**IN THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT**

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No. 2015-1177

IN RE: AQUA PRODUCTS, INC.

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2013-00159.

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# BRIEF OF *AMICUS CURIAE* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA IN SUPPORT OF PETITIONER

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## CERTIFICATE OF INTERESTED PERSONS

Counsel for *amicus curiae* Pharmaceutical Research and Manufacturers of America certifies the following:

1. **The full name of every party or amicus represented by me is:**

   Pharmaceutical Research and Manufacturers of America

2. **The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:**

   N/A

3. **All parent corporations and any publicly held companies that own ten percent or more of the stock of the party or amicus curiae represented by me are:**

   N/A

4. **The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:**

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Dated: October 5, 2016

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## STATEMENT OF INTEREST OF *AMICUS CURIAE*[1]

The Pharmaceutical Research and Manufacturers of America ("PhRMA") represents the country's leading innovative pharmaceutical and biotechnology companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Those efforts produce the cutting-edge medicines, treatments, and vaccines that save, prolong, and improve the quality of the lives of countless individuals around the world every day. Over the past decade, PhRMA's members have secured FDA approval of more than 300 new medicines. Such results are not obtained cheaply. In 2015 alone, PhRMA members invested roughly $58 billion in development of new medicines.

PhRMA seeks to advance public policies that foster innovation and reward its members' investments. To those ends, PhRMA seeks to remove barriers that may arise in the nation's systems, including the patent laws, for protecting the intellectual property of its members—including as *amicus curiae* before this Court. *See, e.g.*, *Ethicon Endo-Surgery, Inc., v. Covidien LP*, No. 14-771; *Acorda Therapeutics Inc. v. Mylan Pharm.*, No. 15-1456. As discussed below, PhRMA is concerned that, by permitting the U.S. Patent and Trademark Office ("PTO") to

[1] In accordance with Federal Rule of Appellate Procedure 29(c)(5), *amicus curiae* certifies that no counsel for either party authored this brief in whole or in part, and that no party or other person other than *amicus*, its members, or its counsel made a monetary contribution to the brief's preparation or submission.

shift the patentability burden regarding substitute claims to patent owners in contravention of Congress's statutory scheme, this Court has constricted the ability of patent owners to amend claims in a way that will stifle innovation and breed uncertainty.

## INTRODUCTION

The Leahy-Smith America Invents Act ("AIA"), 35 U.S.C. § 100 *et seq*., creates a new process called inter partes review that allows a third party to ask the PTO to review and, in certain cases, cancel any claim that the Patent Trial and Appeal Board ("Board") holds unpatentable in light of the prior art. In doing so, Congress envisioned that each patent holder would have the ability to, "at least once in the process, make a motion to do just what he would do in the examination process, namely, amend or narrow the claim." *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2145 (2016) (citing 35 U.S.C. § 316(d)). That "opportunity to amend" was, in the Court's view, what made "use of the broadest reasonable construction standard *** not unfair to the patent holder in any obvious way." *Id*.

The way the PTO interprets its regulations, however, frustrates the ability of patentees to "amend or narrow" their patents as they would have done in the examination process. Although Congress enacted only one burden of proof for inter partes review—placing on *petitioners* the obligation to "prov[e] a proposition of unpatentability by a preponderance of the evidence," 35 U.S.C. § 316(e)—the

PTO has shifted that burden to the patent owner, who is now required to prove that a proposed substitute claim is *not* unpatentable. That reversal cannot be justified by the statutory text, structure, or purpose of the AIA. Indeed, placing the burden on the patent owner rather than the petitioner is antithetical to the Patent Act's traditional allocation of patentability burdens, which have long rested on patent examiners and challengers rather than on patent owners or applicants. Until now, no patent proceeding saddled patent owners with the difficult burden of preemptively anticipating and negating the effect of a broad universe of prior art on a proposed claim.

