April 10, 2012

Via Email: <u>inter partes review@uspto.gov</u>

Mail Stop – Patent Board Director of the United States Patent and Trademark Office Attn: Lead Judge Michael Tierney, *Inter Partes* Review Proposed Rules P.O. Box 1450 Alexandria, VA 22313-1450

> Re: Abbott's Comments on the Proposed Rules Regarding Changes to Implement *Inter Partes* Review Proceedings

Dear Under Secretary Kappos:

Abbott Laboratories ("Abbott") respectfully asks that the United States Patent and Trademark Office ("PTO") consider the following comments on the PTO's proposed rules to implement *inter partes* review ("IPR") proceedings. Abbott's specific comments at this time are below.

I. The PTO should clarify proposed rule 42.102(b).

Proposed Rule 42.102(b) states that if the Director imposes limits on the number of IPR's that may be instituted in any of the first four one-year periods, "[p]etitions filed after an established limit has been reached will be deemed untimely." However, the proposed rule does not address what happens to a petition that has been deemed untimely. For example, if such a petition was timely filed under the American Invents Act ("AIA") but ran afoul of a limit on the number of IPR's in that calendar year, will a petitioner be allowed to refile the petition at the beginning of a new calendar year? Given that the relevant statutes in the AIA focus on timely *filing*¹ of petitions, Abbott asks that the PTO clarify that any petition "deemed untimely" under with this rule may be refiled within a reasonable time period of the subsequent calendar year, for example during the first month of the that calendar year. If the original filing was, in fact, timely under the AIA, then the refiled petition should be considered timely filed as well.

II. The rules should clarify that standing may be challenged at any time.

The proposed rules do not directly address the issue of whether a party may challenge standing at any time during an IPR proceeding. The proposed rules require a petitioner to certify that it has standing in its petition (42.104(a)) and the comments to rule 42.107(c) suggest that preinstitution discovery may be appropriate to challenge standing (77 FR 7046). It is unclear whether these comments and rules suggest that standing may only be challenged before the Board institutes

¹ See e.g., 35 U.S.C. §311(c) ("A petition for inter partes review *shall be filed* after the later of" nine months from patent grant or termination of a post-grant review); *id.* at §315(b) ("An inter partes review may not be instituted if the petition requesting the proceeding *is filed* more than 1 year" after petitioner is served with a complaint of infringement regarding the patent) (emphasis added).

an IPR proceeding. However, the AIA places clear limits on who may institute an IPR proceeding and on what grounds. If at any time in a proceeding it becomes evident that a petitioner has not satisfied, or no longer satisfies, those "standing" requirements, the proceeding should be terminated. Accordingly, the PTO should clarify that standing may be challenged at any time.

III. The PTO should clarify the difference between proposed rules 42.108(a) and 42.108(b).

These two subparts to proposed rule 41.208 appear to differentiate between the PTO's ability to "authorize" IPR proceedings on some or all grounds asserted and to "deny" some or all grounds asserted. However, the authorization of IPR proceedings on some grounds automatically results in the denial of IPR proceedings on the grounds not authorized. Thus, an "authorization" of only some grounds under proposed rule 42.108(a) inherently includes "denials" of some grounds, but the proposed rules list those denials separately under rule 42.108(b). Additionally, only denials made under rule 42.108(b) are identified as a "Board decision not to institute inter partes review." The PTO should clarify the effect of proposed rules 42.108(a) and 42.108(b) and resolve the inconsistencies or state why they are treated differently.

IV. The "default" time period of two months under proposed rule 42.120(b) should be the minimum time allowed for a response.

This proposed rules states that "[i]f no date for filing a patent owner response to a petition is provided in a Board order, the default date" is two months. The patent owner response addressed by this rule is a patent owner's first opportunity to fully address claims in a newly instituted IPR proceeding. Due to the importance of this response and the complexities of IPR proceedings, it may well turn out that the Board grants patent owners longer than two months for responses. However, there should be no uncertainty about the minimum time a patent owner will have to prepare this response. Accordingly, the PTO should make clear that the two month "default" time period represents the minimum time a patent owner will have to prepare a response under this rule.

V. The PTO should clarify how the requirement to "confer" with the Board before filing a first motion to amend will work under proposed rule 42.121(a).

Proposed rule 42.121(a) states that a patent owner may file one motion to amend "but only after conferring with the Board." The PTO's comments to this proposed rule say that the requirement to consult "reflects the Board's need to regulate the substitution of claims and the amendment of the patent to control unnecessary proliferation of issues and abuses." 77 FR 7046. However, the AIA expressly allows a patent owner to file one motion to amend as of right – that is, without permission from the Board. *Compare* 35 U.S.C. §316(d)(1) *with* 35 U.S.C. §316(d)(2). This rule suggests that a patent owner has a burden in relation to its first motion to amend, beyond what is expressly stated in the statute.² The PTO should clarify what that burden is and how a patent owner may meet it, or delete this requirement as contrary to the AIA.

² The AIA places only two limitations on a patent owner's ability to add new claims: (1) that for "each challenged claim" the patent owner proposes "a reasonable number of substitute claims;" and (2) that any amendment does "not enlarge the scope of the claims of the patent or introduce new matter." 35 U.S.C. $\S316(d)(1)$ & (3).

Abbott appreciates the opportunity to provide its perspective on the PTO's proposed rules to implement IPR proceedings.

Respectfully submitted,

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