Selected docket entries for case 15−1177

Generated: 10/25/2016 14:40:43

Filed	Document Description	Page	Docket Text
10/05/2016	92 Amici Brief	2	TENDERED from THE BIOTECHNOLOGY INNOVATION ORGANIZATION (BIO) Title: AMICUS CURIAE BRIEF. Service: 10/05/2016 by US mail, email. [371772]

2015-1177

United States Court of Appeals for the Federal Circuit

IN RE: AQUA PRODUCTS, INC.,

Appellant.

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

THE BIOTECHNOLOGY INNOVATION ORGANIZATION (BIO) AS *AMICUS CURIAE* SUPPORTING APPELLANT

Q. TODD DICKINSON
COLBY B. SPRINGER
POLSINELLI PC
1401 I Street, N.W., Suite 800
Washington, DC 20005
(202) 783-3300
tdickinson@polsinelli.com
cspringer@polsinelli.com

HANS SAUER
BIOTECHNOLOGY INNOVATION ORGANIZATION
1201 Maryland Avenue, S.W.
Washinton, DC 20024
(202) 962-9200
hsauer@bio.org

Counsel for Amicus Curiae BIO

October 5, 2016

CERTIFICATE OF INTEREST

Counsel for *Amicus Curiae* certifies the following:

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

   Biotechnology Innovation Organization ("BIO") (formerly: Biotechnology Industry Organization)

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

   None.

3. All parent corporations and any publicly held companies that own 10 percent of the stock of the party or *amicus curiae* represented by me are:

   None.

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

   Hans Sauer
   DEPUTY GENERAL COUNSEL
   Biotechnology Innovation Organization

   Q. Todd Dickinson
   SHAREHOLDER
   Polisnelli PC

   Colby B. Springer
   PRINCIPAL
   Polisnelli LLP

October 5, 2016

/s/ Hans Sauer
Hans Sauer
Counsel for Amius Curiae BIO

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Rules

Regulations

Other Authorities

STATEMENT OF INTEREST OF AMICUS CURIAE

The Biotechnology Innovation Organization ("BIO") (formerly: Biotechnology Industry Organization) is the principal trade association representing the biotechnology industry domestically and abroad. BIO has more than 1,000 members, which span the for-profit and non-profit sectors and range from small start-up companies and biotechnology centers to research universities and Fortune 500 companies. Approximately 90% of BIO's corporate members are small or mid-size businesses that have annual revenues of under $25 million, and that count their patents among their most valuable business assets. BIO's members depend heavily on robust patent rights and a fair system for adjudicating their validity.

Biotechnology businesses and entrepreneurs have huge reliance interests in the validity of their patents. BIO members commonly devote a decade of effort and in excess of 2 billion dollars to develop innovative products that address unmet medical needs, increase crop yields, and provide real-world tools in the fight against disease, hunger, and pollution. Without the promise of effective and predictable patent rights, these investments would be far more difficult—if not impossible—to undertake. And unlike typical products in, for example, the e-commerce, enterprise software, or mobile communications industries, biotechnology products tend to be protected by only a handful of patents. A

biotech company literally faces the loss of its entire business if but a few, or even just one, of its patents are invalidated. BIO's member companies are extremely sensitive to even the slightest procedural imbalances that exist in the proceedings of the Patent Trial and Appeal Board (PTAB) of the United States Patent and Trademark Office (PTO), including the ability to amend claims in *inter partes* review (IPR). Accordingly, the question of who has the burden of proof, and what must be proved, before a claim amendment can be entered in IPR is of great importance to BIO's membership[1].

BIO files this brief in accordance with the Order issued on August 12, 2016, which states that briefs may be filed without consent or leave of the court.

[1] BIO has no direct stake in the result of this appeal. Nor does BIO take any position on the ultimate validity of the challenged patent or the patentability of the proposed substitute claims. No counsel for a party authored this brief in whole or in part and no such counsel or party, nor any person other than the *amicus curiae* or its counsel, made a monetary contribution intended to fund the preparation or submission of this brief. This brief reflects the consensus view of BIO's members, but not necessarily the view of any individual member.

