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

BRIEF FOR *AMICI CURIAE* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA) AND BIOTECHNOLOGY INNOVATION ORGANIZATION (BIO) IN SUPPORT OF PETITIONER

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STATEMENT OF INTEREST OF *AMICI CURIAE* [1]

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

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. Since 2000, more than 500 new medicines have been approved by FDA. These remarkable results require major investments. In 2015 alone, PhRMA companies invested nearly $60 billion in trying to discover and develop 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.[2]

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[1] Pursuant to Supreme Court Rule 37.3(a), all parties have consented to the filing of this brief. This brief was not authored in whole or in part by counsel for any party. No party and no counsel for any party have made or will make a monetary contribution for the cost of preparing or submitting this brief.

[2] The member companies of PhRMA and BIO are listed on their websites. http://www.phrma.org/about/member-companies; https://www.bio.org/bio-member-directory.

PhRMA and BIO recognize that intellectual property protection provides the incentives that spur research and development needed for the discovery of new drugs, vaccines and biotechnology products. PhRMA and BIO seek to advance policies that enhance the incentives for innovation, and to identify and remove barriers that may impede innovation.

INTRODUCTION AND SUMMARY OF ARGUMENT

The question presented by this case goes to the basic fairness of IPR proceedings and has significant consequences for innovation, especially in the pharmaceutical and biotechnology fields. As organizations that represent leading developers of innovative pharmaceuticals and biotechnology products, PhRMA and BIO have serious concerns about the propriety and fairness of a system that assigns responsibility for instituting IPRs to the PTAB, rather than to the Director, as the statute requires, *see* 35 U.S.C. § 314, and to make matters worse, allocates that responsibility to the same PTAB panel that decides the IPR's ultimate merits. A PTAB panel that has made a threshold determination that a validity challenger has a "reasonable likelihood" of prevailing in an IPR under 35 U.S.C. § 314(a) inevitably is predisposed to confirm its threshold determination when it renders a final decision on the merits.

The results of IPRs bear out this concern. As of August 31, 2016, an astonishing 84.7 % of IPRs that reached a final decision resulted in one or more

claims being invalidated.[3] A fair system, in which the ultimate fact-finder is not predisposed to find patents invalid, would not yield these skewed results.

In addition, a system that commingles the investigative and adjudicative responsibilities in the same PTAB panel strips the IPR process of the independence and impartiality that the America Invents Act (AIA) and the Administrative Procedure Act (APA) both mandate. Fair administration of IPRs, and the applicable provisions of the AIA and APA, require that the threshold decision whether to institute an IPR should not be made by the same PTAB panel that decides the ultimate merits.

ARGUMENT

I. The Issue in This Case is of Serious Concern to Companies Engaged in Developing Innovative Pharmaceutical and Biotechnology Products

Amici have serious concerns about the regulation at issue in this case. PhRMA has repeatedly expressed that concern in written comments to the PTO. Responding to the PTO's Request for Comments on its proposed regulations, PhRMA stated in 2014: "The PTAB panel that conducts an AIA Review should not also institute that review."[4]

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[3] Patent Trial and Appeal Board Statistics (Aug. 31, 2016), https://www.uspto.gov/sites/default/files/documents/2016-08-31%20PTAB.pdf.

[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.

As PhRMA explained, 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]

After 37 C.F.R. § 42.4(a) was enacted, it became apparent that the bias PhRMA had predicted was in fact tainting the IPR process. As PhRMA pointed out in its response to another PTO Request for Comments in 2015, as of October 31, 2015 an overwhelming majority—86.3%—of the PTAB's Final Written Decisions in IPRs had found one or more claims unpatentable.[6]

These skewed outcomes are largely, if not entirely, a consequence of the regulation that allows the same PTAB panel that decides whether to institute an IPR to also be responsible for deciding the IPR's ultimate merits. Once a PTAB panel has made a threshold finding that a petitioner has a "reasonable likelihood" of prevailing in whole or in part in its challenge to a patent's validity, 35 U.S.C. § 314(a), the same panel inevitably is predisposed to confirm that threshold determination when it renders its final decision on the merits.

This is a matter of great concern to *amici* because IPRs increasingly are used to challenge patents in the pharmaceutical and biotechnology industries. In

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[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.

2015, approximately 9% of all IPR petitions were directed at patents covering inventions in those industries; in the first eight months of 2016 (the most recent period for which data is available), that figure rose to 14%.[7] Many of the patents being challenged cover important and valuable inventions.

The potential for unfairness inherent in the current regulatory scheme manifests itself in IPRs' actual outcomes. In 84.7% of final decisions in IPRs, the PTAB panel that instituted the IPR ultimately concludes that at least one patent claim is invalid.[8] In 69.5% of final decisions, the PTAB panel that instituted the IPR ultimately rules that *every* instituted claim is unpatentable.[9] These lopsided outcomes are due, at least in part, to the PTO regulation that allows the same PTAB panel both to institute an IPR and decide the ultimate merits.

