Your Generics & Biosimilars Industry

June 26, 2020

VIA ELECTRONIC MAIL (PTABNPRM2020@uspto.gov)

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-2019-0024, "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"

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 ("Office") Notice of Proposed Rulemaking entitled "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." Specifically, these comments respond to the Office's proposal to "amend the rules to eliminate the presumption in favor of the petitioner for a genuine issue of material fact created by testimonial evidence submitted with a patent owner's preliminary response when deciding whether to institute an IPR, PGR, or CBM review."[1]

We urge the Office not to adopt the proposal, which is inconsistent with the American Invents Act ("AIA") and would make little sense in practice. The proposal allows administrative law judges ("APJ") to weigh competing testimonial evidence and decide genuine issues of material fact without considering cross-examination or rebuttal evidence, all in the context of a preliminary stage that results in a final, non-appealable decision. Under the proposal, APJs would engage in pre-institution trials before trial is even instituted—and if institution is denied, there would be no opportunity for petitioners to appeal clearly erroneous factual findings based on flawed testimonial evidence. The proposal would result in a dysfunctional change to the IPR framework that would be fundamentally unfair to petitioners, and would likely implicate due process concerns. As a practical matter, AAM is concerned that the proposal would make it substantially more difficult for petitioners to challenge competition-stifling patents in a cost-effective and efficient manner, which would ultimately diminish pharmaceutical competition and result in higher prescription drug prices for patients.

I. AAM Has a Strong Interest in an Effective IPR Process

AAM is the nation's leading trade association for manufacturers and distributors of FDA-approved generic and biosimilar prescription medicines. AAM's core mission is to improve the lives of patients by advancing timely access to safe, effective, and affordable generic and biosimilar medicines. Generics

[1] 85 Fed. Reg. at 31729 (May 27, 2020).

represent greater than 90% of all prescriptions dispensed in the United States, but account for only 22% of expenditures on prescription drugs, saving patients and payers nearly $2 trillion over the past ten years.[2] Our members' products are used in more than four billion prescriptions every year.[3]

AAM supports a strong and robust patent system to encourage and enable innovation, and applauds the work of the Office in examining and issuing high-quality patents. AAM's member companies frequently obtain and assert patents themselves. Unfortunately, in the experience of AAM and its member companies, low-quality patents sometimes issue despite the Office's best efforts. This is unsurprising because examiners are charged with completing numerous distinct tasks during the examination process—all of which must be completed on average within a mere 19 hours.[4] 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, generic and biosimilar pharmaceutical companies generally must address patent issues 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 successful in balancing the need for innovative drug therapies while enabling generic and biosimilar pharmaceutical companies to offer patients affordable medicines.

Despite this statutory scheme, some brand-name pharmaceutical companies have found ways to 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. In a number of these cases, the later-filed patents claim small, incremental changes that do not represent genuine innovation or benefit patients. Yet these low-quality, often non-innovative, patents effectively delay generic competition. And such non-innovative patents can force generic and biosimilar pharmaceutical companies into years of slow-moving and costly litigation.

Inter partes review ("IPR") and post-grant review[5] provide a means by which manufacturers of generic and biosimilar medicines can address and correct these patent abuses. As the Supreme Court recently explained, IPR "protects 'the public's paramount interest in seeing that patent monopolies are kept within their legitimate scope.'"[6] According to the Office's data, between September 16, 2012 and November 30, 2018, nearly 1,000 IPR petitions challenged patents listed in the Orange Book, covering biologics, or otherwise in the field of biologics/pharma.[7] During this timeframe, the institution rates for these categories of patents ranged from 50 to 64%.[8]

Many generic pharmaceutical companies have used IPR proceedings to successfully launch their products, providing patients with earlier access to more affordable medications. For example, successful IPRs brought by Noven Pharmaceuticals Inc. paved the way for generic competition to the Exelon® patch

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[2] AAM 2019 Generic Drug and Biosimilar Access & Savings in the U.S., https://accessiblemeds.org/sites/default/files/2019-09/AAM-2019-Generic-Biosimilars-Access-and-Savings-US-Report-WEB.pdf.

