Comments of the Pharmaceutical Research and Manufacturers of America on the PTO's Request for Comments on Trial Proceedings Under the America Invents Act Before the Patent Trial and Appeal Board

The Pharmaceutical Research and Manufacturers of America ("PhRMA") appreciates the opportunity to submit comments in connection with the Patent and Trademark Office's ("PTO" or "Office") Request for Comments on Trial Proceedings Under the America Invents Act Before the Patent Trial and Appeal Board ("PTAB" or "Board").[1]

PhRMA's member companies are leading research-based pharmaceutical innovators devoted to developing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA's membership ranges in size from small emerging companies to multi-national corporations that employ tens of thousands of Americans, and encompass both research-based pharmaceutical and biotechnology companies. The U.S. biopharmaceutical sector supported a total of 3.4 million jobs throughout the economy, and directly employed more than 810,000 Americans in 2011.[2] The industry's overall economic impact is substantial—in 2011, the industry accounted for nearly $800 billion in economic output.[3]

The U.S. biopharmaceutical sector accounts for the single largest share of all U.S. business research and development ("R&D"), representing about one in five dollars spent on domestic R&D by U.S. businesses.[4] PhRMA member investment in discovering and developing new medicines reached over $51 billion in 2013.[5] Medicines developed by the sector have produced large improvements in health across a broad range of diseases, with the rapid growth of biomedical knowledge creating growing opportunities for continued profound advances against our most complex and costly diseases. Developing a new medicine takes between 10 and 15 years of work and costs an average of over $1 billion of investment in R&D.[6] Like innovators across the spectrum of American industries, biopharmaceutical companies make the substantial R&D investments that yield new medicines in reliance on a legal regime that provides protection

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1 79 Fed. Reg. 36,474-36,477 (June 27, 2014).

2 Pharmaceutical Research and Manufacturers of America, *2014 Biopharmaceutical Research Industry Profile*, inside cover (Washington, DC: PhRMA, April 2014) ("2014 PhRMA Profile") (citing Battelle Technology Partnership Practice, *The Economic Impact of the U.S. Biopharmaceutical Industry*, Battelle Memorial Institute (Columbus, OH), July 2013), *available at* http://www.phrma.org/sites/default/files/pdf/2014_PhRMA_PROFILE.pdf.

3 2014 PhRMA Profile, at iii.

4 Battelle Technology Partnership Practice, *The U.S. Biopharmaceutical Industry: Perspectives on Future Growth and the Factors that Will Drive It*, April 2014, *available at* http://www.phrma.org/sites/default/files/pdf/2014-economic-futures-report.pdf.

5 2014 PhRMA Profile, inside cover & 27 (citing Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Membership Survey*, 2013).

6 *Id*. (citing J.A. DiMasi and H.G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different*? Managerial and Decision Economics 2007; 28(4–5): 469–479; J. Mestre-Ferrandiz, J. Sussex, and A. Towse, *The R&D Cost of a New Medicine*, London, UK: Office of Health Economics, 2012; S.M. Paul, et al., *How to Improve R&D Productivity: The Pharmaceutical Industry's Grand Challenge*, Nature Reviews Drug Discovery 2010, 9:203–214.).

for any resulting intellectual property. Our companies rely on patents to protect their inventions and provide an opportunity to recover their research investments. But patents are particularly important to biopharmaceutical innovation given the research-intensive nature of this sector and the substantial investment needed to discover and develop products that meet FDA approval requirements.[7]

Bringing new and improved life-saving and life-improving products to people is the central role of our member companies. Because intellectual property is critical to carrying out this mission, PhRMA members appreciate the efforts of the PTO to revisit its rules and practices regarding trial proceedings under the America Invents Act ("AIA") before the PTAB and the opportunity to offer its perspective on these proceedings. In PhRMA's view, several of the PTO's rules and practices should be modified to address due process and fairness concerns.

I. The PTAB's Trial Proceedings Should Be Modified To Ensure Fairness To Patent Owners.

The rules and practices governing the PTAB's trial proceedings have resulted in PTAB proceedings that appear unfair to patent owners. This is contrary to due process, the AIA, and the U.S. patent system.

Patent owners' rights in their issued patents are protected by the due process guarantees of the Fifth Amendment.[8] This protection is fundamental and was not diminished by the AIA. Instead, as Senator Leahy explained, the purposes of the Leahy-Smith AIA were to "establish a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counterproductive litigation costs, while making sure no party's access to court is denied."[9] As Senator Kyl further explained, "[t]he overarching purpose and effect of the [AIA] is to create a patent system that is clearer, fairer, more transparent, and more objective."[10] This emphasis on due process and fairness is essential to the U.S. patent system. The U.S. patent system is based on providing patent owners with a high quality initial examination process resulting in a substantial and predictable property right that is not subject to unnecessarily duplicative proceedings, so as to foster the investment necessary to bring the technology to the public and achieve the objectives of the patent system. The PTAB's trial proceedings should be structured to reflect this.

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[7] *See* Claude Barfield & John E. Calfee, *Biotechnology and the Patent System: Balancing Innovation and Property Rights*, at 1-2 (AEI PRESS 2007) ("Without patent protection, investors would see little prospect of profits sufficient to recoup their investments and offset the accompanying financial risk."), *available at* http://www.aei.org/files/2007/09/25/20080818_BiotechandthePatent.pdf.; *see generally* Battelle Technology Partnership Practice, *The U.S. Biopharmaceutical Industry: Perspectives on Future Growth and the Factors that Will Drive It*, April 2014; Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 J. INT'L ECONOMIC L. 849 (2002).

[8] "No person shall . . . be deprived of . . . property, without due process of law." U.S. CONST. amend. V.

