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Recent Interpretation of the "On Sale Bar" as Prior Art Provides Lessons for Manufacturers

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Client Advisory
March 16, 2018 by John M. Griem, Jr. and Danielle C. Sullivan

Few issues in patent law are more important than the definition of "prior art" – which is the entire universe of technology that is "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." Every patent application is compared to the prior art to determine if it is novel and not obvious, and therefore worthy of a patent – and every patent asserted in litigation is tested again against any newly uncovered "prior art" to confirm its validity.

Recently, *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc. et al.*, *855* F. 3d 1356 (Fed. Cir. 2017), *req. for rehearing denied, Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries, Ltd.*, Case 2016-1284, 2016-1787 (Fed. Cir. 2018), the Court of Appeals for the Federal Circuit addressed an important open question regarding the scope of "on sale" prior art, looking at the scope of "on sale" prior art under Section 102 of the patent laws, which was amended in 2013 by the Leahy-Smith America Invents Act ("AIA"). Following the amendment, most commentators and the U.S. Patent and Trademark Office read new Section 102 to be limited to "on sale" prior art that was "available to the public", consistent with the implied restriction in the last clause of the section quoted above.

The Federal Circuit, however, construed new Section 102 in *Helsinn* to include as prior art an invention that was the subject of a publicly known sale agreement that nonetheless kept the details of the invention confidential, as further discussed below. Helsinn has now filed a petition for a writ of certiorari to the Supreme Court, which is pending.

Unless and until the Supreme Court hears this case, companies would be well-advised to consider carefully how they structure their license and manufacturing agreements to avoid triggering the expanded scope of "on sale" prior art announced by the Federal Circuit. After reviewing the *Helsinn* decisions, we provide some practical steps to take before filing a patent application to avoid inadvertently creating prior art that can be used against a later-filed patent application.

I. The *Helsinn* Decisions

Under pre-AIA patent law, in force before 2013, an invention is not patentable if it is "in public use or on sale in this country, more than one year prior to the date of application for patent in the United States." (35 U.S.C. §102(b)). Post-AIA changes to the on sale bar section revised it to read "in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention." The import of adding the phrase "otherwise available to the public" is at the crux of the dispute regarding the scope of the "on sale" bar.

Recently, the controlling Court of Appeals for patent law issues, the Federal Circuit, addressed this issue in *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc. et al.*, 855 F. 3d 1356 (Fed. Cir. 2017), *req. for rehearing denied, Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries, Ltd.*, Case 2016-1284, 2016-1787 (Fed. Cir. 2018). Helsinn brought suit against Teva for infringement of

various claims of four patents directed to palonosetron injection doses – U.S. Patent No. 7,947,724 ("'724 patent"), 7,947,725 ("'725 patent"), 7,960,424 ("'424 patent"), and 8,598,219 ("'219 patent"). Three of the patents ('724, '725, and '424) were governed by the pre-AIA law and the fourth patent ('219) was governed by post-AIA §102. Teva argued the patents were invalid based on Helsinn's own actions in preparing for commercial sale of the patented products. On April 6, 2001, almost two years before applying for the patents, Helsinn and MGI Pharma ("MGI"), a pharmaceutical company that markets and distributes in the United States, entered into two agreements, 1) a License Agreement and 2) a Supply and Purchase Agreement. These agreements were announced in a joint press release and in MGI's Form 8-K filings, which included partially redacted copies of both agreements.

Under the Supply and Purchase Agreement, MGI agreed to purchase exclusively from Helsinn and Helsinn agreed to supply MGI's requirements of the 0.25 mg and the 0.75 mg palonosetron products, or whichever of the two dosages were approved for sale by the FDA. *Id*. at 1361. The agreements specified price, method of payment, and method of delivery. *Id*. at 1362. The License Agreement made reference to ongoing clinical trials and stated that in the event that the results were unfavorable and the FDA did not approve the sale of either dosage of the product, Helsinn could terminate the agreement and if the License Agreement were terminated, the Supply and Purchase Agreement would "terminate automatically." *Id*. The two features of the agreements that were not publicly disclosed were the price terms and the specific dosage formulations covered by the agreements. The FDA issued approval of the 0.25 mg dose on July 2003. In 2011, Teva filed an ANDA seeking FDA approval to market a generic 0.25 mg palonosetron product. Helsinn then brought suit under the Hatch-Waxman Act alleging infringement of the patents in suit by the ANDA filing.

