No. 17-1229

IN THE

Supreme Court of the United States

HELSINN HEALTHCARE S.A.,

Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC., *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF *AMICUS CURIAE* INTELLECTUAL PROPERTY OWNERS ASSOCIATION IN SUPPORT OF PETITIONER

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INTEREST OF AMICUS CURIAE

Amicus curiae Intellectual Property Owners Association (IPO) is an international trade association representing companies and individuals across all industries and fields of technology who own or are otherwise interested in intellectual property rights.[1] IPO's membership includes about 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 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 members of IPO's Board of Directors, which approved the filing of this brief, are listed in the Appendix.[2]

IPO's members invest tens of billions of dollars annually on research and development, employing hundreds of thousands of scientists, engineers, and others in the United States to develop, produce, and market innovative new products and services. Many of these innovations take years of research, failure, missteps,

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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 through blanket consent letters.

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

and refinements to reach eureka moments, and still additional time to develop practical applications followed by potential commercialization. To bring new products and services to market, IPO's members often resort to contractual arrangements with third parties for supply and/or distribution because they lack the resources to do it all themselves. Further, in many industries in which IPO members operate, necessity dictates that plans for commercialization begin years before research and development has produced marketable products, particularly, for example, in the pharmaceutical, semiconductor, energy, aerospace, and automotive industries.

Because of the need to timely file for patents on their innovations, this case presents a question of substantial practical importance to IPO members: namely, whether in enacting the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (AIA) Congress changed the on-sale bar defense, as the trial court and USPTO have concluded—a determination with which the Federal Circuit disagreed. A further related question of importance to IPO is, in light of the proper statutory construction, how must IPO members conduct their business to protect and market their innovations without triggering an on-sale bar. IPO members, as well as the parties and indeed all IP stakeholders, need the clarity (if not the certainty) that only this Court can provide regarding proper application of the on-sale defense post-AIA.

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 Federal Circuit 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 claimed invention subject to the sale be made public to be invalidating.

The U.S. Court of Appeals for the Federal Circuit (Federal Circuit) held that Congress did not "change the statutory meaning of 'on sale'" by enacting the AIA, *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 855 F.3d 1356, 1360 (Fed. Cir. 2017). However, the Federal Circuit decision is inconsistent with the USPTO's post-AIA examination guidelines, adopted before the AIA became effective and still followed today. *See* Manual of Patent Examining Procedure, Ninth Edition, Revision 08.2017, Last Revised January 2018 (MPEP) § 2152(d). These examination guidelines were previously the only authoritative guidance post-AIA on whether an invention was on-sale to bar patentability. Indeed, the 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 being issued every day, and the validity and value of many of those patents will remain clouded until this Court settles the present on-sale bar debate. Similarly, both large and small innovators and their business partners need clarity now so they can organize their businesses and contracts to develop, commercialize,

and protect their innovations; making any necessary practice changes to comport with the law. Delay in clarifying this important issue risks laying serious traps for the wary, as well as the unwary.

Furthermore, if the Federal Circuit'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 that part of the Federal Circuit's *en banc* decision in *Medicines Co. v. Hospira, Inc.*, 827 F.3d 1363 (Fed. Cir. 2016) stating that "the offer or contract for sale must unambiguously place the invention on sale, as defined by the patent's claims." *Helsinn*, 855 F.3d at 1366.

Finally, this case represents a fact pattern that will repeat until the legal debate over proper post-AIA construction of the on-sale bar 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. It also will enable IP stakeholders to mitigate their risks when contracting with others to bring innovations to market.

IPO supports the petition to resolve the debate, but takes no position on the merits of the question presented in this case, *i.e.*, whether post-AIA 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 the patentability of the invention.

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) . Congress made fundamental changes to the Patent Act by, among other things, redefining prior art under section 102. *See Helsinn*, 855 F.3d at 1368. The Federal Circuit expressly declined, however, 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.

The Federal Circuit 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 Federal Circuit 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 Federal Circuit's reluctance is also at odds with this Court's 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]." 137 S. Ct. 1514, 1520 (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), which the Federal Circuit decision acknowledges. *See, e.g.*, *Helsinn*, 855 F.3d at 1368; *cf.* Brief of Amicus Curiae Congressman Lamar Smith in Support of Appellees, *Helsinn*, 855 F.3d 1356 (No. 2016-1284), *and* Brief of Amicus Curiae 42 Intellectual Property Professors in Support of Appellant, *Helsinn*, 855 F.3d 1356 (No. 2016-1284) (presenting contrasting statutory construction views).

