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No. 16-

Supreme Court, U.S. FILED

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### In The

## Supreme Court of the United States

ETHICON ENDO-SURGERY, INC.,

Petitioner,

v.

COVIDIEN LP AND MICHELLE K. LEE, DIRECTOR, U.S. PATENT AND TRADEMARK OFFICE.

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

#### PETITION FOR A WRIT OF CERTIORARI

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#### **QUESTION PRESENTED**

Leahy-Smith The America Invents Act. following established principles of administrative law, sets up a scheme in its newly established inter partes patent challenge proceedings that requires separate decisions to be made for institution and adjudication by two different decisionmakers: Act provides that "[t]he Director" of the U.S. Patent and Trademark Office "shall determine whether to institute an inter partes review under this chapter," 35 U.S.C. § 314(b), and that "[t]he Patent Trial and Appeal Board shall \*\*\* conduct each inter partes review instituted under this chapter," id. § 316(c).

The Director subsequently promulgated a regulation providing that "[t]he Board institutes the trial on behalf of the Director." 37 C.F.R. § 42.4(a). As a result, the separate statutory functions in sections 314 and 316(c) are now combined before a single panel of the Board, which first decides whether to institute inter partes review and then rules on the merits.

The question presented is:

Whether the Leahy-Smith America Invents Act permits the Patent Trial and Appeal Board instead of the Director to make inter partes review institution decisions.

#### PARTIES TO THE PROCEEDINGS

Petitioner Ethicon Endo-Surgery, Inc., was the patent owner before the Patent Trial and Appeal Board and the appellant in the court of appeals.

Covidien LP was the petitioner before the Patent Trial and Appeal Board and the appellee in the court of appeals.

Michelle K. Lee, Director, U.S. Patent and Trademark Office, intervened in the court of appeals.

#### **RULE 29.6 DISCLOSURE**

Ethicon Endo-Surgery, Inc. is a subsidiary of Ethicon, Inc., which is a subsidiary of Johnson & Johnson. No publicly held company directly owns 10% or more of Ethicon Endo-Surgery, Inc. stock.

### TABLE OF CONTENTS

QUESTION PRESENTED	i
PARTIES TO THE PROCEEDINGS	ii
RULE 29.6 DISCLOSURE	ii
TABLE OF AUTHORITIES	vi
INTRODUCTION	1
OPINIONS BELOW	3
JURISDICTION	3
RELEVANT STATUTORY AND REGULATORY PROVISIONS	3
STATEMENT OF THE CASE	
A. Statutory and Regulatory Framework	3
B. Factual and Procedural History	
REASONS FOR GRANTING THE WRIT	10
I. THE DIRECTOR'S DELEGATION OF THE INSTITUTION DECISION TO THE BOARD CONTRAVENES THE STATUTE	12
A. The AIA Requires The Director To	
Institute Inter Partes Review	13
1. The AIA assigns a different decisionmaker to each phase of inter partes review	13
2. The Director may not delegate the institution decision to the Board	15
B. Congress Did Not Sanction A Departure From Established Administrative Law Principles	21

II. THE DIRECTOR'S DELEGATION OF	
INSTITUTION AUTHORITY TO THE	
BOARD IS AN EXCEPTIONALLY	
IMPORTANT ISSUE OF PATENT LAW	
AND ADMINISTRATIVE LAW	25
A. The Decision Below Unduly Expands	
Agency Authority	25
B. Disregard Of The Statutory Safeguards	
Governing Inter Partes Review Demands	
Intervention	
CONCLUSION	29
APPENDIX	
Opinion of the U.S. Court of Appeals for	
the Federal Circuit (Jan. 13, 2016)	1a
Order and Opinion of the U.S. Court of	
Appeals for the Federal Circuit Denying	
Rehearing En Banc (June 22, 2016)	39a
Final Written Decision of the Patent Trial	
and Appeal Board (June 9, 2014)	49a
Decision on Institution of Inter Partes	
Review of the Patent Trial and Appeal	
Board (Aug. 26, 2013)	77a
5 U.S.C. § 554	.107a
35 U.S.C. § 3	.111a
35 U.S.C. § 6	.120a
35 U.S.C. § 314	.122a
35 U.S.C. § 315	.124a
35 U.S.C. § 316	.127a
35 U.S.C. § 318	
35 U.S.C. § 325	.133a

	v	
37 C.F.R. § 42.	4	137a

### TABLE OF AUTHORITIES

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Chevron USA Inc. v. Natural Res. Def. Council, Inc.,
467 U.S. 837 (1984)
Corley v. United States, 556 U.S. 303 (2009)20
Cudahy Packing Co. v. Holland, 315 U.S. 357 (1942)
Cuozzo Speed Techs., LLC v. Lee, 136 S. Ct. 2131 (2016)
Federal Election Comm'n v. Democratic Senatorial Campaign Comm., 454 U.S. 27 (1981)
Fleming v. Mohawk Wrecking & Lumber Co., 331 U.S. 111 (1947)16, 17, 18
Gomez v. United States, 490 U.S. 858 (1989)
Halverson v. Slater, 129 F.3d 180 (D.C. Cir. 1997)16
Heckler v. Chaney, 470 U.S. 821 (1985)24
Kingdomware Techs., Inc. v. United States, 136 S. Ct. 1969 (2016)23

