

December 20, 2018

Comments of the Pharmaceutical Research and Manufacturers of America in Response to the USPTO’s Request for Comments on Motion to Amend Practice and Procedures in Trial Proceedings Under the America Invents Act Before the Patent Trial and Appeal Board (Docket No.: PTO-P-2018-0062)

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”) Request for Comments on Motion to Amend Practice and Procedures in Trial Proceedings Under the America Invents Act Before the Patent Trial and Appeal Board (“PTAB” or “Board”).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. Since 2000, PhRMA member companies have invested more than \$600 billion in the search for new treatments and cures, including an estimated \$71.4 billion in 2017 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 submits that improvements to PTAB proceedings are necessary to make them more fair and balanced, provide due process protections for patent owners, and foster the important incentives for innovation provided by the patent system. As such, we appreciate the USPTO’s proposed changes to the motion to amend practice used in inter partes reviews (“IPRs”), post grant reviews (“PGRs”), and covered business method patent (“CBM”) proceedings. We believe the changes, if implemented, would be an important step toward placing the motion to amend practice within the standard envisioned by Congress and could help to alleviate some of the fundamental fairness and due process concerns surrounding post grant proceedings.

¹ 83 Fed. Reg. 54,319 (Oct. 29, 2018).

In the comments below, PhRMA responds to some of the specific questions raised in the USPTO's Request for Comments (as noted in the header for each section) as well as provides some additional thoughts on how the amendment process can be improved.

I. PhRMA Supports the Implementation of Modifications to the Practices and Procedures on Motion to Amend Practice in AIA Proceedings (Question 1)

PhRMA believes that the USPTO's proposed modifications are a step in the right direction in order to establish a more fair and balanced process for amending claims.² The Leahy-Smith America Invents Act ("AIA") clearly envisioned the patent owner having a right to amend its claims in IPR, PGR, and CBM proceedings.³ Current USPTO rules and practices, however, have mostly prevented the exercise of this right.⁴ The modifications proposed by the Office could help facilitate the patent owner's right to freely amend its claims at least once as dictated by the AIA, as well as providing a framework for revised motions to amend, which are also envisioned by the AIA.⁵

PhRMA appreciates the USPTO's efforts to reform the motion to amend process; however, in order to ensure that patent owners get a fair opportunity to amend their claims, the USPTO may want to consider some potential issues regarding the USPTO's proposed timelines as well as other factors described below when modifying its amendment practices and procedures.

II. There Should Be Flexibility in the Motion to Amend Timeline and the USPTO Should Provide Guidance on When Extensions of Time Will Be Granted (Questions 2, 3, 7, and 11)

The proposed timeline for filing a motion to amend, an opposition to a motion to amend, and other related papers filed by both parties after a preliminary decision on the motion to amend are relatively tight and the USPTO should consider adding some flexibility into this process.⁶

² Response to Question 1. *See id.* at 54,324 ("Should the Office modify its current practice to implement the proposal summarized above and presented in part in Appendix A1? Why or why not?").

³ *See* 35 U.S.C. § 316(d)(1) (in an IPR, "the patent owner may file 1 motion to amend the patent"); *id.* § 326(d)(1) (in a PGR or CBM, "the patent owner may file 1 motion to amend the patent"); *see also id.* § 316(d)(2) ("Additional motions to amend may be permitted . . . as permitted by regulations prescribed by the Director").

⁴ According to USPTO data, as of March 2018, patent owners filed motions to amend in 305 completed trials and of those only 7 motions to amend were granted. *See* Patent Trial & Appeal Board Motion to Amend Study (Mar. 31, 2018).

<https://www.uspto.gov/sites/default/files/documents/PTAB%20MTA%20Study%20%28Installment%204%20-%20update%20through%2003-31-2018%29.pdf>.

⁵ *See* 35 U.S.C. §§ 316(d)(1) and 316(d)(2).

