Keywords: pre-AIA 35 U.S.C. § 102(b); AIA 35 U.S.C. § 102(a)(1); on sale bar

Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.
2016-1284, 2016-1787 (Fed. Cir., May 1, 2017)

I. Facts

Helsinn owns four patents directed to reducing chemotherapy-induced nausea and vomiting by using unexpectedly low concentrations of palonosetron. Phase I and II clinical trials were conducted and found a 0.25 mg dose of palonosetron to be effective and Helsinn submitted data for Phase III clinical trials in 2000 to study two doses: 0.25 mg doses and 0.75 mg doses. The four patents at issue each include claims directed to a 0.25 mg dose of palonosetron, and each claims priority to a provisional patent application filed on January 30, 2003. Three of the patents – U.S. Patent Nos. 7,947,724; 7,947,725; and 7,960,424 (hereinafter the "pre-AIA patents") – were filed in 2005 and 2006 while the fourth patent – U.S. Patent No. 8,598,219 (hereinafter the "post-AIA patent") – was filed in May 2013 (after the effective date of the AIA).

In April 2001, nearly two years before applying for a patent, Helsinn entered into a License Agreement and a Supply and Purchase Agreement with MGI Pharma, Inc. ("MGI"), which was announced in a joint press release and in MGI's Form 8-K ("8-K") filing with the Securities and Exchange Commission. The 8-K included partially redacted copies of both agreements, whereby specific dosage covered by the agreements (i.e., 0.25 mg and 0.75 mg doses) was not made available to the public. Subsequently, in 2011, Teva filed an application with the FDA seeking approval to market a generic 0.25 mg palonosetron product. Teva's application included a statement that the claims of the four patents were invalid and/or not infringed. Helsinn then brought suit under the Hatch-Waxman Act, alleging infringement by Teva's application for the generic product of the claims in the four patents that claimed the 0.25 mg dose.

In addressing the issue of an on-sale bar, the district court analyzed the pre-AIA patents under the two-step frame work of *Pfaff v. Wells Electronics, Inc.*, which requires a sale or offer for sale *and* that the claimed invention be ready for patenting. The district court found that the Supply and Purchase Agreement was a sale under § 102(b), but found that the claimed invention was not reduced to practice before the critical date of January 30, 2002 and, therefore, was not ready for patenting. Accordingly, the district court found that the pre-AIA patents were not invalid.

With respect to the post-AIA patent the district court held that the AIA changed the meaning of the on-sale bar and that § 102(a)(1) now "requires a *public* sale or offer for sale of the claimed invention." The court concluded that, to be "public" under the AIA, a sale must publicly disclose the *details* of the invention. The absence of the 0.25 mg dose in the public portions of the Supply and Purchase Agreement meant that no public sale occurred, in addition to the post-AIA patent not being not ready for patenting before the critical date. Accordingly, the district court found that the pre-AIA patents were not invalid.

II. Issues

Did the district court err in finding that the pre-AIA patents were subject to a sale or offer for sale prior to the critical date but were not ready for patenting prior to the critical date?

Did the district court err in finding that the AIA changed the meaning of the on-sale bar in determining that the post-AIA patent was not subject to a sale or offer for sale and err in finding that the invention was not ready for patenting prior to the critical date?

III. Discussion

Pre-AIA Patents*: *On Sale or Offer for Sale

The court affirmed the district court's finding that the pre-AIA patents were subject to sale or offer for sale prior to the critical date. The court revisited the pre-AIA on-sale bar in *Medicines Co. v. Hospira, Inc.*, where a framework was established for determining whether there is an offer for sale. In applying *Medicines*, the court explained that the question of a sale must be analyzed under the law of contracts and must focus on those activities that would be understood to be commercial sales and offers for sale in the commercial community.

The court looked to the Uniform Commercial Code (UCC) in its analysis and noted that a sale occurs 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 sold or bought. The court also pointed out that *Medicines* suggests using additional factors in the analysis, but noted that none of the factors therein (or the UCC) alone are dispositive. The court noted that an absence of the passage of title, the confidential nature of a transaction, and the absence of commercial marketing of the invention weigh against applying the on-sale bar, however, none of these *Medicines* factors were present in the instant case.

