

Nos. 17-2078, 17-2134

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**In the United States Court of Appeals  
for the Federal Circuit**

ACORDA THERAPEUTICS, INC.,  
PLAINTIFF-APPELLANT

ALKERMES PHARMA IRELAND LIMITED,  
PLAINTIFF-APPELLEE,

v.

ROXANE LABORATORIES, INC., MYLAN PHARMACEUTICALS INC.,  
TEVA PHARMACEUTICALS USA, INC.,  
DEFENDANTS-CROSS-APPELLANTS

*ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE,  
CASE NOS. 1:14-CV-00882, 1:14-CV-00922, 1:14-CV-00935, 1:14-CV-00941,  
CHIEF JUDGE LEONARD P. STARK*

**DEFENDANTS-CROSS-APPELLANTS ROXANE LABORATORIES, INC.  
AND TEVA PHARMACEUTICALS USA, INC.'S RESPONSE TO  
PETITION FOR REHEARING EN BANC**

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## CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rule 47.4, counsel of record for Defendant-Cross-Appellant Teva Pharmaceuticals USA, Inc. certifies the following:

1. The full name of the party represented by me is:

Teva Pharmaceuticals USA, Inc.

2. The name of the real party in interest represented by me is:

Teva Pharmaceuticals USA, Inc.

3. Parent corporations and publicly held companies that own 10 percent or more of the stock in the party represented by me are:

Teva Pharmaceutical Industries, Ltd.

4. The names of all law firms and the partners and associates that appeared for the party represented by me in the trial court or are expected to appear in this Court (and who have not or will not enter an appearance in this case) are:

Phillips, Goldman, McLaughlin & Hall, P.A.: John C. Phillips, Jr., Megan C. Haney, David A. Bilson

Dated: November 27, 2018

/s/ Charles B. Klein

Charles B. Klein

*Counsel for Appellee*

*Teva Pharmaceuticals USA, Inc.*

## CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rule 47.4, counsel of record for Defendant-Cross-Appellant Roxane Laboratories, Inc. certifies the following:

1. The full name of the party represented by me is:

Roxane Laboratories, Inc.

2. The name of the real party in interest represented by me is:

Hikma Pharmaceuticals USA Inc.; West-Ward Pharmaceuticals International Limited

3. Parent corporations and publicly held companies that own 10 percent or more of the stock in the party represented by me are:

Roxane Laboratories, Inc. (now “Hikma Labs Inc.”) is an indirect wholly-owned subsidiary of Hikma Pharmaceuticals PLC.

4. The names of all law firms and the partners and associates that appeared for the party represented by me in the trial court or are expected to appear in this Court (and who have not or will not enter an appearance in this case) are:

Phillips, Goldman, McLaughlin & Hall, P.A.: John C. Phillips, Jr., Megan C. Haney, David A. Bilson

Dated: November 27, 2018

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## INTRODUCTION

Acorda has failed to show that this is a case of “exceptional importance” warranting en banc review. *See* Fed. R. App. Proc. 35(a)(2). In a detailed, 53-page opinion, the majority (Judges Taranto and Dyk) applied this Court’s precedents to find no clear error in the factual findings below. While the dissenter (Judge Newman) would have found clear error, there is no legal issue here warranting further review, much less extraordinary, en banc review. To the contrary, the panel rejected a “categorical rule,” and instead applied a “number of variables”—the panel listed at least seven—in its “common-sense,” “fact-specific” inquiry. Op. 46, 49; *infra* at 9 (itemizing variables). The petition should be denied.

In this case, the trial court held Acorda’s patents invalid as obvious, and the panel rejected Acorda’s factual-finding challenges. Acorda does not contest the majority’s holding that, “[i]n light of the record evidence, the district court did not clearly err in finding that a person of skill at the time of the invention would have had a motivation to combine, and a reasonable expectation of success in combining, the teachings of the prior art to arrive at the” alleged invention. Op. 42.