Martin v. Occupational Safety & Health Review Comm'n, 499 U.S. 144 (1991)	21
Russello v. United States, 464 U.S. 16 (1983)	15
St. Jude Med., Cardiology Div., Inc. v. Vol Corp., 749 F.3d 1373 (Fed. Cir. 2014)	
United States v. Giordano, 416 U.S. 505 (1974)	17
Wong Yang Sung v. McGrath, 339 U.S. 33 (1950)	21, 22
STATUTES:	
5 U.S.C. § 554(d)	9, 21
28 U.S.C. § 1254(1) § 1295(a)(4)(A)	
35 U.S.C.  § 3(b)(3)  § 3(b)(3)(B)  § 6(a)  § 6(b)  § 6(b)(1)  § 6(b)(2)  § 6(b)(3)  § 6(b)(4)	
§ 6(c)	5

35 U.S.C. (cont.)	
§ 131	19
§ 132(a)	
§ 141(c)	
§ 251(a)	
§ 314	
§ 314(a)	
§ 314(b)	4, 13
§ 314(c)	4, 13
§ 314(d)	5, 14, 23
§ 315(c)	
§ 315(d)	4, 24
§ 316(a)	5
§ 316(b)	5, 23
§ 316(c)5, 8	3, 14, 25
§ 316(e)	5
§ 318(a)	5, 14
§ 325(d)	4, 14
Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011)	
37 C.F.R.	
§ 42.2	5
§ 42.4(a)	
<b>3</b> ()	
77 Fed. Reg. 48612 (Aug. 14, 2012)	5
157 CONG. REC. S1377 (daily ed. Mar. 8, 2011)	)23
Baker, Richard, America Invents Act Cost the U.S. Economy Over \$1 Trillion, Patently O (June 8, 2015)	

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USPTO's Leadership (Aug. 19, 2015)27
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TREATISE (5th ed. 2010)
Press Release, The White House, President
Obama Signs America Invents Act,
Overhauling the Patent System to
Stimulate Economic Growth, and
Announces New Steps to Help
Entrepreneurs Create Jobs (Sept. 16, 2011)26
USPTO, Patent Trial and Appeal Board
Statistics (July 31, 2016)28

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#### PETITION FOR A WRIT OF CERTIORARI

#### INTRODUCTION

This petition, which arises out of the Patent Trial and Appeal Board's invalidation of Petitioner Ethicon Endo-Surgery, Inc.'s patent in an inter partes review proceeding, presents a fundamental question of statutory interpretation common to the over thousand such proceedings filed annually at the U.S. Patent and Trademark Office (PTO). The Leahy-Smith America Invents Act (Act or AIA) explicitly commits the threshold, discretionary decision to *institute* inter partes review to the Director of the PTO. In equally explicit terms, the AIA charges the Board with conducting any inter

partes review instituted by the Director. Following a longstanding policy of separation-of-functions whereby adjudicatory officers inside an agency (such as administrative law judges or, here, administrative patent judges) are insulated from discretionary executive functions, Congress intended this scheme to protect patent owners against harassment by would-be patent challengers.

Disregarding the AIA's bifurcated decisionmaking structure and the Patent Act's other limits on the statutory power to delegate her functions, the Director has promulgated a regulation diverting all institution decisions from the Director to the Board. Under that regulation, gatekeeping institution decisions and merits adjudication are now combined in the Board.

The Federal Circuit below sustained the validity of that regulation, but it did so (i) disregarding the separation of functions between the Director and the Board that Congress made explicit in the AIA; (ii) relying on expansive notions of"inherent" administrative powers; and (iii) disparaging one of this Court's precedents. As Judge Newman notes in her dissent from the denial of rehearing en banc, "[i]gnoring the statutory division of responsibility is contrary to the plain text and carefully designed structure of the America Invents Act, and imperils the public confidence in the fairness and correctness of these proceedings." App., infra, 42a.

Because the PTO's commingling of decisionmakers departs from unambiguously expressed congressional intent as well as established administrative law principles, and radically distorts the central new mechanism for addressing questions of patent validity, this Court should grant certiorari.

#### OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 1a-38a) is reported at 812 F.3d 1023. The order and opinion respecting the court of appeals' denial of rehearing en banc (App., *infra*, 39a-48a) is reported at 826 F.3d 1366.

#### **JURISDICTION**

The court of appeals entered its judgment on January 13, 2016. Ethicon timely filed a petition for rehearing en banc, which was denied on June 22, 2016. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

# RELEVANT STATUTORY AND REGULATORY PROVISIONS

The relevant statutory and regulatory provisions are reproduced at App., *infra*, 107a-138a.

#### STATEMENT OF THE CASE

#### A. Statutory and Regulatory Framework

1. The AIA creates a process called "inter partes review," which "allows a third party to ask the U.S. Patent and Trademark Office to reexamine the claims in an already-issued patent and to cancel any claim that the agency finds to be unpatentable in light of prior art." Cuozzo Speed Techs., LLC v. Lee, 136 S. Ct. 2131, 2136 (2016) (citation omitted). Congress separated inter partes review into two distinct phases with two distinct decisionmakers.

"[t]he Director [of the PTO] shall First.determine whether to institute an inter partes review." 35 U.S.C. § 314(b). Such review "may," in the Director's discretion, be "authorize[d]" and "instituted" only when "the Director determines \*\*\* 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. § 314(a): see, e.g., AIA, Pub. L. No. 112-29, § 6(c)(2)(B), 125 Stat. 284, 304 (2011) (permitting the Director to set a limit upon the number of inter partes review proceedings in the first years after the Act goes into effect). The "decision to deny a petition is a matter committed to the Patent Office's discretion." Cuozzo, 136 S. Ct. at 2140.

