Appeal Nos. 2016-1284, -1787

United States Court of Appeals

for the

Federal Circuit

HELSINN HEALTHCARE S.A.,

Plaintiff-Appellee,

– v. –

TEVA PHARMACEUTICALS USA, INC.,
TEVA PHARMACEUTICAL INDUSTRIES, LTD.,

Defendants-Appellants.

APPEALS FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY IN CASE NOS. 3:11-CV-03962-MLC-DEA, 3:11-CV-05579-MLC-DEA AND 3:13-CV-05815-MLC-DEA, JUDGE MARY L. COOPER

THE BIOTECHNOLOGY INNOVATION ORGANIZATION (BIO) AS *AMICUS CURIAE* SUPPORTING REHEARING *EN BANC*

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July 14, 2017

CERTIFICATE OF INTEREST

Counsel for *Amicus Curiae* certifies the following:

1. The full name of every party or *amicus curiae* represented by me is:

   Biotechnology Innovation Organization ("BIO") (formerly: Biotechnology Industry Organization)

2. The name of the real parties in interest (if the party named in the caption is not the real party in interest) represented by me is:

   None.

3. All parent corporations and any publicly held companies that own 10 percent of the stock of the party or *amicus curiae* represented by me are:

   None.

4. The names of all law firms and the partners or associates that appeared for the party or *amicus curiae* now represented by me in the trial court or are expected to appear in this court are:

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STATEMENT OF INTEREST OF AMICUS CURIAE

The Biotechnology Innovation Organization ("BIO") (formerly: Biotechnology Industry Organization) is the principal trade association representing the biotechnology industry domestically and abroad. BIO has more than 1,000 members, which span the for-profit and non-profit sectors and range from small start-up companies and biotechnology centers to research universities and Fortune 500 companies. Approximately 90% of BIO's corporate members are small or mid-size enterprises that have annual revenues of under $25 million, and that count their patents among their most valuable business assets. Because modern biotechnological products commonly involve lengthy, resource and investment-intensive development periods, BIO's members depend heavily on robust patent rights and a fair system for adjudicating their validity. Accordingly, certainty regarding the types of transactions and what must be publicly disclosed about those transactions to qualify as invalidating activities under the on-sale bar of the America Invents Act (AIA) is of great importance to BIO.

BIO has no direct stake in the result of this appeal and takes no position on the ultimate validity of the patents at issue. No counsel for a party authored this brief in whole or in part, and no such counsel or party, nor any person other than the *amicus curiae* or its counsel, made a monetary contribution intended to fund the preparation or submission of this brief. This brief reflects the consensus view of BIO's members, but not necessarily the view of any individual member.

ARGUMENT

I. The Panel Decision Incorrectly Interpreting the On-Sale Bar of § 102(a)(1) Will Chill Commercial Activity Necessary to Bring Biotechnological Innovations to the Public

The panel's incorrect interpretation of the 35 U.S.C. § 102(a)(1) on-sale bar will have a chilling effect on the biotechnology industry's ability bring medical advances and lifesaving technologies to market. In adopting the AIA, Congress removed the territorial restrictions to the "on-sale bar" that had limited its application to sales in the United States. Instead of balancing this territorial extension with the elimination of so-called "secret prior art" as Congress had intended,[1] the panel held that a public reference to a sale that reveals no technical details of an invention can nonetheless defeat a patent under § 102(a)(1). The panel's low disclosure threshold and the world-wide reach of the statute injects uncertainty into the validity of swaths of patents. The harm will be particularly acute in the field of biotechnological development, which requires predictability and certainty in patent law to attract investment to bring such high-risk products to market.

