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October 16, 2014

The Honorable Michelle K. Lee
Deputy Under Secretary of Commerce for Intellectual Property &
Deputy Director of the United States Patent and Trademark Office
600 Dulany Street
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ATTN: Scott R. Boalick, Vice Chief Administrative Patent Judge,
Patent Trial and Appeal Board

RE: Comments of Pfizer Inc. in Response to the USPTO Request for Comments on the "Trial Proceedings Under the America Invents Act Before the Patent Trial and Appeal Board" (Fed. Register Vol. 79, No. 36474, June 27, 2014)

Dear Vice Chief Judge Boalick:

Thank you for providing Pfizer Inc. with the opportunity to submit comments to the United States Patent & Trademark Office ("PTO") regarding the PTO's *Request for Comments on Trial Proceedings Under the America Invents Act Before the Patent Trial and Appeal Board* (Fed. Register Vol. 79, No. 36474, June 27, 2014). Pfizer Inc. ("Pfizer") is a premier research-based pharmaceutical company and employs just over 90,000 colleagues in 120 countries. We apply innovative science and commit significant resources to develop our medicines to meet patient needs. As one of the largest R&D pharmaceutical companies in the world, Pfizer is a significant patent owner with a patent portfolio that includes thousands of granted and pending U.S. patents. As a result, rules concerning the Trial Proceedings under the America Invents Act ("AIA trials") are of great importance to us.

Pfizer is supportive of the PTO's efforts to revisit the AIA administrative trial proceeding rules and trial practice guide, and provides the following comments to a selection of the questions presented by the PTO.

1. Under what circumstances, if any, should the Board decline to construe a claim in an unexpired patent in accordance with its broadest reasonable construction in light of the specification of the patent in which it appears?

All claims of an unexpired patent in an AIA trial should be interpreted in the same manner as claims in an Article III patent infringement litigation given that AIA trials are adjudicatory in nature. For reexamination proceedings of unexpired patents, the Federal Circuit has confirmed that the appropriate claim construction standard is the broadest reasonable interpretation in light of the specification of the patent ("BRI"). *See In re Yamamoto*, 740 F.2d 1569 (Fed. Cir. 1989). However, reexamination proceedings differ from AIA trials in the basic nature of the proceedings: reexamination proceedings get the benefit of full claim examination where claim amendments may be made as of right. In contrast, patent owners do not have the right to claim amendments in AIA trials as amendments are subject to motion practice, which as more fully explained in response to question 9, have been not permitted in practice.

Moreover, the use of BRI to construe a patent's claims prior to trial initiation is unprecedented given that claim amendments are not permitted prior to trial initiation. The *Yamamoto* Court distinguished reexamination and reissue proceedings from validity proceedings in a Federal District Court in that the patent owner may amend his claims in reexamination/reissue proceedings. *Yamamoto* at 1572. In AIA trials, claim amendments are not permitted prior to trial initiation under 37 C.F.R. §42.107(d), but the PTAB panel still construes the claims using BRI prior to trial initiation. Using BRI in claim construction prior to trial initiation is inconsistent with the Federal Circuit's reasoning for using BRI in claim construction in reexamination proceedings.

The PTO applies the *Phillips* claim construction standard in reexamination proceedings when claim amendments are not possible, such as in an expired patent. *See Ex parte Papst-Motoren*, 1 USPQ2d 1655 (BPAI 1986) (expanded panel decision). This claim construction standard has been applied by the PTAB in at least one AIA trial. *See Square, Inc. v. Carl Cooper*, IPR 2014-00157, Paper 17 (June 23, 2014). In fact, use of the *Phillips* claim construction standard is consistent with a fundamental tenet of patent law: "[a] patent shall be presumed valid." 35 U.S.C. §282(a). The Supreme Court reviewed §282 in *Microsoft Corp v. i4i Ltd. Partnership*, 131 S.Ct. 2238 (2011) finding that the presumption of validity is separate from "the standard of proof", which was not specifically recited in §282. In amending the patent laws under the AIA, Congress included the evidentiary standard of proof for AIA trials but they did not modify the presumption of validity codified in §282 or add a statutory provision concerning the presumption of validity for patents subject to an AIA trial. Consequently, as the presumption of validity is separate from the standard of proof, the claims of all patents in AIA trials should be construed using the *Phillips* claim construction standard to effectuate the presumption of validity ascribed to patents in §282.

9. Under what circumstances, if any, should a copending reexamination proceeding or reissue proceeding be stayed in favor of an AIA trial? If a stay is entered, under what circumstances should the stay be lifted?