If the Director finds institution appropriate, "the Director's determination under [section 314(a)]" is communicated to the petitioner and patent owner in writing. 35 U.S.C. § 314(c). The "Director, in his or her discretion, may join \*\*\* part[ies] to that inter partes review" that "the Director \*\*\* determines" also have filed petitions "warrant[ing] the institution of an inter partes review," id. § 315(c), and "may determine the manner in which the inter partes review \*\*\* may proceed"—"including providing for stay, transfer, consolidation, or termination"—in relation to "another proceeding or matter involving the patent \*\*\* before the Office," id. § 315(d). In doing so, "the Director" may protect a patent owner from such a proceeding by "tak[ing] into account whether, and reject[ing] the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office." Id. § 325(d). No appeal may be taken from "[t]he determination by the Director whether to institute an inter partes review." *Id.* § 314(d).

Second, following institution, "[t]he Patent Trial and Appeal Board shall, in accordance with section 6 [of title 35], conduct each inter partes review instituted under this chapter." 35 U.S.C. § 316(c). Section 6 specifies that the "Board shall \*\*\* conduct inter partes reviews" by at least "3-member panels" comprised of "administrative patent judges appointed by the Secretary [of Commerce]." § 6(a)-(c); see Cuozzo, 136 S. Ct. at 2137. sections provide for further development of the record, including discovery, briefing, and an oral hearing, 35 U.S.C. § 316(a)—culminating in the Board's issuance of a "final written decision with respect to the patentability" of the claims at issue, id. §§ 316(e), 318(a). The Board's final written decision is appealable to the Federal Circuit. 28 U.S.C. § 1295(a)(4)(A); 35 U.S.C. § 141(c).

2. The Director is required to prescribe regulations governing inter partes review, taking into account "the effect of any such regulation on the economy, the integrity of the patent system, the efficient administration of the Office, and the ability of the Office to timely complete proceedings instituted under this chapter." 35 U.S.C. § 316(a)-(b). Director promulgated regulations 2012,the providing (as relevant here) that "[t]he Board institutes the trial on behalf of the Director." C.F.R. § 42.4(a); see also id. § 42.2 (defining "trial" to include inter partes review). The Director explained that "section 42.4(a) specifically delegates the determination to institute a trial to the Board." 77 Fed. Reg. 48612, 48616 (Aug. 14, 2012).

#### **B.** Factual and Procedural History

- 1. Petitioner Ethicon holds U.S. Patent No. 8,317,070 ("the '070 patent"), which is directed to surgical staplers used to staple, secure, and seal tissues during surgeries. App., *infra*, 3a. In 2010, Respondent Covidien LP began selling surgical staplers—touted as one of its most successful product lines ever—that achieved \$1 billion in sales within three years of introduction to the market. *Id.* at 6a-7a.
- 2. In 2013, Covidien filed a petition for inter partes review, seeking cancellation of all claims of the '070 patent. In support of institution, Covidien submitted (among other documents) eight purported prior art references and a 100+-page expert declaration by a former employee construing the '070 patent claims and labeling them unpatentable. C.A. App. A172-173, A464-576, A580; App., infra, 66a.

Exercising authority delegated pursuant to 37 C.F.R. § 42.4(a), "the Board \*\*\* determined to institute an inter partes review" on the ground that Covidien had satisfied "[t]he standard for instituting an inter partes review \*\*\* set forth in 35 U.S.C. § 314(a)." App., infra, 78a-79a. According to the Board's 24-page institution decision, there was a "reasonable likelihood" that the '070 patent claims, as construed by the Board, were obvious in light of a combination of prior art references. *Id.* at 78a (quoting 35 U.S.C. § 314(a)). In reaching that conclusion, the Board repeatedly "credit[ed] theof Covidien's expert testimony witness [concerning what] one with ordinary skill in the art would have known." Id. at 92a-104a.

Following a "trial" at which no live testimony was heard, the Board—specifically, the same three-member panel that instituted review—issued a final written decision invalidating the '070 patent claims for the same reasons set forth in the institution decision. As an initial matter, the Board held that it was "not persuaded that a change in claim construction from that issued in the Decision to Institute is merited." App., *infra*, 56a-59a. As to obviousness, the Board found that "[Ethicon's] evidence is entitled to less weight than [Covidien's] evidence," again relying on Covidien's expert witness declaration and finding that such evidence "has not been rebutted." *Id.* at 59a-67a.

- 3. Ethicon appealed to the Federal Circuit on the ground that the AIA precludes the Director from delegating her institution authority to the Board. <sup>1</sup> The Director intervened. The Federal Circuit upheld the Board's final written decision in a split decision. <sup>2</sup>
- a. The majority declared that "[t]here is nothing in the statute or legislative history of the statute indicating a concern with separating the functions of initiation and final decision." App., *infra*, 15a. Noting the impracticality of the Director personally

<sup>&</sup>lt;sup>1</sup> Ethicon also appealed (unsuccessfully) the Board's invalidation of the '070 patent claims on the merits. App., *infra*, 21a-24a. That aspect of Ethicon's appeal is not at issue here.

<sup>&</sup>lt;sup>2</sup> The Federal Circuit did not accept Respondents' suggestion that Ethicon had waived the question presented, and was unanimous in rejecting the argument that 35 U.S.C. § 314(d) precluded its resolution on appeal. App., *infra*, 9a-10a. That holding comports with this Court's decision in *Cuozzo*, 136 S. Ct. at 2139-2142.

handling each institution decision, the majority relied upon the general principle that agency heads ordinarily possess "inherent" authority to delegate their functions to their subordinates. *Id.* at 15a-20a.