Its petition focuses, instead, on the panel’s analysis of “objective indicia” of non-obviousness—in particular, this Court’s “blocking-patent doctrine.” *See Merck & Co. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364 (Fed. Cir. 2005) (*Merck*

*I*); Pet. 1. Acorda concedes that, under that doctrine, “the inference of nonobviousness ... from evidence of commercial success[]” is “weak” where “market entry by others was precluded” by an earlier patent. *Merck I*, 395 F.3d at 1376-77; *see also* Pet. 9-10 (citing cases following *Merck I*). Acorda says the trial court and the panel “transform[ed]” that rule, so that “the mere presence of a ‘blocking’ patent now negates objective indicia.” Pet. 15; *accord* PhRMA Br. 6 (accusing panel of adopting a standard “in which objective indicia can be discounted or disregarded *per se*”). The panel said the opposite: “We think ... that the district court’s opinion is best read *not* as invoking a categorical rule, but as drawing conclusions on the limited factual record created in this case bearing on the effect of a blocking patent.” Op. 46 (emphasis added). “[T]he mere existence ... of blocking patents does not, without more, necessarily detract from evidence of commercial success.” Op. 48. Rather, such patents trigger “a fact-specific inquiry.” Op. 47-48.

Undertaking this “fact-specific inquiry,” the trial court found that here “[t]he risk of [infringement] liability’ ... ‘would have provided an independent incentive for a patentee not to develop the invention of the Acorda patents, even if those inventions were obvious.’” Op. 51 (quoting Appx84). Weighing this fact along with all the evidence, the trial court found the patents obvious. Assessing this finding, the majority found “no clear error.” Op. 51-56.

Confirming the lack of legal error here, the Petition quarrels over facts—such as whether “Sanofi-Aventis likely did not use 4-AP because of the blocking effect of the Elan patent.” Pet. 13 (quoting Op. 55). That raises no intra-circuit conflict or question of exceptional importance. Nor is there any need for the full Court to decide whether “the evidence of blocking we have discussed is pertinent, in this case, to the factual question of long-felt but unmet need[.]” Op. 56.

In short, “[t]he role of an en banc court is ‘not simply to second-guess the panel on the facts of a particular case.’” *Apple Inc. v. Samsung Electronics Co., Ltd.*, 839 F.3d 1034, 1087 (Fed. Cir. 2016) (Reyna, J. dissenting)) (quoting *In re Dillon*, 919 F.2d 688, 700 n.3 (Fed. Cir. 1990) (Newman, J., joined by Cowen and Mayer, JJ., dissenting)). Merely disagreeing with a panel opinion “is not a sufficient reason for en banc review.” *Dow Chem. Co. v. Nova Chems. Corp. (Canada)*, 809 F.3d 1223, 1227-28 (Fed. Cir. 2015) (Moore, J., joined by Newman, O’Malley, and Tarranto, JJ., concurring in denial of rehearing en banc). Full-court review is instead a “rare intervention [that] should be reserved for real conflicts as well as cases of exceptional importance.” *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1311 (Fed. Cir. 2006) (Michel, C.J., and Mayer, J., concurring).

This is not such a case. In its meticulous opinion, the panel correctly held that the trial court properly gave the blocking patent here the weight it deserved, taking into close account the record as a whole. The petition should be denied.

## BACKGROUND

As Acorda concedes, it did not discover the active ingredient in its purported invention, known as 4-AP. Pet. 3. Discovered in 1902, 4-AP was tested in the 1970s on neurological diseases and “[f]or several decades” was “the focus of research regarding the treatment of multiple sclerosis” or “MS.” Op. 5. Two key studies, Davis (1987) and Stefoski (1990), showed that MS patients treated with 4-AP showed “mild to marked improvement” in motor function and walking. Op. 5-6. A recently expired patent—called the Elan patent—built on Stefoski and Davis to claim a controlled-release version of 4-AP achieving therapeutic blood levels to treat MS patients. Op. 12-13. The Elan patent is the “blocking” patent here.

The Acorda Patents narrow the scope of the Elan patent to one therapeutically effective dose of 4-AP sustained release—i.e., 10 mg, taken twice-daily—that helps MS patients walk. Reviewing the evidence in detail, the panel held that the trial court properly found all the asserted claims obvious as of the 2004 priority date.

In fact, the panel held that the claimed invention became obvious long before 2004, “in a paper published in 1997 (Schwid) on which Dr. Goodman, Acorda’s expert at trial, was the senior author.” Op. 13. As Schwid reported, patients given 17.5 mg sustained-release 4-AP twice a day for a week “demonstrated a statistically significant improvement over placebo for timed gait”—the drug improved walking—and concluded that “4AP [sustained-release] improved motor function in [MS]

patients.” Op. 14-15 (citations omitted). Schwid advised that “future studies ... further refine dosing regimens to optimize delivery despite a relatively narrow therapeutic window.” Op. 15.

