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PhRMA

April 10, 2012

VIA EMAIL

Mail Stop Patent Board
Director of the United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Attention: Lead Judge Michael Tierney

Re: Docket Nos: PTO-P-2011-0082, 0083, 0084, 0086, and 0094

Dear Judge Tierney,

I am writing on behalf of the Pharmaceutical Research and Manufacturers of America ("PhRMA") to convey the views of PhRMA's members in response to the following notices:

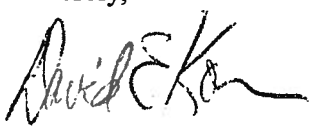
- Rules of Practice for Trials Before the Patent Trial and Appeal Board and Judicial Review of Patent Trial and Appeal Board Decisions [Docket No.: PTO-P-2011-0082].
- Changes to Implement Inter Partes Review Proceedings [Docket No.: PTO-P-2011-0083].
- Changes to Implement Post-Grant Review Proceedings [Docket No.: PTO-P-2011-0084].
- Changes to Implement Derivation Proceedings [Docket No.: PTO-P-2011-0086].
- Practice Guide for Proposed Trial Rules [Docket No.: PTO-P-2011-0094].

PhRMA's members are leading pharmaceutical research and biotechnology companies devoted to researching and developing new medicines to allow patients to live longer, healthier and more productive lives. PhRMA's members lead the way in finding cures and new treatments as well as in developing critically important improvements in existing therapies. Patent protection is an important incentive to promote the innovative research necessary for such advances and to make available to society the benefits of that research.

The enclosed comments include views of PhRMA's members on the subject matter discussed in the notices. PhRMA's members appreciate the PTO seeking comments in these areas, and would welcome further dialogue with the PTO on these important issues.

Please feel free to contact me if you have any questions.

Sincerely,



David E. Korn

Enclosure

Comments of the Pharmaceutical Research and Manufacturers of America
Docket Nos: PTO-P-2011-0082, -0083, -0084, -0086, -0094
April 10, 2012

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

The Pharmaceutical Research and Manufacturers of America ("PhRMA") appreciates the opportunity to submit comments in connection with the Patent and Trademark Office ("PTO" or "Office") Request for Comments on:

- Practice Guide for Proposed Trial Rules.[1/]
- Rules of Practice for Trials Before the Patent Trial and Appeal Board and Judicial Review of Patent Trial and Appeal Board Decisions.[2/]
- Changes to Implement Derivation Proceedings.[3/]
- Changes to Implement Inter Partes Review Proceedings.[4/]
- Changes to Implement Post-Grant Review Proceedings.[5/]

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. A recent study by the Battelle Technology Partnership Practice reports that the U.S. biopharmaceutical sector supported a total of 4 million jobs throughout the economy, and directly employed more than 674,000 Americans in high-quality jobs that pay more than two times the average for U.S. private sector wages in 2009.[6/] The industry's direct economic output in 2009 was $382.4 billion.[7/]

Consistent with the Congressional Budget Office's finding that the pharmaceutical sector is one of the nation's most research-intensive sectors,[8/] PhRMA member investment in discovering and developing new medicines reached nearly $50 billion in 2010.[9/] Medicines

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1/ 77 Fed. Reg. 6868-6879 (Feb. 9, 2012).
2/ 77 Fed. Reg. 6879-6914 (Feb. 9, 2012).
3/ 77 Fed. Reg. 7028-7041 (Feb. 10, 2012).
4/ 77 Fed. Reg. 7041-7060 (Feb. 10, 2012).
5/ 77 Fed. Reg. 7060-7080 (Feb. 10, 2012).
6/ Battelle Technology Partnership Practice, *The U.S. Biopharmaceuticals Sector: Economic Contribution to the Nation*, BATTELLE (Washington, DC), July 2011, at 5, 8.
7/ *Id*. at 6.
8/ A CBO Study: Research and Development in the Pharmaceutical Industry, Pub. No. 2589, Cong. Budget Office, at 9 (Oct. 2006), *available at* http://www.cbo.gov/ftpdocs/76xx/doc7615/10-02-DrugR-D.pdf.
9/ PhRMA Annual Membership Survey, 2010.