If such a fundamental shift in burdens is to take place, it must be accomplished through clear congressional action. But rather than await such action, the PTO, citing policy grounds, has effectively ignored Congress's contrary command. That is true even though *Cuozzo* made clear that the ability to amend claims is a critical piece of the inter partes review process; it is, according to the Supreme Court, precisely what justifies the PTO's application of the patent-narrowing "broadest reasonable interpretation" standard. Fairness concerns, too, militate against requiring patent owners to prove the negative proposition that substitute claims—which may not enlarge the scope of issued claims or introduce new matter—are "not unpatentable" as well. In all events, the statute's text is clear, and it mandates keeping the burden of proving unpatentability in inter partes

review exactly where Congress wanted it: on petitioners, not on patentees or the PTO.

## ARGUMENT

### I. THE PTO MAY NOT REQUIRE A PATENT OWNER TO BEAR ANY PATENTABILITY BURDEN IN INTER PARTES REVIEW AS A CONDITION OF ALLOWING SUBSTITUTE CLAIMS.

#### A. The AIA Unambiguously Requires Inter Partes Review Petitioners To Prove Unpatentability For Both Issued And Substitute Claims.

##### 1. *The Text and Structure of the Inter Partes Review Provisions Place the Burdens of Persuasion and Production on Petitioners, Not Patent Owners.*

The text of the AIA places on petitioners the burden of proving unpatentability for both issued and substitute claims—not on patent owners to show that such claims are *not* unpatentable. Patent owners may file, as a matter of right, one motion to amend the patent to "propose a reasonable number of substitute claims" "[f]or each challenged claim." 35 U.S.C. § 316(d)(1)(B); *see also id.* § 316(d)(2) (providing for additional motions in certain circumstances). The immediately following subsection provides that "the *petitioner* shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence." *Id.* § 316(e) (emphasis added). Congress thus placed the sole burden regarding unpatentability in any "inter partes review instituted under this chapter" squarely on petitioners. *Id.* "Where Congress has prescribed the governing

standard of proof, its choice controls[.]" *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2244 (2011).

As this Court recently confirmed, "[i]n an *inter partes* review, the burden of persuasion is on the petitioner to prove 'unpatentability by a preponderance of the evidence,' 35 U.S.C. § 316(e), and that burden never shifts to the patentee." *In re Magnum Oil Tools Int'l, Ltd.*, --- F.3d ----, No. 2015-1300, 2016 WL 3974202, at *6 (Fed. Cir. July 25, 2016) (citation and quotation marks omitted). That is consistent with the notion that inter partes review is a "system that is predicated on a petition followed by a trial in which the petitioner bears the burden of proof." *Id.* at *10. And, at least where (as here) the disputed issue is whether substitute claims overcome the prior art of record, the "burden of production" likewise remains with the petitioner. *See id.* at *6 (rejecting "the PTO's position that the burden of production shifts to the patentee" because arguing that "challenger failed to meet *its* burden of proving obviousness" is not akin to making an "affirmative defense"). Although a patentee faced with a patentability challenge "would be well advised to introduce evidence," *id.* at *7 n.1, Section 316(e) makes clear that the "*petitioner* continues to bear the burden of proving unpatentability" following institution, *id.* at *7 (emphasis added).

To be sure, *Magnum Oil Tools* was decided in the context of a challenge to issued claims, not substitute claims. But the provision it interprets (35 U.S.C.

§ 316(e)) dictates the evidentiary burden for proving "proposition[s] of unpatentability" generally. That provision makes no distinction between issued and substitute claims—even though Congress plainly knew how to distinguish them. *See* 35 U.S.C. § 318(a) (referring to "claim[s] challenged by the petitioner and any new claim added under section 316(d) [*i.e.*, substitute claims]"). Congress is presumed to have acted intentionally when it made this distinction in Section 318, yet declined to do the same in Section 316. *See Mohsenzadeh v. Lee*, 790 F.3d 1377, 1382 (Fed. Cir. 2015) (courts presume that "Congress acts intentionally where it 'includes particular language in one section of a statute but omits it in another section'") (quoting *Bates v. United States*, 522 U.S. 23, 29-30 (1997)).

