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White Paper

HELSINN HEALTHCARE S.A. V. TEVA PHARMS. USA, INC.:

Under AIA, Public Disclosure of Sale Implicates On-Sale Bar Even Where Details of Invention Are Not Publicly Disclosed

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In *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*,[1] the Federal Circuit determined that public disclosure of a sale of an invention, even when the details of the invention were not made public, can violate the on-sale bar and qualify as invalidating prior art. This decision is the first Federal Circuit analysis of the on-sale bar after the effective date of the AIA. The Federal Circuit found the patents were invalid applying both the pre-AIA and post-AIA versions of 35 U.S.C. § 102.

Helsinn is the owner of four patents directed to a low-dose formulation of palonosetron, an anti-nausea medicine for cancer patients. All four patents claimed priority back to the same provisional application filed on January 30, 2003. Three of the patent applications predated the effective date of the AIA, while one came after.[2] Helsinn's prospective drug products passed Phase I and Phase II clinical trials. On April 6, 2001, while Phase III trials were ongoing and nearly two years before Helsinn filed for patent protection, Helsinn entered into two agreements with MGI Pharma, Inc. ("MGI"). Helsinn agreed to sell "products" to MGI in exchange for an up-front fee, plus ongoing royalties. These "products" were elsewhere defined in the agreement as comprising either 0.25 mg or 0.75 mg doses of palonosetron. The agreements contained a provision addressing the dosage amount of the palenosetron-containing product after achieving FDA approval. The companies announced the agreement in a joint press release, as well as in partially redacted filings provided to the SEC. Neither the public announcement nor the SEC filing disclosed the actual dosage strength of palonosetron. The FDA ultimately approved the marketing of the 0.25 mg product.

Teva subsequently filed an Abbreviated New Drug Application that sought approval of a generic equivalent to the 0.25 mg branded product. Helsinn sued Teva under the Hatch-Waxman act for patent infringement. After a bench trial, the trial court analyzed the sale agreement under the two-part framework of *Pfaff v. Wells Electronics, Inc.*[3] For the on-sale bar to apply, *Pfaff* requires that there must be a sale or an offer for sale and that the invention be ready for patenting. In this case, the trial court found that:

A. With regard to the three pre-AIA patents, there *was* a qualifying sale or offer for sale;

B. With regard to the post-AIA patent, there *was no* qualifying sale or offer for sale; and

C. The invention was not ready for patenting before the critical date for all four patents.

Thus, the trial court found the public disclosure of the announced MGI agreements did not invalidate the four patents.

On appeal, the Federal Circuit considered three questions:

1. Was there a sale of pre-AIA patented goods?

2. Did the AIA change the language of 35 U.S.C. § 102 such that it makes a difference to Helsinn's post-AIA patent?

3. Was the invention ready for patenting before the critical date?

First, the Federal Circuit determined that there was a sale of pre-AIA patented goods. The Court referred to its recent *en banc* decision in *Medicines Co. v. Hospira, Inc.*,[4] where the provisions of the UCC were used to determine if there was a "sale." There, a sale was found to occur when there is a "contract between parties to give and to pass rights of property for consideration which the buyer pays or promises to pay the seller for the thing bought or sold."[5] Under this framework, the Federal Circuit found that an agreement to convey rights of property existed between the parties. It also noted that a contingency to the agreement (FDA approval) did not negate the existence of an agreement. Similarly, any ambiguity regarding dosage strength did not change the existence of a sale.

