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Supreme Court Confirms 'Secret Sales' May Trigger On-Sale Bar

by Troy D. Smith

A FREEBORN & PETERS LLP CLIENT ALERT

ABOUT THIS CLIENT ALERT:

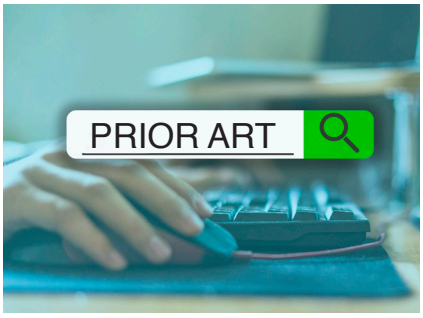
This alert addresses the Supreme Court's opinion in *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.* regarding the scope of the "on-sale bar" to patent applications following the America Invents Act (AIA). The Court clarified that secret sales can qualify as prior art under AIA § 102(a), though the exact boundaries of the post-AIA on-sale bar are somewhat unclear. Following this decision, any agreement with a third party relating to any unfiled inventions should be reviewed to determine whether it affects the deadline to file any corresponding patent applications.

On January 22, 2019, the Supreme Court ruled that a sale of an invention to a third party, who is required to keep the invention confidential, may be an on-sale bar for the invention. Justice Thomas, writing for a unanimous Court, opined that the America Invents Act (AIA) did not change the settled meaning of the term "on sale" from the pre-AIA statute. Secret sales of an invention, which could be an on-sale bar under the previous statute, therefore, may still be an on-sale bar for the invention under the AIA.

Background

Helsinn Healthcare acquired an AIA governed patent related to mitigating effects of chemotherapy using a 0.25 mg dose of palonosetron. More than one year prior to the effective filing date of the patent, Helsinn entered into two confidential agreements with MGI Pharma. One agreement allowed MGI to distribute, promote, market, and sell 0.25 mg doses of palonosetron in exchange for upfront payments and future royalties. The other agreement required MGI to purchase exclusively from Helsinn and provided that Helsinn would supply as much palonosetron as MGI needed. These agreements were publicly announced in a press release and in SEC filings, in which all mention of the 0.25 mg dosage was redacted.

One purpose of the AIA was to better harmonize the United States' patent system with the patent systems of other industrialized nations. Moving the United States from a first-to-invent system to AIA's first-to-file system was viewed as a major step to harmonization.



When Teva sought approval from the FDA to market a generic 0.25 mg palonosetron product, Helsinn sued for patent infringement. Teva countered that Helsinn's patent was invalid because the invention was on sale more than one year before the effective filing date of the application.

The District Court in New Jersey found that the agreements did not bar Helsinn from obtaining a patent covering the 0.25 mg dose because the agreements did not make the claimed invention available to the public. On appeal, the Federal Circuit reversed. The Federal Circuit ruled that if the sale is public, "the details of the invention need not be publicly disclosed in the terms of the sale" to fall within the AIA's on-sale bar. The Supreme Court upheld the Federal Circuit's decision.

The Supreme Court's Decision

Prior to the AIA, a patent could not be granted for an invention that 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." 35 U.S.C. § 102(b) (pre-AIA). Case law established that the one year date for an on-sale bar started when the invention was (i) subject of an offer for sale and (ii) ready for patenting. There was no requirement that the offer for sale itself be made public or that the sale disclosed the details of the invention to the public. Even "secret sales" implicated the on-sale bar once the invention had been reduced to practice, an approach that is unique to the United States.

One purpose of the AIA was to better harmonize the United States' patent system with the patent systems of other industrialized nations. Moving the United States from a first-to-invent system to AIA's first-to-file system was viewed as a major step to harmonization. As the pre-AIA "secret sale" bar was unique to the United States, many commentators believed the AIA changed the scope of the on-sale bar, further harmonizing the U.S. patent system with that of the rest of the world.

In arguing that the AIA removed the "secret sale" bar, Helsinn pointed to an amendment to the statutory language itself. Under the AIA, a patent will not be granted for inventions that were "in public use, on sale, *or otherwise available to the public* before the effective filing date of the claimed invention" 35 U.S.C. 102(a)(1). Helsinn asserted that the addition of the catch-all phrase "or otherwise available to the public" changed the scope of the on-sale bar, excluding secret sales because they were not "available to the public." The United States Patent Office itself took this position, expressly stating in its Manual of Patent Examining Procedures 2152.02(d). ("The 'or otherwise available to the public' residual clause of AIA 35 U.S.C. § 102(a)(1), however, indicates that AIA 35 U.S.C. § 102(a)(1) does not cover secret sales or offers for sale. For example, an activity (such as a sale, offer for sale, or other commercial activity) is secret (non-public) if it is among individuals having an obligation of confidentiality to the inventor").

However, in light of the Supreme Court's reasoning, inventors should cautiously assume that the AIA did not affect the scope of the on-sale bar at all and that any offers for sale – even if kept totally secret – could potentially trigger the bar.

The Supreme Court, however, ruled that the AIA did not change 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 the phrase. The addition of the "catch-all" language was not sufficient for the Court to conclude that Congress intended to alter the settled meaning of "on sale." Accordingly, the Supreme Court held that an inventor's sale of an invention to a third party who is obligated to keep the invention confidential can qualify as prior art under § 102(a). The judgment of the Federal Circuit was affirmed.

Implications

The Supreme Court ruling clarified that secret sales can qualify as prior art under § 102(a), the exact boundaries of the post-AIA on-sale bar are somewhat unclear. For example, the Supreme Court's ruling did not address whether the on-sale bar would have been implicated if Helsinn's agreements had not included the specifically-claimed dosage of palonosetron or, indeed, if the agreements had not been made public at all. However, in light of the Supreme Court's reasoning, inventors should cautiously assume that the AIA did not affect the scope of the on-sale bar at all and that any offers for sale – even if kept totally secret – could potentially trigger the bar.

Until the boundaries of the on-sale bar are further defined, agreements, SEC filings, and commercial activity relating to or disclosing features of an unfiled invention should be reviewed with patent counsel to determine to what extent, if at all, it impacts the timing of the filing of any related patent applications. In addition, patent counsel need to be familiar with clients' product development lifecycles to identify possible on-sale bar issues to avoid Helsinn's fate in this case.

To learn more about how this ruling could effect you, contact Troy Smith at tsmith@freeborn.com or 312-360-6926.

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ABOUT THE AUTHOR

Troy D. Smith

Senior Counsel

Chicago Office
(312) 360-6926

tsmith@freeborn.com

Troy is a member of the Litigation Practice Group. He counsels clients on intellectual property issues with a focus on strategic patent procurement and intellectual property portfolio management.

Troy has extensive experience in computer software and engineering. Prior to becoming an attorney, he worked as a senior software engineer for companies such as Motorola, Shoptalk, and CaseKnowledge.

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CHICAGO
311 South Wacker Drive
Suite 3000
Chicago, IL 60606
(312) 360-6000
(312) 360-6520 fax

NEW YORK
230 Park Avenue
Suite 630
New York, NY 10169
(212) 218-8760
(212) 218-8761 fax

SPRINGFIELD
217 East Monroe Street
Suite 202
Springfield, IL 62701
(217) 535-1060
(217) 535-1069 fax

RICHMOND
411 East Franklin Street
Suite 200
Richmond, VA 23219
(804) 644-1300
(804) 644-1354 fax

TAMPA
1 Tampa City Center
201 North Franklin Street
Suite 3550
Tampa, FL 33602
(813) 488-2920