Nor did Congress do implicitly what it declined to do explicitly. Section 316(e) uses the term "patentability," which typically refers either to pending or to issued claims, rather than the word "validity," which courts and the PTO alike apply to issued claims alone. *See, e.g.*, *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1080 n.7 (Fed. Cir. 2012) ("[I]n the litigation context, validity, rather than patentability, is the issue[.]"); USPTO, MPEP, § 706 (9th ed. Rev. 7, Nov. 2015) (noting that "issues pertinent to patentability" arise in "the course of examination and prosecution," while "validity" becomes pertinent after claims issue). Congress's choice of the phrase "proposition of *unpatentability*," rather than "proposition of *invalidity*," is telling.

Other provisions of the AIA reinforce that Congress meant it when it placed the burden of proof for *any* "proposition of unpatentability" in inter partes review on petitioners. As noted, Section 318(a) provides that the Board may issue a "final written decision with respect to the patentability of any patent claim challenged by the petitioner *and any new claim added under section 316(d)*," *i.e.*, any substitute claims added by amendment. 35 U.S.C. § 318(a) (emphasis added). This section thus indicates that Congress expected qualified claims—*i.e.*, those that neither "enlarge the scope of the claims of the patent" nor "introduce new matter," *id.* § 316(d) & 37 C.F.R. § 42.121(a)(2)(ii)—to be "added" as presumptively patentable *before* the Board evaluates their patentability. *See Prolitec, Inc. v. Scentair Techs., Inc.*, 807 F.3d 1353, 1367 (Fed. Cir. 2015) (Newman, J., dissenting) (noting that § 318(a) "reflect[s] the statutory directive that the new claim should be added, provided that it qualifies under the statute"). Indeed, because the PTO has already found the matter covered by the original claim to be patentable, *a fortiori* a *narrower* claim relating to the same matter that addresses additional prior art also must be patentable.

Especially given that Congress intended the Board to evaluate "patentability" with regard to both issued and substitute claims in the same "final written decision," it would make little sense for Congress to have taken the trouble to allocate the burden of proof with regard to the former type of claim while

remaining silent as to the latter. Instead, Sections 318(a) and 316(e) are naturally read together as providing a single, uniform "patentability" standard with regard to *all* claims—both issued claims and claims "added" by amendment—with the burden at all times on petitioner to prove any "proposition of unpatentability" by a preponderance of the evidence.

*2. The PTO's Decision to Shift the Burden to Patent Owners Cannot Be Squared with the Patent Act.*

Notwithstanding Section 316(e), the PTO interprets its general regulation regarding evidentiary burdens for motions—which provides that a "moving party has the burden of proof to establish that it is entitled to the requested relief" in any Board proceeding, 37 C.F.R. § 42.20(c)—as applicable to motions to amend claims in inter partes review. But a general PTO regulation cannot override Congress's specific choice. "Where a statute is clear, the agency must follow the statute." *Cuozzo Speed Techs.*, 136 S. Ct. at 2142.[2]

Nor would it be sensible to conclude that Congress left a "gap" for the agency to fill here, *Cuozzo*, 136 S. Ct. at 2142, given that neither Congress nor the PTO has *ever* placed a similar patentability burden on a patent owner or applicant.

[2] PTO regulations further require that patent owners must confer with the Board before moving to amend, and that any amendment "respond to a ground of unpatentability involved in the trial." 37 C.F.R. § 42.121(a), (a)(2)(i). Those requirements can only be reconciled with Section 316(e) if they are construed as essentially pleading requirements that require patent owners to show that an amendment pertains (*i.e.*, "respond[s]") to the same "ground of unpatentability" over which the Board instituted inter partes review. *Id.* § 42.108(c).

*See* Jennifer R. Turchyn, *Improving Patent Quality Through Post-Grant Claim Amendments: A Comparison of European Opposition Proceedings and U.S. Post-Grant Proceedings*, 114 MICH. L. REV. 1497, 1515 (2016) (noting the PTO's "unusually high evidentiary burden for patent owners" in inter partes review, given that elsewhere "the Patent Act requires parties other than the patent owner—the examiner in the case of prosecution and the opposing party in the case of litigation—to prove that a claim is unpatentable"). For instance, the Patent Act provides that an applicant "shall be entitled to a patent *unless*" the claimed invention was available to the public before the effective date of the claimed invention, 35 U.S.C. § 102 (emphasis added), which is why "the PTO bears the initial burden of presenting a *prima face* case of unpatentability" during patent examinations, *In re Glaug*, 283 F.3d 1335, 1338 (Fed. Cir. 2002). If the PTO fails to meet that burden, "the applicant is entitled to the patent." *Id.*; *see also* 37 C.F.R. § 1.121 (regulation regarding claim amendments in examination proceedings does not place any burden of proof on patent applicants or owners); *id.* § 1.173 (same for reissue proceedings).

