



Intellectual Property ADVISORY ■

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Supreme Court Determines That the AIA Did Not Alter the Meaning of “On-Sale” Bar

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On January 22, 2019, the U.S. Supreme Court issued a [unanimous opinion](#) in *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA Inc.*, holding that Congress did not alter the meaning of “on sale” when it enacted the Leahy–Smith America Invents Act (AIA). Pre-AIA interpretations of “on sale” are unaltered; the on-sale bar can apply even when the sale does not make details of the invention available to the public. Specifically, under the AIA, “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 [35 U.S.C.] § 102(a).”

Background

Helsinn Healthcare S.A. makes a drug for treating chemotherapy-induced nausea and vomiting. Helsinn entered into a license agreement and a supply and purchase agreement with MGI Pharma Inc. under which MGI would market and distribute FDA-approved formulations of the drug. The agreements included dosage information and required MGI to keep confidential any proprietary information received from Helsinn. The agreements were publicly announced in a joint press release and reported in SEC filings, but with the specific dosage formulations redacted. Nearly two years after entering into the agreements, Helsinn began filing patent applications for formulations of the drug, obtaining several patents, including a patent governed by the AIA.

Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA Inc. sought FDA approval to market a generic version of the anti-nausea drug. Helsinn then sued Teva for patent infringement in the District of New Jersey. In response, Teva argued invalidity because Helsinn’s patented formulation was “on sale,” by virtue of the agreements with MGI, more than one year before the effective filing date of the patent application.

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Before the AIA, Section 102(b) of the Patent Act barred patenting if “the invention was . . . in public use or on sale in this country” more than one year before the effective filing date. The Federal Circuit repeatedly interpreted the statutory term “public” to modify “use” and not “on sale,” and therefore secret or confidential sales could trigger the so-called “on-sale bar.” In the AIA, Congress amended the statutory language (and placed it in Section 102(a)) such that patenting is barred if “the claimed invention was . . . in public use, on sale, or otherwise available to the public” more than one year before the effective filing date.

Helsinn argued to the district court that the AIA altered the meaning of “on sale” by adding the clause “otherwise available to the public” to the list of conditions that may preclude patenting. Under Helsinn’s interpretation of the new language, a sale must make the invention “available to the public” to trigger an on-sale bar. Applying that interpretation, Helsinn argued that its agreements with MGI did not bar patenting because the agreements, while publicly available, did not make the invention available to the public since the specific dosage formulations had been redacted. In contrast, Teva argued that Congress reenacted the phrase “on sale” without modification, and therefore did not change the meaning or disturb settled interpretations of the phrase. According to Teva, if Congress had intended to change the meaning of “on sale,” it would have done so directly and expressly. Teva posited that the AIA language “or otherwise available to the public” merely introduced a new category of invalidating prior art, such as oral presentations.

The district court agreed with Helsinn, holding that under the AIA an invention is not “on sale” unless the sale makes the invention available to the public. The Federal Circuit, however, [reversed](#), ruling that the AIA did not change the meaning of “on sale.” The appeals court explained that, after the AIA, the on-sale bar applies “if the existence of the sale is public.” The details of the invention need not be publicly disclosed, and the public need not be able to ascertain the invention. Therefore, because the Helsinn–MGI agreements constituted a sale of the claimed invention before the critical date, the on-sale bar applied, invalidating Helsinn’s AIA patent. The Federal Circuit specifically rejected Helsinn’s contrary interpretation of the statute, which “would work a foundational change in the theory of the statutory on-sale bar.”

Supreme Court Affirms

Writing for a unanimous Supreme Court, Justice Thomas ruled that “the reenactment of the phrase ‘on sale’ in the AIA did not alter th[e] meaning” of “on sale” as interpreted in the Court’s decision in *Pfaff v. Wells Electronics Inc.* Therefore, “an inventor’s sale of an invention to a third party who is obligated to keep the invention confidential qualifies as prior art for purposes of determining the patentability of the invention.”

After noting that “[e]very patent statute since 1836 has included an on-sale bar,” and after recounting the long history of pre-AIA precedent interpreting the phrase “on sale,” the Court found it significant that Congress “retained the exact language used in its predecessor statute.” The Supreme Court “presume[d] that when Congress reenacted the same language in the AIA, it adopted the earlier judicial construction of that phrase.” The earlier construction included the Federal Circuit’s long-held view “that ‘secret sales’ can invalidate a patent.” In short, the Supreme Court determined that Congress’s addition of the catchall phrase “or otherwise available to the public” in the AIA was “simply not enough of a change for us to conclude that Congress intended to alter the meaning of the reenacted term ‘on sale.’” The new catchall phrase serves only to “capture[] material that does not fit neatly into the statute’s enumerated categories but is nevertheless meant to be covered.”

Impact: Much Ado About Nothing?

The Supreme Court's decision leaves intact decades of precedent interpreting the statutory phrase "on sale." Therefore, pre-AIA interpretations of the phrase will continue to apply, even for patents subject to the AIA. Specifically, secret (nonpublic) sales before the critical date can bar patenting and can serve to invalidate a patent already issued.

The Supreme Court's *Helsinn* decision has one notable, and potentially sizeable, impact on AIA-based patent prosecution occurring before the decision. Since 2013, the U.S. Patent and Trademark Office (USPTO) has interpreted the AIA's "on sale" language to require that an invention be made "available to the public" in order to trigger an on-sale bar. In particular, according to the USPTO's Examination Guidelines issued in 2013, a "secret sale or use activity does not qualify as prior art" under the AIA. The Supreme Court has now rejected that view, meaning the USPTO has issued more than 1 million patents since 2013 under an incorrect interpretation of the on-sale bar. Patent applicants during that time may not have disclosed secret or private sales, on the ground that such sales were not material to patentability under the AIA. Patent owners should revisit their patenting activities since 2013 to ensure compliance with the Supreme Court's interpretation of "on sale" under the AIA. For ongoing or anticipated prosecution, all sales should be evaluated for the possibility of a bar, whether under pre-AIA Section 102(b) or AIA Section 102(a).

Turning to a neighboring statutory phrase—"in public use"—we believe the Supreme Court's interpretation of "on sale" now guides the proper interpretation of that phrase. Like "on sale," Congress reenacted the phrase "in public use" in the AIA without alteration. In *Helsinn*, the Supreme Court specifically relied on that approach: "The new § 102 retained the exact language used in its predecessor statute ... and, as relevant here, added only a new catchall clause ('or otherwise available to the public')." Notably, the Court cited favorably the Federal Circuit's decision in *Woodland Trust v. Flowertree Nursery Inc.* The Supreme Court quoted, and thus embraced, the statement in *Woodland Trust* that "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."

Before the AIA, the USPTO had interpreted "public use" to mean a use that was accessible to the public or commercially exploited. Under the AIA, by comparison, the USPTO interpreted "public use" to apply only when the use was accessible to the public, excluding private uses even when there was commercial exploitation. Here, too, the USPTO's interpretation of the AIA's statutory language appears to be incorrect. We expect courts and the USPTO to interpret *Helsinn* as confirming pre-AIA interpretations of "public use," just as the decision confirms pre-AIA interpretations of "on sale." Accordingly, we expect the public-use bar to continue to include secret uses of manufacturing processes and products that are not able to be reverse-engineered from the resulting products. Going forward, clients should proceed with caution while the USPTO reconsiders its statutory interpretations in light of *Helsinn*. Please reach out to us for guidance in particular scenarios you may be facing.

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