Biotechnology Industry Organization

November 18, 2015

The Honorable Michelle K. Lee
Deputy Under Secretary of Commerce for Intellectual Property
and Deputy Director of the United States Patent and Trademark Office
600 Dulany Street
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Via Electronic Mail to Trials2015@uspto.gov

Dear Director Lee:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to provide comments to the U.S. Patent & Trademark Office (USPTO or Office) in response to its proposed Amendments to the Rules of Practice for Trials Before the Patent Trial and Appeal Board (Board), published in the Federal Register on August 20, 2015. 80 Fed. Reg. 161, 50720 (Proposed Rule). At the outset, it should be noted that the post-grant proceedings as currently structured through regulatory interpretation and Board decisions lack fair balance and unnecessarily disfavor the rights of patent owners. This was not the original intent when the proceedings were created and implemented. Recent statistics show that as of August 31, 2015, approximately 72% of *Inter Partes* Reviews (IPRs) are instituted. As of June 30, 2015, 4,827 of 5,783 instituted claims (83.5%) had been declared unpatentable or canceled, while only 956 (16.5%) claims had been upheld.[1] Parties seeking to invalidate a claim under 35 U.S.C. §102 succeeded 40.3% of the time in IPR proceedings,[2] compared to the 31.1% success rate parties enjoyed in comparable district court cases between 2008 and 2009.[3] As for invalidation attempts brought under 35 U.S.C. §103, challengers had a 59.8% success rate in IPR proceedings,[4] compared to 27.8% in district court.[5]

Biotechnology businesses and entrepreneurs have huge reliance interests in the validity of their patents. BIO 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

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[1] Fitzpatrick, Cella, Harper & Scinto, Just the Stats: IPR: Surviv-al Rate of Instituted Claims, http://www.postgranthq.com/statistics/our-tech-breakdown-of-final-decisions-using-fchs-data/ (last visited Nov. 3, 2015).
[2] Fitzpatrick, Cella, Harper & Scinto, Just the Stats: IPR: Breakdown of Unpatentability Findings in Final Decisions Relative to Claims Challenged, http://www.postgranthq.com/statistics/ipr-breakdown-of-unpatentability-findings-in-final-decisions-relative-to-claims-challenged/ (last visited Nov. 3, 2015).
[3] John R. Allison et al., Understanding the Realities of Modern Patent Litigation, 92 Tex. L. Rev. 1769, 1787 (2014)
[4] See Breakdown of Unpatentability Findings, supra note 2.
[5] See Allison, supra note 3, at 1787

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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 who count their patents among their most valuable business assets. Because modern biotechnological products commonly involve lengthy, expensive, and resource-intensive development periods, BIO's members depend heavily on a robust system of patent rights and a fair system for adjudicating their validity. Without the promise of effective and predictable patent rights, these investments would be far more difficult—if not impossible—to undertake. BIO members commonly devote a decade of effort and up to 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. 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. The manufacturer of a smartphone may take comfort in the fact that it is impossible to tear down the thousands of patents that protect its flagship product, but a biotech company literally faces the loss of its entire business if a few, or even potentially just one, of its key patents are invalidated. It is no wonder, then, that BIO's member companies are extremely sensitive to any unfairness or imbalance in the PTAB's proceedings. In developing new rules of practice for post-grant proceedings, the USPTO should attempt to make the proceedings more equitable to patent owners and closer to the original intent of Congress and the USPTO when the rules were first promulgated.

- **Claim Construction Standard and Amendments**

The Proposed Rule retains the broadest reasonable construction for claim interpretation in IPRs, Post-Grant Reviews (PGRs) and the Transitional Program for Covered Business Method Patents (CBMs), except where the patent will expire before the final written decision is issued. The proposed rule explains that the purpose for this exception is that "[s]uch patents essentially lack any viable opportunity to amend the claims in an AIA proceeding." 80 Fed. Reg. 50722. The proposed rule does not make any changes to the amendment process, but noted that it will follow the guidance presented in *Idle Free Sys., v. Bergstrom, Inc.,* IPR2012-00027 (June 11, 2013) as clarified by M*asterImage 3D, Inc. v. RealD, Inc.*, IPR2015-00040 (June 15, 2015)(referred to herein as the "*Idle Free* Rule"). *See* 80 Fed. Reg. 50722-50725.

