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The On-Sale Bar After High Court Helsinn Ruling

By **Leah Reimer and Kimberly Vines** (January 31, 2019, 1:24 PM EST)

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The recent U.S. Supreme Court case Helsinn Healthcare SA v. Teva Pharmaceuticals USA Inc.[1] highlights the criticality of maintaining invention secrecy before filing a patent application. The court rejected the proposition that amendments to the on-sale bar in the America Invents Act allow the existence of a sale to be made public, even if the invention itself is kept secret. Thus, a sale disclosed to the public can bar patentability, even if the invention itself remains secret to the public.

This ruling begs the question as to whether a secret sale of a secret invention (an invention held confidential between parties) can be a bar to patentability. While not definitive, Helsinn and other case law indicate that at a minimum, patent applicants should keep confidential any marketing, negotiations, agreements or third-party sales activities, even when the third party is under an obligation of confidentiality regarding the invention itself. Since the court could readily find that even a secret sale of a secret invention is in fact a bar under the AIA, better practice is to avoid sales activities of an invention that is "ready for patenting" under Pfaff v. Wells Electronics Inc.[2] prior to filing. Also, because whether an invention is "ready for patenting" under Pfaff is a fact-intensive determination, best practice is to avoid any sales activities before a patent application is filed.

Amendments to the AIA

Before the AIA, § 102(b)[3] barred patenting an invention that was:

> patented or described in a printed publication in this or a foreign country or 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.

The one-year grace period for these exceptions was eliminated under the AIA. Instead, under § 102(a)(1)[4] patenting is barred for an invention that was:

> 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 Manual for Patent Examination and Procedure accordingly changed its guidance regarding on-sale activities. In prior guidance, the MPEP stated that the "on sale" provision includes commercial activity

even if the activity is secret.[5] According to the revised MPEP, the addition of the phrase "or otherwise available to the public" was a residual clause indicating that § 102(a)(1) (post-AIA) does not cover a "secret" sale or offer for sale, i.e., a sale, offer for sale, or other commercial activity "that is secret (non-public) if it is among individuals having an obligation of confidentiality to the inventor."[6] Some commentators have interpreted the statutory amendments and MPEP guidance to mean that only the invention itself needed to be the subject of an obligation of confidentiality for the on-sale bar to apply.

Helsinn v. Teva

Helsinn owned four patents claiming intravenous formulations of palonosetron for reducing the likelihood of chemotherapy-induced nausea and vomiting. All four patents claimed priority to a provisional patent application filed Jan. 30, 2003. The patent before the court was filed after the enactment of the AIA, so §102(a)(1) applied. The one year on-sale bar date was therefore Jan. 30, 2002, meaning that a sale of the invention before that date could invalidate the patent.

Helsinn entered into a licensing agreement and an exclusive supply and purchase agreement with MGI Pharma Inc., effective April 6, 2001, almost nine months before the on-sale bar date. The agreement stated that should Helsinn's formulations become approved by the U.S. Food and Drug Administration, MGI would purchase the palonostron exclusively from Helsinn. The agreement specified the terms including price, method of payment and method of delivery.

The existence of the agreements themselves was not kept secret between the parties. The agreements were announced in a joint press release by Helsinn and MGI and in MGI's Form 8-K filing with the U.S. Securities and Exchange Commission.[7] The SEC filing included partially redacted copies of the agreements, and disclosed the active ingredient (palonosetron), including its chemical structure and use in treating chemotherapy-induced nausea and vomiting. However, the disclosures did not reveal the specific formulation as claimed.

Helsinn argued that these agreements were "secret sales" as to the invention itself, and that the §102(a) on-sale bar should not apply. Helsinn explained that because the claimed formulations were not revealed in the disclosures or in the agreements, the claimed formulations were not "available to the public" within the meaning of §102(a) and thus the on-sale bar was not triggered. On that issue, the district court agreed, the U.S. Court of Appeals for the Federal Circuit reversed,[8] and the Supreme Court affirmed.

In particular, the court rejected Helsinn's arguments that the on-sale bar requires disclosure of the details of the claimed invention. According to the court, because "the new 102 retained the exact language used in its predecessor statute ('on sale') and ... added only a new catchall clause ('or otherwise available to the public')," this was not enough to alter the meaning of "on sale."[9]

In addition, the Federal Circuit in Helsinn found that the legislative and other history of the AIA did not support a finding of congressional intent to change requirements for the on-sale bar. Since the presence of the phrase "or otherwise available to the public" did not alter the pre-AIA meaning of the on-sale bar, the court concluded that a sale or offer for sale known to the public can trigger the on-sale bar, whether or not the invention itself is disclosed to the public.

How Should a Secret Sale of a Secret Invention Be Approached Under the AIA?

The court's finding regarding the AIA and its application to the on-sale bar is limited because the court

found that a sale existed, and that the sale itself was public. Helsinn leaves open the question of whether a secret sale of a secret invention is patentable.

In Helsinn, the court stated that the Federal Circuit has long held that a secret sale can invalidate a patent:

> The Federal Circuit ... has made explicit what was implicit in our precedents. It has long held that "secret sales" can invalidate a patent. E.g., Special Devices, Inc. v. OEA, Inc., 270 F. 3d 1353, 1357 (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 (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").[10]

Perhaps the best clue to future rulings is the Federal Circuit's finding in Helsinn that "a primary rationale of the on-sale bar is that publicly offering a product for sale that embodies the claimed invention places it in the public domain, regardless of when or whether actual delivery occurs." Based on this public policy statement, it is likely that the Federal Circuit would continue to tip the balance in favor a finding of public disclosure when deciding other aspects of the on-sale bar under the AIA.

