The Federal Circuit Has Its Final Say On the "On-Sale" Bar Under the AIA

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Over the last few decades, the United States has been incrementally harmonizing its patent law with the rest of the world. Those efforts continued with the signing of the America Invents Act ("AIA") in 2011. For example, the AIA created a first inventor-to-file patent system, while all but eliminating the best mode requirement. One area where we have not moved as far towards harmonization with the passing of the AIA as some initially thought is patent invalidity based on an "on sale" bar.

Almost as soon as the AIA was enacted, many commentators suggested that the new law eliminated attacks on patentability based on the theory that an embodiment of the invention was "on-sale", but where the invention itself was kept secret. Indeed, the United States Patent and Trademark Office concluded that the AIA did change the prior law, finding that "[t]he 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." *See* Examination Guidelines for Implementing the First Inventor to File Provisions of the Leahy-Smith America Invents Act, 78 Fed. Reg. 11,059, 11,075 (Feb. 14, 2013). One rationale offered for this interpretation is that it is consistent with the broad goal of harmonizing U.S. patent law with the rest of the world. And the rest of the world does not allow patents to be invalidated based on such secret activity (so long as those in the public are not able to reverse engineer the

invention). *See, e.g.*, European Patent Convention Art. 54(2) (2007). But many other commentators held the opposite view – that the AIA did not clearly change the law that such "secret sales" could be bar to patentability.

Those in the harmonization camp have now had their hopes all but completely dashed by the Federal Circuit's January 18, 2018 denial of rehearing and rehearing *en banc* in *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries, Ltd*., Case 2016-1284, 2016-1787 (Fed. Cir. 2018). A faint ray of hope for that camp may still exist since Helsinn has signaled that it will petition the Supreme Court to hear its case, though there is no guarantee the Court will take up that appeal. *See Id. at* Dkt. 199 (Appellee's Mot. to Stay Execution of Mandate) (January 18, 2018).

Helsinn **Facts**

Helsinn is a small family-run Swiss company that acquired a drug, palonsetron, for treating chemotherapy induced nausea and vomiting ("CINV"). One of Helsinn's patents asserted against Teva was subject to the new AIA law and claimed low-dose formulations for treating CINV containing 0.25 mg of palonosetron (as well as other excipients in specified amounts) in a 5 mL solution. In order to finance drug development, Helsinn contracted with a third-party in the United States to license and distribute its yet-to-be-developed final formulation. The deal required that the third party keep Helsinn's claimed inventions strictly confidential. Because the third-party company also was small, its Helsinn agreement was a "material" contract for the third-party company under US securities regulations, which required that it be publicly disclosed. Thus, a redacting copy of the agreement was publicly disclosed such that all formulation-related information was kept secret. *Helsinn Healthcare S.A. v. Dr. Reddy's Labs. Ltd*., No. CV 11-3962 (MLC), 2016 WL 832089, at *29 (D.N.J. Mar. 3, 2016).

"On-sale" novelty destruction Pre-AIA

Section 102(b) the 1952 Patent Act provides that an inventor is not entitled to a patent if, in the United States, the invention was "on sale" or "in public use" more than a year before the patent application is filed. Almost twenty years ago, the US Supreme Court decided that for the on-sale bar to apply: (1) the product must be the subject of a commercial offer for sale; and (2) the invention must be ready for patenting. For decades, US courts have found commercial offers for sale to be

invalidating, even if the details of the invention were kept secret, based at least in part on the policy to urge inventors to promptly disclosure their inventions, while at the same time controlling the risk that an inventor will commercially exploit his invention beyond the statutory patent right term.

In enacting the AIA law, Congress amended § 102 to bar the patentability of an "invention [that] was [1] patented, [2] described in a printed publication, [3] or in public use, [4] on sale, [5] *or otherwise available to the public* before the effective filing date of the claimed invention." 35 U.S.C. § 102(a)(1) (emphasis added) (2017). *See Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc*., 855 F.3d 1356, 1371 (Fed. Cir. 2017). The new law no longer requires an invalidating sale to be in the United States – now it can be anywhere. The issue in *Helsinn* was whether the italicized words, which were not in the 1952 law, now require that all the patentability bars be "available to the public" and therefore, carves out sales or offers for sale where the public could not discern the invention. In particular, Helsinn argued that the new statute expressly precludes such sales by adding the catch-all phrase "otherwise available to the public" to limit each kind of patentability bar. *See Id.*, Principal Brief of Plaintiffs-Appellees Helsinn Healthcare S.A. and Roche Palo Alto LLC, 2016 WL 1698099 at 34-41. Thus, in Helsinn's view, the "otherwise available to the public" applies to each of the categories where an invention was previously: [1] patented, [2] described in a printed publication, [3] in public use, or [4] on sale. *Id*.

The Federal Circuit panel was not persuaded, finding that if Congress had intended to make such an important change in the law, it would have used clearer language. *See Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc*., 855 F.3d 1356, 1371 (Fed. Cir. 2017). The court analyzed its pre-AIA on-sale bar cases and noted that patent forfeiture was found even when there was no delivery of the thing offered for sale, when delivery was set after the critical date and even when, upon delivery, members of the public could not ascertain the claimed invention. *Id*. In fact, numerous "on-sale" cases under pre-AIA section 102, held that the existence of a sale of the invention need not be public for the sale to preclude patentability. *Id*. Moreover, in declining to rehear the case, Judge O'Malley of the Federal Circuit explained numerous reasons why Helsinn's interpretation was not convincing, including that Helsinn's construction of the law would effectively make the "on-sale" bar superfluous because "public use" and "on-sale" bars would cover the same things. *See Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc., Teva*

Pharmaceutical Industries, Ltd., Case 2016-1284, 2016-1787 (Fed. Cir. 2018), Order on Petition for Rehearing En Banc at *8. Thus, the "otherwise available to the public" language of the new statute must presently be interpreted as a new attach-all category not previously captured by the 1952 law: for example – a speech, anywhere in the world that discloses the invention.

Practical Considerations

There is often a need to make distribution agreements public to induce investors to supply funding for product development, especially for small companies, where news of the agreement will likely be published in some form. Because the on-sale bar can be triggered even though the transaction is several steps removed from the consuming public that actually purchases the invention, special care should be exercised in crafting such agreements. This is especially so when the invention has been actually made or has been reduced to writing in an enabling disclosure. In such situations, all that is needed to trigger the bar is for there to be a "commercial sale or offer for sale". Almost always such problems can be avoided if counsel is informed. For example, if for some reason it is not possible to file the application (filing early is strongly encouraged) the transaction can be crafted so as to avoid any transfer of title, the prospect of being "on sale" should be remote.