[9] 157 Cong. Rec. S5322, S5327 (daily ed. Sept. 6, 2011) (statement of Sen. Patrick Leahy).

[10] 157 Cong. Rec. S5319 (daily ed. Sept. 6, 2011) (statement of Sen. Jon Kyl).

However, as currently structured, the rules and practices governing the PTAB's trial proceedings for an *inter partes* review ("IPR") and post-grant review ("PGR") do not appear to provide sufficient fairness and due process to patent holders. For example, the overwhelming majority of petitions for IPR have been granted,[11] the majority of the challenged claims have not been found patentable,[12] and as far as PhRMA is aware, all but one motion to amend challenged claims has been denied.[13] These statistics suggest that the PTAB's trial proceedings do not appear to provide a neutral forum, and instead favor patent challengers over patent owners. [14] Such statistics devalue the efforts of the PTO's examiners and also are likely to undermine confidence in the PTO's initial patent examination process, particularly when combined with the PTAB's use of a broadest reasonable interpretation ("BRI") claim construction standard that disregards patent prosecution history.

The PTAB appears to make the improper assumption that only "bad" patents are challenged in IPR or PGR proceedings, when instead it is more likely that only *valuable* patents are challenged in an IPR or PGR. This potential bias was underscored by recent comments by the chief judge of the PTAB that "the purpose of the these proceedings is 'death squads,' which is to say, to identify some limited number of patents and claims where the claims are

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[11] Patent Trial and Appeal Board, AIA Progress Statistics (as of Oct. 9, 2014), *available at* http://www.uspto.gov/ip/boards/bpai/stats/aia_statistics_10_09_2014.pdf.

[12] As of May 1, 2014, out of 2,874 claims challenged in IPRs (and 1,900 instituted), only 5% of challenged claims were found patentable by the PTAB (8% of instituted claims); 25% of instituted claims were found unpatentable, 22% of instituted claims were cancelled or disclaimed, and 46% of claims were settled or otherwise disposed. *See* U.S. PTO, AIA Trial Roundtables Slides, Denver, CO, at slide 9 (May 8, 2014), *available at* http://www.uspto.gov/ip/boards/bpai/ptab_roundtable__slides_may_update__20140503.pdf; *see also* Cooley LLP, Inter Partes *Review Proceedings*, at 16 (as of June 8, 2014) (reporting a complete invalidation rate of 31% for inter partes reexaminations and 66% for IPR proceedings), *available at* http://www.cooley.com/files/cooley-proprietary-ipr-database.pdf.

[13] *See* Final Written Decision, *Int'l Flavors & Fragrances Inc. v. United States*, IPR2013-00124, Paper No. 12 (P.T.A.B. May 20, 2014) (granting unopposed motion by United States to cancel and substitute claims).

[14] A recent article states, "[r]ecent statistics show that the PTAB strongly favors the petitioner," and "[o]nce a petition is granted, the outcome highly favors the petitioner." Paul J. Korniczky & Elias P. Soupos, *Considerations for Using Post-Grant Proceedings to Attack Patent Validity*, LANDSLIDE September/October 2014, at 34, 34-35, 36-37, *available at* http://www.americanbar.org/publications/landslide/2014-15/september-october/considerations_using_postgrant_proceedings_attack_patent_validity.html#ref3 (citing PTO IPR statistics showing "about 80 percent of petitions to invalidate at least some of the claims in a patent are granted," "[a]bout 60 percent of all challenged claims are being reviewed," "[i]n about 70 percent of IPR trials, all instituted claims were canceled," "[i]n almost all of the remaining trials, at least some of the instituted claims were canceled," and overall "approximately 90 percent of the challenged claims [are] being canceled"). The article's authors also show that the rate of filing petitions is increasing, and that Bio/Pharma patents have had the highest IPR petition institution rate, at nearly 85%. *Id.* at 34-35, Figs. 1 & 3.

unpatentable and make sure they are removed" and that "[i]f [the PTAB] weren't, in part, doing some 'death squadding,' we wouldn't be doing what the statute calls on us to do."[15]

As discussed below in these comments, many of the AIA PTAB rules and practices should be revised in order to abide by the AIA's mandate of fair and objective proceedings. As addressed below, the AIA provides that the PTO Director (and not the PTAB) institutes an IPR or PGR,[16] and that the Director has the ability to deny such institution.[17] According to the AIA, the PTAB's responsibilities are limited to conducting IPRs and PGRs that have already been instituted.[18] This statutory framework clearly envisions a fair proceeding in which decisions on institution and merits are separated, bias is minimized, and due process is protected.

Due process protections are particularly important in proceedings that are only appealable to the Federal Circuit, such as IPR and PGR proceedings. Under 35 U.S.C. § 145 and 35 U.S.C. § 146, parties dissatisfied with a PTAB examination appeal or derivation decision may bring a civil action in a district court rather than appealing to the Federal Circuit. Such district court actions allow parties to supplement the record with additional evidence and witness testimony. However, despite the current limitations on evidence that may be presented in an IPR or PGR proceeding described below, these district court actions are not available after the PTAB issues a final decision in an IPR or PGR proceeding, and the record may not be supplemented in an appeal to the Federal Circuit. Further underscoring the need for due process is the preclusion for patent owners that may result from PTAB final written decisions.[19] PTAB trial proceeding rules

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[15] PTAB Chief Judge James Donald Smith, Patent Public Advisory Committee quarterly meeting, morning session 2 webcast at 50:04-53:10 (Aug. 14, 2014), *available at* http://new.livestream.com/uspto/PPAC20140814; *see also* Ryan Davis, *PTAB's 'Death Squad' Label Not Totally Off-Base, Chief Says*, LAW360, Aug. 14, 2014, http://www.law360.com/articles/567550/ptab-s-death-squad-label-not-totally-off-base-chief-says.