In addition, the Patent Act presumes that issued patents are valid and places "[t]he burden of establishing invalidity *** on the party asserting such invalidity." 35 U.S.C. § 282(a). That litigation burden "never shifts to the patentee to prove validity." *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1359-1360 (Fed. Cir. 2007).

And of course, with regard to *issued* claims in inter partes review, there is no dispute that the Board cannot "improper[ly] shift[]" the burden to the patentee "to prove that the claimed invention would *not* have been obvious." *In re Magnum Oil Tools*, 2016 WL 3974202, at *8.[3]

In short, nothing in the AIA or elsewhere in the Patent Act—and certainly not Congress's placement of the lone "burden of proving a proposition of unpatentability" on *petitioners*, 35 U.S.C. § 316(e)—indicates that Congress intended to allow the PTO to shift the burden of proving patentability to *patent owners* in such an unprecedented manner. *See Cuozzo*, 136 S. Ct. at 2142 (agency has leeway to enact rules only where Congress leaves a gap for agency to fill).

### B. Permitting The PTO To Shift The Patentability Burden To Patent Owners Frustrates Congress's Choice In Permitting Amendment.

The basic structure of inter partes review confirms what the statutory text makes plain: the right to amend claims should not be encumbered by the burden-swapping scheme the PTO has conceived. That is because the liberal amendment of patent claims has traditionally been associated with the "broadest reasonable construction" standard the Board uses to interpret claims in conducting an inter

[3] The same can be seen in pre-AIA practice: in *inter partes* reexamination proceedings, "the examiner retain[ed] the burden to show invalidity," *Rambus Inc. v. Rea*, 731 F.3d 1248, 1255 (Fed. Cir. 2013); and in interference proceedings, a party challenging an existing claim bore the burden of showing that "the claims of the *** application were unpatentable," *Velander v. Garner*, 348 F.3d 1359, 1369-1370 (Fed. Cir. 2003).

partes review. 37 C.F.R. § 42.100(b) ("A claim in an unexpired patent that will not expire before a final written decision is issued shall be given its broadest reasonable construction in light of the specification of the patent in which it appears.").

The "simple reason" that "[p]atent application claims are given their broadest reasonable interpretation during examination proceedings" is "that before a patent is granted the claims are *readily amended* as part of the examination process." *Burlington Indus., Inc. v. Quigg*, 822 F.2d 1581, 1583 (Fed. Cir. 1987) (emphasis added). As this Court explained over three decades ago, the broadest reasonable construction standard governs the process of amending claim language in view of prior art during examination proceedings because it strikes a careful balance between the rights of the inventive community and the rights of the general public. In particular, that approach ensures that "[a]pplicants' interests are not impaired since they are not foreclosed from obtaining appropriate coverage for their invention with express claim language." *In re Yamamoto*, 740 F.2d 1569, 1571 (Fed. Cir. 1984). At the same time, it "serves the public interest by reducing the possibility that claims, finally allowed, will be given broader scope than is justified." *Id.*

Importantly, that rationale—rooted in the relationship between the broadest reasonable construction standard and the right to amend claims freely —extends

beyond the initial examination of a patent. "The same policies warranting the PTO's approach to claim interpretation when an original application is involved have been held applicable to reissue proceedings *because the reissue provision permits amendment of the claims to avoid prior art*." *In re Yamamoto*, 740 F.2d at 1572 (emphasis added) (internal citation omitted). And in light of the fact that the "reexamination law" likewise "g[a]ve[] patent owners the same right," the "reasons underlying the PTO's interpretation of the claims in reissue proceedings therefore justify using the same approach in reexamination proceedings." *Id.* In none of those proceedings did Congress (or the PTO) require the patentee to bear the initial burden of proving the patentability of the amended claim. *See* Part I.A.2, *supra*.