developed by the sector have produced large improvements in health across a broad range of diseases, with the rapid growth of biological 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 research and development.[10/] Like innovators across the spectrum of American industries, pharmaceutical companies make the substantial R&D investments that yield new medicines in reliance on a legal regime that provides protection 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 pharmaceutical innovation given the research-intensive nature of this sector and the substantial investment required to discover and develop products that meet FDA approval requirements.[11/]

Bringing new 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 implement balanced post-grant review proceedings, *inter partes* review proceedings, and derivation proceedings. However, in our view, the PTO's proposed rulemaking departs from the intent of the Leahy-Smith America Invents Act ("AIA"), which is aimed at providing proceedings that are more efficient and fair.

I. The PTO's Proposed Review Procedures Should Be Modified To Streamline the Procedures and Ensure Fairness to Patentees.

The intent of Congress in enacting the post-grant review process was "to enable early challenges to patents, while still protecting the rights of inventors and patent owners against new patent challenges unbounded in time and scope."[12/] Under Secretary Kappos similarly noted that *inter partes* reexamination should "serve to minimize costs and increase certainty by offering efficient and fast alternatives to litigation as a means of reviewing questions of patent

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[10/] Joseph A. DiMasi and Henry G. Grabowski. *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 MANAGERIAL & DECISION ECON. 467-79, 470 (2007); *Drug Discovery and Development: Understanding the R&D Process*, INNOVATION.ORG (PhRMA, Washington, DC), Feb. 2007, at 1-2.

[11/] *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, potential investors would see little prospect of profits sufficient to recoup their investments and offset the accompanying financial risk."); Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MGMT. SCI. 2, at 174-75, T.1 (Feb. 1986) at 173-181 (estimating that without patent protection, 65% of pharmaceutical products would never have been brought to market, while the average across all other industries was a mere 8%); *see generally* Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 J. OF INT'L ECONOMIC L. 849 (2002).

[12/] H.R. Rep. No. 112-98, pt. 1, at 47-48 (2011).

validity."[13/] In order to ensure that post-grant review, *inter partes* review, and derivation proceedings are efficient and fair, we urge that the PTO modify its proposed procedures as described below.

A. The Petition Should Disclose the Entirety of the Petitioner's Case.

As the legislative history of the AIA makes clear, Congress intended that post-grant and *inter partes* review proceedings would "force parties to front-load their cases, allowing these proceedings to be resolved more quickly."[14/] Consistent with the legislative intent and in order to streamline these proceedings, the PTO's regulations regarding the initial filing of a petition to institute a post-grant review, *inter partes* review, or derivation proceeding should require that the petition disclose the entirety of the petitioner's case and effectively serve as the petitioner's main "trial brief." The PTO's proposed rules do not include this requirement and also allow the petitioner to request authorization to file a motion identifying supplemental information once a trial has been instituted.[15/]

Although the PTO's proposed rules require petitions to include supporting evidence and explain the relevance of the evidence to the challenges raised in the petition,[16/] the proposed rules should more clearly require the petition to disclose the petitioner's entire case. As stated in the notice of proposed Rules of Practice for Trials Before the Patent Trial and Appeal Board ("Board"), "[v]ague arguments and generic citations to the record are fundamentally unfair to an opponent and do not provide sufficient notice to an opponent and create[] inefficiencies for the Board."[17/] Furthermore, by allowing a petitioner to make later supplementary filings expanding

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13/ *The America Invents Act: Hearing on H.R. 1249 Before the H. Subcomm. on Intellectual Property, Competition, and the Internet*, 112th Cong. 3 (2011) (statement of David J. Kappos, Under Sec'y of Commerce for Intellectual Property, and Director of the U.S. Patent & Trademark Office), *available at*, http://judiciary.house.gov/hearings/pdf/Kappos03302011.pdf.

