

CLE Bibliography: NAPABA 2018 Panel

The New Political Fight - Solving America's

Drug Pricing Crisis with Patent Law

Priti Krishtel

- Carrier, M.A., (2012). *Why the Scope of the Patent Test Cannot Solve the Drug Patent Settlement Problem*. <http://stlr.stanford.edu/pdf/scopeofthepatent.pdf>, 16 STAN. TECH. L. REV. 1.
 - The article examines three problems with the scope of the patent test as it relates to drug patent settlements: (1) the test automatically assumes legality of the settlement, (2) the test assumes the patent is valid, and (3) the test ignores whether or not the generic drug infringes the patent in question.
- Darrow, J. J., (2007). *The Patentability of Enantiomers: Implications for the Pharmaceutical Industry*. http://stlr.stanford.edu/STLR/Articles/07_STLR_2, STAN. TECH. L. REV. 2.
 - Explores the evolution of patentability of chiral compounds, and in particular racemates and single enantiomers, under U.S. patent law.
- Rogers, D.L., (2014). Federal Circuit's *Obviousness Test for New Pharmaceutical Compounds: Gobbledygook?*, Public Law and Legal Theory Working Paper Series, No. 271.
 - Argues that the Federal Circuit's revised test for obviousness in pharmaceutical cases is inconsistent with KSR, is difficult to understand, and diverts attention from the text of Section 103. The article proposes that the revised obviousness test should be rejected and replaced by a test in line with the general standards Section 103 and KSR.
- Moir, H. V.J., & Palombi, L., (2013). *Patents and Trademarks: Empirical evidence on 'evergreening' from Australia*, ANU College of Arts & Social Sciences The Australian National University and University of Sydney.
 - In-depth analysis of a small number of patent evergreening cases involving litigation in Australia, and also the role of trademarks in evergreening.
- Kesselheim, A.S., Sinha, & M.S., Avorn, J., (2017). *Determinants of Market Exclusivity for Prescription Drugs in the United States*, American Medical Association and JAMA Internal Medicine Volume 177, Number 11.

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- The article explains the duration of patent and regulatory exclusivities as they relate to pharmaceuticals and other legislation that extends or could limit such exclusivity periods.
- Vokinger, K.N., Kesselheim, A.S., Avorn, J., & Sarpatwari, A., (2017). *Strategies That Delay Market Entry of Generic Drugs*, American Medical Association and JAMA Internal Medicine
http://jama.jamanetwork.com/article.aspx?doi=10.1001/jamainternmed.2017.4650&utm_campaign=articlePDF%26utm_medium=articlePDFlink%26utm_source=articlePDF%26utm_content=jamainternmed.2017.4650.
 - This article explores strategies that delay market entry of generic drugs and policy solutions to overcome such strategies and speed up generic competition.
- Kesselheim, A.S., Rome, B.N., Sarpatwari, A., & Avorn, J., (2017). *Six-Month Market Exclusivity Extensions To Promote Research Offer Substantial Returns For Many Drug Makers*, Health Affairs 36, no.2 :362-370 doi: [10.1377/hlthaff.2016.1340](https://doi.org/10.1377/hlthaff.2016.1340), originally published online January 18, 2017.
 - The article examines how an extended market exclusivity of six months as a reward for addressing unmet needs, whether to develop pediatric versions of medicines or to address rare diseases, generates substantial compensation to pharmaceutical manufacturers that far exceeds the cost of clinical trials.
- Lemley, Mark A., *Expect the Unexpected*.
Discusses tension in patent law between two doctrines - obviousness to try and unexpected results, describes how courts have tried to reconcile this tension and concludes that courts should favor obviousness to try as a prevailing doctrine.
- Sarpatwari, A., Sinha, M.S., & Kesselheim, A.S., (2017). *The Opioid Epidemic: Fixing a Broken Pharmaceutical Market*, Harvard Law & Policy Review, Vol. 11.
 - Non rigorous patenting standards and ineffectual policing of both fraudulent marketing and anti-competitive behaviour played an important role in launching and prolonging the opioid epidemic, and is not unique just to the opioid pharmaceutical market.