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Congressman Lamar Smith and Diverse Industry Groups Support Federal Circuit *en banc* Review of AIA's On-Sale Bar

August 2017

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The recent Federal Circuit ruling that the America Invents Act (AIA) on-sale bar renders a patent invalid if the invention was sold prior to the effective filing date of the patent, even if the sale did not publicly disclose the details of the invention, has garnered a lot of attention. There have been five amicus briefs filed supporting an *en banc* review of the decision. They include:

1. Congressman Lamar Smith (lead sponsor of the patent reform bill enacted as the AIA);
2. Pharmaceutical Research and Manufacturers of America (nonprofit association of research-based pharmaceutical and biotechnology companies)
3. Biotechnology Innovation Organization (trade association representing more than 1100 biotechnology companies, academic institutions, state biotechnology centers, and other organizations across the US and 30 other countries)
4. Boston Patent Law Association (association of 1,000 attorneys and other professionals related to intellectual property law)
5. Intellectual Property Owners Association (trade association representing 200 companies and over 12,000 individuals regarding intellectual property rights)

Each of these amicus briefs requests that the full panel decide whether existence of a sale becoming public is in itself sufficient for an "on-sale" bar, or whether the public disclosure must go farther and actually disclose details of the invention in its terms. Congressman Lamar Smith, the Pharmaceutical Research and Manufacturers of America, and the Biotechnology Innovation Organization further assert that the Federal Circuit's ruling in *Helsinn* was incorrect because congressional intent confirms that the subject matter defined by a claim must be available to the public before § 102(a)(1) can operate to invalidate a patent based on an inventor's "on sale" activities.

These requests follow the Federal Circuit reversal of the New Jersey district court which held that the four asserted Helsinn patents were not invalid because (1) Teva did not establish that the three patents governed by the pre-AIA on-sale bar were "ready for patenting" prior to the critical date of January 30, 2002; and (2) there was no "commercial offer for sale" with respect to the patent governed by the post-AIA on-sale bar where a sales

contract was publicly disclosed but the invention itself was not. *See Helsinn Healthcare S.A. v. Reddy's Labs., Ltd.*, 2015 US Dist. LEXIS 167048 at *6-7 (D.N.J. Nov. 13, 2015).

The Federal Circuit held that "after the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of sale." *See Helsinn Healthcare v. Teva Pharmaceuticals USA, Inc., et al.*, 855 F.3d 1356, 1371 (Fed. Cir. 2017).

The Federal Circuit found that a Supply and Purchase Agreement (SPA) executed on April 6, 2001, between Helsinn Healthcare (patent owner) and MGI Pharma (an oncology-focused pharmaceutical company) for MGI to purchase the 0.25 mg and 0.75 mg palonosetron products constituted a sale that embodied the asserted claims of the four patents-in-suit. *Id.* at 1366. Because the SPA was entered prior to the earliest filing date attributable to the four asserted patents, the Federal Circuit found the four asserted patents invalid pursuant to the on-sale bar. *Id.* at 1375.

On June 30, 2017, Helsinn requested that the Federal Circuit rehear the on-sale bar dispute *en banc.* The Federal Circuit has yet to rule on the request. If the Federal Circuit upholds its ruling in *Helsinn*, the post-AIA on-sale bar will have a significant impact on the scope of prior art by triggering invalidity upon an agreement for a sale executed prior to the effective filing date of a patent.

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