Nos. 16-1284, -1787

United States Court of Appeals for the Federal Circuit

Helsinn Healthcare S.A. and Roche Palo Alto LLC,

Plaintiffs-Appellees,

v.

Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals Industries, Ltd.,

Defendants-Appellants.

Appeal from the United States District Court for the District of New Jersey,
Case Nos. 3:11-CV-3962, -5579, -5815, Judge Mary Cooper

BRIEF OF *AMICUS CURIAE*
AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION
IN SUPPORT OF PLAINTIFFS-APPELLEES'
PETITION FOR REHEARING *EN BANC*

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Date: July 14, 2017

2016-1284, -1787

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

HELSINN HEALTHCARE S.A. AND ROCHE PALO ALTO LLC,

Plaintiffs-Appellees,

v.

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

Defendants-Appellants.

CERTIFICATE OF INTEREST

In accordance with FED. CIR. R. 47.4 and FED. R. APP. P. 26.1, counsel for Amicus, American Intellectual Property Law Association, certifies the following:

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

American Intellectual Property Law Association.

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 parties represented by me are:

None.

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

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STATEMENT OF INTEREST OF *AMICUS CURIAE*

The American Intellectual Property Law Association ("AIPLA") is a national bar association of approximately 14,000 members who are involved directly or indirectly in the practice of patent, trademark, copyright, and unfair competition law, as well as other fields of law affecting intellectual property. AIPLA has no stake in any of the parties to this litigation or in the result of this case.[1] AIPLA's only interest is in seeking correct and consistent interpretation of the law as it relates to intellectual property issues. This brief is filed pursuant to a Motion for Leave and with the consent of Appellants Teva Pharmaceuticals USA Inc. and Teva Pharmaceutical Industries Ltd., and Appellee Helsinn Healthcare S.A.

ARGUMENT

This case involves a question of exceptional importance, namely, whether 35 U.S.C. § 102(a), as amended by the America Invents Act ("AIA"), requires an invention to be available to the public to constitute prior art. As the first precedent on the issue, the panel's opinion will bind future panels unless it is changed by the

[1] After reasonable investigation, AIPLA believes that (a) no member of its Board or Amicus Committee who voted to prepare this brief, or any attorney in the law firm or corporation of such a member, represents a party to this litigation in this matter, (b) no representative of any party to this litigation participated in the authorship of this brief, and (c) no one other than AIPLA, its members who authored this brief, and their law firms or employees, made a monetary contribution to the preparation or submission of this brief.

Court *en banc*. *E.g.*, *Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356, 1359 n.* (Fed. Cir. 1999).

The question is important not only because it is one of first impression but because it defines prior art, a fundamental building block of the first-inventor-to-file ("FITF") system created by the AIA. The success of this system requires a simple and transparent process for identifying prior art. The AIA created a more simple, transparent system in part by eliminating secret prior art such as confidential, non-experimental sales. The panel's opinion would defeat Congressional intent to make determinations of whether a sale constitutes prior art more predictable and less expensive.

I. THE PANEL OPINION MISCONSTRUES THE STATUTORY LANGUAGE AND MISAPPREHENDS THE LEGISLATIVE HISTORY

A. Under The AIA, A Sale Must Make The Claimed Invention Available To The Public To Qualify As Prior Art

Congress passed the AIA in 2011 as the first major reform of U.S. patent law since the 1952 Patent Act, transforming the former "first to invent" ("FTI") into the current FITF system. The AIA revised the language of Section 102(b) of the 1952 Act and moved it into a new Section 102(a)(1), as follows:

> **(a) Novelty; Prior Art**. ~~**Conditions for patentability; novelty and loss of right to patent**~~ A person shall be entitled to a patent unless—
>
> (1) 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 available to the public before the effective

> filing date of the claimed invention; ~~more than one year prior to the date of the application for patent in the United States~~….

35 U.S.C. § 102(a)(1) (2012). The critical differences between the pre- and post-AIA versions of this language include:

(1) the title is changed to strike "loss of right to patent" and to insert "Prior Art," reflecting the provision's focus on defining prior art; [2]

(2) "claimed" now appears before "invention,"[3]

(3) "in this country" no longer appears after "in public use or on sale;"

(4) "or otherwise available to the public" was added following the list of patent-defeating references; and,

(5) "more than one year prior to the date of the application for patent in the United States" was changed to "before the effective filing date of the claimed invention."

The panel decision failed to give full effect to these revisions, despite the plain language of § 102(a)(1) and its legislative history requiring that a prior art reference be available to the public. The panel cites and relies upon only portions

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[2] As argued in Congressman Smith's amicus brief in support of rehearing *en banc* (Dkt. No. 139 at 6-7), and AIPLA's amicus brief to panel (Dkt. No. 93 at 15), even AIA § 102's title shows Congress's intent to limit prior art to public disclosures and to eliminate losses of right to patent known as statutory bars. The panel opinion is mistaken when it refers to AIA § 102(a) as a "bar to patentability," *e.g.*, *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 855 F.3d 1356, 1363 (Fed. Cir. 2017), and many of the cases cited in the panel decision are not relevant.

