November 15, 2011

Via Email: <u>aia implementation@uspto.gov</u>

U.S. Patent and Trademark Office Mail Stop Comments—Patents Commissioner of Patents P.O. Box 1450 Alexandria, VA 22313-1450

Re: Abbott's AIA Implementation Comments on Discovery in Inter Partes Review and Post-Grant Review, Joinder/Consolidation of Multiple Proceedings, and the Threshold for Inter Partes Review and Post-Grant Review

Dear Sir or Madame:

Abbott Laboratories ("Abbott") respectfully requests that the United States Patent and Trademark Office ("PTO") consider the following comments in response to its request for comments on the implementation on the America Invents Act ("AIA"). Abbott agrees with and appreciates the PTO's decision to solicit comments on this new legislation in advance of rule making, and welcomes the opportunity to provide input on the implementation of the AIA. Abbott's specific comments at this time are below.

I. Discovery Rights and Obligations in Post-Grant Reviews and Inter Partes Reviews

In contrast to preexisting reexamination procedures, the AIA expressly provides for some discovery in both Post-Grant Reviews and Inter Partes Reviews ("the Reviews"). In formulating regulations regarding such discovery, the PTO should keep in mind that establishing broad discovery rights for the Reviews should be avoided for many reasons, including the following:

 Broad discovery rights are contrary to a primary goal of the Reviews. Congress intended the Reviews as speedy and efficient alternatives to protracted and expensive patent



litigation in federal courts. See H.R. Rep. No. 112-98, Part I at 45 (noting that Congress originally created the reexamination process "in the expectation that it would serve as an effective and efficient alternative to often costly and protracted district court litigation"). Every establishment of a discovery right or obligation in the Reviews moves such proceedings closer in form and substance to federal court patent litigation, lessening the ability of the Reviews to fulfill this goal.

• Broad discovery rights are not consistent with the "considerations" to which Congress stated the PTO should advert in rule making for the Reviews. Congress expressly stated that, in establishing regulations for the Reviews, the PTO should consider the effects of the regulations on the economy, the patent system and the ability of the Patent Office to complete these proceedings in the prescribed time period (generally one year). Statutory time limitations, staffing limitations and the possible harm to the economy if the Reviews were to become cumbersome, protracted and expensive (i.e. similar to federal court litigation), strongly indicate that discovery rights under the rules established by the PTO should prevent the Reviews from becoming too cumbersome, too slow, or too expensive.

The PTO should establish rules that balance the new ability to take discovery for parties to the Reviews with the need to avoid burdening the parties to the Reviews and the PTO with the time consuming trappings of federal court litigation. In doing this, the PTO must also acknowledge that Congress indicated that different discovery rules were appropriate for Post-Grant Review and Inter Partes Review. Specifically, Congress stated that possible discovery procedures for Post-Grant Reviews are "limited to evidence directly related to factual assertions advanced by either party in the proceeding," but did not expressly limit the forms of discovery allowed. In contrast, Congress more narrowly proscribed the boundaries of possible discovery rules for Inter Partes Reviews, stating that "such discovery shall be limited to (A) the deposition of witnesses submitting affidavits or declarations; and (B) what is otherwise necessary in the interest of justice."

In light of all of the above, Abbott offers the following for the PTO's consideration in rule making regarding discovery for the Reviews:

Post-Grant Review

- O Limited document production without authorization. Upon request of the opposing party, the petitioner and patent owner must each produce documents sufficient to establish factual assertions advanced in the parties' briefs, and any affidavit or declaration submitted by the parties. The requesting party must identify with particularity the factual assertions regarding which it seeks document production.
- Additional document requests require authorization. Because document production can be enormously time consuming, expensive and inefficient, the PTO

- should be leery of requiring anything beyond the document production described above. But if a party believes additional document production is required, the PTO should require parties to seek authorization for any such requests and require the parties to show good cause for such a request. The authorization request should identify the documents sought and explain how the documents are reasonably calculated to lead to admissible evidence on a ground of invalidity at issue. All parties should be limited to one such additional request, and the requesting party should compensate the producing party for the document production in advance of production at a reasonable rate per page of production (e.g. \$0.25).
- Party depositions. A party may file a petition seeking authorization to take a single deposition of the opposing party concerning specified factual assertions advanced by the opposing party. This deposition may be of an individual, or of an entity as provided in Federal Rule of Civil Procedure 30(b)(6). The petition shall set forth with particularity the topics of the proposed deposition. The deposition shall be limited to seven hours. The requesting party should be required to compensate the deponent for travel expenses (e.g. at the government mileage rate) and a reasonable and normal hourly rate. By allowing 30(b)(6) depositions, the PTO balances the need to allow discovery into factual assertions advanced by a party against the very real burden of multiple fact depositions of a party.
- O Third-Party depositions. A party may file a petition seeking authorization to depose an individual third-party who submits a declaration or affidavit. Any such deposition should be subject to the same requirements as delineated above under "Party depositions."
- No additional third-party discovery shall be permitted. For the PTO to maintain the
 efficiency of the review and meet the statutory deadlines imposed, no
 additional third-party discovery should be allowed.
- O No interrogatories or requests for admission shall be permitted. Use of these federal court discovery tools would add significant expense and delay to the Post-Grant Review process, as both drafting and responding are time-consuming and expensive. Additionally, use of these tools would require a mechanism for resolving disputes over the adequacy of responses. Such a mechanism would only further delay and frustrate the purpose of a review.
- Protection for production of confidential information. Given that it is highly probable that parties who choose to file Reviews will be marketplace competitors of patent owners, requiring parties to produce confidential information to establish an invalidity case in these proceedings should be limited. While a party may file a petition seeking discovery of confidential information, whether by document request or deposition, this petition must establish that

