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

### BRIEF OF THE BIOTECHNOLOGY INNOVATION ORGANIZATION AND THE ASSOCIATION OF UNIVERSITY TECHNOLOGY MANAGERS AS AMICI CURIAE SUPPORTING PETITIONER

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#### INTEREST OF THE AMICI CURIAE1

The **Biotechnology Innovation Organization** (**BIO**) is the principal trade association representing the biotechnology industry domestically and abroad. BIO has more than 1,100 members, which span the for-profit and non-profit sectors and range from small startup companies and biotechnology centers to research universities and Fortune 500 companies. Approximately 90% of BIO's corporate members are small or mid-size businesses that have annual revenues of under \$25 million.

Because modern biotechnological products commonly involve lengthy, expensive, and resourceintensive development periods, BIO's members depend heavily on a strong, stable, and nationally uniform system of patent rights and protections. Without the promise of effective patent rights, these investments would be far more difficult—if not impossible—to undertake. Many BIO members devote years of effort and many millions of dollars to developing an innovation protected by a single patent, leaving BIO members especially vulnerable to misapplication of the standards that lead to patent invalidation and restrict judicial review of those decisions.

<sup>&</sup>lt;sup>1</sup> All parties have consented to the filing of this brief. Petitioner's consent is on file with the Clerk; respondent's written consent is submitted with this brief. No counsel for a party authored any part of this brief, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amici curiae*, their members, or their counsel made a monetary contribution to the brief's preparation or submission.

The Association of University Technology Managers (AUTM) is a nonprofit organization dedicated to bringing research to life by supporting and enhancing the global academic technology transfer profession through education, professional development, partnering, and advocacy. AUTM's more than 3,200 members represent managers of intellectual property from more than 300 universities, research institutions, and teaching hospitals around the world, as well as numerous businesses and government organizations.

This case concerns inter partes review (IPR) proceedings before the Patent Trial and Appeal Board (PTAB). An IPR is a proceeding brought against a patent owner in which the PTAB can invalidate its patents on certain grounds-even patents issued many years ago and previously upheld by the courts. Since Congress created IPRs in the Leahy-Smith America Invents Act (AIA), the PTAB has begun rereviewing patents from every discipline, including biotechnology patents. The PTAB has liberally construed the limitations on its jurisdiction to permit it to institute IPRs and cancel patents even over weighty procedural objection. And at present, most patents that enter an IPR do not survive; current statistics show that a patent is systematically more likely to be found invalid by the PTAB than by U.S. district courts. Likewise, the IPR proceeding invalidates patent claims at a higher rate than previous or alternative administrative patent-challenge proceedings in the Patent and Trademark Office (PTO). Clearly, the PTAB is invalidating patents at an extraordinary rate.

The questions presented in this case implicate two of the foundational legal conclusions that have allowed the PTAB, even in a relatively short time, to cut a remarkable swath through the ranks of issued patents with barely a light tap on the brakes by the Federal Circuit. First, the Federal Circuit has held that the Patent Trial and Appeal Board (PTAB) may invalidate patents by construing their claims in a way that would never be used in an infringement case in district court, and then finding that artificially broad interpretation too broad to be patentable. Second, the Federal Circuit has held that the PTAB may invalidate patents in an IPR without any court ever being permitted to review whether the PTAB has violated the procedural limitations on its cancellation authority that Congress wrote into the Ameri-BIO, AUTM, and their members ca Invents Act. have a substantial interest in the Court's resolution of those questions.

#### SUMMARY OF ARGUMENT

A. The PTO's adoption of the broadestreasonable-interpretation standard of claim construction in IPR proceedings was fundamentally wrong. That standard does not fit with the litigation-lite mechanism that Congress created, and the PTO's attempt to make it fit goes far beyond any rulemaking authority that Congress conferred.

1. The broadest-reasonable-interpretation standard serves a valid purpose when a patent is being examined. During the back-and-forth process of examination, construing claims as broadly as possible can allow the examiner and the applicant to spot and correct ambiguities in a claim, resulting in betterdefined patent rights that can be relied on for business decisions, provide public notice, and improve the claim's chances of surviving in future litigation.

In the IPR setting, by contrast, the broadestreasonable-interpretation standard does only one it makes patents more likely to flunk the thing: PTAB's standard for patent validity, which is already harder to survive than in district court because the challenger's burden in an IPR is lower. The features that make the standard useful in reexamination do not work in IPRs, because of the differences in how those proceedings work. Congress intended for an IPR to be a more efficient version of a lawsuit in district court. In an IPR, therefore, the PTAB should construe the claims as a district court would-under the ordinary-meaning standard, as elucidated in Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005).

The Federal Circuit doubled down on its comparison of IPRs to reexaminations by suggesting that the process for amending claims is sufficiently similar in both proceedings (and thus the same claimconstruction standard is warranted). That observation is ungrounded in reality. Claim amendments in reexaminations are relatively easy to obtain, as they are given to patent owners on an "as needed" basis, the product of a give-and-take between patent examiner and patent owner. Amending a claim by motion in a PTAB proceeding, on the other hand, has been well-nigh impossible, thanks to the many roadblocks the PTAB has erected. The numbers bear that out: in the four-and-a-half years since enactment of the America Invents Act, the PTAB has granted only *five* motions to amend. And the PTO has left open no other avenue of amending claims once an IPR begins.

2. Had Congress really intended to transplant the claim-construction standard used in examinations to this different, adversarial context, Congress could-would-have made that curious choice plain in the statute. It did no such thing, and its mere silence is not enough to allow the PTO to impose that standard through rulemaking. The PTO has no statutory authority to promulgate the type of substantive rule necessary to make such a selection. Rules on claim construction are substantive in nature, yet the PTO lacks the authority to promulgate substantive rules. For more than a hundred years, substantive patent law has been made in Congress and interpreted in the courts; it has not been made by an agency. The AIA did nothing to change that. The Federal Circuit's cursory analysis of the PTO's rulemaking authority-devoid of any context-was flawed.

