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.

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

## REPLY BRIEF FOR THE PETITIONER


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## REPLY BRIEF FOR THE PETITIONER

Despite 45 pages of briefing in opposition, it remains undisputed that the question presented—a question of statutory interpretation that implicates fundamental tenets of administrative law—affects *every* inter partes review (IPR) proceeding. Nor is there any dispute that the America Invents Act (AIA), at every turn, expressly confers the discretionary decision to *institute* IPR on the *Director* of the Patent and Trademark Office (PTO), but expressly confers the authority to *conduct* IPR on the *Patent Trial and Appeal Board*. What remains disputed is whether the Director, in contravention of established administrative law principles, can

subvert that statutorily bifurcated decisionmaking process and vest the Board (typically the same panel) with both institution and adjudication authority. This Court should grant certiorari to finally resolve this important issue.

### A. The Importance Of The Question Presented Is Beyond Doubt

As confirmed by ten individual *amici* consisting of leading American innovators across industries, as well as two associations representing over 1,000+ pharmaceutical and biotechnology companies, the PTO's rule combining the institution and adjudication functions in the Board has "substantial practical importance" for patent rights and "significant consequences for innovation." Brief of *Amici Curiae* 3M Company et al. 1-2; Brief of *Amici Curiae* PhRMA & BIO 2. As Covidien acknowledges (BIO 1), the "institution procedure *** has [been] used in the over five thousand post-grant proceedings"—a number increasing by the day—a fact that militates in favor of (not against) review.

It is also clear that the Federal Circuit reached the result below only by disparaging a precedent of this Court as something "lower courts no longer follow," and by relying on supposedly "inherent" agency powers. Pet. App. 17a, 20a. Although Covidien is correct that the question presented does not raise a "constitutional issue" (BIO 7), that is no reason to "ignore[]" the well-documented "taint of prejudgment" ("actual or perceived") (Pet. 10, 12) that flows equally from the Federal Circuit's disregard of this Court's precedent, longstanding administrative safeguards, and the AIA's explicit statutory scheme.

Despite the Government's confounding suggestion (BIO 8), the lack of a circuit conflict in a patent case—in which the Federal Circuit is the *exclusive* forum for appeal—does not diminish the need for further review. Even Respondents do not suggest that delaying review for another case or vehicle would serve any purpose.

Given the stakes, this Court's review is warranted to restore "public confidence in the fairness and correctness of [IPR] proceedings." Pet. App. 42a (Newman, J., dissenting from denial of rehearing en banc).

### B. Respondents' Threshold Arguments Pose No Barrier To This Court's Review

**1.** Covidien's argument (BIO 23-24) that Ethicon lacks Article III standing—one not advanced by the Government—borders on the frivolous. If this Court were to invalidate the PTO's institution regulation, the Board's decision rendering Ethicon's claims unpatentable (which inextricably flows from the structural error introduced by that regulation) must also be vacated—at least in the first instance. That remedy plainly satisfies any redressability concern. *See FEC v. Akins*, 524 U.S. 11, 25 (1998) ("[T]hose adversely affected by a discretionary agency decision generally have standing to complain that the agency based its decision upon an improper legal ground.").

The unremarkable fact that the Board "might later, in the exercise of its lawful discretion, reach the same result"—once it has cured the legal defect—"does not destroy Article III" jurisdiction. *Akins*, 524

U.S. at 25. Indeed, the only "speculative" (Covidien BIO 24) question here is what would happen *after* vacatur, *i.e.*, whether the Director (or her proper delegee) would actually institute IPR and whether the Board would then find any such claims unpatentable.

**2.** Conversely, Covidien does not join the Government's argument (BIO 8-10) that the AIA's bar on appealing the Director's institution determinations, 35 U.S.C. § 314(d), precludes review in this case—for good reason. The Federal Circuit correctly rejected that precise argument. Pet. App. 9a-10a.

