2014-1771

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

ETHICON ENDO-SURGERY, INC.,

Appellant,

v.

COVIDIEN LP,

Appellee.

APPEAL FROM THE UNITED STATES PATENT AND TRADEMARK OFFICE, PATENT TRIAL AND APPEAL BOARD IN NO. IPR2013-00209

DIRECTOR'S RESPONSE TO PETITION FOR REHEARING EN BANC

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TABLE OF CONTENTS

Page(s)

TABLE OF AUTHORITIES

Cases: **Page(s)**

Statutes:

Regulation:

Legislative Material:

Other Authorities:

INTRODUCTION

When Congress passed the America Invents Act (AIA), it gave the Director of the Patent and Trademark Office (PTO) the authority to decide whether or not to institute an inter partes review of an issued patent. The panel correctly held that the Director may lawfully delegate that decision-making authority to the Patent Trial and Appeal Board (PTAB), the subordinate entity within the PTO with the greatest expertise and experience in resolving patentability disputes. As the panel explained, the Director not only has the inherent authority as the head of the PTO to subdelegate matters like this to the PTAB, but also has broad rulemaking power to establish regulations governing inter partes review. Nothing in the AIA precludes her from exercising her inherent authority or her rulemaking power in this manner. Indeed, her decision to delegate matters to the PTAB advances one of the central purposes of the AIA—that is, to expedite the resolution of contested questions of patentability.

The panel's construction of the AIA is correct and does not conflict with any decision of this Court or the Supreme Court. The petition for rehearing en banc should be denied.

STATEMENT

A. Statutory and Regulatory Background

Congress created inter partes review as an administrative procedure that third parties could use to challenge the validity of issued patent claims outside of court. *See*

35 U.S.C. § 311 *et seq.* The procedure, created in 2011 as part of the AIA, was designed to replace the old inter partes reexamination process, which had proven both time-consuming and inefficient. 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. S1376 (Daily Ed. Mar. 28, 2011) (statement of Sen. Kyl).

As this Court has explained, inter partes reviews proceed in two distinct phases. *St. Jude Med., Cardiology Div., Inc. v. Volcano Corp.*, 749 F.3d 1373, 1375-76 (Fed. Cir. 2014). During the first phase, the Director of the PTO decides whether to "institute" a review of the patent claims challenged in the petition. 35 U.S.C. § 311(a). Such review may only be instituted if the petition "shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." *Id.* § 314(a). If the agency decides to institute such a review, the petitioner and the patent-holder then proceed to the second phase of the process: a trial before the PTAB. The purpose of the trial is to determine whether any of the challenged patent claims should be canceled. Following the trial, which generally must conclude within a year of the initial decision to institute review, *id.* § 316(a)(11), the PTAB must issue a written decision addressing the patentability of each claim at issue in the trial, *id.* § 318(a).

To ensure that this process runs efficiently, Congress gave the Director broad rulemaking powers under the AIA to prescribe regulations "establishing and governing inter partes review." 35 U.S.C. § 316(a)(4). The Director, in exercising these

powers, must consider various factors, including "the efficient administration of the Office, and the ability of the Office to timely complete proceedings instituted under this subchapter." 35 U.S.C. § 316(b). Conscious of this requirement, the Director has exercised her rulemaking authority—as well as her inherent authority as the head of the PTO—and delegated to the PTAB the task of deciding whether or not to institute review of a challenged patent. 37 C.F.R. § 42.4(a).

B. Procedural History

In 2013, Covidien petitioned the PTO for inter partes review of an Ethicon patent, U.S. Patent No. 8,317,070, which claims a surgical stapler. A panel of the PTAB, exercising its authority under 37 C.F.R. § 42.4(a), granted the petition and instituted a review of the challenged patent claims. Following a trial on the merits, the same panel then issued a written decision concluding that all of the challenged claims are unpatentable as obvious over prior art.

Ethicon appealed the panel's decision to this Court, arguing—for the first time—that the PTO's process for deciding Covidien's petition was improper. In particular, Ethicon challenged the Director's authority, under the AIA, to delegate to the PTAB the initial decision whether to institute an inter partes review. Ethicon further argued that allowing the same panel of the PTAB to make both the institution decision and the final decision raised due process concerns. The Director intervened to address these arguments.