[16] *See* 35 U.S.C. § 314(b) ("[t]he Director shall determine whether to institute an inter partes review"); *id.* § 324(c)("[t]he Director shall determine whether to institute a post-grant review").

[17] *See* 35 U.S.C. § 325(d) ("In determining whether to institute or order a proceeding under this chapter [PGR], chapter 30, or chapter 31 [IPR], the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.").

[18] *See* 35 U.S.C. § 316(c) ("The Patent Trial and Appeal Board shall, in accordance with section 6, conduct each inter partes review instituted under this chapter."); *id*. § 326(c) ("The Patent Trial and Appeal Board shall, in accordance with section 6, conduct each post-grant review instituted under this chapter.").

[19] *See, e.g.*, 37 C.F.R. § 42.73(d)(3) ("A patent applicant or owner is precluded from taking action inconsistent with the adverse judgment, including obtaining in any patent: (i) A claim that is not patentably distinct from a finally refused or canceled claim; or (ii) An amendment of a specification or of a drawing that was denied during the trial proceeding, but this provision does not apply to an application or patent that has a different written description."); *Rules of Practice for Trials Before the Patent Trial and Appeal Board and Judicial Review of Patent Trial and Appeal Board Decisions*, 77 Fed. Reg. 48,612, 48,647, 48,649 (Aug. 14, 2012) ("The Office will examine a claim presented in a subsequent proceeding on the merits and apply the [patent owner] estoppel if the claim is not patentably distinct from the finally refused or cancelled claim, similar to a ground of rejection based on *res judicata* (*see, e.g.*, MPEP § 706.03(w)).").

and practices therefore risk erroneously depriving patent owners of their valuable patent rights, in violation of the requirements of due process and in contravention of the intent of the AIA. Additional procedural safeguards are needed in order to make sure that patent owners are provided with a sufficient opportunity to be heard.

The PTO's focus on the speed of IPR and PGR proceedings, rather than on the objectivity and due process afforded in those proceedings, appears to have driven its IPR and PGR rules and procedures, which has unfairly skewed IPR and PGR proceedings against patent owners. Many of PhRMA's specific comments below result from this. In order to ensure that AIA PTAB proceedings are fair and satisfy due process requirements, PhRMA urges the PTO to modify its rules and procedures as described below.

Claim Construction Standard

1. The PTAB's procedures should be revised to use the *Phillips* claim construction standard and not the broadest reasonable interpretation standard.

As per PhRMA's previously submitted comments,[20] the broadest reasonable interpretation ("BRI") claim construction standard should not be used when construing claims in PTAB proceedings under the AIA. The PTAB should construe claims in a manner consistent with a court claim construction analysis under *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). The PTAB trial procedures are quasi-adjudicative procedures rather than continuing prosecutions of patent applications;[21] therefore, the claim construction standard used for these adjudicative proceedings should be the same as that used by courts.

The use of BRI in PGR and IPR proceedings is inconsistent with the AIA, because using BRI requires the PTO to ignore prosecution history when construing claims. The AIA does not dictate that, and even provides that the PTO may take prosecution history into account when deciding whether to institute an IPR or PGR.[22]

Disregarding prosecution history by using BRI is also inefficient. The prosecution history includes the prior interaction between the patent applicant and the PTO and is a record that guides court interpretation. Ignoring this prosecution history unduly elongates and complicates IPR and PGR proceedings, leads to instituting more proceedings than necessary,

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[20] *See Comments of the Pharmaceutical Research and Manufacturers of America in Response to the PTO's Request for Comments on Implementation of Trial Proceedings Described in the America Invents Act*, Docket Nos: PTO-P-2011-0082, -0083, -0084, -0086, -0094 (filed Apr. 10, 2012) ("April 2012 PhRMA Comments").

[21] The America Invents Act "converts inter partes reexamination from an examinational to an adjudicative proceeding, and renames the proceeding 'inter partes review.'" H.R. Rep. No. 112-98, pt. 1, at 46-47 (2011).

[22] *See* 35 U.S.C. § 325(d) ("In determining whether to institute or order a proceeding under this chapter [PGR], chapter 30, or chapter 31 [IPR], the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.").

undermines the public notice function of the prosecution history, and unfairly requires patent owners to defend claims as if they were broader than the claims narrowed and granted during prosecution. Using a *Phillips*-type claim construction standard would be more efficient and more consistent with the AIA.

The PTO's apparent rationale for using a BRI standard was that claims could be amended in an IPR or PGR, as in a patent's original prosecution.[23] However, the AIA provides only one opportunity for a patent owner to amend claims in an IPR or PGR proceeding as a matter of right,[24] unlike the multiple opportunities for amendment in prosecution or reexamination. Furthermore, as discussed below in topic no. 2, in practice, patent owners have been essentially unable to amend their claims.[25] This further highlights the more adjudicative (rather than examinational) aspect of IPR and PGR proceedings and provides additional support for the use of a *Phillips*-type construction.

The different claim construction standards applied in court proceedings versus IPR or PGR proceedings prevent IPR and PGR from serving as real alternatives to court litigation. This frustrates one of the purposes of the AIA, which was to "streamline the current 'inter partes' system so that it will be a more efficient alternative to litigation."[26] Instead, it has been reported that most patents subject to an IPR also have been asserted in district court litigation.[27] Therefore, patent owners are being forced into duplicative proceedings with different standards potentially leading to inconsistent and unpredictable results. Use of these two different standards is also fundamentally unfair to patent owners because it results in a broader claim construction when invalidity is being evaluated at the PTAB but a narrower construction when infringement is an issue at the district court.

