No. 15-446

In The
Supreme Court of the United States

CUOZZO SPEED TECHNOLOGIES, LLC,

Petitioner,

v.

MICHELLE K. LEE, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR, PATENT AND TRADEMARK OFFICE,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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INTEREST OF *AMICUS CURIAE*[1]

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the

[1] This brief is filed with the written consent of all parties through letters of consent on file with the Clerk. No counsel for any party authored this brief in whole or in part, and no person or entity other than *amicus curiae*, its members, or its counsel made a monetary contribution intended to fund its preparation or submission.

country's leading innovative pharmaceutical and biotechnology companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Those efforts produce the cutting-edge medicines, treatments, and vaccines that save, prolong, and improve the quality of the lives of countless individuals around the world every day. Over the past decade, PhRMA's members have secured FDA approval of more than 300 new medicines. Such results are not obtained cheaply. In 2014 alone, PhRMA members invested roughly $51 billion in development of new medicines.

PhRMA seeks to advance public policies that foster innovation and reward its members' investments. 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. *See, e.g.*, *Commil USA, LLC v. Cisco Systems, Inc.*, No. 13-896; *Association for Molecular Pathology v. Myriad Genetics, Inc.*, No. 12-398; *Microsoft Corp. v. i4i Ltd. P'ship*, No. 10-290. As discussed herein, the Federal Circuit's decision upholding the Patent and Trademark Office's adoption of the "broadest reasonable interpretation" standard for *inter partes* review proceedings creates one such unjustified barrier of particular importance.

INTRODUCTION AND SUMMARY OF ARGUMENT

In response to growing concern that the costs of patent litigation were negatively affecting the climate for investment and innovation, Congress enacted the Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284 (2011). The AIA took the considered step of shifting the adjudication of some patent validity disputes from district courts to the U.S. Patent and Trademark Office (PTO) through the creation of new post-grant proceedings—including *inter partes* review (IPR)—conducted by the Patent Trial and Appeals Board (PTAB). In Congress's view, IPR would serve as a cost-effective and efficient surrogate to litigating patent validity in district court.

The Federal Circuit's decision, however, puts IPR on an entirely different path: while a district court gives patent claims their ordinary and customary meaning, *see Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-1313 (Fed. Cir. 2005) (en banc), the PTAB applies the "broadest reasonable interpretation" (BRI) standard historically reserved for the PTO's issuance and reexamination of patents, *see* 37 C.F.R. § 42.100(b). PhRMA agrees with Petitioner that the decision below is incorrect on the merits. PhRMA writes separately to emphasize that, if left to stand, the decision below will introduce considerable uncertainty in the construction of patent claims, increase the risk of conflicting invalidity decisions, and undercut a central reform that Congress enacted to strengthen the U.S. patent system. All of those consequences threaten the

predictability and strength of protection that the patent system provides to innovators and the public alike. Accordingly, this Court's review is necessary to effectuate Congress's intent that patent claims in IPR proceedings be given their ordinary and customary meaning.

ARGUMENT

I. THE CLAIM CONSTRUCTION STANDARD FOR IPR PROCEEDINGS IS AN ISSUE OF EXCEPTIONAL IMPORTANCE

Because claim construction determines the scope of patent claims, it is often a vital step to adjudicating the validity of those claims. *See Bancorp Servs., LLC v. Sun Life Assurance Co. of Can. (U.S.)*, 687 F.3d 1266, 1273-1274 (Fed. Cir. 2012). The Federal Circuit's ratification of the PTO's BRI regulation has set the claim construction standard applicable in the AIA's newly created and frequently invoked invalidity proceedings. But it has done so in a manner that inevitably will have far-reaching and detrimental consequences for the patent system. As such, the decision below warrants this Court's review. *See* Pet. App. 62a (Newman, J., dissenting from denial of petition for rehearing *en banc*) ("All of the *amici curiae* criticize the panel majority position and urge *en banc* attention to this 'matter of exceptional importance.'").

1. As this Court has long recognized, "[t]he limits of a patent must be known for the protection of the patentee, the encouragement of the inventive genius of others, and the assurance that the subject of the patent will be dedicated ultimately to the

public." *General Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 369 (1938). Such clarity cannot be achieved under the Federal Circuit's endorsement of a dual standard for claim construction, which creates a forum-dependent scheme for assessing the protection provided by, and validity of, an issued patent.

