



6 WEST HUBBARD STREET  
SUITE 500  
CHICAGO, IL 60654  
[www.rmmslegal.com](http://www.rmmslegal.com)

312-527-2157 main phone  
312-527-4205 main fax

**William A. Rakoczy**  
312.222.6301 Direct Phone  
312.222.6321 Direct Fax  
[wrakoczy@rmmslegal.com](mailto:wrakoczy@rmmslegal.com)

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*Submitted By Email: PTABNPR2018@uspto.gov*

Mail Stop Patent Board  
Director of the United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450  
Attn: Vice Chief Administrative Patent Judges  
Michael Tierney or Jacqueline Wright Bonilla  
PTAB Notice of Proposed Rulemaking 2018

Re: Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings  
Before the Patent Trial and Appeal Board  
83 Fed. Reg. 21,221 (May 9, 2018)  
Docket No. PTO-P-2018-0036  
Regulatory Information No. 0654-AD16

Dear Judges Tierney and Bonilla:

We submit this comment on behalf of Mylan Pharmaceuticals Inc. (“Mylan”) who commends the U.S. Patent and Trademark Office (“PTO” or the “Agency”) on its continued commitment to ensuring U.S. patent quality and enhancing the post-grant review proceedings created by Congress under the America Invents Act (AIA). Mylan appreciates the opportunity to provide comments to the Agency in response to the proposed rule entitled *Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board* (“Proposed Rule”).

Mylan is one of the largest generic and specialty pharmaceutical manufacturers in the world. It is dedicated to providing greater public access to high-quality medicines by bringing lower-priced drugs and biologics to the market. Mylan has fought tirelessly to bring patients the earliest possible access to more affordable medicine. In approximately the last five years alone, Mylan’s patent challenges in district courts and through *inter partes* review (IPR) have allowed consumers to benefit from earlier access to generic competition for more than \$35 billion of annual costs of branded drug products. To do so, Mylan has erased more than 285

years of life from invalid patent claims, which should never have issued and would otherwise have continued to block lower-priced competition.

Mylan thanks the PTO for considering these comments and would welcome any further dialogue or opportunity to assist the PTO in this manner.

## INTRODUCTION

The Proposed Rule would amend the regulations for IPR, post-grant review (PGR), and covered business method (CBM) proceedings (collectively, “AIA Proceedings”), by “replacing the current claim construction standard for interpreting unexpired patent claims and claims proposed in a motion to amend, with an approach that is the same as the standard used by Article III federal courts following *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc).” (*Proposed Rule*, 83 Fed. Reg. at 21,222). In addition, the Proposed Rule would also amend the regulations to allow the PTO to consider any prior claim construction determination concerning a term of the involved claim in a civil action, or an ITC proceeding, that is timely made of record in a IPR, PGR, and CBM proceeding. (*Id.*)

Currently, the PTO construes unexpired patent claims and proposed amended claims in AIA Proceedings under the broadest reasonable interpretation (BRI) standard. (*Proposed Rule*, 83 Fed. Reg. at 21,222). Under this standard, “the PTO must give claims their broadest reasonable construction consistent with the specification.” *See, e.g., In re ICON Health & Fitness, Inc.*, 496 F.3d 1374, 1379 (Fed. Cir. 2007). This means words of a claim are given their plain meaning unless the plain meaning is inconsistent with the patent specification. In comparison, district courts and the ITC use the *Phillips* standard and construe the claims in light of the specification, prosecution history, and evidence extrinsic to the patent. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005). Since the BRI standard focuses on the patent specification while the *Phillips* standard considers additional types of evidence, the *Phillips* standard can sometimes produce a narrower construction than the BRI standard. This means that the BRI standard could potentially read on a broader universe of prior art, making it the appropriate standard for assessing patentability, since it “helps ensure precision while avoiding overly broad claims, and thereby helps prevent a patent from tying up too much knowledge, while helping members of the public draw useful information from the disclosed invention and better understand the lawful limits of the claim.” *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144-45 (2016) (citing *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2129 (2014); *In re Yamamoto*, 740 F.2d 1569, 1571 (Fed. Cir. 1984)).

The PTO’s proposal to shift the *Phillips* standard comes after the Agency’s longstanding and consistent use of the BRI standard for more than 100 years. In fact, the Proposed Rule comes nearly six years after the PTO initially decided to apply the BRI standard in AIA Proceedings and two years after the Supreme Court unanimously concluded that the PTO’s use of the BRI standard in AIA Proceedings was a reasonable exercise of its rulemaking authority. (*Changes to Implement Inter Partes Review Proceedings, Post-Grant Review*

