

IN THE
Supreme Court of the United States

ETHICON ENDO-SURGERY, INC.,

Petitioner,

v.

COVIDIEN LP., *et al.*,

Respondents.

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

**BRIEF OF *AMICI CURIAE* 3M COMPANY,
BRISTOL-MYERS SQUIBB CO., ELI LILLY
AND COMPANY, GLAXOSMITHKLINE
LLC, ILLINOIS TOOL WORKS INC.,
INTERDIGITAL, INC., PFIZER, INC.,
THE PROCTER & GAMBLE COMPANY,
QUALCOMM INCORPORATED,
AND CARGILL, INC. IN SUPPORT
OF PETITIONER**

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INTERESTS OF *AMICI CURIAE*

Amici 3M Company, Bristol-Myers Squibb Co., Eli Lilly and Company, GlaxoSmithKline LLC, Illinois Tool Works Inc., InterDigital, Inc., LLC, Pfizer, Inc., The Procter & Gamble Company, Qualcomm Incorporated, and Cargill, Inc.* are representative of the most innovative companies in America. *Amici* develop, manufacture, and sell technology-based products in a wide range of industries, including the pharmaceutical, agricultural, automotive, consumer product, and telecommunications industries. In total, they invest tens of billions of dollars annually on research and development and employ hundreds of thousands of scientists, engineers, and others in the United States to develop, produce, and market innovative new products and services. To protect their inventions, *amici* collectively hold tens of thousands of U.S. patents and file numerous patent applications every year at the United States Patent and Trademark Office (“USPTO”).

Because of their investment, this case presents a question of substantial practical importance to *amici*: namely, whether the Leahy-Smith America Invents Act (“AIA”) permits the Director of the USPTO to delegate the institution decision in inter partes reviews (“IPRs”)

* Pursuant to Rule 37.6, *amici* affirm that no counsel for a party authored this brief in whole or in part, nor has any counsel, party, or third person other than *amici* or their counsel made any monetary contribution intended to fund the preparation or submission of this brief. Pursuant to Rule 37.2, counsel of record for all parties received notice of *amici*'s intent to file this brief at least ten days before the due date. The parties have consented to the filing of the brief, and copies of their letters of consent are being filed herewith.

to the Patent Trial and Appeal Board (“PTAB”), thereby eliminating the separation of the institution decision and the final written decision on the merits that the AIA sets forth. The Federal Circuit’s holding, that the statute does not preclude the same PTAB panel from making the institution decision and the final determination, has had and will continue to have significant ramifications for *amici* and all technologically-driven companies in the United States. The way in which the USPTO carries out IPRs has reduced the value of issued U.S. patents while increasing the uncertainty concerning the value of investing in future research and development. This uncertainty will hurt the flow of investment essential to making the future innovations desperately needed to power the American economy in the decades to come. Accordingly, *amici* have a substantial interest in the question presented here and in ensuring that the USPTO correctly implements procedures that adhere to the framework established by Congress for inter partes review.

SUMMARY OF ARGUMENT

When Congress established inter partes review, it did so in a precise manner to ensure that challenged U.S. patents receive a fair hearing. Congress accomplished this by dividing the IPR process into two distinct stages heard by two distinct bodies. First, Congress assigned the preliminary institution decision phase to the Director of the USPTO. 35 U.S.C. § 314. Second, for those reviews that the Director decides to institute, Congress assigned the conduct of the review to the Patent Trial and Appeal Board. 35 U.S.C. § 6(b)(4). This intentional division of decision-making authority ensures that the threshold decision to institute an IPR neither preordains nor prejudices the later decision on the merits.

Presumably for reasons of institutional convenience, the USPTO has chosen to ignore the statutory division of responsibilities for the two stages of inter partes review and has assigned the PTAB to handle both phases. *See* 37 C.F.R. § 42.4(a). Under current USPTO practice, instead of the PTAB providing an independent and fresh set of eyes during the merits phase, the same panel of judges who already decided to institute inter partes review sits as the merits panel as well.

The entirely predictable result of this improper comingling of duties is that an overwhelming percentage (approximately 81.1%) of patent claims for which an IPR has been instituted are canceled as unpatentable during the merits stage. *See* PTAB Statistics, at 12 (July 31, 2016), *available at* <https://www.uspto.gov/sites/default/files/documents/2016-07-31%20PTAB.pdf>. And of the more than 1000 “trials”¹ that have reached a final decision, 85% of the final written decisions cancel all or some of the instituted claims as unpatentable. *Id.* at 10. Ignoring the statutory division of responsibility established by Congress has turned the merits phase into a rubberstamp proceeding to the detriment of granted patent claims otherwise entitled to a statutory presumption of validity. 35 U.S.C. § 282.

In this case, the Federal Circuit incorrectly construed the plain text, structure, and purpose of the AIA. The majority panel decision affirmed an overly expansive reading of the statute allowing the Director to designate

1. IPRs are decided based on written submissions and an oral argument. The USPTO refers to the oral argument as a “trial.” *See* 37 C.F.R. § 42.4(a) .

the PTAB as the authority responsible for both institution and final decisions in inter partes review, notwithstanding the clear Congressional intent to the contrary.

