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.

BRIEF OF AMICUS CURIAE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA IN SUPPORT OF HELSINN HEALTHCARE S.A.

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July 14, 2017

CERTIFICATE OF INTEREST

Counsel for Amicus Curiae Pharmaceutical Research and Manufacturers of America certifies the following:

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

Pharmaceutical Research and Manufacturers of America

2. The name of the real party in interest represented by me is:

N/A

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

PhRMA has no parent corporation and no publicly traded company owns 10% of more of its stock. However, its membership includes companies that have issued stock or debt securities to the public. A list of PhRMA's members is available at: www.phrma.org/about/member-companies.

4. The names of all law firms and the partners or associates that appeared for Pharmaceutical Research and Manufacturers of America in proceedings before the district court or are expected to appear in this Court are:

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

INTEREST OF *AMICUS CURIAE*

The Pharmaceutical Research and Manufacturers of America ("PhRMA") represents biotechnology and pharmaceutical companies devoted to discovering and developing medicines.[1] Those efforts produce the cutting-edge treatments that save, prolong, and improve the quality of the lives of countless individuals around the world every day. Over the past decade, more than 350 new medicines have been approved by the Food and Drug Administration ("FDA"). In view of the significant failure rate of biopharmaceutical research and development, and the substantial requirements of the FDA to demonstrate safety and efficacy of new products, those results are not obtained cheaply. In 2015 alone, PhRMA members invested roughly $60 billion in discovering and developing new medicines.

PhRMA seeks to advance public policies that foster innovation in new medicines, including by ensuring adequate patent protection to enable and incentivize its members' substantial investments in research and development. To those ends, PhRMA seeks to remove barriers that may arise in the nation's systems, including the patent laws, for protecting the intellectual property of its members — including as *amicus curiae* before this Court.

[1] A complete list of PhRMA members is available at http://www.phrma.org/about/members (last visited Jul. 14, 2017). Members include Eisai Inc., Plaintiff-Appellee's U.S. marketing partner for Aloxi®, the product at issue in this appeal, and Teva US Specialty Medicines, a corporate affiliate of Defendants-Appellants.

PhRMA has no interest in the outcome of this case. All parties have consented to the filing of this brief. A motion for leave to file accompanies this brief. No party to this appeal drafted any portion of this brief. No party to this appeal or any person other than PhRMA, certain of its members not including Eisai Inc. or Teva US Specialty Medicines, or its counsel contributed any money that was intended to fund preparing or submitting the brief.

ARGUMENT

I. THE STATUTORY LANGUAGE RESULTED FROM SEVEN YEARS OF AMENDMENT AND DEBATE

Rehearing en banc is necessary because the panel's decision does not take into account the years-long process of amending Section 102(a)(1) that preceded the Leahy-Smith America Invents Act of 2011. The wording of that section had been hashed out in numerous revisions of multiple bills, starting with Rep. Smith's first draft of what became H.R.2785, the Patent Reform Act of 2005.

The high degree of attention Congress paid to the development of Section 102(a)(1) in the bills leading up to the 2011 Act reflects its unmistakable intent to limit the invalidating effect of the on-sale bar to public activities. The legislative history of Section 102(a)(1) in the 2011 Act extends well beyond "floor statements made by individual members of Congress" concerning public use. Panel opinion, sl. op. at 19. It encompasses years of effort during which Congress struggled to find the proper expression of its intention to redefine the on-sale bar. The enacted

language was not amended or significantly debated during consideration specifically of the 2011 Act because all that work had been done in prior years. Rehearing en banc will afford the Court an opportunity to consider the impact of the full legislative history on its construction of the statute.

Under former Section 102(b), a "person shall be entitled to a patent unless":

> … 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 …

Each Patent Reform Act bill, starting in 2005, experimented with language to encapsulate Congressional intent to require public availability of the claimed invention. The first iteration was Rep. Lamar Smith's committee print, which provided (underlining and strikethrough reflect changes from old 102(b)):

> … the claimed 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~~, or otherwise known …

Patent Act of 2005, H.R. ____, Committee Print, 109th Cong. (April 14, 2005), available at: https://patentlyo.com/media/docs/2005/05/DraftPatentStatuteDDC.pdf (last visited July 9, 2017).

