14-1771

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

BRIEF FOR *AMICI CURIAE* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AND BIOTECHNOLOGY INNOVATION ORGANIZATION IN SUPPORT OF APPELLANT ON PETITION FOR REHEARING *EN BANC*

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CERTIFICATE OF INTEREST

Counsel for *amici curiae* Pharmaceutical Research and Manufacturers of America and Biotechnology Innovation Organization certifies the following:

1. **The full name of every party or amicus represented by me is:**

   Pharmaceutical Research and Manufacturers of America, and Biotechnology Innovation Organization

2. **The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:**

   N/A

3. **All parent corporations and any publicly held companies that own ten percent or more of the stock of the party or *amici curiae* represented by me are:**

   N/A

4. **The names of all law firms and the partners or associates that appeared for the party or amicus in the lower tribunal or are expected to appear in this court are:**

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Dated: March 14, 2016

/s/ Gregory L. Diskant
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STATEMENT OF INTEREST OF *AMICI CURIAE*[1]

The *amici* are Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Innovation Organization (BIO).[2]

PhRMA represents leading pharmaceutical and biotechnology companies. Its members develop cutting-edge medicines, treatments and vaccines that save and improve the lives of countless individuals. Over the past decade, PhRMA members have secured FDA approval of more than 300 new medicines. These remarkable results require a remarkable investment; in 2014 alone, PhRMA companies invested over $51 billion in discovering and developing new medicines.

BIO is the world's largest biotechnology trade association, representing over 1,000 companies, academic institutions and biotechnology centers. Its members engage in pioneering research and development of biotechnological healthcare, agricultural and environmental products. Most of BIO's corporate members are small or mid-size businesses that have annual revenues of less than $25 million. Such companies account for a substantial portion of the biopharmaceutical research pipeline.

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[1] *Amici* PhRMA and BIO certify that no counsel for the parties authored this brief in whole or in part, and no party or other person made a monetary contribution to the brief's preparation or submission. *See* Fed. R. App. P. 29(c)(5).

[2] The member companies of PhRMA and BIO are listed on their websites. http://www.phrma.org/about/member-companies; https://www.bio.org/articles/bio-members-web-site-links. Their members include Johnson & Johnson, the parent company of Ethicon Endo-Surgery, Inc.

When the members of PhRMA and BIO invest in the research to develop innovative technology, they do so with the expectation that the intellectual property arising from their efforts will be protected by the just administration of United States patent law. PhRMA and BIO seek to advance policies that incentivize their members' investments in research and development, and to identify and remove barriers that may impede innovation.

INTRODUCTION

A divided panel of this Court upheld a PTO regulation providing that the same panel of the Patent Trial and Appeal Board (PTAB) is entrusted with deciding both: (a) whether to institute an *inter partes* review (IPR), and (b) the ultimate merits if an IPR is instituted. 37 C.F.R. § 42.4.

Allocating the initiation responsibility to the same entity that decides the ultimate merits is fundamentally unfair because it biases the PTAB panel to uphold its initial decision at trial on the merits. Recognizing this unfairness, the Leahy-Smith America Invents Act (AIA) provides for a system of divided responsibilities. The PTO Director is responsible for deciding whether an IPR should be instituted and, if so, a panel of the PTAB is responsible for deciding the ultimate merits. *See* 35 U.S.C. §§ 314(a), 318(a).

The PTO's allocation of both responsibilities in the same entity raises serious due process concerns. The Supreme Court has long cautioned that due

process protections can be threatened when an agency commingles the functions of initiating and deciding disputed proceedings. In this case, placing the institution decision in the hands of the ultimate decision-maker raises a serious risk of prejudgment because an IPR may only be instituted upon a determination—made without full participation from the patent holder—that there is a "reasonable likelihood" that the patent is invalid. 35 U.S.C. § 314(a). Even an otherwise fair-minded panel of judges would naturally be prone to reaffirm that initial determination at trial on the merits. This concern is not hypothetical. As of January 31, 2016, an astonishing 86.5 % of patents in IPRs have had one or more claims invalidated after a "fair" trial.[3]

Fair administration of IPRs requires—as the AIA provides—that the decision whether to institute an IPR should not be made by the same PTAB panel that decides the ultimate merits. A division of responsibilities is required by the AIA and by due process. Because of the increase in IPR proceedings, and their unfair results, this issue is of great importance and merits en banc review.

[3] Patent Trial and Appeal Board Statistics (Jan. 31, 2016) http://www.uspto.gov/sites/default/files/documents/2016-01-31%20PTAB.pdf.

