



July 9, 2018

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: Vice Chief Administrative Patent Judges
Michael Tierney or Jacqueline Wright Bonilla

Via Electronic Mail to PTABNPR2018@uspto.gov (Docket PTO-P-2018-0036)

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. §§ 42.100, 42.200, and 42.300 as set forth in 83 Fed. Reg. 90, 21221, published on May 9, 2018. BIO commends the USPTO on its proposal to adopt the standard set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc) for construing disputed claim terms in *inter partes* reviews, post-grant reviews, and covered business method reviews ("post-grant proceedings") at the Board. Adopting the *Phillips* claim construction standard will improve consistency of results between the Board, district courts, and the International Trade Commission; reduce incentives for parallel-track litigation; and increase efficiency between forums.

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 to post-grant proceedings that will make the proceedings more equitable for patent owners.

The Proposed Rule Will Improve Post-Grant Proceedings and Is Consistent with The AIA.

BIO strongly supports implementation of the proposed rule, which will replace the BRI claim construction standard applied by the Board in post-grant proceedings with the standard set forth in *Phillips* used by district courts and the ITC in patent cases. The Board currently applies the *Phillips* standard to expired patents and claims expected to expire during a post-grant proceeding. Accordingly, implementation of the proposed rule will result in a uniform application of the *Phillips* standard for all claims assessed in the Board's post-grant proceedings, in district court proceedings, and at the ITC.

The proposed rule, if adopted, will increase efficiency, better utilize administrative and court resources, and reduce incentives for parallel-track litigation. Post-grant proceedings were intended to be an administrative alternative to district court litigation to address patentability and validity. Yet the vast majority of patents that are the subject of post-grant proceedings – over 80% – are or were involved in parallel district court litigation. This redundant use of proceedings is likely encouraged, at least in part, by the differing claim construction standards applied by the Board and the courts. There is little efficiency to be gained where two different forums concurrently interpret the same legal instrument – the patent – under different standards. Instead, multiple challenges proceed across the two forums, with the tribunals often having to make redundant fact findings. Adoption of the USPTO's proposed rule will improve the ability to resolve disputes in one forum, rather than duplicate litigation in two forums.

The proposed rule will also help balance the equities of post-grant proceedings and remove an inherent unfairness in the current system that disfavors patent owners. For patent claims being assessed in a post-grant proceeding and in district court litigation, the current system in which the Board applies BRI instead of the *Phillips* standard tends to advantage the petitioner over the patent owner. Given the opportunity, a potential infringer can obtain a broader claim construction for its invalidity case at the Board and a narrower claim construction for its non-infringement arguments at the district court. This dichotomy disadvantages the patentee and can lead to incongruous results. The USPTO's proposal to harmonize the claim construction standards is a sensible and appropriate way to attempt to cure this undue harm to patent owners.

BIO suggests that the USPTO give guidance, either in the finalized rule or through other mechanisms such as a new standard operating procedure, that addresses how the Board will consider a prior district court claim construction relevant to a post-grant proceeding. The Board should provide guidance on how the parties may keep it apprised of district court claim construction proceedings. The Board should also explain what weight a district court construction will be afforded. BIO recommends that in the rare instances in which the Board rejects a district court's construction, the Board should detail why the construction was rejected, including an explanation of any evidence that compelled deviation from the court's determination.

The Proposed Rule Can Be Implemented with only Minor Modifications to Procedural Practice.

BIO further supports the proposed rule because its implementation will not require significant changes to procedural practice before the Board. Adoption of the proposed rule additionally provides the Board with opportunities to further clarify current practice and to consider additional modifications to post-grant proceedings that will benefit patent owners and petitioners alike.

The Board Should Continue Issuing Non-Final Claim Constructions in its Institution Decisions Where Claim Construction is Disputed and Necessary.

The proposed rule does not require deviation from the Board's current practice of performing an initial claim construction analysis in its institution decisions. Current practice requires the petitioner to set forth its claim construction positions in its petition. Patent owners may address claim construction in the preliminary patent owner response. There is no reason why adoption of the *Phillips* standard would require a change to the Board's practice of assessing claim construction issues (to the extent necessary) for its institution decision. Specialized briefing or other formal proceedings relating to claim construction should only rarely, if ever, be necessary prior to institution.

The Board should continue to provide non-final initial claim construction determinations in the Board's institution decisions. First, in many cases, claim construction will be instructive as to whether institution is warranted. Second, parties will be advised of the panel's initial assessment of claim construction issues early on and will be able to better target and manage further claim construction discovery and briefing if a post-grant trial is in fact instituted. However, claim construction should not be a permissible basis for a petitioner to bring new prior art into a proceeding.