ARGUMENT

I. The PTO May Impose No Burden of Proving "Patentability" in an IPR; Instead, the Petitioner Bears the Burden of Persuasion as to Unpatentability of a Substitute Claim.

The Court's first *en banc* question asks if the PTO may require the patentee to bear a burden of production, or a burden of persuasion, regarding patentability of proposed substitute claims during the course of a IPR proceeding before the PTAB. DKT. NO. 60 (ORDER ON PETITION FOR REHEARING (2015-1177)) at 2.

BIO submits that the PTO may not require the patentee to bear a burden of proving patentability of a proposed substitute claim. However, the PTO may require the patentee to come forward with information relating to the threshold conditions of 35 U.S.C. § 316(d) and its implementing Rule 42.121. *See* 35 U.S.C. § 316(d) (providing for a motion to substitute claims); *cf.* 37 C.F.R. § 42.121(a)(2)(ii) (setting forth grounds for denial of such a motion).

This requirement would facilitate the determination that the amendment (i) does not enlarge the scope of the claims, (ii) introduces no new matter, and (iii) is responsive to a ground of purported invalidity on which the PTAB proceeding was instituted. 37 C.F.R. § 42.121(a)(2)(i), (ii).

Rule 42.121 further provides that the patentee's motion to amend set forth "support in the original disclosure of the patent for each claim that is added or

amended" and "[t]he support in an earlier-filed disclosure for each claim for which benefit of the filing date . . . is sought." 37 C.F.R. § 42.121(b)(1), (2).

Following this strictly enumerated showing by the patentee, the petitioner must produce information that establishes the unpatentability of the substitute claim. *See* 35 U.S.C. § 316(e) ("the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence"). By its plain terms, Section 316(e) requires a petitioner that believes the substitute claim to be unpatentable to bear the burden of persuasion for that proposition. Neither the IPR statute nor its implementing rules establish or allocate a contrary burden of proving "patentability." Because the burden of showing unpatentability must be carried by the petitioner, the patentee accordingly has no affirmative duty to prove patentability of a substitute claim. *See, e.g., Abbvie Inc. v. Mathilda & Terence Kennedy Inst. Of Rheumatology Trust,* 764 F.3d 1366, 1378-80 (Fed. Cir. 2014) (addressing the distinction between "patentable" and "unpatentable" claims under Section 103). Similarly, there is no duty to prove the patentability of an original instituted claim.

If the Board finds that the petitioner's showing is insufficient to establish the unpatentability of the an original or substitute claim by a preponderance of the evidence, the Board must rule in favor of the patentee. 35 U.S.C. § 318(a) (the PTAB "shall issue a final written decision with respect to the patentability of any

patent claim [and any new claim under Section 316(d)] challenged by the petitioner") (emphasis added).

The Court's second *en banc* question is presented in two parts. The Court first asks whether the PTAB may *sua sponte* challenge the patentability of a proposed substitute claim if the petitioner does not do so or does so in an inadequate manner. DKT. NO. 60 at 2-3. The Court then inquires—in the event the answer is yes—as to where the burdens of persuasion and production would lie under such circumstances. *Id.* at 3.

BIO submits that the Board should tread carefully when inquiring about the 'adequacy' of any petitioner opposition to a proposed substitute claim. The PTAB's role as impartial adjudicator is threatened by, if not wholly incompatible with, the concept of acting as a quasi-intervenor that might seek to remedy any perceived substantive shortcomings in a party's submissions. *Cf. In re Magnum Oil Tools Int'l, Ltd.*, 2015-1300, 2016 WL 397402, at *10 (Fed. Cir. July 25, 2016) ("while the PTO has broad authority to establish procedures for revisiting earlier-granted patents in IPR, that authority is not so broad that it allows the PTO to raise, address, and decide unpatentability theories").