Despite rejecting Ethicon's reliance on (inter alia) Cudahy Packing Co. v. Holland, 315 U.S. 357 (1942) (in which this Court inferred an absence of an implied authority to delegate where Congress had provided an explicit but limited authority to delegate) as a precedent "lower courts no longer follow," App., infra, 17a, the majority acknowledged that delegation authority must yield to congressional intent to preclude a particular delegation. But it found no such congressional intent with respect to delegation of the institution function to the Board. The majority discounted Congress's (i) explicit division of inter partes review into an institution determination by the Director and a subsequent trial by the Board, 35 U.S.C. §§ 314, 316(c); (ii) provision of express delegation authority to the Director only for the officers and employees she appoints or hires (and thus not authorizing delegations to the judges of the Board, who are appointed by the Secretary of Commerce), id.  $\S 3(b)(3)(B)$ ; and (iii) delineation of the Board's jurisdiction as including only the "conduct" of inter partes review proceedings, id. § 6(b)(4), not the institution of such proceedings. App., infra, 16a-20a.

The majority further concluded that "Congress's vesting of broad rulemaking powers in the head of the agency is an alternate source of authority to delegate." App., *infra*, 20a. In its view, Congress "intended the Director to have power by rulemaking to define the structure of inter partes review,

including the power to subdelegate tasks assigned to her in the interest of efficiency." *Id.* Finding Congress to have been "ambiguous" as to whether institution "requires [the Director's] personal participation," the majority deferred to the Director's regulation as a "permissible interpretation of the statute." *Id.* (citing *Chevron USA Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842-843 (1984)).

The majority rejected any due process or separation-of-functions concerns arising collapsing the institution and adjudication function into a single decisionmaker. It characterized both the institution decision and the final written decision "adjudicative" and therefore discounted the relevance of the Administrative Procedure Act's (APA) prohibition on "investigative or prosecuting" participating infinal adjudicative personnel App., infra, 12a-13a & n.3 (quoting 5 decisions. U.S.C. § 554(d)).

b. Judge Newman dissented. She explained that the question was not whether the Director could delegate the institution determination at all; all parties agreed that it would be permissible for the Director to delegate the determination to an examiner or solicitor, for example. App., *infra*, 26a-27a. Instead, the question was whether that delegation could be made to the Board—a purely adjudicative body—when the statute "divided the functions of institution and trial into separate bodies within the PTO." *Id.* at 26a.

Judge Newman concluded that "proceedings in which the Board makes both decisions \*\*\* cannot be reconciled with the statute," which "repeats several times the requirement that the Director make the institution decision." App., *infra*, 26a, 35a. Noting the criticism of "actual or perceived bias" stemming from a system in which "administrative patent judges are put in the position of defending their prior decisions to institute the trial," Judge Newman further observed that Congress's goal to provide "rigorous inquiry and confident adjudication as a surrogate for district court litigation" is served only by dividing the institution and final-decision functions. *Id.* at 26a, 32a (citation and internal quotation marks omitted).

4. Ethicon filed a timely petition for rehearing en banc, supported by trade associations, corporations, and legal academics as *amici*. The Federal Circuit denied the petition.

Judge Newman authored a further dissent from the denial of rehearing en banc. She warned that "[i]gnoring the statutory division of responsibility is contrary to the plain text and carefully designed structure of the America Invents Act, and imperils the public confidence in the fairness and correctness of these proceedings." App., *infra*, 42a.

#### REASONS FOR GRANTING THE WRIT

The question presented affects a fundamental aspect of every inter partes review proceeding: whether the Board, the ultimate adjudicator, may replace the Director (or her proper delegee) as the institution decisionmaker. The government cannot avoid the unambiguous instruction, repeated throughout the AIA, that the *Director* is responsible for *instituting* inter partes review, while the *Board* is responsible for *conducting* it. The AIA therefore

leaves no room for a regulation that delegates the institution function to the Board—a body that Congress made clear shall have the power only to conduct any inter partes review already instituted by the Director.

In attempting to avoid the plain text of the AIA, the Federal Circuit assumed that the Director possesses an "inherent" authority to delegate her statutorily specified duties, ostensibly buttressed by Because the Patent Act Chevron deference. elsewhere limits the Director's authority to delegate her duties only to officers and employees whom she appoints and hires, it follows that the Director may not delegate such duties to the administrative law judges whom the Secretary of Commerce appoints to The Federal Circuit and the Director the Board. have no license to expand the scope of that delegation authority in the name of expediency-particularly where, as here, the delegation violates the text of the AIA.

Beyond the statute's terms and structure, a system in which the Board institutes inter partes review on a finding of a reasonable likelihood of invalidity, and thereafter tests that finding in an inter partes review trial, runs headlong into established administrative law limits. As this Court has explained, in order to guard against the propensity of a single decisionmaker to uphold its prior actions, Congress has long required (most notably, through the APA) a separation of executive and adjudicative functions below the level of an agency head. It was thus no accident that Congress, in enacting the AIA, envisioned that an executive officer (the Director or a proper delegee) would make

the discretionary decision to institute inter partes review, and that the judges of the Board would conduct that review independent of preconceived notions formed in the institution phase.

The Director's removal of the separation-offunctions safeguard fundamentally alters the nature of inter partes review—to the detriment of the innovative community and the public. The Board's final decisions not only bear the taint of prejudgment; they unsurprisingly result in the affirmance of institution decisions and the invalidation of patent claims in the vast majority of cases. Given the rapid growth of inter partes review into the primary means for reviewing patent validity, this Court should grant certiorari to ensure that those proceedings are conducted as Congress intended.