3. The practical consequence of the PTO's erroneous selection of the broadest-reasonableinterpretation standard is that district court invalidity proceedings and IPRs are on unequal footing. Despite the fact that both proceedings are designed to answer the same question—whether the patent is invalid—they use different legal standards to answer that question. And because the PTAB's standard is friendlier to those challenging a patent's validity, the district court has become all but irrelevant. This is not the parallelism that Congress intended; IPR was meant to serve as an alternative to, not a replacement for, district court litigation.

B. By statute, the PTAB cannot institute an IPR unless the petition satisfies certain threshold requirements, *e.g.*, that the petition is timely, names all real parties in interest, and lists the grounds and evidence for attacking claims as invalid. Based on an overly broad reading of 35 U.S.C. § 314(d), the Federal Circuit incorrectly held that the PTAB's determinations on any of these threshold matters is immune from judicial review, even once the PTAB renders a final decision that is appealable as of right.

Reading § 314(d) as an absolute bar on any judicial review of any issue related to the decision to institute runs contrary to the plain text of the statute, which states that decisions to institute "under this section," i.e., § 314, are not reviewable. What is unreviewable is the PTAB's decision that there is a "reasonable likelihood" a petitioner would prevail on challenging at least one claim listed in the petition, *see* 35 U.S.C. § 314(a). This reasonable reading complies with the presumption of judicial review, which requires that statutes restricting such review be narrowly construed.

The Federal Circuit's unwillingness to review threshold questions related to institution has already prevented judicial review of PTAB decisions on two important threshold requirements: timeliness and identifying the proper real party in interest. This Court cannot allow the Federal Circuit to stay silent on these threshold issues forever. Innovators are already bereft of guidance on key questions related to the decision to institute an IPR. That the PTAB is unwilling to make its decisions precedential does not help this lack of guideposts. The Court should set aside the Federal Circuit's mistaken and unreasonable interpretation of 35 U.S.C. § 314(d) and allow for limited judicial review of certain threshold questions related to the decision to institute an IPR.

#### ARGUMENT

### A. The PTAB's Unprecedented Use Of The Broadest-Reasonable-Interpretation Standard In IPRs Has No Basis In Patent Law.

Inter partes review is an agency proceeding with no real predecessor in the history of patent law. Until Congress adopted the AIA in 2011, the PTO had a number of procedures designed to resolve questions about patent validity by reopening the patent examination process, but it never had a truly adjudicative procedure, one that fully replicated the adversarial process. District-court litigation was the only contemporary analogue to what an IPR is now, but even that comparison is imperfect; Congress intended for IPRs to serve as a more streamlined and efficient means of litigating certain frequently-arising questions of patentability in a simplified proceeding at the agency level. IPRs are litigation lite.

Both the PTAB and the Federal Circuit have recognized a fundamental difference between IPR proceedings and more traditional mechanisms for review. See, e.g., Abbott Labs. v. Cordis Corp., 710 F.3d 1318, 1326 (Fed. Cir. 2013) (describing the shift from "an examinational to an adjudicative proceeding"); Nichia Corp. v. Emcore Corp., No. IPR201200005, 2014 WL 574596, at \*27 (PTAB Feb. 11, 2014) ("An *inter partes* review is more adjudicatory than examinational in nature."). But that recognition has amounted to little more than lip service. Indeed, when it comes to standards of claim construction, both the agency and the court of appeals have all but turned a blind eye to the fact that IPR proceedings are different, unique, and unprecedented.

In this case, the Federal Circuit justified IPRs' use of the broadest-reasonable-interpretation standard because the PTO has traditionally used it in examinations. Pet. App. 13a; Amendments to the Rules of Practice for Trials Before the Patent Trial and Appeal Board, 80 Fed. Reg. 50,720, 50,722 (Aug. 20, 2015). Yet IPRs are not traditional, and they are not examinations—they are a deliberate break from what the PTO has done in the past, in an effort to shake off past inefficiencies of having parallel proceedings before the agency and the district court.

If any comparison is to be made, it should be to district-court litigation, which the IPR process was designed to mimic. And district courts have used a decidedly different standard of claim construction the ordinary-meaning standard, as elucidated by the Federal Circuit in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005). That standard governs any attempt to invoke the patent or to design around it, because only district courts can hear an infringement claim. And it governs any district-court litigation over invalidity. The same standard should apply in IPR proceedings.

Conducting IPRs using the ill-fitting broadestreasonable-interpretation standard has resulted in unprecedented rates of patent invalidation. Of the 732 IPRs completed as of December 31, 2015, 87% have resulted in at least one claim being invalidated. A standard of claim construction intended to refine and perfect patents is now being used to invalidate them *en masse*.

Patent judges are not patent examiners. The PTO has already recognized that an IPR is "neither ex parte patent prosecution nor patent reexamination or reissue." 80 Fed. Reg. at 50,724. The next logical step is for the PTO to abandon the legal standard used in the examination procedures that, it acknowledges, are different, and to apply the legal standard used in the most closely-related proceeding, district-court litigation. Instead the PTO has conflated legal standards in a way that jeopardizes the integrity of Congress's nascent reforms to the patent system.

This Court must correct the PTO's foundational legal error before it causes irreversible damage to the patent system. It should take into account what the PTAB and the Federal Circuit have ignored: (1) key distinctions between the functions of IPR proceedings and other PTO procedures; (2) the practical reality that PTAB proceedings, unlike examinations, do not actually allow amendments; and (3) Congress's deliberate decision not to give the PTO the authority to change substantive patent law by rule, as that responsibility belongs to Congress itself, with interpretive authority ultimately in this Court.

### 1. The PTAB's Choice Of Claim Construction Standard Fails To Account For Elementary Distinctions Between IPR Proceedings And Other, More Traditional PTO Procedures, Such As Reexaminations.

The Federal Circuit justified the PTAB's use of the broadest-reasonable-interpretation standard by comparing IPRs to more traditional PTO procedures, such as examination, interference, and reexamination. It deemed the old and the new to be similar enough to justify using the same claim-construction standard for both.<sup>2</sup> The Federal Circuit reached this conclusion only by disregarding how IPR is different. IPR proceedings are "distinct proceedings, with distinct parties, purposes, procedures, and outcomes." *Cf. In re Etter*, 756 F.2d 852, 857 (Fed. Cir. 1985).

