UNITED STATES

BioPharma Patents

QUICK NEWS & PRACTICE TIPS

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Harness Dickey ranked #2 U.S. patent firm based on objective performance in front of the USPTO by Juristat, a leading data-analytics source for U.S. patent prosecution metrics!

A. **A "contract supplier" exception to the on-sale bar?** The Medicine's Company ("MC") sells an injectable formulation of bivalirudin under the brand name Angiomax®, which advantageously contains only a very small amount of Asp9-bivalirudin. While MC was researching procedures to keep Asp9-bivalirudin levels low, they contracted with Ben Venue labs to test their experimental procedures. Some of this contract work was done more than one year before MC filed an application to cover the low-Asp9 bivalirudin formulations. Hospira convinced a three-judge panel of the Federal Circuit Court of Appeals ("CAFC") that MC's patent claims were invalid under the one year on-sale bar to novelty.[1] The panel held that it did not matter that Ben Venue was acting as MC's agent, or that Ben Venue was under a duty of confidentiality to MC prior to filing. The panel decision was widely criticized because the on-sale bar would not apply if MC had done the trials in-house, which means that this is essentially a penalty on MC for being too small to do the manufacturing itself. The full CAFC has agreed to reconsider the case *en banc*.[2] The USPTO has intervened as a friend-of-the-court to urge the en banc court to create a special "contract supplier" exception to the on-sale bar. **A "contract supplier" exception could benefit small pharma innovators, who often rely on contract manufacturers.**

B. **U.S. patent rights not exhausted by foreign sales!** The CAFC recently reconsidered whether U.S. patents are exhausted by sales abroad. The controlling law on this point (*Jazz Photo*) has long held that U.S. patents are only exhausted by U.S. sales. The Supreme Court recently held, however, that a U.S. copyright was exhausted by a textbook sale in Thailand (*Kirtsaeng v. John Wiley Publishing*). Sitting *en banc*, the CAFC held that *Kirtsaeng* applies only to copyrights, and changes nothing about U.S. *patent* law.[3] **Therefore, for example, when a patented pill is sold in Canada, the U.S. patent is not exhausted by the Canadian sale.**

C. **Purdue's OxyContin® claims held obvious.** Purdue owns patents covering an improved formulation of oxycodone hydrochloride having very little 14-hydroxycodeinone. Purdue sued Epic and other generic drug manufacturers who filed abbreviated new drug applications ("ANDAs") to market generic versions of Purdue's OxyContin®. A district court held that Purdue's patents were invalid as obvious. The patents purported to solve the problem of how to reduce contaminant content below 10 ppm. Purdue discovered that the contaminant formed during an acid treatment step in the manufacturing process. Once this was discovered, Purdue solved the problem by adding a hydrogenation step after the acid treatment. The discovery of the source of the problem was not obvious. Under U.S. patent law (the so-called "*Eibel Process* doctrine"), a claimed invention can be nonobvious if the source of the problem was not obvious, even if the claimed solution might well be obvious in view of the problem. MPEP §2141.02.III. However, the CAFC carved out an exception to the *Eibel Process* doctrine in this case.[4] Some of the ANDA defendants use other methods to reduce contaminant content. **The CAFC held that where there are other ways to solve the problem, and where the other ways do not rely on the patentee's discovery of the problem source, the patentee's discovery cannot establish nonobviousness.**

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[1] *Meds. Co. v. Hospira, Inc.*, 115 U.S.P.Q.2d 1587 (Fed. Cir. 2015) (withdrawn)
[2] *Meds. Co. v. Hospira, Inc.*, 116 U.S.P.Q.2d 2017 (Fed. Cir. 2015) *(en banc)*
[3] *Lexmark Int'l. v. Impression Prods.*, 117 U.S.P.Q.2d 1817 (Fed. Cir. 2016) *(en banc)*
[4] *Purdue Pharma v. Epic Pharma,* 117 U.S.P.Q.2d 1733 (Fed. Cir. 2016)