*Proceedings, and Transitional Program for Covered Business Method Patents*, 77 Fed. Reg. 48,680, 48,697 (August 14, 2012)); *Cuozzo*, 136 S. Ct. at 2144-45. Despite receiving affirmation by the Supreme Court that use of the BRI standard was consistent with Congress' purpose in enacting the AIA, its legislative history, and the PTO's past practice, the PTO now seeks to change course without providing adequate justification for its change. As Representative Lofgren recently observed, "[i]t looks to me that people who disagreed with [the AIA] and lost in the Congress, they went to the Supreme Court, they lost in the Supreme Court, and now they're going to [the PTO], and [the PTO is] reversing what Congress decided to do and what the Court said was permissible to do." *Oversight of the United States Patent and Trademark Office: Hearing Before the H. Comm. on the Judiciary*, 115th Cong. (May 22, 2018) (statement of Rep. Lofgren, Member, H. Comm. on the Judiciary).<sup>1</sup>

Mylan believes that the PTO should retain its long-standing and consistent practice of applying the BRI standard in patentability reviews, including AIA Proceedings. For the reasons discussed below, Mylan believes that applying the BRI standard best achieves the Congressional goal of "provid[ing] a meaningful opportunity to improve patent quality and restor[ing] confidence in the presumption of validity that comes with issued patents in court." H.R. Rep. No. 112-98, pt.1, at \*48 (Jun. 1, 2011). More specifically, the PTO's shift from BRI to the *Phillips* standard is fundamentally inconsistent with Congress' over-riding purpose in enacting the AIA, namely to craft a more efficient mechanism (compare *ex parte* and *inter partes* reexaminations) to reassess its earlier patentability decisions and correct mistakes where appropriate to improve patent quality and promote genuine innovation. Furthermore, the PTO's proposed adoption of the *Phillips* standard is an unreasoned and unjustified departure from the PTO's 100-plus year history of using the BRI standard for patentability determinations. Consequently, if the Proposed Rule is implemented, the PTO's actions would be arbitrary and capricious.

## DISCUSSION

### **I. The PTO's Proposed Rule Frustrates the Policy Congress Sought to Implement and Will Undermine the Purpose of the AIA.**

#### **A. Congress Intended AIA Proceedings To Be A "Second Look" At Patentability And Have A Purpose Distinct From District Court Proceedings—The BRI Standard Best Effectuates This Purpose.**

Pursuant to its authority under the Patent Clause, Congress tasked the PTO with the broad and critically important responsibility to evaluate patentability. *See generally Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 95-96 (2011). Consistent with this role, in 2011, Congress significantly expanded the previous procedures (*ex parte* and *inter partes*

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<sup>1</sup> <https://judiciary.house.gov/hearing/oversight-of-the-united-states-patent-and-trademark-office/>

reexamination) by which the PTO could review the patentability of issued patents. *See* 157 CONG. REC. S5347, S5375 (Sept. 7, 2011) (“the post-grant review procedures of Section 6 [*e.g.*, AIA Proceedings] are hardly novel but rather are based on longstanding procedures established by Congress”). Congress’ principle purpose in crafting these new AIA Proceedings – just as its purpose had been in creating *ex parte* and *inter partes* reexamination – was to “improve patent quality by expanding the role of third parties to the patent examination process, *creating a stream-lined first-window, postgrant review to quickly challenge and weed out patents that never should have been issued in the first place.*” 157 CONG. REC. S5347, S5354 (Sep. 7, 2011) (statement of Sen. Leahy) (emphasis added); *see also id.* at S5375 (as with the previous post-issuance reexamination proceedings, Congress created “a mechanism for removing patents that should never have been granted by the PTO because they did not meet the requirements for a valid patent set by Congress in the Patent Act”).

Evolving from PTO’s decades long authority to reexamine and cancel issued patents, Congress crafted AIA Proceedings to be an efficient mechanism to “allow companies . . . to go back to the PTO and demonstrate, with the appropriate prior art, that the patent shouldn’t have been issued in the first place. That way bad patents can be knocked out in an efficient administrative proceeding, avoiding costly litigation.” 157 CONG. REC. S1053 (Mar. 1, 2011) (statement of Sen. Schumer); *see also Cuozzo*, 136 S. Ct. at 2137 (IPRs evolved from *ex parte* and *inter partes* reexaminations which similarly allowed the PTO to reassess its earlier patentability decisions and correct mistakes where appropriate). Indeed, Congress recognized that the Agency’s ability to reassess patentability in an administrative proceeding separate from litigation could “better inform the district court of the patent’s validity” and “restore confidence in the presumption of validity that comes with issued patents in court.” 157 CONG. REC. H4420, H4425-26 (June 22, 2011) (Statement of Rep. Goodlatte) (“When such a defendant company truly believes that the patent being asserted is invalid, it is important for it to have an avenue to request the PTO to take another look at the patent in order to better inform the district court of the patent’s validity.”); H.R. Rep. No. 112-98 at \*48 (AIA Proceedings provide “a meaningful opportunity to improve patent quality and restore confidence in the presumption of validity that comes with issued patents in court.”); 157 CONG. REC. S1325 (Mar. 7, 2011) (Statement of Sen. Sessions) (“This will allow invalid patents that were mistakenly issued by the PTO to be fixed early in their life, before they disrupt an entire industry or result in expensive litigation.”).