C. Panel Decision

A panel of this Court affirmed the cancellation of Ethicon's claims and rejected Ethicon's challenge to the PTO's processes. The panel held that the Director could 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." Op. 13. The panel further held that the delegation was a proper exercise of the Director's "broad rulemaking power." Op. 17. Rejecting Ethicon's assertion that the AIA precluded such delegation, the panel explained 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." Op. 13. To the contrary, the Court noted, "Congress obviously assumed that the Director would delegate." Op. 15.

The panel likewise rejected Ethicon's due process argument, citing several Supreme Court and court of appeals decisions which had upheld administrative procedures that, like inter partes review, involve a single decision-maker who participates in multiple stages of an agency's decision-making process. Op. 9-10, 12 n.4. The panel explained that the PTAB's participation at the institution phase of an inter partes review was unremarkable, noting that it was "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." Op. 11 (citations omitted). Particularly given Ethicon's failure to cite any contrary case law, the panel concluded that there were

"no due process concerns in combining the functions of the initial decision and final disposition in the same Board panel." Op. 13.

Judge Newman dissented. Although she acknowledged that the Director could delegate the institution decision to certain subordinates within the PTO, she would have held that the AIA precludes such delegation to the PTAB specifically. Dis. Op. 1-2. Judge Newman did not, however, point to any explicit constraints that Congress imposed on the Director's inherent authority or rulemaking powers in the AIA.

ARGUMENT

Ethicon does not suggest that any decision of this Court or the Supreme Court conflicts with the panel's decision. Instead, it contends that the panel erred in upholding the Director's delegation to the PTAB of the institution phase of inter partes review. That contention does not provide grounds for rehearing. The panel's decision was correct and its reasoning was anchored firmly in both the text and purpose of the AIA and supported by longstanding principles of administrative law. The petition should therefore be denied.

A. The panel correctly held that the Director has the authority to delegate the institution decision to the PTAB.

As noted above, the panel majority identified two separate sources of authority for the Director's delegation of the institution decision to the PTAB – her inherent authority as head of PTO and her rulemaking powers under the AIA. *See* Op. 18 ("In short, both as a matter of inherent authority and general rulemaking authority, the

Director had authority to delegate the institution decision to the Board."). Thus, to demonstrate that the panel's decision was incorrect, Ethicon would have to show that Congress intended to restrict *both* of these sources of the Director's authority. It cannot make such a showing here.

The Supreme Court has long recognized that agency heads have the inherent authority to delegate matters to their subordinates. *See, e.g.*, *Fleming v. Mohawk Wrecking & Lumber Co.*, 331 U.S. 111, 122 (1947) (holding that an agency administrator had the authority to delegate to regional administrators the power to sign and issue subpoenas where there was "no provision in the [relevant] Act negativing the existence of such authority"). The courts of appeals, likewise, "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." *Kobach v. U.S. Election Assistance Comm'n*, 772 F.3d 1183, 1190 (10th Cir. 2014).

Following these established precedents, the panel in this case correctly concluded that the Director has the authority to delegate the institution decision to the PTAB, a subordinate entity within the PTO.[1] Indeed, Congress expected the

[1] Congress vested in the Director all of the "powers and duties of the United States Patent and Trademark Office," 35 U.S.C. § 3(a)(1), and established the PTAB as part of that "Office," *id.* § 6(a). The Director is also specifically empowered to prescribe rules governing PTAB proceedings and to set the pay of the PTAB's administrative patent judges. *Id.* §§ 3(b)(6), 316(a).

Director to subdelegate matters like the institution decision. As the panel explained, "the Director, as head of the PTO, regularly assigned tasks to subordinate officers" before the AIA was enacted and Congress no doubt expected that the practice would be "carried over to the AIA." Op. 15; *see also* 35 U.S.C. § 6(a) (providing that the PTAB would inherit all pre-AIA delegations of authority that the Director previously made to the Board of Patent Appeals and Interferences). Accordingly, when Congress passed the AIA, it "necessarily assum[ed] that the popularity of inter partes review and the short time frame to decide whether to institute inter partes review would mean that the Director could not herself review every petition." Op. 15-16.

