



December 21, 2018

The Honorable Andrei Iancu
Attn: Acting Deputy Chief Administrative Patent Judge
Jacqueline Wright Bonilla or Vice Chief
Administrative Patent Judge Michael Tierney
Mail Stop Patent Board, Director of the United States
Patent and Trademark Office
P.O. Box 1450, Alexandria, VA 22313-1450

Via Email: TrialRFC2018Amendments@uspto.gov

Re: PTAB Request for Comments 2018 (Docket No. PTO-P-2018-0062)

Dear Director Iancu:

The Biotechnology Innovation Organization (“BIO”) appreciates the opportunity to provide comments on the Office’s proposed changes to the amendment procedures currently available in post-grant proceedings before the Patent Trial and Appeal Board (“Board”) conducted pursuant to the America Invents Act (“AIA”). *See* Patent and Trademark Office, Request for Comments, 83 Fed. Reg. 209, 54319-54326 (Oct. 31, 2018) (hereinafter, “the proposed changes”). BIO is the principal trade association representing the biotechnology industry, domestically and abroad. BIO has more than 1,000 members, spanning the for-profit and non-profit sectors and ranging from small start-up companies and biotechnology centers to major research universities and Fortune 500 companies. Approximately 90% of BIO’s corporate members are small or midsize businesses that have annual revenues of under \$25 million.

Because modern biotechnological products commonly involve lengthy, expensive, and resource-intensive development periods, BIO’s members depend heavily on a robust system of patent rights and a fair system for adjudicating their validity. The ability to obtain and protect appropriate patent scope is critically important. Without the promise of effective and predictable patent rights, these investments would be far more difficult, if not impossible, to undertake. Accordingly, BIO’s members are eager for and support improvements to post-grant proceedings that will make them more equitable for patent owners. BIO takes this opportunity to provide its comments on the proposed changes and some suggestions on how to improve the process.



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A. General Comments

BIO applauds the Office for striving to improve its amendment process, which as currently implemented does not provide patent owners a meaningful opportunity to amend their claims. In general, BIO supports a recalibration of the process to enable patent owners to narrow their claims to an appropriate scope, rather than having no scope at all as a result of cancellation.

BIO understands that this is no simple task, given the statutory timeline for completing AIA trials. We appreciate the great amount of work and deliberation that has gone into the proposed changes and view the proposed process as a clear improvement over existing amendment practice. It bears consideration, however, that the changes as currently proposed require motions to amend to be filed very early during the AIA trial – too early in the view of many BIO members. BIO also believes that the ensuing opposition process, while basically sound, should be modified as set forth below.

Overall, BIO recommends that:

(1) The proposed front-loading of the schedule governing motions to amend is not necessary and should not be adopted. The existing schedule, requiring submission of the motion to amend at the same time as the patent owner response, allows for the regular discovery periods to govern development of the record on proposed amendments and should not be altered as proposed.

(2) The proposed preliminary decision should be issued, at the patent owner's request, one month after submission of the patent owner's sur-reply. The preliminary decision should provide guidance on perceived deficiencies and offer the patent owner guidance as to how to have its proposed amendments granted.

(3) The patent owner should be pre-authorized to submit a revised motion addressing any issues noted in the Board's preliminary decision, narrowing the proposed claims. The revised motion should not be accompanied by any testimonial evidence, eliminating the need for a subsequent period of discovery. The Board should also consider giving patent owners an opportunity to submit a revised motion following the oral hearing, if new issues were raised by the Board or the petitioner at that later stage in the proceeding.

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B. Specific Responses

The Office has posed a series of specific requests for comments. BIO provides comments for each request, referring back as needed to responses that address more than one request.

Question 1: “Should the Office modify its current practice to implement the proposal summarized above and presented in part in Appendix A1? Why or why not?”