Rep. Smith's draft bill stimulated extensive hearings and significant revisions, which culminated in the first bill formally introduced in the House of Representatives, H.R.2795, 109th Congress (2005-2006) (Patent Act of 2005) (underlining and strikeout reflect changes from immediately prior quoted version):

> … the claimed invention was patented, described in a printed publication, or otherwise publicly known …

This amendment shows that Congressional intent to limit the definition of prior art to public accessibility of the claimed invention was in the very first bill in the lengthy legislative process that was to follow.

The 2005 bill, along with a companion Senate bill (S.3818) having an identically-worded section 102(a)(1), were not enacted. Congress renewed its patent reform efforts in 2007 with the simultaneous introduction of H.R.1908 and S.1145, which reintroduced express references to public use and sale:

> …the claimed invention was patented, described in a printed publication, or ~~otherwise publicly known~~ in public use or on sale …

In committee, the House version was further amended to:

> … the claimed invention was patented, described in a printed publication, ~~or~~ in public use, or on sale …

House Committee Report No. 110-314, which accompanied the House bill, specifically addressed Section 102(a)(1), noting the importance of retaining an express reference to public use or sale (emphases added):

> Additionally, there is nothing inherent in a first-to-file system that will deter inventors from making use of their inventions as trade secrets and then some time later filing a patent application for the invention. Thus, **the maintenance of the "public use" and "on sale" definitions of prior art are needed** to prevent such activity.

> The Committee also chose to eliminate any geographical limitations placed on the "in public use" and "on sale" prior art found in the current Sec. 102(b). These limitations were first created in an era where it took weeks to travel to other countries and information concerning inventions in other countries, was limited at best. Given advances in communications technology and transportation, the average person knows about what is happening in his own neighborhood. As such, there is no longer a need to distinguish, for prior art purposes, between a **public use or sale** in this country versus one in another. Furthermore, most other countries do not limit prior art to domestic knowledge.

Debate in the Senate on this version resulted, however, in explicitly restoring the requirement for public availability:

> … the claimed invention was patented, described in a printed publication, or in public use, ~~or~~ on sale, or otherwise available to the public …

Senate Committee Report No. 110-259 echoed the House's reference to public availability of prior art and emphasized that maintaining the express bars must be tempered by limiting them to public availability (emphases added):

> [T]his section also, and necessarily, modifies the prior art sections of the patent law. Prior art will be measured from the filing date of the application **and will typically include all art that publicly exists** prior to the filing date, other than disclosures by the inventor within one year of filing. Prior art also will no longer have any geographic limitations; thus in section 102 the "in this country" limitation as applied to "public use" and "on sale" is removed, and the phrase "available to the public" is added to clarify the broad scope of relevant prior art, as well as to **emphasize the fact that it must be publicly available.**

S. Rept. 110-259, 110th Congress (2007-2008). Subsequent bills in the 111th and

112th Congresses retained this language and reiterated the discussion of Section 102(a)(1) from Senate Committee Report No. 110-259.

As the legislative history recounted above shows, the themes of public availability and public on-sale activity permeated all versions of the statute. Throughout the seven-year process to enact patent reform, Congress consistently viewed invalidating on-sale activities through a lens of public availability of the claimed invention. The panel's decision appears not to have fully appreciated the lengthy legislative development of the AIA's on-sale bar, and rehearing is therefore appropriate.

II. PATENT OFFICE GUIDANCE REQUIRES THE CLARITY AND STABILITY THAT ONLY EN BANC REVIEW CAN PROVIDE

Rehearing en banc is required also to allow the Court to provide a definitive statement of the law to the United States Patent and Trademark Office ("USPTO"). The USPTO currently is engaged in the examination of hundreds of thousands of patent applications subject to the statutory provision at the heart of the present dispute. Its core function is to apply the definition of prior art in Section 102 to determine patentability of claimed inventions. Any judicial interpretation of this definition has fundamental and universal effects on how the USPTO carries out its functions. It also has fundamental and universal effects on whether and when stakeholders choose to engage the patent system, because the contour of the prior-art law affects what public acts may be engaged in without jeopardizing patent rights.

The Court's review of this central statutory provision therefore should be done by way of an authoritative and stable en banc opinion that the USPTO and patent community can rely upon.