The sole question in an IPR proceeding is whether certain patent claims are invalid "under section 102 or 103." 35 U.S.C. § 311(b); *see also id.* § 321(b) (post-grant review "relate[s] to invalidity of the patent or any claim"). The same validity question may also be adjudicated by federal district courts. *Id.* § 282(b)(2) & (3). Claims in an IPR proceeding, however, may be construed differently than the same claims in a district court proceeding. That is because the PTO in an IPR proceeding evaluates claims under a BRI standard, which ignores prosecution history and extrinsic evidence, whereas a district court applies the "ordinary and customary meaning" principles of claim construction set forth in *Phillips*, 415 F.3d at 1312-1313. Application of those distinct claim construction standards will disparately "capture the scope of the actual invention that is disclosed, described, and patented." *Fenner Invs., Ltd. v. Cellco P'ship*, 778 F.3d 1320, 1323 (Fed. Cir. 2015) (citation and internal quotation marks omitted).

That difference in claim scope, in turn, can lead to different conclusions as to validity of the same claims: the broader a claim construction, the greater the availability of potentially invalidating prior art. Not surprisingly, then, application of inconsistent

standards will lead to inconsistent results that undermine the predictability of the patent system. *See Innovation Act: Hearing on H.R. 3309 Before the H. Comm. on the Judiciary*, 113th Cong. 8 (2013) (statement of David J. Kappos) ("[H]aving the USPTO apply a different standard than the courts is leading, and will continue to lead, to conflicting decisions.").[2] A patent is either invalid or it is not; it cannot be both under the same provision of federal law. By virtue of the decision below, however, a patent claim could be (correctly) found valid by a district court under *Phillips*, but also (correctly) found invalid by the PTAB in an IPR proceeding under the BRI standard.

That new reality clouds and diminishes patent rights to the detriment of patent holders, innovators, and the public at large. Uncertainty regarding the scope of patent claims and their validity is costly to the inventive community and discourages innovation. As this Court has recognized, uniformity in claim construction is critical to avoid "a zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims [that] would discourage invention only a little less than unequivocal foreclosure of the field." *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 390 (1996) (citation and quotation marks omitted).

Such uncertainty is of particular concern to PhRMA's members, which invest billions in research and development to discover and develop new

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[2] *Available at* http://judiciary.house.gov/_files/hearings/113th/10292013/Kappos%20Testimony.pdf.

therapies.[3] Meaningful patent protection is required to justify that investment, especially in the face of frequent validity challenges in litigation arising under the Hatch-Waxman Act. *See Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1356 (Fed. Cir. 2008). Disparate claim construction standards undermine the predictability and strength provided by patent protection.

The Federal Circuit's decision also propagates the inefficiencies that Congress intended to eliminate when it enacted the AIA. By all accounts, IPR was created to "streamline the current 'inter partes [reexamination]' system so that it will be a more efficient alternative to litigation." 157 CONG. REC. S1348-02 (daily ed. Mar. 8, 2011) (statement of Sen. Leahy); *see* H.R. REP. NO. 112-98, pt. 1, at 48 (2011) (noting intent to institute "early-stage process for challenging patent validity"). Yet an IPR can serve as an *alternative* to litigation only if the district court and the PTAB consider the question of validity for the same claims in a consistent manner.

To the extent the BRI standard enlarges the scope of patent claims beyond the construction compelled under *Phillips*, the tribunals confront the same patent claims in name only. These distinct claim construction approaches create an unfair system where patent claims are considered in a narrower manner for infringement purposes in district court and a broader manner for IPR validity

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[3] PhRMA, 2015 Profile, Biopharmaceutical Research Industry, Key Facts (inside cover) (Apr. 2015), http://www.phrma.org/sites/default/files/pdf/2015_phrma_profile.pdf.

challenges; such a system skews results against patent holders and leads to inconsistent determinations. And the decision below undercuts Congress's intent to have validity adjudicated *either* in district court *or* in the PTAB to avoid duplicative adjudication.[4]

2. These concerns are far from academic. The PTAB's application of the BRI standard has seen 79% of IPR petitions granted,[5] with 87% of final written decisions finding at least some claims unpatentable.[6] By contrast, invalidity challenges litigated in federal court prevail only 42% of the time. *See* John R. Allison et al., *Understanding the Realities of Modern Patent Litigation*, 92 TEX. L. REV. 1769, 1787 (2014). That significant discrepancy belies any suggestion

