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 FOR INTELLECTUAL PROPERTY OWNERS ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFF-APPELLEE'S PETITION FOR REHEARING *EN BANC*

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July 11, 2017

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Helsinn Healthcare S.A. **v.** Teva Pharmaceuticals USA, Inc.

Case No. 2016-1284, -1787

CERTIFICATE OF INTEREST

Counsel for the:
☐ (petitioner) ☐ (appellant) ☐ (respondent) ☐ (appellee) ☒ (amicus) ☐ (name of party)

Intellectual Property Owners Association

certifies the following (use "None" if applicable; use extra sheets if necessary):

1. Full Name of Party Represented by me	2. Name of Real Party in interest (Please only include any real party in interest NOT identified in Question 3) represented by me is:	3. Parent corporations and publicly held Companies that own 10 % or more of stock in the party
Intellectual Property Owners Association	None	None

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court (**and who have not or will not enter an appearance in this case**) are:

None

July 11, 2017
Date

/s/ Mark W. Lauroesch
Signature of counsel

Please Note: All questions must be answered

Mark W. Lauroesch
Printed name of counsel

cc:

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Intellectual Property Owners Association (IPO) submits this brief as an *amicus curiae* under Federal Rule of Appellate Procedure 29(b) and Rules 29 and 35(g) of this Court. IPO supports the petition for rehearing *en banc* filed by Plaintiff-Appellee Helsinn Healthcare S.A. (Helsinn).

INTEREST OF AMICUS CURIAE

IPO is a trade association representing companies and individuals in all industries and fields of technology who own or are otherwise interested in intellectual property rights.[1] IPO's membership includes more than 200 companies and over 12,000 individuals who are involved in the association either through their companies or as inventor, author, executive, law firm, or attorney members. Founded in 1972, IPO represents the interests of all owners of intellectual property. IPO regularly represents the interests of its members before Congress and the United States Patent and Trademark Office (USPTO) and has filed *amicus curiae* briefs in this Court and other courts on significant issues of intellectual property law. The

[1] No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than the *amicus curiae* or its counsel made a monetary contribution to its preparation or submission. Both parties have consented to the filing of this brief and a motion for leave to file is being filed with this brief.

members of IPO's Board of Directors, which approved the filing of this brief, are listed in the Appendix.[2]

SUMMARY OF ARGUMENT

There is a debate about whether Congress changed the "on-sale" defense to a patent infringement claim in enacting the AIA, as articulated in the parties' and amici briefing and the conflicting decisions of the trial court and panel below. The debate has two aspects. First, whether the post-AIA on-sale bar excludes private sales, and second, whether a public sale requires that the invention claimed in the patent subject to the sale be made public to be invalidating.

En banc consideration is warranted because the parties, and IP stakeholders, need the clarity (if not the certainty) that only the full Court can provide regarding how the on-sale bar operates in the post-AIA world. Thus, this case "involves a question of exceptional importance," satisfying at least one of the criteria for *en banc* review. *See* Fed. R. App. P. 35(a)(2).

En banc review is also warranted because the panel's decision is inconsistent with the USPTO's post-AIA examination guidelines, previously the only authoritative guidance on the post-AIA on-sale bar. USPTO's guidelines have governed examination of many hundreds of thousands of patent applications. More post-AIA innovations are being made, applications are being filed, and patents are

[2] IPO procedures require approval of positions in briefs by a two-thirds majority of directors present and voting.

being issued every day, and the validity and value of many of those patents will remain clouded until the on-sale bar debate is settled. Similarly, innovators large and small and their business partners need clarity now so they can organize their businesses and contracts to develop, commercialize, and protect their innovations, and make any necessary practice changes. Delay in clarifying this important issue risks laying serious traps for the wary, as well as the unwary.

En banc consideration is also "necessary to secure or maintain uniformity of [this Court's] decisions." Fed. R. App. P. 35(a)(1). If the panel's construction of the post-AIA on-sale bar is correct, then its holding that the mere existence of a public sale or offer for sale that does not disclose the invention as claimed is inconsistent with the Court's *en banc* decision in *Medicines Co. v. Hospira, Inc.*, 827 F.3d 1363 (Fed. Cir. 2016) that "the offer or contract for sale must unambiguously place the invention on sale, as defined by the patent's claims."

Finally, *en banc* review is appropriate because this case represents a fact pattern that will repeat until the legal debate over proper construction of the on-sale bar post-AIA is settled. A prompt resolution will enable the USPTO to examine patent applications and allow applicants to make appropriate disclosures regarding putative on-sale activities under the correct rubric. In addition, absent a unanimous decision by the Court *en banc*, a petition for a *writ of certiorari* is likely. All concerned would therefore benefit from this expert Court's full and considered review.

