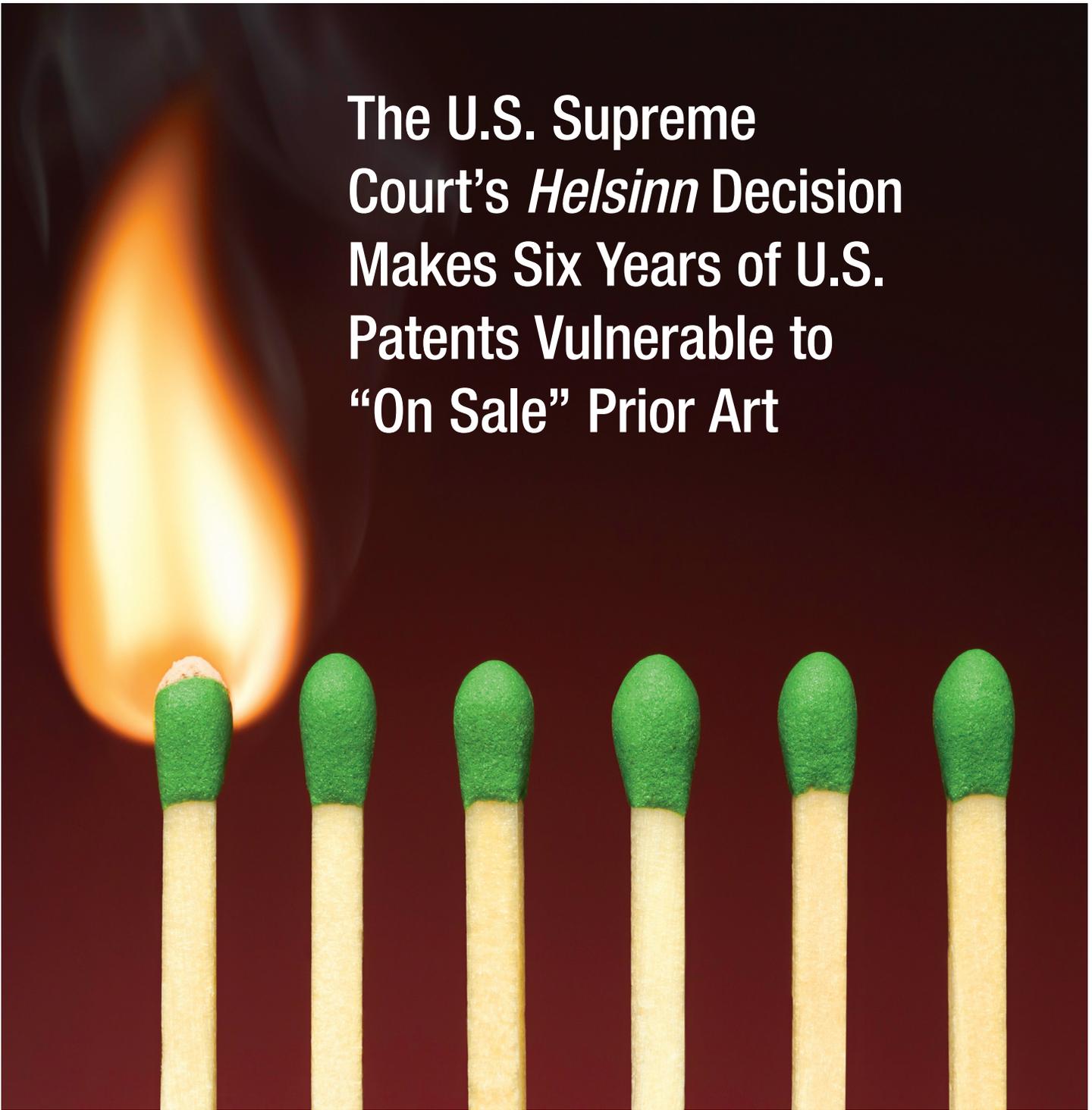


The U.S. Supreme Court's *Helsinn* Decision Makes Six Years of U.S. Patents Vulnerable to "On Sale" Prior Art



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To the surprise of the USPTO and many patent practitioners, an inventor's sale of an invention can qualify as

invalidating prior art under the America Invents Act, regardless whether the sale was public or private.

The 2011 America Invents Act (AIA) changed U.S. patent law from a first-to-invent to a first-to-file system, starting with new patent applications filed on or after March 16, 2013. The AIA also made fundamental changes to the requirements of novelty and nonobviousness for inventions claimed in those applications. Most of the changes were easily understood, but until January 22, 2019, it was unclear whether Congress intended to relax a certain condition for patentability. The Supreme Court's answer that day came as a surprise to the U.S. Patent and Trademark Office and many patent practitioners. As a result, many AIA patents issued before January 22 are vulnerable to unexpected invalidity challenges.

