Comments of the Pharmaceutical Research and Manufacturers of America
Docket No. PT0–P–2015–0055
November 18, 2015

Comments of the Pharmaceutical Research and Manufacturers of America on the PTO's Request for Comments on a Proposed Pilot Program Exploring an Alternative Approach to Institution Decisions in Post Grant Administrative Reviews

The Pharmaceutical Research and Manufacturers of America ("PhRMA") appreciates the opportunity to submit comments in connection with the Patent and Trademark Office's ("PTO" or "Office") Request for Comments on a Proposed Pilot Program Exploring an Alternative Approach to Institution Decisions in Post Grant Administrative Reviews.[1]

PhRMA's member companies are leading research-based pharmaceutical innovators devoted to developing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA's membership ranges in size from small emerging companies to multi-national corporations that employ tens of thousands of Americans, and encompasses both research-based pharmaceutical and biotechnology companies. The U.S. biopharmaceutical sector supports a total of 3.4 million jobs throughout the economy, and directly employs more than 810,000 Americans.[2] The industry's overall economic impact is substantial, accounting for nearly $800 billion in economic output.[3]

The U.S. biopharmaceutical sector accounts for the single largest share of all U.S. business research and development ("R&D"), representing about one in five dollars spent on domestic R&D by U.S. businesses.[4] PhRMA member investment in discovering and developing new medicines reached over $51 billion in 2014.[5] Medicines developed by the biopharmaceutical sector have produced large improvements in health across a broad range of diseases. The rapid growth of biomedical knowledge has created opportunities for profound advances against our most complex and costly diseases. However, developing a new medicine takes between 10 and 15 years of work and costs an average of $2.6 billion of investment in R&D.[6] Only two of every ten marketed drugs return revenues that exceed or match the R&D investment.[7] Like innovators across the spectrum

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[1] 80 Fed. Reg. 51,540–51,542 (Aug. 25, 2015).

[2] PhRMA, *2015 Biopharmaceutical Research Industry Profile*, inside cover (Apr. 2015), http://www.phrma.org/sites/default/files/pdf/2015_phrma_profile.pdf ("2015 PhRMA Profile").

[3] 2015 PhRMA Profile, Letter from PhRMA's President and CEO.

[4] Battelle Technology Partnership Practice, *The U.S. Biopharmaceutical Industry: Perspectives on Future Growth and the Factors that Will Drive It*, Apr. 2014, at 7, http://www.phrma.org/sites/default/files/pdf/2014-economic-futures-report.pdf.

[5] 2015 PhRMA Profile, inside cover.

[6] Tufts Center for the Study of Drug Development, *Cost to Develop and Win Marketing Approval for a New Drug is $2.6 Billion* (Nov. 18, 2014), http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study (estimating the cost to develop a new drug at $2.558 billion).

[7] 2015 PhRMA Profile, inside cover; *see also* Ernst R. Berndt, Deanna Nass, Michael Kleinrock, & Murray Aitken, *Decline in Economic Returns From New Drugs Raises Questions About Sustaining Innovation*, Health Affairs, Feb. 2015, *available at* http://content.healthaffairs.org/content/34/2/245.abstract.

of American industries, biopharmaceutical companies make the substantial R&D investments that yield new medicines in reliance on a legal regime that provides protection for any resulting intellectual property. In particular, PhRMA's members rely on patents to protect their inventions and provide an opportunity to recover their R&D costs. Patents are critical for biopharmaceutical innovation given the research-intensive nature of this sector and the substantial upfront investment needed to discover and develop products that meet FDA approval requirements.[8]

Bringing new and improved life-saving and life-improving products to people is the driving mission of our member companies. Because intellectual property is critical to carrying out this mission, PhRMA members appreciate the efforts of the PTO to revisit its rules and practices regarding IPR institution decisions and the opportunity to offer PhRMA's perspective on these proceedings. PhRMA is also providing comments on the proposed rules that were published on August 20, 2015 and designed to address the growing due process and fairness concerns raised by AIA trial proceedings. PhRMA's comments below focus only on suggested modifications to the PTO's proposed pilot program exploring an alternative approach to institution decisions.

I. The PTAB's Proposed Pilot Program Should be Instituted Only if Modified to Ensure Fairness.

The PTO has requested comments on a proposed pilot program under which the determination of whether to institute an IPR would be made by a single judge from the Patent Trial and Appeal Board ("PTAB" or "Board"), with two additional judges being assigned to the IPR if a trial is instituted.[9] According to the PTO, "[w]hen possible, the trial panel assignment would maintain the role of the single [judge] as the judge generally managing the proceeding during trial."[10]

The PTO currently has a panel of three PTAB Administrative Patent Judges ("APJs") decide whether to institute a trial. The same three-APJ panel then conducts the trial, if one is instituted. As PhRMA has noted in its prior comments, this practice raises fairness and due process concerns for patent owners.[11] In order to institute an IPR, the PTAB panel must decide

[8] *See* Claude Barfield & John E. Calfee, *Biotechnology and the Patent System: Balancing Innovation and Property Rights* 1–2 (AEI PRESS 2007), https://www.aei.org/wp-content/uploads/2013/12/-biotechnology-and-the-patent-system-book_121440333605.pdf ("Without patent protection, investors would see little prospect of profits sufficient to recoup their investments and offset the accompanying financial risk."); *see generally* Battelle Technology Partnership Practice, *The U.S. Biopharmaceutical Industry: Perspectives on Future Growth and the Factors that Will Drive It*, April 2014; Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 J. INT'L ECON. L. 849 (2002).

