No. 16-366

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,

Respondents.

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

BRIEF OF COVIDIEN LP IN OPPOSITION

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CORPORATE DISCLOSURE STATEMENT

The sole parent corporation or publicly held company that owns 10 percent or more of the stock of Covidien LP (formerly known as Tyco Healthcare Group LP) is Medtronic PLC.

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INTRODUCTION

After fully participating in a post-grant proceeding in the Patent Office, and after its patent was held invalid, Petitioner Ethicon Endo-Surgery, Inc. raised for the first time on appeal a challenge to the Patent Office's procedure for instituting review. But this Court has already found that Congress gave the Patent Office wide latitude to issue rules governing post-grant proceedings and that the Patent Office's decision to institute review is generally not reviewable. *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2137, 2140, 2141 (2016). Also, Ethicon does not contest that its patent is substantively invalid, which was affirmed by the Federal Circuit, mooting the technical procedural issues raised in the petition. There simply is no reason to upend the institution procedure the Patent Office has used in the over five thousand post-grant proceedings since the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (AIA), was enacted.

Ethicon challenges only the court of appeals decision upholding the Patent Office regulation providing: "The Board institutes the trial on behalf of the Director." 37 C.F.R. 42.4(a). The AIA gives the Director authority to determine whether a post-grant proceeding, such as an inter partes review, should be instituted, and she has delegated this task to the Patent Trial and Appeal Board, of which she is a member. *Id.*; 35 U.S.C. §§ 314(a), 6(a). The practice of delegating the institution decision to a panel of technically trained Board judges does not contravene the AIA. Pet. App. 15a-21a.

Congress's specific grant of the institution power to the Director does not simultaneously mean that this function cannot be delegated. Subdelegation is prohibited only when there is a clear congressional intent to do so. Ethicon itself has conceded that the

Director need not review every post-grant petition personally and may delegate that authority. Brief of Appellant at 29, *Ethicon Endo-Surgery, Inc. v. Covidien LP*, 812 F.3d 102 (Fed. Cir. 2016) (No. 14-1771) (D.I. 17, 18). The Federal Circuit found that "Congress obviously assumed that the Director would delegate" (Pet. App. 18a), and noted that Ethicon could "point to no * * * aspects of the AIA here suggesting that delegation by the Director to the Board is impermissible," *id.* at 17a. Ethicon's petition still cannot point to any aspect proscribing delegation to the Board.

In *Cuozzo*, this Court considered the rulemaking authority granted to the Patent Office in the AIA. The Court determined that, through 35 U.S.C. § 316(a)(4), the Patent Office was given broad rulemaking authority in the inter partes review context, even beyond what it possessed previously. *Cuozzo*, 136 S. Ct. at 2142-2143.

Here, the Federal Circuit recognized that express grant of authority as confirmed by *Cuozzo*: "Congress undoubtedly 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." Pet. App. 20a. In light of that broad grant, and given that "reference to 'the Director' in the [AIA] is ambiguous as to whether it requires her personal participation" to institute proceedings, the Federal Circuit held 37 C.F.R. 42.4(a) "is a permissible interpretation of the statute" entitled to deference under *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842-843 (1984). Pet. App. 20a; *see also Cuozzo*, 136 S. Ct. at 2144 ("We conclude that the regulation represents a reasonable exercise of the rulemaking authority that Congress delegated to the Patent Office.").

There are no issues here that merit a writ of certiorari, and the Court should deny Ethicon's petition.

STATEMENT OF THE CASE

I. Party Background

This case involves medical instruments. Respondent Covidien LP is a leader in global healthcare. It develops a wide range of industry-leading products found in almost every hospital. Covidien's endomechanical instruments, including the Tri-Staple™ surgical stapler used to secure tissue, are important technologies that enhance quality of life and improve outcomes for patients.

Ethicon is a competitor of Covidien. Ethicon obtained U.S. Patent No. 8,317,070 (the '070 patent) broadly claiming aspects of surgical staplers that had earlier been developed by Covidien and its predecessors.

II. Board Proceedings

Relying on its own portfolio of patents as prior art, Covidien petitioned for inter partes review of claims 1-14 of Ethicon's '070 patent. The Board instituted review on six separate grounds. After a full trial, conducted over a year and culminating with an oral hearing, the Board found that the '070 patent claims were unpatentable for obviousness under 35 U.S.C. § 103. *See* Pet. App. 2a-3a, 7a, 50a.