Staying a copending *ex parte* reexamination or reissue proceeding is grossly unjust to patent owners given the legislative purposes of these proceedings. In particular, staying a reissue proceeding in favor of an AIA trial is unjust to the patent owner given that the reissue statute is remedial in nature for the correction of errors and is based on fundamental principles of equity and fairness, which "should be construed liberally." *Medrad, Inc. v. Tyco Healthcare Group LP*, 466 F.3d 1047, 1052 (Fed. Cir 2006). Similarly, staying an *ex parte* reexamination proceeding in favor of an AIA trial is an unjust result to the patent owner as all reexamination proceedings

must be given "special dispatch" under 35 U.S.C. §305. Due to this "special dispatch" status accorded by Congress, the Federal Circuit has held that the PTO does not have the statutory authority to stay a reexamination. *See Ethicon Inc. v. Quigg* 849 F.2d 1422 (Fed. Cir. 1988). Even though the *Ethicon* case pre-dates AIA trials, its holding is still valid today as the patent law amendments enacted with the AIA did not change this statutory description of reexamination proceedings as requiring "special dispatch".

From a practical perspective, while the rules permit claim amendments, the reality has been that only one claim amendment motion has been granted (partially) in an AIA trial and in that trial the U.S. Department of Agriculture was the patent owner and the motion was unopposed by the petitioner. *See International Flavors & Fragrances, Inc. v. U.S. Department of Agriculture,* IPR2013-00124, Paper 12 (May 20, 2014). Thus, in practice, AIA trials adjudicate the patent claims as granted while reexamination and reissue proceedings are generally focused on the examination of the patent claims as amended. Consequently, staying an *ex parte* reexamination or reissue proceeding while allowing an AIA trial to continue to conclusion may foreclose examination of claims that have been amended to address newly cited prior art, correct an error or otherwise address a validity issue that was not present or addressed during the original examination of the patent. Any stay of reissue or reexamination proceedings is contrary to the legislative purposes and is unjust to patent owners.

10. Under what circumstances, if any, should an AIA trial be stayed in favor of a copending reexamination proceeding or reissue proceeding? If a stay is entered, under what circumstances should the stay be lifted?

The PTO should promulgate a rule or rules requiring a stay of the consideration of any AIA trial petition for a patent with a copending reexamination or reissue proceeding in the interest of securing the just resolution of all related proceedings. Staying consideration of an AIA trial petition prior to trial initiation will not impact the PTO's deadlines and will be fair to patent owners by providing an opportunity to amend claims in light of newly cited art or to correct an error. The stay could be lifted upon issuance of the reissue patent or reexamination certificate. Creating a rule requiring a stay of the consideration of an AIA trial petition prior to trial initiation when there is a copending reexamination or reissue proceeding is in fact consistent with Congress' intent in providing broad procedural powers to the PTO to permit the PTO "to weed out marginal challenges and preserve the office's own resources". Patent Reform Act of 2011, S. 1041, 157th Cong. (2011).

11. Under what circumstances, if any, should a copending reexamination proceeding or reissue proceeding be consolidated with an AIA trial?

As a preliminary matter, little overlap exists between reexamination/reissue proceedings and AIA trials. It is therefore difficult to envision how a consolidated proceeding would satisfy the legislative purposes of all proceedings: to create a speedy, cost effective patent challenge mechanism (AIA trials), a fair and equitable proceeding to correct errors (reissue proceeding) and to revisit claims in light of newly discovered prior art (reexamination). Due to the minimal overlap between copending reexamination/reissue proceedings and AIA trials, consolidating these examinational proceedings with an AIA trial would likely substantially prejudice patent owners. If the PTO promulgates rules creating consolidated proceedings, the PTO should maintain the due process elements of reexaminations/reissues in the interest of creating a fair and equitable proceeding for patent owners.

13. Under what circumstances, if any, should a petition for an AIA trial be rejected because the same or substantially the same prior art or arguments previously were presented to the USPTO in a different petition for an AIA trial, in a reexamination proceeding or in a reissue proceeding?

The PTO should promulgate new rules for petitions that use the same or substantially the same prior art or arguments as previously presented in a different petition for an AIA trial for the same patent ("duplicative petitions") including a rule defining the considerations for duplicative petitions, such as the filing party's relationship to the real party in interest of the first filed petition. Serial petitions filed by the same real party in interest should not be permitted, similar to the *inter partes* reexamination rule, C.F.R. §1.907(a), which prohibited a third party requester or its privies from filing serial *inter partes* reexamination requests.