[9] U.S. Patent and Trademark Office, Request for Comments on Proposed Pilot Program Exploring an Alternative Approach to Institution Decisions in Post Grant Administrative Reviews, 80 Fed. Reg. 51,540, 51,540–51,542 (Aug. 25, 2015).

[10] 80 Fed. Reg. at 51,541.

[11] *See* Comments of the Pharmaceutical Research and Manufacturers of America, Docket No. PTO-P-2014-0031 (Oct. 16, 2014), http://www.uspto.gov/sites/default/files/ip/boards/bpai/phrma_20141016.pdf.

that there is a reasonable likelihood that the petitioner will prevail with respect to at least one of the challenged patent claims. The panel therefore becomes invested in its finding that the challenged patent is deficient at a very early stage of the proceeding. Because the IPR process as implemented by the PTO involves successive determinations by the same decisionmaker of the same underlying question—that of patent validity—it raises serious due process concerns. *See* 5 U.S.C. § 554(d) (separating agency decision-making functions). The PTAB's practice is particularly troubling given that currently, the institution determination involves a record based on testimonial evidence from only the patent challenger; the patent owner is precluded from relying on testimonial evidence in its preliminary response. The PTAB must therefore make its initial decision based on a one-sided record.

Moreover, and as PhRMA has addressed previously, the decision of whether to institute an IPR should not be made by an APJ.[12] Rather, the institution decision falls within the purview of the Director of the PTO or her delegate.[13] The AIA provides that it is the responsibility of the Director of the PTO to establish the rules for IPRs and post-grant review ("PGR") proceedings, and to determine whether to institute an IPR or PGR.[14] Separately, the AIA enumerates the duties of the PTAB, which do not include instituting IPRs or PGRs. The PTAB's duties are specified as "conduct[ing] inter partes reviews and post-grant reviews pursuant to chapters 31 [Inter Partes Review] and 32 [Post-Grant Review]."[15] In Chapters 31 and 32, the PTAB's duties similarly are limited to "conduct[ing] each . . . review instituted under this chapter."[16] The AIA thus separates the responsibility for instituting an IPR or PGR from the responsibility for conducting an instituted IPR or PGR.[17] The PTO has emphasized in briefing before the Federal Circuit that this separation of functions was intentional: "Congress separated the decision to institute an inter partes review from the decision on the merits of the challenge to the patent…[and] allocated the power to institute an inter partes review to the Director of the United States Patent and Trademark Office."[18]

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[12] Comments of the Pharmaceutical Research and Manufacturers of America, Docket No. PTO-P-2014-0031 (Oct. 16, 2014), http://www.uspto.gov/sites/default/files/ip/boards/bpai/phrma_20141016.pdf.

[13] The AIA's new *inter partes* review proceedings replaced *inter partes* reexamination proceedings, which were similarly bifurcated into institution and merits phases. *See Belkin Int'l, Inc. v. Kappos*, 696 F.3d 1379, 1382 (Fed. Cir. 2012) (explaining that the inter partes reexamination provision created "a two-step process" separating the decision by the Director to institute a reexamination from the examiner's proceedings on the merits). As with other executive decisions of the Director, the decision of whether or not to initiate an *inter partes* reexamination was final and non-appealable. *Id.*

[14] 35 U.S.C. §§ 314; 316; 324; 326.

[15] 35 U.S.C. § 6(b)(4).

[16] 35 U.S.C. §§ 316(c); 326(c).

[17] *See also In re Proctor & Gamble*, No. 14-121, PTO Response Brief, Dkt. No. 19, at 9 (Fed. Cir. Mar. 13, 2014) ("After the Director…makes a decision on the petition for inter partes review, statutory responsibility shifts to the Board to conduct the proceeding[.]").

[18] *Id.* at 6.

The PTO rightly noted that the Director of the PTO functions as a "gatekeeper" with discretion to initiate IPR petitions.[19]

Consistent with this statutory language, it is the responsibility of the Director or her delegate to determine, in her executive capacity, whether or not an IPR should be instituted. If instituted, a PTAB panel of "no fewer than three APJs" will review the petition on the merits.[20]

Although the PTO's pilot program does not comport with the language of the AIA, it does appear to recognize at least some of the fairness concerns posed by current PTAB practices. Unfortunately, the proposed pilot program does not go far enough to effectively avoid potential prejudice to patent owners. The PTO has requested public input on five specific questions related to the proposed pilot program, each of which PhRMA will address in turn.

1. Should the USPTO conduct the single-APJ institution pilot program as proposed herein to explore changes to the panel assignment practice in determining whether to institute review in a post grant proceeding?