The Federal Circuit also held that confidential details of an invention as claimed need not be publicly disclosed to trigger the on-sale bar. *See Helsinn*, 855 F.3d at 1370-71. Conversely, a confidential sale should arguably avoid triggering the on-sale bar (even as amended by the AIA), consistent with the Federal Circuit's holding in its *en banc Medicines* decision, 827 F.3d at 1376 ("the confidential nature of the transactions is a factor which weighs against the conclusion that the transactions were commercial in nature."). 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 Helsinn*, 855 F.3d at 1361. Thus, the nature of this case's agreements and circumstances – where the claimed subject matter was kept secret – bear directly on how any innovator might contract with others to develop claimed inventions for commercialization, significant factors that warrant this Court's consideration.

II. The Federal Circuit 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 Federal Circuit decision. *See* MPEP § 2152.02(d). For the last five 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 Federal Circuit'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 March 17, 2018). These numbers are increasing as time passes.

As discussed above, the Federal Circuit 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. *Helsinn*, 855 F.3d at 1371. The USPTO's 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 added). The USPTO's MPEP further states that "[t]he 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." *Id.* (emphasis added).

Under the USPTO's post-AIA construction of the on-sale bar, the agreements in this case would not bar patentability or 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 to the USPTO, the consistency of its construction with the district court's and the disagreement between that construction and the Federal Circuit'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.

III. The Federal Circuit Decision in This Case Is Facially Inconsistent with the Federal Circuit'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 Federal Circuit held that the post-AIA on-sale bar applies to all public sales, including sales that do not disclose an invention as defined by the patent's claims. *See Helsinn*, 855 F.3d 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 Federal Circuit decision does not allow inventors the same flexibility for license agreements that must be publicly disclosed, *see supra* Argument Section I, 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 Federal Circuit panel below and the Federal Circuit's *en banc Medicines* decision alone is sufficient reason to grant Helsinn's petition. The Federal Circuit 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.

Judge O'Malley took issue with this argument in the concurrence to the denial of the petition for *en banc* for this matter, which she characterized as a mischaracterization of *Medicines. Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, No. 2016-1284, 2016-1787, slip op. at 2 (Fed. Cir. Jan. 16, 2018) (O'Malley, J., concurring). Judge O'Malley correctly pointed out that *Medicines'* determination that the agreements at issue did not place the invention on sale was based on a number of factors, including confidentiality, not one of which was "of talismanic significance." *Medicines*, 827 F.2d at 1326. IPO agrees, but nevertheless maintains that the weighing of the factors underlying (i) whether the invention was the subject of a commercial sale and (ii) whether the claimed subject matter is made public, was treated differently and inconsistently in the Federal Circuit decision below, in *Medicines,* and in the USPTO guidelines, and warrants this Court's attention and harmonization.

Further, the policy discussion in the concurrence below misapprehends IPO's *amicus* position, which is that the Court should determine whether Congress changed the on-sale bar, not whether the consequences of applying

pre-AIA on-sale bar jurisprudence should be avoided on policy grounds. *Helsinn*, No. 2016-1284, 2016-1787, slip op. at 4-5 (O'Malley, J., concurring). Here, the policy issues bear directly on whether Congress intended to change the on-sale bar, and should be considered in resolving this important question.

In this regard, this Court has previously stated the policy underlying the on- sale bar: "The patent laws therefore seek both to protect the public's right to retain knowledge already in the public domain and the inventor's right to control whether and when he may patent his invention." *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 65 (1998). After considering that Congress allowed the inventor first a two year grace period, and then one year, the Court promulgated its two factor test for the on-sale bar. *Id.* at 65, 67-68. IPO submits this policy focus on "knowledge in the public domain" warrants this Court's consideration in the issues presented here.

In any event, in the concurring opinion below the discussion of statutory construction bolstering the Federal Circuit panel's conclusion that the AIA did not change the on-sale bar, *Helsinn*, No. 2016-1284, 2016-1787, slip op. at 5-10 (O'Malley, J., concurring), and the role of policy considerations underlying the on-sale doctrine, *id.* at 10-13, do not resolve the fundamental debate presented by Helsinn's petition. Rather, these discussions illuminate and help frame whether the Federal Circuit's, the USPTO's, or some other construction of the post-AIA on-sale bar is correct. Indeed, the concurrence below suggests that this issue is ripe for review by this Court. *Id.* at 13. As discussed *supra* at Summary of Argument, passing time leaves IP stakeholders increasingly at risk, and warrants clear guidance from this Court.

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 are commonplace in industries where patent holders, including IPO members, 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 Federal Circuit 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 *Medicines* and the USPTO's guidelines. 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.

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 Helsinn*, 855 F.3d at 1360 n.1. Thus, the Court has a unique opportunity to determine in the first instance whether Congress changed the "on-sale" bar 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 Federal Circuit decision in this case and its *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.

CONCLUSION

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

Respectfully submitted,

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