14/ 157 Cong. Rec. S1041 (daily ed. Mar. 1, 2011) (statement of Sen. Jon Kyl).

15/ *See* Proposed 37 C.F.R. § 42.123 (allowing a petitioner after an *inter partes* review trial is instituted to "request authorization to file a motion identifying supplemental information relevant to a ground for which the trial has been instituted"); Proposed 37 C.F.R. § 42.223 (allowing a petitioner after a post-grant review trial is instituted to "request authorization to file a motion identifying supplemental information relevant to a ground for which the trial has been instituted.").

16/ *See, e.g.*, Proposed 37 C.F.R. § 42.22(a)(3) (any petition must include "a detailed explanation of the significance of the evidence"); Proposed 37 C.F.R. § 42.104(b)(5) (requiring petition for *inter partes* review to include the "supporting evidence relied upon" and "state the relevance of the evidence"); Proposed 37 C.F.R. § 42.204(b)(5) (requiring petition for post-grant review to include the "supporting evidence relied upon" and "state the relevance of the evidence"); Proposed 37 C.F.R. § 42.405(c) (requiring petition for derivation proceedings to be "supported by substantial evidence"); *see also* 77 Fed. Reg. 6868, 6873 (Feb. 9, 2012) (petitions must identify relevance of evidence to issues raised).

17/ 77 Fed. Reg. 6879, 6885 (Feb. 9, 2012).

the evidence described in a petition,[18/] the proposed rules decrease the efficiency and increase the cost of the review or proceeding. For these reasons, requiring petitions to fully disclose the petitioner's case and serve as the petitioner's main "trial brief" would be more fair to the patent owner and increase the efficiency of a review or proceeding.

Requiring that the petition disclose the petitioner's entire case is consistent with the text of the AIA. The AIA provides that petitioners for *inter partes* review, post-grant review, and derivation proceedings must identify their claims and supporting evidence "with particularity."[19/] The AIA also provides that petitions for *inter partes* or post-grant review must include "other information as the Director may require by regulation."[20/] Including the petitioner's complete case within the petition is particularly important, because the AIA states that the determination whether to institute an *inter partes* review, a post-grant review, or a derivation proceeding is "final and nonappealable."[21/]

The PTO thus should require that the petition and its attachments lay out all of the affirmative evidence, including any live testimony upon which petitioner intends to rely in its patent challenge. Upon agreement to a standing protective order, the patent owner should be given immediate access to any confidential information included with the petition, including all documents relied upon in support of the petition.

In addition, along with its petition, the petitioner should be required to make an initial disclosure of all evidence of which it is aware that may bear on the fair resolution of the issues raised in the petition, including information relating to the identities of additional pertinent witnesses and documents. When a prior public use or sale issue is raised, all persons having knowledge, and all documents relating to that alleged public use or sale should be disclosed with the petition. When an obviousness issue is raised, all persons having knowledge, and all documents relating to secondary considerations of non-obviousness, should be required to be disclosed with the petition.

18/ *See* Proposed 37 C.F.R. § 42.123 (allowing a petitioner after an *inter partes* review trial is instituted to "request authorization to file a motion identifying supplemental information relevant to a ground for which the trial has been instituted"); Proposed 37 C.F.R. § 42.223 (allowing a petitioner after a post-grant review trial is instituted to "request authorization to file a motion identifying supplemental information relevant to a ground for which the trial has been instituted.").

19/ *See* AIA Section 6, § 312(a)(3) (petitioners for *inter partes* review must identify claims, grounds, and supporting evidence "with particularity"); *id.*, Section 6, § 322(a)(3) (petitioners for post-grant review must identify claims, grounds, and supporting evidence "with particularity"); *id.*, Section 4, § 135(a) (petitioners for derivation proceedings must set forth basis "with particularity" and support petition with "substantial evidence").

20/ *See* AIA Section 6, § 312(a)(4) (*inter partes* review); *id.*, Section 6, § 322(a)(4) (post-grant review).

