



September 16, 2014

Via Email: TrialsRFC2014@uspto.gov

The Hon. Michelle K. Lee
Deputy Under Secretary of Commerce for Intellectual Property
Deputy Director of the United States Patent and Trademark Office
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

RE: [Docket No. PTO-P-2014-0031] Response to Request for Comments on Trial Proceedings Under the America Invents Act Before the Patent Trial and Appeal Board

Dear Deputy Director Lee:

On behalf of Hospira, Inc., I write in response to the United States Patent and Trademark Office's ("PTO") Request for Comments on Trial Proceedings Under the America Invents Acts Before the Patent Trial and Appeal Board ("Request"). Hospira thanks the PTO for the opportunity to provide its written comments to some of the topics and questions in the Request.

Hospira's Background

Hospira is a global specialty pharmaceutical and medication delivery company. It conducts operations throughout the world, including in the United States, Canada, Latin America and South America; Europe, the Middle East and Africa; and Asia, Japan and Australia. Hospira is the global leader in injectable pharmaceuticals, and it is one of the top global providers of medication management systems, such as infusion pumps, related software and services, dedicated administration sets, gravity administration sets, and other device products. In addition, Hospira maintains a market leadership position in biosimilars in Europe.

Hospira's Comments

CLAIM CONSTRUCTION STANDARD

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.

Hospira's Comments: Hospira advocates no changes to the current standard for construing claims in IPR proceedings.

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MOTIONS TO AMEND

2. What modifications, if any, should be made to the Board's practice regarding motions to amend?

Hospira's comments: Hospira advocates that no changes be made to the current standard. Some practitioners have suggested that the burden of providing an expert to prove validity of any proposed amended claims should be shifted from the Patent Owner to the Petitioner. If this shift were to be adopted, the Petitioner would have the burden of providing an expert to challenge the validity of the proposed amended claims. Hospira proactively notes that such an alternative should be rejected at least to the extent that it extends the statutory IPR timeline because the fixed timeline is one of the perceived benefits of the IPR framework.

Hospira's view is that the Patent Owner should bear the responsibility of justifying the scope of its amended claims, much like current practice during prosecution before the PTO. Proposed amendments in IPR proceedings only arise after the panel has determined that there is a "reasonable likelihood" that the challenged claims are invalid over the art cited in the Petition. If a Patent Owner elects to attempt to amend its claims in view of the prior art, it presumably has done so after analyzing the prior art and developing arguments supporting the more narrow claims. Requiring the Patent Owner to articulate its reasoning supporting patentability in the form of an expert declaration is not unreasonable.

PATENT OWNER PRELIMINARY RESPONSE

3. Should new testimonial evidence be permitted in a Patent Owner Preliminary Response? If new testimonial evidence is permitted, how can the Board meet the statutory deadline to determine whether to institute a proceeding while ensuring fair treatment of all parties?

Hospira's comments: No changes should be made to the current standard. The challenged patent has issued after a comprehensive examination by the PTO during which the Patent Owner had the opportunity to submit its best evidence of and arguments for patentability. However, should the PTO ultimately decide to modify the rules to allow the Patent Owner to submit new testimonial evidence, such evidence should be presented within the current time period for submitting the Preliminary Response.

OBVIOUSNESS

4. Under what circumstances should the Board permit discovery of evidence of non-obviousness held by the petitioner, for example, evidence of commercial success for a product of the petitioner? What limits should be placed on such discovery to ensure that the trial is completed by the statutory deadline?

Hospira's comments: "Additional discovery" should be limited to the "interests of justice" standard pursuant to the *Garmin* factors applied by the Board in past.

REAL PARTY IN INTEREST

5. Should a patent owner be able to raise a challenge regarding a real party in interest at any time during a trial?

Hospira's comments: Hospira opposes any change that would allow a Patent Owner to challenge the identity of a real party in interest *at any point* during a trial. The rules already require the Petitioner to identify the real party in interest at the outset of the IPR and provide that a Patent Owner may challenge the Petitioner's identification of a real party in interest before or with the filing of the Patent Owner's Preliminary Response. (IPR Final Rules, 77 Fed. Reg. 48680, 48685 (Aug. 14, 2012).) Allowing the Patent Owner to raise a challenge regarding the identity of the real party in interest at any later time during the trial

could delay the proceedings. Hospira submits that the focus of the IPR proceeding should remain the validity of the challenged patent claims. Any estoppel issues arising from the IPR would relate to subsequent litigation after a finding of patentability of the challenged claims. Therefore, the identity of the real party in interest can be adequately challenged in the course of that subsequent litigation.

ADDITIONAL DISCOVERY

6. Are the factors enumerated in the Board's decision in *Garmin v. Cuozzo*, IPR2012-00001, appropriate to consider in deciding whether to grant a request for additional discovery? What additional factors, if any, should be considered?