Ethicon continues to argue "that the final decision is invalid because it was made by the same panel that instituted [IPR]." Pet. App. 10a. Although Ethicon emphasizes the administrative law arguments it made below (rather than due process) to reinforce its statutory construction before this Court, Ethicon has by no means "abandoned" (SG BIO 9) its ultimate challenge to the Board's final written decision. *See* Pet. 21-22; *see also* C.A. App. Br. 34; C.A. Reply Br. 20; Oral Arg. 9:57-11:36, 25:40-26:16. Nor can the Government point to any statement in the Federal Circuit's decision that would restrict its section 314(d) analysis to only a (secondary) portion of Ethicon's appeal. To the contrary, the Federal Circuit rejected the Government's attempts to cut off Ethicon's principal challenge to the legality of the PTO's institution regulation. Indeed, the Federal Circuit recognized that "we must first decide whether we have jurisdiction to address the combination of functions issue" as a whole. Pet. App. 9a. This is utterly unsurprising given that, until now, the

Government had never sought to bifurcate Ethicon's argument for appealability purposes. Far from urging the Federal Circuit to find that "[s]ection 314(d) d[oes] not bar judicial consideration of" half of Ethicon's appeal, SG BIO 9, the Government below argued that the appeal was barred *in its entirety*, C.A. Br. 13-17.

The Government's invocation of this Court's decision in *Cuozzo Speed Technologies, LLC v. Lee*, 136 S. Ct. 2131 (2016), cannot salvage its attempt to expand section 314(d) to cover this case. Unlike in *Cuozzo*, the "legal dispute at issue" here is *not* "an ordinary dispute about the application of certain relevant patent statutes" to the institution decision, such as whether the petition was "pleaded 'with particularity.'" *Id.* at 2139 (quoting 35 U.S.C. § 312). Nor do Ethicon's "grounds for attacking the decision to institute [IPR] consist of questions that are closely tied to the application and interpretation of statutes related to [that] decision," such as where "a patent holder merely challenges the Patent Office's 'determin[ation] that the information presented in the petition *** shows that there is a reasonable likelihood' of success." *Id.* at 2141-2142 (second alteration and ellipsis in original) (quoting 35 U.S.C. § 314(a)).

Ethicon's broader structural challenge, by contrast, "depend[s] on other less closely related statutes"—*i.e.,* separate provisions of the AIA and the Patent Act, Pet. 13-14; pp. 7-9, *infra*—"that present other questions of interpretation that reach, in terms of scope and impact, well beyond [section 314]." *Cuozzo*, 136 S. Ct. at 2141. *Cuozzo* explicitly preserves review of whether the Board "act[ed]

outside its statutory limits" or "'in excess of statutory jurisdiction.'" *Id.* at 2141-2142 (quoting 5 U.S.C. § 706(2)(C)).

Although the Government purports to rely on *Cuozzo*, in reality it seeks to *extend* (BIO 10) section 314(d) to any situation where an argument "logically implies that the institution decision itself was illegal" (an issue independently worthy of this Court's review). The upshot of the Government's sweeping rule, however, is to insulate the PTO's regulation—or any institution procedures it might choose to employ for that matter—from judicial review altogether. This Court has repeatedly eschewed statutory constructions that "foreclose all meaningful judicial review," *Free Enter. Fund v. Public Co. Accounting Oversight Bd.*, 561 U.S. 477, 489-490 (2010), and *Cuozzo* does not break from that tradition.

As precedent indicates, provisions like section 314(d) bar an attack on an institution decision when "[a]ny error in that decision [would be] washed clean during the *** proceeding." *In re Hiniker Co.*, 150 F.3d 1362, 1367 (Fed. Cir. 1998), *cited approvingly by Cuozzo*, 136 S. Ct. at 2140. Because the structural error arising from the Board's institution of IPR cannot be "washed clean" by a final decision in this or any other case, the Government's argument contravenes *Cuozzo*'s assurance that "[s]uch 'shenanigans' may be properly reviewable in the context of § 319 [appeals of final decisions] and under the Administrative Procedure Act" (APA). 136 S. Ct. at 2142.

### C. Respondents' Merits Defense Of The Federal Circuit's Decision Cannot Shield It From Further Review

**1.** On the merits, Respondents spill much ink (SG BIO 10-13; Covidien BIO 6-11) arguing that the Director has "inherent" and other rulemaking authority to delegate matters to subordinates. But as the Federal Circuit and Respondents concede, that "unexceptionable" proposition (SG BIO 10; Covidien BIO 10) includes the critical caveat that Congress may limit such delegation. Accordingly, the question here is *not* whether the Director generally or with respect to "other basic responsibilities" has the power to delegate or exercise rulemaking authority (SG BIO 11-12); nor is it whether the Director can delegate the institution function to certain agency subordinates (she obviously can). Instead, the question is whether Congress has withheld the "authority to delegate a particular function" to a particular entity "by express provision of the Act or by implication." *Fleming v. Mohawk Wrecking & Lumber Co.*, 331 U.S. 111, 121 (1947). Congress has done so with respect to delegation of the institution decision to the Board, Pet. 12-18, and none of Respondents' four reasons for disregarding congressional intent has merit.