21/ *See* AIA Section 6, § 314(d) (*inter partes* review); *id.*, Section 6, § 324(e) (post-grant review); *id.* Section 3, § 135(a) (derivation proceedings).

After filing its petition, the petitioner should not thereafter be allowed to introduce new evidence in support of its contentions. Later introduction of evidence by the petitioner should be limited to rebuttal evidence of positions taken by the patentee, and/or evidence bearing on the credibility of patentee's witnesses. Without such a limitation, a petitioner could withhold evidence or arguments until late in the review process, which would be unfair to the patentee, especially if the patentee has no ability to respond to the new allegations. For example, if the petitioner were to include new evidence in its reply to the patentee's response, the patentee may not have a further opportunity to respond.

B. The Patent Owner's Preliminary Response Should be Allowed to Include All of the Evidence the Patent Owner Wishes to Rely on to Rebut the Petition.

The PTO regulations implementing the post-grant and *inter partes* review processes should be set up to ensure that the processes are efficient and allow for equal opportunities for the petitioner and patentees to present their arguments. The proposed regulations concerning the content of the patentee's preliminary response should be revised.

The proposed regulations place no limits on the type of information that can be included in a requester's petition for post-grant or *inter partes* review. Therefore, petitioners can, and likely will, include expert affidavits or declarations in support of their petitions. In contrast, the proposed rules specifically bar patentees from presenting their own testimonial evidence in their preliminary response to the petition.[22/] This lopsided restriction is not found in the text of the AIA. In fact, the proposed restriction on 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 *inter partes* or post-grant review.[23/] If patent owners can make that required showing only through testimonial evidence, that information by definition cannot be presented as Congress intended. As proposed, this incongruity between what the petitioner is allowed to present and what the patent owner is allowed to present is unfair to patentees and may implicate due process issues. Moreover, it also forces the PTO to make a decision on whether to institute a post-grant or *inter partes* proceeding without the ability to review all of the available evidence.

The patentee should be allowed to include in its preliminary response all of the evidence the patentee wishes to rely on to rebut the petition, including testimony by affidavit or declaration. Evidence presented by the patent owner should be weighed in the same manner as

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22/ *See* Proposed 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"); Proposed 37 C.F.R. § 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").

23/ *See* AIA Section 6, § 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.*, Section 6, § 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").

like evidence presented by the petitioner. Such a full disclosure by the patentee in its preliminary response should be encouraged. In this way, the PTO may decide whether to institute a proceeding on the basis of the best available information, and avoid declaring an *inter partes* or post-grant review except in cases where it appears that the PTO has mistakenly issued the patent in question. This is especially important given the significant economic hardship these proceedings could impose on many patentees.

The PTO's proposed regulations also would require the patentee's preliminary response to be filed within two months of the granting of a filing date to the request.[24/] Given the length of time that requesters have to prepare their petitions (i.e., at least 9 months in the case of a post-grant review and potentially years in the case of an *inter partes* review), patentees should be allowed at least three months to file a preliminary response, and longer if good cause is shown. By giving patentees enough time to prepare a thorough preliminary response, the PTO will be able to review all of the available evidence in making its determination on whether to implement a review proceeding.

C. If a Review Is Initiated, the Patent Owner Should Be Assured At Least Three Months of Discovery and Well-Regulated Depositions.

The PTO's proposed regulations provide that, if no time for filing a patent owner response to a petition is provided in a Board order, the default date for filing a patent owner response is two months from the date of the institution of the review.[25/] As discussed above, given the amount of time a requester has to prepare its petition, such a short deadline for the patent owner's response is unfair. In order to allow the patent owner sufficient time to take discovery and file a response, the patent owner should be assured at least three months of discovery. An additional 30 days would not unduly lengthen the review processes, because this would only constitute three months of the twelve to eighteen months allowed under the AIA to complete the review.[26/] In fact, the "representative timeline" and the model scheduling order provided in the Practice Guide for Proposed Trial Rules both suggest allowing four months for the patent owner to file a response to the petition if review is initiated.[27/]

[24/] *See* Proposed 37 C.F.R. § 42.107(b) (patent owner's preliminary response to an *inter partes* petition "must be filed no later than two months" after notice that the petition was given a filing date); Proposed 37 C.F.R. § 42.207(b) (patent owner's preliminary response to a post-grant review petition "must be filed no later than two months" after notice that the petition was given a filing date).