[3] *Id.*

[4] Michael D. Frakes & Melissa F. Wasserman, *Is the Time Allocated to Review Patent Applications Inducing Examiners to Grant Invalid Patents?: Evidence from Micro-Level Application Data*, Nat'l Bureau of Econ. Research Working Paper 20337, at 7 (July 2014), http://www.nber.org/papers/w20337.pdf.

[5] These comments focus on IPR, but apply to all forms of post-grant review that the Board conducts.

[6] *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1374 (2018) (citation omitted).

[7] USPTO, *Orange Book patent/biologic patent study and district court pharma litigation study*, at 14 (July 18, 2019), https://www.uspto.gov/sites/default/files/documents/Boardside%20Chat%20-%20Orange%20Book%20and%20Biologics%20%282019-07-11%29-IQ_807521-Final.pdf.

[8] *Id.* at 18.

for the treatment of Alzheimer's and Parkinson's disease.[9] Similarly, generic pharmaceutical companies successfully defeated the claims of a patent covering the drug Zytiga®, allowing for the launch of generic versions of the drug to treat prostate cancer.[10] And through a series of IPRs, numerous other drug patents have been invalidated—in whole or in part—through IPR, including patents for Lantus®, Herceptin®, Rituxan®, Avastin®, and Neulasta®.[11]

For reasons such as these, AAM has long been a supporter of IPR and the Office's efforts to implement IPR proceedings efficiently and effectively. For example, at a Senate Judiciary Committee Hearing for STRONGER, AAM emphasized the importance of IPR, explaining it provides "cost-effective, efficient procedures . . . to ensure that questionable, non-innovative patents may be efficiently invalidated."[12] AAM explained why IPR is "critically necessary to help get invalid patents—including those blocking more affordable generic and biosimilar medicines—declared invalid as quickly as possible."[13] At another Senate Judiciary Committee Hearing, AAM highlighted some of the ways IPR has improved the patent system as compared to examination or district court litigation.[14] In particular, IPR "allows a patent owner's arguments to be tested through cross-examination and the submissions of opposing experts in a way that examination does not allow," and "allows invalidity issues to go before experts from within the Patent Office, rather than lay jurors or generalist federal trial judges."[15] AAM likewise 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*.[16]

Accordingly, AAM has a strong interest in defending an IPR framework that permits its members to efficiently invalidate non-innovative patents and chip away at harmful patent monopolies.

II. The Office's Proposal Abandons its Well-Reasoned Rationale Against Weighing Testimonial Evidence at the Institution Stage

The Office's proposal seeks to "eliminate" its current rule that, at the institution stage, "a genuine issue of material fact created by [patent owner's] testimonial evidence will be viewed in the light most favorable to the petitioner solely for purposes of deciding whether to institute an *inter partes* review."[17] This is not the first time the Office has considered the role of patent owners' testimonial evidence at the institution stage. But it would be the first time that the Office would allow APJs to weigh testimonial evidence and decide issues of material fact without any cross-examination.

The Office's new rule stands in sharp contrast to its prior stance on patent owner testimonial evidence. For example, in a 2012 rulemaking implementing the AIA, the Office forbade pre-institution patent owner testimonial evidence, explaining that "[t]he AIA [does] not expressly provide for the submission of testimonial evidence by the patent owner prior to institution."[18] The Office's rationale for forbidding patent owner testimonial evidence was entirely practical—"[a]llowing for new testimony and the resulting cross-examination prior to the institution of a proceeding would negatively impact the ability of the Office to

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[9] *Novartis AG V. Noven Pharm. Inc.*, 853 F.3d 1289 (Fed. Cir. 2017) (affirming IPR decisions).

[10] *BTG Int'l Ltd. v. Amneal Pharm. LLC*, 923 F.3d 1063 (Fed. Cir. 2019) (affirming IPR decisions)

[11] *See* AAM, Statement for the Record, Senate Judiciary Committee Hearing on the "Support Technology and Research for Our Nation's Growth and Economic Resilience Patents Act of 2019 ('STRONGER')," at 2-3 (Sept. 11, 2019).