Consistent with Congress’ objective of creating an efficient mechanism separate and apart from district court litigation, the Supreme Court, in a unanimous decision, recognized that AIA Proceedings are “less like a judicial proceeding and more like a specialized agency proceeding” having a purpose and procedures different from district court litigation. *Cuozzo*, 136 S. Ct. at 2143-44 (a unanimous Court joined Justice Breyer’s opinion with respect to Parts I and III). More specifically, the Supreme Court recognized that the unique features of IPR and its predecessors:

*indicate[s] that the purpose of the proceeding is not quite the same as the purpose of district court litigation.* The proceeding

involves what used to be called a reexamination (and, as noted above, a cousin of inter partes review, ex parte reexamination, 35 U.S.C. § 302 et seq., still bears that name). The name and accompanying procedures suggest that the *proceeding 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*.

(*Id.* at 2144) (emphasis added); *see also Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1370, 1373 (2018) (noting that IPR is a “reconsideration of the Government’s decision to grant a public franchise” and evolved from Congress’ creation of “administrative processes [such as *ex parte* and *inter partes* reexam] that authorize the PTO to reconsider and cancel patent claims that were wrongly issued.”); *see also See In re Swanson*, 540 F.3d 1368, 1377 (Fed. Cir. 2008) (observing that reexaminations, the predecessor to IPRs, are “conducted according to the procedures established for initial examination,” 35 U.S.C. § 305, and PTO examination procedures have distinctly different standards, parties, purposes, and outcomes compared to civil litigation”) (quoting *In re Etter*, 756 F.2d 852, 856 (Fed. Cir. 1985)).

One of those differing features is the use of the BRI standard for claim construction in contrast to the *Phillips* standard used in district court litigation. To facilitate a fair and fulsome “second look” at patentability, the Supreme Court recognized that the PTO’s use of the BRI standard reflects the PTO’s statutory role as the gatekeeper of patentability and the ability of the patent owner to amend claims during AIA Proceedings. Indeed, the Court observed that the BRI standard gives the PTO the best chance of reexamining patentability and correcting its own mistakes, thus fulfilling Congress’ goal of improving patent quality overall:

[T]he broadest reasonable [interpretation] standard increases the possibility that the examiner will find the claim too broad (and deny it), use of that standard encourages the applicant to draft narrowly. This helps ensure precision while avoiding overly broad claims, and thereby helps prevent a patent from tying up too much knowledge, while helping members of the public draw useful information from the disclosed invention and better understand the lawful limits of the claim.

*See Cuozzo*, 136 S. Ct. at 2144-45 (citing *Nautilus*, 134 S. Ct. at 2129; *Yamamoto*, 740 F.2d at 1571). Accordingly, the use of the BRI standard reinforces the PTO’s role as the assessor of patentability, is consistent with the PTO’s decades long authority to review and cancel patents that fail to meet the statutory standards for patentability, and ultimately is the best standard to effectuate Congress’ goals in enacting the AIA.

**B. The BRI Standard Is Consistent With the Legislative History of the AIA, Particularly Given The PTO's Long-Standing And Consistent Use Of The BRI Standard For Over A Century.**

The PTO and its predecessor have uniformly applied the BRI standard for more than 100 years in office proceedings, including initial examinations, interferences, and post-grant proceedings. *In re Cuozzo Speed. Techs., LLC*, 793 F.3d 1268, 1276 (Fed. Cir. 2015) (recognizing that the BRI standard “has been applied in every PTO proceeding involving unexpired patents.” (emphasis added)). More specifically, for nearly 40 years, the PTO has applied the BRI standard in both *ex parte* and *inter partes* reexaminations—the predecessor post-issuance proceedings from which AIA Proceedings directly evolved from. *In re Yamamoto*, 740 F.2d 1569, 1571 (Fed. Cir. 1984) (affirming PTO’s use of BRI standard in reexamination proceedings); *see generally*, 157 CONG. REC. S5347, S5375 (Sept. 7, 2011) (AIA Proceedings are “hardly novel but rather are based on longstanding procedures established by Congress”).<sup>2</sup> In addition, the Agency has also applied the BRI standard for decades in patent interference proceedings, which are adjudicative in nature and, similar to AIA Proceedings, involve limited discovery and the ability to amend patent claims by motion. *See, e.g., Cuozzo*, 136 S. Ct. at 2145-46; *Bamberger v. Cheruvu*, 55 U.S.P.Q.2d 1523, 1527 (B.P.A.I. 1998) (broadest reasonable construction standard applies in interference proceedings).