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

[26/] *See* AIA Section 6, § 316(a)(11) (allowing 12 to 18 months for *inter partes* review after a review is initiated); *id.*, Section 6, 326(a)(11) (allowing 12 to 18 months for post-grant review after a review is initiated).

[27/] *See* 77 Fed. Reg. 6868, 6869, 6875-6876 (Feb. 9, 2012).

During discovery, the patent owner should be allowed to immediately begin taking deposition testimony from the petitioner's declarants. Although the discussion in the Practice Guide for Proposed Trial Rules states that "the patent owner may begin deposing the petitioner's declarants once the proceeding is instituted,"[28/] the proposed rules provide only that compelled direct testimony "may only be taken during a testimony period set by the Board."[29/] Instead, the rules should provide explicitly that the patent owner should be allowed to begin deposing the petitioner's declarants as soon as an *inter partes* or post-grant review is initiated.

In addition, the patent owner should have access to any other directly relevant discovery as may be needed and not already within the patent owner's control. The AIA provides that in an *inter partes* review, discovery beyond the deposition of witnesses submitting affidavits or declarations must be "necessary in the interest of justice," and that for post-grant review discovery must be "limited to evidence directly related to factual assertions advanced by either party in the proceeding."[30/] Granting the patent owner access to directly relevant discovery not already within the patent owner's control would satisfy these AIA discovery provisions because it would be both in the interests of justice and directly related to factual assertions made in the proceeding. The proposed rules instead provide that "[a] party may move for additional discovery" beyond cross-examination or other routine discovery, or that a party may file a motion for authorization to compel testimony or the production of documents or things.[31/] Requiring the patentee to file motions in order to obtain directly relevant evidence is inefficient and could cause unfair delay.

With regard to depositions, the burden and expense of producing witnesses for depositions should rest on the party propounding the testimony. The proposed rules currently allow the Board to order the opposing party to bear the costs.[32/] In addition, the proposed rules do not provide several needed default parameters for depositions. For example, in the absence of an agreement as to where the witness should be deposed, the propounding party should be obligated to produce the witness for testimony in Washington, D.C. During a deposition, a default time period of questioning should be set, with 7 hours as the recommended default questioning period (in accordance with the Federal Rules).[33/] Cross and re-cross of the questioning should be limited to the subject matter of the prior questioning and to credibility and impeachment. Cross and re-cross of the questioning also should be limited to one-half of the time taken by the previous questioner. No party should be required to disclose, prior to the time of its use, any evidence used solely for impeachment. Unavailability of evidence within the time

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28/ 77 Fed. Reg. 6868, 6869, 6875-6876 (Feb. 9, 2012).

29/ Proposed 37 C.F.R. § 42.53(b)(1).

30/ AIA, Section 6, § 316(a)(5) (*inter partes* review); *id.*, Section 6, § 326(a)(5) (post-grant review).

31/ Proposed 37 C.F.R. § 42.51(c), § 42.52.

32/ *See* Proposed 37 C.F.R. § 42.53(f) ("Except as the Board may order or the parties may agree in writing, the proponent of the direct testimony shall bear all costs associated with the testimony, including the reasonable costs associated with making the witness available for the cross-examination.")

33/ *See* Fed. R. Civ. P. 30(d)(1).

constraints of a deposition should constitute grounds for terminating the proceeding without prejudice. Providing such default rules would permit depositions to proceed more efficiently.

D. The Patent Owner Should Be Assured of At Least One Month After the Close of its Discovery Period in Which To File a Response to the Petition.

The PTO's proposed regulations provide that, if no time for filing a patent owner response to a petition is provided in a Board order, the default date for filing a patent owner response is two months from the date of the institution of the review. [34/] As discussed above, given the amount of time a requester has to prepare its petition, such a short deadline for the patent owner's response and amendments is unfair.