The panel's holding is troubling because it opens the floodgates to potential invalidating prior art while impeding the ability of patentees and their business

[1] As explained in the previously filed brief for amici PhRMA and BIO, Congress elected to do so as part of its effort to harmonize U.S. patent law with international practice and to eliminate so-called "secret prior art." Brief for Amici Curiae Pharmaceutical Research and Manufacturers of America et al. in Support of Plaintiffs-Appellees, at 10-13 and 15-18.

partners to monitor and assess the impact of such disclosures on their patents. Even before the panel's expansion of the doctrine, secret prior art had been recognized as difficult to evaluate, casting great uncertainty into patent validity. *See* Intellectual Property Owners Association, *Comments on Proposed Rules and Examination Guidelines* 3 (Oct. 5, 2012) ("[P]atent litigation . . . [is] burdened with extensive discovery into whether or not a patentee secretly sought to sell or offer to sell his invention.") Under the panel decision, a reported transaction anywhere in the world can have a patent-defeating effect despite disclosing insufficient technical and financial details to apprise a third-party of what exactly was sold or whether the transaction qualifies as a sale. To illustrate, take the example of the active pharmaceutical ingredient at issue in this case, palonosetron (a previously known compound (op. at 4)). A third-party Japanese manufacturer could have issued a press release in Tokyo announcing an agreement to manufacture palonosetron without any reference to dosage, formulation, or transaction details, prior to the effective date of Helsinn's U.S. Patent No. 8,598,219.[2] Helsinn and potential investors would not have been able to ascertain from the press release whether the agreement might qualify as a sale under the Uniform Commercial Code or under Japanese law,[3] nor

[2] The '219 patent is the only patent at issue in this appeal that is governed by the AIA. The '219 patent claims a 0.25 mg dose of palonosetron with specific amounts of EDTA and mannitol in a 5 ml sterile aqueous isotonic solution. Op. at 5.

[3] This Court has referred to the UCC to determine whether a domestic transaction qualifies as a commercial offer for sale. *Medicines Co. v. Hospira, Inc.*, 827 F.3d

would they have been able to assess if the subject to be manufactured was the same or different from the inventions claimed in the '219 patent. The invalidating effect, if any, of the press release would have been unpredictable, making licensing and other investment in product development much less likely.

Further complicating the matter is the fact that the press release may not have even been readily accessible. Many of the patent-invalidating disclosures at issue after the panel's decision are likely to occur in settings that are not consistently and realistically accessible to skilled scientists, professional searchers, and patent examiners. Accordingly, investors and business partners cannot be certain that disclosures in, for example, foreign-language business periodicals or foreign regulatory filings, were identified in pre-investment prior art searches. Knowing this to be the case, it is not unreasonable to assume that investors will be more wary in investing in early-stage technology for fear that crucial patents covering the technology will be later invalidated, despite all reasonable due diligence.

The error in the panel's decision is compounded by the fact that small biotech companies, like Helsinn, will be disproportionally disadvantaged due to their business model. Large biotech companies often have the resources to develop their products without seeking partners. Smaller companies, on the other hand, require

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1363, 1375-76 (Fed. Cir. 2016). It is not at all clear whether *foreign* post-AIA transactions should be evaluated under American or under foreign law for purposes of the AIA on-sale bar.

partnering with third parties to share the high cost and risk of biotech product development. If either party to a transaction is a public company required to report material events, as was the case here with MGI's 8-K filing, then the chance that a potentially invalidating transaction will be referenced in a public disclosure increases. Accordingly, the small company would be exposed to risk that a larger, vertically integrated company would not. As a result, smaller companies may be forced to work with third-party partners under less favorable circumstances.