The Office should modify its current amendment procedures to make the process more feasible, balanced, and predictable. First, a preliminary decision on a proposed amendment, when requested by the proponent, would be a welcome addition to the process because it could provide useful guidance at an early stage as to how to remove prior art of concern and resolve the parties’ dispute. This ultimately could conserve resources of the Office and the parties. Second, while the Office’s current proposal is a significant step towards providing a more robust amendment process, the proposal as outlined may have unintended consequences and may create tension with instructions provided by the courts in *Oil States Energy Services, LLC v. Greene’s Energy Group, LLC*, 138 S. Ct. 1365 (2018) and *Aqua Prod., Inc. v. Matal*, 872 F.3d 1290 (Fed. Cir. 2017) (en banc). For example, in *Oil States*, the Court again emphasized the “paramount interest” in seeing that patent rights are “kept within their legitimate scope.” *Oil States*, 138 S. Ct. at 1374 (citations and quotations omitted). An amendment process that does not provide adequate procedural protections to the patent owner may be more likely to result in claim cancellation rather than amendment to an appropriate, “legitimate scope.”¹ Further, as explained in *Aqua Products*, a patent owner may only propose a substitute claim “by responding to an *instituted ground of unpatentability*.” *Aqua Products*, 872 F.3d at 1306 (citing 35 U.S.C. § 316(d)(1); 37 C.F.R. § 42.121(a)(2)(i)). Accordingly, a schedule that requires submission of proposed substitute claims prior to the patent owner’s response would be premature, as the patent owner will not have had an opportunity to fully consider the grounds of unpatentability set forth in the institution decision. As explained in detail in response to Questions 2, 3, 7, 11, and 13, permitting the motion to amend to come later in the proceeding and allowing the patent owner more opportunities to respond and

¹ See also *Aqua Products*, 872 F.3d at 1299 (“Simply put, the patent owner’s right to propose amended claims is an important tool that may be used to adjust the scope of patents in an IPR.”) (citing 35 U.S.C. § 316(d)(3)); *id.* at 1312 (“As the PTO itself testified before Congress, providing a patent owner with a meaningful opportunity to amend subject to minimal statutory and regulatory criteria helps ‘preserve the merited benefits of patent claims better than the win-all or lose-all validity contests in district court.’ PTO Gen. Counsel Toupin Statement, at 10.”).

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revise its proposed substitute claims would be consistent with the policy objective of allowing patent owners to obtain substitute claims of appropriate scope, rather than no scope whatsoever.

Question 2: “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.”

The motion to amend should not come due 1.5 months after institution as provided in the Office’s proposed changes. The motion to amend should be due at the same time as the patent owner response. As noted above in response to Question 1, having the motion to amend and the patent owner response due at the same time permits the patent owner a reasonable amount of time to propose substitute claims in response to instituted grounds of unpatentability. The opposition to the motion to amend should be due at the same time as the petitioner reply. The patent owner should also be permitted to submit revised substitute claims at least one time after the oral hearing. This final opportunity will allow the patent owner to respond to guidance by the Board and ultimately arrive at substitute claims of appropriate scope, rather than no scope whatsoever. Submission of a motion to amend and going through the subsequent amendment process, or submission of revised substitute claims shortly after the oral hearing responsive to concerns raised by the Board and/or arguments made by the petitioner should ordinarily constitute good causes to allow the panel to extend the proceeding for up to an additional six months. 35 U.S.C. §§ 316(a)(11), 326(a)(11); 37 C.F.R. §§ 42.100(c), 42.200(c). The value in promoting the integrity of the patent system by allowing brief extensions in such proceedings in order to obtain proper patent scope is consistent with the goals of the AIA. *See Aqua Products*, 872 F.3d at 1309 (“And, §§ 316(d)(2) and 317, in combination, contemplate the use of amendments as a settlement tool, indicating that Congress contemplated narrowing amendments which would relieve a petitioner of any threat of infringement, while allowing the patent, as amended, to survive.”)

Question 3: “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?”

The proposed timeline is too front-loaded and compact and could introduce unnecessary gamesmanship due to the discrepancy in timing among different submissions addressing same or similar issues. As written, it could adversely impact the parties’ ability to present their cases. The timeline should be altered so that a first motion to amend is due at the same time as the patent owner’s response. The petitioner will have the regular discovery period, and any opposition to the motion will be due at the same time as the petitioner reply. The patent owner will have the regular discovery period, and any reply is due at the same time as the patent owner’s sur-reply. The Board

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could issue its preliminary decision within one month. The patent owner should then be permitted to submit a revised amendment (without any testimonial evidence), addressing any issue noted in the Board’s preliminary decision regarding compliance with the rules, narrowing the proposed substitute claim(s) (e.g., to overcome any prior art), or revising the claim to address any § 112 issues that were introduced by the amended claim language. The petitioner then may submit a response (without any testimonial evidence) within two weeks of that. The patent owner may submit a reply within one week of that. Sur-replies could be permitted, but should not be necessary in the typical case. As an alternative to submitting a revised amendment prior to the oral hearing, the patent owner could also be authorized to submit another revised motion to amend (without testimonial evidence) within a short period of time following the oral hearing to address new issues that were raised late during the proceeding. In such instances the petitioner may submit another response without testimonial evidence, and the patent owner may submit a reply.

