



Six months out a Supreme Court case still leaves patent questions unanswered

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Early this year the United States Supreme Court held in *Helsinn Healthcare S.A. v. Teva Pharmaceuticals U.S.* that the America Invents Act (AIA) may have actually broadened the scope of what counts as a sale. As patent practitioners know, 35 U.S.C. § 102 prohibits applicants from obtaining patents for any invention that has been “on sale” for more than a year before the effective patent-filing date. This on-sale restriction existed previously, but the AIA added a confusing catchall phrase barring patents for inventions that were “otherwise available to the public,” and also removed the requirement that the sale be in the United States. Until *Helsinn*, it was unclear whether this catchall phrase rendered more invention ineligible for patent protection.

How “private” does a sale have to be to avoid the on-sale bar?

Helsinn Healthcare S.A. entered into a confidential agreement with MGI Pharma, Inc. to market and sell a new drug. Details about the drug were not made public, but the existence of the sale was. Nearly two years later, *Helsinn* filed a provisional patent application for their new drug, which eventually led to U.S. Patent No. 8,598,219. *Helsinn* filed suit against *Teva Pharmaceuticals U.S.*, asserting infringement of the '219 patent. The District Court ruled that the AIA had changed the definition of “on sale,” and that sales where details of the invention were not disclosed to the public now did not qualify as “sales” for the purpose of § 102. The Federal Circuit reversed the District Court’s ruling, and the Supreme Court granted certiorari to resolve the question.

In his unanimous opinion, Justice Clarence Thomas noted that the new language of the post-AIA on-sale bar was adopted in light of a well-developed body of law holding that a sale did not need to disclose invention details to bar patenting. Because post-AIA § 102 retained the same “on sale” phrase, the new catchall phrase did not now require invalidating sales to publicly disclose details of the invention. According to Justice Thomas, attempting to alter the well-settled meaning of “on sale” in this manner would be “fairly oblique,” and thus was “not enough of a change for us to conclude that Congress intended to alter the meaning of the re-enacted term ‘on sale.’” As such, Justice Thomas concluded 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.”

The broad language in the Supreme Court's opinion does not clarify whether private sales that don't reveal invention details prohibit patenting. The Federal Circuit's opinion distinguished *Helsinn's* sale from prior cases where the existence of the sale itself was a secret, and specifically concluded that "if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of sale." However, the Supreme Court did not distinguish between public sales that keep invention details private and private sales whose existence is never revealed.

Six months after the Court's decision in *Helsinn*, no lower courts have answered this question about unrevealed private sales. In *Barry v. Medtronic*, the Federal Circuit held that the on-sale bar was not implicated because the invention was not ready for patenting at the time of the alleged sale, prior to the critical date. 914 F.3d 1310, 1331 (Fed. Cir. 2019). And in *Quest Integrity USA, LLC v. Cokebusters USA Inc.*, the Federal Circuit confirmed that the sale of a product "produced by performing a claimed process implicates the on-sale bar." 924 F.3d 1220, 1227 (Fed. Cir. 2019). The Southern District of Texas addressed *Helsinn* more directly in *Schlumberger Tech. Corp. v. BICO Drillings Tools, Inc.*, but simply noted that even under *Helsinn*, it is only private sales by the patentee that implicate the on-sale bar, not private sales by third parties. 2019 WL 2450948, *6 and *9-*10 (S.D. Tex., June 12, 2019).

How do foreign sales affect the on-sale bar?

Helsinn also created some uncertainty about the scope of prior art. Pre-AIA, a purely foreign use or sale did not trigger the on-sale bar. The AIA, however, removed the geographical limitation of all prior art, including the on-sale bar. Thus, it remains to be seen if confidential transactions and activities in foreign countries can now trigger the on-sale bar.

Is there a distinction between secret sales and secret uses?

Helsinn also did not distinguish between secret commercial *sales* and secret commercial *uses*. However, the Supreme Court did endorse the dictum from the Federal Circuit's 1998 *Woodland Trust* decision ("... an inventor's own prior commercial use, albeit kept secret, may constitute public use or sale under 102(b), barring him from obtaining a patent."). In doing so, the Court seems to be saying secret commercial sale and secret commercial use are to be treated similarly. Thus, a trade secret or private commercial use may also now trigger the on-sale bar.

It remains to be seen if a trade secret or private commercial use by one party can trigger the on-sale bar against another party. *Helsinn* hints that secret commercial sale and secret commercial use are to be treated similarly. In other words, *Helsinn* is saying that a trade secret or private commercial use, just like the "private sale" in *Helsinn*, can be prior art under 35 U.S.C. § 102(a). While § 102(b) provides exceptions for certain disclosures made by the inventors, § 102(b) makes no exceptions for disclosures made by a third party. As such, private commercial use by one party may trigger the on-sale bar against another party. While the Court clarified that the term "on sale" means the same as in pre-AIA law, it remains to be seen if pre-AIA case law on exceptions to the on-sale (and "public use") bars for experimental use still remains authoritative in view of the changes in AIA. Thus, while the meaning of "on sale" may remain the same after *Helsinn*, the full impact of *Helsinn* will be significant and will trap the unwary.

What questions should companies ask themselves following the Supreme Court's decision in *Helsinn*?

- Are any of their sales affected by the USPTO's interpretation of the post-AIA on-sale bar? Beginning with the 9th Edition published in 2014, the MPEP indicated that sales under post-AIA § 102 "must make the invention available to the public." M.P.E.P. § 2152.02(d). Companies that have made potentially invalidating sales in reliance of this statement will want to ensure that they file an application prior to the end of the one-year grace period.
- Are their sales private, or publicly disclosed? Because neither the *Helsinn* opinion or any subsequent opinions determined whether such private sales trigger the on-sale bar, it is still possible that these private sales, if occurring prior to the critical date, could invalidate any future patents on the invention.
- Are there international sales that are now covered by the on-sale bar? The Court's decision did make it clear that the on-sale bar is now expanded to cover international sales.
- Are there private commercial uses? The Court did hint that private secret sales and private commercial use are to be treated similarly, so private commercial uses, even without a sale, might be setting a company up for problems down the line.

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