The history of palonosetron development is illustrative. The molecule was invented by Syntex (a small company) before 1991, Syntex was then bought by Roche (a big company) in 1994. *Helsinn Healthcare S.A. v. Dr. Reddy's Labs. Ltd.*, No. 11-3962, 2016 WL 832089, at *8 (D.N.J. Mar. 3, 2016). By 1997 Roche decided that palonosetron carried too much commercial and technical risk, and divested the program to small company Helsinn which was willing to take on such risk. *Id.* at *9-10, 12. Subsequent clinical development work was fraught with greater difficulty and expense than hoped. *Id.* at *12, 27. By 2000, Helsinn needed a partner to help with massive clinical trial expenses. Principal Brief of Helsinn Healthcare S.A. et al. at 5. Multiple large drug companies turned down the opportunity. *Id.* Eventually, Helsinn found another small company, MGI, that was willing to share the risk in exchange for future and uncertain commercialization rights to the US market. In the end, even though large pharmaceutical companies had repeatedly declined to get

involved, palonosetron was developed into an important and successful drug. *Id.* at 2-3. The story of Aloxi is a success story of small-company invention, small-company collaboration, and small-company risk-sharing, made possible only through the kind of transaction that this Court has now declared patent-defeating.

II. The Panel's Decision Raises Important Questions Concerning The Types of Transactions That Will Become Invalidating Prior Art

In tension with the AIA's goal of improving predictability, the panel's ruling increases uncertainty as to which types of transactions might be invalidating under § 102(a)(1). It is common in any innovative industry for one or more arm's length transactions to precede the introduction of a product in the market. And these transactions are commonly referred to one way or another in the public sphere, for example by press release, investor call, blog post, or SEC filing. But the panel never made clear whether the mere mention of a transaction in the public realm or something more is required to make "the existence of the sale public" (op. at 27) and trigger the on-sale bar. In fact, the panel appeared to rely on more than just the public announcement of the transaction in MGI's 8-K to conclude that the sale[4] was public: it noted that the benefits and uses of palonosetron in treating chemotherapy-induced nausea and vomiting, the chemical structure of palonosetron, and the fact that the products subject to the contract were IV pharmaceutical preparations for human use

[4] Helsinn disputes that the distribution agreement constitutes a sale. *See* Petition for Rehearing En Banc of Helsinn Healthcare S.A., at 4-5.

were all made public. Op. at 21. Without more guidance, uncertainty will further cloud patent validity and stifle transactions common to the biotechnology industry.

While the facts of this case involve a supply agreement, the patent-defeating effect of many more transactions common to the biotechnology industry are called into question by the panel decision. For example, assume Company A sells a library of one hundred compounds to Company B for further development in the treatment of Condition Z. While each of the compounds has shown promise in early screens—arguably rendering each compound ready for patenting—Company B undertakes further screening to find the most effective compound in the library. If a patent is later filed on that compound, it is unclear whether a reference to the sale of the library in an earlier press release could invalidate that patent. As another example, assume startup Company D discovers promising Molecule Y and is later acquired by public Company E. The publicly available acquisition documents note the beneficial properties of Molecule Y. It is unclear whether the publicly announced acquisition would render a later patent claiming a treatment using Molecule Y invalid.

No public policy concern would be served by finding these transactions invalidating under the on-sale bar. Neither example placed an invention in the public domain, so allowing a patent on the invention would not improperly deprive the public. *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 148-49 (1989) (explaining that pre-AIA sections 102(a) and (b) of the patent statute

functioned to prevent injury to the public resulting from removal of knowledge from the public domain). Nonetheless, the panel decision casts serious doubt as to whether patent protection would still be available for these inventions.

The cloud of confusion surrounding the effect of these transactions will complicate patent prosecution and increase doubt as to the validity and enforceability of subsequently-issued patents. Applicants are required to submit information material to patentability during prosecution. 37 C.F.R. § 1.56. Under the current framework left by the panel decision, applicants will face great difficulty in assessing what transactions need to be disclosed to the PTO, and over-disclosure could lead to charges of submitting irrelevant information to the PTO or possibly violating a disclosure agreement between the client and a contracting party.