The flaws of the Federal Circuit's reasoning are clearest with respect to patent reexamination, the only post-grant procedure on which the Federal Circuit relies to justify invocation of the "traditional" broadest-reasonable-interpretation standard.<sup>3</sup> The purpose of a reexamination is diametrically opposite

<sup>&</sup>lt;sup>2</sup> Pet. App. 13a ("Nonetheless, the broadest reasonable interpretation standard has been applied by the PTO and its predecessor for more than 100 years in various types of PTO proceedings." (collecting cases)); *id.* at 14a ("This court has approved of the broadest reasonable interpretation standard in a variety of proceedings, including initial examinations, interferences, and post-grant proceedings such as reissues and reexaminations.").

<sup>&</sup>lt;sup>3</sup> The Federal Circuit also referred to examinations and interference proceedings; these procedures are even poorer bases of comparison, as they are both *pre*-grant procedures.

that of an IPR: a reexamination is a cooperative process between the examiner and the patent owner, wherein the PTO acts in the public interest by defining the scope of patent rights that it grants, denies, or reaffirms. In contrast, an IPR is an adjudicative proceeding where one party tries to invalidate the patent of another, and the PTO furnishes them with an impartial tribunal.

One major purpose of a reexamination is to refine claims and ultimately to correct errors that are usually the fault of the PTO. Patlex Corp. v. Mossinghoff, 758 F.2d 594, 604 (Fed. Cir. 1985) ("The reexamination statute's purpose is to correct errors made by the government, to remedy defective governmental (not private) action, and if need be to remove patents that should never have been granted."); see also Bloom Eng'g Co. v. N. Am. Mfg. Co., 129 F.3d 1247, 1249 (Fed. Cir. 1997) ("The purpose of the reexamination procedure is to permit a patentee or other interested person to obtain review and if necessary correction of the claims resulting from the initial examination of the patent."). Reexaminations are not intended to be a hostile process; they depend on a fluid exchange between a patent examiner and a patent owner. During this exchange, claims "can be amended, ambiguities . . . recognized, scope and breadth of language explored, and clarification imposed." In re Zletz, 893 F.2d 319, 321 (Fed. Cir. 1989). In fact, Congress was well aware of the fact that the result of a reexamination has historically been clarification and amendment (66% of reexaminations) rather than

cancellation (12%) of challenged claims.<sup>4</sup> Reexaminations thus do not necessarily result in the cancellation of a claim; they can also help strengthen the validity of the patent. Gould v. Control Laser Corp., 705 F.2d 1340, 1342 (Fed. Cir. 1983) ("One purpose of the reexamination procedure is to eliminate trial of that issue (when the claim is canceled) or to facilitate trial of that issue by providing the district court with the expert view of the PTO (when a claim survives the reexamination proceeding)."). Because of this benefit, patent owners may voluntarily choose to undergo a reexamination. Fresenius USA, Inc. v. Baxter Int'l, Inc., 582 F.3d 1288, 1305 (Fed. Cir. 2009) (Newman, J., concurring) ("[Reexamination] can be a useful and powerful tool for the benefit of both patentees and those interested in restricting or eliminating adversely held patents.").

IPR proceedings, however, cannot serve an errorcorrecting purpose to the same extent as reexaminations. This was a deliberate choice on Congress's part; Congress imposed time limits, eliminated layers of administrative review, and crafted an overall adversarial process that necessarily constrains amendment opportunities in IPRs relative to reexaminations. In the House Judiciary Committee's discussion on the closely related Post-Grant Review process (compare 35 U.S.C. ch. 31 with id. ch. 32), the committee acknowledged that Post-Grant Review was "[u]nlike reexamination proceedings, which pro-

<sup>&</sup>lt;sup>4</sup> U.S. Patent and Trademark Office, *Ex Parte Reexamination Filing Data* 2 (Sept. 30, 2014), http://www.uspto.gov/sites/ default/files/documents/ex\_parte\_historical\_stats\_roll\_up\_ EOY2014.pdf.

vide only a limited basis on which to consider whether a patent should have issued." H.R. Rep. No. 112-98, pt. 1, at 47 (2011). And tilting Post-Grant Review and IPR proceedings toward a purpose of validity-determination rather than error-correction ensured that the procedure would be "quick" and "efficient." *Id.* As a result, patent owners do not benefit from IPR proceedings as currently constituted, unlike reexaminations. For one, they cannot preemptively initiate IPR proceedings. *See* 35 U.S.C. § 311(a) ("[A] person who is not the owner of a patent may file [an IPR petition] . . . ." (emphasis added)). And even if they prevail in one proceeding, they are always at risk of being subjected to another.

One of the Federal Circuit's foundational premises was therefore incorrect—IPR proceedings are nothing like reexaminations. The two procedures have different goals and accord different benefits; the use of a claim-construction standard in reexamination thus does not justify its use in IPR.

> 2. The Federal Circuit Based Its Endorsement Of The PTAB's Erroneous Choice Of Claim Construction Standard On An Unrealistic Understanding Of How The PTAB Conducts Its Proceedings.

Perhaps stemming from its conflation of IPRs with other patent proceedings, the Federal Circuit also mistakenly observed that the process of amending a claim in IPR proceedings, while "cabined," is sufficiently similar to the process of amending a claim in a patent reexamination. In the court's view, that observation was another reason to justify use of the broadest-reasonable-interpretation standard in IPR proceedings. But the Federal Circuit failed to recognize that the amendment process in IPR proceedings is effectively futile, leaving patent owners with no opportunity to amend claims so that they have a better chance of surviving PTAB scrutiny. Even the PTO has candidly acknowledged that the standards for amendment are substantively different.