In particular, the court could readily find that the phrase "otherwise available to the public" applies not to the circumstances of an on-sale bar, but rather to the types of activities that can present a bar via public disclosure. Under this interpretation, the phrase is a "catchall" provision intended to capture types of public disclosure other than those enumerated, i.e., printed publications, public uses, and sales.[11] The court could thus find that the amended language allows any sale, even if secret, to be a public disclosure because it allows a third party to possess the invention.

The court's citations to Special Devices and Woodland Trust above show that the court is willing to defer to the Federal Circuit and current case law directed to the on-sale bar. This case law, including Pfaff v. Wells Electronics[12] and Federal Circuit cases subsequent to Pfaff, do not explicitly state that a commercial offer for sale must be public to qualify under the first prong under Pfaff. Instead, as outlined by the Federal Circuit in its Helsinn decision,[13] confidentiality of a transaction weighs against application of the on-sale bar, although not determinative alone.[14] In addition to Woodland Trust, the Federal Circuit cited J.A. LaPorte v. Norfolk Dredging Co.,[15] where an inventor patent owner allowed a third party to photograph and sell the claimed device before the on-sale bar date. The third party encouraged the inventor to file a patent application, but the inventor delayed. The court found the inventor's conduct contributed to finding an on-sale bar.

A case from the Federal Circuit's pre-Pfaff jurisprudence was cited in the Helsinn decision, even though it was developed in the context of the Federal Circuit's earlier "totality of the circumstances" standard. While instructive, it also provides no bright-line rules. In 1985, in In re Caveney,[16] the Federal Circuit rejected an argument that an offer to sell an invention to a purchaser that was "kept secret from the trade" should not trigger the on-sale bar. As stated by the Caveney court, the general rule is that a sale or an offer for sale triggers the on-sale bar, but an exception to the rule exists where a patented method "is kept secret and remains secret after a sale of the unpatented product of the method ... . [T]he activity in the instant case is distinguishable . ... Here the claimed invention was disclosed to the purchaser."[17]

The distinction between a public offer for sale and a secret sale may not be as relevant in the post-AIA world as it once was. Under the first-inventor-to-file provisions, applicants are encouraged to file as

soon as possible because disclosures by third parties prior to filing can serve as prior art. The practicalities of business, however, still render this an important question, whether the sale is to a potential customer, or even back to the applicant under a tolling agreement.

The above review shows that the minimum best practice regarding the on-sale bar is to keep confidential any marketing, negotiations, agreements or other third-party sales activities, even when the third party is under an obligation of confidentiality regarding the invention itself. Because a disclosure, even in confidence, to any third party may not prevent application of the on-sale bar, a better practice is to avoid sales activities of an invention that is ready for patenting under the first prong of Pfaff prior to filing. However, since Federal Circuit case law regarding whether an invention is "ready for patenting" under Pfaff is also a fact-intensive determination, the best practice — where possible — is to file before any sales activities or third-party disclosure whatsoever.

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[1] Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc. et al., No. 17-1229 (Jan. 22, 2019).

[2] Pfaff v. Wells Elects., Inc., 525 U.S. 55 (1998).

[3] 35 U.S.C. § 102(b) (2006) (pre-AIA).

[4] 35 U.S.C. § 102(a)(1) (2013) (post-AIA).

[5] MPEP 2152.02(d), citing MPEP 2133.03(b), subsection III.A (Ninth Ed., Revision 08.2017. Last Revised January 2018).

[6] MPEP 2152.02(d) (Ninth Ed., Revision 08.2017. Last Revised January 2018).

[7] Applicants should be particularly wary where, as here, a sale or invention could be made public by any mandatory regulatory filings, such as required disclosures by the SEC.

[8] Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc. et al., 855 F.3d 1356 (Fed. Cir. 2017).

[9] Helsinn, slip op. at 7.

[10] Id.

[11] See discussion at MPEP 2152.02(e) (Ninth Ed., Revision 08.2017. Last Revised January 2018).

[12] In Pfaff v. Wells Electronics, the Court announced a two-pronged analysis to determine whether the on-sale bar applies when, before the critical date, the claimed invention was (1) was the subject of a

commercial sale or offer for sale; and (2) was ready for patenting. Pfaff v. Wells Elects., Inc., 525 U.S. 55 (1998).

[13] Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc. et al., 855 F.3d 1356 (Fed. Cir. 2017).

[14] Helsinn at 1367 (Fed. Cir. 2017), citing Medicines Co. v. Hospira, Inc., 827 F.3d 1363 (Fed. Cir. 2016). See also discussion Id. at 1364, stating that possible factors in determining whether a sale occurred, as set forth in Medicines Co., included absences of the passage of title, the confidential nature of a transaction, and the absence of commercial marketing.

[15] J.A. LaPorte, Inc. v. Norfolk Dredging Co., 787 F.2d 1577 (Fed. Cir. 1986).

[16] In re Caveney, 761 F.2d 671 (Fed. Cir. 1985).

[17] Id. at 675–76.