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# Supreme Court Report


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## Supreme Court Affirms Secret Sales Are Still Prior Art, Can Bar Patenting

On Tuesday, January 22, 2019, the U.S. Supreme Court held in *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA Inc.* that the America Invents Act (AIA) did not narrow the scope of the on-sale bar in patent cases, and that prior "secret sales" of an invention may invalidate a patent on the invention. Emphasizing that prior to the enactment of the AIA the term "on sale" had a well-settled judicial interpretation that included confidential sales, the Court held that Congress' inclusion of additional language in the AIA was not enough to evince a clear intent to change the scope of the on-sale bar for patents filed after the AIA was enacted.

## Background and Facts of the Case

Helsinn Healthcare S.A. (Helsinn) is a Swiss-based pharmaceutical company that owns U.S. Patent no. 8,598,219 (the '219 patent), among others. The '219 patent is directed to a formulation of palonosetron, the active ingredient in Helsinn's branded drug Aloxi, used to treat chemotherapy-induced nausea and vomiting. In January 2003, nearly two years before Helsinn filed its first provisional patent application covering palonosetron, Helsinn entered into two agreements with MGI Pharma, Inc. (MGI) for the license and sale to MGI of 0.25 mg and 0.75 mg doses of palonosetron.

Although the agreements were publicly announced in a joint press release, specific dosage formulations and details of the invention were not publicly disclosed, and MGI was under an obligation to keep confidential any proprietary information received under the agreements. In 2011, Teva Pharmaceuticals USA, Inc. (Teva) sought FDA approval to market a generic version of the 0.25 mg palonosetron product. Helsinn sued Teva for infringing its patents, including the '219 patent. The Federal Circuit ultimately found the '219 patent barred by the prior sale.

## Brief History of the On-Sale Bar

Every U.S. patent statute since 1836 has included some version of an on-sale bar. *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 67 (1998). The bar is generally intended to prevent the inventor from first selling the invention publicly, achieving widespread distribution, and later patenting the invention, thus excluding the public from any further use of the invention. Prior to the AIA's effective date of March 16, 2013, the on-sale bar was embodied in the patent statute at 35 U.S.C. § 102(b) as follows:

"*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***."—pre-AIA 35 U.S.C. § 102(b) (emphasis added)

The courts, prior to the AIA, consistently held that "secret sales," where the sale was kept confidential or where the invention was sold but required to be kept confidential, still trigger the on-sale bar and may be invalidating prior art. The AIA adopted the "on sale" language from the pre-AIA statute in 35 U.S.C. § 102(a)(1), but added the catch-all phrase "or otherwise available to the public," as follows:

"*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***." AIA 35 U.S.C. § 102(a)(1) (emphasis added)

Helsinn argued that the phrase "or otherwise available to the public" effectively modifies the preceding phrases, including "on sale" such that only public sales would be prior art under post-AIA patent applications. The Court disagreed, stating that it found no clear evidence that Congress intended to alter the scope of the on-sale bar. In adopting the pre-AIA interpretation of the on-sale bar, the Supreme Court further clarified that "secret sales" indeed remain within the scope of the on-sale bar, even if the sale is not publicly disclosed.

## The Supreme Court's Holding Runs Counter to Current USPTO Procedures

The United States Patent and Trademark Office (USPTO) has, to

date, interpreted the on-sale bar differently as applied to post-AIA patent applications, adopting Helsinn's position in the examination of patent applications. In particular, the current version of Manual of Patent Examining Procedure (MPEP) explicitly instructs patent examiners to consider the phrase "on sale" in the AIA as having the same meaning as "on sale" pre-AIA, "*except that the sale must make the invention available to the public*." MPEP 2152.02. Thus, the USPTO's interpretation and current examination practice excludes "secret sales" from the scope of the on-sale bar. While we expect the MPEP and USPTO procedures to be amended in the near future to align with the Supreme Court's holding in *Helsinn*, the current procedure and practice may have resulted in the issuance of certain patents that may be susceptible to challenge or invalidations in the future based on pre-filing secret sales.

## Takeaways

The AIA represented a tectonic shift in U.S. patent policy, and, as this decision demonstrates, its full scope and effect remain in flux. Entities that previously relied on nondisclosure agreements or other confidentiality provisions for protection from potentially invalidating prior sales may be at risk, and any such actions that were taken in reliance of the USPTO's current procedures should be reviewed with the help of counsel. Although it will depend on the specific terms of the agreement, common commercial arrangements, such as outsourcing, manufacturing, and evaluation agreements, may inadvertently result in on-sale bars against patentability. Furthermore, depending on the circumstances, it may be that even a single sale or offer to sell may bar patentability, and, as embodied in the Supreme Court's holding in *Helsinn*, there is no requirement that the sale or offer for sale be public.

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