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VIA EMAIL: MTABurden2019@uspto.gov

The Honorable Andrei Iancu
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Mail Stop Patent Board
PO Box 1450
Alexandria, VA 22313-1450

Attention: Lead Administrative Patent Judge Christopher L. Crumbley or Lead Administrative Patent Judge Susan L. C. Mitchell, PTAB Notice of Proposed Rulemaking 2019

Re: Docket No. PTO-P-2019-0011

Dear Director Iancu:

I am writing on behalf of the Pharmaceutical Research and Manufacturers of America ("PhRMA") to convey the enclosed views of PhRMA's members in response to the Notice of Proposed Rulemaking on Rules of Practice To Allocate the Burden of Persuasion on Motions to Amend in Trial Proceedings Before the Patent Trial and Appeal Board. PhRMA's members appreciate the opportunity to provide comments on the proposal.

Please feel free to contact me if you have any questions.

Respectfully submitted,

/S/

David E. Korn

Enclosure

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Comments of the Pharmaceutical Research and Manufacturers of America in Response to the USPTO's Proposed Rules of Practice To Allocate the Burden of Persuasion on Motions To Amend in Trial Proceedings Before the Patent Trial and Appeal Board (Docket No.: PTO-P-2019-0011)

The Pharmaceutical Research and Manufacturers of America ("PhRMA") appreciates the opportunity to submit comments in connection with the United States Patent and Trademark Office's ("USPTO" or "Office") Notice of Proposed Rulemaking on Rules of Practice To Allocate the Burden of Persuasion on Motions To Amend in Trial Proceedings Before the Patent Trial and Appeal Board ("Board") (the "Notice"). 84 Fed. Reg. 56,401 (Oct. 22, 2019).

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. 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. PhRMA appreciates the work of the USPTO in providing incentives for innovation in biopharmaceuticals and other sectors, including the ongoing work to consider potential reforms to PTAB procedures.

Intellectual property protections are essential for biopharmaceuticals given the costly, lengthy and risky process for discovering, developing, and obtaining FDA approval for medicines. The U.S. biopharmaceutical industry supports more than 4.74 million jobs across the economy and is the single largest funder of domestic business research and development (R&D). While medicines developed by the industry have produced large improvements in health across a broad range of diseases, such development is costly and risky, as developing one new medicine takes over a decade and costs an average of $2.6 billion. 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 USPTO's ongoing efforts with respect to updating motion to amend practice in post-grant trial proceedings. PhRMA submitted comments in 2018 in response to the request for comments regarding Motion to Amend Practice and Procedures in AIA proceedings (83 Fed. Reg. 54319), but did not address specifically the issue raised in the new notice. PhRMA submits that care should be taken to promote fair and balanced procedures that provide due process protections for patent owners and foster the important incentives for innovation provided by the patent system.

In the comments below, PhRMA addresses the proposed contours with respect to "instances where a party does not meet its burden, [and] the Board may, in the interests of justice, justify a determination regarding the patentability of amended claims based on the record as a whole." 84 Fed. Reg. 56,401. Specifically, PhRMA urges that the following precautions be taken when a petitioner fails to meet its burden in opposing a motion to amend and the Board exercises its discretion to step in "in the interests of justice."

I. The Board Should Step in Only in Rare Circumstances

PhRMA agrees that, as the Notice suggests, the Board should step in to evaluate a motion to amend that is unopposed, or considered to be insufficiently opposed, by a petitioner only in rare circumstances. *See* 84 Fed. Reg. at 56,404 ("The Office anticipates that the Board will exercise such discretion only in rare circumstances."). As a general matter, post-grant trial proceedings are adversarial adjudications, not examinations. "Congress chose to structure a process in which it's the petitioner, not the Director, who gets to define the contours of the proceeding." *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1355 (2018). If a petitioner does not oppose a motion to amend, there is little if any basis for the Board to step into the shoes of the petitioner. This is especially pertinent where a petitioner withdraws from the proceeding, such that there is no ongoing controversy and the trial should be terminated.

Unless a patent owner has expressly requested that a pending motion to amend be treated as not contingent, and requests that the motion to amend be evaluated even absent continued involvement or opposition by the petitioner, the original patent claims should be preserved, and the Board should allocate its limited resources elsewhere. For example, if the petitioner ceases to participate in the trial as the result of a settlement, continuing adjudication from the Board would discourage future settlements and lead to even higher demand on the limited resources of the Office.