Due to the logistics of completing discovery and preparing and presenting expert testimony, the patent owner should be assured of at least one month after the close of its discovery period within which to file its response to the petition. This extension would not unduly lengthen the review processes, because this would only constitute one month of the twelve to eighteen months allowed under the AIA to complete the review.[35/] In fact, the "representative timeline" and the model scheduling order provided in the Practice Guide for Proposed Trial Rules both suggest allowing four months after a review initiated in order for the patent owner to complete discovery and file a response to the petition.[36/]

E. The Patent Owner Should Be Given More Flexibility in Making Claim Amendments and the Estoppel Provisions Should Be Modified.

The proposed regulations do not specify when the patent owner will have an opportunity to amend the patent,[37/] but the "representative timeline" and the model scheduling order provided in the Practice Guide for Proposed Trial Rules both suggest that the patent owner's response and the patent owner's motion to amend the patent may be due at the same time.[38/] Also, the

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34/ *See* Proposed 37 C.F.R. § 42.120(b) ("the default date for filing a patent owner response is two months from the date the inter partes review was instituted"); Proposed 37 C.F.R. § 42.220(b) ("the default date for filing a patent owner response is two months from the date the post-grant review is instituted").

35/ *See* AIA Section 6, § 316(a)(11) (allowing 12 to 18 months for *inter partes* review after a review is initiated); *id.*, Section 6, 326(a)(11) (allowing 12 to 18 months for post-grant review after a review is initiated).

36/ *See* 77 Fed. Reg. 6868, 6869, 6875-6876 (Feb. 9, 2012).

37/ *See* Proposed 37 C.F.R. § 42.121(a) (allowing a patent owner in an *inter partes* review to file one motion to amend a patent "but only after conferring with the Board"); Proposed 37 C.F.R. § 42.221(a) (allowing a patent owner in a post-grant review to file one motion to amend a patent "but only after conferring with the Board").

38/ *See* 77 Fed. Reg. 6868, 6869, 6875-6876 (Feb. 9, 2012).

proposed rules allow a patent owner's motion to amend a patent "only after conferring with the Board."[39/]

Once a post-grant or *inter partes* review is instituted, the patent owner should be able, as a matter of right, to file a motion presenting a reasonable number of substitute claims *at any time* before the filing of the patent owner's response to the petition. Moreover, because the first motion to amend is by right,[40/] there should be no burden to "confer" with the Board.[41/] Furthermore, patentees should be able to file additional motions to amend the patent, for good cause, until the filing of the patentee's final response or reply on the merits. If new claim limitations not previously appearing in the claims at issue are added, at any time until the filing of the petitioner's opposition to the amendments, the petitioner should be permitted to elect not to respond to those claims on the merits, in which case the petitioner would not be subjected to any estoppels with respect to those claims.

As currently proposed, a patent owner who loses a claim in a post-grant review or *inter partes* review will be estopped from pursuing a claim in a continuation application or any other application that could have been filed in response to a properly raised ground of unpatentability for the lost claim.[42/] Contrary to the proposed rules, no estoppels against presenting different claims in a later continuation should arise against a patent owner. This rule, nowhere authorized in the AIA, could be grossly unfair to patent owners.

F. The Petitioner Should Be Assured of At Least Three Months After the Patent Owner Response To File a Rebuttal.

The AIA provides that the PTO must give a petitioner "at least 1 opportunity to file written comments within a time period established by the Director."[43/] The Practice Guide for Proposed Trial Rules suggests that petitioners could have two months to reply to a patent owner's response and amendments with rebuttal written comments, but no proposed rules provide a default period for this reply.[44/]

In order to provide the petitioner with sufficient time, the petitioner should have at least three months after the patent owner files its response in which to take depositions of the patent

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39/ *See* Proposed 37 C.F.R. § 42.121(a) (*inter partes* review); Proposed 37 C.F.R. § 42.221(a) (post-grant review).