Consideration of duplicative petitions filed before the trial initiation decision on the first filed AIA trial petition for the patent could be stayed until after the trial initiation decision for the first petition. However, duplicative petitions filed after the joinder deadline under 37 C.F.R. §§42.122(b), 42.222(b) should be terminated at an early stage to conserve patent owner costs and PTO resources. Serial petitions filed outside of the permissible joinder timeframe circumvent the joinder provisions and are a form of patent owner harassment. As recognized by the Congressional Committee, quiet title to patent owners ensures continued investment of resources- the new post-grant proceedings under the AIA "are not to be used as tools for harassment or a means to prevent market entry through repeated litigation and administrative attacks on the validity of a patent. Doing so would frustrate the purpose of the section as providing quick and cost effective alternatives to litigation." H.R. Rep. No. 112-98, at 48 (2011).

Furthermore, multiple AIA trials could lead to inconsistent results from different PTAB panels. In accordance with the Standard Operating Procedure 2 of the Board, every routine decision of the PTAB is "binding law of the case." *See* Board SOP 2 (Revision 8) August 12, 2013, Section V(B). Although the PTAB has precedential decisions which are binding on all panels, routine decisions on patentability of the same patent claims using the same or substantially the same prior art or argument as previously presented in another AIA trial should be binding between panels as "binding law of the case" under the doctrine of horizontal *stare decisis*. Application of this doctrine would increase PTO efficiency and ensure consistent results.

17. What other changes can and should be made in AIA trial proceedings? For example, should changes be made to the Board's approach to instituting petitions, page limits, or request for rehearing practice?

A. Redundant grounds

The current PTAB practices regarding "Redundancy" and its relationship to estoppel raise many questions that adversely impact the predictability of the strength and the finality of decisions regarding pharmaceutical patents. Further, the use of "Redundancy" as a management tool by the PTAB appears to be evolving in an expansive manner resulting in unpredictability. For example, in *Oracle Corp. v. Clouding IP LLC,* (IPR2013-00075), Paper 8 (May 3, 2013), a

ground was granted as anticipated by a reference referred to as Schilit, but grounds were denied based on obviousness over references Schilit and Barrett. However, if anticipation is overcome for any reason there is no recourse with respect to the obviousness ground and, accordingly, "Redundancy" should not be applied where the grounds are in different statutory classes. Another exemplary scenario when "Redundancy" should not be decided is when a reference can be sworn around, since the petitioner can benefit from an alternate ground based on a different reference that cannot be sworn around.

The estoppel provisions do not fully clarify whether those grounds held as "Redundant" may be used in future challenges. Should estoppel not apply, the patent owner may face a series of successive IPR's regarding those "Redundant" grounds (as the PTAB selects limited grounds in successive IPR's). At a minimum, the mere potential for such actions casts a cloud of unpredictability on the patent asset. While this issue may eventually be decided by the courts (see also *Synopsys, Inc. v Lee et al Virginia Eastern Dist. Ct.*, 1:2014cv00674 (June 5, 2014)), the PTAB could adopt some measures that would begin to mitigate the issues raised above by limiting the ability of petitioners to take a "scatter shot" approach in filing IPR petitions.

For example, the PTAB could adopt rules limiting the number of grounds and also limit the number of IPR's from a petitioner regarding the same patent. A similar practice has been adopted in *inter partes* reexaminations under 37 C.F.R. 1.907(a). The PTAB could also adopt rules regarding redundancy that would be similar to the MPEP §806 guidelines regarding restriction practice.

B. Joinder Procedures

Although PTAB panels have the discretionary power to grant joinder of parties to an initiated AIA trial under 35 U.S.C. §§315(c), 325(c), the PTO should create procedural rules for joinder to create consistency between proceedings. One such rule would be to make the joining party a junior participant. This role of junior participant could allow the real party in interest for the first filed petition (original petition) to have primary control of the case. For example, the original petitioner would file "consolidated filings" with "separate filings" filed by the joined party of a limited nature as established in *Dell, Inc. v. Network-1 Security Solutions, Inc.*, IPR2013-00385, Paper 17 (July 29, 2013). As a further aspect of the junior party role, the junior party should have no basis to continue a terminated proceeding if the original petitioner and patent owner successfully settle the AIA trial and the motion to terminate is granted. This rule would bring consistency to the joinder procedure and would help to limit the participation of a joined party to the appropriate level given their limited contribution to the proceeding.

