CLE Bibliography: NAPABA 2018 Panel

The New Political Fight - Solving America’s Drug Pricing Crisis with Patent Law

Priti Krishtel

  - 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.

  - Explores the evolution of patentability of chiral compounds, and in particular racemates and single enantiomers, under U.S. patent law.

  - 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.

  - In-depth analysis of a small number of patent evergreening cases involving litigation in Australia, and also the role of trademarks in evergreening.

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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.


- 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.