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Client Alert Commentary

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Supreme Court Says a Secret Sale Qualifies as Prior Art Under AIA

Helsinn *confirmed that the AIA did not alter the meaning of the "on-sale" bar.*

In *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc*, the Supreme Court addressed whether a confidential sale of an invention to a third-party may operate as prior art against a patent under the "on-sale" bar in the 2011 Leahy–Smith America Invents Act (AIA).[1] The Court answered in the affirmative, adhering to pre-AIA precedent.

Background

Every patent statute since 1836 has included an on-sale bar. The pre-AIA statute prevented a person from receiving a patent if, "more than one year prior to the date of the application for patent in the United States," "the invention was ... on sale" in the United States.[2] The AIA retained the on-sale bar and added the catchall phrase "or otherwise available to the public."[3] The United States Patent and Trademark Office (USPTO) interpreted that additional language as changing the "on-sale" bar to require that such sales be public.[4] But the USPTO's statutory interpretations are not binding on federal courts.

Helsinn Healthcare developed a drug called palonosetron to treat chemotherapy-induced nausea and vomiting. Helsinn entered into agreements with MGI Pharma to distribute, promote, and sell palonosetron in a certain dosage form. The agreements required MGI to keep that information confidential. Nearly two years later, Helsinn filed a patent application covering the same dosage. The resulting patent is governed by the AIA.[5]

Later, Helsinn sued Teva Pharmaceutical Industries for patent infringement. In defense, Teva argued that Helsinn's patent was invalid under the AIA's "on-sale" bar because Helsinn sold the claimed dosage to MGI more than one year before the patent application. Helsinn argued that the AIA's "on-sale" bar did not apply because there was no public disclosure of the dosage amounts as a result of its agreements with MGI. The district court agreed.[6] But the Federal Circuit reversed, holding that the invention need not be publicly disclosed to fall within the AIA's "on-sale" bar.[7]

The Supreme Court Decision

The Supreme Court unanimously affirmed. The Court held that the AIA — like the pre-AIA statute — precludes a person from obtaining a patent on an invention that was "on-sale" before the effective filing date of the patent application.

The Court explained that, although its precedent did not expressly address the issue of whether a sale (or offer) must be public to trigger the "on-sale" bar, the Federal Circuit had long held that "'secret sales' can invalidate a patent."[8] Accordingly, "[i]n light of this settled pre-AIA precedent on the meaning of 'on sale,' [the Supreme Court] presume[d] that when Congress reenacted the same language in the AIA, it adopted the earlier judicial construction of that phrase."[9] And the Court determined that Congress's addition of a catchall clause "or otherwise available to the public" was "simply not enough of a change" for the Court to infer congressional intent to alter existing precedent.[10]

Implications for *Helsinn*

Helsinn did not change the law. Patent owners and innovators should be aware that confidential or private sales of their invention may still bar patent rights, even if the sales omitted any public disclosure of the inventions. Instead, the best practice is *still* to file for a patent as soon as possible — and in no event more than a year after a sale of the claimed invention.

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[1] Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc., 586 U.S. ___, 2019 WL 271945 (2019).

[2] 35 U.S.C. § 102(b) (2006 ed., Supp. IV).

[3] 35 U.S.C. § 102(a)(1).

[4] MPEP 2152.02(d) On Sale [R-11.2013]; see also Examination Guidelines for Implementing First Inventor to File Provisions of the Leahy-Smith America Invents Act, 78 FR 11059 at 11060 (col. 3) (Feb. 14, 2013).

[5] The patent was filed in May 2013 and the AIA applies where the effective filing date on or after March 16, 2013.

[6] Helsinn, 2019 WL 271945, at *3.

[7] Id.

[8] Id. at *5 (citing, inter alia, Consolidated Fruit-Jar Co. v. Wright, 94 U.S. 92, 94 (1877) ("[A] single instance of sale or of use by the patentee may, under the circumstances, be fatal to the patent ...."); Special Devices, Inc. v. OEA, Inc., 270 F.3d 1353, 1357 (Fed. Cir. 2001) (invalidating patent claims based on "sales for the purpose of the commercial stockpiling of an invention" that "took place in secret"); Woodland Trust v. Flowertree Nursery, Inc., 148 F.3d 1368, 1370 (Fed. Cir. 1998) ("Thus an inventor's own prior commercial use, albeit kept secret, may constitute a public use or sale under §102(b), barring him from obtaining a patent")).

[9] Id.

[10] Id.