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Legal Sidebar

Do "Secret Sales" Trigger the On-Sale Bar to Patentability under the America Invents Act?

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UPDATE (January 25, 2019): On January 22, 2019, the Supreme Court issued its opinion in Helsinn Healthcare S.A. v. Teva Pharmaceuticals Inc. *Justice Thomas's opinion for a unanimous Court held that a commercial sale of an invention to a third party who is required to keep an invention confidential places an invention "on sale" within the meaning of the Patent Act. The Court reaffirmed its holding in* Pfaff v. Wells Electronics, Inc. *that a patentable invention is considered "on sale" if it is (1) "the subject of a commercial offer for sale"; and (2) "ready for patenting." More specifically, the Court concluded that the 2011 America Invents Act's addition of a new catchall category of prior art that is "otherwise available to the public" did not alter the "well-settled meaning" of the on-sale bar, which requires an inventor to apply for a patent within one year after an invention is on sale.*

The original post on Helsinn v. Teva*, from December 3, 2018, is reproduced below.*

In general, an inventor must apply for a patent within one year after she puts her invention "on sale." Under longstanding precedent, an invention was considered to be "on sale" even if the sale (or the invention itself) was kept secret from the public. To use the patent law jargon, the traditional rule was that even a secret sale triggers the statutory "on-sale bar" to patentability.

Changes to patent law made by the 2011 Leahy-Smith America Invents Act (AIA) have raised questions about the continuing validity of this judicial interpretation of the on-sale bar. In its new definition of "prior art"—that is, the state of knowledge that is publicly known or available at the time of the patent application—the AIA retained the "on sale" category. However, the AIA also added a new catchall category of prior art: anything "otherwise available to the public before the effective [patent] filing date of the claimed invention."

In *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA Inc*., the Supreme Court granted certiorari to address whether the addition of the "otherwise" clause affects the meaning of the on-sale bar. Specifically, the Court will consider whether the sale of an invention to a third party, even if kept confidential, still triggers the on-sale bar, or if, per the "otherwise" clause, a commercialization must make the invention "available to the public" in order for the invention to be considered "on sale."

The outcome in *Helsinn v. Teva* could significantly change the scope of invalidating prior art and the actions that impact the patentability of inventions. As a result, the case has attracted substantial interest

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from patent law stakeholders, including through the thirty amicus briefs filed with the Court. Notably, two Members of Congress who were actively involved in the drafting of the AIA—Representatives Lamar Smith and Zoe Lofgren—have each filed amicus briefs, on opposite sides of the issue. *Helsinn v. Teva* is of particular interest to Congress because it presents a major issue of statutory interpretation regarding the AIA, the most significant patent reform law in over fifty years.

The Supreme Court is scheduled to hear argument in *Helsinn v. Teva* on December 4, 2018. This Sidebar reviews the legal and factual background to the case and analyzes the principal arguments of each side.

Section 102, Before and After the AIA

Perhaps the most basic requirement for a patent is that the invention must be novel. Granting a patent that removes extant knowledge from the public domain would conflict with the constitutional purpose of patent law: the advancement of innovation and useful technologies. Although one often thinks of novelty as measured against the work of others, in some circumstances the actions of the inventor herself can render an invention nonpatentable. For example, in *Pennock v. Dialogue*, a landmark 1829 Supreme Court opinion, the Court held that an invention is not patentable if the inventor permits "the thing invented to go into public use, or to be publicly sold for use, before he makes application for a patent." Congress eventually codified this holding, but granted the inventor a grace period (currently one year) in which a patent application must be made following the public use or sale of the invention.

Novelty is defined against the state of the prior art at the time of the patent application. Under former section 102(b) of the 1952 Patent Act, no person could obtain a patent if 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." The Supreme Court has held that the on-sale bar of former section 102(b) is triggered when the invention is (1) "ready for patenting"; and (2) "the subject of a commercial offer for sale."

The AIA retained the "on sale" language, but also added a new catchall category of prior art. Under current section 102(a)(1), an invention is not patentable if it 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 one-year grace period is now set forth in a separate subsection.)