BIO strongly recommends that the USPTO use the same claim construction standard for all patents in these proceedings and that the claims should be given their ordinary meaning to a person of ordinary skill in the art. *See Phillips v. AWH Corp.*, 415 F. 3d 130 (Fed. Cir. 2015) . In addition, BIO recommends that claim amendments be allowed more reasonably and as provided for in the regulations currently in force.

The post-grant proceedings were intended to be an administrative alternative to district court litigation. The proceedings provide for an administrative trial on patentability/validity. Because the post-grant proceedings are an alternative to district court litigation, it follows that the district court claim construction standard should be used. Further, a remarkably large percentage of patents in IPR – over 80% – are or were involved in district court litigation, meaning that the same grounds for invalidating the same patent claims may be – indeed are being – litigated by the same parties at the same time, in two different places, both with appeals to the same reviewing appellate court. This raises a real question as to whether the USPTO should be using a

claim interpretation standard that is more conducive to a finding of invalidity than would be the case in district court, and creates a real risk of inconsistent outcomes.

Importantly, the House and Senate versions of the next round of patent legislation both include provisions requiring the use of the district court claim construction standard in post-grant proceedings. The House Bill that has been reintroduced in the 114th Congress provides that claims shall be construed "as such claim would be in a civil action to invalidate a patent under 282(b), including construing each claim of the patent in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Innovation* Act, H.R. 3309, 113th Cong., 2d Sess; Section 9(c). *See also PATENT* Act, S. 1137, 114th Cong. (2015). Congress clearly recognizes a need to change the claim construction standard, reinforcing its original intent that IPR be a faster and cheaper alternative to district court litigation, not a systematically easier way to invalidate patents.

In addition, the rationale for using the broadest reasonable construction has been shown through Board practice not to be justified. The USPTO adopted the broadest reasonable construction standard because the patent owner was to be afforded an opportunity to amend claims similar to amendments allowed in an *ex parte* re-examination. This was the purported trade-off for the broadest reasonable claim construction standard. *See* 80 Fed. Reg. 50721-50722 (August 20, 2015) ("[T]he 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."); Office Patent Trial Practice Guide, 77 Fed. Reg. 48755, 48764 (August 14, 2012) ("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."). It was thought that the patent owner could amend the claims with more specificity and that this would be beneficial for the patent system and follow-on innovation because the scope of the claims would be more precise. But this has not proven true in practice; there is no meaningful ability to amend claims.

The original regulations regarding amendments only require: (1) support in the original written description, (2) the amendment is a narrowing amendment, and (3) the amendment relates to a ground upon which the trial was instituted. 37 CFR § 42.121. Yet, a panel of Board judges imposed new requirements in *Idle Free Sys., v. Bergstrom,* IPR2012-00027 (June 11, 2013). Although the requirements were clarified in *Masterimage 3D, Inc. v. Reald, Inc.*, IPR2015-00040 (June 15, 2015), the issue remains whether any of these new requirements were properly imposed on patent owners.

The new *Idle Free* requirements may violate the Administrative Procedure Act (APA) because (1) a Patent Trial and Appeal Board ("PTAB") panel cannot amend 37 CFR § 42.121 by imposing the additional requirements in the *Idle Free* decision; and (2) the PTAB improperly placed the burden of proof on patent owners to prove patentability where the AIA statute clearly states that the petitioner has the burden to prove unpatentability. *See* 35 USC §§ 316(e), 326(e); AIA § 18.

In doing so, the PTAB reinterpreted a definitive regulation issued by the USPTO Director that established the requirements for a motion to amend. This is improper because "[w]hen an agency has given its regulation a definitive interpretation, and later significantly revises that interpretation, the agency has in effect amended its rule, something it may not accomplish without notice and comment." *Alaska Prof'l Hunters Ass'n v. FAA,* 177 F.3d 1030, 1034 (D.C.Cir.1999). As the Supreme Court has noted, APA rulemaking is required if an interpretation "adopt[s] a new position inconsistent with . . . existing regulations." *Shalala v. Guernsey Mem'l Hosp.,* 514 U.S. 87, 100, 115 S.Ct. 1232, 131 L.Ed.2d 106 (1995). A PTAB panel cannot amend USPTO regulations at least where the decision is not precedential. This proposed rulemaking apparently tries to cure that problem without modifying the regulation by expressly adopting the *Idle Free* Rule.

