NOVARTIS

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VIA E-MAIL ONLY
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Lead Judge Michael Tierney
Derivation 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 Derivation Proceedings

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 Derivation Proceedings, 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 ("AIA") is a meritorious and worthwhile endeavor, and wishes to assist the Office in developing its implementation rules and guidance by submitting these comments.

The AIA creates a new "Derivation Proceeding" by which the Patent Trials and Appeals Board (PTAB) will determine which of two inventors should be considered the "true inventor" of an invention claimed in two, separate patent applications filed by two, different entities. The AIA authorizes the inventor of a later-filed application to petition for a determination that another party named in an earlier-filed patent application allegedly derived a claimed invention from an inventor named in the petitioner's application and filed the earlier application without authorization. The proposed rules outline the basic requirements for filing such a petition.

Timing of the Petition for Derivation Proceedings

The Office proposes to add new subpart E to 37 C.F.R. § 42 (Trial Practice Before the Patent Trial and Appeal Board) to reflect the AIA's new derivation proceeding to determine the "true inventor" (as opposed to the first inventor) of a claimed invention. The proposed new proceeding allows an inventor of a later-filed application ("petitioner") to petition the Board to make a determination that the inventor of an earlier-filed application derived the invention from the petitioner and filed the earlier application without authorization from the petitioner. In that situation, petitioner may be entitled to a patent even though the applicant for the other party filed earlier than petitioner did. In light of the AIA's shift of the US patent system to a "first inventor to file" system, Novartis supports a proceeding by which the "true inventor" would be awarded the patent in a situation where an earlier filer derived the invention from another and filed the application without authorization. Understanding that the proposed rules are an attempt to implement a proceeding that has not been a part of the U.S. patent system to date, and is not a part of other patent systems throughout the world, it is believed that the proposed subpart E to 37 C.F.R. part 42 is unclear in some respects and that the required threshold for granting a petition is too high.

The Office proposes to implement a proceeding by which a "true inventor" who files his/her patent application after another inventor claiming the same invention can show that the earlier-filed application was derived from the true inventor and filed without authorization. As explained in the discussion of the proposed rules, the intent is that a petition for a derivation proceeding must be filed within one year after publication of the earlier-filed application. In particular, the Office explains:

> Proposed § 42.403 would provide that a petition for a derivation proceeding must be filed within one year after the first publication of a claim to an invention that is **the same or substantially the same as the respondent's earlier application's claim** to the invention. Such publication may be the publication by the USPTO ... or by the World Intellectual Property Organization of an international application designating the United States. 35 U.S.C. 135(a), as amended, will provide that a petition for instituting a derivation proceeding may only be filed within the one-year period of the **first publication to a claim**

> **to an invention that is the same or substantially the same as the earlier application's claim to the invention.** The proposed rule is consistent with 35 U.S.C. 135(a), as amended, because the **earlier application's first publication of the allegedly derived invention triggers the one-year bar date.** While the statute's use of the phrase "a claim" is ambiguous inasmuch as it could include the petitioner's claim as a trigger, such a broad construction could violate due process. For example, the petitioner could be barred by publication of its own claim before it had any knowledge of the respondent's application. Such problems may be avoided if the **trigger for the deadline is publication of the respondent's claim.**

It is unclear which publication is meant to trigger the one-year bar date. The Office's explanation of the proposed rules seems to state both that the publication of the later-filed claim ("publication of a claim to an invention that is the same or substantially the same as the respondent's earlier application's claim") and that the publication of the earlier-filed claim ("earlier application's first publication") trigger the deadline. As written, the proposed § 42.403 seems to state that the trigger for the deadline is the publication of the petitioner's claim - the "petition for a derivation proceeding must be filed within one year after the first publication of a claim to an invention that is the same or substantially the same as the earlier application's claim to the allegedly derived invention." We interpret the phrase "a claim to an invention that is the same or substantially the same as the earlier application's claim" to refer to the later-filed claim because the earlier application's claim would not likely be "substantially the same" as itself. Novartis would like the Office to clarify which publication will trigger the 1 year bar under 35 U.S.C. § 135(a).

According to the proposed rules, a derivation proceeding is "unlikely to be declared" if the petitioner's claim (i.e., the later-filed claim) is not otherwise in condition for allowance. Assuming that the trigger for the deadline is publication of the earlier-filed claim, the deadline will be either one year after publication of the USPTO application (i.e., 18 months after filing a regular application in the U.S.) or one year after the WIPO publication of the application (i.e., 6 months after filing a PCT application). Even if a PCT application and a U.S. national application are filed on the same day, the WIPO publication will typically occur first. Furthermore, many global companies file 35 USC § 371 patent applications in the US, i.e., national stage

applications, rather than directly filing a US national patent application. As a result, in many cases the derivation petition deadline will be one year after the WIPO publication date. But, one year after the WIPO publication date will also be the deadline for national stage entry of the alleged deriver's application. At national stage entry of the alleged deriver's application (i.e., the earlier application), neither the alleged deriver's application nor the petitioner's application (i.e., the later application) is likely to have been searched or reviewed by the USPTO. So, how is it that a petitioner is to request a grantable derivation petition when it is unlikely that his or her claim will have even been examined, much less be in condition for allowance?

