NOVARTIS

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April 9, 2012

VIA E-MAIL ONLY
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Lead Judge Michael Tierney
Patent Trial Proposed Rules
U.S. Patent and Trademark Office
Mail Stop Comments—Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Re: Comments on Proposed Rules to Implement the AIA with regard to Trial Rules for the Patent Trial and Appeals Board (PTAB)

Dear Judge Tierney:

Novartis Corporation ("Novartis") respectfully requests that the United States Patent and Trademark Office ("Office") consider the following comments in response to the Office's Request for Comments on the Proposed Rules related to Trial Rules for the PTAB, which were published in the Federal Register on February 9, 2012. Novartis believes that the Office's interest in soliciting comments on the appropriate implementation of the America Invents Act is a meritorious and worthwhile endeavor, and wishes to assist the Office in developing its implementation rules and guidance by submitting these comments.

Proposed 37 C.F.R. § 42.51(b)(3)

The Office proposes 37 C.F.R. § 42.51(b)(3) specifying discovery rules for PTAB trials. The proposed rule requires that the parties to a trial file ". . . noncumulative information that is inconsistent with a position advanced by the patent owner or petitioner during the proceeding." The proposed rule requires the submitting party to submit this information without being requested to do so by the opposing party. The Office says, ". . . the proposed rule makes the production of such information routine," and claims that this information would typically be provided in response to an opponent's discovery requests, so

requiring submission would expedite the proceeding by eliminating the need for a discovery request. (Federal Register 77, February 9, 2012, p. 6887).

The phrase ". . . noncumulative information that is inconsistent with a position . . ." mirrors the language in 37 C.F.R. § 1.56 describing the materiality standard for the duty to disclose. The Office announced last year (Federal Register 76, July 21, 2011, p. 43631) that it would revise this language in § 1.56, to update the rule as a result of the *en banc* Federal Circuit decision in *Therasense, Inc. v. Becton, Dickinson & Co.* Despite that announcement, the Office uses the "old" language from § 1.56 in the new 37 C.F.R. § 42.51(b)(3). Does the Office intend to have one standard for disclosure under § 1.56 and a separate, pre-*Therasense* standard, for disclosure before the PTAB? If yes, this invites the problems of pre-*Therasense* times to the PTAB proceedings. If not, the Office is urged to update the language in the proposed rule to clarify the standard for disclosure in PTAB proceedings.

Novartis believes submission of information in PTAB proceedings should be governed by the standards applicable to the Duty of Candor in § 1.56. Discovery extending beyond that should only occur in response to an opposing party's credible and specific motion for discovery. The Office should also clarify whether information in the original file history of the patent at issue needs to be filed within the PTAB proceeding; Novartis believes information in the file history is already accessible and should not need to be resubmitted.

As currently written, the rule also requires the submitter of information to characterize the content of submitted documents. The proposed rule states that, "[t]he party submitting the information must specify the relevance of the information, including where the information is presented in a document and, where applicable, how the information is pertinent to the claims." This exceeds the scope of a reply to a discovery request. Documents turned over in response to a discovery request would be provided with no characterization or explanation. This requirement also invites time wasted on challenges to the sufficiency of the submitting party's characterization. Even the pre-*Therasense* version of § 1.56(b)(2) did not require characterization of documents submitted to the USPTO.

Novartis believes the PTAB should not impose on the parties an obligation to characterize information filed under this rule. A petitioner (the party initiating a PTAB proceeding) should be expected to make its own case, not given a free fishing expedition, and the patentee should not be required to make the petitioner's case for invalidity. The Federal Register said requiring the submitting party to explain the reference or information would keep the Board from having to "play archeologist with the record" (Federal Register 77, February 9, 2012, p. 6888). That concern is misplaced, though: the burden of identifying relevant portions of documents lies with the parties, not the Board.

Proposed 37 C.F.R. § 42.73(d)(3)(ii)

The Office proposes 37 C.F.R. § 42.73(d) which sets forth estoppel provisions that result from a PTAB judgment. Proposed rule 37 C.F.R. § 42.73(d)(3)(ii) states that a patent owner or applicant whose claim is canceled as part of an adverse PTAB judgment, is precluded from "obtaining in any patent . . . [a] claim that could have been filed in response to any properly raised ground of unpatentability for a finally refused or cancelled claim . . ." during the PTAB trial proceeding.

The phrase ". . . could have been filed. . ." is extremely broad, very susceptible to interpretation, and inappropriately limits a patent owner's/applicant's future rights. Under the proposed rule, a PTAB judgment canceling a claim would preclude future issuance of a claim with a much narrower scope, even a claim having 10 or more additional limitations, for example. A judgment canceling a genus claim would appear to preclude later issuance of a claim to a species within that genus—apparently even if other generic claims encompassing the later species claim were allowed. During a trial before the PTAB, there may have been factual, procedural and/or strategic reasons that prevented such narrower claims from being entered into the proceedings. Yet, the proposed rule would prevent later issuance of the narrower claim on procedural grounds, regardless of its inherent patentability, possibly under circumstances much different than those prevailing at the time of the trial.

Magnifying the broad scope of this estoppel to the patent owner/applicant is the provision in the proposed rule that all claims that "could have been filed" are precluded ". . . in any patent . . . ." "In any patent" seemingly encompasses continuation, divisional and continuation-in-part applications, as well as claims arising out of reissue and reexamination proceedings or even applications in a family different than the patent involved in the PTAB proceeding. "Any patent," therefore, could also preclude claims in patents that have different specifications or inventors than the patent at issue in the PTAB trial.

Novartis urges the Office to eliminate part (d)(3)(ii) of § 42.73. Rule 42.73(d)(3)(i), which prevents patent owners/applicants from obtaining a claim ". . . to substantially the same invention . . ." as a claim canceled in a PTAB trial, already provides significant estoppel safeguards to the Office. Alternatively, the terms "could have been filed" and "in any patent" in the proposed rule should be modified to be less expansive, less susceptible to later interpretation, and less limiting to patent owner's/applicant's rights to obtain later claims.

Respectfully submitted,

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