NOVARTIS

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VIA E-MAIL ONLY
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U.S. Patent and Trademark Office
Mail Stop Comments—Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Attn: Cynthia L. Nessler, Senior Legal Advisor

Re: Novartis's Comments on Proposed Rules to Implement the AIA with Regard to Supplemental Examination

Dear Ms. Nessler:

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 Supplemental Examination, which were published in the Federal Register on January 25, 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 it in developing these implementation rules and guidance. Our specific comments at this time are as follows:

1. The Office proposes to add new sections 37 C.F.R. §§ 1.610(d) and (e) regarding supplemental examination (hereinafter "Rule" or "Rules"). In short, these sections state that a supplemental examination request will not be granted a filing date unless it meets all of the features and formats of new Rules 1.605, 1.610(a) and (b), and 1.615. The only exceptions to this stringent requirement

are for the cover sheet and table of contents, and even then it is at the discretion of the Office whether or not to accord a filing date.

Rules 1.605, 1.610(a) and (b), and 1.615 contain numerous requirements and restrictions. Rule 1.610(b) alone lists 12 requirements (some of which are multi-part items) that a supplemental examination request must contain. As a result, the risk of not getting a filing date due to informalities is substantial. Concurrently, the AIA added 35 U.S.C. §257(c), which provides that a patent may be held unenforceable if an allegation has been pled with particularity in a civil action or in a Paragraph IV Hatch-Waxman proceeding **before** the date of a request for supplemental examination to consider, reconsider, or correct information forming the basis for the allegation. *See* §257(c)(1) and (c)(2)(A). This could be construed to mean 'before the filing date of the request,' and if it were interpreted that way, obtaining an early filing date may be critical in these cases. Moreover, if the supplemental examination request is published in PAIR and does *not* obtain its original filing date, it is possible that a third party could use the request as a basis for filing suit alleging defects that the requester has attempted to address. This would frustrate the purpose of the supplemental examination process.

Accordingly, Novartis suggests that, if a supplemental examination request that is otherwise substantially complete fails to meet one or more of the requirements of Rules 1.605, 1.610(a) and (b), and 1.615, when the Office issues an invitation to correct these defects, the invitation should indicate that timely correction is required for the original filing date to be recognized. A satisfactory response to the invitation would result in the proper accordance of the original filing date of the request with regard to any information that is clearly identified as a basis for the original request.

2. The Office proposes to add new Rule 1.620(e), which states that interviews are prohibited during the supplemental examination proceeding. While the prohibition of interview requests by the patentee may promote efficiency, it seems unnecessarily restrictive to prevent the Examiner from initiating an interview with the patentee should the Examiner deem it helpful. The Office has stated that the requirement of Rule 1.620(e) "will assist the Office to process the request for supplemental examination within the three-month statutory period." 77 FR 3672 (January 25, 2012). Allowing the Examiner to initiate an interview should only be beneficial to Office efficiency. Accordingly, Novartis suggests that Rule 1.620(e) be amended to permit Examiner-initiated interviews.

3. The Office proposes to add new Rule 1.620(f) that would preclude a Patent Owner from filing any amendments during a supplemental examination proceeding. As stated in the Federal Register, no claim amendments would be possible until after an Office Action on the merits in an *ex parte* reexamination initiated pursuant to a Supplemental Examination request. *Id*. This would remove an option that promotes efficiency in *ex parte* reexaminations, thus making reexaminations initiated from a request for supplemental examination less efficient than those based on *ex parte* requests.

Accordingly, Novartis proposes to modify Rule 1.620(f) to allow claim amendments included with the request, and also proposes a revised new Rule 1.610(c):

> (c) The request may also include <u>(1)</u> an explanation of why each item of information submitted with the request does or does not raise a substantial new question of patentability, <u>and/or (2) a proposed amendment in accordance with §1.530.</u>

Prohibiting amendments before the claims are examined could force the Office to examine claims the patent owner would have cancelled: the proposed rule would allow for amendment of the claims, would not require any action by the Office unless reexamination is ordered, and would streamline the reexamination proceeding in at least some cases.

The Office suggests that amendments "are not appropriate in a supplemental examination proceeding," *see id.* (third column), but Novartis finds nothing in the AIA to support that position or to necessitate the proposed new Rule 1.620(f). While the statute precludes filing a Patent Owner Statement in a reexamination originating from a supplemental examination request, it does not appear to preclude amending the claims for such reexaminations. In this sense, the proposed Rule allowing claim amendments to be submitted with a request for supplemental examination is in accord with the rules regarding *ex parte* reexamination, specifically Rule 1.510(e), which authorizes including a proposed amendment with a reexamination request. Novartis believes the suggested modifications to Rules 1.610(c) and 1.620(f) will benefit both the Office and the patent owner, and will better serve the objectives of the supplemental examination process.

Respectfully submitted,

Betty Ryberg