


California Motor Transport did refer to the antitrust defendants’ “purpose to deprive ... competitors of meaningful access to the ... courts.” 404 U.S., at 512, 92 S.Ct., at 612. See also id., at 515, 92 S.Ct., at 614 (noting a “purpose to eliminate ... a competitor by denying him free and meaningful access to the agencies and courts”); id., at 518, 92 S.Ct., at 615 (Stewart, J., concurring in judgment) (agreeing that the antitrust laws could punish acts intended “to discourage and ultimately to prevent [a competitor] from invoking” administrative and judicial process). That a sham depends on the existence of anticompetitive intent, however, does not transform the sham inquiry into a purely subjective investigation.

A winning lawsuit is by definition a reasonable effort at petitioning for redress and therefore not a sham. On the other hand, when the antitrust defendant has lost the underlying litigation, a court must “resist the understandable temptation to engage in post hoc reasoning by concluding” that an ultimately unsuccessful “action must have been unreasonable or without foundation.” Christiansburg Garment Co. v. EEOC, 434 U.S. 412, 421–422, 98 S.Ct. 694, 700, 54 L.Ed.2d 648 (1978). Accord, Hughes v. Rowe, 449 U.S. 5, 14–15, 101 S.Ct. 173, 178–179, 66 L.Ed.2d 163 (1980) (per curiam). The court must remember that “[e]ven when the law or the facts appear questionable or unfavorable at the outset, a party may have an entirely reasonable ground for bringing suit.” Christiansburg, supra, 434 U.S., at 422, 98 S.Ct., at 701.

In surveying the “forms of illegal and reprehensible practice which may corrupt the administrative or judicial processes and which may result in antitrust violations,” we have noted that “unethical conduct in the setting of the adjudicatory process often results in sanctions” and that “[m]isrepresentations, condoned in the political arena, are not immunized when used in the adjudicatory process.” California Motor Transport, 404 U.S., at 512–513, 92 S.Ct., at 613. We need not decide here whether and, if so, to what extent Noerr permits the imposition of antitrust liability for a litigant's fraud or other misrepresentations. Cf. Fed.Rule Civ.Proc. 60(b)(3) (allowing a federal court to “relieve a party ... from a final judgment” for “fraud ..., misrepresentation, or other misconduct of an adverse party”); Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp., 382 U.S. 172, 176–177, 86 S.Ct. 347, 349–350, 15 L.Ed.2d 247 (1965); id., at 179–180, 86 S.Ct., at 351–352 (Harlan, J., concurring).

This tort is frequently called “malicious prosecution,” which (strictly speaking) governs the malicious pursuit of criminal proceedings without probable cause. See W. Keeton, D. Dobbs, R. Keeton, & D. Owen, Prosser and Keeton on Torts § 120, p. 892 (5th ed. 1984). The threshold for showing probable cause is no higher in the civil context than in the criminal. See Restatement (Second) of Torts § 674, Comment e, pp. 454–455 (1977).

1 Ante, at 1928. See also ante, at 1929: “[S]ham litigation must constitute the pursuit of claims so baseless that no reasonable litigant could realistically expect to secure favorable relief”; ante, at 1928: “If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is immunized under Noerr....” But see ante, at 1929: “The existence of probable cause to institute legal proceedings precludes a finding that an antitrust defendant has engaged in sham litigation.” And see ante, at 1930: “Columbia's copyright action was arguably ‘warranted by existing law”’ under the standards of Federal Rule of Civil Procedure 11. These varied restatements of the Court's new test make it unclear whether it is willing to affirm the Court of Appeals by any of these standards individually, or by all of them together.

2 The Court's recent decision in Farrar v. Hobby, 506 U.S. 103, 113 S.Ct. 566, 121 L.Ed.2d 494 (1992) makes me wonder whether “10 years of litigation and two trips to the Court of Appeals” to recover “one dollar from one defendant,” id., at 116, 113 S.Ct., at 575, (O'CONNOR, J., concurring), would qualify as a reasonable expectation of “favorable relief” under today's opinion.