III. The Federal Circuit's Decisions

Ethicon appealed the invalidation of the '070 patent to the Federal Circuit, which affirmed the Patent Office's decision. *See id.* at 2a-3a, 7a, 21a-24a. Ethicon

does not challenge the substantive determination of invalidity here. Pet. 7 n.1.

Ethicon also raised, for the first time on appeal, a technical complaint with the way the Patent Office decides to institute inter partes review proceedings. Ethicon expressed no such concern when the institution decision was made or while the matter was proceeding before the same Board panel that made the institution decision. Ethicon argued that the Board's final decision should be set aside because the same Board panel instituted and tried the case, allegedly depriving it of an impartial decision-maker. Pet. App. 8a-10a.

The Federal Circuit rejected Ethicon's argument, focusing on the Board's delegation authority:

> [B]oth as a matter of inherent authority and general rulemaking authority, the Director had authority to delegate the institution decision to the Board. There is nothing in the Constitution or the statute that precludes the same Board panel from making the decision to institute and then rendering the final decision.

Id. at 20a-21a. The court added that "Ethicon can point to no legislative history or any other aspects of the AIA here suggesting that delegation by the Director to the Board is impermissible." *Id*. at 17a. To the extent the "reference to 'the Director' in the statute is ambiguous as to whether it requires her personal participation," the Federal Circuit deemed 37 C.F.R. 42.4(a) a permissible interpretation of the statute under *Chevron*. *Id*. at 20a.

Ten judges of the Federal Circuit agreed that the issue did not merit reconsideration en banc. *Ethicon*

Endo-Surgery, Inc. v. Covidien LP, 826 F.3d 1366 (Fed. Cir. 2016) (per curiam).

REASONS FOR DENYING THE PETITION

I. This Case Does Not Raise an Issue of Exceptional Importance

Ethicon first complained about the Patent Office's post-grant procedure on appeal. Ethicon's failure to raise this issue when the agency could have addressed it shows that it was not important even to Ethicon. It only became important to Ethicon after the Board found its '070 patent invalid. But the Federal Circuit affirmed the invalidity determination, which Ethicon no longer challenges, making Ethicon's petition moot.

This Court has recognized the "important public interest" in getting rid of "worthless patents" that unfairly restrict competition. *Lear, Inc. v. Adkins*, 395 U.S. 653, 663-664, 670 (1969) (citation omitted). And in *Cuozzo*, the Court also noted that in the AIA, Congress gave the "Patent Office significant power to revisit and revise earlier patent grants." 136 S. Ct. at 2139-2140. When it came to determining whether the decision to institute an inter partes review proceeding should be appealable in view of this power, the Court stated:

> We doubt that Congress would have granted the Patent Office this authority, including, for example, the ability to continue proceedings even after the original petitioner settles and drops out, [35 U.S.C.] § 317(a), if it had thought that the agency's final decision could be unwound under some minor statutory technicality related to its preliminary decision to institute inter partes review.

Id. at 2140.

Ethicon also does not seriously challenge that the Director has authority to delegate the decision to institute an inter partes review petition. Ethicon has conceded that the Director need not personally make every institution decision. Reply Brief of Appellant at 10, *Ethicon Endo-Surgery, Inc. v. Covidien LP,* 812 F.3d 1023 (Fed. Cir. 2016) (No. 14-1771) (D.I. 43, 45) ("But Ethicon agrees that the Director need not personally make IPR institution decisions." (citation omitted)). Nor would it be practical to do so. Congress legislated knowing full well that impracticability. The only question is whether Congress expressly precluded the Director from delegating that authority to the Board, of which the Director is a member. It did not. This is precisely the type of technical argument that this Court noted in *Cuozzo* should not allow a party to unwind a finding of invalidity. 136 S. Ct. at 2140.

While Ethicon suggests that the Director could delegate that authority to the patent examining corps, nothing in the AIA indicates that Congress sought that result, and there is nothing to suggest that the examining corps would be better suited to decide institution. In any event, the decision of who should make the institution decision is properly left to the discretion of the Director. Nothing about the exercise of that discretion rises to the level of an issue of exceptional importance warranting this Court's intervention.

While Ethicon raised constitutional avoidance issues to the appellate court,[1] it has abandoned that argument

[1] At the heart of Ethicon's appeal was its contention that judges on Board panels necessarily suffer from "bias" because they have already decided once against the patent owner at institution. Brief of Appellant at 35-43, *Ethicon Endo-Surgery, Inc. v. Covidien LP*, 812 F.3d 1023 (Fed. Cir. 2016) (No. 14-1771) (D.I.

here. Ethicon did not raise due process at all in its petition to this Court. *Republic of Argentina v. NML Capital, Ltd.*, 134 S. Ct. 2250, 2254-2255 (2014) (stating that the Court "need not take up [certain] issues today, since Argentina has not put them in contention," and noting that it would only decide the narrow question posed in the petition for a writ of certiorari). Thus, this petition presents no constitutional issue of exceptional importance.