It does not appear that new 35 U.S.C. § 135(c), allowing the Board to defer derivation proceedings in certain circumstances, will necessarily help the petitioner. New section 135(c) allows the Board to defer action on a derivation petition proceeding for up to three months after a patent is issued from the earlier application that includes a claim that is the subject of the petition or until the termination of a proceeding under chapter 30, 31, or 32 involving the patent of the earlier applicant. Depending upon the subject matter of the applications in question, it is highly unlikely that the earlier application will issue as a patent within one year after its earliest publication.

Therefore, it is our position that the currently-proposed deadline for filing a petition for derivation proceeding, including the requirement that the petitioner's claim be in condition for allowance at the time of the request, will be almost impossible to meet. Perhaps the Office intends to grant a petitioner a derivation petition filing date (hence allowing the petitioner to meet the 1 year limit in 35 U.S.C. § 135(a)), but will then defer instituting (or denying) a derivation proceeding until after an alleged deriver's patent has issued from the earlier application. Presumably, in this scenario, prosecution on the petitioner's application will be held in abeyance until the derivation petition is granted (or denied), at which point the petitioner will be given opportunity to amend his or her claims to parallel those found in the granted patent of the alleged deriver so the claims are presumed to be in condition for allowance, but this is not discussed in the Office's draft rules for derivation proceedings. Therefore, Novartis would like the Office to clarify how the Office intends to

treat derivation petitions filed when a petitioner's claim is not otherwise in condition for allowance.

Standard for Initiation of Derivation Proceedings

To be grantable, a petition for a derivation proceeding must include the following:

1. a showing that the petitioner has at least one claim that is the same or substantially the same as the earlier-filed claim and that it is not patentably distinct from the invention disclosed to the respondent;
2. sufficient information to identify the application or patent for which the petitioner seeks a derivation proceeding;
3. a demonstration that the earlier invention was derived from an inventor name in the petitioner's application and the earlier application was filed without authorization.

The evidence supporting the claim of derivation will not be considered sufficient unless it is supported by substantial evidence, including at least one affidavit addressing communication of the derived invention and a lack of authorization to file the application. The proposed rules further require that the showing of communication be corroborated. It is unclear whether one affidavit addressing communication will be enough to be considered "substantial evidence" of derivation, or whether something additional will be required. Will corroboration of communication also have to be shown via an affidavit, or will it require evidence of a written communication? The requirements for a sufficient showing of derivation in order to even get a proceeding started seem onerous, particularly for the alleged "true inventor" of a claimed invention.

We would propose that the evidence required for having a petition for a derivation proceeding granted be less onerous for the petitioner. The requirements for proving derivation can be more onerous, so that the respondent does not "lose" his/her claimed invention if he/she truly did not derive the invention from the petitioner. But, if the petitioner sincerely believes that the invention was derived from his communication with the respondent and filed without authorization, he/she should have the opportunity to show that through the course of the proceeding.

Granting of a Filing Date

Proposed rule § 42.407 provides the requirements for receiving a filing date for the petition. If the Office deems the request fails to satisfy any of several criteria (i.e., it does not comply with § 42.405 (content of petition), respondent has not been properly served, or the fee was not included) then the petitioner will be given one month to correct the deficiency unless the one-year time period after publication of respondent's application has run. Proposed rule § 42.407(b) provides that a filing date will not be granted until the petition is deemed to be complete.

Because the proposed Rule hinges on the ambiguous term "satisfies," there is the potential that petitioners may miss the opportunity to be granted a filing date for a petition filed very close to the statutory deadline. It is unclear from the proposed Rule whether the term "satisfies" means that the elements of Rule 42.407 (including the elements of Rule 42.405) 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 alleging derivation. 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 will not be granted; should a filing date not be granted by the statutory deadline, the possibility of instituting a derivation proceeding would be lost. Thus, the goal of issuing patents to true inventors through the derivation 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 derivation request even if the request is imperfect, as there is no such mandate in 35 U.S.C. § 325(c). Novartis suggests that the Office should instead grant a filing date where 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 preserve the original filing date. It is not anticipated that there will be vast numbers of derivation 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 derivation statute would be better served if the Office allows petitioners with some leeway when bringing such a case to the Office for consideration.

As an alternative, Novartis suggests that the Office clarify the language of section 42.207 to provide that a filing date will be accorded a petition for a derivation proceeding provided that all the elements of Rule 42.407 (including the elements of Rule 42.405) are present in the petition. To the extent that the Office seeks to challenge the sufficiency of an element of the petition, provided that petitioner made a good-faith effort to satisfy the requirements of Rule 42.407(including the elements of Rule 42.405), this should not preclude the granting of a filing date for the petition.

Respectfully submitted,

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