Furthermore, in order to enhance efficiency and predictability, if a court has already construed a claim term that is the subject of an IPR or PGR, then the PTAB should adopt that construction in order to avoid inconsistent results. Without such a rule, a patent claim could be

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[23] *Changes to Implement Inter Partes Review Proceedings, Post-Grant Review Proceedings, and Transitional Program for Covered Business Method Patents*, Final Rule, 77 Fed. Reg. 48,680, 48,697 (Aug. 14, 2012) (listing "[t]he typical justifications for using the 'broadest reasonable interpretation standard'" as including "particularly the ability to amend claims").

[24] *See* 35 U.S.C. § 316(d)(1) (in an IPR, "the patent owner may file 1 motion to amend the patent"); *id.* § 326(d)(1) (in a PGR, "the patent owner may file 1 motion to amend the patent").

[25] As far as PhRMA is aware, only one motion to amend claims has been granted. *See* Final Written Decision, *Int'l Flavors & Fragrances Inc. v. United States*, IPR2013-00124, Paper No. 12 (P.T.A.B. May 20, 2014) (granting unopposed motion by United States to cancel and substitute claims).

[26] 157 Cong. Rec. S1348, S1350 (daily ed. Mar. 8, 2011) (statement of Sen. Patrick Leahy).

[27] *See* RPX Corporation, *2013 NPE Litigation Report*, at 41 (Charts 63 and 64 showing that over 97% of all non-practicing entity ("NPE") patents and 70% of all operating company patents subject to an IPR have been asserted in U.S. district court), *available at* http://www.rpxcorp.com/wp-content/uploads/2014/01/RPX-2013-NPE-Litigation-Report.pdf; *see also* Paul J. Korniczky & Elias P. Soupos, *Considerations for Using Post-Grant Proceedings to Attack Patent Validity*, LANDSLIDE, September/October 2014, at 34, 35, *available at* http://www.americanbar.org/publications/landslide/2014-15/september-october/considerations_using_postgrant_proceedings_attack_patent_validity.html#ref3 (citing PTO statistics that 80-90% of petitions are also in litigation in district courts).

found valid and infringed by a district court under a *Phillips*-type construction while the same claim could be found invalid under the PTAB's BRI standard. These inconsistent results cause uncertainty, undermine the public notice function of patents, and diminish patent rights.

Motion To Amend

2. The PTAB should freely allow motions to amend patent claims.

In conjunction with employing the *Phillips*-type claim construction described in topic no. 1 above, the PTAB should freely allow motions to amend patent claims. Current rules and practices have made it seemingly impossible to amend claims in AIA PTAB proceedings. As noted above, as far as PhRMA is aware, all but one motion to amend has been denied.[28] Especially given the current use of BRI to construe claims in these proceedings, the inability to amend claims is profoundly unfair to patent owners. The AIA clearly envisioned the patent owner having a right to amend its claims in these proceedings.[29] Current rules and practices, however, have prevented the exercise of this right.

Under 37 C.F.R. § 42.121, a motion to amend can only be denied when: "i) [t]he amendment does not respond to a ground of unpatentability involved in the trial; or ii) [t]he amendment seeks to enlarge the scope of the claims of the patent to introduce new subject matter." However, the PTAB has added additional requirements such as placing the burden on the patent owner to not only prove patentability of its amended claims, but to also show "general patentability over prior art."[30] This is inconsistent with the PTO's own regulations and is contrary to the AIA, which specifically requires that petitioners, not patent owners, "shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence."[31]

Furthermore, in IPRs and PGRs, the PTAB's rules require a patent owner's motion to amend its claims to present both the proposed amended claims and all argument supporting the

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[28] *See Int'l Flavors & Fragrances Inc. v. United States*, IPR2013-00124, Paper No. 12 (P.T.A.B. May 20, 2014) (granting unopposed motion by United States to cancel and substitute claims).

[29] *See* 35 U.S.C. § 316(d)(1) (in an IPR, "the patent owner may file 1 motion to amend the patent"); *id.* § 326(d)(1) (in a PGR, "the patent owner may file 1 motion to amend the patent").

[30] Final Written Decision, *Idle Free Sys, Inc.. v. Bergstrom, Inc.*, IPR 2012-00027, Paper No. 66, at 33 (P.T.A.B. Jan. 7, 2014).

[31] 35 U.S.C. § 316(e) ("In an inter partes review instituted under this chapter, the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence."); *id.* § 326(e) ("In a post-grant review instituted under this chapter, the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence.")

motion within 15 pages.[32] The patent owner also usually must file its motion to amend at the same time that it files its Patent Owner's Response.[33] Therefore, the patent owner must put forward all its arguments for patentability without knowing whether the original or amended claims will be reviewed by the PTAB. The PTAB's heightened proof requirements, tight page limitations, and difficult timing, combined with the fact that motions to amend are almost never granted, raise fundamental fairness and due process concerns.

For the reasons discussed above, the PTAB's rules and practices need to be amended such that BRI is no longer used and patent owners are able to freely amend their claims at least once as a matter of right as dictated by the AIA.[34]

Patent Owner Preliminary Response

3. New testimonial evidence should be permitted in a Patent Owner Preliminary Response.

As discussed in PhRMA's previously submitted comments,[35] and the comments of the Committee of Six Experts,[36] the regulations should be revised such that new testimonial evidence should be permitted in a Patent Owner Preliminary Response. Current regulations bar the patent owner from presenting new testimonial evidence in its preliminary response.[37] The petitioner,

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[32] *See* 37 C.F.R. § 42.121(a) (in an IPR, "[a] patent owner may file one motion to amend a patent"); *id.* § 42.221(a) (in a PGR, "[a] patent owner may file one motion to amend a patent"); *id.* § 42.23(b) ("All arguments for the relief requested in a motion must be made in the motion."); *id.*§ 42.24(a)(1)(v) (15-page limit for motions) ; *see also* Paul J. Korniczky & Elias P. Soupos, *Considerations for Using Post-Grant Proceedings to Attack Patent Validity*, LANDSLIDE, September/October 2014, at 34, 37, *available at* http://www.americanbar.org/publications/landslide/2014-15/september-october/considerations_using_postgrant_proceedings_attack_patent_validity.html#ref3 ("The burden to prove patentability, coupled with a 15-page limit, significantly limits the ability to amend.").

