No. 16-377

In the Supreme Court of the United States

LIFESCAN SCOTLAND, LTD., PETITIONER

v.

PHARMATECH SOLUTIONS, INC., ET AL

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

BRIEF FOR THE FEDERAL RESPONDENT IN OPPOSITION

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QUESTION PRESENTED

Whether the Patent Act of 1952, 35 U.S.C. 1 *et seq.*, prohibits the Director of the U.S. Patent and Trademark Office from delegating to the Patent Trial and Appeal Board the decision whether to institute an inter partes review.

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OPINIONS BELOW

The per curiam judgment of the court of appeals affirming without opinion (Pet. App. 1a-2a) is reported at 633 Fed. Appx. 789. The final written decision of the Patent Trial and Appeal Board (Pet. App. 5a-41a) is not published in the *United States Patents Quarterly* but is available at 2014 WL 3885938. The Board's decision to institute inter partes review (Pet. App. 42a-67a) is available at 2013 WL 8595951.

JURISDICTION

The judgment of the court of appeals was entered on January 20, 2016. A petition for rehearing was denied on May 10, 2016 (Pet. App. 3a-4a). On August 2, 2016, the Chief Justice extended the time for filing a petition for a writ of certiorari to and including September 20, 2016, and the petition was filed on that

date. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

The issue in this case is whether the Director of the Patent and Trademark Office (PTO) has authority to delegate to the Patent Trial and Appeal Board (PTAB or Board), an entity within the PTO, the decision whether to institute an inter partes review proceeding. The Federal Circuit upheld that authority in *Ethicon Endo-Surgery, Inc.* v. *Covidien LP*, 812 F.3d 1023 (Fed. Cir. 2016), petition for cert. pending, No. 16-366 (filed Sept. 20, 2016). In this case, the Federal Circuit affirmed the PTAB's decision to invalidate various claims of petitioner's patent. Pet. App. 2a; see *id.* at 7a.

1. a. Congress established the PTO within the Department of Commerce, 35 U.S.C. 1(a), and it vested the "powers and duties" of the PTO in a single "Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office" (the Director), 35 U.S.C. 3(a)(1). The Patent Act of 1952, 35 U.S.C. 1 *et seq.*, accordingly vests many of the PTO's functions in the Director personally. 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).

To assist the Director in the discharge of her duties, Congress also created a Deputy Under Secretary and Deputy Director (the Deputy Director), 35 U.S.C. 3(b)(1); separate Commissioners for Patents and Trademarks, 35 U.S.C. 3(b)(2)(a); and two expert tribunals of administrative judges, the PTAB and the Trademark Trial and Appeal Board, 35 U.S.C. 6(a); 15

U.S.C. 1067. The Director has repeatedly delegated aspects of her statutory authority to those offices, both before and after the enactment of the Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284 (2011). See PTO, Dep't of Commerce, *Manual of Patent Examining Procedure* (*MPEP*), Ch. 1000, § 1002.02 (9th ed. Mar. 2014); *id.* § 1002.02 (8th ed., Rev. 2 May 2004). In addition to the offices established by statute, Congress also provided for "other officers and employees" of the PTO. 35 U.S.C. 3(b)(3). Congress authorized the Director to create additional positions within the agency, delegate functions to the occupants of those positions, and appoint other officers and employees to fill them. *Ibid.*

This case concerns the authority of the Director to delegate a decision to the PTAB, the expert tribunal for resolving contested questions of patentability. Congress established the PTAB as an entity "in the [Patent and Trademark] Office" and provided that the PTAB consists of the Director, the Deputy Director, the Commissioners, and the administrative patent judges. 35 U.S.C. 6(a). The PTAB replaced the former Board of Patent Appeals and Interferences, which previously performed many of the same functions. When Congress created the PTAB, it provided that "[a]ny reference in any Federal law, Executive order, rule, regulation, *or delegation of authority*, or any document of or pertaining to the Board of Patent Appeals and Interferences is deemed to refer to the Patent Trial and Appeal Board." *Ibid.* (emphasis added).

b. Congress has long provided administrative mechanisms for third parties to ask the PTO to reconsider the patentability of claims in an issued patent.