Thus, in enacting the AIA, Congress was well aware that the BRI standard was the prevailing claim construction standard in PTO proceedings that evolved into or are procedurally similar to AIA Proceedings. *See Miss. ex rel. Hood v. AU Optronics Corp.*, 571 U.S. 161, 169 (2014) (“[W]e presume that Congress is aware of existing law when it passes legislation.”); *see also Hall v. United States*, 566 U.S. 506, 516 (2012). Indeed, the legislative history is devoid of any evidence of Congressional intent to change the prevailing BRI standard for AIA Proceedings. In fact, the legislative history indicates that Congress was not only aware of the PTO’s longstanding and consistent use of the BRI standard, but that it also expected the Agency to adopt this standard for AIA Proceedings. *See* 157 CONG. REC. S1375 (Mar. 8, 2011) (statement of Sen. Kyl) (allowing written statements to be considered in IPR “should . . . allow the Office to identify inconsistent statements made about claim scope—for example, cases where a patent owner successfully advocated a claim scope in district court that is broader than the ‘broadest reasonable construction’ that he now urges in an *inter partes* review”).<sup>3</sup>

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<sup>2</sup> *See also Oil States*, 138 S. Ct. 1370-71 (“[o]ver the last several decades, Congress has created administrative processes that authorize the PTO to reconsider and cancel patent claims that were wrongly issued” starting from the creation of *ex parte* reexamination in 1980, *inter partes* reexamination in 1999; and *inter partes* review in 2011); *Cuozzo*, 136 S. Ct. at 2137-38 (same).

<sup>3</sup> In addition, when describing the nine (9) differences between IPR proceedings and its predecessor *inter partes* reexaminations, Congress does not identify eliminating the BRI standard as one of these changes. H.R. Rep. No. 112-98 at \*46-47.

Merely six years ago, the PTO itself recognized Congress' awareness of the longstanding and consistent use of the BRI standard and its alignment with the legislative history for the AIA. (77 Fed. Reg. 48,680, 48,697) (August 14, 2012) (“[t]he adoption of the [BRI] standard is . . . consistent with the legislative history of the [AIA] which indicates that Congress was aware of the [BRI] standard and expected the Office to apply the standard to the new [AIA] review proceedings.”) Significantly, the Agency concluded that “[n]othing in the legislative history indicates that Congress or the drafters of the legislation considered a different standard for [AIA Proceedings]. Congress could have set forth a different standard in the [AIA], but instead, Congress provided the statutory mandate for the Office to prescribe regulations to set forth a standard.” (*Id.*)

### **C. The BRI Standard Is Consistent With Other Provisions Of The AIA.**

The BRI standard is congruent with the overall framework of the AIA and the PTO's role as the assessor of patentability. Indeed, the BRI standard best effectuates Congress' over-riding purpose of improving patent quality and promoting genuine innovation at least because it is consistent with (1) the patent owner's opportunity to amend its patent claims under §§ 316(d)(1)(B) and 326(a)(9); (2) the lower evidentiary standard under §§ 316(e) and 326(e) and the lack of the statutorily-mandated presumption of validity; (3) the PTO's authority under §§ 315(d) and 325(d) to consolidate AIA Proceedings with other PTO proceedings and matters involving the same patent; and (4) Congress' directive under §§ 318(a) and 328(a) for the PTO to determine patentability of challenged claims and newly added claims.

First, application of the BRI standard is consistent with the AIA, since the statute contemplates the possibility of claim amendments to clarify the scope of the patent owner's exclusive rights. *See* 35 U.S.C. § 316(d)(1)(B); *see also id.* at § 326(a)(9). It is of no consequence that the ability to amend claims in AIA Proceedings may be limited when compared to the patent applicant's ability to amend during the initial prosecution of the patent since, as noted above, the PTO has long applied the BRI standard in interference proceedings which both limits the patent owner/applicant's ability to amend and is adjudicatory in nature. BPAT Standing Order (Mar. 8, 2011).<sup>4</sup> Courts have consistently recognized that application of the BRI standard for construing claims works in tandem with the patent owner's ability to amend patent claims. *Cuozzo*, 136 S. Ct. at 2145 (the “opportunity to amend, together with the fact that the original application process may have presented several additional opportunities to amend the patent, means that use of the [BRI standard] is, as a general matter, not unfair to the patent holder in any obvious way.”); *see also Yamamoto*, 740 F.2d at 1572 (upholding the PTO application of the BRI standard given that the patent owner “had an opportunity during reexamination in the PTO to amend his claims to correspond with his contribution to the art.”); *In re Reuter*, 651 F.2d 751 (C.C.P.A. 1981) (applying the BRI standard to reissue proceedings where the patent owner

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<sup>4</sup> <http://www.uspto.gov/sites/default/files/ip/boards/bpai/interf/forms/standingordermar2011.pdf>

has the ability to amend claims); *In re Prater*, 415 F.2d 1393, 1404-05 (C.C.P.A. 1969) (holding that the BRI standard is appropriate when amendment is available).

Thus, the BRI standard and the ability to amend claims have long worked hand in hand to encourage patent owners to draft clear and exact claim terms commensurate with the scope of his or her actual contribution to the art and provide notice to the public regarding the metes and bounds of the claimed invention. The PTO itself recognized as much six years ago when it adopted the BRI standard for AIA Proceedings:

An essential purpose of the broadest reasonable claim interpretation standard in the amendment process is to encourage a patent owner to fashion clear, unambiguous claims. Only through the use of the broadest reasonable claim interpretation standard can the Office ensure that uncertainties of claim scope are removed or clarified. Since patent owners have the opportunity to amend their claims during IPR, PGR, and CBM trials, unlike in district court proceedings, they are able to resolve ambiguities and overbreadth through this interpretive approach, producing clear and defensible patents at the lowest cost point in the system.