[33] *See* 37 C.F.R. § 42.121(a)(1) (in an IPR, "Unless a due date is provided in a Board order, a motion to amend must be filed no later than the filing of a patent owner response."); *id.* § 42.221(a)(1) (in a PGR "Unless a due date is provided in a Board order, a motion to amend must be filed no later than the filing of a patent owner response.").

[34] *See* 35 U.S.C. § 316(d)(1) (in an IPR, "the patent owner may file 1 motion to amend the patent"); *id.* § 326(d)(1) (in a PGR, "the patent owner may file 1 motion to amend the patent").

[35] *See* April 2012 PhRMA Comments, n.20 above.

[36] "[T]he patent owner should be allowed to include with its preliminary response any evidence offered to rebut the petition, including testimonial evidence." *Comments of the Committee Appointed by the American Bar Association IP Law Section, the American Intellectual Property Law Association, and the Intellectual Property Owners Association on the United States Patent and Trademark Office's Proposed Regulations Relating to Post-Grant Review, Inter Partes Review and the Transitional Program for Covered Business Method Patents Under the Leahy-Smith America Invents Act*, at 3, 6-10 (filed Apr. 9, 2012), *available at* http://www.uspto.gov/aia_implementation/comment-aba-aipla-ipo.pdf.

[37] *See* 37 C.F.R. § 42.107(c) (patent owner's preliminary response to a petition for inter partes review "shall not present new testimony evidence beyond that already of record"); *id.* § 42.207(c) (patent owner's preliminary response to a petition for post-grant review "shall not present new testimony evidence beyond that already of record").

however, is not prevented from including such evidence (including expert declarations) in its petition and, in fact, such evidence is often included. This lopsided restriction is not found in the text of the AIA and is fundamentally unfair to the patentee.

Restricting patent owners' use of testimonial evidence could prevent patent owners from fully meeting the AIA's requirement that preliminary responses set forth how a petition has failed to meet the AIA's standards for instituting an IPR or PGR.[38] If patent owners can make that required showing only through testimonial evidence, that information by definition cannot be presented as Congress intended. This incongruity between what the petitioner is allowed to present and what the patent owner is allowed to present raises fairness and due process concerns. Instituting an IPR or PGR based on the petitioner's evidence without comparable evidence from the patent owner unfairly disadvantages the patent owner. Moreover, it also forces the PTO to make a decision on whether to institute a PGR or IPR proceeding without the ability to review all of the available evidence.

In addition to fairness concerns, allowing patent owners to include testimonial evidence in a Patent Owner Preliminary Response would make evaluating an IPR or PGR institution more efficient. The PTO would be able to consider a more complete record when making an institution decision, which may lead to fewer IPR or PGR institutions, or institutions on a smaller number of claims or issues. The PTO also would be able to consider this additional evidence before institution, and thus before the twelve- to eighteen-month review period begins.[39]

Obviousness

4. The PTAB should permit discovery of evidence of non-obviousness held by the petitioner.

The PTAB should permit discovery of evidence of non-obviousness held by the petitioner in all cases. For example, the PTAB should permit discovery of evidence of the commercial success of a petitioner's product that embodies the claimed invention, as well as other objective evidence of non-obviousness. Current PTAB regulations and practices generally require prior authorization before filing discovery motions in IPRs and PGRs, including motions for discovery

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[38] *See* 35 U.S.C. § 313 (patent owner's preliminary response must "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"); *id.* § 323 (patent owner's preliminary response must "set[] forth reasons why no post-grant review should be instituted based upon the failure of the petition to meet any requirement of this chapter").

[39] *See* 35 U.S.C. § 316(a)(11) ("requiring that the final determination in an inter partes review be issued not later than 1 year after the date on which the Director notices the institution of a review under this chapter, except that the Director may, for good cause shown, extend the 1-year period by not more than 6 months"); *id.* § 326(a)(11) ("requiring that the final determination in any post-grant review be issued not later than 1 year after the date on which the Director notices the institution of a proceeding under this chapter, except that the Director may, for good cause shown, extend the 1-year period by not more than 6 months").

of information regarding secondary considerations of non-obviousness.[40] These motions have been frequently denied. However, such discovery relating to non-obviousness is "necessary in the interests of justice," as required by the AIA.[41] If such evidence exists, fairness and due process support allowing the patent owner to more freely discover this information and use it in the proceedings in order to present a balanced case.

Real Party in Interest

5. The patent owner should be permitted to discover the real party in interest.

The institution, stay, and estoppel provisions of the AIA depend on knowing the identity of the petitioner or real party in interest.[42] Patent owners should be able to freely discover the real party in interest at any time during a trial in order to discern whether such AIA provisions apply.[43]

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[40] *See* 37 C.F.R. § 42.51(b) (for non-"routine" discovery, "[t]he parties may agree to additional discovery between themselves," but [w]here the parties fail to agree, a party may move for additional discovery."); *id.* § 42.20(b) ("A motion will not be entered without Board authorization."); Decision, *Garmin Int'l Inc. v. Cuozzo Speed Technologies, LLC*, IPR 2012-00001, Paper No. 26 (P.T.A.B. Mar. 5, 2013) (denying motion for additional discovery regarding secondary considerations of non-obviousness, and listing factors to consider when moving for such additional discovery).