Ethicon does not dispute that the Director may delegate the institution decision to certain subordinates, such as solicitors or examiners. *See* Pet. 2, 6. Nor does Ethicon suggest that anything in the AIA expressly prohibits delegations to the PTAB. Nevertheless, it contends that Congress implicitly precluded the Director from delegating the institution decision to the PTAB. *See* Pet. 10-11. For support, Ethicon points to 35 U.S.C. § 3(b)(3), which authorizes the Director to "appoint such officers, employees (including attorneys), and agents of the Office as [she] considers necessary . . . and delegate to them such of the powers vested in the Office as the Director may determine."

Section 3(b)(3) simply makes clear that the Director is empowered to make delegations even to persons whose positions the Director herself creates. *See* Op. 16-17 (explaining that section 3(b)(3) is merely "a source of authority for the Director to

appoint subordinates and assign them tasks"). The statute imposes no restriction on the Director's authority to delegate tasks to *other* subordinates with the PTO. *See United States v. Mango*, 199 F.3d 85, 90 (2d Cir. 1999) ("Congress may mention a specific official only to make it clear that this official has a particular power rather than to exclude delegation to other officials."). Ethicon's contrary interpretation would produce the absurd consequence that the Director could not delegate tasks to the Deputy Director or the Commissioner for Patents, who (like the PTAB members) are appointed by the Secretary of Commerce rather than by the Director herself. As the panel observed, "[i]t would indeed be strange to read § 3(b)(3) as limiting delegation" in this way. Op. 17.

Ethicon's reliance on 35 U.S.C. § 6(b) is likewise unavailing. That provision authorizes the PTAB to "conduct inter partes reviews," among other tasks. *Id.* It does not restrict the PTAB's authority exclusively to the tasks listed in that provision. To the contrary, the provision immediately preceding § 6(b) makes clear that Congress knew the Director would delegate other tasks to the PTAB. In § 6(a), Congress expressly provided that the PTAB would inherit all of the prior "delegation[s] of authority" that the Director had made to the Board of Patent Appeals and Interferences, the entity that the PTAB replaced: "Any 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." *Id.* § 6(a) (emphasis added). Thus, Congress

specifically contemplated that the Director could "delegat[e]" matters to the PTAB beyond those listed in § 6(b). Further, if Ethicon's interpretation of § 3(b)(3) were correct, *all* delegations from the Director to the PTAB would be invalid, because the Director does not appoint the PTAB members. The panel correctly rejected Ethicon's cramped view of the Director's authority.

In any event, the panel made clear that the Director was permitted to delegate the institution decision to the PTAB not only as an exercise of her inherent authority but also as an exercise of her broad rulemaking powers. Congress empowered the Director to prescribe rules "govern[ing] the conduct of the proceedings in the Office" in general, 35 U.S.C. § 2(b)(2), and "governing inter partes review" in particular, *id.* § 316(a)(4). The PTO's rule authorizing the PTAB to make the institution decision "on behalf of the Director," 37 C.F.R. § 42.4(a), under standards set forth by the Director, falls squarely within that rulemaking authority. Moreover, it represents a reasonable interpretation of the AIA provision authorizing "the Director" to institute inter partes review, 35 U.S.C. § 314, and is therefore entitled to deference. Op. 17-18; *see also Kobach*, 772 F.3d at 1191 (giving *Chevron* deference to agency's determination that its enabling statute "permitted a limited subdelegation of decisionmaking authority"); *Mango*, 199 F.3d at 92 ("[W]e find the Secretary [of the Army] reasonably interpreted [the relevant statute] to permit subdelegation of permit-issuing authority to district engineers and their designees."). The Director's subdelegation of the institution decision is therefore presumptively permissible.

B. The panel's decision does not contravene any principle of administrative law.

Ethicon contends that the Director's delegation of authority to the PTAB violates longstanding principles of administrative law. In particular, it points to a provision of the Administrative Procedure Act, 5 U.S.C. § 554(d), which generally prohibits any "employee or agent engaged in the performance of investigative or prosecuting functions for an agency" from "participat[ing] or advis[ing] in the [agency's] decision" in that matter.

