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Federal Circuit Returns the On-Sale Bar to Status Quo for AIA Patents

Contrary to USPTO guidance, invention details need not be publicly disclosed to trigger on-sale bar for AIA patents.

The Leahy-Smith America Invents Act (AIA)[1] is widely considered the most significant overhaul of US patent law since the Patent Act of 1952. Although the AIA became effective in 2013, the Federal Circuit has only recently had the opportunity to interpret the AIA's new or amended provisions because of the time required for AIA patents to be issued, litigated and come up on appeal. The US Patent and Trademark Office (USPTO), however, has processed hundreds of thousands of patent applications under new AIA provisions every year since the AIA became effective without the benefit of guidance from the Federal Circuit on what some of those provisions mean. One such provision is the on-sale bar under 35 U.S.C. Section 102, which prohibits patenting an invention that was on sale prior to seeking patent protection.

Product Development and the On-Sale Bar Under the AIA

Prior to the AIA, Section 102 prohibited patenting any invention that was "on sale in this country, more than one year prior to the date of the application for patent" even if the terms of the sale did not disclose the details of the claimed invention.[2] As a part the AIA, Congress amended Section 102 to bar the patentability of any invention that was "on sale, *or otherwise available to the public* before the effective filing date of the claimed invention."[3] The USPTO appears to have interpreted Congress' addition of the phrase "or otherwise available to the public" to require that the details of the claimed invention be publicly disclosed in the terms of the sale before the on-sale bar is triggered.[4] Some district courts have agreed with the USPTO, and alleged infringers have relied on those interpretations when defending against AIA patents that may be subject to the on-sale bar.

The on-sale bar has long posed a challenge for businesses facing competitive pressure to come to market early with new technologies. For example, in the biopharmaceutical industry, developing a new medicine and seeking US Food and Drug Administration (FDA) approval takes between 10 and 15 years with research and development (R&D) investment costs averaging US$2.6 billion.[5] As a result, innovator companies may enter into third-party manufacturing or distribution agreements to come to market as quickly as possible after FDA approval. Such activities potentially put biopharmaceutical companies at risk of running afoul of the on-sale bar.

Helsinn Healthcare v. Teva Pharmaceuticals

On May 1, 2017, the Federal Circuit addressed the scope of the on-sale bar under the AIA. In *Helsinn Healthcare v. Teva Pharmaceuticals USA, Inc.*, the Federal Circuit held that the AIA does not change

well-settled law that if the existence of a sale is public, the details of the invention need not be publicly disclosed in the terms of the sale to trigger the on-sale bar.[6]

Helsinn Healthcare (Helsinn) owns four patents directed to products for reducing chemotherapy-induced nausea and vomiting — one of which is governed by the AIA.[7] In 2001, almost two years before applying for its patents, Helsinn entered into a supply and distribution agreement with MGI Pharma, Inc. (MGI) under which MGI would pay Helsinn an up-front fee as well as future royalties to distribute Helsinn's products.[8] With the exception of price terms and specific dosages of the products, Helsinn and MGI's agreement was publicly disclosed in a joint press release, as well as MGI's Form 8-K filing, which included a redacted version of the agreement.[9] Helsinn later brought suit against Teva Pharmaceuticals (Teva), alleging that the filing of Teva's abbreviated new drug application would infringe various claims of Helsinn's patents.[10] Teva argued that Helsinn's AIA patent was invalid because Helsinn and MGI entered into the supply and distribution agreement before the critical date of the patent, thereby triggering the on-sale bar provision of Section 102(a).[11]

The district court disagreed, finding that Helsinn's patent was not invalid under Section 102(a) because no "public" commercial sale or offer for sale had occurred.[12] The district court reasoned that by adding the phrase "or otherwise available to the public" to AIA Section 102(a), the AIA changed the standard for the on-sale bar to require that a sale must publicly disclose the details of the invention.[13] The court held that because neither the press release nor the Form 8-K filing publicly disclosed the claimed dosage of the product, no public sale had occurred for purposes of Section 102(a).[14]

