



The Honorable Andrei Iancu
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Madison Building
600 Dulany Street
Alexandria, VA 22313-1450

Re: **Comments from the Association for Accessible Medicines
Regarding Docket No. PTO-P-2018-0036,
“Changes to the Claim Construction Standard for Interpreting Claims in Trial
Proceedings Before the Patent Trial and Appeal Board”**

Dear Director Iancu:

The Association for Accessible Medicines (“AAM”) is pleased to provide these comments in response to the U.S. Patent and Trademark Office’s (“PTO” or the “Office”) Notice of Proposed Rulemaking entitled “Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board.” We urge the Office not to adopt the proposal, which will bring a standard used in litigation into a proceeding that the Office has successfully convinced the Supreme Court is *not* litigation. At a minimum, the Office should not disrupt settled expectations by applying the standard to matters already pending.

AAM is concerned that the proposal will frustrate the PTO’s important effort to improve patent quality and allow some pharmaceutical patents that are not based on true innovation to block competition from more affordable generic and biosimilar medicines. The consequences of such a policy would be diminished pharmaceutical competition and higher prescription drug prices for patients and taxpayers in the United States.

AAM’s Interest In A Strong, Effective IPR Process

AAM’s core mission is to improve the lives of patients by advancing timely access to safe, effective, and affordable generic and biosimilar medicines. Our association represents the manufacturers and distributors of generic and biosimilar pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. AAM is the sole association representing America’s generic and biosimilar pharmaceutical sector. Our members’ products are used in more than three billion prescriptions every year. Generics represent greater than 89% of all prescriptions dispensed in the U.S., but only 26% of expenditures on prescription drugs, saving patients and payers nearly \$5 billion every week.¹

¹ \$253 billion in total savings in 2016, equivalent to approximately \$5 billion every week. AAM 2017 Generic Drug Access & Savings in the U.S., <https://accessiblemeds.org/sites/default/files/2017-07/2017-AAM-Access-Savings-Report-2017-web2.pdf>.





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AAM applauds the work of the United States Patent and Trademark Office (“PTO”) in examining and issuing high-quality patents. AAM supports a strong and robust patent system to encourage and enable innovation. AAM’s member companies frequently obtain and assert patents themselves. Unfortunately, in the experience of AAM and its member companies, despite the Office’s best efforts, low-quality patents sometimes issue. Not only do these patents discourage and disable innovation, they lead directly to higher health-care costs, by closing off market alternatives and foreclosing the savings that generic competition can bring.

Because of two statutory schemes, the Hatch-Waxman Act and the Biologics Price Competition and Innovation Act (“BPCIA”), generic and biosimilar pharmaceutical companies must address possible patent infringement before launching a product, through costly and protracted patent infringement litigation. These statutory schemes were designed to create a robust generic and biosimilar drug marketplace, and, as a whole, have been a resounding success.

Indeed, some brand-name pharmaceutical companies have found ways to game the system and slow the availability of affordable generics and biosimilar medicines to patients. By abusing the patent system, brand name pharmaceutical companies can extend patent-supported monopolies for years. For example, “ever-greening” is the practice of filing many patents on a single drug over the course of many years, to extend the patentee’s rights well beyond the patent term Congress has prescribed for a single invention. In many cases, the later-filed patents claim small, incremental changes to a drug’s formulation that provide no genuine innovation and no benefit to patients. Yet these low-quality, often non-innovative, patents effectively delay generic competition.

Inter partes review (IPR) and post-grant review (PGR)² provide a means by which manufacturers of generic biosimilar medicines can address and correct these patent abuses. For those reasons, AAM has long been a supporter of these procedures, and of the Office’s efforts to implement them efficiently and effectively. For example, AAM supported the Office’s position and defended the constitutionality – and important role – of IPR in the recent Supreme Court case *Oil States Energy Services, LLC v. Greene’s Energy Group, LLC*.³

AAM Opposes The Office’s Proposal

The Office currently uses the “broadest reasonable interpretation” or “BRI” standard both in examination and in IPR. It apparently does not plan to change its use of that standard in examination. Changing the standard *only* for IPR would create a host of inconsistencies and practical problems. Most significantly, it would undermine the very rationale for IPR, a rationale that the Office has successfully advanced before the Supreme Court: that a patent should not remain in force if it should not have survived examination in the first place. Adopting the Office’s

² In these comments, we use IPR as shorthand for all forms of post-grant review that the Board conducts.