5 Litton Systems, Inc. v. American Telephone & Telegraph Co., 700 F.2d 785 (CA2 1983), cert. denied, 464 U.S. 1073, 104 S.Ct. 984, 79 L.Ed.2d 220 (1984). The Second Circuit found that AT & T's continued filing of administrative tariffs long after those claims had become objectively unreasonable supported a jury's sham finding. AT & T's anticompetitive actions were in fact so far removed from the act of petitioning the government for relief that Chief Judge Oakes and Judge Meskill also held, in reliance on Continental Ore Co. v. Union Carbide & Carbon Corp., 370 U.S. 690, 82 S.Ct. 1404, 8 L.Ed.2d 777 (1962), and Cantor v. Detroit Edison Co., 428 U.S. 579, 96 S.Ct. 3110, 49 L.Ed.2d 1141 (1976) (plurality opinion), that tariff filings with the Federal Communications Commission were acts of private commercial activity in the marketplace rather than requests for governmental action, and thus were not even arguably protected by the Noerr–Pennington doctrine. Litton Systems, 700 F.2d, at 806–809.

6 Westmac, Inc. v. Smith, 797 F.2d 313 (CA6 1986), cert. denied, 479 U.S. 1035, 107 S.Ct. 885, 93 L.Ed.2d 838 (1987). Although the Sixth Circuit did hold that the genuine substance of an anticompetitive lawsuit creates a rebuttable presumption of objective reasonableness, given the facts of that case—in which the antitrust plaintiff had presented strong evidence that the defendants' lawsuit, which followed a long and unsuccessful lobbying effort, had been motivated solely for the anticompetitive harm the judicial process would inflict on it—that modest reservation was probably wise. Evidence of anticompetitive animus in Westmac was in fact so great that Chief Judge Merritt thought that the plaintiff had successfully rebutted the presumptive reasonableness of defendants' lawsuit. The delay from the defendants' combined lobbying and litigation attack had allegedly sent the plaintiff into bankruptcy, and memos from one defendant to its attorney had stated, “ ‘If this [lobbying activity] doesn't succeed, start a lawsuit—bonds won't sell,’ ” 797 F.2d, at 318, and (in a statement repeated to a codefendant), “ ‘if nothing else, we'll delay sale of the bonds,’ ” id., at 322 (Merritt, C.J., dissenting) (emphasis omitted). In any event, the Sixth Circuit rule—to the extent that it would apply in a case as simple as this one—would result in the same conclusion we reach here.

7 Federal Prescription Service, Inc. v. American Pharmaceutical Assn., 214 U.S.App.D.C. 76, 663 F.2d 253 (1981), cert. denied, 455 U.S. 928, 102 S.Ct. 1293, 71 L.Ed.2d 472 (1982). In that case, the antitrust plaintiff alleged a 2–decade long conspiracy to lobby, boycott, and sue it (in state licensing boards, state legislatures, the marketplace, and both state and federal courts) out of existence. In spite of those allegations, the Court of Appeals found that the defendant's actions, which primarily consisted in lobbying for the abolition of plaintiff's mail-order prescription business, were immune under Noerr–Pennington.

8 In Grip–Pak, Inc. v. Illinois Tool Works, Inc., 694 F.2d 466 (1982) (Posner, J.), cert. denied, 461 U.S. 958, 103 S.Ct. 2430, 77 L.Ed.2d 1317 (1983), the antitrust defendant's alleged violations of several provisions of the Sherman and Clayton Acts included much more than the filing of a single lawsuit; they encompassed a broad scheme of monopolizing the entire relevant market by: purchasing patents; threatening to file many other, patently groundless lawsuits; acquiring a competitor; dividing markets; and filing a fraudulent patent application. In In re Burlington Northern, Inc., 822 F.2d 518 (CA5 1987), cert. denied, 484 U.S. 1007, 108 S.Ct. 701, 98 L.Ed.2d 652 (1988), the plaintiffs alleged, and produced evidence to support their theory, that the defendant had filed suit solely to cause them a delay of crippling expense, and
the defendants had either brought or unsuccessfully defended a succession of related lawsuits involving petitioners' right to compete. In both of these cases the Courts of Appeals ably attempted to balance strict enforcement of the antitrust laws with possible abuses of the judicial process. That they permitted some reliance on subjective motivation—as even we have done in cases alleging abuse of judicial process, see *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508, 513–518, 92 S.Ct. 609, 613–615, 30 L.Ed.2d 642 (1972)—is neither surprising nor relevant in a case involving no such allegations.


86 S.Ct. 347
Supreme Court of the United States

WALKER PROCESS EQUIPMENT, INC., Petitioner,
v.
FOOD MACHINERY AND CHEMICAL CORPORATION.

No. 13.
Decided Dec. 6, 1965.