*First*, in failing to distinguish the discretionary IPR institution power from other executive powers granted to the Director, Respondents read 35 U.S.C. § 314(a) in isolation. SG BIO 11-12, 14; Covidien BIO 11-12, 15. But to discern whether Congress has constrained the Director's ordinary authority to delegate her powers, section 314(a)'s assignment of the institution function must be read against the

statutory structure and specific provisions at issue. One set of pertinent provisions assigns the Board the functions of *conducting* IPRs and rendering *final* decisions—and no more. 35 U.S.C. §§ 6(b)(4), 316(c), 318(a). It follows that the Director may not add a distinct function, such as *institution*, that would expand the Board's carefully circumscribed duties and that would destroy the institution-adjudication dichotomy reflected in the AIA's plain terms. Pet. 14-15, 20-21; *see Cudahy Packing Co. v. Holland*, 315 U.S. 357, 364 (1942).

Rather than engage that statutory text, Respondents invoke snippets of legislative history indicating, for example, "that Congress assigned the conduct of [IPRs] to the [Board] in order to streamline the process." SG BIO 14; *see also* Covidien BIO 12 (citing floor statement relating to covered business method review). That may be true as far as it goes. But such snippets nowhere endorse assigning the *institution* of *IPRs* to the Board to further streamline the process, at the expense of patent owners and the AIA's competing goals. Pet. 26-28. In any event, such cherry-picked legislative history cannot displace the AIA's "authoritative expression of the law." *City of Chi. v. Environmental Def. Fund*, 511 U.S. 328, 337 (1994).

*Second*, Respondents' construction of 35 U.S.C. § 3(b)(3), treating it as an affirmative grant of delegation authority that just duplicates the Director's otherwise implied authority, makes little sense. Pet. 17-21, 25-26. Contrary to Respondents' insistence (SG BIO 15-16; Covidien BIO 12-14), there is nothing "absurd" about interpreting section 3(b)(3) as a limit on delegation. Taking Respondents'

example, the Deputy Director is "vested with 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) (emphasis added). But an "absence" occurs, and the Deputy Director may exercise that vested authority, any time the Director so instructs.

The Government also offers 35 U.S.C. § 6(a)'s transfer of delegated authority from the prior Board of Patent Appeals and Interferences to the Board as proof that Director delegation to the Board is not precluded. SG BIO 12-13. The Government, however, overlooks the fact that for a number of years the Board was appointed by the Director rather than the Secretary of Commerce, Covidien BIO 13, thereby avoiding section 3(b)(3)'s limitation on Director delegation to officers, employees, and agents appointed by the Secretary. Moreover, designating panels to adjudicate particular cases and reviewing certain examiner decisions (SG BIO 12 n.2) are part and parcel of duties already assigned to the Board in section 6(b) and have nothing to do with institution. The Government's endeavor to cast institution as "similar" to other prior delegations therefore comes up short.

*Third*, the AIA's statutory text and structure undercut Respondents' plea for *Chevron* deference and the refrain that the Federal Circuit's decision "follows" from or is "confirmed" by *Cuozzo*. SG BIO 13; Covidien BIO 2, 7-9, 11 n.2, 15. Except with respect to its certworthiness, this case differs markedly from *Cuozzo*. In *Cuozzo*, where not a single AIA provision addressed the claim construction standard for IPR, the Court proceeded to "step two" of *Chevron* to determine whether the Director had

reasonably exercised her rulemaking authority. *See* 136 S. Ct. at 2142. Here, the case begins and ends at "step one" of *Chevron*: the AIA sets forth a bifurcated scheme of instituting and then conducting IPRs; several AIA provisions separate the Director's and the Board's respective responsibilities within that scheme in a manner that precludes the Board from instituting IPR; and yet another provision precludes the Director from delegating the institution function to the Board. Pet. 3-5, 13-17, 19-21. Whatever the extent of the Director's rulemaking authority, it does not imbue the Director with the power to make delegations in contravention of the AIA. *See Fleming*, 331 U.S. at 121.

