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Helsinn Redo Request Is Important Opportunity For Fed. Circ.

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It has been almost six years since Congress passed the Leahy-Smith America Invents Act, in which Congress amended 35 U.S.C. § 102 to read in part:

> [a] person shall be entitled to a patent unless the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.[1]

After the passage of the AIA, there was much speculation regarding how the phrase "or otherwise available to the public" would affect the traditional § 102 prior art categories of "patented," "printed publication," "public use" and "on sale," which remained the same after the AIA. By this change, many concluded that the AIA eliminated secret art derived from another's invention and secret prior inventions by another.[2] The AIA's new first-inventor-to-file system incentivized the rapid filing of patents, so some believed that it was no longer necessary to bar patentability based on secret art. Further, because this phrase could be interpreted in at least two ways — narrowing prior art to include only what was "otherwise available to the public" and excluding secret sales and secret commercial activity or expanding prior art to include additional activity that was "otherwise available to the public" without affecting traditional prior art categories — the patent law community has been waiting for the courts to explain the legal meaning of this phrase.

The Federal Circuit had the opportunity to interpret the phrase in Helsinn Healthcare SA v. Teva Pharmaceuticals USA Inc.,[3] but declined to do so. Instead, in nonprecedential dicta, the Federal Circuit indicated that application of the phrase "otherwise available to the public" may be limited and very fact-specific.[4]

Recently, Helsinn filed a petition for en banc review. A number of amici, including Rep. Lamar Smith, R-Texas, also filed briefs. Rep. Smith was the lead sponsor of the AIA bill (the "Smith" of the Leahy-Smith America Invents Act) and managed consideration of the bill in the House of Representatives.

In his brief, Rep. Smith argued that the panel decision was counter to the legislative text and Congress' intent in passing the legislation.[5] Rep. Smith asserted that the "insertion of the available to the public limitation was entirely intentional"[6] and that the panel ignored a committee report

stating that the public accessibility touchstone applied to all § 102(a)(1) questions, including "on sale" activities.[7]

Additionally, Rep. Smith contended that the AIA required that the panel should have addressed "whether these 'on sale' activities rendered available to the public the subject matter defined by the invalidated claims."[8] The on-sale bar, he argued, should only apply if the sale disclosed the subject matter of the patent.[9] Further, because the term "claimed invention" is now in the statute, he contended that the court is "obliged to undertake an element-by-element and limitation-by-limitation comparison of the claims at issue to the subject matter that the panel found had become available to the public, i.e., to determine if each claim limitation had expressly or inherently become publicly accessible."[10] And under this analysis, he argued, the court should have concluded differently.

Later this month, Teva's reply brief will be due. Ultimately, it remains to be seen whether the Federal Circuit will take advantage of this important opportunity to provide a much-needed interpretation of the phrase "or otherwise available to the public."

What Helsinn Tells Us About the Meaning of "Otherwise Available to the Public"

Helsinn arose from an abbreviated new drug application litigation relating to palonosetron compositions and methods claimed in four Helsinn patents, three of which were filed before the AIA and one that was filed after the AIA.[11]

Teva asserted that all four patents were invalid under 35 U.S.C. § 102(b) (pre-AIA) or 35 U.S.C. § 102(a)(1) (AIA) because the claimed invention was on sale more than one year before the respective priority dates.[12] Teva cited two agreements between Helsinn and MGI — a license agreement and a supply and purchase agreement[13] — that included an $11 million upfront payment for the claimed compositions of palonosetron. After the sale, the parties issued a joint press release and filed a U.S. Securities and Exchange Commission report, disclosing the agreement, with price terms and claimed dosage amounts (i.e., 0.25 mg of palonosetron) redacted.

The district court analyzed whether the sale barred patentability under pre-AIA § 102 for the ’724, ’725, and ’424 patents and under AIA § 102(a)(1) for the ’219 patent. Citing Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co. Inc.[14], the court concluded that the press release and SEC report represented an invalidating sale under pre-AIA law but not an invalidating sale under the AIA.[15] According to the court, Congress changed the interpretation of the on-sale bar to require that the terms of the sale be public. To be "public" under the AIA, the court reasoned that the sale must publicly disclose the details of the invention. Here, the claimed subject matter — the dosage of 0.25 mg of Helsinn's palonosetron formulation — was not disclosed to the public.[16] Thus, the '219 patent was held valid under the AIA.