Acorda claims—as it did below and to the panel—that Schwid reported an earlier “failed” Elan clinical trial. Pet. 4, 15. But that supposed “failed” study was never published and is mentioned only in the abstract and one paragraph in the background section of the Schwid reference. Op. 13. One reason the study was never published may have been that it gauged success under something called the “Expanded Disability Status Scale,” which Acorda’s expert conceded “may have been an inadequate outcome variable.” Op. 14. And “[b]y 1997”—seven years before the priority date—“the art expressly explained why improvement of [MS] symptoms with 4-AP was promising despite the failed 1994 Elan study.” Op. 55.

Sure enough, the next year, Acorda licensed the Elan Patent to formulate a 4-AP sustained-release drug for MS patients. Op. 16. “Acorda reviewed Elan’s research ... then conducted its own clinical trials.” *Id.* In 2000-01, Acorda’s expert, Dr. Goodman, helped run these trials and published the results of one of the Phase II clinical studies in the prior art—twice in early 2003 publications (Goodman I and Goodman II), and once in a 2002 poster presentation he used to describe these results to skilled artisans. Op. 16-23. These references were “the most important prior art in the obviousness analysis in this case.” Op. 23.

The Goodman Poster, for example, notes that “[r]ecent clinical studies [referring to Schwid] have indicated that [4-AP] promotes improvement in motor strength, walking, fatigue, and endurance in people with [MS].” Op. 19. The Poster defined the study objectives as: “(1) ‘[d]etermine safety of multiple doses of [sustained-release 4-AP]’ ... and (2) ‘[o]btain evidence of efficacy and dose-response using several outcome measures.’” *Id.* Regarding the first objective, the Poster reports “‘more severe adverse events,’ including seizures, occurred ‘[a]t doses above 40 mg/day,’” and “‘[l]ittle added benefit, and increased [adverse events,] at doses above 50 mg/day.’” Op. 20-23. As to efficacy, the Poster noted “[e]vidence of dose-response in 20-40 mg/day range” and a “[s]ignificant benefit on timed walking ... and lower extremity strength.” Op. 23.

Taken together, Schwid and Goodman disclosed a narrow range of 10-20 mg twice daily that safely and effectively helped MS patients walk. Appx71. Dr. Goodman conceded “that the Goodman Poster ‘suggest[s]’ ‘that the range for further testing would be the 20 to 40 milligrams per day [10 to 20 mg twice-daily] range.’” Op. 39. He also acknowledged that “‘a person of ordinary skill in the art in December 2003 would have been motivated ... to design a study along the lines of what became the 202 study,’ which tested the 10 mg twice-daily dose.” *Id.*

After a four-day bench trial, the district court “held that the defendants had proven that the asserted claims of the Acorda patents are invalid for obviousness.”

Op. 28. “Based on the publications discussed above, as well as expert testimony,” the court found, “as of 2004 (the priority date), a relevant skilled artisan would have been motivated to administer a stable dose of 10 mg of 4-AP twice daily and had a reasonable expectation of success in ... improving the walking ability of [MS] patients.” *Id.* Additionally, “the Acorda patents’ claim limitations regarding serum levels (the pharmacokinetic limitations) were inherent in the dosing claimed.” *Id.* As to objective indicia of obviousness, the trial court found, among other things, “that the Elan patent was a ‘blocking patent’ for the claimed methods of the Acorda patents: any marketer of a drug for uses practicing those methods would need a license to the Elan patent—to which Acorda, for years preceding the 2004 priority date, had an exclusive license from Elan.” Op. 28-29.

On appeal, the panel rejected Acorda’s challenge to all three of these findings. *First*, the panel addressed “the relevant skilled artisan’s motivations and expectations regarding the administration of a stable 10 mg 4-AP dose twice daily to improve walking.” Op. 31. The panel affirmed the district court as to all aspects of this challenge, finding:

- (1) “Acorda has not shown that Schwid renders the court’s findings ... clearly erroneous”;
- (2) “a person of skill would have a reasonable expectation of success for a stable-dosing scheme at low doses”; and
- (3) “Schwid, Goodman as a whole, and expert testimony supply a sufficient basis for ... finding ... a reasonable expectation of success.”