*Fourth*, Respondents (like the Federal Circuit, Pet. 18-19) place undue weight (SG BIO 16-17; Covidien BIO 16-18) on speed—forsaking the other sound objectives of the AIA. *See* Pet. App. 43a-44a (Newman, J., dissenting from denial of rehearing en banc) (describing how Congress "meticulously incorporated safeguards against *** harassment of patentees"). Allowing delegation of the institution decision to the Board simply because it would be "consistent" with the overarching goal of streamlining post-grant review of patents, or because the Board is generally equipped to "resolv[e] contested questions of patentability," SG BIO 17, proves too much. *See Director, Office of Workers' Comp. Programs v. Newport News Shipbuilding & Dry Dock Co.*, 514 U.S. 122, 136 (1995) ("Every statute purposes, not only to achieve certain ends, but also to achieve them by particular means—and there is often a considerable legislative battle over what those means ought to be. The withholding of

agency authority is as significant as the granting of it, and we have no right to play favorites between the two.").

Expediency is not the AIA's sole goal. In treating it as so, the Director's delegation of the institution function to the Board "[t]hreaten[s] the viability of this new system." Pet. App. 31a (Newman, J., dissenting).

**2.** Respondents fare no better in attempting to avoid fundamental administrative law principles—especially the separation of executive and adjudicative functions embodied in 5 U.S.C. § 554(d)—upon which Congress premised the IPR dichotomy of Director institution and Board adjudication.[1]

Instituting and conducting IPR cannot be cast as "merely phases of the same adjudicatory process." Covidien BIO 20; *see* SG BIO 18. Respondents contest neither the "wide discretion" the Director is afforded in instituting IPR (SG BIO 18), nor that the exercise of that discretion is indistinguishable from an administrative prosecutorial function. Pet. 22-24. Like an agency that declines to take an enforcement action in response to a third-party petition, the Director's consideration of IPR petitions must take

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[1] Covidien's assertion (BIO 18-19) that Ethicon "waived" an APA argument is meritless. As Covidien recognizes, the Federal Circuit expressly considered Ethicon's reliance on section 554(d). Pet. App. 12a-13a n.3. Moreover, Ethicon does not press a "stand-alone APA claim," Covidien BIO 19, when it relies on administrative law principles to *reinforce* its interpretation of the AIA, *see* Pet. 11-12, 21-24; p. 4, *supra*.

into account "a number of factors"—both merits and non-merits—meant to prevent IPRs from visiting on patent owners the same untenable costs and impediments to innovation associated with the regime Congress scrapped. *Heckler v. Chaney*, 470 U.S. 821, 831 (1985) (factors include agency resources and "overall policies"). Accordingly, the fact that the filing of an IPR petition that satisfies a reasonably-likely-to-prevail standard is a prerequisite to the Director's decision to institute does not transform her ultimate exercise of quintessentially "executive discretion" (Covidien BIO 22) into an adjudication.

Beyond section 554(d), the APA does in fact "impose[] [a] separation obligation as to those involved in preliminary and final decisions." Covidien BIO 20 (quoting Pet. App. 12a-13a n.3). Even where (unlike here, Pet. 21-22) a "particular 'employee or agent'" does not initiate an action and then make the "ultimate decision in that case," SG BIO 19, it is "beyond doubt" that "the safeguards [the APA] did set up" prevent a discrete group of agency actors from collectively making both decisions. *Wong Yang Sung v. McGrath*, 339 U.S. 33, 45-46 (1950) (disapproving of scheme even though "the presiding inspector may not be the one who investigated the case," because "the inspector's duties include investigation of like cases; and while he is today hearing cases investigated by a colleague, tomorrow his investigation of a case may be heard before the inspector whose case he passes on today"). Respondents do not dispute that those longstanding safeguards apply to the "initiat[ion] [of agency] action." *Id.* at 42; *see* Pet. 21.

As such, Respondents' focus (Covidien BIO 20-22; *see* SG BIO 17) on whether the Board is "able to *** perform[]" some aspect of the broader institution calculus, as well as whether the Director retains the ability to review the Board's (unlawful) institution decisions "when necessary," misses the point. Undoubtedly, "for efficiency's sake," the Board *could* "institut[e] thousands" of IPRs en route to ruling on the merits. Covidien BIO 22. But this Court has refused to "accord any weight to the argument" that the "evils from the commingling of functions"—including when the decisions are "forwarded to [an agency head]" for further review—can be "ameliorate[d]" by considerations of "inconvenience and added expense." *Wong Yang Sung*, 339 U.S. at 46. In "determin[ing] that the price for greater fairness is not too high," *id.* at 46-47, Congress flatly rejected the notion that such commingling was a "salutary feature" (Covidien BIO 12) to be embraced.

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The petition for a writ of certiorari should be granted.

Respectfully submitted.

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