40/ *See* AIA, Section 6, § 316(d)(1) (*inter partes* review); *id.*, Section 6, 326(d)(1) (post-grant review).

41/ *See* Proposed 37 C.F.R. § 42.121(a) (allowing a patent owner in an *inter partes* review to file one motion to amend a patent "but only after conferring with the Board"); Proposed 37 C.F.R. § 42.221(a) (allowing a patent owner in a post-grant review to file one motion to amend a patent "but only after conferring with the Board").

42/ *See* Proposed 37 C.F.R. § 42.73(d)(3).

43/ AIA, Section 6, § 316(a)(13) (*inter partes* review); *id.*, Section 6, 326(a)(12) (post-grant review).

44/ 77 Fed. Reg. 6868, 6869, 6876 (Feb. 9, 2012).

owner's declarants and affiants, and to file written comments. These written comments should be limited to the rebuttal of the patent owner's position and related credibility issues. The petitioner should not be allowed to introduce new evidence or issues in support of its challenge in the response to the patent owner's arguments.

G. Motions Practice Should Be Limited.

The Practice Guide for Proposed Trial Rules states that "[o]nce the time for taking discovery in the trial has ended, the parties will be authorized to file motions to exclude evidence believed to be inadmissible."[45/] The Practice Guide further suggests that motions to exclude evidence could be due three weeks after the patent owner's reply regarding patent amendments, with oppositions to motions to exclude due two weeks later, and replies to the oppositions due one week later.[46/] The PTO's proposed rules estimate the cost to a party for each motion, opposition, and reply to be $34,000 for a derivation proceeding, $44,200 for a post-grant review, and $47,600 for an *inter partes* review.[47/]

In order to decrease cost and increase efficiency of the review proceedings, all issues relating to admissibility of evidence should be raised in the petitioner and patentee's responses and replies, rather than through later motion practice. Requiring the filing of separate motions to address admissibility issues will only increase the complexity, cost, and length of these proceedings. When warranted, the Board may expand the page limit requirements.

H. The Parties Should Be Assured that the Oral Hearing Will Not Be Scheduled Sooner than 45 Days after the Petitioner Files its Written Comments.

The proposed rules do not provide enough clarity regarding the amount of time petitioners and patent owners will have to prepare for the oral hearing guaranteed by the AIA.[48/] For instance, the Federal Register notices mention oral hearings but do not specify any default time periods regarding the timing of these hearings.[49/]

The parties should be assured that the oral hearing will not be scheduled sooner than 45 days following the filing of the last reply to be filed in the proceeding, whether that is the petitioner's written comments (where the patent owner has proposed no patent amendments) or the patent owner's reply regarding amendments (where the patent owner has proposed patent

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45/ 77 Fed. Reg. 6868, 6869 (Feb. 9, 2012).

46/ 77 Fed. Reg. 6868, 6876 (Feb. 9, 2012); *see also* Proposed 37 C.F.R. § 42.25 (providing for default filing times of one month to oppose a motion and one month to reply to an opposition).

47/ 77 Fed. Reg. 6879, 6897 (Feb. 9, 2010).

48/ *See* AIA, Section 6, § 316(a)(10) (providing either party with the right to an oral hearing as part of an *inter pates* review proceeding); *id.*, Section 6, § 326(a)(10) (providing either party with the right to an oral hearing as part of a post-grant review proceeding)

49/ *See* Proposed 37 C.F.R. § 42.70.

amendments). Scheduling the hearing sooner would not provide the parties sufficient time to prepare for the hearing.

I. Appearance *Pro Hac Vice* Should Be Limited Except in Rare Cases.

The proposed rules provide that attorneys may appear *pro hac vice* during a proceeding "upon a showing of good cause, subject to such conditions as the Board may impose."[50/] Although the discussions of the proposed rules acknowledge that proceedings before the PTO "can be technically complex" and that "the grant of a motion to appear *pro hac vice* is a discretionary action taking into account the specifics of the proceedings," the rules themselves do not sufficiently emphasize that appearance *pro hac vice* should be the exception, and that registered practitioners should always be involved.[51/]

The adjudicatory derivative proceedings, post-grant reviews, and *inter partes* reviews will be technically, legally, and procedurally complex. Counsel registered to practice before the PTO, or otherwise experienced litigation attorneys familiar with the subject matter at issue in a review, will be best equipped to manage these complexities.