Op. 31-42. As a result, “the district court did not clearly err in finding that a person of skill at the time of the invention would have had a motivation to combine, and a reasonable expectation of success in combining, the teachings of the prior art to arrive at the Acorda invention of a stable regimen of 10 mg twice-daily sustained-release 4-AP to improve walking in multiple sclerosis patients.” Op. 42.

*Second*, the panel rejected the notion that “a skilled artisan would not have a reasonable expectation of success regarding the invention of the Acorda patents because the prior art did not teach or suggest a final limitation of the asserted claims—the pharmacokinetic limitation.” Op. 42-43. As the panel explained, affirming the trial court, the claimed pharmacokinetic effects were all disclosed in the prior art and inherent in the claimed 10 mg dose. Op. 43-45.

*Third*, the panel considered and rejected Acorda’s final argument—namely, that the district court erred in analyzing the objective indicia of obviousness. Op. 45-56. “Acorda focuse[d] on the district court’s reliance on the Elan patent as a blocking patent for the Acorda patents’ claimed inventions, in determining that commercial success, failure of others, and long-felt but unmet need did not ‘support’ or ‘militate in favor of’ nonobviousness.” Op. 45. Although “Acorda characterizes the district court as having applied a categorical rule that a blocking patent defeats the significance of such objective indicia to the obviousness determination,” “the district

court’s opinion is best read not as invoking a categorical rule, but as drawing conclusions on the limited factual record created in this case bearing on the effect of a blocking patent.” Op. 45-56.

As the panel explained, “[t]he existence of ... a blocking patent may deter non-owners and non-licensees from investing the resources needed to make, develop, and market ... a later ‘blocked’ invention, because of the risk of infringement liability and associated monetary or injunctive remedies.” Op. 46. The panel then discussed at length the Court’s blocking-patent jurisprudence, which requires weighing a “number of variables”:

- “the costliness of the project”;
- “the risk of research failure”;
- “the nature of improvements that might arise from the project, and whether such improvements will be entirely covered by the blocking patent”;
- “the size of the market opportunities anticipated for such improvements”;
- “the costs of arriving at the improvements and getting them to market”;
- “the risk of losing the invention race to a blocking-patent owner”; and
- “the risk that the blocking-patent owner ... will altogether refuse to grant a license ... or will demand so large a share of profits that the whole project is not worthwhile for the potential innovator—all evaluated in light of other investment opportunities.”

Op. 48-49.

In other words, “a blocking patent ... *can* be evidence that can discount the significance of evidence that nobody but the blocking patent’s owners or licensees

arrived at, developed, and marketed the invention covered by the later patent at issue in litigation.” Op. 49 (emphasis added). “But the magnitude of the diminution in incentive in any context—in particular, whether it was great enough to have actually deterred activity that otherwise would have occurred—is ‘a fact-specific inquiry.’” *Id.* (quoting *Merck Sharp & Dohme Corp. v. Hospira, Inc.*, 874 F.3d 724, 731 (Fed. Cir. 2017) (*Merck II*)).

This totality-of-the-circumstances approach reflects a “common-sense recognition that, as a theoretical matter, a blocking patent may *or may not* deter innovation[.]” Op. 48 (emphasis added). And it was “[a]gainst this background” that the panel “conclude[d] that the district court did not err in viewing the Elan patent, among other evidence, as evidence that discounted the weight of Acorda’s evidence [of secondary considerations] so that ‘the evidence as a whole’ ... ‘prove[d] clearly and convincingly that the Acorda Patents are invalid due to obviousness.’” Op. 50.

## **REASONS FOR DENYING THE PETITION**

### **I. The panel did not “expand” or “transform” blocking-patent principles; it carefully applied the existing, “fact-specific” rule of *Merck I* and *II*.**

According to the Petition, “the mere presence of a ‘blocking’ patent now negates objective indicia, even absent evidence of actual blocking.” Pet. 15. Acorda accused the district court of doing the same thing, “characteriz[ing] the district court as having applied a categorical rule that a blocking patent defeats the significance of ... objective indicia.” Op. 45-46. But as the panel explained, “the district court’s

opinion is best read not as invoking a categorical rule, but as drawing conclusions on the limited factual record ... bearing on the effect of a blocking patent.” Op. 46. The same is true of the panel opinion, which laid out no fewer than seven variables to test the effect of a blocking patent—including:

- “the risk of research failure”;
- “the nature of improvements that might arise from the project”; and
- “the size of the market opportunities.”