Because Ethicon has given up a due process claim here, its suggestions that the Board's decision bears the "taint of prejudgment" and that "administrative patent judges are put in the position of defending their prior decisions to institute the trial," should be ignored. Pet. 12, 27-28 (citations omitted). Moreover, any arguments by amici that there are due process concerns are irrelevant now.

II. The Federal Circuit's Decision Follows the Governing Statute

Ethicon's petition relies on the separate provisions of the AIA describing institution by the Director and trial proceedings by the Board, respectively, under 35 U.S.C. §§ 314(a) and 316(c). But, as the Federal Circuit held, Congress's grant of the institution power to the Director does not mean that the function cannot be delegated to the Board.

A. The Director Has Broad Rulemaking Authority

The Patent Office Director has broad statutory authority to issue regulations. Under 35 U.S.C.

17, 18). The Federal Circuit, however, rejected Ethicon's allegedly "serious due process concerns," *id*. at 35, since the law is clear that a judge's "pretrial involvements" *do not* "'raise any constitutional barrier against the judge's presiding' over the later trial." Pet. App. 13a (quoting *Withrow v. Larkin*, 421 U.S. 35, 56 (1975)).

§ 2(b)(2)(A), the Patent Office "may establish regulations * * * govern[ing] the conduct of proceedings in the Office." "[B]y this grant of power," notes the Federal Circuit, "we understand Congress to have 'delegated plenary authority over PTO practice * * * ' to the Office." *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1335 (Fed. Cir. 2008) (second alteration in original) (citation omitted).

The AIA conveys further rulemaking authority to the Patent Office. The statute provides that the "Director shall prescribe regulations," *inter alia*, "establishing and governing inter partes review." 35 U.S.C. § 316(a)(4). The AIA also mandates: "In prescribing regulations under this section, the Director shall consider 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(b).

Pursuant to these express grants of authority, the Patent Office issued regulations governing inter partes reviews, including the one subdelegating institution decisions to the Board. *See* 37 C.F.R. 42.4(a), 42.108. On appeal, the Federal Circuit recognized that express grant of authority—as later confirmed by the Court in *Cuozzo*—was an important ground supporting the Patent Office's institution procedures. *See* 136 S. Ct. at 2137, 2144 (the AIA "grants the Patent Office the authority to issue rules. § 316(a)(4) * * * . [W]hether we look at statutory language alone, or that language in context of the statute's purpose, we find an express delegation of rulemaking authority * * * .."). The Federal Circuit declared:

> Congress's vesting of broad rulemaking powers in the head of the agency is an alternate

> source of authority to delegate. * * * Congress undoubtedly 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.

Pet. App. 20a. The Federal Circuit's conclusion here that § 316(a)(4) gave the Patent Office broad rulemaking authority to conduct inter partes reviews is consistent with *Cuozzo*, 136 S. Ct. at 2142-2143.

B. Subdelegation Is Presumptively Permissible Under This Court's Precedent

Subdelegation is prohibited only when there is a clear congressional intent to do so. *United States v. Giordano*, 416 U.S. 505, 513-514 (1974); *accord Kobach v. U.S. Election Assistance Comm'n*, 772 F.3d 1183, 1190 (10th Cir. 2014) (appellate courts "are unanimous in permitting subdelegations to subordinates, even where the enabling statute is silent, so long as the enabling statute and its legislative history do not indicate a prohibition on subdelegation"), *cert. denied*, 135 S. Ct. 2891 (2015). Consistent with the "unanimous" practice of other circuits, *id*., the Federal Circuit stated:

> The implicit power to delegate to subordinates by the head of an agency was firmly entrenched in *Fleming* * * * , where the Supreme Court held the administrator of an agency could delegate the power to sign and issue subpoenas to regional administrators despite absence of an explicit authorization in the statute. "When a statute delegates authority to a federal officer or agency, subdelegation to a

> subordinate federal officer or agency is presumptively permissible absent affirmative evidence of a contrary congressional intent."

Pet. App. 16a (first citing *Fleming v. Mohawk Wrecking & Lumber Co.*, 331 U.S. 111, 122 (1947), and then quoting *U.S. Telecom Ass'n v. FCC*, 359 F.3d 554, 565 (D.C. Cir. 2004)). The general principle of presumptive permissibility to delegate is so widely accepted that this Court has called it "unexceptional." *Giordano*, 416 U.S. at 514.

