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June 26, 2020

Comments of the Pharmaceutical Research and Manufacturers of America on the USPTO's Request for Comments for Changes to the PTAB Rules of Practice for Instituting on All Challenged Patent Claims and All Grounds and Eliminating the Presumption at Institution Favoring Petitioner as to Testimonial Evidence (Docket No. PTO-P-2019-0024)

The Pharmaceutical Research and Manufacturers of America ("PhRMA") appreciates the opportunity to submit comments in connection with the United States Patent and Trademark Office ("USPTO" or "Office") Notice of Proposed Rulemaking on Patent Trial and Appeal Board ("PTAB") Rules of Practice for Instituting on All Challenged Patent Claims and All Grounds and Eliminating the Presumption at Institution Favoring Petitioner as to Testimonial Evidence.[1]

PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier and more productive lives. The U.S. biopharmaceutical industry supports about 4 million jobs across the economy, with more than 800,000 employees across companies working every day to research and develop new treatments and cures for patients. Since 2000, PhRMA member companies have invested more than $900 billion in the search for new treatments and cures, including an estimated $79.6 billion in 2018 alone.[2] While medicines developed by the industry have produced large improvements in health across a broad range of diseases, they come with significant risks and costs for the industry, as developing one new medicine takes over a decade and costs an average of $2.6 billion.

Intellectual property protections are essential for biopharmaceuticals given the costly, lengthy and risky process for discovering, developing, and obtaining FDA approval for medicines. It is important that the USPTO maintain the intellectual property protections afforded by the Patent Act in order to foster research and development of innovations that benefit patients. PhRMA appreciates the work of the USPTO in providing incentives for innovation in biopharmaceuticals and other sectors, including its ongoing work to consider potential reforms to PTAB procedures and to provide leadership to improve intellectual property protections domestically and internationally.

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 USPTO to revisit its rules and practices regarding trial proceedings under the America Invents Act ("AIA") before the PTAB and the opportunity to offer PhRMA's perspective on these proposals. For the reasons outlined below, PhRMA supports the USPTO's proposed changes to its rules.

[1] 85 Fed. Reg. 31728-732 (May 27, 2020).
[2] 2019 Profile: Biopharmaceutical Research Industry, *available at* https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/0-9/2019-Profile-Booklet_FINAL_NoBleeds.pdf.

Comments of the Pharmaceutical Research and Manufacturers of America
Docket No. PTO-P-2019-0024
June 26, 2020

I. PhRMA Supports the Proposal to Change the Rules of Practice for Instituting a Review to Require that it be on All Grounds of Unpatentability for the Challenged Claims that are Asserted in the Petition

PhRMA supports the USPTO's proposal to change its rules of practice to either institute PTAB proceedings on all grounds of unpatentability for all claims that are challenged in the petition or deny the petition. This change is consistent with direction of the Supreme Court in *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348 (2018), and the decision in *AC Technologies SA v. Amazon.com*, 912 F.3d 1358 (Fed. Cir. 2019).

The USPTO's proposal to institute on all grounds for all challenged claims provides increased certainty for patent owners. Under the proposed rule, patent owners may face fewer serial challenges because a petitioner that brought forward any ground on a claim in an instituted petition that proceeds to final decision would be estopped from bringing that ground in a subsequent challenge. In contrast, under the current rule that permits partial institution, *Shaw Industries Group, Inc. v. Automated Creel Systems, Inc*., 817 F.3d 1293 (Fed. Cir. 2016), the estoppel would not apply to the grounds the PTAB declined to review when it instituted on other grounds in a petition. The proposed rule therefore would limit the grounds that a petitioner can bring forth against a claim in subsequent challenges. This proposed rule would also increase certainty for patent owners before institution because an all or nothing approach allows the patent owner to anticipate the claims and grounds to be reviewed in the PTAB proceeding should institution occur.

II. PhRMA Supports the USPTO's Proposal to Change the Rules to Conform to the Current Standard of Practice of Providing Sur-Replies to Principal Briefs and Providing that a Patent Owner Response and Reply May Respond to a Decision on Institution

PhRMA supports the USPTO's proposal to change its rules to conform to the current practice of allowing the filing of sur-replies to principal briefs. This change addresses potential fairness and due process concerns because it allows a patent owner to respond to any new exhibits or other new information in the petitioner's reply, and it reduces limitations on the patent owner's opportunity to be heard.