The Changes and Ambiguity Introduced by the AIA

Before the effective date of the AIA, Section 102 of the U.S. patent law, (35 U.S.C. §102), provided that a nonpublic sale, offer for sale, or commercial use of an invention by the inventor (or the inventor's employer or other assignee) could be prior art that was citable against the inventor's own patent application. If the inventor's nonpublic sale, offer for sale, or commercial use occurred more than one year before the date of the application, pre-AIA patent law denied the inventor a right to a patent for that invention, and any patent that was improperly issued was subject to invalidation in the courts. The United States was the only industrialized country that allowed an inventor's own nonpublic activity to be used in this way as prior art.

Since the enactment of the AIA, scholars have puzzled over whether certain language in the AIA indicated Congress' intent to bring U.S. patent law's treatment of an inventor's prior, nonpublic activity into line

with the rest of the world. The critical issue was whether the AIA's new list of prior art, in 35 U.S.C. §102(a)(1), included every sale, offer for sale, or commercial use by an inventor, or only such activity when it was "available to the public." Section 102(a)(1) states:

(a) *Novelty; Prior Art.*—A person shall be entitled to a patent unless—

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(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 problem arose from the ambiguity caused by Congress' placement of "on sale" just before "otherwise available to the public." The prior art types listed before the on-sale type—already patented, published, and in public use—are all public in nature, as is prior art that is "otherwise available to the public." When Congress inserted "on sale" between "in public use" and "otherwise available to the public," the sentence could be read to mean that that a sale needed to be known to the public ("made available to the public") to be considered on-sale prior art that would bar an inventor's subsequent attempt to patent an invention. This meaning made sense to many because it would have made U.S. patent law compatible with the laws of its trading partners, a stated goal of the act.

For these and other reasons, the U.S. Patent and Trademark Office (USPTO), as well as many scholars and practitioners, interpreted the new language to mean that an inventor's own confidential sale activity or secret commercial uses could no longer be used as prior art against the inven-

tor. See, e.g., U.S. Patent and Trademark Office, Manual of Patent Examining Procedure, §2152.02 (9th ed. Rev. 08.2017). Others believed that such a meaning was not intended because lower courts had long considered that on-sale prior art, as used in the version of §102 that preceded the AIA, included an inventor's confidential sale and secret uses. Judge Learned Hand, for one, took the latter view, reasoning that such an interpretation was necessary to prevent an inventor from enjoying exclusive rights to an invention for more than the statutory patent term. See *Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516, 520 (2d Cir. 1946) (holding that an inventor "shall not exploit his discovery competitively after it is ready for patenting; he must content himself with either secrecy, or legal monopoly").

The Resolution and Ramifications of *Helsinn*

Finally, more than seven years after Congress enacted the AIA, the U.S. Supreme Court weighed in with its decision in *Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*, 586 U.S. ___, 2019 WL 271945 (Jan. 22, 2019) (*Helsinn*). It held that a company's confidential agreement to supply an invention *can* be used against it, even when material aspects of the invention were kept confidential. The plaintiff, *Helsinn*, is a Swiss drug company that was developing a new drug. It entered into an agreement with a U.S. company to license the drug and supply the drug for distribution in the United States, once the drug received U.S. Food and Drug Administration (FDA) approval. In return, *Helsinn* received royalty income that it likely used to help fund FDA trials. *Helsinn* announced the agreement publicly but kept details of the invention secret. *Teva*, the alleged infringer, claimed that the agreement constituted on-sale prior art that rendered the patent invalid.

The Supreme Court ruled that decisions that predated the America Invents Act interpreting the term "on sale" were "settled," and Congress meant for "on sale" in the AIA to be interpreted the way that it had been interpreted before, effectively overturning the USPTO's contrary interpretation. It reasoned that Congress's

addition of the catchall phrase “or otherwise available to the public” was not clear enough to mark a change from the precedent that predated the AIA. As a result, the secrecy of *Helsinn*’s agreement was irrelevant to a prior art analysis, which has made patents filed by practitioners who relied on the USPTO’s AIA interpretation potentially vulnerable to invalidity, based on secret, prior art that may or may not have been disclosed to the USPTO.

Helsinn causes an inventor to forfeit all rights in an invention when sales activity occurred more than a year before the inventor filed a patent application. It also gives a challenger solid grounds to challenge the validity of any patent that was improperly granted after such acts. Challenges based on on-sale prior art are good subjects for summary judgment motions, since the thing that is subject to the on-sale bar is typically the same as or an obvious variant of the thing that has been patented.

Helsinn, combined with an America Invents Act change to the long-standing “grace period” under U.S. patent law, puts an inventor’s rights at risk for another reason. The previous law gave an inventor the opportunity to “swear behind” a second inventor’s disclosure if the date of the second inventor’s disclosure fell within a one-year grace period immediately after the original inventor’s sale or offer to sell. The ability to swear behind such “intervening prior art” often provided the applicant with an opportunity to claim priority of inventorship and to receive a patent having the same force and effect that would be accorded a patent based on an application that was filed before any “on-sale” or intervening disclosure event occurred.

