



ALERTS

U.S. Supreme Court Holds Secret Sales Remain Prior Art

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The U.S. Supreme Court recently handed down its much-anticipated decision in *Helsinn Healthcare S. A. v. Teva Pharms. USA, Inc.*, Case No. 17-1229 (U.S. Jan. 22, 2019). The issue in *Helsinn* was whether confidential or secret sales remain prior art after the America Invents Act (the AIA) amended § 102(a) of the Patent Code to define prior art as anything “patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.” The court unanimously concluded that the AIA did not remove confidential or secret sales from the prior art.

Factual and Procedural Background

Helsinn Healthcare S. A. is a small, family-owned and operated private Swiss cancer care company with headquarters in Lugano, Switzerland. At the relevant times, Helsinn’s business model involved contracting with partners for commercial distribution and marketing of its products. Consistent with this model, Helsinn executed a License Agreement and a Supply and Purchase Agreement with MGI Pharma for a product covered by the claims of the patents-in-suit and the parties executed them before the “on-sale” critical date.

Also before the “on-sale” critical date, Helsinn and MGI Pharma issued a joint press release announcing the execution of the agreements, and MGI Pharma filed a Form 8-K report with the SEC that described the agreements. While the press release and 8-K filing referred to the execution of these agreements and to the active ingredient

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(palonosetron), they did not disclose all the elements of the claim, most notably the dosage. The agreements themselves at all times remained confidential except for the few details disclosed in the press release and Form 8-K.

After Helsinn sued Teva for infringing various patents, Teva asserted the defense that the patents were invalid as anticipated by the “secret sale” of the invention to MGI Pharma. Most of the patents were governed by pre-AIA law, but one was governed by the AIA. The district court ruled that the AIA had eliminated secret sales as prior art, and basing its decision on the language of the statute – that the word “otherwise” implied that all the prior categories under post-AIA § 102(a) involve public disclosures – as well as the legislative history, patent office guidelines, and public policy.

On appeal, the U.S. Court of Appeals for the Federal Circuit reversed the district court’s decision. The appellate court found that the AIA did not change the meaning of “on sale” in the circumstances of this case, emphasizing that the issue is fact-sensitive and as such, confidential or secret sales of the invention can still be invalidating prior art. The Federal Circuit also denied rehearing en banc, with Judge O’Malley again noting that the decision was narrow and based on the facts of the case. These rulings set the case up for the Supreme Court’s review.

The Supreme Court Unanimously Affirms the Federal Circuit in a Brief Opinion

When the Supreme Court agreed to hear the case, many thought it would reverse the Federal Circuit, as it has on a fairly regular basis over the last decade or so. Notwithstanding the briefs urging reversal filed by former Congressman Lamar Smith, one of the namesakes of the AIA, the federal government, and several major patent bar associations, the court affirmed in an opinion that spanned only nine pages. The Court’s reasoning is summarized in the following passage:

In light of this settled pre-AIA precedent on the meaning of “on sale,” we presume that when Congress reenacted the same language in the AIA, it adopted the earlier judicial construction of that phrase. The new §102 retained the exact language used in its predecessor statute (“on sale”) and, as relevant here, added only a new catchall clause (“or otherwise available to the public”). As *amicus* United States noted at oral argument, if “on sale” had a settled meaning before the AIA was adopted, then adding the phrase “or otherwise available to the public” to the statute “would be a fairly oblique way of attempting to overturn” that “settled body of law.” The addition of “or otherwise available to the public” is simply not enough of a change for us to conclude that Congress intended to alter the meaning of the reenacted term “on sale.”

Slip op. at 7-8 (citations omitted). The Supreme Court’s opinion, combined with the Federal Circuit’s decision in the underlying appeal and the language of the AIA itself, actually expand the on-sale bar because the AIA removes the “in this country” limitation on the reach of the bar. In other words, after the AIA and *Helsinn*, sales (secret or not) anywhere in the world can serve as prior art if they took place more than one year before the filing of the patent application.

Avoiding or Overcoming the On-Sale Bar

All is not necessarily lost, however, for those who wish or need to try to commercialize their inventions before deciding to file a patent application.

First, § 102 requires “the claimed invention” to be on sale (secret or otherwise) that does not disclose all the elements of the invention even to the other party should not invoke the bar.

Second, the AIA retains a one-year grace period so that any type of commercial sale is not prior art if it takes place within one year of the filing of a patent application. Because the AIA awards patents to the “first-inventor-to-file,” patent applicants are encouraged to file promptly in any event so they do not lose the “race to the Patent Office” as it is colloquially known.

Third, in *Medicines Co. v. Hospira, Inc.*, 827 F.3d 1363 (Fed. Cir. 2016) (*en banc*), the court held that “a contract manufacturer’s sale to the inventor of manufacturing services where neither title to the embodiments nor the right to market the same passes to the supplier does not constitute an invalidating sale under § 102(b).” *Id.* at 1381. Thus, an inventor can use such contract manufacturing services without fear of triggering the on-sale bar to patentability, although the inventor should adhere closely to the facts of the *Medicines Co.* case.

Finally, the Supreme Court’s *Helsinn* decision does not appear to disturb the long-standing “experimental use” exception to the on-sale bar. Only commercial sales trigger the bar; experimental sales made to perfect the invention do not. The experimental sales exception, however, is highly fact-specific and thus expensive and risky to litigate. When considering the “experimental use” exception, courts analyze a number of factors, including:

(1) the necessity for public testing, (2) the amount of control over the experiment retained by the inventor, (3) the nature of the invention, (4) the length of the test period, (5) whether payment was made, (6) whether there was a secrecy obligation, (7) whether records of the experiment were kept, (8) who conducted the experiment, . . . (9) the degree of commercial exploitation during testing, . . . (10) whether the invention reasonably requires evaluation under actual conditions of use, (11) whether testing was systematically performed, (12) whether the inventor continually monitored the invention during testing, and (13) the nature of contacts made with potential customers.

Allen Eng’g, Inc. v. Bartell Indus., Inc., 299 F.3d 1336, 1353 (Fed. Cir. 2002). Thus, inventors hoping to rely on this doctrine to save the validity of their patents must have evidence directed to many of these factors.

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