The USPTO should explicitly state in the final rule that any claim construction determinations made in the institution decision are non-final. The rule should also make clear that in cases of trial institution, any initial claim construction determinations are subject to modification during the trial, similar to how district courts approach claim construction throughout the duration of a case. The Board currently operates consistent with these notions, however, the harmonization of the Board's claim construction standard with that of district courts may generate uncertainty over the preclusive effect of a Board determination in future proceedings. Of course, an initial claim construction determination is built on a limited evidentiary record and little briefing, and preclusion should not apply in subsequent actions. Nonetheless, without explicit clarification of the non-final nature of initial claim construction determinations, there may be potential for confusion in future proceedings, requiring unnecessary expenditure of resources for parties and courts alike.

The Board Should Permit Claim Construction Discovery But Need Not Adopt Formalized Markman-Style Briefing or Hearings.

Parties should be given a full opportunity to brief and seek discovery on the issue of claim interpretation during an instituted post-grant trial. Because claim construction is currently conducted in post-grant trials, current practices can be maintained or modified as necessary on a case-by-case basis. The Board should consider permitting the panels to be flexible in how they allocate proceeding resources for claim construction purposes, depending on the needs of the case. BIO does not expect implementation of the proposed rule to generally, or even often, require an additional round of claim construction specific briefing or a specialized Markman-style hearing. Such additional briefing or hearings would raise the costs for the parties and strain the Board's resources. Moreover, adoption of the *Phillips* standard should not require these additional expenditures. While *Phillips* is a different legal standard than the BRI standard, in many cases the evidence to be considered in interpreting the claims will be substantially the same – the patent, its file history, and whatever extrinsic evidence is provided.

The Board Should Consider Additional Mechanisms to Address the Impact of Claim Construction in Post-Grant Proceedings.

The USPTO should amend 37 C.F.R. § 42.108(c) such that any genuine issue of material fact created by testimonial evidence submitted with a patent owner preliminary response and pertaining to an issue of claim construction is **not** viewed in the light most favorable to the petitioner. First, claim construction is a question of law. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S.Ct. 831 (2015). Interpretation of the intrinsic record is a legal inquiry, and the only possibly relevant fact findings would have to concern extrinsic evidence. A dispute over extrinsic claim construction evidence would be tangential at best to the merits of the case, and it should never warrant institution of a proceeding. Second, Rule 42.108(c) is disproportionately harmful to patent owners. The Rule in its current form permits institution where the petitioner has not met its burden, subjecting patent owners to unnecessary post-grant trials. *See, e.g., Mylan Pharm. Inc. v. UCB Pharma GMBH*, IPR2016-00512 (P.T.A.B.) (Papers 12 and 37) (relying on 42.108(c) to institute but ultimately finding the subject claims not proven unpatentable). Extension of this rule to factual claim construction disputes under *Phillips* would result in more unwarranted institutions, adding unnecessary costs to patent owners and the Board.

The USPTO could also consider mechanisms that would allow parties in instituted post-grant trials to request a construction prior to the oral hearing. A stipulation, for example, that one party cannot prevail under the construction would permit consenting parties to minimize expenditure of resources in reaching a final written decision, and proceed to an appeal sooner. Because briefing is typically complete in advance of the oral hearing, the Board would have the resources to perform this claim construction but need only do so in cases where the parties voluntarily seek a pre-hearing claim construction order. The reviewing court would also benefit by not having to review unnecessary factual findings pertaining to the prior art.

The Board's Adoption of the *Phillips* Standard for Assessing Proposed Claim Amendments is Warranted.

Use of the *Phillips* standard is appropriate for claim amendments in post-grant proceedings. In a post-grant trial, the patent owner is afforded one opportunity to propose amended claims. By statute, that amendment must be narrowing. See 35 U.S.C. §§ 316(d), 326(d). Because of this inherent narrowing, there should be less concern regarding any purported need to broadly compare the new claim against the art of record. The Board should be well-versed in the technology and art of record at the time it considers proposed substitute claims. Having construed the original claims using the *Phillips* standard, the Board will be in a position to readily determine if an amended substitute claim, as understood using the *Phillips* standard, avoids the prior art.

Further, hybrid application of the *Phillips* standard to the original claims and BRI to proposed substitute claims could lead to aberrant results. A proposed substitute claim will share most of its limitations with the original claim from which it depends. These limitations should be construed the same for both claims. If different claim construction standards were to be applied, the substitute claim could paradoxically be broader than the original claim from which it depends. To the extent claim amendments require additional claim construction, the Board should allow flexibility in how each panel permits the parties to set forth their viewpoints, including the possibility of requesting an initial construction from the panel.