One of the reasons that the PTO uses the broadest-reasonable-interpretation standard in reexamination proceedings is that "a patentee is able to amend its claims during reexamination." In re Rambus, Inc., 753 F.3d 1253, 1255 (Fed. Cir. 2014). During the reexamination process, a patent owner has the "ability to amend his claims to avoid cited prior art." In re Yamamoto, 740 F.2d 1569, 1572 (Fed. Cir. 1984). In doing so, the applicant may, "as needed," "correct errors in claim language and adjust the scope of claim protection." Id.

The standard for construction is different, however, if the claim cannot be altered. If "a reexamination involves claims of an expired patent," a patent examiner uses the *Phillips* standard of claim construction because "a patentee is unable to make claim amendments." In re Rambus, 753 F.3d at 1256 (citing Manual of Patent Examining Procedure § 2258(G)). The PTAB, too, understands that use of a different claim construction standard is appropriate in IPR proceedings when claims are expired and can no longer be amended. *E.g., Denso Corp. v. Netlatch, LLC*, No. IPR2015-00473, 2015 WL 4467405, at \*3 (PTAB July 15, 2015); W.L. Gore & Assocs., Inc.

v. Lifeport Sciences LLC, No. IPR2014-01319, 2015 WL 799478, at \*4 (PTAB Feb. 23, 2015) ("The Board's review of claims of an *expired* patent, however, is similar to that of a district court's review."). Like the PTO in the reexamination context, the PTAB already understands that the lack of an ability to amend a claim necessarily requires use of the Phillips standard. See Compass Bank v. Maxim Integrated Products, Inc., No. CBM2015-00102, 2015 WL 5921097, at \*5 (PTAB Oct. 7, 2015) (instructing parties to brief claim construction under both the broadest-reasonable-interpretation standard and the *Phillips* standard because the patent could expire before issuance of the PTAB's final written decision). What it fails to acknowledge, however, is that its existing prescriptions for amendment are wholly inadequate and merely illusory.

Indeed, the process of amending a claim during an IPR proceeding is nowhere near as liberal as amendment in reexamination. Amendments are granted "as needed" in reexaminations; by contrast, amendment is not granted as of right in an IPR, not even if the amendment corrects the claim defects cited as grounds for instituting the IPR in the first place. Instead, the PTAB makes patent owners satisfy a heavy additional burden of proof and persuasion. In an oft-cited yet nonprecedential decision, the PTAB set forth the following framework for seeking claim amendments by motion in an IPR:

> A patent owner should identify specifically the feature or features added to each substitute claim, as compared to the challenged claim it replaces, and

come forward with technical facts and reasoning about those feature(s), including construction of new claim terms, sufficient to persuade the Board that the proposed substitute claim is patentable over the prior art of record, and over prior art not of record but known to the patent owner. The burden is not on the petitioner to show unpatentability, but on the patent owner to show patentable distinction over the prior art of record and also prior art known to the patent owner.

*Idle Free Sys., Inc. v. Bergstrom, Inc.*, No. IPR2012-00027, 2013 WL 5947697 (PTAB June 11, 2013); *see also Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1304-08 (Fed. Cir. 2015) (discussing *Idle Free* factors in deferential review of a PTAB denial of a motion to amend).

Thus, the PTO has not drawn the type of equivalence between the amendment processes in IPRs and reexaminations that the Federal Circuit relied on, Pet. App. 15a-17a. Rather, the PTO has candidly acknowledged that its standards for amendment are markedly different. It justifies the more burdensome standard in IPRs by noting that, unlike reexamination or other non-adjudicatory review procedures, the PTAB in an IPR does not "conduct a prior art search to evaluate the patentability of the proposed substitute claims" when presented with a motion to amend. 80 Fed. Reg. at 50,724. So it (dubiously) imposes the burden on patent owners to prove a negative—that the new claims not only contain elements not in the prior art, but that they would not have been obvious. See, e.g., Illumina Cambridge Ltd. v. Intelligent Bio-Systems, Inc., --- F. App'x ----, 2016 WL 363498, at \*3-\*6 (Fed. Cir. Jan. 29, 2016).

Because of the burdensome amendment process in an IPR, patent owners believe it is virtually impossible to amend a claim by motion with the PTAB's approval. And that belief is corroborated by fact the PTAB has been exceedingly stingy in granting motions to amend filed in IPRs. Of the 134 motions to amend filed in PTAB proceedings to date, only five have been granted.<sup>5</sup> Compounding the problem is that patent owners have no meaningful guidance on what would be "sufficient to persuade the Board that the proposed substitute claim is patentable over the prior art of record." See Microsoft Corp., 789 F.3d at 1304-05 (noting that Idle Free is "not binding authority" under the PTAB's rules). There seems to be little rhyme or reason behind the PTAB's decisions to allow amendments of claims by motion. Of the handful of claims that were successfully amended by motion, most were unopposed.

In fact, the PTAB is so hostile to amendment that it has even said no *when no party opposed the amendment*. In one case—as it happens, involving

<sup>&</sup>lt;sup>5</sup> Reg Synthetic Fuels LLC v. Neste Oil OYJ, No. IPR2014-00192, 2015 WL 3609359 (PTAB June 5, 2015); Chi. Mercantile Exch., Inc. v. 5th Market, Inc., No. CBM2013-00027, Paper No. 38 (PTAB Mar. 23, 2015); Riverbed Tech., Inc. v. Silver Peak Sys., Inc., Nos. IPR2013-00402, IPR2013-00403, 2014 WL 7405745, 2014 WL 7405746 (PTAB Dec. 30, 2014); Int'l Flavors & Fragrances, Inc. v. United States, No. IPR2013-00124, 2014 WL 2120542 (PTAB May 20, 2014).

the Government as the patent owner—the PTAB denied a motion to amend one particular claim because the Government had failed to provide certain evidence. See Int'l Flavors & Fragrances, Inc. v. United States, No. IPR2013-00124, 2014 WL 2120542, at \*9 (PTAB May 20, 2014) (claim 45).

