Comments of the Pharmaceutical Research and Manufacturers of America
Docket No. PT0–P–2015–0053
November 18, 2015

Comments of the Pharmaceutical Research and Manufacturers of America on the PTO's Request for Comments on Amendments to the Rules of Practice for Trials 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 Amendments to the Rules of Practice for Trials 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 encompasses both research-based pharmaceutical and biotechnology companies. The U.S. biopharmaceutical sector supports a total of 3.4 million jobs throughout the economy, and directly employs more than 810,000 Americans.[2] The industry's overall economic impact is substantial, accounting 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 2014.[5] Medicines developed by the biopharmaceutical sector have produced large improvements in health across a broad range of diseases. The rapid growth of biomedical knowledge has created opportunities for profound advances against our most complex and costly diseases. However, developing a new medicine takes between 10 and 15 years of work and costs an average of $2.6 billion of investment in R&D.[6] Only two of every ten marketed drugs

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[1] 80 Fed. Reg. 50,720–50,747 (Aug. 20, 2015).

[2] PhRMA, *2015 Biopharmaceutical Research Industry Profile*, inside cover (Apr. 2015), http://www.phrma.org/sites/default/files/pdf/2015_phrma_profile.pdf ("2015 PhRMA Profile").

[3] 2015 PhRMA Profile, Letter from PhRMA's President and CEO.

[4] Battelle Technology Partnership Practice, *The U.S. Biopharmaceutical Industry: Perspectives on Future Growth and the Factors that Will Drive It*, Apr. 2014, at 7, http://www.phrma.org/sites/default/files/pdf/2014-economic-futures-report.pdf.

[5] 2015 PhRMA Profile, inside cover.

[6] Tufts Center for the Study of Drug Development, *Cost to Develop and Win Marketing Approval for a New Drug is $2.6 Billion* (Nov. 18, 2014), http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study (estimating the cost to develop a new drug at $2.558 billion).

return revenues that exceed or match the R&D investment.[7] 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 for any resulting intellectual property. In particular, PhRMA's members rely on patents to protect their inventions and provide an opportunity to recover their R&D costs. Patents are critical for biopharmaceutical innovation given the research-intensive nature of this sector and the substantial upfront investment needed to discover and develop products that meet FDA approval requirements.[8]

Bringing new and improved life-saving and life-improving products to people is the driving mission 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 PhRMA's perspective on these proceedings. In PhRMA's view, although some of the proposed new rules are a step in the right direction, several of the PTO's rules and practices should be further modified to address the growing due process and fairness concerns raised by these proceedings.

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

The AIA created new trial proceedings "to increase the quality and certainty of patent rights and offer cost-effective, timely alternatives to district court litigation."[9] In creating these new trial proceedings, Congress expressly recognized the need to protect the rights of legitimate patent owners: "This new post-grant review process . . . would enable early challenges to patents, *but also protect the rights of inventors and patent owners against endless litigation*. The reason we want to ensure that the [PTO] issues high quality patents [,] is to incentivize investment in truly innovative technological advances and provide more certainty for investors in these inventions."[10]

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[7] 2015 PhRMA Profile, inside cover; *see also* Ernst R. Berndt, Deanna Nass, Michael Kleinrock, & Murray Aitken, *Decline in Economic Returns From New Drugs Raises Questions About Sustaining Innovation*, HealthAffairs, Feb. 2015, http://content.healthaffairs.org/content/34/2/245.abstract.

[8] *See* Claude Barfield & John E. Calfee, *Biotechnology and the Patent System: Balancing Innovation and Property Rights* 1–2 (AEI PRESS 2007), https://www.aei.org/wp-content/uploads/2013/12/-biotechnology-and-the-patent-system-book_121440333605.pdf ("Without patent protection, investors would see little prospect of profits sufficient to recoup their investments and offset the accompanying financial risk."); *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 ECON. L. 849 (2002).

[9] Senate Debate, 157 Cong. Rec. S5347, S5354, (daily ed. Sept. 7, 2011) (Statement of Administration Policy on H.R. 1249).