# I. THE DIRECTOR'S DELEGATION OF THE INSTITUTION DECISION TO THE BOARD CONTRAVENES THE STATUTE

Congress "establishe[d] a two-step procedure for inter partes review: the Director's decision whether to institute a proceeding, followed (if the proceeding is instituted) by the Board's conduct of the proceeding and decision with respect to patentability." St. Jude Med., Cardiology Div., Inc. v. Volcano Corp., 749 F.3d 1373, 1375-1376 (Fed. Cir. 2014) (emphasis added). That considered choice to entrust those two decisions to distinct decisionmakers, plainly stated in the AIA, cannot be overridden by regulation. See Federal Election Comm'n v. Democratic Senatorial Campaign Comm., 454 U.S. 27, 32 (1981) ("[Courts] must reject administrative constructions of the statute, whether reached by adjudication or by rule-making, that are

inconsistent with the statutory mandate or that frustrate the policy that Congress sought to implement.").

# A. The AIA Requires The Director To Institute Inter Partes Review

1. The AIA assigns a different decisionmaker to each phase of interpartes review.

Contrary to the Federal Circuit's conclusion that "nothing in the statute \*\*\* indicat[es] a concern with separating the functions of institution and final decision," App., *infra*, 15a, that concern is replete throughout the provisions governing inter partes review. As Judge Newman observed in dissent, "[t]he bifurcated design of post-grant review is clear not only from the language of [AIA] §§ 314(a) and 316(c), but pervades the structure of these post-grant proceedings. Congress unambiguously placed these separate determinations in different decisionmakers, applying different criteria." *Id.* at 28a.

Most fundamentally, the AIA expressly (and repeatedly) assigns the threshold institution decision to the Director—not to the Board. It specifies the standard under which "[t]he Director may \*\*\* authorize an inter partes review to be instituted," 35 U.S.C. § 314(a) (emphasis added); the deadline by which "[t]he Director shall determine whether to institute an inter partes review," id. § 314(b) (emphasis added); the steps the Director shall take to "notify the petitioner and patent owner, in writing, of the Director's determination under subsection (a)" to institute inter partes review, id. § 314(c) (emphasis added); and that "[t]he determination by the Director

whether to institute an inter partes review \*\*\* shall be final and nonappealable," id. § 314(d) (emphasis added). See also id. § 315(c) (permitting Director to join parties "[i]f the Director institutes an inter partes review") (emphasis added); id. § 325(d) (specifying that "the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office") (emphasis added). Nowhere does the AIA refer to an institution decision by the Board or otherwise contemplate the Board's participation in that stage of the proceeding.

Instead, the AIA limits the Board's authority to adjudication. *post*-institution The provision governing the "[c]onduct of inter partes review" states that the "Board shall \*\*\* conduct each inter partes review instituted under this chapter." U.S.C. § 316(c). The provision establishing the Board likewise enumerates "conduct[ing] inter partes reviews"—but not instituting inter partes reviews as one of the Board's "[d]uties." Id. § 6(b)(4).3 And the sole decision assigned to the Board is a "final written decision with respect to \*\*\* patentability" that is necessary only "i[f] an inter partes review is instituted and not dismissed." Id. § 318(a).

The terms and structure of the AIA thus foreclose the reassignment of the institution decision from the Director to the Board at every turn. See

<sup>&</sup>lt;sup>3</sup> The other enumerated duties concern reviewing decisions in examination and reexamination proceedings, as well as conducting derivation proceedings. 35 U.S.C. § 6(b)(1)-(3).

Gomez v. United States, 490 U.S. 858, 872 (1989) (explaining that a "carefully defined grant of authority" in a statute "should be construed as an implicit withholding of [other] authority"); see also Russello v. United States, 464 U.S. 16, 23 (1983) ("Congress acts intentionally and purposely in the disparate inclusion or exclusion.").

This case is not one in which "the [AIA] contains \*\*\* a gap" that may be filled by the reasonable interpretation of the Director. Cuozzo, 136 S. Ct. at 2142. Quite the opposite, the AIA "is clear" that the Director—not the Board—is responsible instituting inter partes review. Id. As such, "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, 467 U.S. at 842-843; Cuozzo, 136 S. Ct. at 2142 ("[T]he [PTO] must follow the statute."). The Federal Circuit's invocation of Chevron deference, App., infra, 20aparticularly when coupled with a purported exercise of the Director's "inherent" delegation authority that independently conflicts with the Patent Act (see pp. 15-21, infra)—is no answer.

- 2. The Director may not delegate the institution decision to the Board.
- a. The Federal Circuit acknowledged (as it must) that the AIA consistently refers to the Director's institution decision and the Board's final written decision on the merits. App., *infra*, 15a. The court nonetheless opined that both decisions could be made by the Board because "the Director" has "inherent authority and general rulemaking authority" to delegate the institution function to the

Board. *Id.* at 20a. Neither of those supposed sources of authority can surmount the self-evident separation of decisionmakers that Congress demanded.

As Judge Newman explained, the Federal Circuit's reasoning misses the proper inquiry:

[F]ram[ing] the issue as a simple exercise of the Director's rulemaking and/or delegation authority \*\*\* obscures the legislative point; the Director may generally subdelegate, and may exercise procedural rulemaking authority, with regard to these proceedings. Here, however, the statute creates an explicit distinction between the institution phase assigned to the Director, and the merits phase conducted by the [Board]. question presented, therefore, is whether the PTO may ignore the explicit provision and congressional statutory The answer is intent to the contrary. unequivocally no.

App., infra, 46a.