In the AIA, Congress substantially expanded those procedures and streamlined the process to more efficiently resolve petitions. As relevant here, the AIA replaced the former inter partes reexamination process with the new inter partes review process. See generally 35 U.S.C. 311-319; *Cuozzo Speed Techs., LLC* v. *Lee*, 136 S. Ct. 2131, 2137 (2016). As one of the AIA's co-sponsors explained, the new procedure was conceived to "substantially accelerate the resolution of inter partes cases." 157 Cong. Rec. 3430 (2011) (statement of Sen. Kyl).

Inter partes review proceeds in two phases. After receiving a "petition to institute an inter partes review" of a particular patent under 35 U.S.C. 311(a), the Director may institute the proceeding if she finds that "there is a reasonable likelihood" that the challenger would prevail on one of the claims challenged in the petition. 35 U.S.C. 314(a); see 37 C.F.R. 42.108. The determination "whether to institute an inter partes review * * * shall be final and nonappealable." 35 U.S.C. 314(d). Exercising her rulemaking authority, as well as her inherent authority as the head of the PTO, the Director has delegated the institution decision to the PTAB. 37 C.F.R. 42.4(a).

If the PTAB grants a petition to institute an inter partes review, it then conducts a trial-like adversarial proceeding to determine the patentability of the challenged claims. 35 U.S.C. 316. The PTAB resolves the proceeding by issuing a "final written decision with respect to the patentability" of the claims at issue. 35 U.S.C. 318(a). That final written decision may be appealed to the Federal Circuit. See 35 U.S.C. 141(c), 319.

2. Respondent Pharmatech Solutions, Inc., petitioned the PTO for inter partes review of petitioner's U.S. Patent No. 7,250,105. Pet. App. 6a. That patent claims a method for measuring the concentration of a substance in a liquid, such as the level of glucose in blood. *Id.* at 7a-11a.

a. A three-judge panel of the PTAB, exercising the institution authority delegated by the Director, granted the petition and instituted a review of the challenged patent claims. Pet. App. 42a-67a. Petitioner did not contend that the Director's delegation to the PTAB was in any respect invalid, nor did it suggest that the PTAB lacked authority to rule on the petition or request that a different panel of the PTAB conduct the trial on the merits. Following the trial, a panel of the PTAB, which included two of the same administrative patent judges who had participated in the institution decision, issued a final written decision concluding that all of the challenged claims were unpatentable as obvious over prior art. *Id.* at 7a.

b. Petitioner appealed the PTAB's decision to the Federal Circuit, arguing for the first time that the Patent Act prohibits the Director from delegating the institution decision to the PTAB. Pet. C.A. Br. 57-60. Petitioner asserted that 35 U.S.C. 314(b) requires the Director to make the institution determination, whereas 35 U.S.C. 6(c), 316(c), and 318(a) require a panel of the PTAB to conduct the inter partes review proceeding and issue the final written decision. Pet. C.A. Br. 57-60. Petitioner further contended that 35 U.S.C. 3(b)(3) prohibits the Director from delegating authority to the PTAB because the Director does not appoint the Board's administrative patent judges. *Ibid.*

3. While petitioner's appeal was pending before the Federal Circuit, a divided panel of that court issued a decision rejecting similar challenges to the inter partes review process. See *Ethicon*, *supra*.

a. In that case, the court of appeals first held that it had jurisdiction to consider Ethicon's challenge. The court stated that Ethicon "does not challenge the institution decision, but rather alleges a defect in the final decision," by arguing "that the final decision is invalid because it was made by the same panel that instituted inter partes review." *Ethicon*, 812 F.3d at 1029. The court further explained that 35 U.S.C. 314(d) "does not prevent [it] from hearing a challenge to the authority of the [PTAB] to issue a final decision." 812 F.3d at 1029.

b. On the merits, the *Ethicon* court rejected Ethicon's argument that having the same panel of the PTAB make both the institution decision and the final determination as to patentability violated the Due Process Clause. The court explained that in *Withrow* v. *Larkin*, 421 U.S. 35 (1975), this Court held that combining investigative and adjudicatory functions in one body does not raise due process concerns. *Ethicon*, 812 F.3d at 1029. The court further explained that the structure of the PTO process is "less problematic" than the decisionmaking structure in *Withrow* because "[b]oth the decision to institute and the final decision are adjudicatory decisions and do not involve combining investigative and/or prosecutorial functions with an adjudicatory function." *Id.* at 1030. The court observed that the PTO's decisionmaking structure is "directly analogous to a district court determining whether there is 'a likelihood of success on the merits' and then later deciding the merits of a

case." *Ibid.* The court also noted that, although the Administrative Procedure Act prohibits "'[a]n employee or agent engaged in the performance of investigative or prosecuting functions for an agency' from participating 'in the decision . . . except as witness or counsel,'" it "imposes no separation obligation as to those involved in preliminary and final decisions." *Id.* at 1030 n.3 (brackets in original) (quoting 5 U.S.C. 554(d)).