³ 138 S. Ct. 1365 (2018).





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proposal would force the Board to leave in place patents that should not have survived examination.

Just two years ago, the PTO offered the following reasons for maintaining the BRI claim-construction standard for IPRs:

- Using the BRI standard “is consistent with the Office’s long-standing practice in post-issuance proceedings”;⁴
- Using the BRI standard “encourages clear and unambiguous claim drafting”;⁵
- Using the BRI standard “promotes consistency across all reexaminations, reissues, and AIA proceedings involving the same patent or family of patents”;⁶
- Using the BRI standard is appropriate because a “reasonable opportunity to amend exists”;⁷ and “Appropriate rationales exist to apply the broadest reasonable interpretation claim construction standard when there is an ability to clarify claim scope and to apply a *Phillips* construction when no opportunity to amend exists and claims should be construed to preserve validity if possible”;
- “Applying the broadest reasonable interpretation standard in the proceedings serves an important patent quality assurance function.” And “the application of the broadest reasonable interpretation for claims furthers the congressional goal of providing ‘a meaningful opportunity to improve patent quality and restore confidence in the presumption of validity that comes with issued patents in court.’”⁸

Nothing has changed. These rationales are just as applicable today. And as set forth in more detail below, the Office’s proposal contains significant legal and practical flaws.

I. The Office Should Retain The BRI Claim-Construction Standard For All Proceedings at the Patent Office, Rather Than Make IPR A Unique And Anomalous Exception.

All types of proceedings before the Office currently use the BRI standard, from examination to reexamination to PTAB trials to PTAB appeals. Indeed, the Office has used the BRI standard for more than 100 years.⁹ As a result, even though the procedures differ in certain respects at

⁴ 81 Fed. Reg. 18,752.

⁵ *Id.*

⁶ *Id.*

⁷ *Id.*

⁸ *Id.*, quoting H.R. Rep. No. 112–98(I) at 48 (2011), reprinted in, 2011 USCCAN 67, 78 (discussing post-grant proceedings).

⁹ *Cuozzo Speed Techs. LLC v. Lee*, 136 S. Ct. 2131, 2135 (2015).





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different stages, the enterprise is fundamentally the same: to determine whether the claimed invention satisfies the statutory limitations on patentability.

The Office's proposal would change that, and not for the better. As we explain in these comments, the resulting disuniformity would create disruption and undermine IPR.

**A. Abandoning The BRI Standard Would Disregard IPR's Core Mission:
Canceling Patents That Should Not Have Issued**

The basic premise of IPR is that sometimes a claim survives *ex parte* examination even though, if the examiner had had the benefit of more information, it would not have issued (at least not in the same form). IPR allows a third party, the petitioner, to bring that additional information to the Office's attention, and allows the Office to fix its mistake. For that reason, both the Supreme Court and the Director (through the Solicitor General) have repeatedly described IPR as a reconsideration of a decision that has already occurred.

Most recently, the Supreme Court emphasized that IPR "is 'a second look at an earlier administrative grant of a patent,'" and that it involves "the same statutory requirements" and "the same interests as the determination to grant a patent in the first instance."¹⁰ In that same case, the Director's brief defending the statute repeatedly described IPR as a reconsideration of the agency's own decisions and a correction of the agency's own mistakes.¹¹ Similarly, the Director argued and the Court held that despite the different procedures, the Office "makes the same decision" in an IPR or a reexamination.¹²

The Office's proposal would break that connection. The Board would be forced to uphold a patent even if, under the standard that is and would still be followed in examination, the patent should not have issued. That result would be quite at odds with the "obligation" the Director acknowledged in *Oil States*: "'to protect the public' from improperly issued patents, which impose high social costs."¹³

For example, 35 U.S.C. § 102 forbids patenting an invention that is not novel because it is disclosed in the prior art. So as to capture as much of the prior art as possible in this inquiry, an examiner looks at the claims under the BRI standard. Accordingly, if on one reasonable reading a patent claims an invention that is already in the prior art, then an examiner must reject the patent as drafted. But if the Office adopts its proposal, then the Board might have to reach a different conclusion in IPR. Suppose that the IPR petitioner brings to the Board's attention a piece of prior art that, on one reasonable reading of the claim, anticipates the patent. If the

¹⁰ *Oil States*, 138 S. Ct. at 1374.