(77 Fed. Reg. at 48,764). In fact, applying the BRI standard in conjunction with the opportunity to amend may be the only way to advance the AIA's goal of increasing the quality of patents under any of the three possible outcomes of AIA Proceedings: (1) the review confirms the challenged claims as drafted are novel and nonobvious and the patent is properly entitled to the statutory presumption of validity; (2) patentability defects not identified during the initial *ex parte* examination process are corrected by amendment, resulting in a higher quality patent; or (3) the challenged claims are cancelled and a weak patent that never should have been granted or used to block competition is eliminated. Consequently, applying any claim construction standard other than the BRI standard will be incongruent with the patent owner's ability to amend patent claims during AIA Proceedings under §§ 316(d)(1)(B) and 326(a)(9).

Second, along with the ability to amend, the BRI standard is also accordant with the lower evidentiary standard and lack of presumption of validity governing AIA Proceedings. More specifically, in district courts, patents are construed under the *Phillips* standard and are presumed valid, with clear and convincing evidence required to prove otherwise. 35 U.S.C. § 282; *Microsoft*, 564 U.S. at 95; *Phillips*, 415 F.3d at 1314. In contrast, claims in AIA Proceedings are construed under the BRI standard and enjoy no statutory presumption of validity such that the petitioner only has "the burden of proving a proposition of unpatentability by a preponderance of the evidence." 35 U.S.C. §§ 316(e), 326(e); *see, e.g., Dome Patent LP v. Lee*, 799 F.3d 1372, 1379 (Fed. Cir. 2015) ("[w]hen the Patent Office institutes *ex parte* reexamination, it reopens prosecution to determine whether the claimed subject matter should have been allowed in the first place. At that point, there is no need to presume that the Patent Office had 'done its job' in the previous examination. Accordingly, the presumption of validity is

no longer applicable”).<sup>5</sup> Notably, these are the same standards that govern the initial prosecution of a patent application and stem from the PTO delegated role as the assessor of patentability. *Oil States*, 138 S. Ct. at 1374 (finding IPR “involves the same basic matter as a grant of a patent,” and the fact that IPR occurs after the patent has issued “does not make a difference here” since these proceedings “involve[] the same interests as the determination to grant a patent in the first instance”). Alignment of these three standards is inextricably intertwined with each other and correlate to the patent owner’s ability to amend its patent claims during AIA Proceedings. The PTO acknowledged as much when it observed that “[t]he typical justifications for using the [BRI standard]—particularly the ability to amend claims, application of the lower ‘preponderance of the evidence standard’ for determining patentability (35 U.S.C. 316(e), as amended, and 35 U.S.C. 326(e), and the absence of a presumption of validity)—are explicitly provided for by the [AIA], or consistent with it.” (77 Fed. Reg. at 48,697). As such, application of the BRI standard in AIA Proceedings is part and parcel to Congress’ statutory mandate of applying a lower burden of proof and the absence of a statutory presumption of validity.

Third, application of the BRI standard is also compatible with the PTO’s statutory authority to consolidate AIA Proceedings with another PTO proceeding or matters involving the same patent, such as reissue or reexamination proceedings, under 35 U.S.C. § 315(d); *id.* at § 325(d). As discussed below, since the PTO’s Proposed Rule does not suggest changes to the claim construction standard for PTO proceedings or matters outside AIA Proceedings, it is difficult to see how the PTO could apply different claim construction standards within a single consolidated proceeding. This difficulty may make it more likely that the PTO will not consolidate patentability challenges related to the same patent thereby effectively rendering §§ 315(d) and 325(d) meaningless and forgoing an opportunity to efficiently resolve concurrent proceedings.

Finally, the BRI standard is also aligned with Congress’ directive under §§ 318(a) and 328(a) for the PTO to determine “the *patentability* of any patent claim challenged by the petitioner and any new claim added,” as opposed to the validity analysis undertaken by a district court in litigation. 35 U.S.C. § 318(a); *id.* at § 328(a) (emphasis added). As the PTO previously recognized, this “distinction confirms Congress’ intent for the [PTO] to apply the typical framework it currently applies in existing patentability determinations”—including application of the BRI standard. (77 Fed. Reg. at 48,698).

**D. Adopting the *Phillips* Standard Could Make It Difficult For The PTO To Comply With the Congressional Deadline For Completing Such Proceedings.**

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<sup>5</sup> Courts have recognized the presumption of validity and heightened evidentiary standard in litigation arise from deference to the PTO’s specialized expertise. *See, e.g., KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 426 (2007) (courts presume validity because “the PTO, in its expertise, has approved the claim”). But deference to administrative expertise is not an issue during AIA Proceedings when the Agency reviews its own work to correct its own mistakes.