[12] *Id.* at 2.

[13] *Id.* at 2-3.

[14] *See* AAM, Statement for the Record, Senate Judiciary Committee Hearing on the "Intellectual Property and the Price of Prescription Drugs: Balancing Innovation and Competition," at 2-3 (May 7, 2019).

[15] *Id.* at 3.

[16] 138 S. Ct. 1365 (2018).

[17] 85 Fed. Reg. at 31728; 37 C.F.R. § 42.108(c).

[18] 77 Fed. Reg. at 48701 (Aug. 14, 2012) (citing 35 U.S.C. § 313).

meet the statutory requirements . . . . [and] would result in more upfront costs to the parties."[19] Likewise, the Office explained that "cross-examination would be provided in most situations in which the patent owner relies on testimonial evidence, resulting in [a] delay" if the testimonial evidence was presented before institution.[20]

In 2016, the Office changed course, but with a critical and necessary caveat. The Office amended the rules to allow the patent owner to file new testimonial evidence in its preliminary response.[21] Importantly, the Office acknowledged that permitting such testimonial evidence necessitated "the caveat that, if a genuine issue of material fact is created by testimonial evidence, the issue will be resolved in favor of petitioner solely for institution purposes."[22]

The Office refused to weigh testimonial evidence at the institution stage, explaining doing so would be "inappropriate and contrary to the statutory framework for AIA review."[23] This is "because a denial of institution is a final, non-appealable decision," making it patently unfair to "decid[e] disputed factual issues in favor of the patent owner when a petitioner has not had the opportunity to cross-examine patent owner's declarant."[24]

The Office also recognized that "a petition should not be denied based on testimony that supports a finding of fact in favor of the patent owner when the petitioner has not had an opportunity to cross-examine the declarant."[25] It is only appropriate to weigh testimonial evidence post-institution because "[i]t is only through the trial process that each party is afforded a full and fair opportunity to cross-examine declarants."[26]

The Office's current proposal abandons its previous well-reasoned analysis. Now, the Office proposes to weigh "any testimonial evidence submitted with a patent owner's preliminary response . . . as part of the totality of the evidence."[27] In effect, the proposal would allow APJs to weigh competing (but not cross-examined) testimonial evidence and decide issues of material fact without sufficient means to assess witness credibility, enabling petition denials based on potentially flawed and erroneous testimonial evidence.

While the Office frames this proposal as "consistent with the statutory framework,"[28] its analysis is unmoored from the statute. Nowhere does the Office reconcile its prior finding that such a rule "is inappropriate and ***contrary to*** the statutory framework for AIA review."[29] Despite proposing to weigh testimonial evidence, the proposal does not contemplate that petitioners would be entitled to pre-institution cross-examination or replies at all, despite its prior observation that "a petition should not be denied based on testimony that supports a finding of fact in favor of the patent owner when the petitioner has not had an opportunity to cross-examine the declarant."[30] Nor does the proposal attempt to address

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[19] *Id.*

[20] *Id.*

[21] 81 Fed. Reg. at 18755 (Apr. 1, 2016).

[22] *Id.*

[23] *Id.* at 18756 (citing 35 U.S.C. §§ 316(a)(5), 326(a)(5)).

[24] *Id.*

[25] *Id.*

[26] *Id.*

[27] 85 Fed. Reg. at 31729.

[28] *See id.* at 31730 (citing *Hulu, LLC v. Sound View Innovations LLC*, Case IPR2018–01039, Paper No. 29 at 3, 19 (P.T.A.B. Dec. 20, 2019)).

[29] 81 Fed. Reg. at 18756 (emphasis added).

[30] *Id.*

the many ways in which weighing testimonial evidence "would negatively impact the ability of the Office to meet the statutory requirements set out in 35 U.S.C. 314(b) . . . and would result in more upfront costs to the parties."[31]

The Office's proposal lacks foundation in the statute and realities of IPR. As set forth in more detail below, the proposal usurps the purpose of the institution stage—which is intended to be merely preliminary, and not a time to weigh testimonial evidence—and simultaneously deprives petitioners of the procedural safeguards in place post-institution. The Office's rationale for enacting the proposal is also untethered to the proposal itself, which is wide-sweeping and would at a minimum require a rule giving petitioners a pre-institution reply as of right. The Office's proposal contains significant legal and practical flaws and should not be adopted.