The *Ethicon* court also rejected Ethicon's argument that the AIA prohibits the Director from delegating the institution decision to the PTAB. The court held that the Director can lawfully assign the institution decision to the PTAB under the "longstanding rule that agency heads have implied authority to delegate to officials within the agency, even without explicit statutory authority and even when agency officials have other statutory duties." 812 F.3d at 1031 (citing *Parish* v. *United States*, 100 U.S. 500 (1880); *Fleming* v. *Mohawk Wrecking & Lumber Co.*, 331 U.S. 111 (1947); *United States* v. *Giordano*, 416 U.S. 505 (1974)).

The *Ethicon* court explained that nothing in the AIA's text or legislative history suggested that the delegation to the PTAB at issue there was impermissible. 812 F.3d at 1031. The court noted that Congress had "obviously assumed that the Director would delegate," and that the Director had "regularly assigned tasks to subordinate officers" before the AIA's enactment. *Id.* at 1032. The court rejected Ethicon's argument that 35 U.S.C. 3(b)(3)(B) prohibits the Director from delegating functions to officers whom she does not appoint. *Ethicon*, 831 F.3d at 1032-1033. The court concluded that Section 3(b)(3) is a "source

of authority for the Director to appoint subordinates and assign them tasks," and that it "cannot be read" to limit the Director's ability to delegate to non-appointees because that reading would preclude the Director from delegating tasks to the Deputy Director, who is appointed by the Secretary of Commerce. *Id.* at 1033.

The *Ethicon* court also held that the Director's "broad rulemaking power" is an "alternate source of authority to delegate." 812 F.3d at 1033. The court explained that the Director has promulgated a rule allowing the PTAB to institute inter partes review proceedings on the Director's behalf, and that the rule is entitled to deference. *Ibid.* (citing *Chevron U.S.A. Inc.* v. *Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842-843 (1984)).*

4. One week after deciding *Ethicon*, the court of appeals issued a per curiam judgment in this case affirming the PTAB's decision without opinion. Pet. App. 1a-2a. The court denied petitioner's subsequent petition for rehearing en banc. *Id.* at 3a-4a.

5. Petitioner in this case filed its petition for certiorari on September 20, 2016. That same day, Ethicon filed its own petition for a writ of certiorari. See *Ethicon Endo-Surgery, Inc.* v. *Covidien LP*, No. 16-366. Ethicon's petition remains pending before this Court.

ARGUMENT

Petitioner contends (Pet. 5-6) that the court of appeals' per curiam judgment in this case was con-

* Judge Newman dissented. Although she acknowledged that the Director can delegate the institution decision to certain subordinates within the PTO, *Ethicon*, 812 F.3d at 1035, she concluded that the AIA precludes the Director from delegating the decision to the PTAB, *id.* at 1035-1040.

trolled by its decision in *Ethicon Endo-Surgery, Inc.* v. *Covidien LP*, 812 F.3d 1023 (Fed. Cir. 2016), petition for cert. pending, No. 16-366 (filed Sept. 20, 2016). Petitioner asks the Court to hold this petition pending its final disposition of the petition for certiorari in *Ethicon*.

The government agrees that this case and *Ethicon* raise substantially similar issues. The government's brief in opposition in *Ethicon* argues that the petition in that case should be denied. For the reasons stated in that brief in opposition, the Court should deny the petition in this case as well. If the Court grants certiorari in *Ethicon*, however, it should hold this petition pending its merits decision in *Ethicon* and then dispose of the petition as appropriate in light of that decision.

CONCLUSION

The petition for a writ of certiorari should be denied. In the alternative, if the Court grants the petition for a writ of certiorari in *Ethicon Endo-Surgery, Inc.* v. *Covidien LP*, No. 16-366, the petition in this case should be held pending the Court's merits decision in *Ethicon* and then disposed of as appropriate in light of that decision.

Respectfully submitted.

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