

March 5, 2012

VIA E-MAIL ONLY

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U.S. Patent and Trademark Office
Mail Stop Comments—Patents
Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Attn: Kenneth M. Schor, Senior Legal Advisor

Re: Novartis' Comments on Proposed Rules to Implement the AIA with
Regard To Submission of Patent Owner Statements

To Whom It May Concern:

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 published in the Federal Register on January 5, 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.

Patent Owner’s Statements “Made” Versus “Filed” in a Federal Court or the Office

The Office proposes to rewrite 37 C.F.R. § 1.501 (Citation of Prior Art and Written Statements) to reflect the AIA’s amendments to 35 U.S.C. § 301, concerning the type of information that may be submitted to the Office and added to the file of an issued patent. Amended Section 301 will permit any person at any time to submit not only written prior art (as in the past), but also “statements of the patent owner filed in a proceeding before a Federal Court or the Office in which the patent owner took a position on the scope of any claim of a particular patent.” AIA, § 6(g)(1); 35 U.S.C. 301(a)(2) (as amended). Novartis fully supports the Office’s efforts to rewrite the Rules to conform to the amended statute. In the case of § 1.501, however, the Office’s proposed rule includes substantive restrictions on the submission of written

statements that appear inconsistent with the statute, and would not accomplish what Congress intended.

Specifically, the Office proposes to include in the rule a restriction that “submission of a statement of the patent owner made outside of a Federal Court or Office proceeding and later filed for inclusion in a Federal Court or Office proceeding is not permitted by this section, and such a submission will not be entered into the patent file.” (Proposed 37 C.F.R. § 1.501(a)(2)). As set forth above, Section 301(a)(2) contains no such restriction, instead affirmatively and broadly permits the submission of any “statement[] of the patent owner **filed** in a proceeding before a Federal Court or the Office in which the patent owner took a position on the scope of any claim of a particular patent.” AIA, § 6(g)(1); 35 U.S.C. 301(a)(2) (as amended) (emphasis added). Congress’s use of the term “filed” clearly indicates an intent to permit the submission of written statements **filed** in a Federal Court or Office proceeding, irrespective of whether the statement was actually *made* during the proceeding, or was made in another forum or at another time and subsequently filed in a Federal Court or Office proceeding. Had Congress intended to restrict such statements to those “made” in a Federal Court or Office proceeding, it would have used the term “made” instead of “filed.” Section (b) of the amended statute further indicates a broad scope, providing that as long as the person citing the filed written statement explains its pertinence to at least one claim of the patent, the “written statement[] and the explanation thereof **shall** become a part of the official file of the patent.” *Id.* at § 301(b) (as amended) (emphasis added). The proposed rule restricting such statements to those actually “made” in a Federal Court or Office proceeding, and further providing that statements made elsewhere “will not be entered into the patent file” even after they have been filed with a Federal Court or Office is inconsistent with the letter and intent of the new statute.

To support its proposed restriction, the Office cites H.R. Rep. No. 112–98, Part 1, at page 46 (2011) (“[t]his addition will counteract the ability of patent owners to offer differing interpretations of prior art in different proceedings”). This excerpt from the House Report, however, plainly refers to the overall intent of the new

statute, namely counteracting a patent owner's ability to offer one claim interpretation in a first Federal Court or Office proceeding, and a differing interpretation later in an Office proceeding "ordered or instituted pursuant to section 304, 314, or 324." *See* § 301(d) (as amended) ("A written statement submitted pursuant to subsection (a)(2), and additional information submitted pursuant to subsection (c), shall not be considered by the Office for any purpose other than to determine the proper meaning of a patent claim in a proceeding that is ordered or instituted pursuant to section 304, 314, or 324.") Nothing in the cited House Report indicates a further intent to limit written submissions to those actually "made" in the earlier proceeding, or to exclude statements filed, but not made, in such proceedings. To the contrary, like the statute that the Report is aimed at explaining, the Report states that "[t]he Act expands the category of documents that may be cited in a reexamination proceeding to include written statements of the patent owner that have been filed in a proceeding before a Federal Court or the USPTO regarding the scope of claims." H.R. Rep. No. 112-98, Part 1, at page 46 (2011) (emphasis added).

In addition to being inconsistent with the statute, Novartis believes that a rule restricting written statements to those actually "made" in a Federal Court or Office proceeding is not necessary to achieve the Office's objective of curtailing the submission of self-serving or otherwise unreliable written statements. For one thing, in many proceedings, hearsay and other evidentiary rules will prevent the acceptance of such statements for filing, rendering such statements ineligible under Section 301(a) without the need to read unstated restrictions into the statute. Further, because Section 301(a) permits "any person, at any time" to submit materials for inclusion in the patent file, anyone with an interest in the outcome of a reexamination may submit responsive statements or prior art putting the patent owner's statements in context. Lastly, as the statute itself makes clear, the Office is by no means obliged to adopt any written statements of the patent owner that were filed in a prior proceeding, or even to give any particular weight to the statements. Under the statute as written, the Office need only add such statements to the patent file and "consider" them when determining the proper meaning of the claims in a Section 304, 314, or 324

proceeding. Thus, the Office itself can ultimately decide how reliable the statement is and identify any inconsistencies with other statements.

Because Proposed 37 C.F.R. § 1.501(a)(2) is inconsistent with Section 301(a), Novartis respectfully requests that the Office strike the portion of this rule restricting written statements to those “made” in prior Federal Court or Office proceedings, and adopt a rule permitting the submission of any statement “filed” in such proceedings, consistent with the letter and intent of the statute.

Meaning of “Patent Owner”

Neither the AIA nor the proposed rules clarify the meaning of the term ‘patent owner’ yet the term is an important one, because the statute and rules authorize entry only of statements by the patent owner that have been filed in a Federal Court or the Office. Novartis requests the Office to consider clarifying in the rule how this term will be interpreted, so both third-party submitters and patent applicants can better understand what statements will be accepted.

It is often the case that the party pursuing or defending a patent before the Office, or enforcing a patent in a Federal Court, is an acquirer or exclusive licensee of the patent, rather than the original title holder, so statements filed in these proceedings may have been made by parties other than the current patent owner. Moreover, a patent can have multiple (joint) owners. In such circumstances, a statement filed in a Federal Court or in the Office by a party asserting the patent may be made by a party that is not identical to the current title holder of the patent. The legislative history makes it clear that the intent of the statute is to preclude a party from attempting to enforce a patent under one interpretation while advocating a different claim interpretation before the Office, or otherwise officially advocating inconsistent claim interpretations. See, e.g., H.R. Rep. No. 112–98, Part 1, at page 46 (2011) (“[t]his addition will counteract the ability of patent owners to offer differing interpretations of prior art in different proceedings”). Neither a joint owner nor an assignee or licensee should be able to frustrate the purpose of this statute by filing inconsistent statements about claim scope in the name of a party that is not identical to that of the current title holder. If an assignee, licensee or joint owner seeks to

benefit from statements made regarding the scope of the patent claims, then such statements should be binding upon them in a later proceeding even if the entity is not identical to the current title holder. The proposed rules should clarify how this term will be interpreted, and in view of the statutory intent, Novartis requests that the Office interpret the term 'patent owner' to encompass any party who has standing or exercises authority to enforce the patent in a Federal Court, or act before the Office in proceedings directed at the patent, including prior assignees, exclusive licensees, and joint owners.

Respectfully submitted,



Betty Ryberg