Synopsis
Patent infringement suit. The defendant filed a counterclaim. The United States District Court for the Northern District of Illinois, Eastern Division, dismissed the infringement complaint and the amended counterclaim, without leave to amend and with prejudice. The defendant appealed. The Court of Appeals for the Seventh Circuit, 335 F.2d 315, affirmed. Certiorari was granted. The Supreme Court, Mr. Justice Clark, held that the enforcement of a patent procured by fraud on the patent office may be violative of the Sherman Act provided the other elements necessary to a Sherman Act case are present, and that in such event the treble damage provisions of the Clayton Act would be available to an injured party. The court further held that the case should be remanded for the counterclaimant to clarify the asserted violations of the Sherman Act and to offer proof thereon.

Reversed and remanded.

Attorneys and Law Firms

**348  *173 Charles J. Merriam, Chicago, Ill., for petitioner.
Daniel M. Friedman, Washington, D.C., for the United States, as amicus curiae.
Sheldon O. Collen, Chicago, Ill., for respondent.

Opinion

Mr. Justice CLARK delivered the opinion of the Court.

The question before us is whether the maintenance and enforcement of a patent obtained by fraud on the Patent Office may be the basis of an action under s 2 of the Sherman Act, 1 and therefore subject to a treble damage claim by an injured party under s 4 of the Clayton Act. 2 The respondent, Food Machinery, & Chemical Corp. (hereafter Food Machinery), filed this suit for infringement of its patent No. 2,328,655 covering knee-action swing diffusers used in aerating equipment for sewage treatment systems. 3 Petitioner, Walker Process Equipment, *174 Inc. (hereafter Walker), denied the infringement and counterclaimed for a declaratory judgment that the patent was invalid. After discovery, Food Machinery moved to dismiss its complaint with prejudice because the patent had expired. Walker then amended its counterclaim to charge that Food Machinery had 'illegally monopolized interstate and foreign commerce by fraudulently obtaining and maintaining *** its patent *** well knowing that it had no basis for *** a patent.' It alleged fraud on the basis that Food Machinery had sworn before the Patent Office that it neither knew nor believed that its invention had been in public use in the United States for more than one year.
prior to filing its patent application when, in fact, Food Machinery was a party to prior use within such time. The counterclaim
further asserted that the existence of the patent had deprived Walker of business that it would have otherwise enjoyed. Walker
prayed that Food Machinery's conduct be declared a violation of the antitrust laws and sought recovery of treble damages.

The District Court granted Food Machinery's motion and dismissed its infringement complaint along with Walker's amended
counterclaim, without leave to amend and with prejudice. The Court of Appeals for the Seventh Circuit affirmed, 335 F.2d 315.
We granted certiorari, 379 U.S. 957, 85 S.Ct. 657, 13 L.Ed.2d 553. We have concluded that the enforcement of a patent procured
by fraud on the Patent Office may be violative of s 2 of the Sherman Act provided the other elements necessary to a s 2 case
are present. In such event the treble damage provisions of s 4 of the Clayton Act would be available to an injured party.

I.

As the case reaches us, the allegations of the counterclaim, as to the fraud practiced upon the Government by Food Machinery as
well as the resulting damage suffered by Walker are taken as true. We, therefore, move immediately to a consideration
of the legal issues presented.

Both Walker and the United States, which appears as amicus curiae, argue that if Food Machinery obtained its patent by fraud
and thereafter used the patent to exclude Walker from the market through 'threats of suit' and prosecution of this infringement
suit, such proof would establish a prima facie violation of s 2 of the Sherman Act. On the other hand, Food Machinery says
that a patent monopoly and a Sherman Act monopolization cannot be equated; the removal of the protection of a patent grant
because of fraudulent procurement does not automatically result in a s 2 offense. Both lower courts seem to have concluded that
proof of fraudulent procurement may be used to bar recovery for infringement, Precision Instrument Mfg. Co. v. Automotive
Maintenance Machinery Co., 324 U.S. 806, 65 S.Ct. 993, 89 L.Ed. 1381 (1945), but not to establish invalidity. As the Court of
Appeals expressed the proposition, 'only the government may 'annul or set aside' a patent,' citing Mowry v. Whitney, 14 Wall.
434, 20 L.Ed. 858 (1872). It went on to state that no case had 'decided, or hinted that fraud on the Patent Office may be turned
into an original affirmative action, instead of as an equitable defense. * * * Since Walker admits that its anti-trust theory
depends on its ability to prove fraud on the Patent Office, it follows that * * * Walker's second amended counterclaim failed
to state a claim upon which relief could be granted.' 335 F.2d, at 316.