Although Ethicon admits that "agency heads generally have authority to delegate their tasks" (Pet. 16), it relies on *Cudahy Packing Co. of Louisiana v. Holland*, 315 U.S. 357, 364 (1942), to suggest an affirmative grant of authority is required (Pet. 18). Ethicon argues that the Federal Circuit gave the case a "backhanded dismissal" such that it "cries out for this Court's attention." *Id.*; *see also id.* at 8. The opposite is true.

The Federal Circuit carefully assessed *Cudahy*, finding its applicability had been expressly limited by this Court's later discussion in *Fleming*. Pet. App. 17a. In *Fleming*, this Court distinguished the case by name, observing that the "legislative history of the Act involved in the *Cudahy* case showed that a provision granting authority to delegate the subpoena power had been eliminated when the bill was in Conference." *Fleming*, 331 U.S. at 120. Thus, there was a clear, contrary congressional intent manifest in *Cudahy*, removing it from the ambit of a presumptively permissible delegation. *Id*. at 121; *see also* Pet. App. 17a ("[T]he Supreme Court later clarified in *Fleming* that the *Cudahy* decision was based on explicit legislative history * * * .

Cudahy simply stands for the unremarkable proposition that congressional intent to preclude delegation can sometimes be found in the legislative history.").[2]

The Federal Circuit properly followed this Court's analysis in distinguishing *Cudahy*, holding that "[w]hen a statute delegates authority to a federal officer or agency, subdelegation to a subordinate * * * is presumptively permissible absent affirmative evidence of a contrary congressional intent." Pet. App. 16a (citation omitted). Nothing in the Federal Circuit's treatment of fact-bound *Cudahy* "cries out" for this Court's review. Pet. 18.

C. Subdelegation Is Not Clearly Prohibited Under the AIA

Under the AIA, Director delegation of the institution decision to the Board is *not* prohibited. Ethicon urges that the existence of separate provisions for institution decisions and trial proceedings itself establishes that institution cannot be delegated to the Board. But nowhere is such a restriction remotely, much less clearly, expressed in the statute. Just because Congress specifically gave the Director the power to institute, 35 U.S.C. § 314(a), does not imply an inability to delegate that function to the Board. Pet. App. 15a; *Giordano*, 416 U.S. at 513-514 ("[M]erely vesting a duty in the [agency head] * * * evinces no intention whatsoever to preclude delegation to other officers * * * .").

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[2] This Court also noted in *Fleming* that the "Act involved in the *Cudahy* case granted no broad rule-making power." 331 U.S. at 121. That observation makes *Cudahy* all the more inapplicable in this case where the Patent Office has abundant rulemaking power, as confirmed in *Cuozzo*. *See* pp. 7-9, *supra*.

The Federal Circuit closely scrutinized the AIA and congressional record to determine that there was "nothing in the statute or legislative history of the statute indicating a concern with separating the functions of initiation and final decision." Pet. App. 15a. Indeed, the legislative history even contains a specific mention of administrative patent judges making the institution decisions. In June 2011, only a few months before the AIA was enacted, Representative Lamar Smith said: "[I]t bears repeating that defendants cannot even start this program unless they can persuade *a panel of judges* at the outset of the proceeding that it is more likely than not that the patent is invalid." 157 Cong. Rec. E1183-84 (daily ed. June 23, 2011) (emphasis added). The need to pass before a panel of technically trained administrative patent judges before institution was seen as a salutary feature for patent owners. *See id*. Ethicon cites no contrary legislative history.

In sum, on the question of whether the AIA prohibits Director delegation to the Board, there is simply "no provision in the present Act negativing the existence of such authority," neither "can the absence of such authority be fairly inferred from the history and content of the Act." *See Fleming*, 331 U.S. at 121-122. Because, still, "Ethicon can point to no legislative history or any other aspects of the AIA here suggesting that delegation by the Director to the Board is impermissible," there is nothing to suggest that the Director may not assign this task to the Board. Pet. App. 17a.

D. A Provision on Appointments Does Not Limit Delegation

In the absence of an express prohibition on delegation in the AIA, Ethicon reaches for another provision

in the Patent Act, enacted years prior. It is irrelevant here.