ARGUMENT

I. THE ISSUE PRESENTED IS OF GREAT CONCERN TO *AMICI*

The regulation allocating responsibility for making IPR institution decisions to the same PTAB panel that ultimately decides the merits is a matter of great concern to *amici*. For example, PhRMA repeatedly has expressed that concern in written comments to the PTO. In 2014, in responding to the PTO's Request for Comments, PhRMA stated: "The PTAB panel that conducts an AIA Review should not also institute that review."[4] Entrusting different decision makers with these responsibilities "would increase patent owners' due process protections, reduce perceptions of bias, and more fully meet the requirements of the AIA."[5] In responding to another PTO Request for Comments in 2015, PhRMA reported that not only was there a perception of bias, but that partiality had *in fact* tainted the IPR process. As PhRMA noted, as of October 31, 2015, an overwhelming majority—86.3%—of the PTAB's Final Written Decisions on IPRs found one or more claims unpatentable.[6]

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[4] Comments of PhRMA, PTO-P-2014-0031, Oct. 16, 2014 ("2014 Comments") at 13. http://www.uspto.gov/sites/default/files/ip/boards/bpai/phrma_20141016.pdf.

[5] *Id.* at 14.

[6] Comments of PhRMA, Doc. No. PTO-P-2015-0055, Nov. 18, 2015 ("2015 Comments") at n.22. http://www.uspto.gov/sites/default/files/documents/PTAB%20Pilot%20Corp%20PhRMA%20Comments.pdf.

In *amici*'s view, these lopsided outcomes are due, at least in part, to the PTO regulation that places responsibility for instituting an IPR in the hands of the same PTAB panel that decides the ultimate merits. That regulation is at odds with the AIA, raises serious due process issues and has led to a system that has proven to be fundamentally unfair in practice.

II. DELEGATION OF IPR INSTITUTION AUTHORITY TO THE ULTIMATE DECISION-MAKER—THE PTAB—CONTRAVENES THE AIA'S LETTER AND PURPOSE

The AIA expressly provides for different decision-makers to decide whether an IPR should be instituted and, if an IPR is instituted, to hear the evidence and render a final decision. *See* 35 U.S.C. §§ 314(a), 318(a). *Amici* agree with the reasoning of Judge Newman's dissent, and Appellant's arguments, that placing institution decisions in the hands of the same PTAB panel that decides the merits "violates the text, structure, and purpose of the America Invents Act." Dissent at 7. Moreover, as Appellant demonstrates in its Petition for Rehearing En Banc, the regulation undermines the statute's express provision authorizing the Director to delegate functions only to a limited body of individuals. Doc. No. 66 at 11 (citing 35 U.S.C. § 3(b)(3)(B)). In and of itself, this is reason enough for this Court to review the matter en banc.

III. DELEGATION TO THE PTAB RAISES SERIOUS DUE PROCESS ISSUES

En banc consideration of the statute is further warranted because of the serious constitutional issues at stake—issues given short shrift by the panel majority. As the Supreme Court has held, "a statute must be construed, if fairly possible, so as to avoid not only the conclusion that it is unconstitutional but also grave doubts upon that score." *Rust v. Sullivan*, 500 U.S. 173, 191 (1991) (quotation marks omitted).[7]

Here, the constitutional issue is manifest. Can PTAB judges act as neutrals after making an initial determination—after hearing fully from the petitioner, but not the patent owner—that one or more claims at issue are reasonably likely to be unpatentable? That is the heart of the matter and that is plainly unfair. "The requirement of neutrality has been jealously guarded by this Court." *Marshall v. Jerrico, Inc.*, 446 U.S. 238, 242 (1980). As the Supreme Court has emphasized, a "fair trial in a fair tribunal is a basic requirement of due process," and "[t]his applies to administrative agencies which adjudicate as well as to courts." *Withrow*, 421 U.S. at 46. "Fairness of course requires [at least] an absence of actual bias in

[7] "This canon is followed out of respect for Congress, which we assume legislates in the light of constitutional limitations." *Rust*, 500 U.S. at 191. Indeed, "legislators and others concerned with the operations of administrative agencies have given much attention to whether and to what extent distinctive administrative functions should be performed by the same persons." *Withrow v. Larkin*, 421 U.S. 35, 51 (1975).

the trial of cases," but "our system of law has always endeavored to prevent even the probability of unfairness." *In re Murchison*, 349 U.S. 133, 136 (1955). Thus, "[e]very procedure which would offer a *possible temptation* to the average man as a judge . . . which might lead him not to hold the balance" between parties "nice, clear and true," "denies . . . due process of law." *Tumey v. Ohio*, 273 U.S. 510, 532 (1927) (emphasis added).

