

April 9, 2012

**VIA E-MAIL ONLY**[post\\_grant\\_review@uspto.gov](mailto:post_grant_review@uspto.gov)

Lead Judge Michael Tierney,  
Post-Grant Review 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  
Post-Grant Review

Dear Judge Tierney:

Novartis Corporation (“Novartis”) respectfully requests that the United States Patent and Trademark Office (“Office”) consider the following comments in response to its Request for Comments on the Proposed Rules related to Post-Grant Review (PGR), which were published in the Federal Register on February 10, 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.

**Grounds for Initiating Post-Grant Review**

The Office proposes to add new section 37 C.F.R. (hereinafter “Rule” or “Rules”) § 42.208 concerning the grounds for initiating a PGR proceeding. In brief, proposed Rule 42.208(a) stipulates that the Board may “authorize the review to proceed on all or some of the challenged claims and on all or some of the grounds of unpatentability asserted for each claim.” Proposed Rule 42.208(b) states that prior to instituting PGR, the Board “may deny some or all grounds for unpatentability for some or all of the challenged claims.” Lastly, proposed Rule 42.208(c) states that PGR will not be granted “for a ground of unpatentability, unless the Board decides

that the petition supporting the ground would, if un rebutted, demonstrate that it is more likely than not that at least one of the claims challenged in the petition is unpatentable.” Thus, the proposed Rule 42.208 provides that PGR may be instituted on a claim-by-claim or ground-by-ground basis. Novartis believes the proposed rulemaking is inconsistent with the plain language of the AIA provision codified at 35 U.S.C. § 324.

Section 324, relating to the institution of PGR, provides:

The Director may not authorize a post-grant review to be instituted unless the Director determines that the information presented in the petition . . . if such information is not rebutted, would demonstrate that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable.

The statutory language of § 324 is plain on its face: PGR will not be instituted unless it is more likely than not that at least one of the challenged claims is unpatentable. The proposed Rules, however, have modified the statutory text to require an evaluation of whether to institute PGR on a ‘ground-by-ground’ basis (“Post-grant review shall not be instituted for a ground of unpatentability”) or a ‘claim-by-claim’ basis (“the Board may authorize the review to proceed on all or some of the challenged claims”). While 35 U.S.C. § 326 does state that the “Director shall prescribe regulations . . . setting forth the standards for the showing of sufficient grounds to institute a review under subsections (a) and (b) of section 324,” Novartis believes that this does not give the Office such broad rule-making authority so as to evaluate whether to institute PGR on a claim-by-claim and ground-by-ground basis. While the Director is authorized by § 326 to set standards for this showing, the required showing does not change: if a petitioner can meet the ‘more likely than not’ standard for at least one claim, then the request for PGR should be granted. The proposed Rule has, in essence, raised the standard to require that each ground and each claim must be assessed before PGR is initiated, while the threshold in the statute only requires one claim to appear unpatentable. Implementation of the proposed Rule may unduly burden a petitioner and is beyond the rulemaking authority granted to the Office.

Accordingly, Novartis suggests that the Office modify proposed Rule 42.208 to conform to the statutory language of 35 U.S.C. § 324 such that PGR will be instituted if it is more likely than not that at least one challenged claim would be found unpatentable. Proposed Rule 42.208(a)-(c) could be amended as follows:

~~(a) When instituting post-grant review, the Board may authorize the review to proceed on all or some of the challenged claims and on all or some of the grounds of unpatentability asserted for each claim.~~

~~(b) At any time prior to institution of post-grant review, the Board may deny some or all grounds for unpatentability for some or all of the challenged claims. Denial of a ground is Board decision not to institute post-grant review on that ground.~~

~~(c) Sufficient grounds. Post-grant review shall not be instituted for a ground of unpatentability, unless the Board decides that the petition supporting the ground would, if unrebutted, demonstrate that it is more likely than not that at least one of the claims challenged in the petition is unpatentable. The Board's decision will take into account a preliminary patent owner response where such a response is filed.~~

~~(b) Additional grounds. Sufficient grounds under § 42.208(c) may be a showing that the petition raises a novel or unsettled legal question that is important to other patents or patent applications.~~

### Granting of a PGR Filing Date

The Office proposes to add new Rule 42.206 relating to the granting of a filing date to a petition for PGR. The proposed Rule provides that a filing date will not be given to a petition for PGR unless “the petition satisfies” several criteria (i.e., complies with the requirements of § 42.204 (grounds for standing, service, and identification of the challenge), respondent has not been properly served, or the fee was not included). Rule 42.206(b) provides that in the event of an incomplete petition, the Office will permit correction of the

petition within the earlier of one month from the notice of the incomplete petition or the time remaining in the statutory deadline for filing PGR.

Because the proposed Rule hinges on the ambiguous term “satisfies,” there is the potential for petitioners to miss the opportunity to be granted a filing date for a petition filed close to the statutory deadline. It is unclear from the proposed Rule whether the term “satisfies” means that the elements of Rule 42.206 (including the elements of rule 42.204) are merely present in the petition, or whether they are present in the petition and the Office agrees with the sufficiency of, for example, the grounds for standing and the identification of the challenge (which includes the assertion of a claim construction, statutory basis for invalidity, and correctly identified and marked exhibits). If a petition is filed at or close to the statutory filing deadline, a ‘present and sufficient’ standard would create a high likelihood that a number of petitions would not be granted; should a filing date not be granted by the statutory deadline, the possibility of instituting PGR would be lost. Thus, the goal of improving patent quality through the PGR process would be undercut by an unreasonably strict application of the filing date requirements.

Furthermore, it is not clear why the Office will not grant a filing date for a PGR request even if the request is imperfect, as there is no such mandate in 35 USC § 325(c) for this. Novartis suggests that the Office should instead grant a filing date where only minor deficiencies are present, just as a patent application is accorded a filing date, even though, for example, an incomplete oath is presented. The Office could then provide an opportunity to correct any defects, e.g., a one-month non-extendable deadline, in order to retain the original filing date. It is not anticipated that there will be vast numbers of PGR proceedings filed at the Office each year, and giving the requester a short time to correct defects should not be a burden or unduly slow the proceedings. Novartis respectfully submits that the purpose of the PGR statute would be better served if the Office allows petitioners some leeway when bringing such a case to the Office for consideration.

As an alternative, Novartis suggests that the Office clarify the language of Rule 42.206 to provide that a filing date will be accorded a petition for PGR as long as all the elements of Rule 42.206 (including the elements of rule 42.204) are present in the petition. A challenge by the Office to the sufficiency of an element of the petition, such as a proposed claim construction, should not preclude the granting of a filing date for the petition provided that the petitioner made a good-faith effort to satisfy the requirements of Rule 42.206 (including the elements of rule 42.204).

Respectfully submitted,



Betty Ryberg