NOVARTIS

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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: Nicole D. Haines, Legal Advisor

Re: Novartis' Comments on Proposed Rules to Implement the AIA with Regard To Pre-Issuance Submissions by Third Parties

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.

Notice of Non-Compliant Submissions

In the Office's comments related to 37 C.F.R. § 1.290, the Office notes that it does not routinely intend to notify a third party submitter if the party's submission under 35 U.S.C. § 122(e) and 37 C.F.R. § 1.290 is not compliant. Novartis requests that the Office reconsider this position.

New 35 U.S.C. § 122(e) was enacted to increase the chance for relevant prior art to be submitted during examination, and provides a vehicle to enable third parties to assist the Office in identifying the most relevant prior art for consideration in the examination of a particular patent application. It provides a limited window of time for such references to be submitted to the Office, and prescribes how such references are to be submitted. The Office will determine whether these third-party submissions

are properly presented, and if they are, the Office will enter the submission into the application file. In the discussion of the proposed rule, the Office indicates it will not notify a submitting party if its submission is non-compliant; the submission will just not be entered into the file.

Novartis requests that the Office notify a third-party submitter if its submission under 37 C.F.R. § 1.290 is not compliant. If a third party submitting information is not notified that a submission is not compliant (and why such submission is not compliant), it is quite possible that the third party will miss the limited statutory time period in which such art may be submitted. If the third party does not cure the deficiency in the submission within the statutory time period, then the submission would not be entered and it would not be considered by the Examiner – even though it may be highly relevant to patentability. This would not achieve the purpose of 35 U.S.C. § 122(e), and it would discourage the relevant public from contributing to the Office's function. Thus, Novartis requests that the Office notify a third party submitter whenever the party's submission is deemed non-compliant under 35 U.S.C. §122(e) and 37 C.F.R. § 1.290, in order to provide that party with an opportunity to attempt timely resubmission. Ideally, in the interest of efficiency, Novartis respectfully requests that the notice include the reason for non-compliance as well.

Notice of Compliant Submissions

In the Office's comments related to 37 C.F.R. §1.290, the Office also notes that it does not intend to notify an Applicant when a compliant submission under 35 U.S.C. § 122(e) and 37 C.F.R. § 1.290 has been entered into the image file wrapper (IFW) for the Applicant's pending patent application. Novartis requests that the Office reconsider this position.

Many practitioners do not routinely monitor the IFW on the USPTO PAIR site, and rely instead on their own internal paper and/or electronic file wrappers for a complete prosecution file. If the Office does not notify the Applicant of such submissions that are being entered into the IFW, the Applicant may only become aware that a submission under 35 U.S.C. § 122(e) and 37 C.F.R. § 1.290 has been

entered into the IFW upon citation of references from that submission in a subsequent Office Action.

There are at least two problems that may occur if an Applicant is not notified of a compliant third party submission as soon as possible upon its entry into the IFW. First, patent offices in other jurisdictions, e.g., Israel, routinely request an Applicant to provide art cited in the corresponding case in the United States or other countries. To do so, practitioners review their own files for art and forward their findings to the foreign agent. If the IFW contains art that has never been sent to the Applicant, such art could be missed. This could result in an Applicant's failure to properly discharge a duty of candor toward another patent office, merely because the Applicant did not actively and regularly search the IFW for notice of such submissions. It could also result in other patent offices proceeding with their examination without benefit of relevant references.

Second, in the interest of compact prosecution, it would benefit both the Office and the Applicant for the Applicant to know about relevant art as early as possible. Early awareness of a reference from a compliant third party submission could facilitate an Applicant's submission of preliminary or supplemental amendments and arguments, which could avoid the need for an entire round of prosecution in which the art may be cited in a rejection. Furthermore, making an Applicant aware of a compliant third party submission that is entered into the IFW as early as possible could facilitate an early interview with the Examiner. Thus, Novartis requests that the Office, as a policy, promptly notify the Applicant about each submission under 35 U.S.C. § 122(e) and 37 C.F.R. § 1.290 that is entered into the IFW.

Respectfully submitted,

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