ARGUMENT

I. Proper Application of the Post-AIA On-Sale Bar Is Critically Important to All Industries and Fields of Technology

This case presents an important issue of first impression: whether Congress substantively changed the on-sale bar in section 102 of the Patent Act when it enacted the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (AIA). Congress made fundamental changes to the Patent Act by, among other things, redefining prior art under section 102. *See Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 855 F.3d 1356, 1368 (Fed. Cir. 2017) (Panel Decision). But the panel expressly declined to address how those changes, which it deemed limited to "public use" activities, affect application of the on-sale bar, *see id.* at 1368-69, a critically important issue that this Court should decide *en banc*.

The panel also rejected Helsinn's argument that the on-sale bar under the AIA does not include "secret sales." *Id.* at 1367-69. But as the arguments made below point out, secret prior art creates uncertainty and is a drag on the patent system, and there is some basis to believe that Congress wrote secret on-sale activities out of the on-sale bar by adding the language "or otherwise available to the public." *See, e.g.*, 157 Cong. Rec. 3415 (2011) (remarks of Sen. Leahy) ("[S]ubsection 102(a) was drafted in part to do away with precedent under current law that private offers for sale . . . may be deemed patent-defeating prior art."). Thus, the panel's decision might leave secret prior art within the on-sale bar, given

the decision's reluctance to address the issue, perpetuating uncertainty and confusion.

The panel's reluctance is also at odds with recent Supreme Court precedent. In *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, "the only question [was] whether Congress changed the meaning of §1400(b) [the patent venue statute] when it amended §1391 [the general venue statute]." No. 16-341, slip op. at 8 (U.S. May 22, 2017). Because the amended "version of §1391 does not contain any indication that Congress intended to alter the meaning of §1400(b)," the Court answered that question in the negative. *Id.*

But here there are arguably numerous indications that Congress intended to alter the meaning of both section 102 and the on-sale bar, as evidenced by its various considerations of whether to include the on-sale bar as an invalidity defense (and in what form), as the panel's decision acknowledges. *See, e.g.*, Panel Decision at 1368; *cf.* Brief for Congressman Lamar Smith as Amicus Curiae *and* Brief for 42 Intellectual Property Professors as Amici Curiae (presenting contrasting statutory construction views).

The panel also held that confidential details of an invention as claimed need not be publicly disclosed to trigger the on-sale bar. *See* Panel Decision at 1370-71. Conversely, a confidential sale should arguably avoid triggering the on-sale bar (even as amended by the AIA), as this Court held in its *en banc* decision in

Medicines Co. v. Hospira, Inc., 827 F.3d 1363, 1376 (Fed. Cir. 2016). Yet Helsinn's partner, a publicly traded company, publicly disclosed its agreements with Helsinn in redacted form in its Form 8-K filing to comply with SEC regulations. *See* Panel Decision at 1361. Thus, the nature of this case's agreements and circumstances bear directly on how any innovator might contract with others to develop claimed inventions for commercialization, significant factors that warrant this Court's *en banc* review.

II. The Panel Decision Is Inconsistent with the USPTO's Post-AIA View of the Scope of the On-Sale Bar

Before the effective date of the AIA, the USPTO adopted its interpretive guidelines, including the only authoritative interpretation of new AIA section 102 until the panel's decision. For the last four years, patent applicants and examiners have followed those guidelines in considering what information to disclose and the significance of that disclosure. More importantly, the USPTO has examined hundreds of thousands of patents based on a reading of the on-sale bar that is consistent with the district court's construction below but inconsistent with the panel's construction. According to statistics from the USPTO, just under a million patents were granted between 2013 (the year the AIA went into effect) and 2015. *See* USPTO Patent Technology Monitoring Team, U.S. Patent Statistics Chart, Calendar Years 1963-2015, available at

https://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm (last visited June 1, 2017).

As discussed above, the panel held that, notwithstanding enactment of the AIA, the on-sale bar applies to a public sale even if an invention is not disclosed in the terms of the sale. Panel Decision at 1371. The USPTO's Manual of Patent Examining Procedure (MPEP), however, takes a different view of the scope of the post-AIA on-sale bar. There, "[t]he 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*." MPEP § 2152.02(d) (emphasis); *see also id.* ("The pre-AIA 35 U.S.C. 102(b) 'on sale' provision has been interpreted as including commercial activity even if the activity is secret. . . . AIA 35 U.S.C. 102(a)(1) uses the same 'on sale' term as pre-AIA 35 U.S.C. 102(b). The 'or otherwise available to the public' residual clause of AIA 35 U.S.C. 102(a)(1), however, indicates that AIA 35 U.S.C. 102(a)(1) does not cover secret sales or offers for sale. For example, 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.").