The panel properly rejected this argument, explaining that § 554(d) "imposes no separation obligation as to those involved in preliminary and final decisions." Op. 11 n.3. Objectively determining whether a sufficient threshold showing has been made to commence an inter partes review is not an "investigative or prosecuting function[]" in the sense of the APA. Indeed, the institution decision and the final decision are not separate "functions" at all: as this Court has recently explained, they are simply two stages of the same adjudicative proceeding. *See St. Jude*, 749 F.3d at 1375-76. Section 554(d) therefore does not require the separation of agency personnel in this context. Ethicon points to no authority suggesting otherwise.[2]

[2] Indeed, the Director may be involved at both stages of an inter partes review even under Ethicon's interpretation of the AIA: the Director is also, by statute, a member of the PTAB. 35 U.S.C. § 6(a). If Congress intended to preclude any agency personnel who participated in the institution decision from later participating in the merits decision, it would not have expressly authorized the Director to participate in both decisions.

Even if Ethicon were correct in its interpretation of § 554(d), moreover, that would not affect the validity of the Director's delegation of the institution decision to the PTAB. Section 554(d) merely prohibits the specific "employee or agent" who conducts a specific prosecution or investigation from participating in the agency's ultimate decision in that case. It does not affect the Director's discretion to delegate the institution decision to the Board in the first instance, as Ethicon suggests in its petition.

C. The Director's delegation of authority to the PTAB does not raise due process concerns.

Ethicon does not appear to challenge the panel's due process ruling in its rehearing petition. Amici assert, however, that the panel erred in holding that the combination of the institution and final decision functions in the PTAB raises due process concerns.[3] *See* Amici Curiae Br. of Pharm. Research & Mfrs. of Am., et al. 6-10; Amici Curiae Br. of Eleven Law Profs. 1-10. There is no proper basis for granting rehearing on a theory not pressed by the petitioner itself. Regardless, amici's arguments are without merit.

As the panel correctly explained, the "Supreme Court has never held a system of combined functions to be a violation of due process, and it has upheld several such

[3] To the extent that Ethicon contends that rehearing en banc is necessary to reconsider the due process issue, that contention is unavailing for the same reasons set forth above and in the panel opinion.

systems." Op. 10 (quoting Richard J. Pierce, Jr., *Administrative Law Treatise* § 9.9, p. 892 (5th ed. 2010)). Indeed, in the leading case on the subject, the Supreme Court upheld a state medical board's decision to suspend a physician's license, despite the fact that the same panel of the board had investigated the physician before issuing the suspension. *Withrow v. Larkin*, 421 U.S. 35, 58-59 (1975). The Court in that case rejected the physician's argument that the combination of investigative and adjudicatory functions in a single decision-maker created an unconstitutional risk of bias or otherwise violated due process. *See id.* at 58 (noting that "the combination of investigative and adjudicative functions does not, without more, constitute a due process violation"). This Court has likewise "held that there is no due process issue when, in the anti-dumping context, a Department of Commerce official makes both the decision to institute and then the final determination." Op. 10 (citing *NEC Corp. v. United States*, 151 F.3d 1361, 1374 (Fed. Cir. 1998)).

It follows *a fortiorari* that there is no due process problem in allowing the same decision-maker in an adjudicative proceeding to render both initial and final decisions in the same case. Indeed, as the panel noted, the relationship between the institution decision and final decision during inter partes review is "directly analogous" to the relationship between various preliminary and final decisions that courts routinely

make during litigation. Op. 11-12.[4] Neither Ethicon nor amici have offered persuasive reasons why the bifurcation of these decisions during inter partes review raises greater due process concerns than the bifurcation of similar decisions during ordinary litigation.

CONCLUSION

For the foregoing reasons, the petition for rehearing en banc should be denied.

Respectfully submitted,

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[4] *See also Withrow*, 421 U.S. at 56 ("Judges repeatedly issue arrest warrants on the basis that there is probable cause to believe that a crime has been committed [and] . . . . preside at preliminary hearings where they must decide whether the evidence is sufficient to hold a defendant for trial. Neither of these pretrial involvements has been thought to raise any constitutional barrier against the judge's presiding over the criminal trial and, if the trial is without a jury, against making the necessary determination of guilt or innocence.").

CERTIFICATE OF SERVICE

I hereby certify that on April 12, 2016, I electronically filed this brief with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the appellate CM/ECF system. I further certify that I will cause paper copies to be filed with the Court within two days of this filing.

The participants in the case are registered CM/ECF users and service will be accomplished by the appellate CM/ECF system.

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