Helsinn also argued that the FDA's approval of the 0.25 mg dose was a condition precedent to the sale. However, the court found that that conditions precedent, such as regulatory approval, are a basic feature of contract law. Furthermore, the court found that the absence of FDA or other regulatory approval before the critical date does not prevent a sale or offer for sale from triggering the on-sale bar. Alternatively, Helsinn argued that even if the agreement for the sale of the 0.25 mg dose could be an invalidating sale, the agreement was uncertain because it covered the 0.25 mg dose, the 0.75 mg dose, and both doses. The court responded that it is clear that these two hypothetical agreements would individually trigger the on-sale bar for the 0.25 mg dose and the 0.75 mg dose, respectively and there is no reason to distinguish between a single agreement that covers two potential products and two separate agreements each covering a single one of the two products. Accordingly, the court found that the offer or contract for sale unambiguously placed *the invention* on sale, as defined by the patent's claims and, accordingly, there was a sale for purposes of pre-AIA § 102(b).

Post-AIA Patent*: *On Sale or Offer for Sale

The court reviewed Helsinn's argument (and the district court finding) that AIA 35 U.S.C. § 102(a)(1) changed the law pertaining to the on-sale bar by adding the "otherwise available to the public" phrase as modifying the on-sale clause. Helsinn's argued that this statutory interpretation was supported by floor statements made by individual members of Congress. The court noted that each of the floor statements that Helsinn referred to applied to cases that involved a public use where the invention was not, as a result of the use, disclosed to the public. That is, none of the floor statements identified any sale cases that would be overturned by the amendment to AIA 35 U.S.C. § 102(a)(1). Additionally, even if the floor statements were intended to overrule secret or confidential sales, that would have no effect on the present case, as there is no question about the existence of a public sale by Helsinn.

Helsinn further argued that the AIA did more than overrule the "secret sale" cases and relied on the "otherwise available to the public" language in the statue and argued that since the 0.25 mg dose of palonosetron was not disclosed to the public, the on-sale bar does not apply. In other words, Helsinn argued that the details of the claimed invention would have to be publicly

disclosed before the on-sale bar is triggered. The court reasoned that such a disclosure as a condition of the on-sale bar would constitute a foundational change in the theory of the statutory on-sale bar decided in *Pennock v. Dialogue.* There, the Supreme Court held that failing to find such a sale invalidating "would materially retard the progress of science and the useful arts and give a premium to those who should be least prompt to communicate their discoveries."

The court noted that the question of whether the details of the invention must be disclosed in the terms of sale when a sale is made public had been answered in *RCA Corp. v. Data Gen. Corp.*, which rejected the argument that "bid documents themselves much disclose the invention with respect to all claim elements" since there can be an offer for sale or a sale of a claimed invention even though *no* details are disclosed. The court reiterated that prior cases have applied the on-sale bar even when there is no delivery, when delivery is set after the critical date, or even when upon delivery, members of the public could not ascertain the claimed invention. The court concluded that the details of the invention need not be publicly disclosed in the terms of sale, and thus the pre-AIA and AIA on-sale bars applied.

Pre-AIA and Post-AIA Patents*: *Reduction to Practice

The court also addressed the issue of whether the invention was ready for patenting as of the critical date of January 30, 2002 for all of the patents at issue. Under *Pfaff*, there are at least two ways an invention can be ready for patenting (1) by proof of reduction to practice before the critical date or (2) by proof that prior to the critical date the inventor had prepared drawings or descriptions to enable a person skilled in the art to practice the invention. With respect to the test for reduction to practice, an invention is reduced to practice when the inventor (A) constructed an embodiment that met all of the limitations and (B) determined that the invention would work for its intended purpose.

The issue on review pertains to whether or not Helsinn had determined the invention would work for its intended purpose of reducing the likelihood of chemotherapy induced nausea and vomiting. The court noted that the standard required to show an invention would work for its intended purpose varies from the FDA standards for approval of new drugs. The court determined that the district court clearly erred in applying too demanding of a standard and that FDA approval is not a pre-requisite for the invention to be ready for patenting. The court noted that the evidence was overwhelming that the patented invention would work for its intended purposes based in part on test results submitted to the FDA during clinical trials, press releases, and declarations submitted by the inventors during prosecution of the patents. The court concluded that the invention was ready to practice and was ready for patenting before the critical date.

IV. Conclusion

The court reversed the judgment of the district court and found that the catch-all clause added to AIA 35 § U.S.C. 102(a)(1) does not invalidate years of case law interpreting the "public use" and "on sale" statutory language, in the absence of a clear repudiation by Congress.

V. <u>On-Sale Bar Pre-AIA and Post-AIA:</u>

Pre-AIA: 35 U.S.C. 102: A person shall be entitled to a patent unless —

…

(b) the invention 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, …

Post-AIA: 35 U.S.C. 102(a)(1):

(a) NOVELTY; PRIOR ART.—A person shall be entitled to a patent unless—

(1) the claimed invention 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; …