II. The Board's Discretion Should Be Carefully Exercised

If the Board nevertheless finds it necessary to step in "in the interests of justice," for example, to evaluate a motion to amend where petitioner has chosen to continue with the trial but not oppose the amendment, there must be clear limitations around the scope of the Board's actions.

First, the Board's consideration of a motion to amend beyond the scope of petitioner's arguments should be limited to new limitations in proposed substitute claims. Otherwise, the Board would be reopening patent prosecution of the already-examined original claim limitations, which is not the purpose or purview of post-grant trial proceedings.

Second, the Board's consideration should be limited to only those grounds and theories of unpatentability raised by the petitioner with respect to the original claims and should further not address any additional issues beyond the basic requirements for motions to amend for which the proposed rulemaking already allocates the burden to the patent owner. Again, the Board should decide and resolve a dispute based on the arguments and issues raised by the parties, not raise new patentability challenges or step into the shoes of the petitioner. *See* Arthrex, Inc. v. Smith & Nephew, Inc., No. 2018-1584, 2019 WL 3938271, at *3 (Fed. Cir. Aug. 21, 2019) ("[A]n agency may not change theories in mid-stream without giving respondents reasonable notice of the change and the opportunity to present argument under the new theory. Nor may the Board craft new grounds of unpatentability not advanced by the petitioner." (internal quotation marks and citations omitted)). In any case, permissible amended claims necessarily fall within the scope of the original claims, and the patent owner already bears the burden to so demonstrate according to the proposed rules. The Notice explains that "the rules would specify that the burden of persuasion is on the patent owner to show that the motion complies with the requirements of 35 U.S.C. 316(d) or 326(d) (requiring that a motion to amend propose a reasonable

number of substitute claims, and that substitute claims do not enlarge scope of the original claims of the patent or introduce new matter)." 84 Fed. Reg. at 56,404.

Third, PhRMA agrees with the Notice that the Board must base any *sua sponte* findings on the relevant evidence of record. *See* proposed 37 C.F.R. § 42.221(d)(3) ("Irrespective of paragraphs (d)(1) and (2) of this section, the Board may, in the interests of justice, exercise its discretion to grant or deny a motion to amend for any reason supported by the evidence of record.") This evidence of record should be limited to the evidence submitted by the parties in the proceeding, and the Board must not make new evidence of record. As noted above, it is the petitioner, not the Board, who defines the contours of a post-grant trial proceeding. *See SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1355 (2018).

III. The Patent Owner Must Have an Opportunity to Respond

If the Board does step in "in the interests of justice" and (contrary to the above) does raise any new issues of patentability or additional evidence relating to a motion to amend that the patent owner has not yet had an opportunity to address, then Administrative Procedure Act protections, due process, and the interests of justice require that the patent owner be provided with a meaningful opportunity to respond before the Board reaches a final written decision. To the extent the Board is permitted to raise new issues or evidence at all (which it should not be), such issues and evidence should be presented in writing and the patent owner then afforded an opportunity to respond in writing and at oral hearing before any final written decision. This would be consistent with practice as it appears to be contemplated by the Notice, *e.g.*, stating that "The Office expects that the Board will [make a determination of unpatentability on a ground not advanced by petitioner] only in rare circumstances, and only where the patent owner has been afforded the opportunity to respond to that evidence and related grounds of unpatentability." *See* 84 Fed. Reg. at 56,404.

Further, any such decision by the Board to intervene *sua sponte* should itself provide a "good cause" basis for extending the 12-month statutory deadline. *See* 37 C.F.R. § 42.100(c) (providing that the 12-month deadline "can be extended by up to six months for good cause by the Chief Administrative Patent Judge"). In these rare circumstances, the Board's provision of good cause extensions is necessary to further its mission of ensuring fair procedures in AIA trials, including providing patent owners a meaningful opportunity to respond to any new issues of patentability or additional evidence introduced into the trial by the unsolicited filing of the Board's paper. The provision of good cause extensions in these rare circumstances would also ensure that the Board has the necessary amount of time to adequately address the issues presented in any final written decision.

IV. Conclusion

PhRMA appreciates the Office's efforts with respect to motion to amend practice in post-grant trials and the opportunity to offer its perspective on the Office's proposals. PhRMA and its member companies are committed to helping the Office develop fair and balanced proceedings today and in the years to come.