II.

We have concluded, first, that Walker's action is not barred by the rule that only the United States may sue to cancel or annul a
patent. It is true that there is no statutory authority for a private annulment suit and the invocation of the equitable powers
of the court might often subject a patentee 'to innumerable vexatious suits to set aside his patent.' Mowry, supra, 81 U.S. at 441.
But neither reason applies here. Walker counterclaimed under the Clayton Act, not the patent laws. While one of its
elements is the fraudulent procurement of a patent, the action does not directly seek the patent's annulment. The gist of Walker's
claim is that since Food Machinery obtained its patent by fraud it cannot enjoy the limited exception to the prohibitions of s 2
of the Sherman Act, but must answer under that section and s 4 of the Clayton Act in treble damages to those injured by any
monopolistic action taken under the fraudulent patent claim. Nor can the interest in protecting patentees from 'innumerable
vexatious suits' be used to frustrate the assertion of rights conferred by the antitrust laws. It must be remembered that we deal
only with a special class of patents, i.e., those procured by intentional fraud.

Under the decisions of this Court a person sued for infringement may challenge the validity of the patent on various grounds,
including fraudulent procurement. E.g., Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co., 324 U.S.
806, 65 S.Ct. 993, 89 L.Ed. 1381 (1945); Hazel-Atlas Co. v. Hartford-Empire Co., 322 U.S. 238, 64 S.Ct. 997, 88 L.Ed. 1250

86 S.Ct. 347, 15 L.Ed.2d 247, 147 U.S.P.Q. 404 (1944); Keystone Driller Co. v. General Excavator Co., 290 U.S. 240, 54 S.Ct. 146, 78 L.Ed. 293 (1933). In fact, one need not await the filing of a threatened suit by the patentee; the validity of the patent may be tested under the Declaratory Judgment Act, 28 U.S.C. s 2201 (1964 ed.). See Kerotest Mfg. Co. v. C—O Two Fire Equipment Co., 342 U.S. 180, 185, 72 S.Ct. 219, 222, 94 L.Ed. 200 (1952). At the same time, we have recognized that an injured party may attack the misuse of patent rights. See, e.g., Mercoid Corp. v. Mid-Continent Investment Co., 320 U.S. 661, 64 S.Ct. 268, 88 L.Ed. 376 (1944). To permit recovery of treble damages for the fraudulent procurement of the patent coupled with violations of s 2 accords with these long-recognized procedures. It would also promote the purposes so well expressed in Precision Instrument, supra, 324 U.S. at 816, 65 S.Ct. at 998:

‘A patent by its very nature is affected with a public interest. * * * (It) is an exception to the general rule against monopolies and to the right to access to a free and open market. The far-reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct and that such monopolies are kept within their legitimate scope.’

III.

Walker's counterclaim alleged that Food Machinery obtained the patent by knowingly and willfully misrepresenting facts to the Patent Office. Proof of this assertion would be sufficient to strip Food Machinery of its exemption from the antitrust laws. By the same token, Food Machinery's good faith would furnish a complete defense. This includes an honest mistake as to the effect of prior installation upon patentability—so-called ‘technical fraud.’

To establish monopolization or attempt to monopolize a part of trade or commerce under s 2 of the Sherman Act, it would then be necessary to appraise the exclusionary power of the illegal patent claim in terms of the relevant market for the product involved. Without a definition of that market there is no way to measure Food Machinery's ability to lessen or destroy competition. It may be that the device—knee-action swing diffusers used in sewage treatment systems does not comprise a relevant market. There may be effective substitutes for the device which do not infringe the patent. This is a matter of proof, as is the amount of damages suffered by Walker.

As respondent points out, Walker has not clearly articulated its claim. It appears to be based on a concept of per se illegality under s 2 of the Sherman Act. But in these circumstances, the issue is premature. As the Court summarized in White Motor Co. v. United States, 372 U.S. 253, 83 S.Ct. 696, 9 L.Ed.2d 738 (1963), the area of per se illegality is carefully limited. We are reluctant to extend it on the bare pleadings and absent examination of market effect and economic consequences.