[10] Senate Debate, 157 Cong. Rec. S929, S952, (daily ed. Feb. 28, 2011), (testimony of Sen. Grassley) (emphasis added). Congress noted that the changes made were "not to be used as tools for harassment or a means to prevent market entry through repeated litigation and administrative attacks on the validity of a patent." America Invents Act, H.R. Rep. No. 112-98, at 48 (2011), *as reprinted in* 2011 U.S.C.C.A.N. 67, 78.

As currently structured, however, the rules and practices governing the PTAB's trial proceedings for *inter partes* review ("IPR") and post-grant review ("PGR") do not provide for a fair and efficient alternative to defending against patent lawsuits in federal court. Indeed, the overwhelming majority of IPR petitions have been granted,[11] and the vast majority of final written decisions have found at least some of the challenged claims unpatentable.[12] In contrast, patent challengers prevail on invalidity claims in federal district court only 42% of the time.[13] The PTAB's perceived bias in favor of patent challengers has also led to increasing abuse of IPR proceedings, including petition filings by hedge funds shorting stock to drive down share prices, parties primarily seeking to extract a financial settlement from patent holders, and litigants presenting the same or substantially the same arguments that were unsuccessful in federal court.

PhRMA appreciates recent efforts by the PTO to address these concerns by reviewing the rules related to trial practice for IPR and PGR. Although the PTO's proposed rulemaking offers several changes to IPR and PGR procedures, additional changes are essential if these proceedings are to both comply with the spirit of the AIA, and to provide the due process required of any proceeding that may deprive a patent owner of his/her property right in an issued United States patent. PhRMA urges the PTO to amend its proposed rules as described below.[14]

A. Claim Construction Standard

1. The PTAB's procedures should be revised to use the *Phillips* claim construction standard to interpret *all* patent claims.

In its proposed rulemaking, the PTO indicated that the PTAB would continue to apply the broadest reasonable interpretation ("BRI") standard to claims of an unexpired patent in IPR and PGR proceedings. The PTAB will apply the *Phillips*-type claim construction only for claims of a patent that will expire prior to the issuance of a final decision, because, according to the PTO, "such patents essentially lack any viable opportunity to amend the claims in an AIA proceeding."[15]

[11] As of October 31, 2015, the PTAB instituted trials in 70% of the IPRs in which it made an institution decision in fiscal years 2014, 2015, and 2016. *See* USPTO, Patent Trial and Appeal Board Statistics, slide 7, http://www.uspto.gov/sites/default/files/documents/2015-10-31%20PTAB.pdf.

[12] As of October 31, 2015, 630 IPRs reached a Final Written Decision. Of those 630 Final Written Decisions, 544 Final Written Decisions (86.3%) found at least some claims unpatentable. The PTAB has only found that no instituted claims were unpatentable in 86 Final Written Decisions. *See* USPTO, Patent Trial and Appeal Board Statistics, slide 9, http://www.uspto.gov/sites/default/files/documents/2015-10-31%20PTAB.pdf.

[13] *See* John B. Allison, Mark A. Lemley, & David L. Schwartz, *Understanding the Realities of Modern Patent Litigation*, 92 TEX. L. REV. 1769, 1794 (2014).

[14] In addition, PhRMA believes that Congress should take steps to reform additional aspects of the PTAB's procedures to ensure fairness to patent owners, including by changing the evidentiary standard applied in such proceedings from a "preponderance of the evidence" to "clear and convincing evidence." This change would make the evidentiary standard applied by the PTAB consistent with the standard used by federal district courts.

[15] 80 Fed. Reg. at 50,722.

As discussed in PhRMA's previously submitted comments[16], the BRI claim construction standard should not be used when construing any claims in PTAB trial proceedings under the AIA. Instead, the PTAB should construe claims in a manner consistent with a federal court claim construction analysis under *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc) (claim terms should be given "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention"). In contrast to prosecution of patent applications, PTAB trial procedures are more adjudicative. *Idle Free Systs. v. Bergstrom, Inc.*, IPR2012-00027, Paper 26, at 7 (June 11, 2013) ("An *inter partes* review is neither a patent examination nor a patent reexamination."); *see also Abbott Labs v. Cordis Corp.*, 710 F.3d 1318, 1326 (Fed. Cir. 2013) (The AIA "convert[ed] inter partes reexamination from an examinational to an adjudicative proceeding.") (internal quotation omitted). The claim construction standard used in IPR and PGR therefore should be the same as that used by courts.