In essence, the *Idle Free* Rule expands the basis for the PTAB to facially reject a motion to amend without properly following notice and comment rulemaking. "For an administrative agency may not slip by the notice and comment rule-making requirements needed to amend a rule by merely adopting a *de facto* amendment to its regulation through adjudication." *Marseilles Land & Water Co. v. Fed. Energy Regulatory Comm'n*, 345 F.3d 916, 920 (D.C. Cir. 2003). The same violation exists here.

The *Idle Free* Rule creates an obligation on patent owners that is not a reasonable interpretation of Rule 42.121 because it requires them to address all known prior art and describe the patentability of the claims over that art. Rule 42.121 enumerates the requirements of a motion to amend, and this is not one of them. *See Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1549 (Fed. Cir. 1996) (interpretation of regulation that contradicts statute or regulation is unreasonable) (citing *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.,* 467 U.S. 837, 842-45 (1984)).

The *Idle Free* Rule also shifts the burden of proving patentability to the patent owner, which is improper. In *Idle Free*, the PTAB premised its reasoning that a patent owner must show patentability "over prior art not of record but known to the patent owner" on 37 C.F.R. § 42.20(c). That rule states: "*Burden of proof.* The moving party has the burden of proof to establish that it is entitled to the requested relief." The PTAB's interpretation of the rule is arbitrary and capricious because it is in conflict with the AIA. The AIA expressly states: "In an inter partes review instituted under this chapter, **the petitioner shall have the burden of proving a proposition of unpatentability** by a preponderance of the evidence." § 316(e). *See also* § 326(e); AIA § 18. Nowhere in the statute does the burden shift to the patent owner to prove patentability. Thus, the PTAB's interpretation is clearly at odds with the statute and Congressional intent. *See, e.g.*, *Fed. Express Corp. v. Holowecki*, 552 U.S. 389, 401–02 (2008) (rejecting an interpretation of a regulation because it would be in "tension with the structure and purposes" of the authorizing statute); *Tafas v. Doll*, 559 F.3d 1335, 1359 (Fed. Cir. 2008) (quoting *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.,* 467 U.S. 837, 842-43 (1984) ("If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.")).

There are additional reasons why the PTAB's burden of proof standard is wrong. *First*, while the Federal Circuit has suggested that adjudicated cases may serve as a vehicle for forming

agency policies and for deciding open issues of law, *Animal Legal Defense Fund v. Quigg*, 932 F.2d 920, 929 (Fed. Cir. 1991), the PTAB's decision is neither appropriate policy nor a legal decision. Rather, its burden shift is a substantive change in the law, which the PTAB clearly cannot do. *See, e.g.*, *Tafas v. Doll*, 559 F.3d 1345, 1353 (Fed. Cir. 2009) (gathering cases holding USPTO has no substantive rulemaking authority).

Second, placing the burden of proof on the patent owner also is inconsistent with the rules governing post-grant proceedings and traditional examination of patents. Although Rule 42.20 generally places the burden of proving the relief requested in a motion on the movant, the Director has provided through Rule 42.121 what the movant (i.e., patent owner) must prove in a motion to amend. Rule 42.121 says nothing about the patent owner proving patentability, and it properly does not because the initial burden of proof is traditionally on an examiner to prove unpatentability. *Tafas*, 559 F.3d at 1364. In that regard, as the patent challenger is essentially stepping into the shoes of an examiner, the burden is properly on the petitioner.

- **Representations to the Board**

The proposed rule amends the rules dealing with the duty of candor to provide for a Rule 11-type certification for all papers filed with the Board. One of the requirements is that the petitioner's representative must certify that the petition "is not being presented for any improper purpose, such as to harass, cause unnecessary delay, or needlessly increase the cost of the proceeding."

BIO does not oppose this requirement, but recommends that it provide as an example of improper purpose the filing of a petition for the purpose of affecting the price of a patent owner's stock or other securities. Such a filing is not being made to improve the quality of patents, as the challenger has no interest in whether the patent is actually determined to be valid or invalid. To accomplish this change, BIO requests that the following parenthetical be inserted after the word "harass": "(including for the preliminary purpose of affecting the price of patent owner's stock or other securities)."

