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Post-approval safe harbor…or not?

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Section 271(e)(1) of United States Code Title 35 provides a safe harbor when infringement is reasonably related to a FDA submission. This past session, the United States Supreme Court denied *certiorari* to two patent infringement cases claiming a safe harbor in regards to a drug post-FDA approval.Both accused infringers contend that if they infringed, the infringement was to provide FDA with post-approval data. The Court of Appeals for the Federal Circuit denied safe harbor in *Classen* but allowed safe harbor in *Amphastar*. The U.S. government asserts that the two Federal Circuit decisions can be reconciled. However, there are two distinct judicial views on the Federal Circuit. This session will address whether the two decisions are reconcilable or if there is a continued split in the law.

Biography

Brian R. Dorn, Ph.D., is a patent attorney at Barnes & Thornburg LLP's Minneapolis office. He has an array of experience in intellectual property with particular emphasis on biotech, pharmaceutical and medical device patent prosecution and opinion work. His practice also includes international patenting, where he works with universities, companies, and patent attorneys outside the United States to obtain patents in and outside the United States. He earned his *J. D. magna cum laude* and his Ph.D. from the University of Florida Colleges of Law and Medicine, respectively, in 2003. Full biography at http://www.btlaw.com/brian-r-dorn.

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