Helsinn v. Teva: Factual and Procedural History

The dispute in *Helsinn v. Teva* concerns Helsinn's patents on formulations of palonosetron, a drug used to reduce chemotherapy-induced nausea and vomiting (CINV). Although the use of palonosetron to treat CINV was not itself new, Helsinn has patented several novel intravenous formulations of the drug.

On April 6, 2001, nearly two years before it applied for a patent, Helsinn entered into a license and purchase agreement (the License Agreement) with MGI Pharma, Inc. (MGI). Under the terms of the contract, MGI agreed to pay $11 million to Helsinn, plus future royalties, in exchange for the right to purchase the palonosetron formulations from Helsinn. The License Agreement was contingent on the Food and Drug Administration (FDA) approving the new formulations, which subsequently occurred. With the exception of the specific formulations (which were redacted), the License Agreement was made public as part of MGI's filings with the Securities and Exchange Commission.

In 2011, Teva filed an abbreviated drug application with the FDA, seeking to produce a generic version of the palonosetron formulations. Helsinn sued Teva for patent infringement, and Teva defended on several grounds, including that the patents-in-suit were invalid due to the on-sale bar. Helsinn's patents arise from a January 30, 2003 provisional application. A sale or public use before the critical date—January 30, 2002, one year before the patent application—would trigger the on-sale bar and invalidate the patent.

Thus, the critical question in *Helsinn v. Teva* is whether the April 2001 License Agreement sufficed to put the invention "on sale."

The district court held that the on-sale bar did not invalidate Helsinn's patent under the AIA. (Other patents-in-suit were issued before the effective date of the AIA, and are therefore not at issue in the Supreme Court appeal.) The court reasoned that the AIA amendments had changed the meaning of "on sale" such that only *public* sale would trigger the on-sale bar. Although the existence of the License Agreement was announced publicly, the claimed invention itself was not publicly disclosed. Therefore, in the view of the district court, the invention was not on sale in a way that was "available to the public," and thus the License Agreement did not trigger the AIA's on-sale bar.

The U.S. Court of Appeals for the Federal Circuit reversed in part. The Federal Circuit first analyzed the License Agreement under its pre-AIA case law, finding that the agreement had "all the hallmarks of a commercial contract for sale" that triggers the on-sale bar. Next, the court analyzed whether the AIA changed the meaning of "on sale" through the addition of the "otherwise available to the public" clause. The court concluded that, whatever the impact the AIA may have on "secret sale" cases, the License Agreement in *Helsinn* was, in fact, *not* secret because the existence of the contract was publicly disclosed. Although the palonosetron formulations were kept secret from the public, the panel reasoned that requiring the sale to publicly disclose the *invention itself* would work a "foundational change" in the on-sale bar, effectively overruling *Pennock v. Dialogue* and other seminal cases. The Federal Circuit concluded that Congress's addition of the "otherwise" clause, which left the phrase "on sale" intact, did not effect such a sweeping change in the law.

On June 25, 2018, the Supreme Court granted certiorari.

Must an Invention be "Available to the Public" to be "On Sale"?

In its merits brief, Helsinn relies primarily on the plain text of section 102(a)(1), with particular emphasis on the word "otherwise," to argue that the AIA altered the scope of the on-sale bar. In Helsinn's view, when a residual or catchall provision (here, the new "otherwise" clause) concludes a list of more specific categories, the other items in the list must be understood "in light of" the catchall provision. Relying on a definition of "otherwise" as meaning "in a different way or manner," Helsinn asserts that this word explicitly links the final clause to the other prior art categories. Thus, Helsinn argues that when Congress says that the invention must be "in public use, on sale, or otherwise available to the public," the natural interpretation is that "on sale" is limited to sales that make invention publicly available.

To buttress its argument, Helsinn relies on both legislative history and analogous Supreme Court precedent. As to legislative history, Helsinn points to floor statements from Senator Jon Kyl and Representative Lamar Smith suggesting that the "otherwise" clause was intended to overrule judicial opinions that had held that secret sales of an invention were patent-defeating prior art. As to precedent, Helsinn relies heavily on *Paroline v. United States* as presenting a similar issue of statutory interpretation. *Paroline* concerned a statute providing restitution for victims of child pornography. The statute enumerated several categories of covered losses—such as "medical services" and "lost income"—followed by a "catchall category" of "any other losses suffered by the victim as a proximate result of the offense." The Supreme Court interpreted the catchall clause as imposing a proximate cause requirement on all of the enumerated categories, not just the final one.

