



June 26, 2020

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: Michael Tierney, Vice Chief Administrative Patent Judge
Re: 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

Via Electronic Mail to PTABNPRM2020@uspto.gov (Docket PTO-P-2019-0024)

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. §§ 42.23, 42.24, 42.108, 42.208, 42.120, and 42.220 as set forth in 85 FR 31728, published on May 27, 2020 ("Notice of Proposed Rule Making"). BIO supports the Office's use of administrative rule making procedures to ensure that the regulations governing post-grant patent proceedings (*inter partes* review, post-grant review, and covered business method review) are well-considered, formalized, and consistent with statutory mandates.

BIO is the principal trade association representing the biotechnology industry domestically and abroad. BIO has approximately 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.

The Office's Notice of Proposed Rule Making sets forth three categories of proposed changes to the rules governing post-grant proceedings. BIO addresses each such proposal below.



1. Amendment of §§ 42.108(a)-(b) and 42.208(a)-(b) to require that the Board institute on all challenged claims and all grounds raised, or deny a petition in its entirety

The Office proposes to amend certain rules in order to require that the Board either deny institution of a petition or institute a proceeding on all claims challenged and on all grounds raised in the petition. By way of these amendments, the Office seeks to formalize its compliance with the Supreme Court’s mandate in *SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348 (2018) and certain aspects of the Office’s April 26, 2018 Guidance on the Impact of SAS on AIA Trial Proceedings.

BIO supports these proposed amendments. BIO agrees with the Office’s interpretation of *SAS* as instructing that the Board either institute a proceeding on all patent claims challenged in the petition or none at all. Although the Court’s *SAS* decision did not explicitly state that the Board cannot institute on less than all grounds raised in a petition, BIO believes that an “all claims – all grounds” approach is consistent with the Court’s decision and within the Office’s statutory authority. *See, e.g.*, 35 U.S.C. § 316(a). Further, including all grounds raised in a petition in the post-grant trial proceeding will increase efficiency. First, under this approach, all grounds can be dealt with in a single proceeding which will minimize the waste of party and Office resources. Second, there will be less confusion over what grounds can be raised in related district court litigation, thus making the estoppel provisions of 35 U.S.C. § 315(e)(2) more predictable and robust. Finally, there can be no viable allegation of unfairness to the petitioner because the petitioner was the one who selected the Patent Trial and Appeal Board (PTAB) as the venue to bring its challenges.

2. Amendment of §§ 42.23, 42.24, 42.120, 42.220 to permit (1) replies and patent owner responses to address issues discussed in the institution decision, and (2) sur-replies to principal briefs

Amendment of §§ 42.23, 42.24, 42.120, 42.220 as outlined in the Notice of Proposed Rule Making would formally promulgate current PTAB trial practice guidance by permitting (1) patent owner responses and petitioner replies to address issues discussed in an institution decision, and (2) the filing of sur-replies to principal briefs. BIO supports these proposed changes because they will help streamline proceedings and clarify issues for trial. The changes to §§ 42.120 and 42.220 are of particular importance. An institution decision by its nature questions whether the Office properly issued a patent in the first place. Because of the patent owner’s reliance interests in its property rights and the negative impact invalidation of a duly issued patent can have, patent owners should be given full and fair opportunity to address issues framed by the Board’s institution decision as well as to provide focused sur-replies to the petitioner’s papers.



3. Amendment of §§ 42.108(c) and 42.208(c) to eliminate the presumption in favor of petitioner for a genuine issue of material fact created by testimonial evidence

Finally, the Office proposes to eliminate the presumption in favor of petitioners set forth in §§ 42.108(c) and 42.208(c). BIO supports this change because, as amended, the rule is more consistent with the statutory mandate that the petitioner bears the burden of establishing that institution is warranted. 35 U.S.C. §§ 314(a), 324(a). A presumption in the petitioner's favor prior to institution is inconsistent with the statutory mandate.

To further illustrate, it is instructive to consider the ways in which a patent owner's preliminary response resembles a factual attack-based motion to dismiss for lack of subject matter jurisdiction under Fed. R. Civ. P. 12(b)(1). "A factual attack . . . is an argument that there is no subject matter jurisdiction because the facts of the case ... do not support the asserted jurisdiction." *Const. Party of Pa. v. Aichele*, 757 F.3d 347, 358 (3d Cir. 2014). Likewise, the purpose of a patent owner preliminary response is to assert that the petitioner has failed to demonstrate that the standard for institution has been met. 37 C.F.R. §§ 42.108(c), 42.208(c). For example, a patent owner preliminary response attacking the de-facto publication date of a reference relied on in an *inter partes* review petition would be analogous to a factual-attack motion to dismiss under Fed. R. Civ. P. 12(b)(1). Just as a district court plaintiff bears the burden of establishing subject matter jurisdiction, *see, e.g., Mortensen v. First Federal Sav. and Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977), so does the petitioner bear the burden of proof to meet the threshold for institution of an *inter partes* review or post-grant review. And in both of these contexts, the tribunal has the power to weigh facts to fulfill its obligation to determine whether the plaintiff or petitioner has met its burden. As the Third Circuit has explained

Because at issue in a factual 12(b)(1) motion is the trial court's jurisdiction[,], its very power to hear the case[,], there is substantial authority that the trial court is free to weigh the evidence and satisfy itself as to the existence of its power to hear the case. In short, no presumptive truthfulness attaches to plaintiff's allegations, and the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims.

Id. On the other hand, a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6), is not analogous to the patent owner preliminary response. The outcome of a 12(b)(6) motion is a ruling on the legal merits of a plaintiff's claims. Weighing of facts is not proper in a 12(b)(6) motion, and all factual allegations in the complaint must be taken as true. If this approach were taken in the *inter partes* review or post-grant review contexts, then all petitions would necessarily result in institution. Clearly, this is not what the statute contemplates. To the contrary, the statutory



language addressing the sufficiency of the information presented in the petition and the existence of differing standards for institution (reasonable likelihood of prevailing, 35 U.S.C. § 314(a); more likely than not unpatentable, 35 U.S.C. § 324(a)), strongly indicate that “facts matter” at the institution stage. Accordingly, it would make no sense to afford a petitioner any presumptions in its favor with respect to facts asserted in its petition.

There are additional benefits to the Office’s proposed rule change. Without amending these rules, patent owners are discouraged from submitting testimonial evidence with the patent owner preliminary response. This disadvantages patent owners by increasing the likelihood that they will be subject to the time, expense, and threat of institution. Moreover, it also is more likely to waste the time and resources of the Office by tipping the scale in favor of institution even in cases in which testimonial evidence at the patent owner preliminary response stage could have made it clear that institution is unwarranted.

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

Respectfully submitted,

Biotechnology Innovation Organization

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