The same briefing schedule would apply if the patent owner elects not to submit a revised amendment, instead just commenting on the preliminary decision. As with the revision briefing, the petitioner would get an opportunity to respond to the comments and the patent owner could file a reply. Sur-replies could be permitted, but should not be necessary in the typical case.

Furthermore, the Office should consider the impact of joinder on its proposed amendment procedure. Currently, joinder of time-barred petitioners is a prevalent practice in *inter partes* review (IPR) proceedings involving Orange Book-listed patents. How and when a patent owner elects to amend its claims often takes into account the involved petitioner, which in the case of joinder, can evolve if the Office allows joinder of additional petitioners. To keep the amendment process manageable and fair, the Office should clearly articulate that any joined petitioner must be a silent understudy and that, with respect to proposed substitute claims, only joint filings from petitioners will be accepted (i.e., each joined petitioner will not be allowed its own papers).

Question 4: “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?”

The Board should not provide a preliminary decision unless the patent owner requests one. In other words, requesting a preliminary decision should be the patent owner’s option. While in most cases, a patent owner will likely request a preliminary decision, in some instances, the patent owner may prefer to not have such a decision issue. For example, the parties may be close to resolving their dispute, and the issuance of a preliminary decision may complicate matters further thus unnecessarily requiring additional expenditure of agency and party resources. In addition,

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there may be concern that such a preliminary, non-binding opinion may nevertheless improperly impact co-pending litigation, licensing efforts, or ongoing prosecution.

Question 5: “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?”

The preliminary decision should address compliance with the rules, any prior art believed to render the proposed claims unpatentable, and any perceived § 112 problems. In the case of IPR, § 112 considerations should be strictly limited to subject matter added or deleted from the claims, consistent with practice in *inter partes* reexamination (*see* 37 C.F.R. § 1.906). The Supreme Court has explained that despite renaming *inter partes* reexamination as IPR, Congress nonetheless intended both types of agency adjudication to have the same basic purpose. *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144 (2016). It logically follows that proposed claim amendments should be approached in the same manner for IPR as they were for *inter partes* reexamination.

The preliminary decision should also address any claim construction issues that impact a decision on the motion to amend. While the institution decision should provide non-final initial claim constructions where necessary, additional claim construction issues may arise by way of a motion to amend. By providing early, non-binding constructions in a preliminary decision on a motion to amend, the parties will be better able to target their arguments and the patent owner may be able to provide clarification, either by further claim refinement or lexicography. This can only improve the efficiency of the proceeding and will not require much if any additional work by the Board as the Board will have to understand the scope of the proposed substitute claims in order to render its assessment in the preliminary decision.

The preliminary decision should not create any presumption or otherwise change the burden of production or persuasion on either the patent owner or petitioner, and the Board should be able to conclude differently in the final written decision than in the preliminary decision even though no new evidence, argument or claim amendment is presented after the preliminary decision.

Question 6: “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

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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?”

The revised motion to amend should be limited to: remedying a problem identified in the Board’s preliminary decision; narrowing the claim(s) (e.g., to overcome prior art); resolving any § 112 issues; or addressing any claim construction issue. By the same token, the petitioner should not be permitted to add new prior art or declaratory evidence at this stage. Like the patent owner, the petitioner is limited to discussing whether the revisions resolve the outstanding issues. These limitations on scope and content will help ensure that no further discovery is needed.

Question 7: “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?”

The parties should be given one round of briefing that permits declaratory evidence and any related discovery. This first round should align with the briefing schedule on the merits, as is the case under the existing procedures. Namely, the opening motion to amend should come due at the same time as the patent owner response and the petitioner’s opposition should come due at the same time as the petitioner’s reply. The patent owner’s reply on the motion should come due at the same time as the patent owner’s sur-reply. In this way, the discovery periods for the merits and the motion overlap. Any briefing after the Board’s preliminary decision, e.g., on a revised motion to amend, should not include any declaratory evidence absent a showing of good cause.