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[4] *See generally* PhRMA, Comments on Trial Proceedings Under the America Invents Act 5-7 (Oct. 16, 2014), http://www.uspto.gov/sites/default/files/ip/boards/bpai/phrma_20141016.pdf; THE COALITION FOR 21ST CENTURY PATENT REFORM, ENSURE THAT USPTO POST-GRANT PROCEEDINGS ARE FAIR TO ALL PARTIES app. 2, at 9-12 (2015), http://www.patentsmatter.com/issue/pdfs/20150316_AgendaforPatentReforminthe114thCongress.pdf; THE COALITION FOR 21ST CENTURY PATENT REFORM, WHY THE PTO'S USE OF THE BROADEST REASONABLE INTERPRETATION OF PATENT CLAIMS IN POST-GRANT AND INTER PARTES REVIEWS IS INAPPROPRIATE UNDER THE AMERICA INVENTS ACT (2013), http://www.patentsmatter.com/issue/pdfs/ThePTOsUseOfBRIIsInappropriate6-19-2013.pdf.

[5] Docket Navigator, IPR Institution Decisions (May 2015), http://home.docketnavigator.com/wp-content/uploads/2015/05/stays-and-institution-rates.pdf.

[6] USPTO, Patent Trial and Appeal Board Statistics 9 (Sept. 30, 2015), http://www.uspto.gov/sites/default/files/documents/2015-09-30%20PTAB.pdf.

that IPR invalidity determinations are a surrogate for those made in district court.

As a recent IPR petition demonstrates, moreover, the application of different claim construction standards works against Congress's goal of streamlining invalidity proceedings. *See* J. Steven Baughman et al., *Coordinating PTAB and District Court Litigation*, PRAC. L.J., Dec. 2014/Jan. 2015, at 34, 36 (reporting that 80% of patents subject to an IPR are also involved in district court litigation). For years, Allergan had been defending against challenges in court under the Hatch-Waxman Act that four Orange-Book listed patents covering its combination eye-drop product used for treating glaucoma are invalid for obviousness. After construing the asserted claims using the principles outlined in *Phillips*, a district court concluded that there was insufficient proof that a claim of U.S. Patent No. 7,030,149 would have been obvious to someone of ordinary skill in the art. The Federal Circuit affirmed, and this Court denied review. *See Allergan, Inc. v. Sandoz, Inc.*, 726 F.3d 1286, 1293-1294 (Fed. Cir. 2013), *cert. denied*, 134 S. Ct. 1764 (2014).

Following the conclusion of the federal court litigation, however, "a recently-formed, self-described privately-held investment venture" filed an IPR petition raising the *same* invalidity issue. *The Impact of Abuse Patent Litigation Practices on the American Economy: Hearing Before the S. Comm. on the Judiciary*, 114th Cong. 18-19 (2015) (statement of Hans Sauer, Ph.D, General Counsel for Intellectual

Property, Biotechnology Industry Association)[7]; *see also* Complaint, *Allergan, Inc. v. Ferrum Ferro Capital, LLC*, No. 8:15-cv-992 (C.D. Cal. June 19, 2015) (alleging that subsequent IPR filing was extortion attempt by shell company). Citing the Federal Circuit's decision in this case and the PTO's regulation, the IPR petition candidly argued that the application of the BRI standard compelled the invalidation of the same patent claim on the same obviousness grounds. *See* Petition for Inter Partes Review of U.S. Patent No. 7,030,149, at 7, 15-16, *Ferrum Ferro Capital, LLC v. Allergan Sales, LLC*, No. IPR2015-00858 (P.T.A.B. filed Mar. 9, 2015).[8]

Despite ultimately declining to institute IPR proceedings under either claim construction standard, the PTAB readily accepted that "[f]or *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable interpretation in light of the patent specification." *Ferrum Ferro Capital, LLC v. Allergan Sales, LLC*, No. IPR2015-00858, 2015 WL 5608290, at *3, *5-*7 (P.T.A.B. Sept. 21, 2015) (citing 37 C.F.R. § 42.100(b); *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1275-1278 (Fed. Cir. 2005)). Thus, if the petitioner had prevailed, the Federal Circuit would have faced the prospect of declaring Allergan's patent claim obvious, even though it had rejected that argument already.

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[7] *Available at* http://www.judiciary.senate.gov/imo/media/doc/03-18-15 Sauer Testimony.pdf.

[8] *Available at* http://fishpostgrant.com/wp-content/uploads/IPR2015-00858-petition.pdf.