In instances where the petitioner does not oppose the proposed substitute claim, the Board must nonetheless decide whether the substitute claim meets the requirements of Section 316(d) and its implementing regulations. This inquiry is

limited to the determination that a proposed substitute claim (i) is not broader in scope than any originally granted claim, (ii) does not present new matter, (iii) responds to a ground of unpatentability that forms the basis of the instituted PTAB proceeding,[2] and (iv) has proper written description support in the original disclosure and any previously filed applications for which a claim of priority is made. 37 C.F.R. §§ 42.121 (a)(2)(i), (ii); 37 C.F.R. § 42.121(b)(1), (2).

To the extent a proposed claim amendment enlarges the scope of the claim, introduces new matter, is unsupported by original disclosure of the patent, or is not otherwise entitled to a desired priority date, the PTAB may deny the claim on its own accord. Similarly, if the proposed amendment *prima facie* fails to distinguish a substitute claim from at least one ground of invalidity on which the IPR proceeding was instituted, the PTAB can require the patentee to show cause why the substitute claim should not be denied.

[2] *C.f. Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292 (Fed. Cir. 2015) at 1308 ("Section 42.121(a)(2)(i) simply requires that a patentee's amendment be made in order to "respond to a ground of unpatentability involved in the trial," and not for some other reason. As the PTO explained, this rule is meant to "enhance efficiency of review proceedings. . . . [A]ny amendment that does not respond to a ground of unpatentability most likely would cause delay, increase the complexity of the review, and place additional burdens on the petitioner and the Board.")(citing *Changes to Implement Inter Partes Review Proceedings, Post–Grant Review Proceedings, and Transitional Program for Covered Business Method Patents*, 77 Fed.Reg. 48,680, 48,705 (Aug. 14, 2012).

In any event, such challenges must be limited to the art and argument that was applied against the original claim. *See* 37 C.F.R. § 41.121(a)(2)(i) (requiring a motion to amend to "respond to a ground of unpatentability involved in the trial"); *see also Magnum Oil*, at *10 (proscribing new unpatentability theories from the scope of PTAB authority). The PTAB cannot itself challenge the substitute claim using new art or argument that might be applicable against the original claim. To do so would constitute a new, additional ground of unpatentability affecting the original claim outside the scope of the instituted grounds of the proceeding. *See* 35 U.S.C. § 314(a) ("[t]he Director may not authorize an *inter partes* review to be instituted unless the Director determines that . . . the petition filed under section 311 . . . shows that there is a reasonable likelihood that the petitioner would prevail") (underlining added); *see also SAS Inst., Inc. v. ComplementSoft, LLC*., No. 2015-1347, 2016 U.S. App. LEXIS 10508, at 46 * 20-21 (Fed. Cir. June 10, 2016) ("[a]n agency may not change theories midstream").

Challenges to the patentability of the substitute claim must similarly be limited to the amendatory subject matter such as patentability defects that were manifestly caused by the amendment. To do otherwise, especially in the context of an *inter partes* review, would open the door to rejections under Sections 112 or 101 that would apply with equal force against amended and unamended claims alike. Such a proposition would broaden the IPR proceeding beyond its statutory

scope. *See* 35 U.S.C. § 311(b) ("[a] petitioner . . . may request to cancel as unpatentable 1 or more claims . . . only on a ground that could be raised under section 102 or 103").

The balance between the various types of post-grant review was achieved with great difficulty and care during the legislative process. One compromise was to limit the scope of the IPR process to questions of anticipation or obviousness based on patents and printed publications, similarly to *inter partes* reexamination. To permit a back-door use of other grounds for purported invalidation would not only significantly risk upsetting that careful balance, but would be contrary to Congress's intent.

As to the second element of the Court's question and regarding the burdens of persuasion, if the requirements of Section 316(d) (including Rule 42.121) are met, narrowed claims that are free of the instituted grounds should be deemed presumptively patentable. Therefore, if the petitioner does not challenge the substitute claim, the Board's role will be limited to confirming that the requirements of Rule 41.121 are met, or to present reasons why the substitute claim fails to satisfy Rule 42.121 on the existing record.