Question 8: “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?”

If the petitioner declines to participate, the Board should assess, on a case-by-case basis, whether examiner support is necessary. The Board should issue a reasoned order explaining why examiner support is deemed necessary (or unnecessary) in a given proceeding. The Board should weigh any such examiner advisory report as it would weigh arguments made by a present and participating petitioner. The examiner’s prior art searches should be limited to those relevant to



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the new limitations and should not constitute a *de novo* examination of the substitute claim. It is important to bear in mind that, as the Federal Circuit recently explained in *Aqua Products*:

[A]mended claims added to an IPR are neither untested nor unexamined. The original claims issued following an examination under all criteria set forth in Title 35. Because proposed amended claims must be narrower in scope and cannot add new matter, they necessarily were subjected to that same earlier examination and are reassessed to determine whether they are supported by the patent's written description.

Aqua Products, 872 F.3d at 1314.

BIO and its members also encourage the Office to clarify that there are other statutorily prescribed procedures available before the Office that may be better suited for the examination (as opposed to adjudication) of amended claims post-grant, and in particular, the Office should explicitly make the reissue process available to the patent owner to correct any errors in the claims that have been found unpatentable by the Board in a final written decision.

Question 9: “Should the Board solicit patent examiner assistance in other circumstances, and if so, what circumstances? For example, should the Board solicit patent examiner assistance when the petitioner remains in the AIA trial but chooses not to oppose the motion to amend?”

The Board is authorized to make findings based upon the record, even where a petitioner declines to participate. 35 U.S.C. § 317(a); *see also Cuozzo Speed Techs.*, 136 S. Ct. at 2139-40. It follows that the Board should be able to consider whether examiner support is needed if the petitioner drops out or fails to meaningfully participate. It is expected, however, that examiner support would not be necessary.

The Board also has discretion to terminate a proceeding. *GTNX, Inc. v. INTTRA, Inc.*, 789 F.3d 1309, 1313 (Fed. Cir. 2015) (“We see nothing in the statute or regulations applicable here that clearly deprives the Board of that default authority.”); *see also Medtronic, Inc. v. Robert Bosch Healthcare Sys., Inc.*, 839 F.3d 1382, 1386 (Fed. Cir. 2016) (same). Should the Board be faced with a situation in which the claim amendment presents an issue requiring substantial examination efforts, or petitioner's lack of participation makes the process untenable, overly complicated, or where continuing the proceeding under those circumstances is otherwise not in the interests of justice, the Board should consider terminating the proceeding outright.

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Question 10: “Should a motion to amend filed under the proposed new process be contingent or non-contingent? For purposes of this question, ‘contingent’ means that the Board will provide a final decision on the patentability of a proposed substitute claim only if it determines that a corresponding original claim is unpatentable (as in the current proposal); and ‘non-contingent’ means that the Board will provide a final decision on the patentability of substitute claims in place of determining the patentability of corresponding original claims.”

The Office should continue to allow patent owners to elect contingent treatment of any motion to amend. The Office’s current practice of allowing patent owners to propose substitute claims contingent on whether the original claims are determined to be unpatentable is a vital option and should be preserved. The ability to pursue substitute claims while also defending the patentability of the original claims ensures that exercising the statutory right to “propose a reasonable number of substitute claims” does not surrender the co-existing right to defend the patentability of original claims. 35 U.S.C. § 316(d); 35 U.S.C. § 316(a)(8). Both rights provide necessary recourse for the patent owner, absent which due process would be jeopardized.

Question 11: “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?”

As discussed in response to Questions 2, 3 and 7, the first round of briefing, which would precede the preliminary decision, should align with the briefing on the merits. The option for submitting a revised amendment should be a compact process focused on allowing the patent owner to address any issues identified by the Board, further narrowing proposed amendments, or addressing any § 112 issues. This compact process should not involve declarants or discovery.

Question 12: “What impact would implementing the proposals above have on small or micro entities who participate as parties in AIA trial proceedings?”

Changes to the process that make amendments a viable option are in the interest of small or micro-entities, who may wish to preserve their patents in some form. The comments above for improving the current proposal are intended to make that process more efficient and less costly. Clarification on reissue and other processes available for these patent owners to correct errors in the claims that have been found unpatentable in a final written decision should also help these patent owners better preserve their rights in the otherwise patentable inventions.