Aside from the fact that the AIA forecloses a contrary result, there is no reason to conclude that claim amendments in an inter partes review should be treated any differently. Just as a patentee in a reexamination proceeding can "propose any amendment to his patent *** thereto, in order to distinguish the invention as claimed from the prior art *** or in response to a decision adverse to the patentability of a claim of a patent" so long as the proposed amendment does not "enlarg[e] the scope of a claim of the patent" under the broadest reasonable construction standard, 35 U.S.C. § 305, a patentee in an inter partes review may suggest a "reasonable number of substitute claims" that do "not enlarge the scope

of the claims of the patent or introduce new matter" under that same standard, *id.* § 316(d)(3); *see* 37 C.F.R. § 42.100(b).

These similarities caution against a material constriction of the amendment right under PTO regulations, and counsel in favor of leaving the petitioner before the PTO with the task of proving the unpatentability of an amended claim. The PTO's Director recently underscored her view of the connection between amendment in inter partes review and other proceedings before the Supreme Court: "[T]here is no restriction on amendment opportunities that materially distinguishes [inter partes review] proceedings from their predecessors in the patent statute." Br. of Resp't at 26-27, *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131 (2016) (No. 15-446) (second alteration in original) (citation and internal quotation marks omitted). In fact, the patent owner's ability to amend is, in the Director's view, the "*principal feature* that *** justif[ies] use of the broadest-reasonable-construction standard in initial examinations and in other post-issuance administrative proceedings." *Id.* at 17 (emphasis added); *see id.* at 23-27 (emphasizing availability of amendment in inter partes review).

That the Supreme Court accepted the Director's argument in *Cuozzo*—a month after the now-vacated panel decision in this case—further undermines her position here. In discussing the broadest reasonable construction standard, the Court cited *In re Yamamoto* approvingly and noted that the PTO "has used this

standard for more than 100 years" to further the private and public interests discussed above. *Cuozzo Speed Techs.*, 136 S. Ct. at 2145. And in upholding the use of that claim construction standard in inter partes review, the Court reasoned that a "patent holder may, at least once in the process, make a motion to *do just what he would do in the examination process*, namely, amend or narrow the claim." *Id.* (emphasis added); *accord* Br. of Resp't at 13, *supra* ("[T]he restrictions on potential amendments [in inter partes review] are comparable to those that apply in other post-issuance proceedings in which the agency has long used the broadest-reasonable-construction method."). That amendment opportunity is the major feature that, in the Supreme Court's view, ensures that use of the broadest reasonable interpretation standard is "not unfair to the patent holder[.]" *Cuozzo*, 136 S. Ct. at 2145. Yet requiring a patentee to prove patentability (or disprove unpatentability) as part of the amendment process is emphatically *not* "just what he would do in the examination process." *Id.* at 2145. To allow that significant difference would run headlong into a key premise upon which the Court relied in approving the PTO's adoption of the broadest reasonable construction standard.

### C. The PTO's Position Guts The Right To Amendment At Enormous Cost To The Inventive Community And The Public At Large.

A proceeding where the broadest reasonable construction standard is applied, but where amendment of claims is constrained by the need to prove

patentability and negate the effect of prior art, is manifestly unfair and impractical for at least three reasons.

*First*, the PTO's interpretation leaves the statutory right to amend claims, which the PTO relied on to justify its use of the broadest reasonable construction standard in the first instance, essentially an empty shell. By the PTO's own count, since the inception of inter partes review, only 2 motions to amend have been granted and 4 motions to amend have been granted in part—*i.e.*, a denial rate of 95% for decided motions. USPTO, PATENT TRIAL AND APPEAL BOARD MOTION TO AMEND STUDY, 4, 6 (Apr. 30, 2016), https://www.uspto.gov/sites/default/files/documents/2016-04-30%20PTAB%20MTA%20study.pdf. Rejecting the PTO's burden-swapping position would dramatically increase the rate of amendment and provide the protection to patent owners that Congress intended. *See, e.g.*, *id.* at 6 (stating that only 8% of motions to amend were denied because the claims enlarged the scope of the patent or there were an unreasonable number of substitute claims proposed).