Nor does the use of BRI in *ex parte* post-grant proceedings require that BRI likewise be used for proposed substitute claims in AIA trials. The claim amendment procedure in AIA post-grant proceedings is not akin to examination, supplemental examination, re-examination or reissue. Unlike AIA trials, *ex parte* examinational proceedings were designed to accommodate prior art searching, rejections, and responsive amendment and argument with the examiner, resulting in multiple opportunities to adjust claim language, and with the possibility of *ex parte* appeals. AIA trials, on the other hand, were designed as motion-based, adversarial proceedings in which the petitioner, as the proponent of unpatentability, would have the burden of proof, and the APJ panel deciding whether that burden was met.

If a substitute claim were to be narrowly construed under *Phillips*, added to a patent after an adversarial process, and later asserted in litigation, that substitute claim would be presented on an intrinsic record that would likely leave less ambiguity as to its scope than a claim that was issued under the BRI standard. Accordingly, using *Phillips* for interpreting substitute claims in AIA trials is likely to contribute to business certainty in any subsequent disputes over the patent. *Phillips* inherently results in claims of more sharply defined scope, thus eliminating the need for renewed claim construction battles in the event of later litigation, clarifying noninfringement positions of potential or accused infringers, and facilitating business resolution of commercial disputes. Overall, therefore, using *Phillips* to construe substitute claims is entirely consistent with the goals of the AIA.

The Board Should Apply the *Phillips* Standard to All Pending Cases.

BIO supports making the proposed rule, if finalized, applicable to all then-pending post-grant proceedings. If the rule were applied prospectively-only, the Board could find itself with a glut of petitions being submitted prior to the rule's effective date by petitioners seeking to retain the BRI standard. This would strain administrative resources and cause unnecessary delay. Moreover, making the rule applicable to pending proceedings would be consistent with existing practices, under which parties to post-grant trials already know that claim construction is generally subject to modification until the end of the trial. BIO supports application of the new rule to all pending cases within the Board's jurisdiction, including those in which a final written decision has issued but time remains to request rehearing; or in which the time to file a notice of appeal has not expired. In such cases, the additional work required of the Board should be minimal because the record will have been already developed and only the rare case will require additional evidence or briefing. Similarly, the rule should be applied to any remanded cases that return to the Board from the Court of Appeals. Uniform application of the rule will promote fairness to all participants regardless of the petition filing date or speed of the proceeding.

There should be little to no prejudice to parties in ongoing post-grant proceedings by application of the new standard.¹ First, the change in claim construction standard will not affect the Board's constructions in all cases. Second, even in cases in which the change in standard matters for claim interpretation, it should have no effect on how the prior art is interpreted. And third, parties to ongoing proceedings and the patent community at large are on notice of the proposed rule. Accordingly, there is adequate notice and time to adjust as necessary. Indeed, application of the proposed rule once finalized to pending cases would be consistent with the criteria set forth in *Landgraf v. USI Film Prods.*, 511 U.S. 244 (1994); see also *Thorpe v. Housing Authority of Durham*, 393 U.S. 268, 281-83 (1969) (holding that a mandatory update to the agency's promulgated rules must be applied to a then-pending action); *Goodyear Tire & Rubber Co. v. DOE*, 118 F.3d 1531 (Fed. Cir. 1997) (concluding that the DOE had lawfully applied a newly adopted rule to a then-pending action).

In the same vein, BIO recommends that the USPTO promulgate the proposed rule as soon as possible. Unnecessary implementation delays would cause uncertainty and fairness concerns in now-ongoing cases that are approaching a final written decision and in which the claim construction standard could be outcome-determinative.

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¹ It is difficult to imagine what sort of harm a petitioner could realistically allege it will suffer by implementation of this rule. Post-grant proceedings may only be brought by someone other than the patent owner. 35 U.S.C. §§ 311(a); 321(a). Surely a petitioner cannot be said to have a reliance interest in how the USPTO might interpret the claims of a patent that the petitioner itself does not own. Moreover, even under current practice claim construction does not typically become final until the final written decision, and is subject to modification on appeal, meaning that under any claim construction standard a petitioner cannot reasonably have relied on a term being construed as the petitioner so wished.

BIO appreciates the opportunity to provide these comments on the USPTO's proposed rule regarding adoption of the *Phillips* claim construction standard in post-grant proceedings, as set forth in 83 Fed. Reg. 90, 21221. The proposed rule is a positive step towards re-balancing post-grant proceedings so that patent owners are treated more fairly, efficiencies are preserved between the USPTO and the courts, and consistency of results is promoted.

Respectfully submitted,

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