*Supra* at 9 (quoting Op. 49). Again, this multi-factor approach reflected a “common-sense recognition that, as a theoretical matter, a blocking patent may *or may not* deter innovation[.]” Op. 48 (emphasis added).

In short, Acorda’s “categorical rule” charge bears no resemblance to the panel opinion. But en banc review demands a legal hook—some doctrinal or textual question of “exceptional importance.” *See* Fed. R. App. P 35(a)(2); Fed. Cir. R. 35(b)(1). And unlike one of its amici, Acorda refuses to say that *Merck I* was wrongly decided. *See* BIO Br. 4 (“*Merck* ... rests on the unsupported assumption that the mere existence of a foundational patent would have prevented commercialization”). Instead, Acorda says the panel “expanded” and “transform[ed]” what it calls this Court’s “blocking-patent doctrine.” Pet. 1, 2, 4, 9-15. According to Acorda, that doctrine applies only in two situations: (1) where the patent’s blocking power is strengthened by regulatory exclusivity; *and* (2) when considering commercial success, but no

other secondary considerations. Pet. 9-12; PhRMA Br. 9 n.3. Acorda is mistaken on both scores.

*First, Merck I* observed that “[f]inancial success is not significantly probative” where “others were legally barred from commercially testing” the claimed inventions—such as where FDA has granted exclusivity to a patented product. 395 F.3d at 1377. But *Merck I* never limited its reasoning to such cases. Nor have any of this Court’s decisions applying *Merck I* done so. *See Syntex (U.S.A.) LLC v. Apotex, Inc.*, 407 F.3d 1371, 1383 (Fed. Cir. 2005) (not requiring regulatory exclusivity); *Galderma Laboratories, L.P. v. Tolmar, Inc.*, 737 F.3d 731, 740-741 (Fed. Cir. 2013) (same); *Merck II*, 874 F.3d at 730-31 (same). For example, *Galderma* found blocking-patent principles “applie[d] *forcefully*” where the patents “blocked the market entry of 0.3% adapalene products until their expiration in 2010, long after Galderma invented 0.3% adapalene compositions of the asserted claims.” 737 F.3d at 740-41 (emphasis added). As Acorda’s amicus admits, *Galderma* never suggested that regulatory exclusivity was required. *See PhRMA Merits Br. 7.*

*Second*, this Court has never suggested that blocking-patent principles apply only to commercial success. Nor would it make sense to read such a restriction into *Merck I*, *Merck II*, and later precedents. As the panel explained, blocking patents can counterbalance evidence of purported long-felt need and failure of others.

“*Merck II*’s reasoning reflects a common-sense recognition that, as a theoretical matter, a blocking patent may or may not deter innovation in the blocked space by commercially motivated potential innovators other than the owners or licensees of the blocking patent.” Op. 48. “[A] blocking patent therefore can be evidence that can discount the significance of evidence that nobody but the blocking patent’s owners or licensees arrived at, developed, and marketed the invention covered by the later patent at issue in litigation.” Op. 49.

By applying these sound principles to other secondary considerations, the panel did not “expand” blocking-patent principles or “transform” the teachings of *Merck I and II*. To the contrary, the panel held that “the evidence of blocking” here and its effect on long-felt need was “*not dispositive*.” Op. 56 (emphasis added). It certainly considered the “evidence of blocking” “pertinent,” but also held that Acorda’s evidence of the failure of others and long-felt but unmet need was “weak[.]” Op. 54-55; *see also infra* 7-10. Taking these factors together, along with a host of others, the panel held that secondary considerations did not defeat the showing of obviousness *in this case. Id.*

Instead of this nuanced approach, Acorda insists that the blocking-patent inquiry should abruptly stop at commercial success. Pet. 2. But each case is different. Rather than adopt a bright-line rule, it makes more sense to allow trial courts to weigh the effect of blocking patents together with all other secondary considerations.

To be sure, blocking patents tend to discourage innovation. But “the magnitude of the diminution in incentive in any context—in particular, whether it was great enough to have actually deterred activity that otherwise would have occurred—is ‘a fact-specific inquiry.’” Op. 49 (quoting *Merck II*, 874 F.3d at 731).