¹¹ Br. for the Federal Resp., *Oil States*, *supra*, at 4, 16, 20, 23, 30, 36, 47.

¹² *Id.* at 24; see *Cuozzo*, 136 S. Ct. at 2144 (IPR "offers a second look at an earlier administrative grant of a patent. Although Congress changed the name from 'reexamination' to 'review,' nothing convinces us that, in doing so, Congress wanted to change its basic purposes, namely, to reexamine an earlier agency decision.").

¹³ Br. for the Federal Resp., *supra*, at 20 (citations omitted).



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examiner had known about that piece of art, he or she would have had to reject the claim; it could not have issued from the Office. But under the Office's proposal, the Board would have to construe the claim under the *Phillips* standard, and might reach a different conclusion. In short, it might have to sustain even a claim that the examiner would have rejected—and would now reject, if the claim were reexamined.

In that world, IPR would cease to be a “reconsideration” of a prior decision and starts to look like something else entirely, resolving a question the Office never considered during examination. That is not the procedure Congress created, the Director defended, and the Supreme Court upheld.

B. Because IPR Permits The Amendment Of Claims, The Office's Proposal Would Allow Patentees To Obtain New Claims In IPR That They Could Not Have Obtained After Examination

The IPR statute allows the patent owner to file a motion to amend the claims.¹⁴ Indeed, that amendment procedure was a key feature of IPRs, as the Supreme Court emphasized in sustaining the Office's decision to apply the BRI standard in IPR.¹⁵ But the Office's new proposal would turn that feature into something Congress never anticipated: an opportunity to obtain claims that could not survive examination.

In deciding whether to allow an amendment, the Board must determine whether the amended claim is patentable. And under the Office's proposal, the Board would have to carry out that function using not the BRI standard, but the *Phillips* standard: the Notice of Proposed Rulemaking makes quite clear that the new standard would apply not only to “a claim of a patent,” but also to “a claim proposed in a motion to amend.”¹⁶

The result would be the issuance of patents through amendment that have never been examined *and could not survive examination*. That is far removed from Congress's intent in permitting a limited right to amend claims in IPR.

C. The *Phillips* Standard Is Inconsistent With The IPR Statute

Congress mandated that the PTAB can only cancel patent claims during an IPR if the patent challenger proves that the claims are unpatentable by a preponderance of the evidence.¹⁷ This standard of proof is lower than the clear and convincing standard used in district courts.¹⁸

¹⁴ 35 U.S.C. § 316(d).

¹⁵ *Cuozzo*, 136 S. Ct. at 2145; see also *Aqua Prods., Inc. v. Matal*, 872 F.3d 1290, 1298-99 (Fed. Cir. 2017) (en banc) (opinion of O'Malley, J.) (“[T]he 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.”).

¹⁶ 83 Fed. Reg. 21,226 (proposed 37 C.F.R. §§ 42.100(b), 42.200(b), 42.300(b)).

¹⁷ 35 U.S.C. §§ 316(e), 326(e).

¹⁸ 35 U.S.C. § 282.



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Congress intended that the presumption of validity that applies to an issued patent in litigation should *not* apply when the Office itself is reconsidering its own prior action.

In sharp contrast, as the Office noted in its Notice of Proposed Rulemaking, interpreting claims according to the *Phillips* standard includes construing claims to preserve their validity.¹⁹ This is directly contrary to Congress’s purpose in creating IPR—to provide a second objective look at the patent’s validity, without presuming that the patent is valid.

Indeed, the reason for this aspect of the *Phillips* standard is that in court, the patentee no longer has a chance to fix any problems with the patent. That is not so in IPR (just as it is not so in reexamination, another context where no presumption of validity applies²⁰): the patentee has an opportunity to amend, so it makes no sense to *also* give the patentee the benefit of a saving construction when the patent’s validity is dubious.