II. The PTAB's Current Claim Amendment Practices are Inconsistent with Congressional Intent

In essentially unchanged language, the ability of the patentee to amend its claims was a constant feature of the proposed post-grant review processes

considered by four Congresses with little debate or controversy.[3] This lack of contest or debate clearly suggests that Congress assumed that claim amendments in *inter partes* review would be a common and otherwise unremarkable procedure that would unfold as a matter of course if not of right.

Other aspects of the legislative history lend further support to this conclusion. For example, the 2007 Senate report on S. 1145 tersely, but clearly, stated that patent owners were to be given the opportunity to amend "as a matter of right." S. REP. NO. 110-259 at 22 (2008). A year later, then Senator John Kyl of Arizona commented that a written institution decision would be desirable because it would "give the patent owner a sense of what issues are important to the board and where he ought to focus his amendments." 154 CONG. REC. S9988. The House Report on H.R. 1249, too, indicated that the bill would allow for a reasonable number of claim amendments. H.R. REP. NO. 112-98(I) at 76 (2011). In the same report, various Representatives approvingly noted the high rate of "modification or nullification" of patent claims in *inter partes* reexamination and the desire to retain this feature in the new IPR proceedings. *Id.* at 164.

If Congress had complaints about *inter partes* reexamination (and it had many), the frequency at which these proceedings resulted in amended claims was

[3] For example, compare early versions of the amendment provision, e.g., S. 3818, 109TH CONG. § 318 (2006), with the final version that was enacted, H.R. 1249, 112TH CONG. § 326 (2011).

not among them as any such concerns are conspicuously absent from the legislative record. As Congress was no doubt aware, claim "modification" had long been the predominant outcome in *inter partes* reexamination, where 61% of these decided proceedings resulted in amended claims.[4] In contrast, only 2% of the motions seeking to amend claims in IPR proceedings have been granted, which means that considerably less than 1% of these proceedings result in claim modification.[5] Such a precipitous decline in the number of proceedings ending in amended claims is astonishing and demands an explanation absent any sign that Congress intended such a drastic change. There is simply no evidence to suggest that Congress, in reforming *inter partes* reexamination into the adjudicatory *inter partes* review proceeding, considered claim amendments undesirable. The surprisingly low rate of amendments demands not just an an explanation but also the sorely needed clarifications set forth elsewhere in this brief.

The PTO has argued that this profound change in policy is an unremarkable result of its new administrative powers under the AIA. Yet, the PTO's current

---

[4] U.S. Patent and Trademark Office, Inter Partes Reexamination Filing Data (Sept. 30, 2013), http://www.uspto.gov/patents/stats/inter_parte_historical_stats_roll_up_EOY2013.pdf

[5] U.S. Patent and Trademark Office, Patent Trial and Appeal Board Motion to Amend Study (Apr. 30, 2016), https://www.uspto.gov/sites/default/files/documents/2016-04-30%20PTAB%20MTA%20study.pdf

practice is in gross contradiction to both the statute and the PTO's own public declarations that "the Office will continue to apply a broadest reasonable interpretation standard because at the time that a petition is filed . . . the patent owner's ability to amend remains available" and "[a]bsent a change in statutory authority, the Office cannot withdraw the opportunity to amend claims in AIA trial proceedings." 80 FED. REG. 50721-50722 (Aug. 20, 2015). "Since patent owners have the opportunity to amend claims during IPR, PGR, and CBM trials, unlike in district court proceedings, they are able to resolve ambiguities and over breadth through this interpretive approach, producing clear and defensible patents at the lowest cost point in the system." *Office Patent Trial Practice Guide*, 77 FED. REG. 48755, 48764 (Aug. 14, 2012).

Despite such pronouncements, the PTO's actions suggest that it views claim amendments as fundamentally incompatible with the new adjudicatory framework of post-grant proceedings. The results speak for themselves and evince a clear mistrust in the PTAB as to whether the adversarial process that was so clearly intended by Congress can produce a proper analysis of any such amendments. As a result, scores of patents that were once preserved in narrowed form are instead being invalidated in their entirety.