Judge Newman is correct. Although agency heads generally have authority to delegate their tasks, Congress may explicitly or implicitly circumscribe delegation by either restricting that authority or the delegee's ability to undertake delegated tasks. See Fleming v. Mohawk Wrecking & Lumber Co., 331 U.S. 111, 121 (1947) (delegation authority may be limited "by express provision \*\*\* or by implication"); Halverson v. Slater, 129 F.3d 180, 188-189 (D.C. Cir. 1997) (holding that "Congress's evident intent to circumscribe the [delegee's] operations within narrow geographic and functional

boundaries \*\*\* necessarily limits the Secretary's [statutory delegation] authority"). That is true where the statute elsewhere provides for general delegation authority, see United States v. Giordano, 416 U.S. 505, 514 (1974) ("Despite § 510 [general delegation authority], Congress does not always contemplate that the duties assigned to the Attorney General may be freely delegated."), or where "a rule-making power" serves as "an adequate source of authority to delegate," Fleming, 331 U.S. at 121. At bottom, the question is whether a "provision in the \*\*\* Act negative[s] the existence of such authority" or "the absence of such authority [can] be fairly inferred from the history and content of the Act." Id. at 121-122.

Here, the Federal Circuit acknowledged but gave short shrift to those principles. App., *infra*, 16a (stating that delegation may be precluded by "evidence of a contrary congressional intent," such as "the enabling statute" and "legislative history") (citation and quotation marks omitted). As an initial matter, the AIA's express division of labor between the Director (instituting review) and the Board (conducting review) itself forecloses the former from delegating away her statutorily specified institution authority to the latter.

In addition, Congress made clear that the Director may delegate her duties only to officers and employees whom she appoints or hires. See 35 U.S.C. § 3(b)(3) (providing that "[t]he Director shall \*\*\* appoint such officers, employees \*\*\*, and agents of the Office as the Director considers necessary" and "delegate to them such of the powers vested in the Office as the Director may determine"). There is no similar provision authorizing unconstrained

delegation to officials whom she does not appoint, such as the Board's administrative law judges who are "appointed by the Secretary [of Commerce]." *Id.* § 6(a). Congress certainly could have imbued the Director with that broader delegation authority, but the fact that it did not "lend[s] support to the view that when Congress desired to give authority to delegate, it said so explicitly." *Fleming*, 331 U.S. at 121.

This Court's decision in Cudahy Packing Co. v. Holland—finding "fairly inferable that the grant of authority to delegate the power of inspection and the omission of authority to delegate the subpoena power shows a legislative intention to withhold the latter" underscores that point. 315 U.S. at 364. The AIA's omission of certain PTO officials (including the Board's judges) from its authorization to delegate to other PTO officials is meaningful. The Federal Circuit's backhanded dismissal of Cudahy on the supposed ground that "lower courts no longer follow it" cries out for this Court's attention. App., infra, 17a 1 RICHARD J. PIERCE, (quoting ADMINISTRATIVE LAW TREATISE § 2.7, at 125 (5th ed. 2010)).

b. The Federal Circuit discounted all of those statutory and precedential limits on delegation on the view that "Congress obviously assumed that the Director would delegate" rather than "review every petition" herself. App., infra, 18a; see id. at 20a ("Congress undoubtedly intended the Director to have power by rulemaking \*\*\* to subdelegate tasks assigned to her in the interest of efficiency."). That purported efficiency justification cannot surmount the AIA's text, but it is a non sequitur in any event.

Although "the Director, as head of the PTO, regularly assign[s] tasks to subordinate officers" in situations such as (re)issuing patents, *id.* at 18a (citing 35 U.S.C. § 131, 132(a), 251(a)), those delegations shed no light on whether the delegation of the institution decision to the Board specifically is lawful here.

Even on its own terms, the Federal Circuit's expediency concern is unfounded. Precluding delegation of the institution decision to the Board would not force the Director herself to review every inter partes review petition. As Judge Newman observed, "[o]f course, the Director may designate an examiner or solicitor to conduct this initial review." App., *infra*, 27a (Newman, J., dissenting). Had the Director done so, there would be no issue.

But delegating the institution duty to the Board is another matter. Even beyond the statutory impediments to such a delegation, the Board's administrative law judges are particularly ill-suited to exercise the sort of executive discretion the AIA vested in the Director with respect to institution and associated procedural matters. Indeed, the Federal Circuit all but ignored the fact that Congress armed the Director with the ability (i) to protect the operation of the inter partes review system by declining to institute review even where the statutory threshold is met, and (ii) to determine the manner in which inter partes review and related proceedings should proceed. See pp. 22-24, infra.

Nor is there any basis to read section 3(b)(3) as anything but a constraint on the Director's authority to delegate the institution decision to the Board. The Federal Circuit took the view that section 3(b)(3) fails to impose that constraint because it is not directed at a particular "function" and does not expressly limit the Director's authority to delegate to other independently appointed officials. App., infra, 19a. But there is no reason to treat express authority to delegate particular functions differently from express authority to delegate to particular officials; either Congress's provision of limited delegation authority indicates that Congress did not intend to permit other delegations by implication. To hold otherwise would furnish the Director with an unbounded delegation authority that renders section 3(b)(3)(B) entirely superfluous. See Corley v. United States. 556 U.S. 303. 314 (2009) (rejecting interpretation "at odds with one of the most basic interpretive canons" of avoiding surplusage).

At any rate, considering section 3(b)(3) together with the scope of the Board's authority—something the Federal Circuit did not do—demonstrates that delegation scheme does cabin Congress's Director's inherent or implied delegation authority by The Director may freely delegate to her appointees, but with respect to other PTO officials she may assign only those tasks consistent with the scope of the authority that Congress conferred on those officials. See Gomez, 490 U.S. at 864 ("When a statute creates an office to which it assigns specific duties, those duties outline the attributes of the office. Any additional duties performed pursuant to a general authorization in the statute reasonably should bear some relation to the specified duties."). With respect to inter partes review, the only jurisdiction that Congress conferred on the Board is the power to "conduct" inter partes review. 35 U.S.C. § 6(b)(4).