it is highly probable that the confidential information sought would materially change the outcome of at least one ground of invalidity at issue. Moreover, if the production of confidential information is permitted in these extraordinary circumstances, the PTO should establish stringent requirements regarding protecting the confidentiality of information produced in discovery. Before authorizing a request that seeks the production of confidential information, the PTO shall provide a protective order limiting its disclosure in a manner that would protect the producing party from harm. The language of this order should be consistent with any other protective order in place governing both parties (such as one in a concurrent litigation) and should include mechanisms to ensure that confidential information is not used for improper purposes. For example, the PTO should require that individuals affiliated with the requesting party who receive such information agree to not participate in prosecution of patent applications related to the subject matter of the confidential information.

Inter Partes Review

- Depositions. The AIA expressly allows the PTO to authorize depositions of witnesses submitting declarations or affidavits. Accordingly, a party may file a petition seeking authorization to take a deposition of any affiant or declarant. The petition shall set forth with particularity the topics of the proposed deposition. The deposition shall be limited to seven hours. The requesting party should be required to compensate the deponent for travel expenses (e.g. at the government mileage rate) and a reasonable and normal hourly rate. Consistent with Congress' intent, no other depositions (e.g. third party or 30(b)(6)) should be routinely allowed. Any requests for additional depositions should meet the standards for "additional discovery" discussed below.
- Additional discovery. Congress clearly intended discovery in Inter Partes
 Review to be very limited, with depositions of affiants and declarants the
 only routine form of discovery. Accordingly, any party seeking discovery
 beyond the depositions of affiants or declarants ("Additional Discovery")
 may file a petition explaining with particularity what Additional Discovery is
 needed and why the party believes that the interests of justice require the
 discovery. To the extent the Additional Discovery requested is in the form
 of a deposition, the same rules that apply to the depositions of affiants and
 declarants shall apply. To the extent the Additional Discovery requested is in
 the form of document requests, the parties should be limited to one such
 request, and the requesting party should compensate the producing party for
 the document production in advance of production at a reasonable rate per

page of production (e.g. \$0.25). Any other form of discovery (e.g. interrogatories or requests for admission) should not be permitted as these other forms of discovery are time-consuming, expensive and inefficient and would upset the balance Congress intended between allowing discovery in Inter Partes Reviews and creating efficient and relatively rapid vehicles for resolution of these disputes.

II. Joinder or Consolidation of Multiple Proceedings

Section 315 of the AIA allows the PTO to join multiple petitions for Inter Partes Review against the same patent, while section 325 similarly grants the PTO discretion to join multiple petitions for Post-Grant Review of the same patent. These provisions to join like review to like review are appropriate and may result in greater efficiencies in the Reviews, particularly if the PTO includes considerations of delay to the original review as a significant factor in whether or not to join reviews.

But Sections 315 and 325 additionally allow the PTO to consolidate an Inter Partes Review (section 315) or a Post-Grant Review (section 325) with "any other proceeding or matter" on the patent that is before the PTO. (The sections also allow the PTO to stay, transfer or terminate any such proceeding; Abbott has no comment on those provisions of the AIA.) A broad reading of the statute would allow the PTO to consolidate an Inter Partes Review or a Post-Grant Review with an Ex Parte Reexam, as long as they all were on the same patent. In the event the PTO determines that consolidation of an Inter Partes Review and an Ex Parte Reexam, or a Post-Grant Review and an Ex Parte Reexam, are appropriate, the PTO should establish rules that maintain the integrity of the distinct forms of post issuance reviews. For example, an Ex Parte Reexam Requestor should not be allowed to participate in or have access to discovery from the Post-Grant Review process, nor should any of the estoppel provisions relevant to the Post-Grant Review process be applied to the Ex Parte Reexam Requestor. Any such merger should be limited so that no party receives either procedural benefits or procedural limitations from the merger.

III. Thresholds for Initiating the Reviews

The AIA provides for different standards for initiating the Reviews. To initiate an Inter Partes Review, Section 314 requires that a petitioner show "that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." To initiate a Post-Grant Review, Section 324 requires a petitioner to "demonstrate that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable." In proposing rules to effectuate these two standards, the PTO should keep in mind that the clear Congressional intent (as well as established case law) is that these standards are different, and the "more likely than not" standard for Post-Grant Review is "a slightly higher threshold" than the reasonable likelihood standard of Inter

Partes Review. 157 Cong. Rec. S1360, S1375 (daily ed. March 8, 2011) (statement of Sen. Kyl). Congress chose this slightly higher threshold for Post-Grant Reviews "because some of the issues that can be raised in post-grant review, such as enablement and section 101 invention issues, may require development through discovery. The Office wants to ensure that petitioners raising such issues present a complete case at the outset, and are not relying on obtaining information in discovery in the post-grant review in order to satisfy their ultimate burden of showing invalidity by a preponderance of the evidence." *Id.*

Senator Kyl's statements underscore the concerns Abbott has raised in these comments, regarding limitations on discovery, and the need to keep different types of post patent issuance reviews separate. The statements also indicate that the rules promulgated by the PTO regarding the thresholds for the Reviews should make clear that the threshold for grant of a Post-Grant Review is higher than the threshold for grant of an Inter Partes Review.

Sincerely,

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