Addressing the on sale bar issue, the court applied the two-step framework of the Supreme Court's decision in *Pfaff v. Wells Electronics, Inc*., 525 U.S. 55 (1998), which requires 1) that there was a sale or offer for sale and 2) that the claimed invention was ready for patenting. If both prongs are met, then the on sale bar under 35 U.S. C. §102 applies. *Id*. at 1363. For the patents governed by the pre-AIA law, the district court held the Supply and Purchase Agreement was a contract for a future sale of a commercial product and therefore constituted a sale under §102(b), however the invention was not reduced to practice before the critical date of January 30, 2002 and therefore did not satisfy the second prong of *Pfaff*. Regarding the fourth patent, the '219 patent governed by AIA law, the district court held that the AIA changed the scope of the on sale bar and §102 (a)(1) now 'requires a public sale or offer for sale of the claimed invention.'" *Id*. The district court concluded that in order to be 'public' under the AIA, "a sale must publicly disclose the details of the invention." The court found that the Supply and Purchase Agreement "did not constitute a public sale or commercial offer for sale because, although it disclosed the sale agreement and substances of the transaction, it fails to publicly disclose the 0.25 mg dose. The '219 patent was also not ready for patenting before the critical date." *Id*. Therefore, the district court found that the asserted claims of the four patents were not invalid under the §102 on sale bar. *Id*.

Upon review, the Court of Appeals reversed. *Id*. at 1363. The Court first applied the first prong of the *Pfaff* framework, to conclude that the Supply and Purchase Agreement was a contract for the sale of the claimed invention. The court stated "the question must be 'analyzed under the law of contracts as generally understood' and 'must focus on those activities that would be understood to be commercial sales and offers for sale 'in the commercial community.'" *Id*. at 1364. "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 bought or sold.'" *Id*. (citing *Trading Techs. Int'l, Inc. v. eSpeed, Inc*., 595 F.3d 1340, 1361 (Fed. Cir. 2010)). The court then stated that "[t]here is no suggestion that the Supply and Purchase Agreement did not involve transfer of title; it expressly contemplated it. And, while certain details were redacted from the publicly disclosed copy of the Supply and Purchase Agreement, Helsinn does not argue that the transaction itself between Helsinn and MGI remained confidential. Helsinn also commercially marketed its invention before the critical date. It publicly sought 'marketing partners' for its patented [palonosetron] product." *Id*. at 1364.

For those reasons, the Federal Circuit agreed with the district court that there was a sale for purposes of pre-AIA §102(b) prior to the critical date because "there was a sale of the invention under the law of contract as generally understood." *Id*. The court concluded that "an agreement contracting for the sale of the claimed invention contingent on regulatory approval is still a commercial sale as the commercial community

would understand that term." *Id*. at 1365. The court also noted that "[a] contract for sale that includes a condition precedent is a valid and enforceable contract." *Id*.

The Federal Circuit then addressed whether the AIA changed the meaning of the *on sale* bar under 35 U.S.C. §102. "By enacting the AIA, Congress amended §102 to bar the patentability of 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." *Id*. at 1368. The Federal Circuit focused on the term "on sale", and relied on pre-AIA cases construing that term in reaching its decision: "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. The patented product need not be on-hand or even delivered prior to the critical date to trigger the on sale bar." *Id*, at 1370. "[O]ur 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 Federal Circuit left in place a pre-AIA understanding of the term "on sale", even in light of the addition of the "or otherwise available to the public" clause, because Congress did not expressly state its intent to overrule its prior cases: "There is no indication in the floor statements that these members [of Congress] intended to overrule these cases…If Congress intended to work such a sweeping change to our on sale bar jurisprudence and 'wished to repeal…[these prior] cases legislatively, it would do so by clear language." *Id*. at 1371. The court concluded that "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." *Id*. The court then reversed the district court's decision on the basis that the claimed invention was subject to an invalidating contract for sale prior to the critical date of January 30, 2002, and because it concluded that the district court had erred in finding that the claimed inventions were not "ready for patenting prior to the critical date." *Id*.