The *status quo* is unworkable. Absent further intervention by Congress there appears no discernible path forward. This Court, sitting *en banc*, has a timely

opportunity to clarify how the existing statute can and should more realistically accommodate claim amendments in the PTAB.

III. The PTO's Burden-Allocation is Inconsistent with the Statute and Exceeds the PTO's Authority

The PTO is clearly grappling with who has the burden of proof and what must be proved before a claim amendment can be entered during an IPR. The statute and its implementing regulations, however, already provide clear answers to these questions. 35 U.S.C. § 316(d) specifies that patent owners may propose substitute claims that do not enlarge the scope of the challenged patent's claims and do not introduce new matter. PTO Rule 42.121—not disputed here—further specifies that the amendment must be responsive to a ground of unpatentability involved in the IPR, have proper support in the specification, and be entitled to the filing date sought.

In its immediate next subsection, Section 316(e), the statute then specifies that a proposition of unpatentability in an instituted IPR (and not, more narrowly, on an instituted claim) must be proved by the petitioner. The process would seemingly require the patentee to come forward with a proposed claim amendment, explain how that amendment distinguishes the claim over the grounds of unpatentability on which the IPR was instituted, and otherwise show proper support in the specification and entitlement to the desired filing date. If these requirements are met, the burden would shift to the petitioner, as the proponent of

unpatentability, to show that even as amended the claim is still anticipated or obvious. This process would harmoniously align with the IPR statute and its adjudicatory framework.

In stark contrast, however, is the PTO's position. That position stands in much greater tension with the statute and even its own implementing regulations. 35 U.S.C. § 316(e)—in the PTO's view—would actually only apply to some propositions of unpatentability in an instituted IPR, but not to others. Rule 42.121 would set forth only some of the substantive requirements for amendments, but not others. And because the statute is silent as to a burden of showing patentability (as opposed to unpatentability), the PTO proposes that it is free to create and allocate such a burden while enjoying deference for doing so.

For justification of these propositions, the PTO has relied almost entirely on Rule 42.20. Rule 42.20 is an all-purpose rule that was carried over in highly generalized form from pre-AIA rules on contested proceedings. *See e.g.* 37 C.F.R. § 42.121 (2010). Rule 42.20 states, in the most general terms, that a party seeking any form of relief must do so by motion; bears the burden of proof that it is entitled to the requested relief; and must obtain prior Board authorization before filing the motion. The PTO's reliance on Rule 42.20 in this regard is suspect. First, if Rule 42.20 applies to claim amendments then it could not have been legally promulgated under the authority of 35 U.S.C. § 316(a)(9). The filing of a motion

to amend is a right that was created by statute—35 U.S.C. § 316(d); such a motion does not require prior authorization by the Board as the rule would require.

Second, a general agency rule cannot trump a specific statutory provision such as 35 U.S.C. § 316(e), which clearly assigns the burden of proof. And third, if Rule 42.20 did what the PTO proposes, such a burden shift would be a substantive change in the law, which would exceed the PTO's authority. *Director, Office of Workers' Compensation Programs v. Greenwich Collieries*, 512 U.S. 267, 271 (1994) (The "assignment of the burden of proof is a rule of substantive law.");*see also Tafas v. Doll*, 559 F.3d 1345, 1353 (Fed. Cir. 2009) (gathering cases holding PTO has no substantive rulemaking authority).

The IPR statute grants the PTO robust rulemaking power to fill in spaces that Congress left to the PTO for practical implementation of the proceeding so long as those rules are consistent with its legislative intent. But the space the PTO claims to have filled by regulation never existed. There is nothing ambiguous about Congress's allocation of the burden of proving propositions of unpatentability in IPR. Accordingly, this Court's authority to review the PTO's claim amendment process is not constrained by deference to the PTO's rulemaking powers.