[41] 35 U.S.C. § 316(a)(5)(B) (for IPRs, "[t]he Director shall prescribe regulations . . . setting forth standards and procedures for discovery of relevant evidence, including that such discovery shall be limited to . . . what is otherwise necessary in the interest of justice."); *see also id.* § 326(a)(5) (for PGRs, "[t]he Director shall prescribe regulations . . . setting forth standards and procedures for discovery of relevant evidence, including that such discovery shall be limited to evidence directly related to factual assertions advanced by either party in the proceeding.").

[42] *See* 35 U.S.C. § 315(a)(1) ("An inter partes review may not be instituted if, before the date on which the petition for such a review is filed, the petitioner or real party in interest filed a civil action challenging the validity of a claim of the patent."); *id.* § 325(a)(1) (same for PGR); *id.* § 315(a)(2) ("If the petitioner or real party in interest files a civil action challenging the validity of a claim of the patent on or after the date on which the petitioner files a petition for inter partes review of the patent, that civil action shall be automatically stayed" until the patent owner moves to lift the stay, files an infringement action or counterclaim, or moves to dismiss); *id.* § 325(a)(2) (same for PGR); *id.* § 315(b) ("An inter partes review may not be instituted if the petition requesting the proceeding is filed more than 1 year after the date on which the petitioner, real party in interest, or privy of the petitioner is served with a complaint alleging infringement of the patent."); *id.* § 315(e) (In an IPR resulting in a final written decision, "[t]he petitioner . . . or the real party in interest or privy of the petitioner, may not request or maintain a proceeding before the Office with respect to that claim on any ground that the petitioner raised or reasonably could have raised during that inter partes review," and "may not assert either in a civil action . . . or in a proceeding before the International Trade Commission . . . that the claim is invalid on any ground that the petitioner raised or reasonably could have raised during that inter partes review."); *id.* § 325(e) (same for PGR).

[43] In contrast to the PTO's proposed "attributable owner" rules, discovery of the real party in interest for purposes of applying provisions of the AIA is less likely to create overbreadth, undue burden, or other unfairness concerns for patentees. *See* 79 Fed. Reg. 4105-4121 (Jan. 24, 2014).

Additional Discovery

6. The patent owner should be permitted additional discovery.

As discussed in topic nos. 4 and 5 above, the patent owner should be permitted routine discovery of at least objective evidence of non-obviousness and the real party in interest.

Multiple Proceedings

7, 8, 9, 10, 11, 12, 13. Multiple proceedings before the PTO involving the same patent should be coordinated.

The PTAB's trial proceedings should be revised such that patent owners have predictable property rights which are not subject to unnecessarily duplicative proceedings. The proposals below would increase certainty for patent holders to warrant the heavy investments that are often made in the patented inventions.

To increase fairness to patent owners while also allowing the PTO to review issued patents, the PTAB rules should be amended to provide that, if a patent is put into a reexamination or reissue proceeding before an IPR or PGR is instituted, the IPR or PGR should not be instituted, and the reexamination or reissue proceeding should proceed. The AIA specifically provides that in such situations, the Director has the discretion to provide for the "stay, transfer, consolidation, or termination of any such matter or proceeding" before the PTO.[44] Allowing patent owners to proceed with prosecution in reexamination or reissue proceedings would still allow the PTO to consider any new issues raised by a filed IPR or PGR petition that was not instituted, while saving petitioners from estoppel preclusion and substantial fees.[45] This would alleviate due process concerns by providing patent owners the opportunity to participate

[44] *See* 35 U.S.C. § 315(d) ("[D]uring the pendency of an inter partes review, if another proceeding or matter involving the patent is before the Office, the Director may determine the manner in which the inter partes review or other proceeding or matter may proceed, including providing for stay, transfer, consolidation, or termination of any such matter or proceeding."); *id.* § 325(d) ("[D]uring the pendency of any post-grant review under this chapter, if another proceeding or matter involving the patent is before the Office, the Director may determine the manner in which the post-grant review or other proceeding or matter may proceed, including providing for the stay, transfer, consolidation, or termination of any such matter or proceeding.").

[45] For example, the petitioner would save attorney's fees associated with the IPR or PGR as well as being able to get a refund of post-institution fees. *See* USPTO, *Setting and Adjusting Patent Fees*, 78 Fed. Reg. 4212, 4233, 4235 (Jan. 18, 2013) ("The Office also chooses to return fees for post-institution services should a review not be instituted. . . . [The] *inter partes* review post-institution fee . . . would be returned to the petitioner if the Office does not institute a review. . . . [The] post-grant review post-institution fee . . . would be returned to the petitioner if the Office does not institute a review."); Patent Review Processing System (PRPS), Frequently Asked Questions, FAQ E7, *available at* http://www.uspto.gov/ip/boards/bpai/prps.jsp ("If I filed an *inter partes* review petition on or after March 19, 2013, may I request a refund of the post-institution fee paid if the Board decides not to institute a review? Yes, in such a situation, the petitioner may file in PRPS a request for a refund of any post-institution fee paid.").

in less costly proceedings in which their claims may be freely amended while preserving petitioners' rights to later challenge any resulting patent claims.

Another proposal to reduce harassment of patent owners would be to include a rule that carries out the intent of the AIA to take into account the existence of other proceedings and the prior consideration of issues.[46] If the same or substantially the same prior art or arguments that were considered in a previous examination, IPR, PGR, reexamination proceeding, reissue proceeding, or petition therefor, are presented in a petition for an AIA trial proceeding, then the petition should be rejected. The patent owner should not have to expend its resources fighting over the same or substantially the same prior art or arguments.