⁶ Response to Question 2. *See* 83 Fed. Reg. at 54,324 ("Please provide comments on any aspect of the proposed amendment process, including, but not limited to, the content of the papers provided by the parties and the Office and the timing of those papers during an AIA trial."); Response to Question 3. *Id.* ("How does the timeline in Appendix A1 impact the parties' abilities to present their respective cases? If changes to the timeline are warranted, what specific changes are needed and why?"); Response to Question 11. *Id.* at 54,325 ("If the Office implements the proposal in which the Board issues a preliminary decision on a motion to amend, as discussed above, should any additional changes be made to the current default trial schedule to accommodate the new practice?").

The current proposed timeline, in which a patent owner must file its motion to amend one and a half months after an institution decision and one and a half months before the patent owner response, could be difficult to manage and could discourage patent owners from seeking such a motion.⁷ Under the current proposal, a patent owner must first respond to the grounds of unpatentability in its motion to amend before it files its patent owner response.⁸ This forces the patent owner to make its initial patentability arguments in a document with tight page limits⁹ and at an early stage in the proceeding. Similarly, the petitioner must oppose the patentability arguments made in a patent owner's motion to amend before readdressing the same or similar arguments in its petitioner reply. This could be a difficult process for the parties, and it would likely cause inefficiencies as the timeline would result in the parties addressing patentability with the same or similar arguments in two separate and inconsistent briefing schedules.

In order to provide the parties with more time and reduce potential inefficiencies, the USPTO should consider implementing deadlines in which the motion to amend is filed together with the patent owner response and any opposition to the motion to amend is filed with the petitioner reply, as is the current practice. If such a revised timeline is adopted, then the Board's Preliminary Decision on the Motion to Amend would be issued after the petitioner reply, which would provide the Board with the benefit of this filing prior to its preliminary decision. This revised timeline would also prevent the situation envisioned in the current proposal in which the patent owner has to submit its reply to the preliminary decision or revised motion to amend before having the benefit of seeing the arguments in the petitioner's reply.¹⁰

Another important factor to consider with regard to the proposed motion to amend timeline relates to cross-examination of declarant witnesses. The current proposal from the USPTO does not allow cross-examination of declarant witnesses until after the Board's preliminary decision on the motion to amend.¹¹ Most AIA petitions include declarant testimony to support the arguments regarding unpatentability of the patent claims. In a motion to amend, the patent owner must respond to these grounds of unpatentability.¹² Therefore, in order to adequately respond to the grounds of unpatentability in a motion to amend, the Board should afford patent owners' the opportunity to cross-examine the petitioner's declarant witnesses prior to the preliminary decision.¹³ Relatedly, patent owners are likely to submit and rely on declarant testimony to support the patentability of the amended claims. Petitioners should be afforded a similar opportunity to cross-examine the witness before the preliminary decision on the motion

⁷ 83 Fed. Reg. at 54,325-26 (appendices with proposed timelines).

⁸ *Id.* (Appendix A2 Overlay of Proposed New Motion to Amend Process Timeline and AIA Trial Timeline).

⁹ The currently prescribed page-limit on motions to amend is 25 pages. *See* 37 C.F.R. § 42.24(a)(1)(vi).

¹⁰ 83 Fed. Reg. at 54,325-26 (Appendix A2 Overlay of Proposed New Motion to Amend Process Timeline and AIA Trial Timeline).

¹¹ *Id.* at 54,323.

¹² *Western Dig. Corp. v. Spex Techs., Inc.*, IPR2018-00082, Paper 13 at 5-7 (P.T.A.B. Apr. 25, 2018).

¹³ Response to Question 7. *See* 83 Fed. Reg. at 54,324 ("What is the most effective way for parties and the Office to use declaration testimony during the procedure discussed above? For example, how and when should parties rely on declaration testimony? When should cross-examination of declaration witnesses take place, if at all, in the process? At what stage of briefing should a party be able to rely on cross-examination (deposition transcripts) testimony of a witness?").

to amend. Information relating to the cross-examination of these declarant witnesses would also be helpful to the Board in making its preliminary decision on the motion to amend.

If the proposed regulations are changed such that declarant witnesses can be deposed prior to a preliminary decision on the motion to amend, this provides further support for the notion that the proposed timelines should be extended. For example, under the current proposed timeline, a patent owner seeking to depose a declarant whose testimony was submitted with the petition only has one and a half months to take the deposition and draft a response. Similarly, the petitioner only has one and a half months to take the deposition of any patent owner declarant before its opposition to the motion to amend is due. These timeframes could be difficult for both parties.