IV. The PTAB's Requirement that the Patentee Demonstrate the Patentability of a Proposed Substitute Claim is not a Reasonable Interpretation of the Statute

Under the PTAB's interpretation of the statutes and rules, a patentee seeking to amend a claim in IPR must first and foremost distinguish the substitute claim over the grounds on which the IPR was instituted, and show support in the patent's specification and entitlement to the applicable priority date. In the remaining pages of its motion, the patentee is then required to demonstrate the patentability of the substitute claim over other prior art of record. Even after the PTAB's clarifying opinion in *MasterImage*, the scope of such prior art remains broad. *See MasterImage 3D, Inc. v. RealD, Inc.*, IPR2015-00040 (June 15, 2015). References "of record" include those in the IPR petition; those subject to the patentee's disclosure obligations; those in the prosecution history of the patent and its parent applications; in prior reexaminations, reissues, or even other IPR petitions involving the same patent. Many such references might be deemed pertinent to a proposed claim amendment in any number of unforeseeable 2- or 3-way combinations that are impossible to proactively address in a page-limited motion to amend. And a careful and cautious patentee who made substantial volumes of art of record during patent prosecution (as is typical in biotechnology) will be particularly disadvantaged.

With no way of knowing all other combinations of references that will be deemed important by the panel, patentees will often find it impossible to proactively demonstrate "patentability." And even patentees who correctly guess which references might be at bar and, further, which combinations of references to address may still fail if they cannot prove that "one of skill in the art *would not have* a reasonable expectation of success in using [the proposed additional claim element]." *Illumina Cambridge Ltd. v. Intelligent Bio-Systems, Inc.*, 638 Fed. Appx. 999, 1004 (Fed. Cir. 2016) (emphasis added). Where not all combinations of references that should be addressed are foreseeable, and faced with an impossible task of proving negatives - absence of an expectation of success, or an absence of a motivation to combine art - prospects for a successful claim amendment will generally be unrealistic.

The petitioner on the other hand, is more logically positioned to probe the patentability of a substitute claim. The petitioner framed the original invalidity arguments, is well-informed about the prior art, and will often have argued for the claim construction that necessitates the amendment. If it is shown that a proposed claim amendment distinguishes the claim over the grounds of unpatentability on which the IPR was instituted, and otherwise meets the requirements of Rule 42.121, it would be entirely reasonable and efficient to let the petitioner then frame

the reasons why that substitute claim is still unpatentable over the prior art of record.

As it stands, however, the PTAB's process encourages inefficiency and unfocused motion practice. Patentees, as discussed above, will often be unable to predict where to focus their arguments of patentability. Petitioners, in opposition, are under no burden of persuasion to show the unpatentability of the substitute claim. For example, petitioners need not even meet a *prima facie* standard, but are nevertheless entitled to raise additional references and invalidity arguments that provide additional fodder for denial of the claim by the Board. By the time of the oral hearing, the patentee will still often have no notice as to which combination of references the panel would have wanted it to address. Effectively, patentees often operate under an ambiguous, shifting, and unfair 'should have known' standard.

The PTO maintains that an extraordinary burden of proving patentability is warranted because substitute claims are not examined by the Office and because the petitioner can neither be trusted nor burdened with stepping into an examiner's shoes. Yet, one wonders whether the PTO's fear of 'unexamined claims' is fully justified. It is difficult to imagine circumstances under which a substitute claim would be entirely new and unexamined. At the time the amendment is proposed, the challenged claim is still presumed to be clear of the prior art. And if an amendment does no more than remove the particular references on which the IPR

was instituted, why should the presumption that such a narrowed claim continues to be novel and nonobvious be destroyed? As a practical matter, there are safeguards: the subject matter of such a claim *was* examined during original prosecution; the patentee must show that the amendment has full support in the original written description; and the petitioner would get to present its best case why the substitute claim is nonetheless anticipated or obvious. The PTO has never explained why a Board decision on such a record would be inherently less reliable than the decisions it renders under current practice.