This sensible, fact-specific inquiry is exactly what is called for in *Merck I* and *II*. It is no basis for en banc review here.

## **II. The Petition rehashes factual disputes not fit for en banc review.**

Beneath its claims of doctrinal transformation, the Petition—like Judge Newman’s dissent—faults the panel’s analysis of the facts. For example, Acorda says the Elan patent would not have blocked research outside the United States or research protected by the Patent Act’s safe-harbor provision. Pet. 11-13. But the panel considered these very arguments, concluding that they were “relevant,” but “not shown to be weighty *in this case* by any concrete evidence about the particular inventions at issue.” Op. 52 (emphasis added).

Likewise, Acorda disagrees with the trial court’s finding that “Sanofi-Aventis likely did not use 4-AP because of the blocking effect of the Elan patent.” Pet. 13 (quoting Op. 55). But the panel considered that argument, too, and found “Acorda has not shown clear error in that finding.” Op. 55. This does not mean “that the mere presence of a blocking patent on the specific composition used in the invention negated the failure of others.” Pet. 13. It means that Acorda offered no

“persuasive basis for challenging the district court’s findings of the weakness of Acorda’s evidence of the failure of others and long-felt but unmet need.” Op. 54-55. That is a factual question. It does not require convening the whole Court.

Time and again, the panel’s thorough decision proves amply supported by the record. The panel described in close detail the history of research around the world before and after the Elan patent, the nature of Elan’s exclusive license to Acorda, and “unrebutted testimony from an expert in economics and pharmaceuticals that the Elan patent acted as a blocking patent for entities other than Acorda (the exclusive licensee to the Elan patent).” Op. 51. All this evidence introduced at trial “supports a finding that the Elan patent would have deterred entities other than Elan (holder of the Elan patent) and Acorda (exclusive licensee) from investing in research whose reward depended on marketing a drug like Ampyra.” Op. 52.

The panel was right not to second-guess these findings. After all, “[i]f the district court’s account of the evidence is plausible in light of the record viewed in its entirety, the court of appeals may not reverse it even though convinced that had it been sitting as the trier of fact, it would have weighed the evidence differently. 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, 573-74 (1985). Likewise, this Court “give[s] deference to a lower court’s factual findings regarding evidence of secondary considerations.” *Bristol-*

*Myers Squibb Co. v. Teva Pharms. USA, Inc.*, 752 F.3d 967, 978 (Fed. Cir. 2014) (citation omitted). “An examination for unexpected results is a factual, evidentiary inquiry ... and we give the [fact-finding tribunal] broad deference in its weighing of the evidence before it.” *Id.* (internal citations and quotation marks omitted). That is what the panel did here, finding the trial-court findings “supported by the record.” Op. 51.

Because the panel’s decision rests on factual determinations that apply only to this case, the decision cannot “jeopardize” pharmaceutical patents or improvement patents generally. Pet. 15-18; PhRMA Br. 6-8. As the panel cautioned, “we do not prejudice what evidence in another case might demonstrate.” Op. 53 n.17.

### CONCLUSION

The Petition is unfounded. The panel did not “nullif[y]” “factual findings of objective indicia based on an expanded blocking-patent doctrine.” Pet. 15. It considered the presence of the blocking patent as one “pertinent”—not “dispositive”—piece of evidence. In so doing, the panel laid down no categorical rule, but instead considered a “number of variables.” Op. 48-49. In its care and thoroughness, the decision is a model of blocking-patent analysis. It does not come close to justifying the “rare intervention” of full-Court review, which “should be reserved for real conflicts as well as cases of exceptional importance.” *DSU Med. Corp.*, 471 F.3d at 1311. This is not such a case.

Respectfully submitted,

/s/ Charles B. Klein

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and Teva Pharmaceuticals USA, Inc.*

### **CERTIFICATE OF SERVICE**

I certify that, on November 27, 2018, I caused the foregoing Defendants-Cross-Appellants' Roxane Laboratories, Inc. and Teva Pharmaceuticals USA, Inc.'s Response to Petition for Rehearing En Banc to be electronically filed with the Clerk of Court using the CM/ECF system, and thereby served via CM/ECF on all counsel of record who are deemed to have consented to electronic service.

Date: November 27, 2018

/s/ Charles B. Klein

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