The Federal Circuit reversed, finding that the existence of Helsinn and MGI's agreement was public and that the agreement constituted a sale of the claimed invention before the critical date, triggering the on-sale bar provision of AIA Section 102(a).[15] The court addressed whether the AIA changed the meaning of the on-sale bar by adding the language "otherwise available to the public" to Section 102.[16] The court concluded that Congress did not require that the details of the claimed invention be publicly disclosed before the on-sale bar is triggered because "an invention is made available to the public when there is a commercial offer or contract to sell a product embodying the invention and that sale is made public."[17] The court stated that a "primary rationale of the on-sale bar is that publicly offering a product for sale that embodies the claimed invention places it in the public domain, regardless of when or whether actual delivery occurs."[18] Accordingly, requiring that the details of the claimed invention be publicly disclosed before the on-sale bar is triggered "would work a foundational change in the theory of the statutory on-sale bar."[19] The court concluded that AIA patents are subject to the same rule as pre-AIA patents — "if the existence of a sale is public, the details of the invention need not be publicly disclosed in the terms of the sale" to trigger the on-sale bar.[20]

Conclusion

While the Federal Circuit declined to address a number of open questions regarding Section 102,[21] *Helsinn* provides some much needed clarity regarding the scope of the on-sale bar under the AIA. In particular, companies should work closely with counsel when entering into and disclosing third-party agreements when developing, manufacturing and marketing their products prior to filing for patent protection. As *Helsinn* indicates, going forward, the Federal Circuit may disagree with the USPTO's interpretations of other AIA provisions under which thousands of patent applications have been and continue to be processed.

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Endnotes

1 Pub. L. No. 112-29, 125 Stat 284 (Sept. 16, 2011).

2 35 U.S.C. § 102(b) (Pre-AIA): Conditions for Patentability; Novelty and Loss of Right to Patent (Nov. 2015), *available at*, http://www.bitlaw.com/source/35usc/102_(pre%E2%80%91AIA).html (last visited May 31, 2017); *see, e.g.*, *In re Caveney*, 761 F.2d 671, 675-76 (Fed. Cir. 1985) (rejecting the argument that a sale or offer for sale did not trigger the on-sale bar when it had been "kept secret from the trade").

3 35 U.S.C. § 102(a)(1) (emphasis added).

4 MPEP § 2152.02(d) ("The phrase 'on sale' in AIA 35 U.S.C. 102(a)(1) is treated as having the same meaning as 'on sale' in pre-AIA 35 U.S.C. 102(b), except that the sale must make the invention available to the public . . . . The pre-AIA 35 U.S.C. 102(b) 'on sale' provision has been interpreted as including commercial activity even if the activity is secret. See MPEP § 2133.03(b), subsection III.A. AIA 35 U.S.C. 102(a)(1) uses the same 'on sale' term as pre-AIA 35 U.S.C. 102(b). The 'or otherwise available to the public' residual clause of AIA 35 U.S.C. 102(a)(1), however, indicates that AIA 35 U.S.C. 102(a)(1) does not cover secret sales or offers for sale.").

5 Pharm. Research & Mfrs. of Am., *Comments of the Pharmaceutical Research and Manufacturers of America Responding to the United States Patent and Trademark Office's Notice of Roundtables and Request for Comments Related to Patent Subject Matter Eligibility*, Dkt. No. PTO-P-2016-0041, at 1-2 (Jan. 18, 2017), *available at*, https://www.uspto.gov/sites/default/files/documents/RT2%20Comments%20PhRMA.pdf (last visited May 31, 2017).

6 *Helsinn Healthcare v. Teva Pharms. USA, Inc.,* Nos. 2016-1284, 2016-1787, slip op. at 27 (Fed. Cir. May 1, 2017), *available at*, http://www.cafc.uscourts.gov/sites/default/files/opinions-orders/16-1284.Opinion.4-27-2017.1.pdf (last visited May 31, 2017). The court also concluded that the invention was reduced to practice and, therefore, was ready for patenting before the critical date—satisfying both prongs of the Section 102 on-sale bar. *Id.* at 35.

7 *Id.* at 3.

8 *Id.* at 6-7.

[9] *Id*.

[10] *Id*. at 3.

[11] *Id*. at 3-4.

[12] *Id.* at 10.

[13] *Id*. at 19-20.

[14] *Id*. at 10.

[15] *Id*. at 27.

[16] *Id*. at 19-20.

[17] *Id*. at 23.

[18] *Id*. at 24.

[19] *Id*. at 22-23.

[20] *Id*. at 27. The on-sale bar is triggered when the first sale is finalized — in this case, when the supply and purchase agreement was signed. *Id*. at 17, 21-22.

[21] *Id*. at 21-22 (declining to address whether secret sales or uses may trigger the on-sale bar).