In its position, the PTO may feel justified by concerns over delay and complication that might be introduced into the time-limited IPR proceeding if the burdens of persuasion were allocated otherwise. It is true that Congress allocated a typical time of one year from the date of institution to completion of an IPR. But as a practical matter, the Board is taking less time than allotted to complete *inter partes* review. The PTO routinely seeks to conclude principal briefing in its cases by six months, and to arrive at an oral hearing by nine months. The PTO takes great pride in dispensing a form of quick and efficient justice under which it has *not once—in thousands of PTAB proceedings*—felt the need to take even the smallest extension of time as otherwise permitted under 35 U.S.C. § 316(a)(11). The PTO's apparent belief that there is no proceeding, however complicated, that cannot be litigated in the PTAB in nine months is, in itself, cause for concern and

begs the question whether the Board has perhaps systematically been sacrificing due process and basic fairness for the sake of speed and efficiency. For present purposes it is sufficient to note that the statute provides ample time to adjudicate the patentability of substitute claims even if the burden of persuasion is on the petitioner, and that the Board, which otherwise so often reminds litigants of its discretion over the conduct of its proceedings, is free to extend the available time by up to six months.

V. Facilitating More Amendments in IPR Would Advance the Intended Policy Outcomes of the AIA.

One of the most important, if not the most important, goals of the AIA is to improve patent quality.[6] Currently, the outcomes of IPR proceedings are binary: challenged claims either survive the proceeding in unamended form, or, more often than not, are struck down. Because of this all-or-nothing approach, a major policy objective of the AIA – improving the quality of issued patents – remains

[6] "The legislation will accomplish three important goals, which have been at the center of the patent reform debate: improve the application process by transitioning to a first-inventor-to-file system; improve the quality of patents issued by the USPTO by introducing several quality-enhancement measures; and provide more certainty in litigation….The Patent Reform Act will both speed the application process and, at the same time, improve patent quality…High quality patents are the key to our economic growth. They benefit both patent owners and users, who can be more confident in the validity of issued patents. Patents of low quality and dubious validity, by contrast, en-able patent trolls and constitute a drag on innovation. Too many dubious patents also unjustly cast doubt on truly high quality patents" Sen. Patrick Leahy, on the introduction of S. 23; CONGRESSIONAL RECORD, Jan. 25, 2011, S131.

unrealized. It can be fairly asked if the public would not be better served, confidence in the patent system bolstered, and fairness in the marketplace improved, if more patents were to emerge from IPR having undergone amendment with claims that are distinguished over newly-cited art and that more narrowly and clearly define the patentee's rights.

Overall fairness in the marketplace would surely benefit. Patentees may relinquish claim scope, but patent-dependent innovators would at least be able to preserve prospective rights on which they could rely and on which they may build businesses and create jobs. Petitioners and competitors, on the other hand, could develop clearer non-infringement positions and may get the benefit of intervening rights with respect to past activities. Downstream customers and purchasers of infringing technology would be shielded from unfair patent enforcement under the intervening rights provisions of 35 U.S.C. § 252. And, in the event that additional prior art were to come to light, substitute claims would still remain open to subsequent challenge by members of the public in IPR, or in reexamination.

Pressure on the court system would ease as well. The ability to settle IPRs is a prominent aspect of the statute. Congress clearly expected claim amendments to play an important role in the settlement dynamic by going so far as to provide for additional motions to amend in order to facilitate settlements. *See* 35 U.S.C. § 316(d)(2). Moreover, more than 80% of patents in IPR are involved in concurrent

litigation. It is not difficult to forecast that, in a large proportion of concurrent infringement cases in which damages for past infringement are sought, narrowing claim amendments would have great impact not only on questions of claim construction and infringement theories, but also on the calculation of damages. In some instances, amendment may eliminate entitlement to past damages altogether. The appellate workload of the Federal Circuit would likely be positively impacted, as well. With more clearly and narrowly delineated boundaries of the patent right, appeals from both the District Courts and even the PTAB would likely decrease.