D. Applying The *Phillips* Standard In IPR Would Lead To Inconsistencies

The IPR and PGR enabling statutes allow the Office to “consolidate” an IPR with any “[o]ther proceeding or matter involving the [same] patent [that] is before the Office.”²¹ All proceedings at the Office currently use the BRI standard. But if the Office adopts the current proposal, it will make consolidation considerably more difficult: the consolidated proceeding would have to employ two different claim-construction standards simultaneously. The Office would have to read the same words to mean different things at the same time. That result is contrary to both congressional intent (in authorizing consolidation with other examinational proceedings before the Office) and sound considerations of practicality. The potential discordance is yet another reason to reject the Office’s proposal.

E. BRI Encourages Precise Patent Drafting

The use of the BRI standard during examination (initial examination and during reissues, reexamination, IPRs, and PGRs) increases the possibility that the patent examiner will find that a claim is too broad and therefore not patentable over the prior art. To avoid rejection of its claims, a patent owner is motivated to draft narrow and precise patent claims. These narrow and precise claims protect a patent owner’s interest over what it actually invented, but also ensure that the patent owner does not preclude competition for subject matter it did not invent.

As the Supreme Court explained, claims should provide clear notice of what is covered and thereby apprise the public of what is still open to them.²² Ambiguous claim language harms the public by creating a “zone of uncertainty which enterprise and experimentation may enter only at

¹⁹ 83 Fed. Reg. 21221, 21223.

²⁰ MPEP § 2286 (citing *In re Etter*, 756 F.2d 852 (Fed. Cir. 1985)).

²¹ 35 U.S.C. §§ 315(d), 325(d); accord 37 C.F.R. §§ 42.122(a), .222(a).

²² *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2129 (2014).



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the risk of infringement claims.”²³ Employing the BRI during IPRs and PGRs helps to provide clear notice, and prevents the creation of this “zone of uncertainty.”

II. If the Office Decides to Change to the Phillips Standard, the Standard Should Apply Only to Patents that Enter IPR or PGR After the New Rule Issues

The Office has stated that it intends that “any proposed rule changes adopted in a final rule would be applied to all pending IPR, PGR, and CBM proceedings.”²⁴ That proposal is both misguided and unnecessary.

The Board commonly construes the relevant claim terms in its institution decision, based on the parties’ submissions in the petition and the patent owner preliminary response. The Board’s construction, in turn, informs the parties’ litigating positions, their conduct of discovery, their retention of experts, and their presentation of their arguments during the IPR itself.

To change the rules in midstream would be both disruptive and unfair. In hundreds of IPRs, the Board’s claim construction is already set. Changing the standard would impose substantial costs on the parties and, indeed, on the Board itself, which would immediately be required to entertain dozens upon dozens of requests to reopen claim construction—and, perhaps, other proceedings conducted in reliance on the Board’s claim construction.

Even for proceedings in which no IPR has yet been instituted, the same considerations warrant leaving the current claim-construction rules in place. Petitioners address claim construction in their petitions. Accordingly, if a petition has already been filed, the petitioner would by definition be prejudiced by the application of a different standard than the century-old standard that was in effect when the petition was written. And even if briefing were reopened in every case—the minimum standard of procedural fairness—the benefits would not be worth the costs. Indeed, a petitioner that has invested the time and effort to prepare a petition—and perhaps forgone the opportunity to pursue other challenges to other patents—has a substantial reliance interest in conducting the petition under the rules in force when it decided to file for an IPR.

By far the administratively simpler option would be to set an effective date six months after publication of any final rule in the *Federal Register*, and apply the new rule to any IPR petition filed after that date. That step would provide adequate notice to the affected stakeholders and ensure that no petitioner (and, for that matter, no patent owner) must tear up work already completed based on the claim-construction standard that has governed proceedings in the Office for a century.

²³ *Id.*

²⁴ 83 Fed. Reg. 21,224.





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III. Conclusion

AAM thanks the PTO for its tireless efforts in ensuring the high quality of the United States patent system. IPRs and PGRs are a safeguard put in place by Congress to help Office maintain its high standards. Changing the claim construction standard used in IPR to a *Phillips* standard would frustrate the important effort to improve patent quality. The result would be continued patent abuse—and in the pharmaceutical sector, the consequences of such abuse are diminished pharmaceutical competition and higher prescription drug prices for patients and taxpayers in the United States.

Sincerely,

/s/

Jeffrey K. Francer,
Senior Vice President & General Counsel

/s/

Rachel Sher,
Deputy General Counsel