[3] 35 U.S.C. § 100(j) defines "claimed invention" as "the subject matter defined by a claim in a patent or an application for a patent."

of the relevant legislative history, and fails to appreciate the significance of the House Report. The revisions itemized above place the claimed invention in the prior art only if it was on sale "or otherwise available to the public" before the patent's "effective filing date."[4] The term "otherwise" means "in a different way or manner" (*Merriam-Webster's Collegiate Dictionary*, at 823 (10th Ed. 1998)), and reflects that the claimed invention is prior art only ***where it is publicly sold* or *where it is public in a different way or manner***.[5]

The panel decision also incorrectly states that this reading of the statute depends upon "floor statements made by individual members of Congress." 855 F.3d at 1368. The House Report on the AIA expressly states that "[p]rior 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

[4] The panel opinion reveals a misunderstanding of the AIA by referring in several places to the patent's "critical date." 855 F.3d at 1369-71. "Critical date" refers to the date more than one year before the filing of a patent application under the 1952 Act to determine the grace period for such filings. *Monon Corp. v. Stoughton Trailers, Inc.*, 239 F.3d 1253, 1257 (Fed. Cir. 2001). The relevant term for § 102(a)(1) prior art is the "effective filing date," specifically defined at 35 U.S.C. § 100(i).

[5] The USPTO agrees with this construction. In examiner guidelines, it has stated that "otherwise available to the public" in § 102(a)(1) is a "catch-all" provision that focuses on whether the disclosure was "available to the public" rather than whether it falls within another prior art category defined by the statute. 78 Fed. Reg. 11059, 11075 (2d col.). Secret sales or uses do not qualify as prior art, and this applies to all documents and activities itemized in § 102(a)(1). *Id*. at 11062 (2d col.). *See also* Brief for the United States as *Amicus Curiae* (Dkt. 90) at 5. The USPTO's reasonable interpretations are entitled to deference. *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 844, 865-66 (1984).

within 1 year of filing." H.R. REP. NO. 112-98, at 42 (2011) (emphasis added). The House Report continues by saying "the phrase 'available to the public' [was] added to clarify the broad scope of relevant prior art, ***as well as to emphasize the fact that it must be publicly accessible.***" *Id*. at 42-43 (emphasis added). This legislative history confirms the statutory language that all prior art, including sales, must make the invention available to the public.

In this case, the panel erroneously invalidated a patent claim based on (1) a non-public sale and (2) public disclosures about the sale that did not make the invention available to the public. Claim 1 of the patent at issue (8,598,219), which relates to the use of a specific dose of palonosetron to treat side effects of chemotherapy, was the subject of Supply and Purchase Agreement between Helsinn and MGI Pharma, Inc. The panel's on-sale invalidity determination was based on this agreement, a press release about the agreement, and a Form 8-K filing with the Securities and Exchange Commission ("SEC").

These documents, however, failed to make the claimed invention available to the public. The Supply and Purchase Agreement was confidential and neither the press release about the agreement nor the Form 8-K filing at the SEC disclosed the claimed invention. 855 F.3d at 1361-62. The press release described the invention only in general terms, and only a redacted version of the agreement was included

with MGI Pharma's Form 8-K at the SEC. *Id*. Neither disclosed the claimed dosage. *Id*.

In short, this appeal to the full Court is important because the panel decision misconstrued what constitutes prior art under AIA § 102(a)(1), contrary to the statutory language and legislative history. Unless corrected by the Court *en banc*, the panel decision will undermine Congress's intent when enacting the AIA.

B. A Prior Art Sale Under The AIA Must Publicly Disclose All The Elements of A Claim To Be Invalidating

A claim is anticipated only if each and every element of the claim is found, either expressly or inherently, in a single prior art reference and arranged as in the claim. *E.g.*, *Net Moneyin, Inc. v. Verisign, Inc.*, 545 F.3d 1359, 1369-70 (Fed. Cir. 2008). To overcome this black letter rule, the panel stated:

> Our cases explicitly rejected a requirement that the details of the invention be disclosed in the terms of sale. *See RCA Corp. v. Data Gen. Corp.*, 887 F.2d 1056, 1060 (Fed. Cir. 1989), *overruled in part on other grounds by Grp. One,* [*Ltd. v. Hallmark Cards, Inc.*,] 254 F.3d [1041,] 1048 [(Fed. Cir. 2001)].

887 F.3d at 1370. It is striking that the panel not only relied upon pre-AIA cases, but relied on ***dicta*** in those cases. The same paragraph of *RCA* cited by the panel states: "In addition, the bid documents themselves contain a technical description which is sufficient to identify the Cole invention, albeit not set forth in the language of the claims *in haec verba*." 887 F.2d at 1060. Thus, the statement on which the panel relied was *dictum*.

