Intellectual Property Alert:

Federal Circuit Hears Arguments in *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA Inc.*

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October 6, 2016 — On October 4, 2016, the U.S. Court of Appeals for the Federal Circuit heard oral arguments in *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA Inc.*, case number 16-1284. The Court's ruling in this case could ultimately affect the way in which invalidating sales and offers for sale as well as other types of prior art enumerated in 35 U.S.C. § 102 of the America Invents Act (AIA) are interpreted.

The patents at issue in this case cover drugs including the active ingredient palonosetron, a chemical used to treat chemotherapy-induced nausea and vomiting (CINV). This chemical was discovered in the early 1990s by scientists at Syntex, which was later acquired by Roche. Helsinn acquired the rights to palonosetron from Roche in 1998. Helsinn then conducted various Food and Drug Administration (FDA) trials to determine the appropriate concentration of the chemical for clinical use. During this time, Helsinn also entered into a contract with another company named MGI to help fund Helsinn's research and development efforts in return for granting MGI an exclusive license to any drugs found to be effective and ultimately approved by the FDA. In that agreement, Helsinn and MGI further agreed to an ordering procedure and pricing scheme for any palonosetron formulations that the FDA approved. Helsinn later filed for and was granted patents covering its drugs and ultimately brought an infringement suit under the Hatch-Waxman Act, alleging that Teva's proposed generic drugs infringe Helsinn's patents.

Under the AIA, 35 U.S.C. § 102 was modified to impose a much simpler first-to-file patenting regime in the U.S. The AIA replaces the more complicated structure of 35 U.S.C. § 102 under the 1952 Patent Act and defines various categories of prior art appearing before the effective filing date of the patentee. 35 U.S.C. § 102(a) under the AIA states in part:

> 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.

Most of these categories of prior art existed under the 1952 Patent Act and had developed a judicial gloss over the decades. For example, previous cases had held that a "noninforming public use," *i.e.*, a public use made in such a way that the public cannot readily determine the use, constitutes a public use.[1] Moreover, prominent cases have also held that an invalidating public use occurs even

[1] *Egbert v. Lippmann*, 104 U.S. 333 (1881) (finding that the inventor's corset stay, worn inside his fiancé's corset for over 10 years, constituted a public use).

when a patentable machine is kept secret so as long as its products are publically used.[2] Finally, courts have held that secret, confidential, or non-public sales or offers for sale trigger the on-sale bar so as long as the invention is "ready for patenting," which can be shown by proof of a reduction to practice before the critical date or by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention.[3] Under *Pfaff*, even a single sale can trigger the on-sale bar of 35 U.S.C. 102.[4] In addition to these categories, the AIA apparently contemplates a new category of prior art that is "otherwise available to the public." Just exactly what this phrase means and whether or not it affects the way the other categories of prior art are interpreted is a central issue in *Helsinn*.

The district court found Helsinn's patents to be valid and infringed by Teva. In doing so, the court reached two important conclusions about why the on-sale bar was not triggered in this case. First, the court found that the claimed pharmaceutical formulations were not ready for patenting before the critical date even though the agreement with MGI was determined to be a commercial offer for sale. Second, the court found that the on-sale bar of 35 U.S.C § 102 did not apply to one of the patents at issue because the Helsinn-MGI contract did not make the claimed invention "available to the public" under 35 U.S.C. § 102(a)(1).

During oral arguments, Judge Dyk noted that the Helsinn-MGI contract was publicized, and the only thing that was not described in the press release for this agreement was the dosage levels of the claimed drugs. Teva argued that the confidentiality of the dosage levels was irrelevant, given that Helsinn's activities in entering into a contract with MGI constituted commercial exploitation of the claimed invention, implying that the policy behind the on-sale bar was to prevent unintended extensions of the monopoly right granted by a patent. Meanwhile, Helsinn argued that the claimed drugs were not ready for patenting at the time of the Helsinn-MGI contract because the drugs being tested at that time were not deemed to be efficacious at a statistically significant level and, therefore, the on-sale bar was not triggered.

With regard to the second issue, Teva argued that the addition of the phrase "otherwise available to the public" does not change the meaning of the term "on sale" in 35 U.S.C. § 102, as established by decades of precedent. To help them resolve this issue, the judges questioned counsel on which canons of statutory construction should be used to determine what the phrase "otherwise available to the public" modifies. A cursory look at the language of the statute would lead one to conclude that this phrase could modify all of the categories of prior art listed; however, Teva and various intellectual property professors around the country noted that such an interpretation would throw decades of precedent out the window. Rather than changing the way that terms such as "on sale" or "public use" are to be interpreted, Teva argued that the new phrase is meant solely to enumerate a new area of prior art, including tweets and online videos, that the drafters of the 1952 statute did not contemplate.

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[2] *Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516 (2nd Cir. 1946).
[3] *Pfaff v. Wells Electronics*, 525 U.S. 55, 55-69 (1998).
[4] *Id.*

The Court further considered whether the Helsinn-MGI contract constituted an offer to sell, given that Helsinn was testing various dosage levels and any drug Helsinn tested was subject to FDA approval. Teva argued that the Uniform Commercial Code (UCC) makes clear that future or contingent contracts are still contracts for the sale of goods, and that Helsinn started the commercial marketing process by entering into this type of contract. Moreover, Teva argued that the claimed drugs were ready for patenting as they were undergoing FDA clinical trials and, therefore, the promise by Helsinn for a future distribution stream became an invalidating sale. Helsinn countered that the agreement constituted mere preparations for a commercial sale and thus did not trigger the on-sale bar. While the Court seemed to be open to considering the agreement as a basis for invoking the on-sale bar, Judge O'Malley dwelled on Helsinn's point that the product in this case was not defined at the time of the agreement and the money that MGI gave was in return for the exclusive license to a *potential* future product, not a binding purchase order for the claimed drugs.

Meanwhile, the US government argued that the legislative history for the AIA indicates a transaction must make an invention available to the public to trigger the on-sale bar of the AIA and thus secret sales should not trigger the on-sale bar. Because the dosage levels of the claimed drugs were not disclosed in the Helsinn-MGI agreement and MGI was bound to confidentiality, the government argued that the invention here was not made available to the public, and the agreement did not trigger the on-sale bar.

We will continue to watch this case to ascertain whether 35 U.S.C. § 102 under the AIA has added completely new types of prior art that are "otherwise available to the public" in addition to changing the meaning of various types of invalidating prior art, such as prior art sales and public uses.