

April 9, 2012

VIA E-MAIL ONLYinter_partes_review@uspto.gov

Lead Judge Michael Tierney
Inter Partes 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
Inter Partes 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 Inter Partes Review (IPR), 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 these implementation rules and guidance by submitting these comments.

Proposed Rule 42.107(c) provides that a preliminary patent owner response shall not be accompanied by new testimonial evidence. The Office notes that 35 U.S.C. § 316(A)(8), which relates to patent owner responses filed after IPR is granted, expressly requires the submission of evidence. The Office contrasts this with 35 U.S.C. § 313, which relates to patent owner responses filed before IPR is granted, and which has no express requirement for submitting new evidence. Novartis agrees that there is a distinction in the language of 35 USC § 316 and 35 USC § 313, and a patent owner is not

required to submit evidence with a preliminary patent owner response. But 35 U.S.C. § 313 does not prohibit a proprietor from submitting evidence with a preliminary patent owner response. It is quite valuable to allow submission of testimonial evidence immediately to the Office for consideration as to whether an IPR should even be granted. Furthermore, it will be more expedient to have as much evidence considered as early as possible in order to speed up the IPR proceeding. Accordingly, Novartis respectfully requests that the Office revise this rule to allow the patent owner to submit testimonial evidence in a preliminary patent owner response.

Proposed Rule 42.107(e) allows the patent owner to disclaim individual claims and states that no IPR will be instituted based on disclaimed claims. This proposed rule indicates that the Office appreciates the efficiencies gained in being able to dispose of IPR requests at the preliminary response stage. Novartis believes that similar efficiencies would be gained by permitting claim amendments in the preliminary patent owner response. However, proposed Rule 42.107(d) provides that a preliminary patent owner response shall not be accompanied by claim amendments. As would be the case for a disclaimed claim, an amended claim could mean the Board does not have to grant an IPR, or it may significantly reduce issues for the proceeding: at least in some instances, the IPR could be denied and a certificate of correction issued. Accordingly, the Office should revise the rule to allow the patent owner to amend claims in a preliminary patent owner response.

Proposed Rule 42.121(a) indicates that the first motion to amend may be filed following conference with the Board, and subsequent motions to amend would require Board approval.¹ But this rule is unclear as to whether claim amendments must be presented as one-amended-claim-per-one-original-claim, or whether the patentee can submit additional claims. The statute, 35 U.S.C. § 316(d)(B), allows for presentation of a “reasonable number of substitute claims” during an IPR, but this is not directly addressed in the IPR rules.

¹ We assume that the requirement to “confer” with the board is subsumed in the Scheduling Order that will be issued by the Patent Trial and Appeal Board concurrently with a decision to institute the proceeding. If this is incorrect, and some type of additional conference is required in order to file the first motion to amend, we request the Office to clarify this point.

The Practice Guide for Proposed Trial Rules states on page 6875:

The number of substitute claims must be “reasonable.” There is a general presumption that only one substitute claim would be needed to replace each challenged claim. This presumption may be rebutted by a demonstration of need. The presumption balances the one-year timeline for final decision against the patent owner’s need to appropriately define the invention.

Novartis does not believe that this apparent interpretation, i.e., a burdensome presumption that the patentee is limited to one amended claim per original claim, is the appropriate interpretation of a “reasonable number of substitute claims” as allowed by 35 U.S.C. § 316(d)(B). In our view, a “reasonable number of substitute claims” should be interpreted to mean a reasonable number of claims given the particular case at hand, e.g., taking into consideration the number of original patent claims, the complexity of the subject matter, the timing of submission of the amendment, etc. A rule that requires rebuttal of a presumption that no new claims can be added each time a patent owner would add a claim, and adjudication of the sufficiency of such rebuttals, would add inefficiency.

In addition, Novartis proposes the Office should consider allowing the patentee to present alternative claim sets, like the main and auxiliary requests that are permitted in oppositions and oral proceedings at the European Patent Office. By allowing the patentee to present alternative requests in a single stage, the EPO proceedings are often concluded quickly and efficiently. Novartis believes this option could expedite IPR proceedings by allowing consideration of more than one option for resolving the proceedings in a single stage.

Respectfully submitted,



Betty Ryberg