III. The En Banc Court Should Address Whether Secret Sales and Secret Offers for Sale Are Invalidating Under 102(a)(1)

In focusing its inquiry on whether "the existence of a sale or offer was public," (op. at 21) the panel did not address what impact, if any, non-public steps leading up to the public disclosure have on the effective prior art date of the transaction. Pre-AIA cases had indicated that activities preceding public mention of a sale could constitute the date triggering the on-sale bar. *See Pfaff v. Wells Elec., Inc.*, 525 U.S. 55 (1998) (concluding that the date of acceptance of a purchase order constituted date triggering pre-AIA on-sale bar); *J.A. LaPorte, Inc. v. Norfolk Dredging Co.*, 787 F.2d 1577, 1581-83 (Fed. Cir. 1986) ("The date of the purchase agreement is,

therefore, the effective date on which the invention became part of the public domain."). But in this case, the panel provided no analysis of whether the dates on which the (1) offer to enter into the supply and purchase agreement was made, or (2) supply and purchase agreement was executed constitute the dates on which the invention was "on sale." By side-stepping this issue, the panel made it such that the public cannot be certain of the effective prior art date of a public transaction.

Without answering the question of whether it is the public disclosure itself or the non-public transactional steps preceding the public disclosure that qualify as the invalidating act, it is unclear whether the grace period of 35 U.S.C. § 102(b) can apply.[5] That provision provides circumstances under which "[a] ***disclosure*** made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under [102(a)(1)]." 35 U.S.C. § 102(b) (emphasis added). The applicability of this provision can dictate the deadline by which an entity will file a patent application. But without knowing which activity triggers the § 102(a)(1) bar—a non-public offer or a public disclosure of a sale—it is difficult to assess whether a one is entitled to the § 102(b) grace period.

[5] It appears that this issue was not addressed in this case because the parties agreed that all of the patents-in-suit, including the pre-AIA patents, were subject to the one-year grace period provided in pre-AIA § 102(b). Op. at 4 n.1.

IV. The Negative Policy Implications Arising from The Panel's Decision Cannot Be Mitigated Without Intervention of the En Banc Court

While the panel's opinion appears directed to a specific fact pattern, the far-reaching implications of its decision leave the biotechnology industry with few, if any, options to retain certainty in patent protection. There is no path for biotechnology companies, large and small, to manage their transactions to definitively avoid the current vague standard for an invalidating public sale. And while one proposed solution is to proactively file provisional patent applications early and often, this is not a practical solution. Taking the example of the sale of a compound library above, if such a sale were an invalidating public sale, it would have been prohibitively expensive to file provisional applications for each compound. Moreover, such a system would minimize pre-patent exploration of an invention's utility, thus stifling innovation and causing greater burden on the PTO. *See* Cotropia, *The Folly of Early Filing in Patent Law*, 61 HASTINGS L.J. 65 (2009); Karshtedt, *The Riddle of Secret Public Use: A Response to Professor Lemley*, 93 TEX. L. REV 159 (2015). In short, despite the promise of the AIA, the panel decision unambiguously means that we are now worse off than we were under the old law.

CONCLUSION

For these reasons, BIO respectfully submits that en banc reconsideration of this case is warranted.

Respectfully submitted,

Date: July 14, 2017

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Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc., 2016-1284, -1787

CERTIFICATE OF SERVICE

I, Robyn Cocho, being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

Counsel Press was retained by Biotechnology Innovation Organization, Attorneys for Amicus Curie The Biotechnology Innovation Organization to print this document. I am an employee of Counsel Press.

On **July 14, 2017,** counsel has authorized me to electronically file the foregoing **Brief for Amicus Curiae** with the Clerk of Court using the CM/ECF System, which will serve via e-mail notice of such filing to all counsel registered as CM/ECF users, including the following principal counsel for the parties:

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Paper copies will also be mailed to the above principal counsel at the time paper copies are sent to the Court. Any counsel for *Amicus Curiae* appearing at the time of this filing will be served only via CM/ECF email notice.

Eighteen paper copies will be filed with the Court within the time provided in the Court's rules.

July 14, 2017

/s/ Robyn Cocho
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Counsel Press

CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 40(g).

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