The current BRI standard only requires the PTAB to consider the language of the specification and claims, not the prosecution history, in construing claims.[17] Failing to consider the prosecution history ignores important context in the public record regarding the PTO's and applicant's understanding of the claims, and promotes inconsistency with district court results. It is also contrary to the language of the AIA, which specifically provides that the PTO may take prosecution history into account when deciding whether to institute an IPR or PGR proceeding.[18] Moreover, the BRI standard applied by the PTAB is likely to be broader than the "correct" interpretation standard applied by a district court. The different claim construction standards applied in court proceedings versus IPR or PGR proceedings prevent IPR and PGR from serving as a "more efficient alternative to litigation," as Congress intended.[19] Instead, it has been reported that over 80% of patents subject to an IPR are also involved in district court litigation.[20] This statistic suggests that patent owners are being subjected to duplicative proceedings with different standards potentially leading to inconsistent and unpredictable results.

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[16] *See, e.g.*, Comments of the Pharmaceutical Research and Manufacturers of America, Docket Nos. PTO-P-2011-0082, -0083, -0084, -0086, -0094 (Apr. 10, 2012), http://www.uspto.gov/sites/default/files/aia_implementation/comment-pharmaceutical-research.pdf; Comments of the Pharmaceutical Research and Manufacturers of America, Docket No. PTO-P-2014-0031 (Oct. 16, 2014), http://www.uspto.gov/sites/default/files/ip/boards/bpai/phrma_20141016.pdf.

[17] Manual of Patent Examining Procedure ("MPEP"), § 2111, *Claim Interpretation; Broadest Reasonable Interpretation* [R-11.2013], http://www.uspto.gov/web/offices/pac/mpep/s2111.html ("During patent examination, the pending claims must be 'given their broadest reasonable interpretation consistent with the specification.'"); *see also* MPEP, § 2111.01, *Plain Meaning* [R-11.2013], http://www.uspto.gov/web/offices/pac/mpep/s2111.html ("Although claims of issued patents are interpreted in light of the specification, prosecution history, prior art and other claims, this is not the mode of claim interpretation to be applied during examination. During examination, the claims must be interpreted as broadly as their terms reasonably allow.").

[18] *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.").

[19] 157 Cong. Rec. S1335, S1350 (daily ed. Mar. 8, 2011) (statement of Sen. Patrick Leahy).

[20] *See* Practical Law Journal, *Coordinating PTAB and District Court Litigation*, Dec. 2014/Jan. 2015, at 36, https://www.ropesgray.com/~/media/Files/articles/2014/December/LIT-Dec14-Jan15-PTAB-Feature.ashx.

Indeed, criticism of the PTO's use of the BRI standard in these proceedings has been widespread. In addition to stakeholder criticism, former PTO Director Kappos has publicly indicated that, in hindsight, applying the BRI standard in IPRs and PGRs risks inconsistent results,[21] and numerous patent bills have been introduced in the House and Senate that would require the PTO to employ the *Phillips* standard in these proceedings.[22]

At the very least, in connection with its rulemaking, the PTO should revise its regulations to conform its BRI analysis to the holding of *Microsoft Corp. v. Proxyconn, Inc. v. Lee*, No. 2014-1542, -1543 (Fed. Cir. June 16, 2015), which, among other things, requires the PTO to consult the prosecution history in all proceedings where a patent has been brought before the agency for a second review. *See also, e.g.*, *Tempo Lighting Inc. v. Tivoli LLC*, 742 F.3d 973, 977 (Fed. Cir. 2014) (noting that the PTO should consult the patent's prosecution history in proceedings in which the patent has been brought back to the agency for a second review); *In re Suitco Surface, Inc.*, 603 F.3d 1255, 1260 (Fed. Cir. 2010) ("claims should always be read in light of the specification and teachings in the underlying patent").