III. The Presumption is Limited and Appropriate in Light of the IPR Framework

The presumption in favor of petitioners' testimonial evidence is circumscribed and narrowly tailored to the statutory role of the institution stage. Only "a genuine issue of material fact created by [pre-institution] testimonial evidence will be viewed in the light most favorable to the petitioner," and the presumption applies "solely for purposes of deciding whether to institute an *inter partes* review."[32] The Office has explained that the presumption does not apply to all issues of fact—"only when a genuine issue of material fact is created by patent owner's testimonial evidence."[33] And "not every factual contradiction rises to the level of a genuine issue of material fact that would preclude a decision on the factual issue at the preliminary stage of a proceeding."[34] Contrary to the Office's rationale, there is thus little risk that "the presumption in favor of the petitioner may be viewed as discouraging patent owners from filing testimonial evidence with their preliminary responses"—which is frequently filed—or that "some patent owners [may] believe that such testimony will not be given any weight at the time of institution."[35] Further, it is unclear why the Office would want to encourage additional testimonial evidence at the institution stage, which increases the cost and burden on litigants and the Board, as explained below.

It is significant that the presumption applies only during the "threshold" institution stage.[36] Indeed, it is necessitated by the statutory scheme. The AIA makes clear that the institution stage is merely preliminary, and as such, is not a time to weigh testimonial evidence. That is, the institution stage is intended to be a first-look at the sufficiency of the evidence provided in the petition—it is not intended to require a conclusion on the merits without the safeguards provided by post-institution procedures. Several statutory provisions compel this conclusion. For example:

- Petitioners bear different burdens before and after institution: petitioners must only show a "reasonable likelihood" of prevailing at the institution stage, and must show unpatentability by "a preponderance of the evidence" during the proceeding;[37]

- The AIA only expressly contemplates that patent owners can present testimonial evidence *after* institution;[38] and

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[31] 77 Fed. Reg. at 48701.

[32] 37 C.F.R. § 42.108(c).

[33] 81 Fed. Reg. 18756 (emphasis added).

[34] *Id.*

[35] 85 Fed. Reg. at 31729-30.

[36] *See* 35 U.S.C. § 314(a).

[37] *Compare* 35 U.S.C. § 314(a), *with id.* § 316(e).

[38] *Compare* 35 U.S.C. § 313 (permitting the preliminary response to set forth "reasons"), *with id.* § 316(a)(8) (permitting the patent owner's response to include "affidavits or declarations" and "expert opinions"); *see also* 77 Fed. Reg. at 48701 ("Patent owners are

- Unlike final written decisions, institution decisions are generally unreviewable.[39]

So long as the Board continues to permit patent owners to submit testimonial evidence during the institution stage, the presumption is necessary in light of the statutory framework. The presumption is even more necessary in light of the Office's rules. For example, the Office requires that petitioners present all *prima facie* evidence with their petitions, as during trial, a "reply may only respond to arguments raised in the . . . patent owner preliminary response, or patent owner response."[40] In contrast, both by statute and regulation, patent owners may present additional evidence with their post-institution response.[41] The Office also currently does not give petitioners a right of reply or cross-examination pre-institution.[42] Accordingly, the presumption fairly gives preference to petitioners' testimony concerning material issues when petitioners are not allowed, as of right, to cross-examine the declarant or file a reply. The presumption is also unlikely to prejudice patent owners, because—unlike petitioners—patent owners can later introduce new arguments and evidence after institution. As the Board has repeatedly recognized, such a presumption is appropriate at "this preliminary stage, with neither declarant having been cross-examined,"[43] and is entirely consistent with the purpose of institution.