In theory, patent owners can try to amend their claims by other procedures such as reexamination or reissue; in practice, however, these procedures are all but a dead end. Part of the problem is that the PTAB cannot come to an agreement with the rest of PTO (and, for that matter, itself) on how to address claims in parallel administrative proceedings. For example, in one instance, the PTAB issued a stay of a reexamination proceeding for fear that parallel proceedings would yield inconsistent results. Gea Process Eng'g, Inc. v. Steuben Foods, Inc., No. IPR2014-00043, Paper No. 35, at 3-4 (PTAB May 27, 2014); see also Hewlett-Packard Co. v. MCM Portfolio, LLC, No. IPR2013-00217, Paper No. 8, at \*2 (PTAB May 10, 2013) (issuing a stay of a pending reissue). But in another case, the PTAB had determined that a patent owner could move forward with a reexamination while the IPR proceeding was pending, noting that a patent owner in an IPR proceeding was not limited to seeking amendment only in that proceeding. See Game Show Network, LLC v. Stephenson, No. IPR2013-00289, Paper No. 31, at 4 (PTAB Mar. 21, 2014) ("To say that a Patent Owner may request an *ex parte* reexamination to obtain 'a complete remodeling of its claim structure' does not mean . . . that any other form of amendment to claims challenged in an IPR must be obtained within the IPR."). To add to the confusion, the PTO's Central Reexamination Unit concluded differently, explaining that because the question of patentability was before the PTAB in an IPR proceeding, an examiner could not conclude that the patent owner had presented a *new* substantial question of patentability, which 37 C.F.R. § 1.510(b) requires before reexamination may commence.<sup>6</sup> Put differently, if a patent owner is already in an IPR proceeding—a circumstance that might prompt the owner to seek amendment by reexamination—then it is already too late.

It was therefore disingenuous for the Federal Circuit to suggest "the opportunity to amend [in IPR proceedings] is cabined . . . [but] nonetheless available," thereby justifying use of the broadestreasonable-interpretation standard in such proceedings. Pet. App. 17a. Claim amendment in the IPR context looks nothing like claim amendment in reexaminations; calling the former "cabined" was a gross understatement. And by congressional design, IPR can never be a process by which patent owners may have a fair opportunity to "correct errors in claim language and adjust the scope of claim protection *as needed.*" In re Yamamoto, 740 F.2d at 1572 (emphasis added). Even if the PTO were willing and able to promulgate rules that allowed for more liberal

<sup>&</sup>lt;sup>6</sup> See Decision on Request for Reexamination, Reexamination Control No. 09/013,148 (US Patent No. 6,174,237), at 4 (PTO CRU Mar. 21, 2014) ("While the examiner agrees that [the patent owner] presents a substantial question of availability, the fact that the exact question is currently being considered by the PTAB means that the question cannot be considered new."), *available at* http://www.patentspostgrant.com/images/Order-Denying-Reexam-90013148.pdf.

amendment of claims in PTAB proceedings, it is likely that the process of vetting proposed substitute claims would be constrained by the PTAB's obligation to issue a decision within 12 months of institution, as required by statute.<sup>7</sup> See 35 U.S.C.  $\S$  316(a)(11).

### 3. Congress Deliberately Chose Not To Give The PTO The Authority To Impose A New, Substantive Claim Construction Standard.

Perhaps more troubling than the PTAB's use of the wrong legal standard is how the standard came to be adopted. The PTO imposed the broadestreasonable-interpretation standard by promulgating a regulation, describing it as a rule of "Trial Practice Before the Patent Trial and Appeal Board." 37 C.F.R. § 42.100(b) ("A claim in an unexpired patent shall be given its broadest reasonable construction in light of the specification of the patent in which it appears."). But the PTO had no authority to promulgate this rule.

The PTO's selection of a claim-construction standard is substantive in nature, not procedural. Nothing in the Patent Act specifies a particular

<sup>&</sup>lt;sup>7</sup> Cf. Eliot D. Williams & May Eaton, Surviving PTAB Trials as a Patent Owner: Protecting Your Portfolio from the PTAB "Death Squads," 27 No. 1 Intell. Prop. & Tech. L.J. 9, 10 (2015) (explaining that attempting to amend claims by reissue during an IPR proceeding or covered business method review "would make it difficult for the PTAB to complete . . . [trial] within the statutory 12 month period" because the reexamination would require negotiation "over the patentability of the proposed amended claims").

standard for claim construction in IPRs. The selection of a claim-construction standard therefore required some regulatory gap-filling power prescribed by statute, and the PTO has no such power. See Nat'l Family Planning & Reproductive Health Ass'n, Inc. v. Sullivan, 979 F.2d 227, 237 (D.C. Cir. 1992) ("[A] legislative or substantive rule is one that does more than simply clarify or explain a regulatory term . . . a rule is legislative if it attempts 'to supplement [a statute], not to simply construe it." (citation omitted)). Indeed, the Federal Circuit—which defers to the regional circuits on procedural matters-affords no such deference on claim construction, precisely because it has long understood claim construction to be substantive and not procedural. See Biodex Corp. v. Loredan Biomedical, Inc., 946 F.2d 850, 856 (Fed. Cir. 1991) (noting that the Federal Circuit has jurisdiction when it involves a "subject . . . unique to patent law" or is "related to substantive matters unique to the Federal Circuit"); see also, e.g., Lazare Kaplan Int'l, Inc. v. Photoscribe Techs., Inc., 714 F.3d 1289, 1293 (Fed. Cir. 2013) (question of whether "a district court may reopen a prior final judgment as to patent validity . . . based on a claim construction modified by [the court of appeals]" is an issue of patent law warranting no deference to the law of the regional circuit).

The PTO has never had the authority to promulgate substantive rules. That lack of authority stems from a long history of giving the Patent Office (and the PTO) no power to shape substantive law. Indeed, midway through the life of the PTO's predecessor, the Patent Office, this Court took a skeptical view of the Office's ability to substantively influence patent law. See, e.g., McCormick Harvesting Mach. Co. v. C. Aultman & Co., 169 U.S. 606, 612 (1898) (the invalidation of an issued patent for failure to comply with reissue requirements constituted "an invasion of the judicial branch of the government by the executive"). But courts did acknowledge that the Patent Office had the authority to promulgate rules for "a system of practical procedure," i.e., "matters of practice and procedure not involving the merits and final rejection of claims." United States ex rel. Steinmetz v. Allen, 22 App. D.C. 56, 67 (D.C. Cir. 1903), rev'd on other grounds, 192 U.S. 543 (1904).