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Question 13: “Should the Office consider additional options for changing the timing and/or the Board’s procedures for handling motions to amend that are not covered by the proposals above? If so, please provide additional options or proposals for the Office to consider, and discuss the advantages or disadvantages of implementation.”

This question is addressed by the answers to Questions 2, 3, 7, and 11.

Question 14: “Should the Office consider not proceeding with the pilot program in AIA trials where both parties agree to opt-out of the program?”

The Office should implement the changes in all AIA trials that are based on petitions filed after the effective date of the revised amendment process. By doing so, the Office will be better able to gather data and assess the success of the changes. Allowing parties to opt out of the program would delay the Office’s ability to gauge the effectiveness of the changes and consider whether further refinement would be appropriate. Moreover, if consent by all parties in a given AIA trial were required to opt out of the pilot program, there would still be a risk of perceived unfairness to parties in other AIA trials in which at least one party did not opt out. Similarly, if opt out by a single party were allowed, then there is the risk of perceived unfairness to those parties who wish to utilize the proposed changes.

Question 15: “Should the Office engage in rulemaking to allocate the burden of persuasion regarding the patentability of proposed substitute claims in a motion to amend as set forth in the *Western Digital* order? What are the advantages or disadvantages of doing so?”

The Office should engage in formal rulemaking to allocate the burden of persuasion in the amendment process as falling on the petitioner. This will reduce uncertainty. And it would be consistent with the statutory mandate that “the petitioner shall have the burden on proving a proposition of unpatentability by a preponderance of the evidence.” 35 U.S.C. §§ 316(e), 326(e).

Question 16: “If the Office continues to allocate the burden as set forth in the *Western Digital* order, under what circumstances should the Board itself be able to justify findings of unpatentability? Only if the petitioner withdraws from the proceeding? Or are there situations where the Board itself should be able to justify findings of unpatentability



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when the petitioner remains in the proceeding? What are the advantages or disadvantages?”

Regardless of the petitioner’s level of participation, a decision issuing a substitute claim reflects an assessment by the agency that the substitute claim does not “enlarge the scope of the claims of the patent or introduce new matter.” 35 U.S.C. § 316(d)(3). If the Board believes that examiner support is needed, then the Board may be justified in availing itself of those resources in an appropriate circumstance. Ultimately, it is the Board’s responsibility to decide the issues in the proceeding. *Cf. Saint Regis Mohawk Tribe v. Mylan Pharm. Inc.*, 896 F.3d 1322, 1327 (Fed. Cir. 2018) (“The Director bears the political responsibility of determining which cases should proceed.”). Further, as noted above, the Board has broad discretion to terminate a proceeding. Should the petitioner’s lack of participation make the process untenable, overly complicated, a waste of resources, or if continuing the proceeding under those circumstances is otherwise not in the interests of justice, the Board should consider vacating the decision to institute and terminating the proceeding.

Question 17: “If the Office adopts the current proposal including a preliminary decision by the Board on a motion to amend, do the answers to questions 15 and 16 change?”

The ultimate burden of proof does not get reallocated merely because the Board issues a preliminary decision. Like a decision on institution, a preliminary decision on a motion to amend would not shift the ultimate burden to the patent owner. *Cf. In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1376-77 (Fed. Cir. 2016) (“[I]t is inappropriate to shift the burden to the patentee after institution to prove that the patent is patentable . . . [T]he petitioner continues to bear the burden of proving unpatentability after institution, and must do so by a preponderance of the evidence at trial. *See* 35 U.S.C. § 316(e). And, the Board has an obligation to assess the question anew after trial based on the totality of the record.”). Even following a preliminary decision, the petitioner continues to bear the burden of proving “all propositions of unpatentability, including for amended claims” by a preponderance of the evidence. *Aqua Prod., Inc.*, 872 F.3d at 1296.

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C. Conclusion

BIO thanks the Office for its consideration of these comments and recommendations. We look forward to working with the Office further on these changes, which will directly impact BIO's members who rely on patent protection to incentivize large-scale investment in biotechnology innovation.

Respectfully submitted,

BIOTECHNOLOGY INNOVATION ORGANIZATION

/s/ Hans Sauer

Hans Sauer
Deputy General Counsel, VP for Intellectual
Property, Biotechnology Innovation Organization