Ethicon argues that subdelegation to "other officers and employees" in 35 U.S.C. § 3(b)(3)(B) cannot include members of the Board because 35 U.S.C. § 6 was amended in 2008 to provide that members of the Board are appointed by the "Secretary, in consultation with the Director," rather than by the Director directly. Pet. 11-12; 35 U.S.C. § 6(a), *amended by* Pub. L. No. 110-313, § 1(a)(1), 122 Stat. 3014, 3014 (2008), *and* AIA, Pub. L. No. 112-29, § 7(a)(1), 125 Stat. 284, 313 (2011). For context, § 6 was amended due to concerns about whether appointments by the Director violated the Appointments Clause, U.S. Const. art. II, § 2, cl. 2.[3]

On its face, § 3(b)(3)(B) addresses delegation only to the offices that the Director creates. It says nothing about the Director's ability to delegate to the offices created elsewhere by the statute. The Federal Circuit found that 35 U.S.C. § 3(b)(3) is therefore no impediment to delegating institution decisions to the Board in AIA post-grant proceedings. Pet. App. 19a-20a. That provision is actually "a source of authority for the Director to appoint subordinates and assign them tasks. * * * We conclude that the Director here has the inherent authority to delegate institution

[3] Senator Kyl stated, "Section 6 of the [AIA] bill includes all provisions of the bill addressing the jurisdiction of the Patent Trial and Appeal Board and administrative and judicial appeals. In section 6(a), the recodification of section 6 of title 35 is modified so that all members of the PTAB can participate in all proceedings. Also, subsection (d) is added to the recodification of section 6 of title 35. By omitting this provision, the 2009 bill would have effectively repealed the APJ 'appointments fix' that had been enacted in 2008." 157 Cong. Rec. S1377 (daily ed. Mar. 8, 2011).

decisions to the Board." *Id*. "Thus, § 3(b)(3) cannot be read to limit the ability of the Director to delegate tasks to agency officials not mentioned in § 3(b)(3)." Pet. App. 19a.

Ethicon's interpretation of §§ 3(b)(3) and 6 would create the anomalous situation where the Director could not delegate any duties to the Deputy Director or Commissioner for Patents and Trademarks because they are appointed by the Secretary, not the Director. *See* 35 U.S.C. §§ 3(b)(1), (2). Congress only gave the Deputy Director "the authority to act in the capacity of the Director in the event of the absence or incapacity of the Director." 35 U.S.C. § 3(b)(1). As a result, unless the Director can delegate responsibilities to the Deputy Director, he would be left with none except for preparing to act in the event of absence or incapacity of the Director. This absurd result cannot be what was intended by § 3(b)(3).

Nothing in the legislative history surrounding the changes to § 6, or additional ones made in connection with the AIA, shows that Congress intended to limit the Director's authority to delegate responsibilities when it made the Secretary of Commerce ultimately responsible for appointments to the Board. Sections 3(b)(3) and 6 do not show a congressional intent to prohibit Director delegation to the Board in AIA post-grant proceedings.

III. The Regulation Is Entitled to *Chevron* Deference

The regulation allowing the Board to institute trial on behalf of the Director is entitled to deference under *Chevron*, 467 U.S. at 842-843. The Federal Circuit held that reference to "the Director" in the AIA "is ambiguous as to whether it requires her personal

participation," such that institution by the Board on behalf of the Director, *see* 37 C.F.R. 42.4(a), is a permissible interpretation of the statute entitled to deference. Pet. App. 20a.

This result follows the Court's holding in *Cuozzo*: "[W]here a statute leaves a 'gap' or is 'ambigu[ous],' we typically interpret it as granting the agency leeway to enact rules that are reasonable in light of the text, nature, and purpose of the statute. * * * We conclude that the regulation represents a reasonable exercise of the rulemaking authority that Congress delegated to the Patent Office." 136 S. Ct. at 2142, 2144 (second alteration in original).

A. Congress Did Not Speak Directly to the Question at Issue

On the question of "whether Congress has directly spoken to the precise question at issue," *Chevron*, 467 U.S. at 842, the Federal Circuit found that there is nothing in the AIA expressly prohibiting the Director's delegation of institution decisions to the Board. Congress has not spoken directly to this precise question because the reference to "the Director" in the statute is ambiguous as to whether it requires her personal participation. Pet. App. 20a.

The Federal Circuit recognized that Congress speaks throughout the Patent Act of the agency's daily functions as though they were performed personally by the Director, though they plainly are not. *See, e.g.*, 35 U.S.C. § 131 ("the Director shall issue a patent"); 35 U.S.C. § 132(a) ("the Director shall notify the applicant" of the rejection of a patent application); 35 U.S.C. § 251(a) ("the Director shall" reissue amended patents). Pet. App. 18a.