In addition, in order to enhance efficiency and predictability, and to prevent against serial filings,[23] if a court has already construed a claim term that is the subject of an IPR or PGR, the PTAB should, at minimum, adopt that construction in order to avoid inconsistent results. Without such a rule, a patent claim could be found valid and infringed by a district court under a *Phillips*-type construction while the same claim could be found invalid by the PTAB using the BRI standard.

Use of the BRI standard in IPR and PGR proceedings has been justified by the ability of patent owners to amend patent claims.[24] However, although patent owners nominally have an opportunity to cancel claims and propose a substitute claim for each cancelled claim in an IPR or

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[21] *See* H.R. 3309: Hearing Before the H. Comm. on the Judiciary, 113th Cong. 1st Session (Oct. 29, 2013) (Testimony of David J. Kappos), http://judiciary.house.gov/_files/hearings/113th/10292013/Kappos%20Testimony.pdf ("having the USPTO apply a different standard than the courts is leading, and will continue to lead, to conflicting decisions. Moving the USPTO to a consistent standard with that of the courts would resolve such conflict.").

[22] *See, e.g.*, The Innovation Act, H.R. 9, 114th Cong. (2015); The Protecting American Talent and Entrepreneurship ("PATENT") Act of 2015, S. 1137, 114th Cong. (2015); The Support Technology & Research for Our Nation's Growth ("STRONG") Patents Act of 2015, S. 632, 114th Cong. (2015).

[23] Notably, the PTO's proposed rulemaking indicates that decisions regarding estoppel of claims previously presented to the PTAB or to a district court will continue to be made on a case-by-case basis. The PTO has not proposed any rules to curb the institution of serial or duplicative proceedings at this time. Inaction in this area will contribute to inconsistent outcomes, inefficiencies, and uncertainty for patent owners. Additional steps should be taken to ensure that IPR and PGR proceedings are not used to circumvent decisions regarding patentability made in other administrative proceedings or by federal district courts.

[24] 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…").

PGR, such amendments have been essentially unavailable in practice.[25] In other proceedings where the PTO applies the BRI standard, including prosecution and reexamination, patent owners have an unfettered right to amend their claims, including the opportunity to do so after learning of the PTO's position(s) on their patentability. IPR and PGR are therefore more akin to district court litigation, where patent owners do not have the opportunity to amend their claims, than examination by the PTO, where applicants have a liberal right to amend their claims in an iterative process with a patent examiner.

B. Patent Owner's Preliminary Response

1. Patent owners should be permitted to submit testimonial evidence with their preliminary response, and the factual record should be weighed evenly in the institution decision.

The proposed rulemaking appropriately permits patent owners to submit testimonial evidence with their preliminary response. However, the PTO also proposes to amend the rules to provide that any factual dispute that is material to the institution decision be resolved in favor of the petitioner.[26] The PTO's proposal to construe evidence material to institution in favor of the petitioner is inconsistent with the presumption of validity afforded to issued patents and with the placement of the burden of proving invalidity on the patent challenger. It also arguably undoes any benefit of permitting patent owners to submit testimonial evidence with their preliminary response.

The PTAB's proposal to construe disputed issues of fact material to institution in favor of the petitioner is at odds with Congress's placement of the burden of proof on the petitioner. *See* 35 U.S.C. 316(e).[27] It also stands contrary to the practices of federal district courts, which place the

[25] In more than two years of IPR proceedings, the PTAB has allowed patent owners to amend claims only four times. In its August 20, 2015 Notice of Proposed Rulemaking, the PTO nonetheless suggested that the PTAB's current approach to amendment strikes an appropriate balance between the rights of petitioners and patent owners. Therefore, although the AIA clearly contemplates claim amendments in IPR and PGR, *see, e.g.*, 35 U.S.C. §§ 316(d)(1), 326(d)(1), the PTAB will not permit patent owners to amend patent claims at least once as of right. The unavailability of amendment in practice unfairly restricts patent owners' ability to respond to challenges as they could in other PTO proceedings, including ones subject to the BRI claim construction standard and the preponderance of the evidence standard for evaluating patentability. As PhRMA has noted in its previous comments, the PTO should consider providing patent owners with the ability to amend patent claims at least once as of right.