# B. Congress Did Not Sanction A Departure From Established Administrative Law Principles

Not only is the principle of inherent delegation authority insufficient to trump the text and structure the AIA, but a longstanding principle administrative law confirms Congress's choice to limit the Board's role to conducting—not instituting-inter partes review. As the Federal Circuit acknowledged, App., infra, 12a n.3, the APA generally precludes the combination of executive and adjudicative functions below the level of agency head. See 5 U.S.C. § 554(d) (prohibiting an "employee or agent engaged in the performance of investigative or prosecuting functions for an agency in a case" from "participat[ing] or advis[ing] in the decision"); Martin v. Occupational Safety & Health Review Comm'n, 499 U.S. 144, 151 (1991) ("[U]nder the Administrative Procedure Act (APA) [an agency] generally must divide enforcement and adjudication separate personnel[.]"). Congress enacted "ameliorate provision to the evils from the commingling of functions" by separating the "discretionary work of the administrator," action," "initiat[ing] from the work "of the [administrative] judge." Wong Yang Sung v. McGrath, 339 U.S. 33, 42, 46 (1950) (citation and quotation marks omitted).

Concern over those evils is doubly borne out here. In the final written decision, the same three administrative law judges that instituted interpartes review explained that they were "not persuaded that a change in claim construction from that issued in the Decision to Institute is merited," and credited the evidence of obviousness on which institution decision was based. App., infra, 56a-67a. More broadly, "[t]he Board has reversed course and found patentability after institution in just 9% of inter partes reviews." Id. at 47a (Newman, J., dissenting from denial of rehearing en banc). At the very least, those statistics raise the specter of "prejudgment" that the APA's separation-offunction's provision guards against. Id.; see Wong Yang Sung, 339 U.S. at 42 ("Commission decisions affecting private rights and conduct lie under the suspicion of being rationalizations of the preliminary findings which the commission \*\*\* presented to itself.") (citation and quotation marks omitted).

The Federal Circuit rejected the application of the APA's separation-of-functions provision here because it concluded that both the institution and final decisions are "adjudicatory decisions" and do not combine adjudicative and executive functions. App., infra, 13a. Not so. The AIA reflects Congress's intent to make the institution decision discretionary, executive gatekeeping determination distinct from the purely adjudicatory function of deciding patentability. It is plain that institution is not solely an adjudicative function because the AIA does not require the Director to institute an inter partes review whenever the institution standard is satisfied—i.e., whenever there is a "reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged." Rather, the Act provides the U.S.C. § 314(a).

Director with discretion to institute an inter partes review (or not) when that standard is met. Id. (Director "may" institute); see Kingdomware Techs., Inc. v. United States, 136 S. Ct. 1969, 1977 (2016) ("the word 'may' \*\*\* implies discretion"); see also 157 CONG. REC. S1377 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl) (explaining that the AIA reflects a legislative judgment that it is better to turn away some petitions that otherwise satisfy the threshold for instituting review than for the PTO to develop a backlog). That the Director's institution decision is non-appealable—thereby conferring unreviewable discretion on the Director—reinforces that it is an executive function. See 35 U.S.C. § 314(d); Cuozzo, 136 S. Ct. at 2140.

The Director's role in inter partes review is also infused with discretion in other respects. In making the institution determination, Congress contemplated Director would take into considerations outside of the merits of the petition at considerations regarding including operations of the PTO. See, e.g., 35 U.S.C. § 316(b) (requiring the Director to consider, inter alia, the economy, the integrity of the patent system, and the efficient administration of the Office in adopting inter partes review regulations); AIA, Pub. L. No. 112-29, § 6(c)(2)(B), 125 Stat. at 304 (permitting the Director to set a limit upon the number of inter partes review proceedings in the first years after the Act goes into Similarly, "the Director, in his or her discretion, may join \*\*\* a party" that separately files a petition that "the Director \*\*\* determines warrants the institution of an inter partes review." 35 U.S.C. § 315(c). And in the face of related PTO proceedings, "the Director may determine the manner in which the inter partes review \*\*\* may proceed, including providing for stay, transfer, consolidation, or termination"—regardless of the merits. *Id.* § 315(d).

Because the statute contemplates that the Director's threshold management of inter partes review—including the unreviewable institution decision—would turn on factors beyond the application of the institution standard to a particular petition, it is a quintessentially executive function akin to the administrative prosecutorial function. Cf. Heckler v. Chaney, 470 U.S. 821, 831 (1985) (An agency decision whether to initiate an enforcement action "often involves a complicated balancing of a number of factors," including "not only \*\*\* whether a violation has occurred, but whether agency resources are best spent on this violation or another," whether taking action "best fits the agency's overall policies," and "whether the agency has enough resources.").

The Board, as an adjudicative body, is not equipped to make these sorts of discretionary determinations. And assigning the institution decision to that body turns an executive function into a wholly adjudicative one. See App., infra, 78a-79a (instituting inter partes review based exclusively on section 314(a) reasonable likelihood standard without consideration of other factors). The AIA forecloses that result.

#### OF DIRECTOR'S DELEGATION II. THE **AUTHORITY** TO THE INSTITUTION **EXCEPTIONALLY** IS AN BOARD IMPORTANT ISSUE OF PATENT LAW AND ADMINISTRATIVE LAW

commingling of inter partes decisionmakers, as endorsed by the Federal Circuit, subverts congressional intent, flouts statutory limits of delegation authority, exercise and the administrative law established contravenes principles. It also undermines a decades-long effort, culminating in the enactment of the AIA, to "correct flaws in the [U.S. patent] system that ha[d] become unbearable, and to accommodate changes in the economy and the litigation practices in the patent realm." H.R. REP. No. 112-98, pt. 1, at 38-39 (2011). And worse still, it "has devastating consequences for the public confidence in post-grant proceedings and the patent system as a whole." App., infra, 47a (Newman, J., dissenting from denial of rehearing en This Court's review is thus of undeniable banc). importance.