The Court's decision in *Cuozzo* also reflects this pattern of referring to the Patent Office as an entity in which the Director seamlessly delegates tasks to subordinates, without differentiation as to actors. For example, the Court states that "the *Patent Office* * * * 'determin[ed] * * * to institute an inter partes review,'" and that "the *Patent Office* [has] authority to issue 'regulations * * * establishing and governing inter partes review.'" *Cuozzo*, 136 S. Ct. at 2136 (emphases added) (quoting 35 U.S.C. §§ 314(d), 316(a)(4)); *see also id*. at 2137 ("Ultimately, the *Patent Office* makes a final decision allowing or rejecting the application." (emphasis added)); *id*. at 2146 ("The statute gives the *Patent Office* the power to consolidate these other proceedings with inter partes review." (emphasis added)). This underscores the understanding that Congress has vested in the heads of most executive-branch agencies very broad statutory authority to establish regulations and conduct proceedings, including through widespread subdelegation. The Patent Office is no exception.

Knowing the Director's practice and presumptive ability to delegate, Congress could easily have prohibited the Board from making institution decisions had it wanted to. The Federal Circuit was correct that "nothing in the statute or legislative history of the statute" affirmatively bars the Board from this presumptively permissible Director delegation. Pet. App. 15a.

B. Permissible Construction

The second *Chevron* question, whether the agency's interpretation is based on a permissible construction of the statutory language at issue, is also met here.

The AIA provisions establishing inter partes review were intended to permit the validity of patents to be determined quickly and efficiently, and the regulation in question does this. *See Cuozzo*, 136 S. Ct. at 2139-2140 (finding that "a contrary holding would undercut one important congressional objective, namely, giving the Patent Office significant power to revisit and revise earlier patent grants"); *id*. at 2137 (noting that the statute sets forth time limits for completing this review). The Director must consider the "efficient administration of the Office, and the ability of the Office to timely complete proceedings" in promulgating regulations. 35 U.S.C. § 316(b).

Delegating the institution decisions to the same merits panel of the Board effects this legislative mandate. From a practical standpoint, the Director's ability to delegate the institution decision to the Board is absolutely necessary "in view of the magnitude of the task." *Fleming*, 331 U.S. at 122-123. Congress knew that "establish[ing] a more efficient and streamlined patent system that will improve patent quality" and "creat[ing] a timely, cost-effective alternative to litigation," as a practical matter, implicated the Board. *See* Changes to Implement Inter Partes Review Proceedings, Post-Grant Review Proceedings, and Transitional Program for Covered Business Method Patents, 77 Fed. Reg. 48,680, 48,680-01 (Aug. 14, 2012) (codified at 37 C.F.R. 42.100 *et seq.*).

Here, "Congress obviously assumed that the Director would delegate," given the expected volume of petitions and the timing mandated by statute. Pet. App. 18a. Still, no AIA language clearly prevents the Director from delegating anything to the Board—had Congress thought the Board unsuitable for making institution decisions, it could have expressed that

prohibition directly. *See Fleming*, 331 U.S. at 122 ("We would hesitate to conclude that all the various functions granted the Administrator need be performed personally by him or under his personal direction."). It did not.

The Patent Office has thus set forth a permissible interpretation of the statute at 35 U.S.C. § 314(a) entitled to deference, particularly in view of the statutory timing restrictions and unreviewability of institution decisions.

IV. Ethicon's Administrative Procedure Act Arguments Fail

Ethicon argues that the Patent Office's regulation at issue is an unsanctioned departure from administrative law principles, citing the Administrative Procedure Act (APA), 5 U.S.C. § 554(d), as allegedly prohibiting the regulation at 37 C.F.R. 42.4(a). *See* Pet. 21 (stating that "the APA generally precludes the combination of executive and adjudicative functions below the level of agency head"); *id*. at 22 ("The Federal Circuit rejected the application of the APA's separation-of-functions provision here * * * ."). This argument is waived and also fails on the merits.

A. The APA Argument Is Waived

As an initial matter, Ethicon has waived any argument regarding a would-be APA violation. Ethicon never raised the APA as an independent basis for challenging the regulation, either before the Board or on appeal. At the Federal Circuit, Ethicon referred to the APA in cursory fashion.[4] Having failed to make a

[4] Reference to the APA appears only under a "see also" signal at the end of a string cite in the Ethicon Opening brief below; in the Ethicon Reply brief below, the APA is referenced in a single

stand-alone APA claim below, it should not be permitted to now. *Taylor v. Freeland & Kronz*, 503 U.S. 638, 645-646 (1992); *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 147 n.2 (1970) ("Where issues are neither raised before nor considered by the Court of Appeals, this Court will not ordinarily consider them. We decline to do so here." (citing *Lawn v. United States*, 355 U.S. 339, 362-363 & n.16 (1958); *Husty v. United States*, 282 U.S. 694, 701-702 (1931); *Duignan v. United States*, 274 U.S. 195, 200 (1927))).