It should also be noted that several proposals have been floated, within Congress and without, to address improvements to the PTAB amendment process. One category of proposal, in particular, would deal with stated concerns over the judicial examination capability and time limitations in a more robust amendment process by moving more towards a traditional examination and reexamination/reissue model while preserving the time restaints imposed by the statute. See, for example, D. McCombs and A. Ehmke, *Why an IPR Amendment Process Makes Sense*, Law 360, July 15, 2015; http://www.law360.com/articles/710920/why-an-ipr-amendment-off-ramp-makes-sensestated, and A. Baluch and Q. T. Dickinson, *Finding a Middle Ground on Motions to Amend in Inter Partes Review*, IPO Law Journal, June 3, 2015.

http://www.ipo.org/wp-content/uploads/2015/06/Finding-a-Middle-Ground-on-IPR-Amend-Claims.pdf.

Congress may eventually provide further guidance on the operation of the IPR process. If and when that occurs, refined or alternative procedures governing claim amendments may well be included in such legislation, with the support of stakeholders, including BIO. But for the time being, this Court's guidance is needed to establish that the Congressionally-mandated IPR amendment process fulfills the objectives Congress intended: a facile and robust means to improve patent quality, while maintaining the integrity of the post-grant system.

CONCLUSION

For the foregoing reasons, this Court should hold that the USPTO may require the patentee to produce information to support a threshold determination that proposed substitute claims do not broaden the scope of the claims and introduce no new matter, but that the burden of persuasion as to unpatentability of the substitute claim lies with the petitioner.

Respectfully submitted:

/s/ Hans Sauer

HANS SAUER
BIOTECHNOLOGY INNOVATION ORGANIZATION
1201 Maryland Avenue, S.W.
Washinton, DC 20024
(202) 962-9200
hsauer@bio.org

Q. TODD DICKINSON
COLBY B. SPRINGER
POLSINELLI PC
1401 I Street, N.W,. Suite 800
Washington, DC 20005
(202) 783-3300
tdickinson@polsinelli.com
cspringer@polsinelli.com

Counsel for Amicus Curiae BIO

October 5, 2016

United States Court of Appeals
for the Federal Circuit

In re: Aqua Products, Inc., 2015-1177

CERTIFICATE OF SERVICE

I, Elissa Matias, being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

Counsel Press was retained by Amicus Curiae, BIOTECHNOLOGY INNOVATION ORGANIZATION to print this document. I am an employee of Counsel Press.

On **October 5, 2016** counsel has authorized me to electronically file the foregoing ***EN BANC* BRIEF OF BIOTECHNOLOGY INNOVATION ORGANIZATION AS AMICUS CURIAE IN SUPPORT OF APPELLANT** with the Clerk of Court using the CM/ECF System, which will serve via e-mail notice of such filing to all counsel registered as CM/ECF users.

Additionally on this date, the following principal counsel for each party will be served with 2 paper copies:

James R. Barney
Finnegan, Henderson, Farabow,
Garrett & Dunner, LLP
901 New York Avenue, NW
Washington, DC 20001
202-408-4000
james.barney@finnegan.com
Counsel for Appellant

Nathan K. Kelley, Solicitor
United States Patent and
Trademark Office
Office of the Solicitor
PO Box 1450 -- Mail Stop 8
Alexandria, VA 22313
571-272-9035
nathan.kelley@uspto.gov
Counsel for Intervenor

via Express Mail. Any counsel for Amicus Curiae who are registered users, at the time of filing, will also be served via CM/ECF e-mail notice.

Thirty paper copies will be filed with the Court.

October 5, 2016

/s/Elissa Matias
Counsel Press

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION, TYPEFACE REQUIREMENTS AND TYPE STYLE REQUIREMENTS

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) or Federal Rule of Appellate Procedure 28.1(e)

__X__ The brief contains 5,168 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii),or

____ The brief uses a monospaced typeface and contains _____ lines of text, 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) or Federal Rule of Appellate Procedure 28.1(e) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6)

__X__ The brief has been prepared in a proportionally spaced typeface using MS Word 2013 in a 14 point Times New Roman font or

____ The brief has been prepared in a monospaced typeface using _____ _____in a ___ characters per inch_____ font.

October 5, 2016

/s/ Hans Sauer
Hans Sauer
Counsel for Amius Curiae BIO