Permitting a single patent claim to have different constructions and to be valid or invalid depending on the forum—IPR or district court—in which the claim is adjudicated contravenes the uniformity, certainty, and efficiency that the creation of the Federal Circuit was meant to foster. *See Markman*, 517 U.S. at 390. As this Court recently noted in the context of the preclusive effect of proceedings before the Trademark Trial and Appeal Board, the "idea is straightforward" that "[o]nce a court has decided an issue, it is 'forever settled as between the parties, thereby protect[ing] against the expense and vexation attending multiple lawsuits, conserv[ing] judicial resources, and foster[ing] reliance on judicial action by minimizing the possibility of inconsistent verdicts." *B & B Hardware, Inc. v. Hargis Indus., Inc.*, 135 S. Ct. 1293, 1302 (2015) (alterations except first in original) (citations and internal quotation marks omitted). The decision below stands at odds with those values.

II. THE FEDERAL CIRCUIT'S DECISION IS WRONG ON THE MERITS

PhRMA agrees with Petitioner's arguments that the decision below is incorrect on the merits because, *inter alia*, (i) IPR proceedings do not offer a meaningful opportunity to amend claims, and (ii) the PTO exceeded its rulemaking authority in promulgating the BRI regulation. Pet. 23-28. PhRMA does not repeat those arguments here, but a few related points bear emphasis.

As the dissenting panel and en banc opinions explain (Pet. App. 37a-40a, 55a-58a, 65a), the BRI

standard has *never* been applied to decide questions of invalidity in adjudicatory proceedings without the right to amend claims freely. *See In re Yamamoto*, 740 F.2d 1569, 1571-1572 (Fed. Cir. 1984). Because IPRs are also adjudicatory proceedings similar to a district court, and allow amendment of claims only in narrow circumstances satisfied in just a handful of instances to date,[9] they bear little resemblance to prior forms of examination and reissuance proceedings from which the BRI standard derives. Decoupling the BRI standard from an opportunity to amend claims freely, as the decision below did here, "impair[s]" a patentee's interests because it is "foreclosed from obtaining appropriate coverage for the[] invention with express claim language." *Id.* at 1571.

The decision below also misreads the AIA when it finds "no indication" that Congress adopted established claim construction principles from *Phillips*. Pet. App. 15a. Congress intended IPR proceedings to serve as an "efficient alternative to litigation." 157 CONG. REC. S1348-02 (daily ed. Mar. 8, 2011) (statement of Sen. Leahy). Yet the decision below "fails to explain why Congress (or anyone else) would have thought it desirable or necessary for the Board to construe the claims during IPRs under a different legal framework than the one used by

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[9] In more than two years of IPR proceedings, the PTAB has allowed patent owners to amend claims on just four occasions. *See* Edmund J. Walsh et al., *Preparing for Changes in AIA Post-Grant Amendment Practice* n.1 (July 17, 2015), http://www.wolfgreenfield.com/publications/articles/2015/preparing-for-changes-in-aia-post-grant-amendment-practice.

district courts." Pet. App. 54a-55a (joint dissent from denial of petition for rehearing *en banc*).

Congress created IPR by "convert[ing] inter partes reexamination from an examinational to an adjudicative proceeding" that "would take place in a court-like proceeding." H.R. REP. NO. 112-98, pt. 1, at 46, 68. That basic fact—*i.e.*, transforming a purely administrative proceeding into a more district-court-like one—leaves no room for the application of the BRI standard to the construction of issued patent claims in IPR proceedings.

Several AIA provisions confirm that conclusion. *See* Pet. App. 102a (Newman, J., dissenting). For example, 35 U.S.C. § 325(d) expressly provides that the PTO may take prosecution history into account when "determining whether to institute or order" IPR—a determination that requires the PTAB to arrive at an initial claim construction. Similarly, the AIA amends 35 U.S.C. § 301 to allow various new categories of information to be submitted to the PTO, including "statements of the patent owner filed in a proceeding before a Federal court or the Office in which the patent owner took a position on the scope of any claim of a particular patent." *Id.* § 301(a)(2). Significantly, that information becomes part of the prosecution history and can be used only "to determine the proper meaning of a patent claim in a proceeding that is ordered or instituted pursuant to section *** 314 [IPR], or 324 [post-grant review]." *Id.* § 301(d); *see* 157 CONG. REC. S1375 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl) (explaining that Section 301(a)(2) written statements are "to be made a part of the official file of the patent"). The decision below

renders those provisions meaningless because, unlike claim construction under *Phillips*, the BRI standard eschews consideration of the prosecution history. *See Hibbs v. Winn*, 542 U.S. 88, 101 (2004) (canon against superfluity).

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted.

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