PhRMA believes that the pilot program should not be instituted as proposed. The PTO's proposal, under which the determination of whether to institute an IPR will be made by a single PTAB judge, with two additional judges being assigned to the IPR if a trial is instituted, continues to raise fairness concerns. According to the PTAB, the judge with responsibility for making the institution decision will be responsible for "generally managing the proceeding during trial."[21] This raises the possibility that he or she may be more familiar with the underlying facts than the other two judges on the trial panel, and could therefore unduly influence the merits proceedings. Thus, while PhRMA appreciates that the PTO's proposal would bring in additional decision-makers for the trial stage of the proceeding who were not invested in the institution decision, more effective ways of addressing fairness concerns are readily available to the Office, even in the absence of further rulemaking.

In particular, if the agency proceeds with the program, it should ensure that the same APJ who makes the institution decision is precluded from participating in, advising, or considering the merits of the petition. Fully separating the decision to institute an IPR from the decision on the merits would increase patent owners' due process protections and reduce the perception of bias in favor of petitioners.[22] It would also reduce the likelihood that any one

[19] *Id.* at 7.

[20] 35 U.S.C. § 6(c) ("Each appeal, derivation proceeding, post-grant review, and inter partes review shall be heard by at least 3 members of the Patent Trial and Appeal Board, who shall be designated by the Director. Only the Patent Trial and Appeal Board may grant rehearings.").

[21] 80 Fed. Reg. 51,541.

[22] As of October 31, 2015, 630 IPRs reached a Final Written Decision. Of those 630 Final Written Decisions, 544 Final Written Decisions (86.3%) found at least some claims unpatentable. The PTAB has only found that no instituted claims were unpatentable in 86 Final Written Decisions. *See* USPTO, Patent Trial and Appeal Board

judge on the panel would have greater knowledge of the facts or a vested interest in the outcome of the proceeding.

2. What are the advantages or disadvantages of the proposed single-APJ institution pilot program?

As discussed in Part I above, Congress delegated to the Director of the PTO or her delegate the authority to decide whether to institute an IPR or PGR. The PTAB's pilot program—under which a single APJ makes the institution decision and goes on to lead consideration of the petition on the merits—is inconsistent with that legislative directive. Furthermore, although the proposed single-APJ pilot program attempts to address certain fairness issues posed by current PTAB practices, having one PTAB judge make the institution determination and manage the trial proceedings continues to raise concerns.

If, however, the APJ who made the institution decision did not participate in or advise as to the merits phase of an IPR proceeding, then the proposed program would provide fairness advantages over current practices.

3. How should the USPTO handle a request for rehearing of a decision on whether to institute trial made by a single APJ?

As discussed above, PhRMA views the institution decision as one that is committed to the Director's discretion in her executive capacity. If an appropriate executive delegate of the Director was to begin making institution decisions, the Director could easily provide for the reconsideration of those decisions by other executive delegates. Should the Office adopt a procedure in which a single APJ were to institute an IPR or PGR, reconsideration of that institution decision by an expanded panel would appear appropriate, with the proviso that neither the original deciding APJ nor any on the expanded panel should be involved in any subsequent decision on the merits of the matter, or any other decision that is factually related thereto.

Statistics, slide 9, http://www.uspto.gov/sites/default/files/documents/2015-10-31%20PTAB.pdf. These results may stem at least in part from the fact that one PTAB panel decides whether to institute a review, and then confirms its institution decision when ruling on the merits.

4. What information should the USPTO include in reporting the outcome of the proposed single-APJ institution pilot program?

In reporting the outcome of the proposed single-APJ institution pilot program, the PTO should include the following information:

- The technology at issue in the AIA petition (e.g., electrical/computer, mechanical/business method, chemical, bio/pharma, design);
- Whether or not the petition was instituted on any of the challenged claims;
- Whether the claim construction used by the merits panel differed in any material respect from that used in the institution decision;
- Whether the determination of the merits panel differed materially from that of the institution decision; and
- If instituted, whether or not any of the challenged claims were found unpatentable.

5. Are there any other suggestions for conservation and more efficient use of the judicial resources at the PTAB?

In its Request for Comments, the PTO acknowledged that even with additional hiring of PTAB judges, "increases in filings and the growing number of cases may strain the PTAB's continuing ability to make timely decisions and meet statutory deadlines."[23] PhRMA's proposal that institution decisions be made independently by the Director or a non-APJ delegate would allow more judges to be available to handle more post-grant proceedings and backlog. Although the PTO has stated that a single-APJ institution structure would make AIA proceedings more efficient, the risk of biased decision-making far outweighs any potential efficiency benefit offered by the PTO's proposal.

II. Conclusion

PhRMA appreciates the PTO's efforts to revisit its procedures for instituting IPRs and to provide stakeholders the opportunity to comment on the proposed single-APJ institution pilot program. PhRMA and its member companies are committed to helping the PTO find solutions to the many challenges it faces today and in the years to come.

[23] 80 Fed. Reg. 51,541.