PhRMA further supports the USPTO's proposal to change its rules to conform to the current practice of allowing a patent owner to respond to a decision on institution in its response and sur-reply. This change also addresses fairness and due process concerns by allowing the patent owner to be heard regarding the content of an institution decision and the petitioner's reply.

III. PhRMA Supports the USPTO's Proposal to Eliminate the Presumption that a Genuine Issue of Material Fact Created by the Patent Owner's Testimonial Evidence Filed with a Preliminary Response will be Viewed in the Light Most Favorable to the Petitioner for Purposes of Deciding Whether to Institute a Review

PhRMA supports the USPTO's proposal to eliminate the presumption that a genuine issue of material fact created by patent owner's testimonial evidence filed with a preliminary response be viewed in the light most favorable to the petitioner for the purposes of deciding whether to institute a PTAB proceeding.

As PhRMA pointed out in its prior comments on the USPTO's proposed rulemaking that established the presumption, weighing disputed issues of fact material to institution in favor of the petitioner is at odds with Congress's placement of the burden of proof on a petitioner. *See* 35 U.S.C. § 316(e).[3] It also stands contrary to the practices of federal district courts, which place the burden of proof on the party moving for summary judgment and in which all evidence is viewed in the light most favorable to the movant's opponent. The current practice also arguably undoes the benefit of permitting patent owners to submit testimonial evidence with their preliminary response, given that such evidence expressly is not weighed equally as part of the totality of the evidence.[4]

The USPTO acknowledged in its Federal Register notice that a presumption in favor of the petitioner for genuine issues of material fact may be viewed as discouraging a patent owner from filing testimonial evidence with its preliminary response because some patent owners may believe that such testimony will not be given any weight at the time of institution. PhRMA's earlier comments also highlighted concerns about the effects a presumption in favor of the petitioner might have; in particular, we noted that it could discourage patent owners from including testimonial evidence with their preliminary response because patent owners may be unwilling to risk submitting key evidence at a stage in the proceeding when it may not be afforded proper weight. The submission of testimonial evidence in a preliminary response is important to supporting the position of the patent owner defending its patent rights, and a presumption in favor of the petitioner results in uncertainty for patent owners due to the inconsistent treatment of such evidence between the PTAB and the district courts.[5] PhRMA agrees that an evaluation under a totality of the evidence standard reduces that disincentive for patent owners to include such evidence in their preliminary response and potentially makes PTAB proceedings more

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[3] The AIA, in 35 U.S.C. § 314(a), makes clear that the PTO Director may not authorize institution of an IPR unless the Director determines "that the information presented in the petition . . . and any response filed . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least [one] of the claims challenged in the petition." Pursuant to 35 U.S.C. § 316(e), "the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence." Taken together, these provisions establish that an IPR may be instituted if the Director determines that there is a reasonable likelihood the petitioner will prove a proposition of unpatentability by a preponderance of the evidence.

[4] *See* Comments of the Pharmaceutical Research and Manufacturers of America, Docket No. PTO-P-2015-0053 at 6-7 (November 18, 2015), *available at* https://www.uspto.gov/sites/default/files/documents/PTAB%20Rules%20Aug%202015%20Corp%20Phrma%20Comments.pdf.

[5] *See id*.

balanced, with a more even weighing of the evidence and greater likelihood of having a more complete record for the Board to consider when deciding whether to institute a proceeding.[6]

IV. Conclusion

PhRMA appreciates the USPTO's efforts to revisit its rules and practice regarding trial proceedings under the AIA before the PTAB and the opportunity to offer its perspective on these proceedings. PhRMA and its member companies are committed to helping the USPTO find solutions to the many challenges it faces today and in the years to come.

[6] PhRMA submits that weighing genuine issues of material fact created by patent owner's testimonial evidence in favor of the non-moving party (i.e., the patent owner) to align practice with the district courts would further encourage patent owners to submit such evidence.