Nothing has changed with the modern PTO—it still lacks the authority to promulgate substantive rules. In Merck & Co. v. Kessler, 80 F.3d 1543 (Fed. Cir. 1996), the Federal Circuit determined that the phrase "conduct of proceedings" in an earlier statute granting the PTO rulemaking authority did not "grant the Commissioner the authority to issue substantive rules." Id. at 1549-50; see also Animal Legal Def. Fund v. Quigg, 932 F.2d 920, 930 (Fed. Cir. 1991) ("A substantive declaration with regard to the Commissioner's interpretation of the patent statutes" does not fall within the usual interpretation of ['conduct of proceedings']."). Congress agreed, moving the statutory source of the PTO's rulemaking power to a place in the code that "ratified *Merck*'s 'procedure, not substance," construction of the authorizing statute. Joseph Scott Miller, Substance, Procedure, and the Divided Patent Power, 63 Admin. L. Rev. 31, 33 n.9 (2011).

The PTO's lack of substantive rulemaking authority is all the more significant because the PTO tried hard to get that authority, and failed. In 2007, Congress considered—but ultimately did not enact—the Patent Reform Act of 2007, which would have given the PTO substantive rulemaking authority. H.R. 1908, 110th Cong. § 14 (as introduced in the House, Apr. 18, 2007). The Act would have given the Director the authority to "promulgate such rules, regulations, and orders that the Director determines appropriate to carry out the provisions of [Title 35] or any other law applicable to the [PTO] or that the Director determines necessary to govern the operation and organization of the Office." *Id.* The Senate did not take up the bill.

Stymied by legislative inaction and in an effort to manage its ever-increasing workload, the PTO attempted to test the limits of its rulemaking authority promulgating substantive rules—specifically, bv rules that would "limit the number of continuing applications, requests for continued examination, and claims that an applicant could make as a matter of right." See Tafas v. Dudas, 541 F. Supp. 2d 805, 809 (E.D. Va. 2008) (citing 71 Fed. Reg. 61 (Jan. 3, 2006)), aff'd in part, rev'd in part sub nom. Tafas v. Doll, 559 F.3d 1345 (Fed. Cir. 2009), vacated and dismissed as moot, 586 F.3d 1369 (Fed. Cir. 2009). A district court invalidated the rules because they were substantive rules promulgated without statutory authority to make such rules. Tafas, 541 F. Supp. 2d at 817. Although the PTO appealed, the Federal Circuit eventually dismissed the case as most because the PTO had rescinded the controversial rules. Tafas, 586 F.3d at 1371. The court of appeals did, however, leave the district-court decision intact. Id.

Faced with judicial reluctance to sustain new administrative powers, the PTO returned to Congress, this time during consideration of the America Invents Act. The Secretary of Commerce asked that Congress "grant[] the USPTO substantive rulemaking authority," as it "would give the USPTO Director the ability to provide flexibility in the administration of patent rules and procedures." Letter from Gary Locke, Sec'y of Commerce, to the Hon. Patrick J. Leahy, Chairman, S. Comm. on the Judiciary, and the Honorable Jefferson B. Sessions, III, Ranking Member, S. Comm. on the Judiciary, at 2-3 (Oct. 5, 2009). "At a minimum," the Secretary said, "USPTO should have procedural rulemaking authority over proceedings in the agency." *Id.* at 3.

And the minimum is what Congress gave to the PTO. Almost all of the delegations of authority in 35 U.S.C. § 316(a) are unambiguously procedural in nature. Under § 316(a), the PTO has the authority to promulgate rules related to certain procedural aspects of IPR proceedings, such as rules on discovery,<sup>8</sup> rules for filing "supplemental information,"<sup>9</sup> and rules on joinder.<sup>10</sup>

There is no reason to treat § 316(a)(2) and § 316(a)(4) any differently—they should be viewed as grants of authority to promulgate procedural rules and nothing else. The Federal Circuit erred by analyzing these provisions in a vacuum, with no appreciation for the "statutory and historical context" be-

<sup>&</sup>lt;sup>8</sup> 35 U.S.C. § 316(a)(5)-(8).

<sup>&</sup>lt;sup>9</sup> 35 U.S.C. § 316(a)(3).

<sup>&</sup>lt;sup>10</sup> 35 U.S.C. § 316(a)(12).

hind these provisions. Entergy Corp. v. Riverkeeper, Inc., 556 U.S. 208, 223 (2009). It should not have held, especially without analysis, that "§ 316 provides authority to the PTO to adopt the standard in a regulation." Pet. App. 18a. If these statutory provisions were truly meant to be so broad as to give the PTO carte blanche on all things IPR, most of the other provisions in § 316 would be unnecessary, for the PTO could promulgate those rules with its ostensible blanket authority. See Direct Mktg. Ass'n v. Brohl, 135 S. Ct. 1124, 1132 (2015) ("a carefully selected list" must be interpreted to avoid surplusage and "defeat [of] the precision of that list"). Had Congress intended to give the PTO such sweeping power, it would have been more precise in saying so.

> 4. The PTO's Adoption Of The Broadest-Reasonable-Interpretation Standard Frustrates Congressional Intent That PTAB And District Court Proceedings Operate As Alternatives.

Congress intended for IPRs to serve as a "quick and cost effective alternative[] to litigation," not to supplant district-court litigation entirely. H.R. Rep. No. 112-98, pt. 1, at 48. Congress did not want to remove questions of patent validity from generalist Article III courts altogether and commit them to special administrative tribunals (as is the practice in some other countries, *e.g.*, Germany). Yet the PTO's choice of claim-construction standard threatens to achieve exactly that outcome, because the different standard can affect outcomes so significantly.