As noted above, Congress' over-riding purpose in creating AIA Proceedings was to provide a quick and efficient administrative procedure to weed out patents that should never have issued in the first place. *See, e.g.*, 157 CONG. REC. S1036-37 (Mar. 1, 2011) (Leahy); 157 CONG. REC. H4220, H4425 (June 22, 2011) (Goodlatte). To ensure that these proceedings would be conducted within a predictable timeline, Congress imposed a strict statutory timeframe wherein each AIA Proceeding must be completed within one year of institution, which may only be extended by six months for good cause. 35 U.S.C. § 316(a)(11); *id.* at § 326(a)(11).

This statutory time limit means that the PTO is obligated to complete each AIA Proceeding within 12-18 months of institution, which is less than half the average time the PTO took to resolve an *inter partes* reexamination. UNITED STATES PATENT & TRADEMARK OFFICE, INTER PARTES REEXAMINATION FILING DATA (Sept. 30, 2017)<sup>6</sup> (on average, an *inter partes* reexamination took roughly 44 months from filing through certificate issue date—with even more time lapsing if the patent-holder appealed an adverse decision within the Agency); *see also* Alison J. Baldwin & Aaron V. Gin, *Inter Partes Review and Inter Partes Reexamination: More Than Just a Name Change*, 11 SNIPPETS 11, 11-12 (2013) (noting it “took an average of three years to reach a final decision that could be appealed to the Court of Appeals for the Federal Circuit.”). Congress intentionally made this change to ensure that AIA Proceedings would be a cost-effective and efficient way to challenge the patentability of issued patents on a predictable timeline. H.R. Rep. No. 112-98 at \*47.

Adopting the *Phillips* standard used by district courts in full-blown infringement litigation could make it difficult for the PTO to comply with the statutory deadline, which will ultimately threaten Congress' over-riding purpose in creating AIA Proceedings. More specifically, claim construction at the district court often involves considerable briefing, expert testimony (both via declaration and live hearing), technology tutorials, and oral argument—which are expensive and time consuming. *Compare Eon-Net LP v. Flagstar Bancorp*, 653 F.3d 1314, 1327 (Fed. Cir. 2011) (stating defendant “expended over \$600,000 in attorney fees and costs to litigate [] through claim construction.”); *see also Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709, 719 (Fed. Cir. 2014) (noting that costs associated with discovery, *Markman* hearings, and trial are “staggering”) *with* Philip Swain, *The Cost-Effectiveness of PTAB Proceedings*, PTAB BLOG (Nov. 13, 2015) (reporting the median cost for completing a PTAB proceeding (through appeal) as \$350,000).<sup>7</sup> Thus, while the current PTAB procedure allows petitioners and patent owners to present claim construction arguments at both the petition and institution phases, there is currently no mechanism that allows for dedicated claim construction briefing or a *Markman* hearing under current procedures. At the very least, the PTO will need to adjust its procedures to accommodate additional intrinsic and extrinsic evidentiary support (by way of written submission or potentially live testimony), particularly if the PTO's claim constructions

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<sup>6</sup> [https://www.uspto.gov/sites/default/files/documents/inter\\_parte\\_historical\\_stats\\_roll\\_up.pdf](https://www.uspto.gov/sites/default/files/documents/inter_parte_historical_stats_roll_up.pdf)

<sup>7</sup> <http://www.ptab-blog.com/2015/11/13/the-cost-effectiveness-of-ptab-proceedings/>

could have heightened relevance to district court and ITC proceedings as they will be applying the same *Phillips* standard. In addition, lengthier and/or more complex reviews of AIA Proceedings may further constrain the PTO's limited resources, particularly since Congress authorizes the PTO budget based on the assumption that AIA Proceedings would be completed within 12-18 months.

## **II. The PTO Provides Inadequate Explanations For Its Departure From The Agency's Longstanding And Consistent Practice of Construing Patent Claims Using BRI.**

As noted above, the PTO and its predecessor have applied the BRI standard for more than 100 years for the Agency's patentability determinations and reviews of unexpired patents. In fact, the PTO's longstanding and consistent use of this standard was one of the central reasons a unanimous Supreme Court found that the PTO's use of the BRI standard in AIA Proceedings was a reasonable exercise of its rulemaking authority. *Cuozzo*, 136 S. Ct. at 2144-45. In 2012, the PTO itself relied on its "well established" use of the BRI standard in patentability determinations to justify the Agency's initial decision to apply this claim construction standard to AIA Proceedings. (77 Fed. Reg. at 48,697).