IV. Weighing Testimonial Evidence at the Institution Stage Would Give Rise to Due Process Concerns, and at a Minimum, Would Increase Costs and Resources

"[P]etitioners are not disinterested parties in an IPR proceeding."[44] As interested parties, petitioners are entitled to procedural rights under the Administrative Procedure Act ("APA").[45] The APA requires that the Office must provide "all interested parties opportunity for the submission and consideration of facts [and] arguments . . . [and] hearing and decision on notice."[46] Interested parties also have a right "to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the facts."[47] In fact, in "almost *every* setting where important decisions turn on questions of fact, due process requires an opportunity to confront and cross-examine adverse witnesses."[48] The Federal Circuit has found APA violations where the Board failed to provide these necessary procedural

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permitted to rely on new testimonial evidence in response to a petition but the AIA provides for submission of this testimonial evidence after a proceeding has been instituted.").

[39] *See Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2139-40 (2016) (citing 35 U.S.C. §§ 314(d), 319).

[40] 37 C.F.R. § 42.23(b).

[41] 35 U.S.C. § 316(a)(8); *see also, e.g.*, 81 Fed. Reg. at 18756 ("The Office declines to adopt a presumption in favor of the patent owner for disputed facts at the institution stage, as the patent owner will have another opportunity to submit evidence during the trial.").

[42] 37 C.F.R. §§ 42.51(a)-(b), 42.108(c).

[43] *ASUS Comput. Int'l v. Avago Techs. General IP (Singapore) Pte. Ltd.*, IPR2016-00647, Paper No. 7, at 16-17 (P.T.A.B. Aug. 12, 2016); *nXn Partners, LLC v. Nissan Chemical Indus., Ltd.*, IPR2016-00694, Paper No. 7, at 17-18 (P.T.A.B. Aug. 31, 2016) (finding it "appropriate to institute trial so that the disputed testimonial evidence may be tested by cross-examination"); *Cf. Acrux DDS Pty Ltd. v. Kaken Pharm. Co.*, IPR2017-00190, Paper No. 12, at 12 (P.T.A.B. May 1, 2017) (explaining the issue of antedating is "best resolved during trial when . . . both parties are afforded an opportunity to challenge the sufficiency of their opponent's case").

[44] *SAS Inst., Inc. v. ComplementSoft, LLC*, 825 F.3d 1341, 1351 (Fed. Cir. 2016) ("*SAS I*"), *rev'd*

on other grounds, 138 S. Ct. 1348 (2018) (citing 5 U.S.C. § 554(b)(3)).

[45] *See id.*

[46] *Dell Inc. v. Acceleron, LLC*, 818 F.3d 1293, 1301 (Fed. Cir. 2016) (quoting 5 U.S.C. § 554(c)) (citations omitted); *EmeraChem Holdings, LLC v. Volkswagen Grp. Am., Inc.*, 859 F.3d 1341, 1348 (Fed. Cir. 2017) (same); *In re NuVasive, Inc.*, 841 F.3d 966, 971 (Fed. Cir. 2016) (same).

[47] 5 U.S.C. § 556(d); *see also Dell*, 818 F.3d at 1301.

[48] *Goldberg v. Kelly*, 397 U.S. 254, 268-69 (1970) (holding that denying a party any opportunity "to present evidence . . . or cross-examine adverse witnesses" was "fatal to the constitutional adequacy of the procedures") (emphasis added).

protections, including denying an interested party "an adequate opportunity to respond to [an] asserted fact,"[49] or relying on new factual evidence "after [an interested party] could meaningfully respond."[50]

Consistent with these principles, the Office previously recognized that "it is only through the trial process that each party is afforded a full and fair opportunity to cross-examine declarants. A presumption in favor of petitioner for disputed facts, which may be fully vetted during a trial when cross-examination of declarants is available, is appropriate given the effect of denial of a petition."[51] The Office's proposal to abandon the presumption—without any "full and fair opportunity" for petitioners to be heard[52]—violates the APA and raises serious due process concerns.[53]

Under the Office's proposal, APJs would consider testimonial evidence introduced by patent owners—and specifically, decide genuine issues of material fact—without any response from petitioners. As noted above, the Office does not give petitioners a right to cross-examine patent owner's witnesses, file a reply, or file reply expert declarations prior to institution.[54] In fact, such requests are routinely denied.[55] This is because replies are only authorized upon a showing of "good cause," and additional discovery is only permitted if in the "interests of justice."[56] Petitioners would thus have no opportunity to submit facts, arguments, or evidence to rebut any testimonial evidence before APJs would consider the persuasiveness of patent owner's testimonial evidence.