A system that is predisposed towards finding patents invalid does not adequately reward the investments that are needed to promote innovation. This danger is especially acute for the companies *amici* represent. Discovering and testing new drugs and new biotechnology products requires an enormous investment. According to a recent study by the Tufts University Center for Drug Development, the average cost for discovering, developing and seeking regulatory approval for a new drug (including the cost of projects that do not

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[7] *Id.*

[8] Patent Trial and Appeal Board Statistics (Aug. 31, 2016) https://www.uspto.gov/sites/default/files/documents/2016-08-31%20PTAB.pdf.

[9] *Id.*

succeed) is $2.558 billion. Joseph A DiMasi, et al., 47 J. HEALTH ECON. 20 (May 2016).[10] When the members of PhRMA and BIO make the investments needed to discover and develop innovative pharmaceutical or biotechnology products, they do so in the expectation that the intellectual property arising from their efforts will be protected by the just administration of U.S. patent law. A system in which the ultimate fact-finder is predisposed towards finding patents invalid reduces the incentive for pharmaceutical and biotechnology companies to make the massive investments needed for innovation. This redounds to the detriment of the public, which would benefit from the discovery of new treatments and cures for serious disease.[11]

The regulation that allows the same PTAB panel to perform the separate functions of both instituting and adjudicating IPRs does not serve the AIA's "overarching purpose" of promoting fairness and objectivity in the patent system.[12] Instead, that regulation has resulted in a skewed system that

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[10] *Accord*: http://www.phrma.org/sites/default/files/pdf/biopharmaceutical-industry-profile.pdf

[11] *See* Claude Barfield & John E. Calfee, *Biotechnology and the Patent System: Balancing Innovation and Property Rights*, at 1-2 (AEI PRESS 2007) ("Without patent protection, investors would see little prospect of profits sufficient to recoup their investments and offset the accompanying financial risk.") https://www.aei.org/wp-content/uploads/2013/12/-biotechnology-and-the-patent-system-book_121440333605.pdf; *see generally* Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 J. INT'L ECONOMIC L. 849 (2002).

[12] 157 Cong. Rec. S5319 (daily ed. Sept. 6, 2011) (statement of Sen. Jon Kyl).

disproportionately invalidates patents and thereby reduces the incentive for innovation. This important issue merits this Court's review.

II. Commingling the Responsibilities for Instituting and Adjudicating IPRs Raises Serious Fairness Concerns and Violates the AIA and Administrative Procedures Act

As Judge Newman explained in her dissent in this case, placing institution decisions in the hands of the same adjudicative body that decides the ultimate merits "violates the text, structure, and purpose of the America Invents Act." Pet. App. 32a (Newman, J., dissenting). *E.g.*, *compare* 35 U.S.C. § 314(a) (describing the standard under which "[t]he *Director* may … authorize an inter partes review to be instituted") *with* § 318(a) ("If an inter partes review is instituted and not dismissed … the *Patent Trial and Appeal Board* shall issue a final written decision") (emphasis added); *see generally* Pet. 12-24.

Placing institution decisions in the hands of the same PTAB panel that decides the ultimate merits also violates the Administrative Procedure Act. *See* Pet. 21-24. "[L]egislators 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). "Prior to the Administrative Procedure Act, there was considerable concern that persons hearing administrative cases at the trial level could not exercise independent judgment because they were required to perform prosecutorial and investigative functions as well as their judicial work." *Butz v. Economou*, 438 U.S. 478, 513-14

(1978). The APA guards against this concern by prohibiting commingling of investigative and adjudicatory functions. *See* 5 U.S.C. § 554(d)(2) ("An employee or agent engaged in the performance of investigative or prosecuting functions for an agency in a case may not … participate in the decision, recommended decision, or agency review[.]"). The regulation at issue in this case violates that provision and harkens back to the era before the APA established "provisions designed to guarantee the independence of hearing examiners." *Butz*, 438 U.S. at 514.

The APA's statutory prohibition against combining investigatory and adjudicatory functions reflects the important value our legal system has always placed in "endeavor[ing] to prevent even the probability of unfairness." *In re Murchison*, 349 U.S. 133, 136 (1955). 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, and in practice, assigning the decision to institute an IPR to the same PTAB panel that decides the ultimate merits is demonstrably unfair. With PTAB panels concluding that at least one claim is unpatentable in 84.7% of IPRs that the same PTAB panel instituted earlier, the final decision in IPRs is too often a foregone conclusion. [13] These skewed outcomes are a consequence of "assigning the same PTAB panel to both institute and conduct an *inter partes* review,"

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[13] *Compare Richardson v. Perales*, 402 U.S. 389, 410 (1971) ("[A] 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.").

resulting in a system that is "not only contrary to the statute, but has the taint of prejudgment." App. 47a (Newman, J., dissenting). The lopsided outcomes in IPRs suggest that "in practice," *Withrow*, 421 U.S. at 54, PTAB panels that have decided to initiate an IPR are unable in their ultimate decisions to hold the balance between adversarial positions "nice, clear, and true." *Tumey v. Ohio*, 273 U.S. 510, 532 (1927). This commingling of responsibilities violates the APA and the AIA, and is fundamentally unfair to innovators that have obtained patents for their work.

CONCLUSION

This Court should grant certiorari to address the important issue presented by this case.

October 24, 2016

Respectfully submitted,

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