While the PTO is certainly permitted to reverse course and apply, for the first time, a different claim construction standard, it must provide adequate justifications for its departure from its previous policy—particularly given the longstanding and consistent nature of the Agency's application of the BRI standard. The PTO offers three reasons to justify its shift in the Proposed Rule: (1) increase uniformity and predictability of the patent grant; (2) increase judicial efficiency; and (3) reduce potential unfairness that could result from using an arguably broader standard in AIA Proceedings. (*Proposed Rule*, 83 Fed. Reg. at 21,222-23). But none of these reasons, as set forth below, support, much less justify, the Agency's policy change, especially since this shift may lead to absurd results, including inconsistencies within the Agency's own proceedings.

### **A. The PTO's Adoption of the *Phillips* Standard Would Create Inconsistencies Within the Agency and Not Serve The Agency's Stated Objective To Improve Uniformity and Predictability.**

First, the PTO's goal of improving uniformity between the PTAB and other fora ignores the distinct purpose of AIA Proceedings that is separate and apart from the function of district courts and the ITC. As stated above, the features and accompanying procedures of AIA Proceedings (*e.g.*, ability to amend, lower evidentiary standard, no presumption of validity, etc.) confirm that Congress intended these patentability reviews to function as "a second look at an earlier administrative grant of a patent." *Cuozzo*, 136 S. Ct. at 2144. In direct contrast, district court litigation fulfills a separate purpose, these proceedings typically involve claims, defenses,

and other legal issues which cannot be heard within the narrower confines of AIA Proceedings.<sup>8</sup> Indeed, the Supreme Court recognized the possibility of inconsistent results across different fora as a product of the distinct purpose of each proceeding and an inherent result of Congress' regulatory design. *Id.* at 2146. As such, the PTO's stated objective to promote uniformity and predictability across all fora conflicts with Congress' intent in enacting the AIA and crafting an "efficient system for challenging patents that should not have issued" in the first place that is distinct from the specific purpose of district court and ITC litigation. H.R. Rep. No. 112-98 at \*39-40.

Second, while the PTO's justification for its shift in policy is to improve consistency across other fora, the PTO completely ignores the risk of inconsistent results within and among the Agency's own proceedings. For example, the PTO's proposal to apply the *Phillips* standard to claims proposed in a motion to amend could create absurd and inconsistent results within a single patent's prosecution history. More specifically, under the Proposed Rule, a *single* patent may contain some claims prosecuted and evaluated under the BRI standard *and* other newly allowed claims added and prosecuted under the *Phillips* standard. Consequently, it is possible that a new claim proposed in a motion to amend, interpreted under the *Phillips* standard, may result in a broader claim scope than the original claim. In addition, there is also the risk of inconsistent results across the PTO's other proceedings since the Proposed Rule only seeks to change the claim construction standard for AIA Proceedings and not for the other types of post-grant proceedings that may be merged with the AIA Proceeding. In fact, it is not entirely clear how the Agency could even conduct review in a merged proceeding if, for example, an IPR is merged with a derivation proceeding, a reissue application, or a reexamination. (77 Fed. Reg. 48,698) ("[i]t would be anomalous for the Board to have to apply two different [claim construction standards] in the merged proceeding); *see also* *Cuozzo*, 136 S. Ct. at 2146 ("[t]he statute gives the Patent Office the power to consolidate these other proceedings with inter partes review. To try to create uniformity of standards would consequently prove difficult."). Moreover, even if the PTO elects not to merge concurrent proceedings because of these logistical complications (resulting in inefficiencies), there is the potential risk of inconsistent results as the same patent will be construed under two different standards in concurrent PTO proceedings. Simply put, the PTO's Proposed Rule provides no reason or justification for why uniformity with district court and ITC tribunals is preferred over uniformity among the Agency's own proceedings.

Third, changing the claim construction standard for AIA Proceedings will not necessarily improve uniformity and predictability. Since the PTO will continue to use the BRI

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<sup>8</sup> These include, among others, infringement, invalidity for reasons other than anticipation or obviousness based on prior art publications (*e.g.*, prior public use, prior public knowledge or offers for sale, lack of written description, lack of enablement, lack of utility, or improper inventorship under 35 U.S.C. §§ 101, 102, 112, 256), unenforceability due to inequitable conduct, other equitable defenses, damages, and the propriety of an injunction.

standard in other post-grant proceedings, including reexams and reissues, patents resulting from these proceedings could still possibly be later reviewed by a district court using the *Phillips* standard. Moreover, reversals and remands by the Federal Circuit of district court claim constructions under the *Phillips* standard are commonplace, and courts often disagree over proper interpretation of the same term under this standard. For example, in the Federal Circuit's 2015/2016 term, commentators have observed that the Federal Circuit reversed a district court's claim construction in more than a third of its opinions. *See, e.g., GIBSON DUNN, Federal Circuit Year in Review 2015/2016* at 9 (2016).<sup>9</sup>

Fourth, while the Agency alludes to the fact that “the claim construction standard could be outcome determinative,” the Agency provides no evidence of the prevalence of this purported problem sufficient to justify the Agency's departure from the PTO's longstanding and consistent use of the BRI standard for patentability determinations. (*See Proposed Rule*, 83 Fed. Reg. at 21,223).