These procedural concerns are compounded by the finality of institution denials.[57] Because institution decisions are not appealable, weighing testimonial evidence at the institution stage would result in APJs engaging in fact-finding with no possibility of appeal for clearly erroneous factual determinations. Given the Board's obligation to institute all or no claims,[58] the proposal also increases the likelihood that petitions would be outright denied based on testimonial evidence for which petitioners have not yet addressed, such as priority date issues. It would also be entirely unclear *how* APJs could actually weigh such evidence based on competing stacks of paper, and without considering cross-examination or rebuttal evidence. Such a framework would deprive petitioners of their right to be fairly heard before the Board issues an institution decision.

Any remedy to these due process concerns (aside from retaining the presumption) would only increase the parties' costs and decrease the Office's efficiency. The proposal would force petitioners to engage in motion practice seeking pre-institution replies, pre-institution reply declarations, and opportunities for cross-examination. APJs would have to decide such motions and review additional papers and evidence. Essentially requiring a mini-trial before trial is even instituted is inconsistent with the purpose of institution stage—to conduct a preliminary assessment of the sufficiency of the petition. And all of this would have to occur before the statutory deadline for an institution decision, only 3 months after the preliminary

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[49] *In re NuVasive, Inc.*, 841 F.3d at 972.

[50] *Dell*, 818 F.3d at 1301.

[51] 81 Fed. Reg. 18756.

[52] *Id.*

[53] *See* 5 U.S.C. §§ 554(c), 556(d).

[54] *See* 37 C.F.R. §§ 42.51(a)-(b), 42.108(c).

[55] *See, e.g.*, *Mylan Pharm. Inc. v. Bristol-Myers Squibb Co.*, IPR2018-00892, Paper No. 22, at 3-5 (P.T.A.B. Sept. 17, 2018) (agreeing that "the Board is typically capable of evaluating whether there are factual inaccuracies in Patent Owner's Preliminary Response . . . without further briefing from Petitioner"); *Mylan Pharma. Inc. v. Janssen Oncology, Inc.*, IPR2016-01332, Paper No. 16, at 2 (P.T.A.B. Oct. 26, 2016) (denying petitioners' request for a reply because "[t]he Board is capable of evaluating the parties' proposed positions relative to the asserted inconsistencies and related issues in this case based on the information already in the record").

[56] 37 C.F.R. §§ 42.51(b)(2)(i), 42.108(c).

[57] The proposed rule's constitutional implications may also cause a surge in appeals of institution decisions. *See Cuozzo*, 136 S. Ct. at 2141 (declining to "decide the precise effect of § 314(d) on appeals that implicate constitutional questions").

[58] *See SAS Instit., Inc. v. Iancu*, 138 S. Ct. 1348, 1354 (2018).

response is filed.[59] Such a framework is unworkable. Indeed, the Office previously recognized that such a scheme "would negatively impact the ability of the Office to meet" its statutory deadlines "and would result in more upfront costs to the parties."[60]

But such inefficiency is not only inconvenient, it flies in the face of the purpose of IPR. The AIA expressly requires that before engaging in IPR rulemaking, the Office must "consider the effect of any such regulation on . . . the efficient administration of the Office."[61] The Office's own rules likewise require the Office to "secure the just, speedy, and inexpensive resolution of every proceeding."[62] Indeed, just, speedy, and inexpensive resolution of IPRs is precisely what Congress intended in enacting the AIA—"to avoid the significant costs, already recounted, of nullifying a thoroughgoing determination about a patent's validity."[63] Abandoning the presumption simultaneously obliterates this function of IPR.