Patents are a significant property right, obtained only after examination by the USPTO and the payment of fees by patent applicants. This constitutionally-mandated right is intended to spur innovation and investment in new technologies by individuals, academic institutions, small businesses, and large companies. Recognizing the need for predictable and strong patent rights, Congress created inter partes review and specifically gave the Director a gatekeeping role, and substantial discretion, in considering whether an IPR petition should be instituted. In contrast, Congress also provided specific duties to the PTAB and did not include the institution of IPR petitions among them. As currently implemented by the USPTO, the Director has abdicated her statutorily-mandated gatekeeping role and delegated it to the PTAB, thereby creating an imbalanced proceeding that threatens to undermine the value of patents and the overall goals of the patent system. Due to the serious implications for patents involved in IPR proceedings, *amici* respectfully request that this Court grant Appellant's petition for *certiorari*.²

ARGUMENT

The patent statute expressly divides decision-making authority between the Director, who decides whether to institute an inter partes review, and the PTAB, which

2. *Amici* take no position concerning the validity of Petitioner's patent claims. *Amici*'s only interest is in seeing that the USPTO implements a statutorily correct procedure for IPRs.

conducts the inter partes review itself and renders a final decision on the merits. To ensure this division of decision making, Congress sharply limited the PTAB to four **and only four** duties:

- (1) review adverse decisions of examiners;
- (2) review appeals of reexaminations;
- (3) conduct derivation proceedings; and
- (4) **conduct** inter partes reviews and post-grant reviews.

35 U.S.C. § 6(b) (emphasis added). Pointedly, Congress did not include the decision of whether to *institute* an inter partes review as one of the PTAB’s enumerated duties. Instead, Congress assigned this duty to the Director. *Id.* § 314(b) (“The Director shall determine whether to institute an inter partes review ...”). And consistent with this division of duties, the statute is clear that the PTAB’s role in inter partes reviews begins only **after** an inter partes review has been instituted by the Director. *See id.* § 316(c) (“...the Patent Trial and Appeal Board shall ... conduct each inter partes review *instituted* under this chapter”) (emphasis added).

The legal error made by the Director, and affirmed by the Federal Circuit, was to expand the duties of the PTAB to include institution decisions. In defining the duties of the PTAB, Congress could have, but did not, include the institution of inter partes review proceedings. It is legally improper for an appointee of the Executive Branch to alter the statutory limits on the PTAB imposed by Congress.

Consequently, the delegation of the institution review to the PTAB under 37 C.F.R. § 42.4(a) violates the plain language of the patent statute.

The Director's decision to delegate the institution decision to the PTAB should not be insulated by *Chevron* deference. As *Chevron* and its progeny teach, the first question to be considered when deciding whether an agency's interpretation of the statute is entitled to deference is whether Congress has directly spoken to the question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress. *Chevron U.S.A. v. NRDC*, 467 U.S. 837, 842-43 (1984). Here, the intent of Congress is clear. The PTAB was given only four roles, and none includes deciding whether to institute AIA review proceedings. Instead, the structure and text of the statute make it clear that Congress intended the PTAB to conduct AIA review trials only after the institution decision has been made by the Director. The USPTO's interpretation ignores this crucial distinction and is, therefore, entitled to no deference.

The question here is not whether the Director can in general delegate her duties (she can) or whether the Director can delegate the decision to institute IPR proceedings (she can). But what the Director cannot do is unilaterally expand the duties of the PTAB beyond the four limited duties assigned to it by Congress. This improper expansion is the issue that *amici* believe merits granting *certiorari*.

The procedure now implemented by the USPTO and affirmed by the Federal Circuit contradicts the language

of the statute, with the result that patents do not receive the fresh look during the merits phase that Congress intended. This effectively creates a “presumption of unpatentability” during the merits phase, notwithstanding the AIA’s provision that the burden of proof remains with the petitioner throughout the IPR proceeding. 35 U.S.C. § 316(e). The granting of *certiorari* in this case will provide an opportunity for this Court to restore the proper balance to inter partes reviews that Congress intended.

I. The Statute’s Plain Text and Structure Preclude the PTAB from Instituting Inter Partes Review

The plain text of the statute governing IPR proceedings requires two separate and distinct review processes for challenged claims: a threshold institution decision and a final decision. 35 U.S.C. §§ 314(a), 316(c). Likewise, the statute expressly divides the decision-making authority of each process between two separate and distinct decision-makers: the Director, who institutes review, and the PTAB, which conducts the inter partes review following institution by the Director. *Id.* § 314(a) (“The Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented...shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.”); *Id.* § 316(c) (“...the Patent Trial and Appeal Board shall ... conduct each inter partes review instituted under this chapter”). Congress could have assigned responsibility for overseeing both separate phases to only the Director or only the PTAB, but did not.