The creation of IPRs did not constrain district courts in any way from deciding questions of validity. It merely gave patent challengers a new option: they can choose to take their validity challenge to the PTAB, and seek adjudication there. But this choice comes with certain costs. For example, challengers wishing to bring an IPR proceeding cannot also seek a validity determination through a declaratory judgment action in district court. 35 U.S.C. § 315(a)(1). If there is an infringement action pending, challengers must also choose promptly whether to seek adjudication through IPR. See id. § 315(b). Once this choice is made, the challenger is bound by the outcome: stringent estoppel provisions bar the challenger from raising issues in district court that were "raised" or reasonably could have [been] raised during [the IPR]." Id. § 315(e)(2). Put differently, Congress offered patent challengers a choice between two fora; it did not give challengers an entitlement to litigate validity twice in different places, nor did it express a preference for one forum over the other.<sup>11</sup>

For all intents and purposes, therefore, IPR was to be a proceeding that can adjudicate certain discrete questions of patent validity more quickly and cheaply than in the more comprehensive context of district-court litigation. It was not intended as a proceeding that would systematically produce different

<sup>&</sup>lt;sup>11</sup> Where Congress does express such a preference, it can be trusted to do so explicitly. *See, e.g.*, Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 18(b)(1), 125 Stat. 284, 331 (2011) (providing for stays of district-court litigation pending a different type of post-grant review, but making no such provision for IPRs).

outcomes, and thereby displace district courts as a forum for adjudicating patent validity.

The PTO's choice of claim-construction standard, however, has effectively accomplished just that. The agency uses a standard of claim construction under which claims are systematically more likely to be invalidated, and indeed the majority of claims on which an IPR is instituted are invalidated in short order. For a patent challenger, the incentives for using IPR are so great that few rational parties would rely on district courts to adjudicate questions of patent validity. Most patent challengers will seek to open a "second front" in the fight over the patent's validity by taking the surer shot provided by the IPR process-in fact, over 80% of patents in IPRs are simultaneously in district court litigation. This dualinefficiency-the different ism breeds claimconstruction standards encourage additional litigation, as patent challengers who can afford to fight patent validity on a second, less hostile front will invariably do so. The result is a system at odds with the one Congress designed.

\* \* \* \* \*

The PTO's divergence from the district courts on questions of claim construction has undermined confidence in the patent system. Innovators who must protect their businesses against patent infringement find that the current dual system of claim construction works against them two ways: the narrower claim construction in district court favors noninfringement; the broader claim construction in the PTAB favors invalidity. This game of "heads, I win tails, you lose" leaves businesses and their investors with tremendous uncertainty about the fate of business-sustaining patents—how their claims will be construed, and how likely invalidation will be as a result, will systematically depend on the forum a patent challenger chooses. This Court should require the PTAB to use the claim-construction standard that Congress expected it to use, instead of a standard meant for saving patents that is now being used to cancel them.

B. The Federal Circuit Abdicated Its Judicial-Review Responsibilities By Holding That The PTAB's Decisions To Institute Are Unreviewable, Leaving The PTAB With Unfettered Discretion To Disregard Congressional Commands.

Precisely because so many IPRs end up in the same place—cancelling the patent—it is all the more important that the PTAB turn square corners along the way. The statutes governing IPRs and similar PTAB post-grant proceedings contains a number of specific requirements that strictly limit the "who," "what," and "when" of IPRs. Yet the PTAB and the Federal Circuit together have deeply weakened these restraints. The PTAB has regularly invalidated patents even when the patent owner has a substantial procedural argument that the IPR may not proceed. But because the PTAB rejects those procedural arguments at the same time and in the same order as its decision to institute an IPR, the Federal Circuit has held that it may not review those procedural decisions. That holding is incorrect and should be reversed.

Correcting the Federal Circuit's abdication of judicial review will significantly affect the viability of a number of important procedural statutes governing IPRs. For example, the IPR petition must be timely filed.<sup>12</sup> The IPR petitioner must demonstrate that it is not estopped from bringing the petition.<sup>13</sup> As part of the estoppel and timeliness inquiries, the petition must identify the real parties in interest.<sup>14</sup> The petition's cancellation request must be based on "prior art consisting of patents or printed publications."<sup>15</sup> And, of course, as petitioner argues in this case, the petition must identify "each claim challenged" with particularity, providing "the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge to each claim."<sup>16</sup> If any of these requirements is not satisfied, the IPR petition is defective under the express terms of the statute.<sup>17</sup> The Director has no statutory authority to alter any of these requirements.<sup>18</sup> Nor is there even any requirement that they be resolved

<sup>16</sup> 35 U.S.C. § 312(a)(3).

<sup>17</sup> Similarly, post-grant reviews require at the threshold that the patent in question be a post-AIA patent, an issue that has already sparked litigation. *See* 35 U.S.C. § 321 note. Postgrant reviews are subject to a materially identical bar on reviewing institution decisions. *Id.* § 324(e).

<sup>18</sup> She does, however, have the discretion to promulgate rules requiring additional information. 35 U.S.C. § 312.

<sup>&</sup>lt;sup>12</sup> 35 U.S.C. §§ 311(c), 315(b).

<sup>&</sup>lt;sup>13</sup> 35 U.S.C. § 315(e)(1).

<sup>&</sup>lt;sup>14</sup> 35 U.S.C. §§ 312(a)(2), 315(b), (e)(1).

<sup>&</sup>lt;sup>15</sup> 35 U.S.C. § 311(b).

at the petition stage, though that has been the PTAB's practice.

A decision on one of these threshold grounds is not clearly and unambiguously a "determination by the Director whether to institute an inter partes review under this section." Judicial review therefore is not barred by 35 U.S.C. § 314(d), which makes such a determination "final and non-appealable." The Federal Circuit erred in holding otherwise.

1. The Federal Circuit was too quick to abandon the presumption of judicial review-indeed, so quick that the court failed to address the presumption at all. Courts must begin with the "strong presumption" that "Congress did not mean to prohibit all judicial review of [an agency] decision." Bowen v. Mich. Acad. of Family Physicians, 476 U.S. 667, 672 (1986) (quoting *Dunlop v. Bachowski*, 421 U.S. 560, 567 (1975)). "[O]nly upon a showing of 'clear and convincing evidence' of a contrary legislative intent should the courts restrict access to judicial review." Id. (quoting Abbott Labs. v. Gardner, 387 U.S. 136, 141 (1967)). And a corollary to the presumption of judicial review is that courts must construe bars to judicial review narrowly, rather than absolutely. E.g., Lindahl v. Office of Personnel Mgmt., 470 U.S. 768, 779-80 (1985).