On appeal, the Federal Circuit evaluated whether the public disclosures of the agreements were sufficient to invalidate the ’219 patent.[17] The Federal Circuit acknowledged the changed language of the statute and looked to the legislative history to interpret the statute. But in reversing the lower court, the Federal Circuit declined to interpret AIA § 102(a)(1) more broadly than was necessary, held that the AIA did not change the statutory meaning of "on sale" in the circumstances of this case, and held that the ’219 patent was invalid because of the on-sale bar.[18]

The Federal Circuit acknowledged the floor statements made by Sen. Patrick Leahy, D-Vt., and former Sen. Jon Kyl, R-Ariz., who said that the AIA was "to do away with precedent under current [§ 102]

law."[19] Such precedent held that certain secret uses were invalidating under the "public use" prong of § 102(b).[20] But the Federal Circuit emphasized Sen. Kyl's citation of cases involving public uses and his statement that "new section 102(a) precludes extreme results such as these."[21] Because Helsinn dealt with a sale and not a public use, the Federal circuit declined to address the effect of the phrase "or otherwise available to the public" on public uses.[22]

And, the Federal Circuit declined to address the effect of the phrase "or otherwise available to the public" on sales.[23] The Federal Circuit noted that its prior cases have applied the on-sale bar even when there was no delivery, when the delivery was set to occur after the critical date, and when the public could not ascertain the claimed invention.[24] The Federal Circuit noted that the floor statements did not indicate that the senators intended to overrule these on-sale cases.[25] In fact, the Federal Circuit pointed out that Sen. Kyl seemed to have agreed with this proposition, stating that "once a product is sold on the market, any invention that is inherent to the product becomes publicly available prior art and cannot be patented."[26]

The Federal Circuit concluded 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 the sale. Thus, the supply and purchase agreement constituted a sale under AIA § 102(a), notwithstanding the fact that the claimed 0.25 mg dose was not publicly disclosed.

Where Do We Go From Here?

After Helsinn, we are left without clear guidance about the meaning of the phrase "or otherwise available to the public" added to AIA § 102(a). Is it limited to public uses that are said to give "extreme results," and does it only apply to secret sales? In what situation would the court conclude that the claimed subject matter is not otherwise available to the public? It remains to be seen whether the Federal Circuit would uphold the validity of a patent if a sale of the patent were completely secret. Unfortunately it is difficult to tell in view of the Helsinn opinion.

We will have to wait for the Federal Circuit's decision whether to rehear the case. Ultimately, it may be up to the Supreme Court to decide the meaning of "or otherwise available to the public" in AIA § 102(a)(1). In the meantime, the panel from the Federal Circuit has given us little guidance.

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[1] 35 U.S.C. § 102 (2012).

[2] See, e.g., Robert W. Esmond, Donald J. Featherstone, Joel Aldrich, Brenda Crabtree & Dan Lawall, A Best Kept Secret: AIA Allows Patenting of Trade Secrets, 91 PTCJ 1064 (2016) (discussing the AIA's legislative history, textual canons of statutory construction, the statutory construction of similarly-worded language in other statutes, and the opinions of the U.S. Patent and Trademark Office and commentators).

[3] 855 F.3d 1356 (Fed. Cir. 2017).

[4] See id. at 1367-71.

[5] Brief for Congressman Lamar Smith as Amicus Curiae Supporting Appellee, Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc., No. 16-1284 (Fed. Cir., June 30, 2017).

[6] Id. at 7.

[7] Id. at 8 (citing H.R. 1249 Rep. No. 112-98 (2011)).

[8] Id. at 3 (emphasis in original).

[9] Id.

[10] Id.

[11] Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc., 855 F.3d 1356, 1359-60 (Fed. Cir. 2017). U.S. Patent Nos. 7,947,724 ("'724 patent"), 7,947,725 ("'725 patent"), 7,960,424 ("'424 patent"), and 8,598,219 ("'219 patent") were directed to compositions reducing the likelihood of cancer chemotherapy-induced nausea and vomiting (CINV). The '724 patent, the '725 patent, and the '424 patent were filed before AIA. The '219 patent was filed in May, 2013, after AIA took effect.

[12] Helsinn Healthcare, 855 F.3d at 1360. All four patents have a priority date of January 20, 2003. The Agreement occurred on April 6, 2001.

[13] n.b., The Supply and Purchase Agreement was contingent upon Helsinn gaining FDA approval. On appeal, Helsinn argued that the Agreement was a future sale and therefore was not technically a sale. The Court cited a litany of precedent against this argument. See Helsinn Healthcare, 855 F.3d at fn.13 (citing Pfaff v. Wells Electronics, Inc., 525 U.S. 55, 67 (1998); Merck & Cie v. Watson Labs., Inc., 822 F.3d 1347, 1352 (Fed. Cir. 2016); Hamilton Beach Brands, Inc. v. Sunbeam Prods., Inc., 726 F.3d 1370, 1374, 1377 (Fed. Cir. 2013)).

[14] 153 F.2d 516 (2d Cir. 1946).

[15] Helsinn Healthcare S.A. v. Dr. Reddy's Labs. Ltd., No. CV 11-3962, 2016 WL 832089, at *45, 49-52 (D.N.J. Mar. 3, 2016), rev'd sub nom. Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 855 F.3d 1356 (Fed. Cir. 2017).

[16] Id.

[17] Helsinn Healthcare, 855 F.3d at 1367.

[18] Id. at 1360, 1367-71, 1375.

[19] Id. at 1368.

[20] Id.

[21] Id. at 1368-69.

[22] Id.

[23] See, e.g., id. at 1371.

[24] Id. at 1370-71.

[25] Id. at 1371.

[26] Id.
