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Supreme Court declines to narrow on-sale bar

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In *Helsinn Healthcare SA v Teva Pharmaceuticals USA, Inc*, the Supreme Court has unanimously declined to narrow the on-sale bar to public sales only in light of new language in the America Invents Act (35 USC §102).

Before the adoption of the act, Section 102(b) provided that a person is entitled to a patent unless "the invention was . . . 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". This provision is commonly known as the on-sale bar.

When the act came into force in 2011, Section 102 was amended as follows: "[a] person shall be entitled to a patent unless... the claimed invention was... in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention" (§102(a)(1)).

Section 102(b) provides a one-year grace period for disclosures made directly or indirectly by the inventor.

Most significantly, the act added the phrase "or otherwise available to the public" as a basis for the on-sale bar. The meaning of this phrase was the central focus of *Helsinn*. While developing a medication to treat chemotherapy-induced nausea, Helsinn entered into two confidential agreements granting another company the right to distribute, promote and sell that medication in the United States. Nearly two years later, Helsinn filed a provisional patent application covering the medication. Over the next 10 years, Helsinn filed four patent applications that claimed priority to the provisional application filing date. In 2011 it sued Teva Pharmaceuticals for infringing four of its patents, including one filed after the enactment of the act. Teva countered that the post-act patent in suit was invalid under the on-sale bar because the medication was on sale for more than one year before Helsinn filed the provisional patent application.

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The district court held that the post-act patent was not invalid under the on-sale bar because the agreement between Helsinn and its distributor did not publicly disclose the dosage levels of the drug. On appeal, the Federal Circuit reversed the district court's decision and found the post-act patent to be invalid. The court held that "after the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of the sale" for the sale to be invalidating under Section 102.

Helsinn sought – and was granted – Supreme Court review on a single issue – whether, under the America Invents Act, an inventor's sale of an invention to a third party that is obligated to keep the invention confidential qualifies as prior art for the purposes of determining the patentability of the invention. Helsinn's argument focused on the construction of the new catch-all language in Section 102 ("or otherwise available to the public").

The Supreme Court affirmed the Federal Circuit's holding in a nine-to-zero decision, holding that a sale or offer of sale need not make an invention available to the public to constitute an invalidating sale or offer to sell. The court determined that the addition of the phrase "or otherwise available to the public" was not sufficient to indicate that Congress intended to alter the meaning of "on sale".

Helsinn resolves a significant question regarding whether the enactment of the America Invents Act affected the applicability of the on-sale bar to secret sales. Just as before the enactment of the act, an inventor's sale of an invention to a third party who is obligated to keep the invention confidential can be invalidating under Section 102(a).

While the Supreme Court rejected the argument that the phrase "or otherwise available to the public" narrowed the scope of the on-sale bar, it remains to be seen whether courts will interpret this catch-all phrase to broaden the scope of the on-sale bar. For example, "or otherwise available to the public" might be interpreted to include any public distribution or notice of the invention, even if it does not qualify as a sale. Patentees should be cautious about entering into any agreement or engaging in any public disclosure regarding the invention prior to filing a patent application.

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