Hospira's comments: As an alternative to traditional district court litigation, one of the perceived benefits of IPR proceedings is limited discovery focusing on the validity of the challenged patent claims. The *Garmin* factors are consistent with these objectives and provide ample guidance to the Board to evaluate the Parties' requests for any additional discovery.

MULTIPLE PROCEEDINGS

7. How should multiple proceedings before the USPTO involving the same patent be coordinated? Multiple proceedings before the USPTO include, for example: (i) two or more separate AIA trials; (ii) an AIA trial and a reexamination proceeding; or (iii) an AIA trial and a reissue proceeding,

Hospira's comments: Hospira defers to the Board to exercise its discretion to decide on a case-by-case basis whether and how to coordinate multiple proceedings involving the same patent.

8. What factors should be considered in deciding whether to stay, transfer, consolidate, or terminate an additional proceeding involving the same patent after a petition for AIA trial has been filed?

Hospira's comments: Hospira defers to the Board to exercise its discretion to decide on a case-by-case basis whether and how to coordinate multiple proceedings involving the same patent.

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?

Hospira's comments: Hospira defers to the Board to exercise its discretion to decide on a case-by-case basis whether to stay a copending reexam or reissue proceeding.

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?

Hospira's comments: Hospira defers to the Board to exercise its discretion to decide on a case-by-case basis the circumstances for staying an AIA trial.

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

Hospira's comments: Hospira defers to the Board to exercise its discretion to decide on a case-by-case basis whether to consolidate a copending reexam or reissue proceeding.

12. How should consolidated proceedings be handled before the USPTO? Consolidated proceedings include, for example: (i) consolidated AIA trials; (ii) an AIA trial consolidated with a reexamination proceeding; or (iii) an AIA trial consolidated with a reissue proceeding.

Hospira's comments: Hospira defers to the Board to exercise its discretion to decide on a case-by-case basis how to handle consolidated proceedings.

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?

Hospira's comments: Hospira believes that later petitioners should not be foreclosed from pursuing arguments different in scope from arguments that may have been previously presented by an earlier petitioner, even where the prior art presented is the same or substantially the same. Therefore Hospira would oppose implementation of any rule which would result in the rejection of petitions for AIA trials based on the same or substantially the same prior art presented to the USPTO in a different petition for an AIA trial. Within this context, Hospira defers to the Board to exercise its discretion to determine the appropriate circumstances for rejecting a Petition.

EXTENSION OF 1-YEAR PERIOD TO ISSUE FINAL DETERMINATION

14. What circumstances should constitute a finding of good cause to extend the 1-year period for the Board to issue a final determination in an AIA trial?

Hospira's comments: Hospira defers to the Board to exercise its discretion to decide on a case-by-case basis what constitutes "good cause." Note that one of the most important benefits of IPR proceedings is the statutory requirement that a final, written decision will issue within one year from the decision to initiate an IPR trial. Therefore IPR proceedings, which allow for streamlined validity challenges to certain patents, should not be undermined by extending the deadline for issuing a final determination.

ORAL HEARING

15. Under what circumstances, if any, should live testimony be permitted at the oral hearing?

Hospira's comments: Hospira believes that live testimony is generally unnecessary, but that the Board should exercise its discretion to determine whether it is necessary in a particular instance. The Board should contemplate live testimony at the oral hearing where the credibility of a witness is called into question.

16. What changes, if any, should be made to the format of the oral hearing?

Hospira's comments: No changes should be made to the current procedures, which are designed to streamline the proceedings and keep the focus of the IPR on the evidence and arguments presented in the papers.


GENERAL

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?

Hospira's comments: Although outside the jurisdiction of the Board, Hospira takes this opportunity to suggest that either (a) a PTAB written decision nullifying the claims of a challenged patent, or (b) Federal Circuit affirmance of a PTAB decision nullifying the claims of a challenged patent should be confirmed as operating to trigger the failure-to-market forfeiture provisions under 21 U.S.C. § 355(j)(5)(D)(i)(I). Just as in an infringement action in a district court, the Patent Owner in an IPR proceeding would have had an opportunity to present all of its evidence supporting the validity of the claims. Therefore, the fact that the tribunal is PTAB, as opposed to a district court, should not make a material difference in applying the statutory provisions.

Finally, Hospira would like to address the topic of mandatory settlement discussions that was raised during a previous PTO roundtable session. Hospira opposes any requirement for mandatory settlement discussions to the extent they could impact the statutory timeline for conducting an IPR trial. There are various points along the timeline that may naturally lead the parties to explore settlement – notably after the Patent Owner's Response is filed or after the Petitioner's Reply to the Patent Owner's Response – that allow the parties the opportunity to assess the strength of presented arguments in view of the evidence.

Yours sincerely,



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