Furthermore, in many cases, fairness and efficiency concerns would suggest that a review not be instituted. The AIA provides the Director with the discretion to decide not to institute an IPR or PGR.[47] In addition, one of the purposes of the AIA was to "streamline the current 'inter partes' system so that it will be a more efficient alternative to litigation."[48] However, it has been reported that the majority of patents subject to an IPR also have been asserted in district court litigation.[49] The PTAB thus should disfavor instituting an IPR or PGR for a patent that is already being challenged in a district court case, especially if the district court has already construed the patent claims or if the district court has already ruled in favor of the patent owner.

Extension of 1 Year Period To Issue Final Determination

14. The 1-year period for the PTAB to issue a final determination in an AIA trial should be liberally extended.

The 1-year period for the PTAB to issue a final determination in a trial proceeding should be extended by an additional 6 months, as permitted by the AIA, when required by due process

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[46] *See* 35 U.S.C. § 325(d) ("In determining whether to institute or order a proceeding under this chapter [PGR], chapter 30, or chapter 31 [IPR], the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.").

[47] *See* 35 U.S.C. § 314(a) ("The Director may not authorize an inter partes review to be instituted unless . . ."); *id.* § 324(a) ("The Director may not authorize a post-grant review to be instituted unless . . .").

[48] 157 Cong. Rec. S1348, S1350 (daily ed. Mar. 8, 2011) (statement of Sen. Patrick Leahy).

[49] *See* RPX Corporation, *2013 NPE Litigation Report*, at 41 (Charts 63 and 64), *available at* http://www.rpxcorp.com/wp-content/uploads/2014/01/RPX-2013-NPE-Litigation-Report.pdf; *see also* Paul J. Korniczky & Elias P. Soupos, *Considerations for Using Post-Grant Proceedings to Attack Patent Validity*, LANDSLIDE, September/October 2014, at 34, 35, *available at* http://www.americanbar.org/publications/landslide/2014-15/september-october/considerations_using_postgrant_proceedings_attack_patent_validity.html#ref3 (citing PTO statistics that 80-90% of petitions are also in litigation in district courts).

and the interests of justice.[50] For example, the 1-year period could be extended where discovery of objective considerations of non-obviousness is needed or in situations in which more time is needed to consider amended claims. Finishing a PTAB AIA trial proceeding within 12 months, rather than within 18 months, is not as important as providing sufficient due process protections.

Oral Hearing

15, 16. Live testimony should be permitted at the oral hearing.

Where issues of credibility arise, live testimony and cross-examination of key witnesses at the oral hearing would aid the PTAB in making such credibility determinations and should be allowed as a matter of right. This would also address fairness and due process concerns that arise due to the inability of parties dissatisfied with a PTAB decision in an IPR or PGR to supplement the record with additional evidence and witness testimony on appeal.

General

17. a. The PTAB panel that conducts an AIA Review should not also institute that review.

In order to comply with the AIA, and to remove the potential for bias and improper burden shifting, the PTAB panel that conducts an AIA Review should not also have instituted that review. The AIA provides that it is the responsibility of the Director of the PTO to establish the rules for IPRs and PGRs,[51] and to determine whether to institute an IPR or PGR.[52] Separately, the AIA also enumerates the duties of the PTAB, which do not include instituting IPRs or PGRs.[53] For IPRs and PGRs, the PTAB's duties are specified as "conduct[ing] inter partes reviews and post-grant reviews pursuant to chapters 31 [Inter Partes Review] and 32

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50 *See* 35 U.S.C. § 316(a)(11) ("requiring that the final determination in an inter partes review be issued not later than 1 year after the date on which the Director notices the institution of a review under this chapter, except that the Director may, for good cause shown, extend the 1-year period by not more than 6 months"); *id.* § 326(a)(11) ("requiring that the final determination in any post-grant review be issued not later than 1 year after the date on which the Director notices the institution of a proceeding under this chapter, except that the Director may, for good cause shown, extend the 1-year period by not more than 6 months").

51 *See* 35 U.S.C. § 316(a) ("Conduct of inter partes review (a) Regulations.—The Director shall prescribe regulations— . . ."); *id.* § 326(a)("Conduct of post-grant review (a) Regulations.—The Director shall prescribe regulations— . . .").

52 *See* 35 U.S.C. § 314(b) ("[t]he Director shall determine whether to institute an inter partes review"); *id.* § 324(c)("[t]he Director shall determine whether to institute a post-grant review").

53 Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 7, 125 Stat. 284, 313 (2011) (amending 35 U.S.C. § 6); 35 U.S.C. § 6(b) (as amended) ("Duties.—The Patent Trial and Appeal Board shall—(1) on written appeal of an applicant, review adverse decisions of examiners upon applications for patents pursuant to section 134(a); (2) review appeals of reexaminations pursuant to section 134(b); (3) conduct derivation proceedings pursuant to section 135; and (4) conduct inter partes reviews and post-grant reviews pursuant to chapters 31 [Inter Partes Review] and 32 [Post-Grant Review].").

[Post-Grant Review]."[54] In Chapters 31 and 32, the PTAB's duties similarly are limited to "in accordance with section 6, conduct[ing] each . . . review instituted under this chapter."[55] The AIA thus separates the responsibility for instituting an IPR or PGR from the responsibility for conducting an instituted IPR or PGR. The PTAB's role under the AIA is specifically limited to "conduct[ing]" a review that was already "instituted."