Helsinn petitioned the court for rehearing *en banc*. Helsinn's petition was supported by many intellectual property groups. The petition was denied. Circuit Judge O'Malley defended the decision of the Federal Circuit, saying that the decision had been mischaracterized. *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries, Ltd*., Case 2016-1284, 2016-1787 (Fed. Cir. 2018), Order on Petition for rehearing En Banc at 2. Judge O'Malley stated that in her view, "the confidential nature of a transaction is just one part of several factors for determining whether the transaction rises to the level of a commercial sale such that the on sale bar would apply." *Id*. She also stated that the court had not decided that all supply arrangements for future sales were invalidating "on sale" agreements, just that "the particular agreement at issue triggered the on sale bar, in part – but not exclusively – because it was made public." *Id*. at 3. She stressed the fact that "Helsinn did not just disclose the fact it entered into an Agreement with MGI but also submitted a partially redacted copy of the Agreement, the Agreement described the claimed drug formulation 'in detail', and the Agreement 'expressly contemplated' the passage of title and made clear that Helsinn 'commercially marketed its invention before the critical date.'" *Id*.

Judge O'Malley's review of the legislative history "indicate[s] both that Congress's primary focus when amending §102 was on the nature and content of prior art printed publications, not on the on sale bar, and that Congress several times considered, but rejected, the very changes to the on sale bar Helsinn urges us to conclude were actually made." *Id*. at 9. Finally, she said that traditionally, "[a]n 'overriding' concern [underlying the on sale bar] is the risk that an inventor will commercially exploit his invention beyond the statutory term." *Id*. at 10. "The *Pfaff* court made clear 'that we are not to look to broad policy rationale in assessing whether the on sale bar applies. Instead we are to apply a straightforward two-step process – one which permits an inventor to 'both understand and control the first commercial marketing of his invention." *Id*. at 11-12. Judge O'Malley concluded "Congress or the Supreme Court could redefine 'on sale' to exclude mere offers for sale; again we cannot." *Id*. at 13.

Helsinn timely filed a petition for *writ of certiorari* with the U.S. Supreme Court requesting the Court to review and reverse the judgment of the Court of Appeals of the Federal Circuit. Helsinn states the question for review as follows: "Whether, under the Leahy-Smith America Invents Act,

an inventor's sale of an invention to a third party that is obligated to keep the invention confidential qualifies as prior art for purposes of determining patentability of the invention'." Teva has just sought an extension of time to respond to Helsinn's petition.

II. Practical Steps To Take

For any agreement relating to the commercial production of a newly developed product, keeping the agreement confidential, if possible, is a key first step. If some of the agreement must be made public, in a filing with the SEC or otherwise, the parties should try and structure it as a manufacturing agreement, not a supply and sale agreement. Title to the product being produced should always reside with the patent owner during the manufacturing process, if possible. The prior art status of one manufacturing agreement structure was considered by the Federal Circuit in *Medicines Co. v. Hospira, Inc.*, 827 F. 3d 1363 (Fed. Cir. 2016), and the Court determined that the agreement was not an invalidating "on sale" bar to patentability. Alternatively, the parties may wish to leave essential terms to be finally fixed after a patent application has been filed, or after FDA approval has been obtained.

Of course, patent applications directed to the commercial formulation should be filed as soon as possible, even if the prospects for obtaining a patent are not high, if an agreement relating to commercialization of the invention is going to be signed. Doing so might avoid any question as to whether the agreement might be considered prior art.

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