In order for the USPTO and the parties to have some basis to determine the accuracy of the certification and to provide the USPTO with additional data on the uses of post-grant proceedings, BIO recommends that the mandatory disclosures provided for in 37 C.F.R. § 42.8 be expanded. The additional representations regarding the purpose for filing a petition cannot be enforced unless the petitioner is required to disclose the underlying circumstances. Furthermore, some additional disclosure will assist the USPTO in managing the trials more effectively and gathering data to analyze the circumstances surrounding the filing of petitions. The USPTO has the legal authority to require these additional disclosures. As courts have previously recognized, the USPTO has the authority to promulgate regulations that "shall govern the conduct of proceedings in the Office." *Star Fruits S.N.C. v. U.S.*, 393 F.3d 1277, 1282 (Fed. Cir. 2005) (quoting 35 U.S.C. 2(b)(2)); *see also Cooper Techs Co. v. Dudas*, 536 F.3d 1330, 1335 (Fed. Cir. 2008); ("To comply with Section 2(b)(2)(A), a Patent Office rule must be 'procedural' – *i.e.*, it must 'govern the conduct of proceedings in the Office.'"). Pursuant to this authority, the USPTO may require the submission of information that is reasonably necessary to proceedings before it or the treatment of the matter at hand, provided that such requests are not arbitrary or capricious. *See Star Fruit*, 393 F.3d at 1283-84.

To this end, BIO recommends that the rules be amended to require the petitioner to disclose (1) whether the petitioner or real-party-in-interest (RPI) has been accused of infringement of the patent by the patent owner, (2) whether the petitioner or RPI owns stock or other securities of the patent owner, or any financial position that could be affected by a change in the price of such stock or securities, and (3) in instances where the petitioner or RPI has previously filed a petition against the same patent and such previous petition was denied institution, an explanation why the grounds in the renewed petition could not have been presented earlier.

This is a procedural rule and the USPTO has authority to request this information. Without this information, it will be nearly impossible to determine whether the certification is justified and whether the post-grant proceedings are being used for purposes other than patent quality.

- **Disputed Material Facts Pre-Institution**

The proposed rule amends the regulations to provide that evidence concerning disputed material facts will be viewed in the light most favorable to the petitioner for purposes of deciding whether to institute.

BIO urges that this proposal not be adopted in the final rule. The rule is not a reasonable interpretation of the statute, and seems more substantive than procedural in nature. IPR may not be instituted unless the Director determines that the petition and patent owner response "shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." §314 (a). The standard is the same for PGR and CBM, except that the evidentiary burden is 'more likely than not.' §314 (a); AIA §18. The statute is written in such a manner that burden of proof is on the petitioner to show that the institution standard has been met, not the reverse. This proposal flips the burden on the patent owner to show that the evidentiary burden has not been met where evidence regarding material facts may be disputed. To be true to the words of the statute, material facts in dispute should be resolved in favor of the patent owner at both the pre- and post-institution stages. This proposal once again stacks the deck against patent owners. As discussed above, more than 70% of IPRs are instituted. This proposal will only work to increase that percentage.

Such burden shifting is not needed because the petitioner can file a motion to submit a pre-institution reply if the patent owner submits new testimonial evidence. If adopted, this proposal will place a greater financial and resource burden on patent owners who will now need to expend additional funds and effort to defend their patents at the trial stage. The petitioner should have – as the statute contemplates – the burden to clearly show, *without the benefit of any presumptions in its favor*, that a trial should be instituted, thereby saving the patent owner from having to defend the patent in a later trial.

- **Other Provisions**

BIO agrees with the amendments to allow the patent owner to submit new testimonial evidence with the preliminary response and to raise real party in interest issues at any time during the proceeding.

BIO appreciates the opportunity to provide these comments on the USPTO's proposed amendments, and we urge the USPTO to take this opportunity to re-balance the IPR system so that it no longer operates in a manner that is stacked against the interests of patent owners who must rely on their patents as a basis for massive investment in innovation.

Respectfully submitted,

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