Thus, the Federal Circuit should have begun by determining the narrowest clear meaning of the nonappealable "determination" mentioned in § 314(d). The parties to an IPR have a statutory right to appeal from a final written decision. 35 U.S.C. §§ 141(c), 319. Section 314(d) does not withdraw anything from that guarantee of appellate review *except* the "determination . . . whether to institute."

2. Section 314(d) can be read in a way that both fulfills the statute's purpose and preserves meaningful judicial review. It is best construed as a bar *only* on challenging the Director's determination under § 314(a) that "there is," or is not, "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." Even if that were not the best reading, the presumption favoring judicial review would still favor it.

Section 314(d) states that the Director's decision "whether to institute an [IPR] *under this section* shall be final and nonappealable." The phrase "under this section" refers only to § 314(a), the only decision assigned to the Director in all of § 314. By contrast, when § 314 refers to inter partes review *generally*, it refers to "inter partes review *under this chapter*," not just this section. § 314(b) (emphasis added). "Under this section," therefore, refers to the Director's decision under § 314(a), not the IPR writ large.

By contrast, the various threshold grounds that can block an IPR, such as the statute of limitations, come from outside § 314. The statute of limitations, for example, is in § 315(b). A ruling on that ground, therefore, does not naturally fall within the scope of a determination made under "this section," § 314. Nor is it a ruling about the "reasonable likelihood" that the petitioner will prevail at a subsequent step. The PTAB conceivably could decide *not* to institute an IPR that is time-barred on the ground that the time bar defeats the "reasonable likelihood" of success. But in a case where the PTAB *does* institute an IPR, it must rule on procedural objections *on their merits*; it can no longer just weigh the reasonable likelihood of a future outcome. That decision *on the merits* of the procedural objection is then reviewable on appeal from the final written decision.

3. The Federal Circuit has attempted to justify ducking review of these important issues by stating that they implicate only the institution decision, not the PTAB's authority to invalidate. Thus, for example, in Achates Reference Publishing, Inc. v. Apple Inc., 803 F.3d 652 (Fed. Cir. 2015), the court of appeals held that a question about a petition's timeliness was unreviewable because it "does not impact the Board's authority to invalidate a patent claim" and is therefore "fairly characterized as part of the [unreviewable] decision to institute," even if the final written decision addresses the timeliness issue. Id. at 657-68 (alterations omitted). "That the Board considered the time-bar in its final determination," the Federal Circuit said, "does not mean the issue suddenly becomes available for review or that the issue goes to the Board's ultimate authority to invalidate . . . " Id.; accord Synopsys, Inc. v. Mentor Graphics Corp., Nos. 2014-1516, 2014-1530, 2016 WL 520236, at \*2, \*12 (Fed. Cir. Feb. 10, 2016) (similarly holding a timeliness argument unreviewable).

That reasoning is incorrect. A challenge to the PTAB's power to hear a case necessarily implicates its power to grant relief; if the PTAB is powerless to hear a case, it is powerless to hand down a decision in that case canceling a patent.

In the judicial context, defects in seeking or granting discretionary review can and do affect the tribunal's power to grant relief. See, e.g., FEC v. NRA Political Victory Fund, 513 U.S. 88, 90-91, 99 (1994) (holding that this Court lacked jurisdiction because petition for certiorari was untimely); Baldwin Cnty. Welcome Ctr. v. Brown, 466 U.S. 147, 162 & n.1 (1984) (Stevens, J., dissenting) (collecting cases on jurisdictional time limit for petition for leave to appeal). The same is true a fortiori of an agency tribunal, because agencies are entirely creatures of statute and have no power beyond what the statute confers.

4. The Federal Circuit's refusal to review institution decisions has had an unintended collateral consequence, one of great concern to innovators-the absence of review has left PTAB decisionmaking arbitrary, ad hoc, panel-dependent, and unpredictable. The PTAB issues very few precedential decisions in IPRs and similar proceedings; while it has provided some guidance on how it resolves threshold issues such as estoppel, privity, and limitations, that guidance has come in the form of informative papers, which are not binding authority even on the PTAB itself. See Microsoft Corp., 789 F.3d at 1304 ("According to the Board's operating procedures, informative decisions are 'not binding authority,' but are designated as informative in order to provide 'Board norms on recurring issues,' 'guidance on issues of first impression,' and 'guidance on Board rules and practices." (citing Patent Trial and Appeal Board, Standard Operating Procedure 2 (Revision 9), ¶ IV.A–B)). The PTAB's informative papers have, at best, persuasive value. And because of the Federal Circuit's interpretation of the jurisdictional bar,

there is absolutely no hope of a *judicial* decision elucidating any of these matters.

As a result, innovators are left deeply uncertain. The one-year filing requirement, for example, is meant to provide a patent owner with a degree of certainty about whether it will be proceeding before a district court, before the PTAB, or both. But because of the PTAB's erratic, unpredictable, and unreviewed application of that provision, innovators lack any reasonable certainty about whether their valuable intellectual property remains exposed to PTAB proceedings.

\* \* \* \* \*

So long as a statute barring judicial review can be reasonably interpreted in a way that allows for some judicial review, a court should favor an interpretation allowing review over one that bars review absolutely. The Federal Circuit neglected this presumption of judicial review, instead opting for a construction of the appeal bar that gives the PTAB unfettered gatekeeping authority with no judicial scrutiny. Such an oversight cannot be taken lightly when 87% of proceedings that pass through those gates will lead to some form of claim cancellation. Congress mandated that certain statutory requirements be fulfilled before an IPR petition may be considered; a court should oversee the PTAB's institution decisions to ensure that those mandates are satisfied.

### CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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