Ignoring these principles, and the facts of this case, the panel majority insisted that there were "no due process concerns in combining the function of initial decision and final disposition in the same Board panel." Op. at 13. While the Supreme Court has upheld combining functions in certain cases, those decisions are all case-specific. In fact, the commingling of functions in a single decision-maker by itself raises "grave doubts" as to the impartiality of agency proceedings. *Hortonville Joint Sch. Dist. v. Hortonville Educ. Assoc.*, 426 U.S. 482, 493 (1976). The issue is "substantial" and "no single answer has been reached." *Withrow*, 421 U.S. at 51. The Supreme Court has cautioned that where a decision-maker is "not capable of judging a particular controversy fairly on the basis of its own circumstances," the requirement of neutrality is not satisfied. *Hortonville*, 426 U.S. at 493. Where "the special facts and circumstances" of a case demonstrate "that the risk of unfairness" due to "the combination of

investigative and adjudicative functions" is "intolerably high," the guarantees of due process are threatened. *Withrow*, 421 U.S. at 58. That risk is present here.

The regulation in question, 37 C.F.R. § 42.4, authorizes a panel of the PTAB to make the initial determination—on a lopsided evidentiary record that includes new expert testimony for the petitioner, but not for the respondent—whether a reasonable likelihood of unpatentability exists, such that *inter partes* review should be instituted. Nothing in the AIA gives a panel of PTAB judges any authority to make unreviewable decisions, but under the express terms of the AIA, the determination whether to institute an IPR (which the statute assigns to the Director) is "final and nonappealable." 35 U.S.C. § 314(d). Once a panel of the PTAB has made the unreviewable decision to institute an IPR, the task of deciding the merits is then assigned to the exact same PTAB panel. This process plainly invites prejudgment, creating the temptations identified in *Tumey* and its progeny.

This system has proved to be unfair. As the Supreme Court has cautioned, courts "should be alert to the possibilities of bias that may lurk in the way particular procedures actually work in practice." *Withrow*, 421 U.S. at 54. "Clearly, if the initial view of the facts" supporting the preliminary determination "as a practical . . . matter, foreclose[s] fair and effective consideration at a subsequent adversary hearing leading to ultimate decision, a substantial due process question would be raised." *Id.* at 58. The way IPRs "actually work in

practice," *id.* at 54, shows that, in fact, the PTAB has been unable to hold the balance "nice, clear, and true." *Tumey*, 273 U.S. at 532. With the PTAB concluding that one or more claims are unpatentable in 86.5 % of the IPRs that it decides, the final decision is typically a foregone conclusion and the "risk of unfairness" is "intolerably high." *Withrow*, 421 U.S. at 58.

The panel majority brushed aside these due process concerns, citing cases that—on their particular facts—led courts to find that no prejudgment had taken place. But the cases the majority cited involved the question of prejudgment in a particular case, not whether an agency's conduct showed a pattern or practice of prejudgment. Only one case cited by the majority, *Richardson v. Perales*, 402 U.S. 389 (1971), cited data that could shed light on the presence or absence of systemic bias in an agency's procedure, and the data there showed that the challenged proceedings were *not* unfair: "The 44.2% reversal rate for all federal disability hearings in cases where the state agency does not grant benefits . . . attests to the fairness of the system and refutes the implication of impropriety." *Id.* at 410.

Where proceedings are resolved at approximately the same rate in favor of either party, as in *Richardson*, there is no apparent risk of bias. But when cases are resolved in favor of the petitioner 86.5% of the time, and those resolutions come after the ultimate decision-maker already has determined that the petitioner is reasonably likely to succeed, then the requirement of neutrality has not been

"jealously guarded." *Marshall*, 446 U.S. at 242. As PhRMA noted in Comments to the PTO, the concern about neutrality is heightened by the fact that the PTAB's then-chief judge has been quoted as stating that "the purpose of [IPR] proceedings is 'death squads'" designed to "identify" and "remove[]" allegedly invalid patents and claims.[8]

Withrow noted that Congress has addressed this "substantial" due process issue in different ways, "providing for varying degrees of separation from complete separation of functions to virtually none at all." 421 U.S. at 51-52. In the AIA, Congress completely separated those functions, assigning the initiation decision to the Director or her delegate and the merits decision to the PTAB. *See* 35 U.S.C. §§ 314(a), 318(a). The statute should be construed as Congress intended in order to avoid the serious constitutional issues that have become manifest.

IV. CONCLUSION

Amici urge the Court to rehear the panel's decision en banc.

[8] Comments of PhRMA, PTO-P-2014-0031, Oct. 16, 2014 at 3-4, http://www.uspto.gov/sites/default/files/ip/boards/bpai/phrma_20141016.pdf (quoting PTAB C.J. James Donald Smith, Patent Public Advisory Committee quarterly meeting, morning session 2 (Aug. 14, 2014) at 50:04-53:10; available at http://new.livestream.com/ uspto/PPAC20140814).

March 14, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on March 14, 2016, I caused the foregoing Brief for *Amici Curiae* Pharmaceutical Research and Manufacturers of America and Biotechnology Innovation Organization in Support of Appellant on Petition for Rehearing *En Banc* to be electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

March 14, 2016

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