However, even though the per se claim fails at this stage of litigation, we believe that the case should be remanded for Walker to clarify the asserted violations of s 2 and to offer proof thereon. The trial court dismissed its suit not because Walker failed to allege the relevant market, the dominance of the patented device therein, and the injurious consequences to Walker of the patent's enforcement, but rather on the ground that the United States alone may ‘annul or set aside’ a patent for fraud in procurement. The trial court has not analyzed any economic data. Indeed, no such proof has yet been offered because of the disposition below. In view of these considerations, as well as the novelty of the claim asserted and the paucity of guidelines available in the decided cases, this deficiency cannot be deemed crucial. Fairness requires that on remand Walker have the opportunity to make its s 2 claims more specific, to prove the alleged fraud, and to establish the necessary elements of the asserted s 2 violation.

Westlaw © 2022 Thomson Reuters. No claim to original U.S. Government Works.
Reversed and remanded.

*179 Mr. Justice HARLAN (concurring).

I join the Court's opinion. I deem it appropriate, however, to add a few comments to what my Brother CLARK has written because the issue decided is one of first impression and to allay possible misapprehension as to the possible reach of this decision.

We hold today that a treble-damage action for monopolization which, but for the existence of a patent, would be violative of s 2 of the Sherman Act may be maintained under s 4 of the Clayton Act if two conditions are satisfied: (1) the relevant patent is shown to have been procured by knowing and willful fraud practiced by the defendant on the Patent Office or, if the defendant was not the original patent applicant, he had been enforcing the patent with knowledge of the fraudulent manner in which it was obtained; and (2) all the elements otherwise necessary to establish a s 2 monopolization charge are proved. Conversely, such a private cause of action would not be made out if the plaintiff: (1) showed no more than invalidity of the patent arising, for example, from a judicial finding of ‘obviousness,’ or from other factors sometimes compendiously referred to as ‘technical fraud’; or (2) showed fraudulent procurement, but no knowledge thereof by the defendant; or (3) failed to prove the elements of a s 2 charge even though he has established actual fraud in the procurement of the patent and the defendant's knowledge of that fraud.

It is well also to recognize the rationale underlying this decision, aimed of course at achieving a suitable accommodation in this area between the differing policies of the patent and antitrust laws. To hold, as we do, that private suits may be instituted under s 4 of the Clayton Act to recover damages for Sherman Act monopolization knowingly practiced under the guise of a patent procured by deliberate fraud, cannot well be thought to impinge upon the policy of the patent laws to encourage inventions and their disclosure. Hence, as to this class of improper patent monopolies, antitrust remedies should be allowed room for full play. On the other hand, to hold, as we do not, that private antitrust suits might also reach monopolies practiced under patents that for one reason or another may turn out to be voidable under one or more of the numerous technicalities attending the issuance of a patent, might well chill the disclosure of inventions through the obtaining of a patent because of fear of the vexations or punitive consequences of treble-damage suits. Hence, this private antitrust remedy should not be deemed available to reach s 2 monopolies carried on under a nonfraudulently procured patent.

These contrasting factors at once serve to justify our present holding and to mark the limits of its application.

All Citations

382 U.S. 172, 86 S.Ct. 347, 15 L.Ed.2d 247, 147 U.S.P.Q. 404

Footnotes


‘Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a misdemeanor * * *.’

Any person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws may sue therefor in any district court of the United States in the district in which the defendant resides or is found or has an agent, without respect to the amount in controversy, and shall recover three-fold the damages by him sustained, and the cost of suit, including a reasonable attorney's fee.'

3 The patent in question was issued in the name of the inventor, Lannert. But he had previously assigned the patent rights to his employer, Chicago Pump Company, a division of Food Machinery.


5 This conclusion applies with equal force to an assignee who maintains and enforces the patent with knowledge of the patent's infirmity.
United States Code Annotated
Title 15. Commerce and Trade
Chapter 1. Monopolies and Combinations in Restraint of Trade (Refs & Annos)

15 U.S.C.A. § 1

§ 1. Trusts, etc., in restraint of trade illegal; penalty

Effective: June 22, 2004

Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal. Every person who shall make any contract or engage in any combination or conspiracy hereby declared to be illegal shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation, or, if any other person, $1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court.

CREDIT(S)


15 U.S.C.A. § 1, 15 USCA § 1
Current through P.L. 117-148. Some statute sections may be more current, see credits for details

End of Document
§ 2. Monopolizing trade a felony; penalty, 15 USCA § 2


§ 2. Monopolizing trade a felony; penalty

Effective: June 22, 2004

Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation, or, if any other person, $1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court.

CREDIT(S)


Current through P.L. 117-148. Some statute sections may be more current, see credits for details

© 2022 Thomson Reuters. No claim to original U.S. Government Works.