V. The Office Should Resolve its Concerns with Printed Publication Disputes—the Stated Reason Necessitating the Proposal—by Clarifying the Requirements for Proving that a Reference is a Printed Publication

The Office's notice indicates that its proposal is largely motivated by concerns with printed publication disputes. In particular, the Office emphasized that "certain stakeholders have indicated the presumption in favor of the petitioner for genuine issues of material fact created by patent owner testimonial evidence also creates a presumption in favor of the petitioner for questions relating to whether a document is a printed publication."[64] The Office likewise cited its decision in *Hulu*,[65] in which the Panel was tasked with answering "[w]hat is required for a petitioner to establish that an asserted reference qualifies as 'printed publication' at the institution stage?"[66]

There is a fundamental disconnect between the Office's rationale for enacting the rule and the proposal. Printed publication disputes concern only a fraction of pre-institution testimonial evidence. By way of example, the Board has found that patent owners' testimonial evidence created genuine issues of material fact concerning issues of objective indicia of nonobviousness,[67] reasonable expectation of success,[68] the prior art teachings,[69] and inherency.[70] The Office's Trial and Practice Guide similarly provides that the patent owner's preliminary response, and associated testimony, can present evidence that the "prior art lacks a material limitation," the "prior art does not teach or suggest a combination," or that "petitioner's claim interpretation for the challenged claims is unreasonable."[71] None of these issues concern whether a reference is a printed publication. And weighing competing testimony regarding any of these issues at the institution stage would unfairly prejudice petitioners.

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[59] 35 U.S.C. § 314(b).

[60] 77 Fed. Reg. at 48701.

[61] 35 U.S.C. § 316(b).

[62] 37 C.F.R. § 42.1(b).

[63] *Thryv, Inv. B. Click-to-Call Techs., LP*, 140 S. Ct. 1367, 1376 (2020).

[64] 85 Fed. Reg. at 31729.

[65] *Id.*

[66] *Hulu, LLC v. Sound View Innovations, LLC*, IPR2018-01039, Paper No. 15, at 2 (P.T.A.B. Apr. 3, 2019).

[67] *E.g.*, *Mylan Labs. Ltd. v. Aventis Pharma S.A.*, IPR2016-00712, Paper No. 7, at 15 (P.T.A.B. Sept. 22, 2016).

[68] *Id.*

[69] *E.g.*, *Seabery N. A. Inc. v. Lincoln Global Inc.*, IPR2016-00840, Paper No. 11, at 24 (P.T.A.B. Oct. 6, 2016) (informative); *ZTE USA, Inc. v. St. Lawrence Cmmc'ns LLC*, IPR2016-00704, Paper No. 7 at 17 (P.T.A.B. Sept. 15, 2016); *Cf. Amneal Pharm. LLC v. Alkermes Pharma Ireland Ltd.*, IPR2018-00943, Paper No. 8 at 24 (P.T.A.B. Nov. 7, 2018).

[70] *E.g.*, *Pungkuk EDM Wire Manufacturing Co. v. OPEC Eng'g Co.*, IPR2016-00763, Paper No. 14, at 14, 27 (P.T.A.B. Sept. 8, 2016).

[71] Consol. Trial Practice Guide at 49-50 (Nov. 2019).

The Office can readily clarify the requirements for showing that a reference is a printed publication through existing mechanisms, including designating a decision precedential, revising its trial practice guide, or enacting targeted legislation on the issue. In fact, the Office has recently employed some of these mechanisms to resolve its concerns with printed publication disputes. On April 7, 2020, the Board designated *Ex parte Grillo-López* precedential, which articulated the different standards for showing that a reference is a printed publication in IPRs versus *ex parte* proceedings.[72] At the same time, the Board also designated as informative a series of decisions articulating the standards for showing that a reference is a printed publication.[73] These efforts more closely accomplish the Office's goal of clarifying the requirements for showing that a reference is a printed publication without prejudicing petitioners. And to the extent the Office has observed inconsistencies with the sufficiency of a petitioner's printed publication evidence, this is even more reason to employ these mechanisms rather than resort to the proposal. It is inappropriate for APJs to decide hotly contested issues without the benefit of a full record, particularly for an issue such as whether a reference is a printed publication, which is a legal conclusion reviewed without deference.[74]