The statute repeatedly emphasizes the Director’s role in the threshold institution decision step. *See, e.g., id.* § 314(a); *id.* § 314(b) (“The Director shall determine whether to institute an inter partes review...”); *id.* § 314(c) (“The Director shall notify the petitioner and patent owner... of the Director’s determination under subsection (a)...”); *id.* § 314(d) (“The determination by the Director whether to institute an inter partes review...”); *id.* § 315(c) (“If the Director institutes an inter partes review...”); *id.* § 325(d) (“In determining whether to institute or order a proceeding under...the Director may take into account...”).

Similarly, the statute separately emphasizes the PTAB’s role in the final decision review. *See id.* § 316(c) (“...the Patent Trial and Appeal Board shall ... conduct each inter partes review instituted under this chapter”); *id.* § 318(a) (“...the Patent Trial and Appeal Board shall issue a final decision...”); *id.* § 318(b) (“If the Patent Trial and Appeal Board issues a final written decision... the Director shall issue and publish a certificate...”). And in creating the PTAB, Congress expressly defined the limited set of duties to be performed by the PTAB. *See id.* § 6(b). Specifically, the only duties of the PTAB are reviewing adverse decisions of examiners, reviewing appeals of reexaminations, conducting derivation proceedings, and conducting inter partes reviews and post-grant reviews after institution. *Id.* The distinct statutory roles and duties assigned to the Director and the PTAB are clear.

To support the interpretation that the Director may delegate her duties to the PTAB, the majority panel reasoned that because Congress “obviously assumed that the Director would delegate” her duties, she was not precluded from designating her institution review duties to the PTAB. *Ethicon Endo-Surgery, Inc. v. Covidien LP*,

No. 2014-1771, 2016 WL 145576, at *7 (Fed. Cir. Jan. 13, 2016). That the Director could delegate her duties under appropriate circumstances, however, is not the issue. Rather, the question at hand, as pointed out by Judge Newman in her dissent, is whether Congress intended to grant the Director the authority to delegate this particular duty to make institution decisions to the PTAB. *Id.*, at *10 (Newman, J., dissenting). To hold that the Director had the inherent authority to delegate her institution decision to the PTAB is contrary to the expressly enumerated list of duties that Congress chose to assign to the PTAB. Executive discretion cannot override the statute.

II. Delegation of the Institution Decision to the PTAB Deprives Patent Owners of a Fresh Evaluation on the Merits

The Federal Circuit's decision to allow the USPTO Director to grant the PTAB authority over institution decisions tips the balance unfairly against patent owners in IPRs. Once the panel of PTAB judges has decided to institute an IPR, the very same panel of judges then proceeds to consider the merits. The practical problem with this procedure is rooted in human nature. No matter the best intentions of the administrative judges, they will inevitably start their consideration of the merits phase at the same point they ended the institution phase – with a belief that there is a reasonable likelihood that the claims for which they just instituted inter partes review are unpatentable. Indeed, the USPTO has taken the position that the institution decision “operates to shift the burden of producing evidence of obviousness” to the patentee. *See In re Magnum Tools International*, 829 F.3d 1364, 1374 (Fed. Cir. 2016) (reversing the PTAB's cancellation

of claims in an IPR). This procedure stacks the deck against patent owners, obviates the statutory presumption of validity, and is not what Congress enacted in the AIA.

The statistical evidence of this stacked deck is stark. As of July 31, 2016, out of 14,458 claims that were instituted, only 2,737 claims, or 18.9%, were found to be patentable. *See* PTAB Statistics, at 12 (July 31, 2016), *available at* <https://www.uspto.gov/sites/default/files/documents/2016-07-31%20PTAB.pdf>. Similarly, out of the almost 800 trials where a final written decision was rendered, the PTAB maintained its original institution decision favoring the cancellation of claims 85% of the time. *Id.* At 10. And yet, every one of the patent claims that the PTAB canceled had been previously examined by skilled USPTO examiners (at considerable expense to the patentees) and was entitled to a statutory presumption of validity. 35 U.S.C. § 282.

The lack of appealability of the institution decision, *Cuozzo Speed Technologies, LLC v. Lee*, 136 S. Ct. 2131 (2016), only heightens the harm to patent owners of the USPTO's conflation of the institution and merits decisions in IPRs. Patent owners cannot appeal the institution decision, yet it is that initial decision that inherently biases the merits determination towards invalidity. Thus, the availability of an appeal from the merits decision does not remedy the legally erroneous procedure adopted by the USPTO. Only inter partes review by PTAB judges who have not been biased by their own institution decision and who bring a fresh set of eyes can correct this legal error.

CONCLUSION

Assigning the same PTAB panel to both institute and conduct an inter partes review is not what Congress enacted or intended. By limiting the duties of the PTAB to conducting the merits phase and not the institution phase, Congress created a procedure that would guarantee a fresh look by a second set of eyes during the merits phase of every inter partes review. The USPTO has exceeded its authority and deviated from this clear Congressional scheme. Therefore, the Director should be precluded from delegating her responsibility for instituting inter partes review proceedings to the PTAB.

For these reasons, *amici* respectfully request that this Court grant the petition for writ of *certiorari* in this case.

Respectfully Submitted,

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