For these reasons, a motion to appear *pro hac vice* by counsel who is not a registered practitioner should only be granted when the counsel is an experienced litigation attorney with an established familiarity with the subject matter at issue in the contested case. Furthermore, although the Board may authorize a person other than a registered practitioner who possesses such qualifications to appear as counsel in a contested proceeding, the Board should require that a party's lead counsel or representative in such proceedings must be a registered practitioner.

J. The Costs of the Review Proceedings Warrant a Revised Approach.

The AIA provides that petition fees must be "reasonable"[52/] and that the regulations implementing the AIA must take into consideration "the effect of any such regulation on the economy"[53/]. The proposed rules similarly provide as a matter of policy that they should be construed "to secure the just, speedy, and inexpensive resolution of every proceeding."[54/] However, the fees proposed by the PTO to institute a review, and the overall cost of the proceedings, are high. In addition, the framework of review proceedings, as established by the PTO's proposed rules, could result in even higher legal fees and costs that petitioners and patent

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50/ *See* Proposed 37 C.F.R. § 42.10(c).

51/ *See* 77 Fed. Reg. 7041, 7054 (Feb. 10, 2012) (*inter partes* review); 77 Fed. Reg. 7060, 7074 (Feb. 10, 2012) (post-grant review); 77 Fed. Reg. 7028, 7035 (Feb. 10, 2012) (derivation proceedings); 77 Fed. Reg. 6879, 6884, 6901 (Feb. 9, 2012) (Rules of Practice); 77 Fed. Reg. 6868, 6870 (Feb. 9, 2012) (Practice Guide).

52/ AIA, Section 6, § 311(a) (*inter partes* review); *id.*, Section 6, § 321(a) (post-grant review).

53/ AIA, Section 6, § 316(b) (*inter partes* review); *id.*, Section 6, § 326(b) (post-grant review).

54/ Proposed 37 C.F.R. § 42.1(b).

owners participating in the proceedings will incur. We urge the PTO to institute the procedural changes discussed herein in order to lower the proposed fees and the costs of the proceedings.

Instead of instituting such high fees, the PTO should revise its approach to these proceedings in order to enhance efficiency by minimizing motion practice, authorizing automatic protective orders, authorizing certain discovery, restricting the length and subject matters of witness questioning, restricting the number of substantive filings, and providing sufficient time for patentees to prepare comprehensive responses that will assist the PTO in making is determinations.

K. The Proposed Claim Construction Rules Should Be Revised

The PTO's proposed rules for *inter partes* and post-grant reviews state that a claim "should be given its broadest reasonable construction in light of the specification of the patent in which it appears."[55/] This approach, nowhere authorized in the AIA, could result in a situation in which the same claim receives a broader construction at the PTO than in court. The PTO should, instead, adopt a claim construction approach similar to that used by courts.[56/] Such an approach would take into account the prosecution history, which would provide a more equitable outcome. It would also be consistent with the AIA's provision which allows statements of the patent owner filed in a proceeding before a Federal Court or the PTO, in which the patent owner takes a position on the scope of a claim, to be considered by the PTO in determining the proper meaning of a claim in an *inter partes* or post-grant review process.[57/]

II. Conclusion

PhRMA appreciates the PTO's efforts to implement the AIA and the opportunity to offer its perspective on the PTO's proposals. 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.

55/ Proposed 37 C.F.R. § 42.100(b) (*inter partes* review); Proposed 37 C.F.R. § 42.200(b) (post-grant review).

56/ *See* the House Judiciary Committee report on the AIA, which states that "[t]he 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).

57/ AIA, Section 6, §§ 301(a)(2), 301(d).