The ability “to swear behind” was eliminated by the America Invents Act as part of the change from a first-to-invent to first-to-file system. Now, an inventor can disqualify intervening prior art only when the inventor (or another who derives information from the inventor) publicly disclosed the invention before another inventor created intervening art or filed a patent application. As a result, when a second inventor independently develops a product that is similar to a first inventor’s product and publicly discloses the similar product during the grace period that would follow

a first inventor’s secret sale, the second inventor’s disclosure can qualify as prior art and may compromise the first inventor’s patent rights. Even when an inventor *publicly* sells or discloses an invention having elements A, B, and C, if a second inventor later discloses an alternative having elements A, B, and C’, a variant of C,

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during the first inventor’s grace period, the disclosure of element C’ is prior art against the first inventor, and the second inventor is likely to be able to freely patent A, B, and C’. The second inventor’s disclosure of A, B, and C’ can also prevent the first inventor from using the combination of A, B and C’ if the second inventor receives a patent for the alternative. The change in the grace period provides additional opportunities for a challenger to avoid claims of patent infringement.

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mercial use, such as a behind-closed-doors practice of a useful process or method of manufacture, can be used as prior art. But *Helsinn* makes it much more likely that lower courts, and eventually the Supreme Court, will come to that conclusion. The secret, commercial-use doctrine was created by the courts and never codified in U.S. law, and the AIA’s changes to §102 therefore have less direct relevance to secret, commercial uses than to confidential sales activity. The Supreme Court hinted at its approval of the secret, commercial-use doctrine in *Helsinn* by referring to a pro-secret commercial-use doctrine decision issued by the U.S. Court of Appeals for the Federal Circuit in 1998.

Putting *Helsinn* to Use for U.S. Patent Challengers

Helsinn provides an opportunity for patent challengers to discover and use potent, on-sale prior art to invalidate a patent. A challenger should make a special effort to seek discovery of any secret sales, offers for sale, or commercial uses of the claimed invention when the patent at issue is based on an application filed after March 16, 2013. Invalidating secret prior art can take several forms, as long as it occurred after the invention was ready for patenting but before a patent application was filed. Examples include offers and agreements

- to sell products that embody the invention;
- to make products that embody the invention;
- to distribute products that embody the invention;
- to produce and deliver prototypes of products that embody the invention;
- to use a process or method as a trade secret; or
- to opt into any one of the above agreements in the future.

On-sale and commercial-use activity is often conclusive evidence of invalidity when it occurs more than one year before a patent application for the invention is filed. The case for invalidity is typically clear-cut and relatively easy to prove, and a favorable settlement or successful motion for summary judgment can be expected. It is not unusual for such opportunities to arise, since inventors often wait more than

a year to file after making an invention. A one-year delay can result from uncertainty about whether the product is worth protecting, a perceived need to develop aspects of a product that are unrelated to the claimed invention, and an inventor's need to raise additional capital or to obtain regulatory approval, as was the case in *Helsinn*. Other delays simply result from inventors' lack of diligence.

Additional research and analysis are needed if the secret prior art occurred within the one-year grace period. The challenger should determine whether the inventor made prior public disclosures (in addition to creating secret prior art) that included all elements of the claimed invention. The inventor's *public* disclosure during the grace period protects the inventor against subsequent disclosures by others during the grace period. 35 U.S.C. §102(b)(1)(B). The challenger should also determine whether it or an uninterested third party disclosed intervening prior art that can be leveraged against the inventor. If the challenger independently developed a similar invention and disclosed it during the one-year grace period, the challenger can likely make and use its invention without accounting to the inventor. If a third party developed a similar invention and disclosed it during the one-year grace period, the challenger can likely make and use the third party's invention without accounting to the patent owner, subject to payment of a royalty to the third party if it obtains patent rights in the invention.

Conclusion

The America Invents Act marked a profound change in U.S. patent law from first to invent to first to file. The AIA uprooted over 60 years of legal precedent and its complexity and notable ambiguities made its implementation more challenging. *Helsinn* finally resolves one of the most troublesome ambiguities, and it is not surprising that the USPTO and many practitioners disagreed with the Supreme Court's ultimate resolution. The six-year period of uncertainty caused many practitioners and their clients to disregard secret prior art and refrain from disclosing it to the USPTO. *Helsinn* provides a means for patent litigators to take advantage of the long-standing uncertainty. The opportu-

nity should be carefully addressed with due regard for the remaining complexities of the new law. But on-sale prior art, when found, is typically compelling and easily understood, making its pursuit well worthwhile. 