If the motion to amend deadlines are extended as discussed above, the USPTO should also consider extending the deadline for the final written decision up to 6 months.¹⁴ The motion to amend process alone may establish good cause to extend the deadline for the final written decision.

Lastly, if the USPTO is amenable to extending deadlines, the Office should consider providing guidance to patent owners and petitioners regarding the factors the Office will consider when deciding whether to extend the timeline, such as those listed above.

III. The Board Should Issue a Preliminary Decision in Every Proceeding Where a Patent Owner Files a Motion to Amend (Questions 4 and 5)

PhRMA believes that the Board should issue a preliminary decision in every proceeding where a patent owner files a motion to amend that proposes substitute claims.¹⁵ Absent such a decision, it is unclear how the motion to amend process would proceed. Issuing a preliminary decision provides clarity to the parties on the merits of the substitute claims and the procedure for the motion going forward. If the Board does not issue a preliminary decision in every instance, then the Office needs to provide guidance on the factors the Board will consider in determining whether to issue a preliminary decision.

Relatedly, the Board should consider offering, at a minimum, the following information in a preliminary decision: the patentability of the substitute claims, the prior art being considered for the new limitations, and the Board's opinions on the merits of both petitioner's and patent owner's arguments with respect to patentability.¹⁶ By providing such information, the parties

¹⁴ 35 U.S.C. § 316(a)(11) (“[T]he Director may, for good cause shown, extend the 1-year period by not more than 6 months . . .”).

¹⁵ Response to Question 4. *See* 83 Fed. Reg. at 54,324 (“If the Office implements this proposal, should the Board prepare a preliminary decision in every proceeding where a patent owner files a motion to amend that proposes substitute claims?”).

¹⁶ Response to Question 5. *See id.* (“What information should a preliminary decision include to provide the most assistance to the parties in presenting their case? For example, is there certain information that may be particularly useful as the parties consider arguments and evidence to present in their papers, how issues may be narrowed for presentation to the Board, and/or whether to discuss a settlement?”).

can focus their subsequent arguments on the most relevant issues in order to streamline the proceedings.

IV. Prior Art Searches by Examiners Should Be Limited to References Relevant to New Limitations in the Proposed Substitute Claims (Question 8)

In the event that a petitioner ceases to participate in an AIA trial and the Board solicits the assistance of a patent examiner, the patent examiner's report and prior art searches should be limited to those references relevant to the new limitations in the substitute claims.¹⁷ Doing otherwise would result in a motion to amend completely reopening patent prosecution, which is not the purpose of the AIA proceedings.

V. A Petitioner in an IPR Proceeding Should Not Be Able to Expand the Grounds of Challenge if a Motion to Amend Is Filed (Questions 2, 5, and 6)

A petition for inter partes review may only raise grounds of unpatentability under 35 U.S.C. §§ 102 and 103 “and only on the basis of prior art consisting of patents or printed publications.”¹⁸ Since the AIA does not envision challenges under 35 U.S.C. § 101 as part of the IPR process, filing a motion to amend during an IPR proceeding should not open up a patent to challenges under § 101.¹⁹

Both statutory and regulatory authority prevent a patent owner from enlarging the scope of the claims when seeking to amend claims in an IPR.²⁰ Because the scope of the claims cannot be broadened, the amendments sought are unlikely to create any new § 101 issues.²¹ Therefore, petitioners should not be able to circumvent the statutory scheme and challenge amended claims on § 101 grounds simply because a motion to amend is filed.

¹⁷ Response to Question 8. *See id.* at 54,324-25 (“If a petitioner ceases to participate in an AIA trial and the Board solicits patent examiner assistance regarding a motion to amend, how should the Board weigh an examiner advisory report relative to arguments and evidence provided by a patent owner? What type of assistance or information should a patent examiner provide? Should prior art searches by examiners be limited to those relevant to new limitations added to proposed substitute claims and reasons to combine related to such limitations?”).

¹⁸ 35 U.S.C. § 311(b).