[26] To the extent the PTO decides to construe disputed issues of fact in favor of the petitioner, the provision as drafted is overly broad and should apply only to supporting *testimonial* evidence included in the preliminary response.

[27] The AIA, 35 U.S.C. § 314(a), makes clear that the PTO Director may not authorize institution of an IPR unless the Director determines "that the information presented in the petition . . . and any response filed . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least [one] of the claims challenged in the petition." Pursuant to 35 U.S.C. § 316(e), "the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence." Taken together, these provisions establish that an IPR may be instituted if the Director determines that there is a reasonable likelihood the petitioner will prove a proposition of unpatentability by a preponderance of the evidence.

burden of proof on the party moving for summary judgment and in which all evidence is viewed in the light most favorable to the movant's opponent.

In practice, this provision will likely discourage patent owners from including testimonial evidence with their preliminary response. Patent owners may be unwilling to risk submitting key evidence at a stage in the proceeding when it may not be afforded its proper weight. As PhRMA pointed out in its prior comments, restricting patent owners' use of testimonial evidence could prevent patent owners from demonstrating why a requested IPR or PGR should not be instituted. If patent owners can make that required showing only through testimonial evidence, that information by definition cannot be presented as Congress intended.[28] Instituting an IPR or PGR proceeding based on the petitioner's evidence without comparable evidence from the patent owner (or with comparable evidence that is not weighed appropriately), unfairly disadvantages the patent owner. 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, and potentially institute proceedings that could have been avoided if more complete evidence had been available prior to the institution decision. Approximately 70% of IPR petitions, in which institution decisions have been made, have led to instituted reviews based upon such one-sided records.[29] In addition, under current rules, the PTAB panel that decides to institute an IPR or PGR—a determination that necessarily involves adopting a position adverse to the patent owner—must also consider the merits of the petition.[30]

C. Rule 11-Type Certification Requirement

1. The proposed certification will not prevent ongoing abuse of IPR proceedings by patent challengers.

PhRMA supports the PTO's proposal to add a Rule 11-type certification for all papers filed with the Board, as well as the proposed provision for sanctions for noncompliance that would apply to practitioners and the parties. PhRMA believes, however, that this proposed change will do little to prevent the increasing abuse of post-grant proceedings.

The rules governing IPR and PGR already establish a duty of candor and fair dealing on litigants and parties appearing before the PTAB,[31] and the Board has authority to impose sanctions against any party for misconduct, including "abuse of process," and "[a]ny other improper use of

[28] See 35 U.S.C. §§ 313, 324 ("[t]he patent owner shall have the right to file a preliminary response to the petition, within a time period set by the Director, that sets forth reasons why no inter partes review should be instituted based upon the failure of the petition to meet any requirements of this chapter").

[29] *See* USPTO, Patent Trial and Appeal Board Statistics, slide 7, http://www.uspto.gov/sites/default/files/documents/2015-10-31%20PTAB.pdf.

[30] PhRMA is aware of the PTO's request for comments on a proposed pilot program exploring an alternative approach to institution decisions, *see* 80 Fed. Reg. 51,540, 51,540–51,542 (Aug. 25, 2015), and is separately providing comments on the proposed pilot program.

[31] 37 C.F.R. § 42.11 ("Parties and individuals involved in the proceeding have a duty of candor and good faith to the Office during the course of a proceeding.).

the proceeding, including actions that harass or cause unnecessary delay or an unnecessary increase in the cost of the proceeding."[32] In addition, 37 C.F.R. §11.18 establishes that by presenting any paper to the PTO, a party is certifying that the paper is truthful, that it is not being presented for any improper purpose, that the legal contentions in the paper are warranted by existing law or a non-frivolous argument for change in the law, and that the factual contentions have evidentiary support.