*Second*, the patent owner lacks a meaningful opportunity to make the showing required by the PTO. By placing the burden on the patent owner to demonstrate the patentability of the substitute claim as a condition of allowing the amendment, the PTO's position forces the patent owner to prove a negative—*i.e.*, that its amended claims are *not* unpatentable. Discharging that burden entails

addressing not only "the prior art of record," but also "prior art not of record but known to the patent owner." *Idle Free Sys., Inc. v. Bergstrom, Inc.*, No. IPR2012-00027, 2013 WL 5947697, at *4 (P.T.A.B. June 11, 2013); *see MasterImage 3D, Inc. v. RealD Inc.*, IPR2015-00040, 2015 WL 10709290, at *1 (P.T.A.B. July 15, 2015) (clarifying that "prior art known to the patent owner" means "material prior art that Patent Owner makes of record in the current proceeding pursuant to its duty of candor and good faith to the Office under 37 C.F.R. § 42.11, in light of a Motion to Amend," including "not just the closest primary reference, but also closest secondary reference(s) the teachings of which sufficiently complement that of the closest primary reference to be material") (citation and quotation marks omitted). Worse still, a patent owner must ordinarily address that broad universe of prior art in "1 motion to amend," 35 U.S.C. § 316(d)(1), limited to a mere 25 pages of double-spaced, 14-point text, *see* 37 C.F.R. §§ 42.6(a)(2), 42.24(a)(1)(vi), with a portion of that space directed to points other than prior art, *see id.* § 42.121(b) (setting forth required content).

The impracticality of disproving unpatentability within those constraints is far from theoretical. For instance, the Board has found a patent owner proposing amended claims to have fallen short of the duty of candor and good faith where it addressed certain prior art references of record, but explained that it would not be feasible (particularly within the briefing constraints) to address the hundreds of

other references previously asserted against the patent family. *See HTC Corp. v. Advanced Audio Devices, LLC*, No. IPR2014-01154, 2015 WL 9488115, at *21 (P.T.A.B. Dec. 29, 2015); *see also, e.g.*, Final Written Decision 29-31, *Zhongshan Broad Ocean Motor Co. v. Nidec Motor Corp.*, IPR2014-01121 (P.T.A.B. May 9, 2016) (Paper 86) (denying motion to amend where movant distinguished three items of relevant prior art, but not additional prior art that the Board deemed material). The Supreme Court has recently made clear in the patent context the "practical considerations" that disfavor shifting the burden onto a party to "have to work in the dark *** to negate every conceivable *** theory." *Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 134 S. Ct. 843, 849-850 (2014).

*Third*, the current system breeds uncertainty, stifles innovation, and thereby works against the public interest. That is because "[u]nnecessarily restricting the patentee's ability to amend its claims (in contrast with the flexible *inter partes* reexamination process) *** encourage[s] outright invalidation of a patent that may simply require an adjustment in scope." *Synopsys, Inc. v. Mentor Graphics Corp.*, 814 F.3d 1309, 1341 (Fed. Cir. 2016) (Newman, J., dissenting) (second alteration and ellipsis in original) (citation and quotation marks omitted). Yet that is precisely the outcome the PTO's regulation has produced. Scrapping patent claims wholesale, rather than providing a meaningful opportunity to address prior art and preserve claims to the extent possible, squanders the financial and intellectual

capital the inventive community devotes to new discoveries. *See* Richard Baker, *America Invents Act Cost the U.S. Economy Over $1 Trillion*, PATENTLY O (June 8, 2015), http://patentlyo.com/patent/2015/06/america-invents-trillion.html (discussing economic impact of claim invalidation in inter partes review). Averting that result is of particular concern to PhRMA's members, which invest $2.6 billion on average to develop each new cutting-edge medicine and more than $50 billion per year. *See* PhRMA, 2016 PROFILE, BIOPHARMACEUTICAL RESEARCH INDUSTRY, Key Facts (inside cover) (Apr. 2016), http://www.phrma.org/sites/default/files/pdf/biopharmaceutical-industry-profile.pdf.