In response, Teva also relies primarily on the text of the statute, but emphasizes the phrase "on sale" and its longstanding judicial interpretation. Teva notes that Helsinn never actually defines the term "on sale." The plain meaning of "sale," Teva suggests, implies only a transfer of *ownership*, not a disclosure to the public. Teva notes that over a hundred years of judicial interpretation confirm that construction: the Supreme Court has held, for example, that a mere *offer* to sell triggers the on-sale bar, even though an offer does not ordinarily teach the public anything about the invention. As to the "otherwise" clause, Teva

asserts that it does not modify the phrase "on sale" as a grammatical manner, nor does it somehow "reverberate back" through section 102(a) to change the settled meaning of terms that Congress left intact. In Teva's view, the "otherwise" clause simply creates a new, *additional* category of prior art.

Moreover, Teva relies on a canon of statutory construction that, when Congress employs a term of art with a settled meaning, it must provide some "clear indication" if it intends to change that meaning. Here, if Congress had intended to change the meaning of "on sale," it could have explicitly required, for example, that the invention be "on sale publicly," or deleted "on sale" in favor of the "otherwise" category. Teva notes that earlier legislative proposals—in some cases, from the same Members whose floor statements Helsinn relies on—eliminated the on-sale bar entirely and replaced it with a uniform "available to the public" test. In Teva's view, the full drafting history of the AIA reveals that Helsinn's reliance on isolated floor statements is misplaced. (In the alternative, Teva argues that even assuming that there is a "publicness" requirement to "on sale," it is enough that Helsinn sold and disclosed the invention to MGI, a member of the public.)

The parties also debate the policy implications of their interpretations of the on-sale bar, and how they interact with the "first-to-file" patent system established by the AIA. On-sale bar decisions such as *Pennock* are motivated by the twin concerns of encouraging disclosure of inventions, and preventing the use of secrecy to obtain a *de facto* extension of the patent term. Teva claims that eliminating the on-sale bar for secret sales would undermine the purposes of the on-sale bar, permitting inventors to exploit inventions commercially years before applying for a patent—in effect, obtaining monopoly protection for longer periods than patent law permits. Helsinn argues that the policy arguments supporting the secret sale cases have been undermined by the AIA's switch to a first-to-file regime, wherein the first patent applicant gets priority even if she was not the first person to invent the subject matter of the patent. Under the AIA, Helsinn argues, inventors cannot keep their inventions secret without the risk that another inventor will beat them to the patent office.

Supporting Helsinn as amicus curiae, the United States argues that the phrase "on sale" inherently suggests a sale to public, which the "otherwise" clause confirms. The Solicitor General offers a two-prong, unified construction of section 102(a)(1), proposing that an invention can be placed in the public domain if: (i) the inventive idea is made publicly available (as in the case of a prior patent or an enabling publication); or (ii) when physical embodiments of the invention are made available to the public (as in the case of public uses or sales). Here, the License Agreement meets neither prong of the proposed test because it neither disclosed the invention to the public (the palonosetron formulations were redacted), nor made the drug itself available for purchase by the "ultimate customers." Rather, the agreement merely contemplated that MGI, at some point in the future, would provide the product to consumers.

Implications for Congress

As the amicus briefs of Representatives Smith and Lofgren demonstrate, Congress has a strong interest in ensuring that the AIA is interpreted in accordance with its intended meaning. Depending on the result, the Court's opinion in *Helsinn v. Teva* could significantly change the scope of prior art references that invalidate patents, overturning a large body of existing case law interpreting the "on sale" and "public use" categories. This change, in turn, would likely affect the incentives for inventors in applying for a patent, as opposed to keeping an invention secret. In the view of Helsinn and its supporters, this change is precisely what Congress intended to accomplish with the "otherwise" clause. Teva and its supporters view the "otherwise" clause as simply adding a new category of prior art that should not affect the settled meaning of "on sale." It remains to be seen how the Court will rule.

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