Under the USPTO's post-AIA construction of the on-sale bar, the agreements here would not invalidate Helsinn's patent because the invention claimed was not "made available to the public," as the district court found. *See*

Helsinn Healthcare S.A. v. Dr. Reddy's Labs. Ltd., No. CV 11-3962 (MLC), 2016 WL 832089, at *51 (D.N.J. Mar. 3, 2016). Independent of whether any deference is due the USPTO, the consistency of its construction with the district court's and the disagreement between that construction and the panel's construction highlights uncertainty that is unsettling to innovators and patent holders in all industries and fields of technology. That uncertainty is ripe for resolution by this Court sitting *en banc*.

III. The Panel's Decision in This Case Is Facially Inconsistent with the Court's *En Banc* Decision in *Medicines*

Medicines allows inventors to contract for manufacturing services without triggering the pre-AIA on-sale bar, provided their inventions (as defined by a patent's claims) are not "on sale." 827 F.3d at 1374 (application of the on-sale bar "requires that 'the invention' be 'on sale'" and "[t]he 'invention' is defined by the patent's claims.") (quoting 35 U.S.C. § 102(b)), 1377 ("[T]here must be a commercial sale or offer for sale. The statute itself says the invention must be 'on sale,' or that there must be an offer for sale of the invention. . . . The on-sale bar is triggered by actual commercial marketing of the invention, not preparation for potential or eventual marketing.").

But the panel held that the post-AIA on-sale bar applies to all public sales, including sales that do not disclose an invention. *See* Panel Decision at 1370 ("[A]n invention is made available to the public when there is a commercial offer

or contract to sell a product embodying the invention and that sale is made public."), 1371 ("[A]fter the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of sale."). Thus, the panel's decision does not allow inventors the same flexibility for license agreements that must be publicly disclosed, *see* Part I above, that *Medicines* allows for manufacturing agreements.

Again setting aside whether the pre- and post-AIA on-sale bars allow inventors the same degree of flexibility, the inconsistency between the panel's decision and this Court's *en banc Medicines* decision alone is sufficient reason to grant Helsinn's petition. *See* Fed. R. App. P. 35(a)(1). The panel determined that a sale need only be public for the on-sale bar to apply, while *Medicines* held that the "claimed invention" must be the subject of any invalidating sale. This Court should clarify which decision controls for the benefit of all stakeholders.

IV. This Case Presents a Unique Opportunity to Clarify the Application of the AIA's On-Sale Bar

There is no dispute about the terms of the agreements in this case. Indeed, the circumstances surrounding those agreements is commonplace in industries where patent holders partner with others to develop and manufacture new products. Like many pharmaceutical companies, Helsinn needed a partner to develop a drug, bring it to market, and help the millions of cancer patients who suffer from chemotherapy-induced nausea and vomiting. As discussed above, however, the

future of similar, equally-important partnerships is uncertain because the panel's decision does not clearly address the proper application of the AIA's on-sale bar to similar agreements. Also as discussed above, the lack of clarity is only compounded by conflict with this Court's *Medicines* decision and, until the inconsistency is resolved, patent holders, prospective patentees, and other industry participants do not know how to arrange their affairs to allow them to continue contributing to society through innovation.

On the other hand, this case's facts are uncommon in that the four patents-in-suit claim priority to the same provisional application, but only one patent is governed by the AIA. *See* Panel Decision at 1360 n.1. Thus, the Court has a unique opportunity to determine in the first instance whether Congress changed the "on sale" defense to a patent infringement claim when it enacted the AIA. It is difficult to imagine a better case to resolve any inconsistency between the panel decision and the pre-AIA, *en banc* decision in *Medicines*, or to clarify the application of the post-AIA on-sale bar, given the involvement of both pre- and post-AIA patents.

Given the exceptional importance of the question presented, it is also very likely Supreme Court review will be sought. And given that likelihood, a decision from the Court sitting *en banc* would benefit both the parties and the Court. *See Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 132 (2006)

("The question before us is whether claim 13 . . . is invalid in light of the 'law of nature' principle[.] . . . I believe that we should answer that question. . . . [But t]here is [ ] a practical reason for not doing so, namely, that we might benefit from the views of the Federal Circuit, which did not directly consider the question.") (Breyer, J., dissenting from dismissal of *writ of certiorari*); *see also United States v. Bestfoods*, 524 U.S. 51, 72–73 (1998).

CONCLUSION

The Court should grant Helsinn's petition because this case presents important questions of first impression and rehearing *en banc* is necessary to clarify the construction of the post AIA on-sale bar and resolve the panel decision's ambiguity and its facial inconsistency with this Court's decision in *Medicines*.

Respectfully submitted this 14th day of July, 2017,

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APPENDIX

APPENDIX[1]

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United States Court of Appeals for the Federal Circuit

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

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On **July 11, 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 11, 2017

/s/ Robyn Cocho
Robyn Cocho
Counsel Press

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