## II. THE BOARD LACKS AUTHORITY TO RAISE PATENTABILITY CHALLENGES *SUA SPONTE*.

Consistent with the AIA's placement of the burden of proving unpatentability on the petitioner during inter partes review, there is no legal or policy justification for allowing the Board to raise patentability challenges *sua sponte* when the petitioner does not.

To begin with, the AIA assigns the Board only the "[d]ut[y]" to "*conduct* inter partes reviews." 35 U.S.C. § 6(b)(4) (emphasis added). *Participation* in an inter partes review is left to the petitioner and the patent owner. In particular, only "[a] *petitioner* in an inter partes review may request to cancel as unpatentable 1 or more claims of a patent only on a ground that could be raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications."

*Id.* § 311(b) (emphasis added). As discussed above, "[i]n 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.* § 316(e) (emphasis added). And as the Board itself has acknowledged, it may not initiate and conduct a patentability review *sua sponte* on behalf of the petitioner. *See Epicor Software Corp. v. Protegrity Corp.*, No. CBM2015-00006, 2015 WL 1870235, at *22 (P.T.A.B. Apr. 21, 2015) (declining to institute an inter partes review because "[p]etitioner's approach of offering a plurality of prior art references for consideration, with the particular and necessary combination to be selected or chosen by the Board[,] is improper").

Permitting the Board to take on the responsibilities that Congress expressly assigned to petitioners would render those statutory provisions hollow. At bottom, inter partes review is an adjudicatory proceeding "predicated on a petition followed by a trial in which the petitioner bears the burden of proof." *In re Magnum Oil Tools*, 2016 WL 3974202, at *10; *see also PPC Broadband, Inc. v. Corning Optical Commc'ns RF, LLC*, 815 F.3d 747, 756 (Fed. Cir. 2016) (Inter partes reviews "are litigation-like contested proceedings before the Board."); H.R. REP. NO. 112-98, pt. 1, at 46-47 (2011) (AIA "converts inter partes reexamination from an examinational to an adjudicative proceeding" and renames it "inter partes review").

The Board cannot serve its adjudicatory function where it both advances and evaluates patentability arguments.

Indeed, this Court has recently foreclosed such a practice in analogous circumstances. In *Magnum Oil Tools*, a unanimous merits panel held that the Board erred in raising a patentability argument on obviousness when that argument could have been, but was not, included in the petition. *See In re Magnum Oil Tools*, 2016 WL 3974202, at *10. The Federal Circuit cautioned that the Board's authority "is not so broad that it allows the PTO to raise, address, and decide unpatentability theories never presented by the petitioner and not supported by record evidence." *Id.* Rather, the Board's power is curtailed to "arguments that were advanced by a party, and to which the opposing party was given a chance to respond." *Id.* ("An agency may not change theories in midstream without giving respondents reasonable notice of the change and the opportunity to present argument under the new theory.") (quoting *SAS Inst., Inc. v. ComplementSoft, LLC*, 825 F.3d 1341, 1351 (Fed. Cir. 2016)). Limiting the adjudicatory authority of the Board to decide patentability issues presented by the parties is a sound approach as it is "unreasonable to expect that [a party] would have briefed or argued, in the alternative, hypothetical constructions not asserted by [its] opponent." *SAS Inst.*, 825 F.3d at 1351. That conclusion applies with equal force where the patentability of substitute claims is at issue.

## CONCLUSION

For the foregoing reasons, this Court should vacate the Board's denial of Aqua Product's motion to amend and remand the case for further proceedings.

Respectfully submitted,

*/s/ James E. Tysse*

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October 5, 2016

## CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B). The brief contains 4,850 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). The brief has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Times New Roman type style.

## CERTIFICATE OF SERVICE

I hereby certify that, on October 5, 2016, I electronically filed the foregoing *amicus curiae* brief with the Clerk of Court for the United States Court of Appeals for the Federal Circuit by using the Court's CM/ECF system.

All of the participants are registered CM/ECF users and will be served copies of the foregoing Brief via the CM/ECF system.

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