

What High Court Will Consider in Helsinn On-Sale Bar Case

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The [U.S. Supreme Court](#) may soon resolve an issue that has sparked much debate since the enactment of the Leahy-Smith America Invents Act — namely, whether under the AIA, an inventor’s sale of an invention to a third party that is obligated to keep the invention confidential qualifies as prior art for purposes of determining patentability. On Dec. 4, 2018, the Supreme Court is set to hear oral arguments in [Helsinn Healthcare SA v. Teva Pharmaceuticals USA Inc.](#) on that very issue.



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Under Section 102 of the Patent Act, the “on-sale” bar can invalidate a patent when the claimed invention has been the subject of a commercial sale or offer for sale, and the invention is ready for patenting. Before the enactment of the AIA, Section 102 of the Patent Act provided in relevant part that “[a] person shall be entitled to a patent unless ... (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.” The Federal Circuit has construed the pre-AIA statute to apply the on-sale bar even if a patentee’s commercial activities took place in secret. That is, under the pre-AIA statute, a single sale or offer to sell is enough to bar patentability even if the details were confidential.



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The AIA amended the Patent Act to (among other things) eliminate the requirement that an invalidating public use or sale occur “in this country,” regroup the categories of prior art under Section 102, and add the clause “otherwise available to the public.” Section 102 now provides in relevant part that “[a] person shall be entitled to a patent unless — (1) 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.” The AIA’s amendment of the patent statute created uncertainty as to whether the on-sale bar now requires that sales or offers to sell be “public” to qualify as invalidating.

The issue came to a head in the Helsinn Healthcare case, which involves a patent on intravenous formulations of palonosetron for reducing chemotherapy-induced nausea and vomiting. Because of the patent’s effective filing date, it is subject to the AIA. In the district court proceedings, the accused infringer asserted (among other defenses) invalidity of the patent under the on-sale bar based on a supply and purchase agreement and a license agreement between Helsinn and MGI Pharma Inc. for the future sale of Helsinn’s claimed palonosetron product. Among other things, under the agreement, MGI received the rights to purchase from Helsinn any approved palonosetron product and to distribute and market the product upon approval. An appendix to the agreement included a qualitative description of the formulation of the products to be purchased. The agreement was subject to a confidentiality provision.

While the district court determined that the MGI agreement would be a “sale” under the pre-AIA on-sale bar, the court found that the same MGI agreement was not a “sale” under the post-AIA on-sale bar. The district court interpreted the amended statutory language to require a public sale or offer for sale of the claimed invention. The court further held that to be “public,” a sale must publicly disclose the details of the invention. Although a Form 8-K and a press release made the

existence of the MGI agreement known to the public, the court reasoned that the documents did not make the claimed invention itself — i.e., the palonosetron formulation — available to the public.

The Federal Circuit reversed, holding that public disclosure of the fact of a commercial sale invalidates a patent, even if the claimed invention remains secret and thus is not “available to the public.” In doing so, the Federal Circuit declined to read the addition of “otherwise available to the public” as accomplishing what the court characterized as “a foundational change in the theory of the statutory on-sale bar.”[1]

Helsinn appealed to the Supreme Court, challenging the Federal Circuit’s ruling as “untethered to the statutory text” of the patent laws. In its brief, Helsinn first argues that the plain text of the 35 U.S.C. 102(a)(1) requires that a sale make the claimed invention available to the public. According to Helsinn, where a catch-all provision (in this case, “or otherwise available to the public”) follows a list of more specific provisions (including “on sale”), the items enumerated in the specific provisions must be read in light of the catch-all provision.

Second, Helsinn argues that the legislative history supports its interpretation of the AIA — the legislators who enacted the AIA were clear about what they intended to do (impose a public-availability requirement) and how they intended to do it (by adding the catch-all provision).

Third, Helsinn argues that its interpretation of the AIA is also consistent with the AIA’s broader structure, including the switch from a first-to-invent regime to a first-inventor-to-file regime for the purpose of harmonizing American patent law with that of other countries. Helsinn submits that the Federal Circuit’s interpretation would make American law an outlier.

Finally, Helsinn argues that its interpretation promotes the policies underlying the patent system by preserving the basic quid pro quo of the patent system, preventing uncertainty about the status of prior art that would be harmful to the patent system, and encouraging innovation by affording small inventors an opportunity to develop their inventions.

In response, Teva argues that the Supreme Court has always read “on sale” as a term of art that encompasses even a single sale or offer to sell, whether or not the sale or offer publicly discloses the invention’s details. According to Teva, Helsinn’s reading would not only change — but would also drain — the meaning of the term, leaving a sale as nothing more than an example of a disclosure that makes the invention “available to the public.”

Teva puts forth a number of additional arguments in support of its position.

First, Teva argues that placing something “on sale” means making it “available for purchase.”

Second, Teva argues that Congress would have acted more clearly if it sought to change the term’s meaning.

Third, Teva argues that Congress did not indirectly change the meaning of “on sale” by adding the new catch-all category, which was instead added to ensure that the statute captures all public disclosures of the inventions.

Fourth, Teva argues that Congress' treatment of "public" disclosures in the AIA confirms that it did not upset the meaning of "on sale."

Fifth, Teva argues that the AIA's drafting history shows that Congress intended to preserve the on-sale bar's established meaning. After all, contends Teva, the catch-all category was added to the statute in bills that did not include the on-sale bar, and hence could not have been written to modify it.

Sixth, Teva argues that Helsinn's position would leave the on-sale bar incapable of serving the role for which it was created — preventing monopolies from being extended by a lengthy period of commercialization before the patent term.

Finally, Teva argues that the on-sale bar's settled interpretation is consistent with the policies served by other provisions of the AIA. As one example, Teva maintains that there is nothing inconsistent between extending the on-sale bar to international sales and otherwise leaving its established scope intact.

The solicitor general, on behalf of the United States, has sought — and was granted — leave to participate in the upcoming oral argument as *amicus curiae* supporting Helsinn.

If the Supreme Court disagrees with the Federal Circuit's interpretation, the most obvious result will be a narrowing of prior art available under the AIA — that is, certain contracts that constituted a "sale" under the pre-AIA on-sale bar will no longer qualify under the AIA. Moreover, if the court accepts the argument that "otherwise available to the public" modifies each of the preceding provisions of the post-AIA Section 102, a reversal could also render inapplicable a large body of case law relating to prior art based on "public use," as well as under the "on-sale bar."

For example, categories of prior art that could also be affected include instances where an invention is used in public but in a manner that is not ascertainable by the public, and instances involving commercial exploitation by the inventor of a machine or process where the machine or process is held secret. While under the pre-AIA statute and precedent both scenarios can sometimes bar patentability of an invention, a reversal in Helsinn could lead to the elimination of such activity as prior art. Finally, as a practical matter, if secret sales are found to no longer bar patentability, companies may have even more incentive to enter into confidentiality and nondisclosure agreements.

The Supreme Court's ruling is expected in early to mid-2019.

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Disclosure: WilmerHale filed an amicus brief on behalf of amici curiae Pharmaceutical Research and Manufacturers of America and Biotechnology Innovation Organization in connection with the Helsinn Healthcare appeal before the Federal Circuit.

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