Due to the lack of an Article III standing requirement in *inter partes* review as well as the speed and minimal cost to filing or joining an initiated trial, the AIA trials have had the unintended consequence of creating a new business model for pressuring patent owners by uninterested parties: the PTAB troll. This new type of troll, which we are seeing even in the pharmaceutical industry, leverages an AIA trial petition for personal gain such as a settlement agreement or to manipulate the stock price of the patent owner's company by repackaging prior art and/or arguments from a previous proceeding or by filing a petition that is an essential duplication of a petition in an initiated trial and requesting joinder to the initiated trial. *See* http://www.patentspostgrant.com/the-rise-of-the-patent-damage-troll; http://patentlyo.com/hricik/2014/10/unintended-consequences-successful.html?utm_target/=feedburner&utm_medium=email&utm_campaign=Feed%3A+Pate

ntlyO+%28Dennis+Crouch%27s+Patently-O%29; http://interpartesreviewblog.com/iron-dome-launches-ipr-missiles-drama-intrigue-ipr-world/; http://www.ipnav.com/blog/ptab-trolls-going-after-patent-owners/. PTAB trolls, left unabated, will discourage settlements between patent owners and original petitioners and will increase the work load of the PTAB while not serving the public interest. Relegating joined parties to the role of junior participant will help minimize the impact of PTAB trolls.

C. Claim Amendment Practices from European Oppositions

The European Patent Office ("EPO"), after careful examination and grant of patent applications, conducts patent oppositions with a well-established practice of claim amendment procedures. Approximately one third of opposed European patents result in a maintained patent with amended claims and another third of opposed European patents are maintained with the original claims. *See Successful European Oppositions: Analysis for the Patent Information Professional*, World Patent Information, 35(2), p126 at 126 (June 2013). As a global R&D-based pharmaceutical organization, Pfizer has developed considerable expertise in handling EPO oppositions. As such, we would like to highlight certain differences between AIA trial and EPO Opposition claim amendment practices which could facilitate the claim amendment process of AIA trials.

One noticeable difference in European Oppositions is the first instance Opposition Division panel, which includes the primary Examiner who originally granted the subject European patent. This panel decides whether the original granted claims or proposed amended claims are valid. A similar system could be deployed in AIA trials such that claim amendment motion decisions could include a PTO Examiner from the technology center, preferably the examiner who originally granted the subject patent. Including PTO Examiners from the Examination Corps could add value to the PTAB panel in reviewing the invention and prior art background information especially during claim amendment review where the question turns to patentability of new claims in light of the prior art given the examiner's familiarity with the challenges and art in the technology area.

Another point of difference in EPO oppositions is in the process for reviewing the original granted claims of the main request, and the claim amendments proposed in auxiliary requests. The EPO Opposition Division reviews the main request claim set and then the proposed amended claim sets in the order indicated by the patent owner, only reviewing the broadest claim of each claim set until a claim is found to be patentable. Adopting a similar practice for claim amendment motions in AIA trials where the PTAB limits its review to the broadest claim of each of multiple submitted claim sets before reviewing the dependent claims from the claim set would conserve PTO resources while simultaneously permitting the patent owner to file multiple narrowing claims sets as fallback positions. This practice could benefit all parties by allowing narrow, valid claims that cover the most critical inventions to the innovative enterprise.

D. Precedential Opinions

The PTO should consider revising Standard Operating Procedure 2 (SOP 2) with respect to precedential opinions. Given the rising number of AIA trials and Administrative Patent Judges (APJs) in the Trial Division, there are thousands of board decisions and in excess of 100 combinations of APJs on PTAB panels. However, there is only one AIA trial precedential board decision to date. Increasing the number of precedential opinions will add greater consistency

between panels will help to provide more certainty to patent owners. SOP 2 should be modified to minimize road blocks to designating opinions as precedential.

E. Expanded panels

We request clarification on the procedure to obtain an expanded panel review, including what types of decisions are appropriate for an expanded panel review. Standard Operating Procedure 1 permits an expanded panel, but it is unclear whether this procedure applies to AIA trials given the preface statement that the procedure applies to certain panels "in appeals and interferences." However, expanded panels have written some decisions including the motion for joinder and trial institution decision in IPR2014-00508. Clarification on expanded panels would be helpful to AIA trial participants.

Pfizer appreciates the PTO's efforts in requesting public comments on these issues with AIA administrative trial proceeding rules and looks forward to working with the PTO further.

Sincerely,

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