Commensurate with the short shrift given it by Ethicon, the Federal Circuit dispensed with the APA in a single footnote. Under its treatment of the larger due process questions, the Federal Circuit added only that "the APA imposes no separation obligation as to those involved in preliminary and final decisions." Pet. App. 12a-13a n.3.

Given that Ethicon has abandoned its due process mention, it should not be able to bootstrap the APA into this case now. Ethicon's current foray into an extended "executive discretion" argument (*see* Pet. 1-2, 9, 11-12, 19, 21-23) effectively raises a new APA issue, decoupled from the due process rationale the Federal Circuit addressed.

B. The APA Is No Impediment to the Patent Office Regulation

Even if this argument is permitted in its present form, Ethicon's attempt under the APA to contrive

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sentence under due process and is not an independent argument. *See* Brief of Appellant at viii, 34, *Ethicon Endo-Surgery, Inc. v. Covidien LP*, 812 F.3d 1023 (Fed. Cir. 2016) (No. 14-1771) (D.I. 17, 18); Reply Brief of Appellant at vi, 20, *Ethicon Endo-Surgery, Inc. v. Covidien LP*, 812 F.3d 1023 (Fed. Cir. 2016) (No. 14-1771) (D.I. 43, 45).

a binary distinction between "institution" and "adjudication" functions is unconvincing. *See* Pet. 2. The Federal Circuit held that the institution decision and the final written decision are merely phases of the same adjudicatory process, both able to be performed by the Board. *See* Pet. App. 10a-11a. "[T]he Supreme Court," noted the Federal Circuit of combining functions in an agency, "has upheld several such systems." *Id*. at 11a (quoting 2 Richard J. Pierce, Jr., *Administrative Law Treatise* § 9.9, p. 892 (5th ed. 2010)).

The plain text of 5 U.S.C. § 554(d)(2) prohibits only "investigative or prosecuting" personnel from participating in final adjudicative decisions. The Federal Circuit was thus correct when it observed that "the APA imposes no separation obligation as to those involved in preliminary and final decisions." Pet. App. 12a-13a n.3.

Significantly, Ethicon never explains why the Board is unable to perform both duties on its way to deciding patentability, like any judge might at different phases of a proceeding. It suggests that only the Director is able to exercise "discretion" at institution, and that "the Board's administrative law judges are particularly ill-suited to exercise the sort of executive discretion." Pet. 19. Yet, at the same time, Ethicon acknowledges that the Director *can* delegate the institution decision to others. *Id*. It suggests that institution authority can be delegated to patent examiners, *see id*., but does not explain how examiners are better positioned than members of the Board to exercise "discretion." Indeed, allowing examiners or others to fulfill this Director-delegated responsibility could itself run afoul the Appointments Clause, and avoidance principles of statutory construction require its rejection. *Rust v.*

Sullivan, 500 U.S. 173, 190-191 (1991).[5] Ethicon also fails to acknowledge that the Board often exercises its own discretion not to institute a proceeding, even if a petition or ground establishes unpatentability.[6]

And even if the Board makes an institution decision, the Director may still also exercise her discretion. The Director is not bound by a Board decision; in fact, the Board operates subject to the Director's ultimate authority and responsibility. *See In re Alappat*, 33 F.3d 1526, 1535 (Fed. Cir. 1994) (en banc). To avail themselves of such oversight, patent owners may, under existing rules, petition the Director. For example, 37 C.F.R. 1.181(a)(2), titled "Petition to the

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[5] The Supreme Court has held that one who "exercis[es] significant authority pursuant to the laws of the United States" is an "Officer." *Buckley v. Valeo*, 424 U.S. 1, 126 (1976) (per curiam). Examiners are merely employees of the Patent Office, not officers. Thus, contrary to Ethicon's proposed alternative, allowing examiners to make institution decisions could require an impermissible "exercis[e] [of] significant authority" by an employee—particularly since institution is nonreviewable on appeal by congressional design. 35 U.S.C. § 314(d). Members of the Board, however, are indisputably "inferior Officers" and can decide such matters. U.S. Const. art. II, § 2, cl. 2; *see Freytag v. Comm'r*, 501 U.S. 868, 881-882 (1991) (holding that special trial judges of the tax court were "inferior Officers" for purposes of the Appointments Clause).