These rules have not adequately protected patent owners from petitioners seeking to abuse IPR proceedings, and it is difficult to see how an added Rule 11-type certification—without imposing additional disclosure requirements—would do so. For example, although petitioners owe a duty of candor to the PTAB, there is no requirement that petitioners disclose objective evidence of non-obviousness during an IPR or PGR. Moreover, the PTAB has refused to permit discovery of evidence of non-obviousness held by the petitioner in all cases. The PTAB instead has opted to continue deciding patent owners' requests for such discovery on a case-by-case basis, stating in its proposed rules that "some showing of nexus is required to show that additional discovery is necessary in the interest of justice[.]"[33] As a result, the PTAB is widely perceived as a preferred venue for parties who are in possession of objective evidence of non-obviousness. This perception is furthered by the fact that patent owners have so rarely succeeded in invoking a "commercial success" defense in IPR and PGR proceedings.[34]

Nor are petitioners required to disclose whether they have filed another IPR, PGR, or CBM review of the patent at issue. A requirement to disclose potentially duplicative AIA proceedings would promote efficiency and better protect patent owners from potential harassment through serial petitions.

Finally, Wall Street hedge funds have begun to exploit the IPR process as an investment strategy. Hedge fund manager Kyle Bass and his firm, Hayman Capital, have filed 33 IPR petitions challenging pharmaceutical patents while betting against the shares of the targeted patent's owner.[35] Even if the IPRs are not instituted, the damage to the company's shares may

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[32] 37 C.F.R. §§ 42.12(a)(5), (7).

[33] 80 Fed. Reg. at 50,728.

[34] In 82 final written decisions that considered commercial success as a potential defense to patentability (through June 30, 2015), the patent owner prevailed only twice. *See* John Jaroz & Robert Vigil, *Assessing Commercial Success at the U.S. Patent Trial and Appeal Board*, Int'l In-house Counsel Journal, Vol. 8, No. 32, Summer 2015, at 1, http://www.analysisgroup.com/uploadedFiles/Content/Insights/Publishing/Assessing_Commercial_Success_at_US_PTAB.pdf.

[35] *Coalition for Affordable Drugs (ADROCA) LLC v. Acorda Therapeutics, Inc.*, IPR2015-00720 (filed Feb. 10, 2015); *Coalition for Affordable Drugs (ADROCA) LLC v. Acorda Therapeutics, Inc.*, IPR2015-00817 (filed Feb. 27, 2015); *Coalition for Affordable Drugs II LLC v. Shire Inc.*, IPR2015-00988 (filed Apr. 1, 2015); *Coalition for Affordable Drugs II LLC v. NPS Pharmaceuticals, Inc.*, IPR2015-00990 (filed Apr. 1, 2015); *Coalition for Affordable Drugs III LLC v. Jazz Pharmaceuticals, Inc.* IPR2015-01018 (filed Apr. 6, 2015); *Coalition for Affordable Drugs IV LLC v. Pharmacyclics, Inc.* IPR2015-01076 (filed Apr. 20, 2015); *Coalition For Affordable Drugs V LLC v. Biogen International GmbH*, IPR2015-01086 (filed Apr. 22, 2015); *Coalition For Affordable Drugs VI LLC v. Celgene Corp.*, IPR2015-01092 (filed Apr. 23, 2015); *Coalition for Affordable Drugs II, LLC v. NPS*

already be done.[36] There is also evidence of petitioners filing IPRs after seeking to extract payments from patent holders.[37] Therefore, the PTO's misconduct proposal should go further to meaningfully curb such abuses. At minimum, the PTO should require that a petitioner present evidence of secondary considerations of non-obviousness in its possession, such as commercial success, long felt need, or prior failures to achieve the results accomplished by the claimed invention. Fairness and due process considerations support disclosure of this evidence so that the patent owner can present a balanced case.

II. Conclusion

PhRMA appreciates the PTO's efforts to revisit its rules and practices regarding trial proceedings under the AIA 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.