Separating the decision to institute on IPR or PGR from the PTAB's decision on the merits would increase patent owners' due process protections, reduce perceptions of bias, and more fully meet the requirements of the AIA. For example, separating institution decisions from the PTAB's merits decisions would emphasize that the standard for instituting an IPR or PGR is different from the standard for finding a claim invalid in these proceedings. An IPR cannot be instituted unless the petition and any patent owner response "shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."[56] A PGR cannot be instituted unless the petition, if not rebutted, "would demonstrate that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable."[57] However, a claim cannot be found invalid in an IPR or PGR unless the petitioner "prov[es] a proposition of unpatentability by a preponderance of the evidence."[58] Using not only a PTAB panel, but the same PTAB panel, both to institute a review and to rule on the merits can blur the distinction between the threshold standard for institution and the higher standard for a determination on the merits. This is contrary to the requirements of the AIA and is unfair to the patent owner.

If the PTAB panel that conducts an IPR or PGR did not also institute the IPR or PGR, it would minimize the appearance of potential bias, which may be suggested by the high percentage of claims that have been found unpatentable in IPRs. This high percentage may be a by-product of a PTAB panel deciding whether to institute a review, and then the same panel confirming its institution decision when ruling on the merits.

Having the same PTAB panel institute and conduct an IPR or PGR could also result in the panel improperly shifting the burden to the patent owners to show the validity of their patents

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[54] 35 U.S.C. § 6(b)(4) ("The Patent Trial and Appeal Board shall . . . conduct inter partes reviews and post-grant reviews pursuant to chapters 31 [Inter Partes Review] and 32 [Post-Grant Review].")

[55] *See* 35 U.S.C. § 316(c) ("The Patent Trial and Appeal Board shall, in accordance with section 6, conduct each inter partes review instituted under this chapter."); *id*. § 326(c) ("The Patent Trial and Appeal Board shall, in accordance with section 6, conduct each post-grant review instituted under this chapter.").

[56] 35 U.S.C. § 314(a); *see also* 37 C.F.R. § 42.108(c) ("Inter partes review shall not be instituted for a ground of unpatentability unless the Board decides that the petition supporting the ground would demonstrate that there is a reasonable likelihood that at least one of the claims challenged in the petition is unpatentable.").

[57] 35 U.S.C. § 324(a); *see also* 37 C.F.R. § 42.208(c) ("Post-grant review shall not be instituted for a ground of unpatentability, unless the Board decides that the petition supporting the ground would, if unrebutted, demonstrate that it is more likely than not that at least one of the claims challenged in the petition is unpatentable.").

[58] 35 U.S.C. § 316(e); *id*. § 326(e).

once a review is instituted. This is contrary to the AIA, which requires petitioners to "bear the burden of proving that a patent is invalid by a preponderance of the evidence."[59] Having institution decisions made independently of the PTAB panel that instituted the IPR or PGR would address these fairness and impartiality concerns and more appropriately fulfill the requirements of the AIA.

b. Either the petitioner's reply should not present new evidence, or the patent owner should be allowed to respond to any new evidence presented in the petitioner's reply.

To ensure fairness, either the petitioner should not be able to introduce new evidence in its reply to the patent owner's response, or the patent owner should have the right to fully respond to that new evidence in a sur-reply. Current PTAB rules and practices allow the petitioner to file a declaration with its reply, and also allow the patent owner subsequently to cross-examine the declarant.[60] The PTAB then may authorize the patent owner to file very limited "observations" to call particular cross-examination testimony to the PTAB's attention.[61] Instead, the patent owner should be allowed to submit a sur-reply further describing the relevance of this cross-examination testimony, as well as responding to any exhibits or other new information in the petitioner's reply. This would address due process concerns by reducing limitations on the patent owner's opportunity to be heard.

c. The PTAB proceedings should be structured to ensure fairness to the patent owner.

PhRMA's earlier comments to the PTAB's proposed rules highlighted concerns about the PTAB's proposed timing of different filings.[62] For example, PhRMA's prior comments discuss how the patent owner should be assured at least three months of discovery after institution of an AIA proceeding and an additional month to file its response. While the default rule for the filing

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[59] H.R. Rep. No. 112-98, pt. 1, at 46-48 (2011); *see also* 35 U.S.C. § 316(e) ("In an inter partes review instituted under this chapter, the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence."); 35 U.S.C. § 326(e) ("In a post-grant review instituted under this chapter, the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence.")

[60] *Office Patent Trial Practice Guide*, 77 Fed. Reg. 48,756, 48,757-48,758 (Aug. 14, 2012) ("after the petitioner has filed a reply to the patent owner's response . . . , the patent owner may depose the petitioner's declarants").

[61] *Id.* at 48,767-48,768 ("In the event that cross-examination occurs after a party has filed its last substantive paper on an issue, such cross-examination may result in testimony that should be called to the Board's attention . . . . The Board may authorize the filing of observations to identify such testimony . . . . Each observation should be in the following form: In exhibit __, on page __, lines __, the witness testified __. This testimony is relevant to the __ on page __ of __. The testimony is relevant because __. The entire observation should not exceed one short paragraph.").

[62] *See* April 2012 PhRMA Comments, n.20 above.

of a patent owner response is 3 months,[63] in practice, the scheduling order is set such that a patent owner is often only given 2 months from institution to conduct discovery and file its response. This and other issues addressed in PhRMA's prior comments remain concerns for PhRMA.

II. Conclusion

PhRMA appreciates the PTO's efforts to revisit its rules and practices regarding trial proceedings under the AIA before the PTAB and the opportunity to offer its perspective on these proceedings. PhRMA and its member companies are committed to helping the PTO find solutions to the many challenges it faces today and in the years to come.

[63] *See* 37 C.F.R. § 42.120(b) ("the default date for filing a patent owner response is three months from the date the *inter partes* review was instituted"); *id*. § 42.220(b) ("the default date for filing a patent owner response is three months from the date the post-grant review is instituted").