[6] *See, e.g.*, *Conopco, Inc. v. Procter & Gamble Co.*, IPR2014-00628, Paper 23 at 2-3 (P.T.A.B. Mar. 20, 2015) (noting that the Board has discretion not to institute even where petitioner demonstrated a reasonable likelihood of prevailing, and indicating that the panel did not abuse its discretion in exercising discretion not to institute); *Liberty Mut. Ins. Co. v. Progressive Cas. Ins. Co.*, CBM2012-00003, Paper 7 at 2, 3, 6, 12 (P.T.A.B. Oct. 25, 2012) (trimming "numerous redundant grounds [that] would place a significant burden on the Patent Owner and the Board, and would cause unnecessary delays").

Director," states that a "Petition may be taken to the Director: * * * [i]n cases in which a statute or the rules specify that the matter is to be determined directly by or reviewed by the Director * * * ." Thus, by specifying that an institution decision is effected by the Director under § 314, Congress actually ensured that her executive discretion would also be available by petition. *See* 37 C.F.R. 1.181(a)(2) (to invoke a Director's petition, "a statute or the rules [must] specify that the matter is to be determined directly by or reviewed by the Director * * * ."). So while the Board has been tasked with instituting thousands of routine cases, in part for efficiency's sake, the Director can still have the final say when necessary. *Id*.

Congress presumptively knew and legislated against this backdrop. *Minneapolis & St. Louis Ry. Co. v. United States*, 361 U.S. 173, 187 (1959) (presuming that Congress was aware of applicable regulations when enacting pertinent legislation). It crafted the AIA to permit Director delegation to the Board on the one hand, but left in place Director petitions on the other. Taken together, these complementary procedures demonstrate that the decision to institute a petition truly "is a matter committed to the *Patent Office's* discretion" at large. *See Cuozzo*, 136 S. Ct. at 2140 (emphasis added).

Accordingly, the Patent Office's institution procedure *does* have multiple "discretionary" safeguards available to patent owners—if they will make use of them. But Ethicon did not raise these issues below or even attempt to exhaust existing administrative remedies with the Director.

V. Ethicon Lacks Standing

Standing must be shown by any party invoking the remedial powers of the federal courts "throughout all stages of litigation," including all "persons seeking appellate review" before this Court. *See Hollingsworth v. Perry*, 133 S. Ct. 2652, 2661 (2013) (citations omitted). But Ethicon has not maintained standing to pursue this petition due, *inter alia*, to a lack of redressability, because it has not alleged that a favorable decision here could actually remedy its injury—in this case, invalidation of the '070 patent. As one element of the "irreducible constitutional minimum" of standing, "it must be 'likely,' as opposed to merely 'speculative,' that the injury will be 'redressed by a favorable decision.'" *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-561 (1992) (citation omitted). In *Warth v. Seldin*, for example, the Court explained that, to have standing, a party must allege that the "prospective relief will remove the harm." 422 U.S. 490, 505-506 (1975) (finding lack of standing because "the record is devoid of any indication * * * that, were the court to remove the obstructions attributable to respondents, such relief would benefit petitioners").

Here, it is "purely speculative" that a different decision-maker would disagree with the obviousness of Ethicon's patent. *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 42-46 (1976) (finding a lack of standing where there is no substantial likelihood that victory in the suit would avert the injury). Ethicon does not allege that the invalidity result would have been any different with another institution process. *Cf. Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1550 (2016) (holding that petitioner "cannot satisfy the demands of Article III by alleging a bare procedural violation,"

particularly where the result "may be entirely accurate").

In fact, the Federal Circuit confirmed on the merits that Ethicon's patent was irretrievably invalid. Pet. App. 21a-24a. Ethicon does not contest the Federal Circuit's obviousness determination before this Court. Pet. 7 n.1 ("That aspect of Ethicon's appeal is not at issue here."). While patent owners in another case on other facts may satisfy this requirement for standing—i.e., it is "likely" and not "merely speculative" that the injury will be remedied by the relief sought—Ethicon has not done so here. Thus, Ethicon lacks a "personal stake" in maintaining this suit, and advances only a "generalized grievance" insufficient to confer standing. *Warth*, 422 U.S. at 498-499; *Hollingsworth*, 133 S. Ct. at 2662-2663; *Lujan*, 504 U.S. at 560-561.

Because the exercise of the Court's remedial powers is not substantially likely in this case to restore Ethicon's '070 patent from invalidity, redressability in this matter remains "purely speculative," and certiorari should be denied.

CONCLUSION

For these reasons, the Ethicon petition for a writ of certiorari should be denied.

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