#### A. The Decision Below Unduly Expands Agency Authority

By relying on two atextual agency powers—inherent delegation authority plus *Chevron* deference—the Federal Circuit has swept aside statutory constraints on the Director's delegation authority both generally (35 U.S.C. § 3(b)(3)) and with respect to inter partes review institution decisions specifically (id. §§ 314, 316(c)). In doing so, as explained above, the Federal Circuit has trampled on longstanding precedents of this Court that dictate

a nuanced statutory analysis of limits on an agency head's delegation authority, and that require the separation of an agency's executive and adjudicative functions. *See* pp. 15-24, *supra*.

In particular, the Federal Circuit's invocation of the Director's "inherent" delegation authority, coupled with its application of *Chevron* deference to the Director's general rulemaking authority, App., *infra*, 20a, confers on an agency head essentially carte blanche to delegate her powers unless Congress (unrealistically) creates even more specific and explicit limits than already present in the Patent Act. That significant expansion of agency authority, as well as the need to harmonize the administrative law applied to the PTO with general principles of administrative law applied to other agencies, warrants this Court's review.

#### B. Disregard Of The Statutory Safeguards Governing Inter Partes Review Demands Intervention

The creation of inter partes review was a "[k]ey [e]lement[]" of long overdue patent reform. Press Release, The White House, President Obama Signs America Invents Act, Overhauling the Patent System to Stimulate Economic Growth, and Announces New Steps to Help Entrepreneurs Create Jobs (Sept. 16, 2011). 4 But it was not without controversy. The legislative "record is replete with \*\*\* concerns of commentators, patentees, and the PTO" that inter

<sup>4</sup> https://www.whitehouse.gov/the-press-office/2011/09/16/president-obama-signs-america-invents-act-overhauling-patent-system-stim.

partes review would "increase the risks faced by patent holders and dampen their enthusiasm for investing in the development and commercialization of their patented technologies." App., infra, 43a (Newman, J., dissenting from the denial of rehearing en banc) (citation and quotation marks omitted). Congress addressed those concerns by "meticulously incorporat[ing] safeguards against \*\*\* harassment of patentees" and "carefully design[ing] post-grant procedures"—of which "[t]he Director's institution decision" is critical. Id. at 43a-44a; see id. at 45a ("Independence of the two decision-makers is crucial to achieving the statutory purpose.").

In allowing those statutorily mandated safeguards to be removed by regulation for sake of expediency, the Federal Circuit vitiated the careful balance struck by Congress and "[t]hreaten[ed] the viability of this new system." App., infra, 31a The more than 4,000 (Newman, J., dissenting). petitions for inter partes review to date—at least three times as many as initially anticipated-make clear that such proceedings "have become the new frontier of patent litigation." *Id.* at 31a & n.1.; Michelle K. Lee, PTAB Update: Proposed Changes to Rules Governing PTAB Trial Proceedings, Director's Forum: A Blog from USPTO's Leadership (Aug. 19, 2015) (providing statistics).<sup>5</sup> But that new frontier at a minimum bears the "taint of prejudgment," App., infra, 47a (Newman, J., dissenting from denial of rehearing en banc), that naturally arises when

<sup>5</sup> http://www.uspto.gov/blog/director/entry/ptab\_update\_proposed\_changes\_to.

"administrative patent judges are put in the position of defending their prior decisions to institute the trial," id. at 32a (Newman, J., dissenting) (citation and internal quotation marks omitted). Strikingly, according to the PTO's latest statistics, 85% of patents that reach a final written decision are invalidated in whole or in part. USPTO, Patent Trial and Appeal Board Statistics 10 (July 31, 2016)6; see also App., infra, 47a (Newman, J., dissenting from denial of rehearing en banc) ("[J]ust 15.2% of instituted claims survive [ inter partes review."). A patent system with "th[os]e numbers do[es] not bode confidence," App., infra, 47a (Newman, J., dissenting from denial of rehearing en banc), let alone "promote innovation" or "benefit∏ the public," H.R. REP. No. 112-98, pt. 1, at 40; see also Richard Baker, America Invents Act Cost the U.S. Economy Over \$1 Trillion, Patently O (June 8, 2015) (discussing economic impact of inter partes review).7

At stake, therefore, is not only the fair and lawful operation of the inter partes review system, but the strength of the patent system as a whole. In granting certiorari in *Cuozzo*, 136 S. Ct. 2131, this Court signaled the importance of ensuring that inter partes review functions as Congress intended. And as evidenced by the number of certiorari petitions challenging various facets of inter partes review, *e.g.*, *Merck & Cie v. Gnosis S.p.A.*, No. 16-125 (U.S.)

 $<sup>^6</sup>$  http://www.uspto.gov/sites/default/files/documents/2016-07-31%20PTAB.pdf.

<sup>&</sup>lt;sup>7</sup> http://patentlyo.com/patent/2015/06/america-invents-trillion.html.

(standard of review); Cooper v. Square, Inc., No. 16-76 (U.S.) (violation of Article III); MCM Portfolio LLC v. Hewlett-Packard Co., No. 15-1330 (U.S.) (violation of Article III and Seventh Amendment), the manner in which those proceedings are conducted continues to be a subject of pressing concern to stakeholders—including amici that urged the Federal Circuit to reconsider the decision below. Because this case constitutes the most straightforward way to restore the promise of inter partes review as enacted by Congress, this Court's review is warranted.

#### CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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