The panel decision also relied on *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1, 19 (1829), for the proposition that a sale can be invalidating even though it withholds "from 'the public the secrets of [the] invention.'" 855 F.3d at 1369. But *Pennock* also does not support this proposition. In *Pennock*, the "invention claimed was in the mode of making [a] hose…." 27 U.S. at 3. The inventors were Pennock and Sellers. The hose had been sold by another individual, Jenkins, who "had been instructed by them [Pennock and Sellers] in the art of making the hose." *Id*. The *Pennock* decision notes that the inventors had an agreement with Jenkins, *e.g., id.*, but there is no statement or even hint that the agreement imposed any confidentiality obligations on Jenkins. Thus, in *Pennock* the details of the invention were also public because Jenkins knew them. The portion of the *Pennock* opinion quoted by the panel is a series of hypothetical statements, introduced by "if," that do not constitute a holding of the case.

II. THE PANEL DECISION DEFEATS THE AIA'S PURPOSE TO IMPROVE THE EFFICIENCY AND PREDICTABILITY OF THE PATENT SYSTEM

The panel decision in this case requires *en banc* reconsideration because, in undermining the public availability requirement for all of the types of prior art recited in § 102(a)(1), it defeats one of the AIA's primary purposes: to improve the efficiency and predictability of the U.S. patent system.

According to the House Report, "[t]he Act . . . simplifies how prior art is determined, provides more certainty, and reduces the cost associated with filing and litigating patents." H.R. REP. NO. 112-98, at 42 (2011). *See also id*. at 40 (the "legislation is designed to establish a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counterproductive litigation costs."). The AIA § 102(a)(1) requirement that references be publicly available to qualify as prior art simplifies the decision to pursue a patent by decreasing or eliminating the costly investigations needed to determine if there has been any potentially patent-defeating public use or sales activity.

The "publicly available" requirement also limits discovery by eliminating an otherwise fact-intensive inquiry. For example, under AIA § 102(a)(1), invalidating sales are no longer limited to those taking place "in this country." The panel's decision will increase discovery expense where the alleged sale took place overseas. Further discovery will be required to determine whether an alleged sale was experimental.[6] And this additional discovery often triggers disputes that

[6] *E.g.*, *Allen Eng'g, Inc. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1353 (Fed. Cir. 2002) (*quoting EZ Dock v. Schafer Sys., Inc.*, 276 F.3d 1347, 1357 (Fed. Cir. 2002) (Linn, J., concurring)).

require court intervention, extend the length of any trial, and create a voluminous record for appeal.[7]

The panel decision would perpetuate the fact-intensive approach of pre-AIA caselaw. It states: (1) "the AIA did not change the statutory meaning of 'on sale' ***in the circumstances involved here***," 855 F.3d at 1360 (emphasis added); and (2) "[w]e do not find that distribution agreements will always be invalidating under § 102(b) [sic – 102(a)]. We simply find that this particular Supply and Purchase Agreement is." *Id*. at 1371. Contrary to Congressional intent, the panel's approach would require substantial additional time and expense for discovery, motions practice, trial, and appeal to define the specific sales arrangements that do or do not constitute prior art.

Congress also imposed this public availability requirement on prior art to protect U.S. businesses from having their inventions stolen or patents invalidated by unscrupulous foreign competitors. Senator Kyl stated:

> Finally, *validating prior art will depend on publicly accessible information*, not private activities that take place, for example, in a foreign land. As a result, it will be impossible for a third party who derived the invention from a U.S. inventor's public disclosure or patent application to steal the invention or sabotage the U.S. inventor's patent.

[7] Even in 1829 the *Pennock* Court complained that the public use and public sales issue had created a "very voluminous" record and imposed an "extensive and unnecessary burden upon the record." 27 U.S. at 15.

Cong. Rec. S5320 (Sept. 6, 2011) (3d col.) (emphasis added). To allow secret sales anywhere in the world to serve as prior art would facilitate the theft of U.S. inventions, contrary to Congress's expressed intent.

III. CONCLUSION

For all these reasons, the question presented by this case is exceptionally important. This Court should rehear this case *en banc* and affirm the district court's decision that in order to qualify as prior art a sale of the invention must have made the claimed invention available to the public.

Date: July 14, 2017

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PROOF OF SERVICE

The undersigned hereby certifies that on July 14, 2017, I caused a true and correct copy of the foregoing **BRIEF OF *AMICUS CURIAE* AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION IN SUPPORT OF PLAINTIFFS-APPELLEES' PETITION FOR REHEARING *EN BANC*** to be filed via CM/ECF with the Clerk of the Court and thereby to be served electronically upon all counsel of record in this matter.

Dated: July 14, 2017

/s/ Lynn C. Tyler
Lynn C. Tyler
Principal Attorney for Amicus Curiae

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 29(c)(5), I certify that the foregoing **BRIEF OF *AMICUS CURIAE* AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION IN SUPPORT OF PLAINTIFF-APPELLEES' PETITION FOR REHEARING *EN BANC*** was prepared using Microsoft Word 2010, Times New Roman 14 point font, and in relevant part does not exceed ten pages in length, excluding those portions exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and Fed. Cir. R. 32(b), and therefore complies with the size limitation set forth in Fed. R. App. P 35(g).

Dated: July 14, 2017

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