Biotechnology Innovation Organization

25 YEARS OF INNOVATION

December 23, 2019

The Honorable Andrei Iancu
Under Secretary of Commerce for Intellectual Property and
Director of the U.S. Patent and Trademark Office
P.O. Box. 1450
Alexandria, VA 22314

Attn: Lead Administrative Patent Judge Christopher L. Crumbley and
Lead Administrative Patent Judge Susan L.C. Mitchell
Re: PTAB Notice of Proposed Rulemaking 2019

Via Electronic Mail to MTABurden2019@uspto.gov (Docket PTO-P-2019-0011)

Dear Director Iancu:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to provide comments in response to the United States Patent and Trademark Office's proposed revisions to 37 C.F.R. §§ 42.121 and 42.221 as set forth in 84 FR 56401-06, published on October 22, 2019. BIO and its members believe that improvements to the claim amendment process in *inter partes* and post-grant reviews ("post-grant proceedings") are critical to ensuring that patent owners have proper notice and opportunity to amend their claims. Protecting valid patent scope is critical for the biotechnology industry and those who benefit from its innovations.

BIO is the principal trade association representing the biotechnology industry domestically and abroad. BIO has more than 1,000 members which span the for-profit and non-profit sectors and range from small start-up companies and biotechnology centers to research universities and Fortune 500 companies. Approximately 90% of BIO's corporate members are small or mid-size businesses that have annual revenues of under $25 million, and who count their patents among their most valuable business assets. 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. 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 that will make post-grant proceedings more equitable for patent owners.

The Office proposes amendments that will specify that

- a patent owner bears the burden of persuasion to show that a motion to amend complies with certain statutory and regulatory requirements;
- the petitioner bears the burden of persuasion to show that any proposed substitute claims are unpatentable; and

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- in cases where a party does not meet its burden, the Board may exercise its discretion to grant or deny a motion to amend for any reason supported by the evidence of record.

Id. at 56405. BIO agrees that it is appropriate to place the burden of persuasion to show compliance with certain statutory and regulatory requirements on the patent owner, such as those set forth in 37 C.F.R. §§ 41.121(a) and 42.221(a). BIO also agrees that the Office is correct that the burden of persuasion to show unpatentability of any proposed substitute claim should be on the petitioner. Clarification is needed, however, regarding the mechanics of opposing proposed substitute claims on specific grounds and the circumstances under which it would be appropriate for the Board to exercise its discretion to deny a motion to amend for substantive patentability reasons.

The grounds for opposing a proposed substitute claim by the petitioner should not be more expansive than in *ex parte* reexamination and prior *inter partes* reexamination practice.[1] Like these reexamination proceedings, substitute claims in a post-grant proceeding should be opposed only on the basis of patents or printed publications in the record. Section 112 may be raised against a substitute claim only with respect to "amendatory" subject matter; that is, to address any Section 112 defects that were caused by the way the claim was amended. " *C.f.* 37 C.F.R. §§ 1.552, 1.906 ("[c]laims . . . will be examined on the basis of patents or printed publications and, with respect to subject matter added or deleted in the reexamination proceeding, on the basis of the requirements of 35 U.S.C. 112").

In addition, fundamental fairness requires that patent owners be given notice and an opportunity to respond before a proposed substitute claim is denied on a particular ground. For example, a new ground of unpatentability raised in a petitioner's sur-reply in opposition to a motion to amend should not be considered by the Board. Similarly, on the rare occasions in which the Board itself expresses concerns about the substantive patentability of a proposed substitute claim (see more detail below), the patent owner must be given the opportunity to address the issue before a final decision.

In instances in which the petitioner does not meet its burden to prove unpatentability, there may be only very limited circumstances in which the Board would be justified in exercising its discretion to deny a motion to amend. If the patent owner has shown compliance with statutory and regulatory requirements, e.g., no new matter is introduced, the substitute claim has support in the specification and the number of substitute claims is reasonable, and the petitioner does not meet its burden of persuasion, then the motion should ordinarily be allowed. As the Federal Circuit explained:

[1] The Supreme Court has explained that despite renaming *inter partes* reexamination as *inter partes* review, 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 *inter partes* review as they were for *inter partes* reexamination.

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> [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 Prod., Inc. v. Matal, 872 F.3d 1290, 1314 (Fed. Cir. 2017) (en banc).

The Board should not raise grounds of unpatentability itself. While it is true that Board is authorized to make findings even where a petitioner declines to participate, the findings should be based on the ground(s) and evidence that the petitioner had already presented. The adversarial proceedings under *inter partes* or post-grant review would be viewed as biased against patent owners if the Board could effectively assume the role of the petitioner and raise its own grounds of patentability. The Board should not step into the shoes of the petitioner because doing so would mean that the Board would assume the petitioner's burden of initial production and/or eventually showing unpatentability while at the same time acting as the final decider of whether that burden was met. "From the outset, we see that 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 Institute v. Iancu*, 138 S.Ct. 1348, 1355 (2018). In instances where the Board believes there may be a significant, dispositive question of unpatentability that was not addressed by the parties, the Board could indicate such questions in the final written decision to inform the public of the Board's concerns, and any third parties would be free to continue to challenge any claim remaining in the patent under the law.

If the Office decides to allow the Board to raise a new ground or question on its own, the Board should invite the parties to brief such questions specifically.[2] In this way, the burden-allocation would remain on the parties and the Board would maintain its role as adjudicator.[3] There are several mechanisms available that would alleviate concerns about improper substitute claims being entered in the proceeding. For example, if a petitioner were to decline to brief a ground of unpatentability at the Board's request and/or were to drop out of the proceeding, the Board could choose to terminate the proceeding or grant the motion to amend. This approach would strike a balance between encouraging petitioners to brief grounds of unpatentability and protecting legitimate patent scope. In addition, if the Board were to terminate the proceeding based on non-participation by the petitioner, but the Office wanted to further review a question of patentability, then the Director could exercise his or her authority to order *ex parte* reexamination of the claims. *See* 37 C.F.R. § 1.520.

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[2] In such cases, the Board should be instructed that good cause exists to extend the proceeding for up to an additional six months. *See* 35 U.S.C. §§ 316(a)(11) and 326(a)(11).
[3] The petitioner should be limited to briefing the ground of patentability and should not be permitted to add new prior art or declaratory evidence at this stage. This will keep the proceedings manageable and ensure that no further discovery is needed.

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BIO thanks the Office for its consideration of these comments and recommendations. We look forward to continuing our work with the Office on this and other reforms.

Respectfully submitted,

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