#### **B. The *Phillips* Standard Would Not Necessarily Result In Judicial Efficiency.**

Other than relying on the purported percentage of overlap between AIA Proceedings and district court litigation, the PTO offers little explanation for how the adoption of the same claim construction standard will result in judicial efficiency, particularly when the PTAB, district courts, and the ITC will not necessarily be bound by the claim constructions of other fora. More specifically, while the PTAB would be required to consider timely-submitted prior claim constructions from district courts and the ITC under the Proposed Rule, it will not be required to adopt these constructions. As such, it is assumed that the PTAB would still have to conduct its own analysis, including review of the record supporting the previous claim construction determination, to construe the claims in the AIA Proceeding.

Moreover, since the Proposed Rule will not, and indeed cannot, have any bearing on whether district courts or the ITC adopt the PTAB's claim construction determination, it is unclear how the *Phillips* standard would result in judicial efficiency in these other fora. In fact, in order for there to be any chance of these other tribunals even considering, let alone adopting the PTAB's claim construction, the PTO will likely have to modify current claim construction procedures in AIA Proceedings to create a mechanism to allow the parties to develop a sufficient record (*e.g.*, dedicated claim construction briefing or a *Markman* hearing). As noted above, these additional procedures could threaten the PTO's ability to resolve AIA Proceedings by the statutory deadline. Furthermore, though the PTO asserts that the Proposed Rule is not economically significant and would not significantly affect a substantial number of small entities, these added procedures could potentially increase (or accelerate) the cost of AIA Proceedings for some entities as the parties may have to engage in considerable briefing, secure

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<sup>9</sup> [https://www.gibsondunn.com/wp-content/uploads/documents/publications/Federal-Circuit-2015-2016-Year-in-Review.pdf?utm\\_source=IA&utm\\_medium=email&utm\\_campaign=alert](https://www.gibsondunn.com/wp-content/uploads/documents/publications/Federal-Circuit-2015-2016-Year-in-Review.pdf?utm_source=IA&utm_medium=email&utm_campaign=alert).

expert testimony (both via declaration and live hearing), and conduct technology tutorials or oral argument that is typically associated with claim construction under the *Phillips* standard. (See *Proposed Rule*, 83 Fed. Reg. at 21,224-25). Lastly, even if a district court or the ITC adopts the PTAB's claim construction with respect to its patentability assessment, it may not completely eliminate the need for a *Markman* hearing in these other fora if the parties dispute the construction of other claim terms that relate solely to other available defenses, such as non-infringement and indefiniteness.

**C. The PTO's New Claim Construction Standard Would Not Alleviate Perceived Unfairness.**

The PTO asserts that using the same claim construction standard across all fora would reduce any potential unfairness that could result from using the BRI standard in AIA Proceedings. The PTO, however, does not explain how it would be unfair to patent owners if they must defend the patentability of their patents using the exact same standard that was applied to secure issuance of each patent during the initial *ex parte* examination. Moreover, any misapplication of the BRI standard by the PTAB is reviewed by the Federal Circuit *de novo*, further reducing any risk of unfairness. See, e.g., *In re Cuozzo*, 793 F.3d at 1280.

Furthermore, the PTO provides only one example of the perceived unfairness if the PTO does not adopt the *Phillips* standard, stating that it would be inequitable to patent owners "if a competitor's product would not be found to infringe a patent claim if it was sold after the patent's effective filing date, [while] the same product nevertheless could constitute invalidating prior art if publicly sold before the patent's effective filing date." (*Proposed Rule*, 83 Fed. Reg. at 21,223). This example, however, is nonsensical as it pertains to IPRs since these patentability challenges are limited to anticipation (35 U.S.C. § 102) and/or obviousness (35 U.S.C. § 103) grounds, based solely on prior art patents or other printed publications. As such, the relevance of any such defense would only be applicable in district court proceedings where the *Phillips* standard is applied for both infringement and validity purposes.

To the extent that there is any potential for unfairness related to the claim construction standard used in AIA Proceedings, it would likely result from the PTAB's consideration of previous claim constructions by other tribunals even if either or both of the parties did not participate in the prior determination. Under such a scenario, at least one party (likely the petitioner) would be disadvantaged by having to address the relevance of a prior determination even though it was not involved in the proceeding. Furthermore, in some instances, that party may not even have access to the full record supporting the previous claim construction determination if information referenced therein is confidential under a protective order.

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In conclusion, Mylan urges the PTO to maintain the BRI standard for AIA Proceedings, since it both satisfies the Congressional goals of increased patent quality and maintains the efficiency and effectiveness of PTAB proceedings. Mylan appreciates the opportunity to provide comments regarding the appropriate claim construction standard for AIA Proceedings and appreciates the PTO's consideration of these comments. Mylan supports the PTO's on-going commitment to work with the the patent community and industry to ensure that AIA Proceedings continue to be an efficient mechanism that allows the Agency to revisit and reassess patents it may have issued in error.

Sincerely,



William A. Rakoczy  
on behalf of Mylan Pharmaceuticals Inc.