Second, the Court determined that the AIA change to the on-sale bar language in Section 102 did not alter the outcome for the fourth patent. Prior to the AIA, Section 102 barred patentability for an invention "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 the patent."[6] The AIA changed that language to bar patenting 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."[7] The trial court found that this change in language removed the ability of a secret sale to invalidate a patent and that the statute now required that the invention, itself, be public knowledge to render a patent invalid. The Federal Circuit did not decide whether a private sale would implicate the on-sale bar because it found the sale between Helsinn and MGI was public, holding that the on-sale bar only requires the *sale*, not the *details of the invention*, to be public. The Federal Circuit emphasized that a large body of law rejected the idea of requiring public disclosure of the invention in determining whether an invention was on sale. The Federal Circuit held that nothing contained in the AIA or in Congressional floor statements changed this bedrock principle. Thus, the Federal Circuit reversed the trial court on this question without determining if a secret sale would similarly trigger the on-sale bar.

Finally, the Federal Circuit addressed whether the invention was ready for patenting by the critical date of January 30, 2002. Under *Pfaff*, an invention can be ready for patenting by either actual reduction to practice or by showing drawings or other descriptions sufficient for a person skilled in the art to practice the invention. Here, the Federal Circuit determined that the invention was actually reduced to practice before the critical date. The Federal Circuit found that "[a]n invention is reduced to practice when 'the inventor (1) constructed an embodiment that met all the limitations and (2) determined that the invention would work for its intended purpose."[8] The Federal Circuit emphasized the difference between the standard required to show that an invention "worked for its intended purpose" and the standard to receive FDA approval. The Federal Circuit found that to meet the "ready for patenting" standard, the invention needed to be merely "'beyond a probability of failure' but not beyond a 'possibility of failure.'"[9] The Federal Circuit also noted that "[l]ater refinements do not preclude reduction to practice and it is improper to conclude that an invention is not reduced to practice merely because further testing is being conducted."[10] The Federal Circuit identified several pieces of supporting evidence, including the results of the Phase II trials and the Phase III trial protocols that referred to significant reduction in nausea through the use of 0.25 mg palonosetron. Finally, the Federal Circuit pointed to Helsinn's preliminary data tables from the Phase III trial, prepared on January 7, 2002 (23 days before the critical date), that showed that 81% of patients receiving the 0.25 mg dose experienced relief from nausea for 24 hours, as required by the claimed subject matter. On this evidence, the Federal Circuit determined that the invention was actually reduced to practice and ready for patenting under *Pfaff* prior to the critical date.

Based on the Federal Circuit's determination that embodiments of all four patents were offered for sale (and sold) before the critical date, and that the invention was ready for patenting before the critical date, the Federal Circuit reversed the trial court's order and found the four patents invalid under both the pre-AIA and post-AIA versions of Section 102's on-sale bar. In sum, "after the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of the sale" for the on-sale bar to apply.[11]

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[1] *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, Nos. 2016-1284, 2016-1787, slip op. (Fed. Cir. May 1, 2017).

[2] U.S. Patent Nos. 7,947,724, 7,947,725, and 7,960,424 were filed prior to the AIA. U.S. Patent No. 8,598,219 was filed later, under the AIA amendments.

[3] 525 U.S. 55 (1998).

[4] 827 F.3d 1363 (Fed. Cir. 2016)

[5] *Helsinn*, Nos. 2016-1284, 2016-1787, slip op. at 11 (quoting *Trading Techs. Int'l, Inc. v. eSpeed, Inc.* 595 F.3d 1340, 1361 (Fed. Cir. 2010)).

[6] 35 U.S.C. § 102(b) (pre-AIA) (emphasis added).

[7] 35 U.S.C. § 102(a)(1) (emphasis added).

[8] *Helsinn*, Nos. 2016-1284, 2016-1787, *slip op.* at 27 (quoting *In re Omeprazole Patent Litig.*, 536 F.3d 1361, 1373 (Fed. Cir. 2008)).

[9] *Id.* at 29 (quoting *Scott v. Finney*, 34 F.3d 1058, 1062 (Fed. Cir. 1994)).

[10] *Id.* (quoting *Atlanta Attachment Co. v. Leggett & Platt, Inc.*, 516 F.3d 1361, 1367 (Fed. Cir. 2008)).

[11] *Id.* at 27.