The USPTO has operated for the past four years under post-AIA examination guidelines, promulgated in the Federal Register and setting out its substantive interpretation of the law, that state: "The phrase 'on sale' in AIA 35 U.S.C. 102(a)(1) is treated as having the same meaning as 'on sale' in pre-AIA 35 U.S.C. 102(b), **except that the sale must make the invention available to the public**." 78 Fed. Reg. 11059, 11075 (Feb. 14, 2013) (emphasis added). The guidance also explained that "an activity (such as a sale, offer for sale, or other commercial activity) is secret (non-public) if it is among individuals having an obligation of confidentiality to the inventor." *Id.* These guidelines, clearly, are inconsistent with the *Helsinn* panel holding.

This inconsistency has thrown into doubt the validity of countless patents and patent applications subject to the AIA definition of prior art. A company that relied on the USPTO guidance and built a business on a patent despite earlier sales that did not make the claimed invention publicly available now would find itself considerably worse off than if it never had filed a patent application at all; it now might get nothing in exchange for a complete disclosure of a claimed invention in the patent. The scope of this perverse result has not yet been ascertained, but it is

likely significant. The Court should not allow this result to infect and destabilize the entire U.S. patent system, particularly in the pharmaceutical space. Rehearing en banc will enable the Court to marshal the greatest possible judicial resources to address this issue before the effects of the panel decision become permanent. At the very least, an en banc opinion will provide the USPTO with an authoritative basis on which to issue new guidelines, if warranted, that are not in danger of being overturned in short order by later precedent.

If the panel opinion is allowed to stand, the validity questions lingering over patents already issued under the current guidelines will continue to be litigated for the foreseeable future. An en banc opinion now will help to settle this question and restore a measure of stability to Section 102 jurisprudence.

III. THE PANEL DECISION IS CONTRARY TO *MEDICINES CO.* BECAUSE FDA APPROVAL IS SO SUBSTANTIAL A PRECONDITION AS TO RENDER THE CONTRACT A MERE PREPARATION FOR COMMERCIAL SALE

The panel opinion noted that the contract between Helsinn and its distributor MGI Pharma Inc., was contingent on FDA approval but held that the existence of a condition precedent did not undermine its characterization as a sale as of the date of execution. Sl. op. 13-15. The panel consequently distinguished the facts in this case from those in *Medicines Co. v. Hospira, Inc.*, 827 F.3d 1363 (Fed. Cir. 2016) (en banc). But this holding should be reconsidered on rehearing, because the panel opinion relied on questionable authority in reaching it.

First, FDA approval is not like the ministerial construction permit or zoning approval to which the panel opinion analogized by its citations to Williston and Corbin. Sl. op. at 14. Rather, it is an expensive and uncertain *sine qua non* for the marketing of pharmaceuticals. FDA approval in the Helsinn-MGI agreement was a substantial precondition to the offer for sale, because the relevant portion of the agreement was inoperative until the precondition was satisfied. The panel opinion's reliance on comparisons to routine permitting understates both the risk of FDA denial and the central significance of FDA approval to this contract's execution. In the context of the substantial risk and doubt that attends making a contract contingent on FDA approval, an agreement such as that between Helsinn and MGI in this case reasonably can be seen as "mere preparations for commercial sales." *Medicines Co.*, 827 F.3d at 1377.

Second, the cases the panel opinion cites to show that absence of FDA approval before the critical date does not prevent triggering of the on-sale bar (sl. op. 14-15) are inapposite because they did not involve contracts in which FDA approval was an express condition of the offer for sale. In *Enzo*, the sale was made for materials to carry out pre-approval testing; FDA approval simply did not enter into the terms of the agreement there. *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 424 F.3d 1276, 1279 (Fed. Cir. 2005). Similarly in *Bard v. M3*, the offer for sale was not conditioned on FDA approval; rather, one judge in a minority opinion observed

that FDA approval is not required to make a sale a barring event. *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1376 (Fed. Cir. 1998) (opinion of Bryson, J.).

CONCLUSION

For the foregoing reasons, amicus curiae urges the Court to grant en banc review.

Dated: July 14, 2017

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32 and Federal Circuit Rule 35, I certify the following:

1. The brief complies with the type-volume limitations of Federal Circuit Rule 35(g) because, exclusive of the exempted portions, it does not exceed 10 double-spaced pages.

2. The attached petition complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in a proportionally space typeface using Microsoft Word 2016 in 14-point Times New Roman type style.

Dated: July 14, 2017

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CERTIFICATE OF SERVICE

I, Scott E. Kamholz, hereby certify that, on July 14, 2017, the foregoing document was filed and served using the CM/ECF system.

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