In any event, regardless of the presumption, a patent owner can show why a reference is not a printed publication in its preliminary response—without resorting to expert testimony—consistent with its statutory right to "set[] forth reasons why no inter partes review should be instituted based upon the failure of the petition to meet any requirement of this chapter."[75] That is, a patent owner can provide "reasons" why a petitioner failed to show that a reference is a printed publication without implicating the presumption, which is triggered "*only* when a genuine issue of material fact is created by patent owner's *testimonial evidence*."[76] A patent owner can also introduce non-testimonial evidence to show that a given reference is not a printed publication. In this regard, the Board's decision in *Hulu* is entirely consistent with the presumption—the Board can weigh the "totality of the evidence" to determine whether a reference is a printed publication, it simply must weigh *testimonial* evidence in petitioners' favor.[77] For this reason too, the Office's notice fails to identify a reasonable basis for eliminating the presumption.

VI. At a Minimum, if the Proposal is Adopted, the Office Should Provide Petitioners a Pre-Institution Reply as of Right

For all of the above reasons, the Office should not adopt the proposal to eliminate the presumption. But if it does, it is necessary that the Office simultaneously adopt a rule giving petitioners a pre-institution reply as of right.

As a general matter, permitting petitioners to file "a reply brief is consistent with the general long-standing practice of tribunals to allow the party who bears the burden of proof (in this case the AIA petitioner) to file a reply brief."[78] Such a practice is also consistent with the Office's rules post-institution, which recognize

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[72] *Ex parte Grillo-López*, Appeal No. 2018-006082, Appl. No. 13/524,837 (P.T.A.B. Jan. 31, 2020) (precedential).

[73] *Argentum Pharma. v. Res. Corp. Techn. Inc.*, IPR2016-00204, Paper No. 19, at 8-12 (P.T.A.B. May 23, 2016) (informative); *Sandoz Inc. v. AbbVie Biotechnology Ltd.*, IPR2018-00156, Paper No. 11, at 8-13 (P.T.A.B. June 5, 2018) (informative); *Seabery N. A. Inc. v. Lincoln Global Inc.*, IPR2016-00840, Paper No. 11, at 7-8 (P.T.A.B. Oct. 6, 2016) (informative); *In-Depth Geophysical Inc. v. ConocoPhillips Co.*, IPR2019-00849, Paper No. 14, at 4-13 (P.T.A.B. Sept. 6, 2019) (informative).

[74] *See Medtronic, Inc. v. Barry*, 891 F.3d 1368, 1380 (Fed. Cir. 2018).

[75] 35 U.S.C. § 313.

[76] 81 Fed. Reg. at 18756 (emphasis added).

[77] *See Hulu,* Case IPR2018–01039, Paper No. 29 at 3, 21.

[78] Heidi L. Keefe, Response to the Office's Request for Comments, the Office's request for comments, 79 Fed. Reg. at 36494 (June 27, 2014), at 2.

"that reply briefs enable decision-makers to make better and more informed decisions."[79] And permitting replies pre-institution could reduce the frequency of requests for rehearing.[80]

Most importantly here, permitting petitioners to file replies would at least partially minimize the significant harm resulting from weighing testimonial evidence before institution. A pre-institution reply would give petitioners an opportunity to explain why competing testimonial evidence lacks support, is inconsistent with the record, or should be disregarded. This opportunity would reduce, but not eliminate, the fundamental unfairness of giving patent owners the last word while potentially weighing testimonial evidence in their favor. Of course, pre-institution replies would increase the cost and burden on the parties and Board as explained above, and thus maintaining the presumption is more efficient and more consistent with the statutory scheme enacted by Congress.

VII. Conclusion

AAM thanks the Office for its tireless efforts in ensuring the high quality of the United States patent system. IPRs are an important safeguard put in place by Congress to help the Office maintain its high standards. Eliminating the presumption would unfairly make it more difficult for petitioners to efficiently challenge competition-stifling patents, and would likely result in depriving petitioners of their right to a fair proceeding. AAM urges the Office not to adopt the proposal.

Sincerely,

Jeffrey K. Francer,
Interim CEO & General Counsel

[79] *Id.*

[80] *Id.*