¹⁹ Response to Question 2. *See* 83 Fed. Reg. at 54,324 (“Please provide comments on any aspect of the proposed amendment process, including, but not limited to, the content of the papers provided by the parties and the Office and the timing of those papers during an AIA trial.”); Response to Question 5. *Id.* (“What information should a preliminary decision include to provide the most assistance to the parties in presenting their case? For example, is there certain information that may be particularly useful as the parties consider arguments and evidence to present in their papers, how issues may be narrowed for presentation to the Board, and/or whether to discuss a settlement?”); Response to Question 6. *Id.* (“If the Office implements this proposal, should there be any limits on the substance of the claims that may be proposed in the revised motion to amend? For example, should patent owners be permitted only to add limitations to, or otherwise narrow the scope of, the claims proposed in the originally-filed motion to amend?”).

²⁰ *See* 35 U.S.C. § 316(d)(3) (an “amendment . . . may not enlarge the scope of the claims of the patent.”); 37 C.F.R. § 42.121(a)(2)(ii) (“A motion to amend may be denied where . . . [t]he amendment seeks to enlarge the scope of the claims of the patent[.]”); *Western Dig.*, IPR2018-00082, Paper 13 at 5-7.

²¹ Although the Board has previously considered patentability of amended claims under § 101, there is no statutory authority to do so, especially post *Aqua Products, Inc. v. Matal*, 872 F.3d 1290 (Fed. Cir. 2017) when the burden of proof is now placed on the petitioner to prove unpatentability of amended claims.

VI. Estoppel Should Apply to a Petitioner’s Challenge of Amended Claims (Question 2)

Under 35 U.S.C. §§ 315(e) and 325(e), a petitioner is estopped from challenging claims “on any ground that the petitioner raised or reasonably could have raised during that [inter partes or post-grant] review” if the AIA proceeding reaches a final written decision. The Office should clarify that estoppel applies equally to any ground the petitioner raised or reasonably could have raised against any amended claims if the petitioner chooses to oppose the motion to amend.²² Such a clarification would be consistent with the intent of the AIA that petitioners should not be able to challenge the same claims multiple times.

VII. Motions to Amend Should Be Contingent (Question 10)

A motion to amend filed under the new process should be contingent such that the PTAB will only make a patentability determination on the motion to amend if the original claims are found unpatentable.²³ This is the current practice of the Office²⁴ and should not be changed as it guarantees the patent owner the full scope of their valid invention rather than forcing a patent owner to give up valid patent scope.

VIII. The Office Should Retain the Ability of Patent Owners to Pursue Reissue Where Appropriate

Finally, as an alternative to the motion to amend practice, the Office should retain the ability of patent owners to use the reissue process to correct or change any claims that have been found unpatentable. As the Office itself has recognized, the Board does “not *examine* and *allow* or *reject* the substitute claims.”²⁵ The Board itself has suggested the use of reissue proceedings as an alternative avenue when a “patent owner desires a complete remodeling of its claim structure.”²⁶ By seeking a reissue, a patent owner can engage in a more traditional examination process in situations that merit such a procedure.

IX. Conclusion

PhRMA appreciates the Office’s efforts to revise the motion to amend practice for AIA trials and the opportunity to offer its perspective on the Office’s proposals. PhRMA and its member companies are committed to helping the Office find solutions to the many challenges it faces today and in the years to come.

²² Response to Question 2. See 83 Fed. Reg. at 54,324 (“Please provide comments on any aspect of the proposed amendment process, including, but not limited to, the content of the papers provided by the parties and the Office and the timing of those papers during an AIA trial.”).

²³ Response to Question 10. See *id.* at 54,325 (“Should a motion to amend filed under the proposed new process be contingent or non-contingent?”).

²⁴ *Western Dig.*, IPR2018-00082, Paper 13 at 3 (“[W]e ordinarily treat a request to substitute claims as contingent.”).

²⁵ *Ariosa Diagnostics v. Isis Innovation Ltd.*, IPR2012-00022, Paper 166 at 51 (P.T.A.B. Sept. 2, 2014).

²⁶ *Idle Free Sys., Inc. v. Bergstrom, Inc.*, IPR2012-00027, Paper 26 at 6 (P.T.A.B. Jun. 11, 2013).