Pharmaceuticals, Inc., IPR2015-01093 (filed Apr. 23, 2015); *Coalition for Affordable Drugs VI LLC v. Celgene Corp.*, IPR2015-01096 (filed Apr. 23, 2015); *Coalition for Affordable Drugs VI LLC v. Celgene Corp.*, IPR2015-01102 (filed Apr. 23, 2015); *Coalition for Affordable Drugs VI LLC v. Celgene Corp.*, IPR2015-01103 (filed Apr. 23, 2015); *Coalition for Affordable Drugs V LLC v. Biogen MA, Inc.*, IPR2015-01136 (filed May 1, 2015); *Coalition for Affordable Drugs VI LLC v. Celgene Corp.*, IPR2015-01169 (filed May 7, 2015); *Coalition for Affordable Drugs VII LLC v. Pozen Inc.*, IPR2015-01241 (filed May 21, 2015); *Coalition for Affordable Drugs VII LLC v. Pozen Inc.*, IPR2015-01344 (filed June 5, 2015); *Coalition for Affordable Drugs VII LLC v. Pozen Inc.*, IPR2015-01680 (filed Aug. 7, 2015); *Coalition for Affordable Drugs VII LLC v. Horizon Pharma USA, Inc.*, IPR2015-01718 (filed Aug. 12, 2015); *Coalition for Affordable Drugs IX, LLC v. Bristol-Myers Squibb Pharma Co.*, IPR2015-01723 (filed Aug. 13, 2015); *Coalition for Affordable Drugs X LLC v. Anacor Pharmaceuticals, Inc.*, IPR2015-01776 (filed Aug. 20. 2015); *Coalition for Affordable Drugs X LLC v. Anacor Pharmaceuticals, Inc.*, IPR2015-01780 (filed Aug. 20, 2015); *Coalition for Affordable Drugs X LLC v. Anacor Pharmaceuticals, Inc.*, IPR2015-01785 (filed Aug. 20, 2015); *Coalition for Affordable Drugs V LLC v. Hoffmann-LaRoche Inc.*, IPR2015-01792 (filed Aug. 22, 2015); *Coalition For Affordable Drugs XI LLC v. Insys Pharma, Inc.*, IPR2015-01797 (filed Aug. 24, 2015); *Coalition For Affordable Drugs XI LLC v. Insys Pharma, Inc.*, IPR2015-01799 (filed Aug. 24, 2015); *Coalition For Affordable Drugs XI LLC v. Insys Pharma, Inc.*, IPR2015-01800 (filed Aug. 24, 2015); *Coalition for Affordable Drugs VIII, LLC v. The Trustees of the University of Pennsylvania*, IPR2015-01835 (filed Aug. 28, 2015); *Coalition for Affordable Drugs VIII LLC v. The Trustees of the University of Pennsylvania*, IPR2015-01836 (filed Aug. 28, 2015); *Coalition For Affordable Drugs (ADROCA) LLC v. Acorda Therapeutics, Inc.*, IPR2015-01850 (filed Sept. 2, 2015); *Coalition For Affordable Drugs (ADROCA) LLC v. Acorda Therapeutics, Inc.*, IPR2015-01853 (filed Sept. 2, 2015); *Coalition For Affordable Drugs (ADROCA) LLC v. Acorda Therapeutics, Inc.*, IPR2015-01857 (filed Sept. 3, 2015); *Coalition for Affordable Drugs (ADROCA) LLC v. Acorda Therapeutics, Inc.*, IPR2015-01858 (filed Sept. 3, 2015); *Coalition for Affordable Drugs V LLC v. Biogen MA Inc.*, IPR2015-01993 (filed Sept. 28, 2015).

[36] *See, e.g.*, Andrew Chung, *Hedge Fund Manager Kyle Bass Loses Challenge to PhRMA Patents*, Reuters, Aug. 24, 2015, http://www.reuters.com/article/2015/08/24/acorda-therapeut-patents-idUSL1N10Z2O420150824 (noting that Acorda's stock price fell ten percent after a review of the first Ampyra patent was filed on February 10, 2015).

[37] Compl., *Allergan, Inc., et al. v. Ferrum Ferro Capital LLC, et al.*, No. 15-cv-992,ECF No. 1 (C.D. Cal. June 19, 2015); Motion for Sanctions, *Coalition For Affordable Drugs (ADROCA) LLC v. Celgene Corp.*, IPR2015-01169 (filed Aug. 19, 2015).