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VIA E-MAIL ONLY

(oath_declaration@uspto.gov)

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

Re: Novartis' Comments on Proposed Rules to Implement the AIA with regard to Oath or Declaration Practice

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 6, 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.

Proof for Assignee or Party To Whom the Inventor Is Obligated To Assign

New 35 U.S.C. §118 of the AIA authorizes a party other than the inventor(s) to file a patent application in appropriate circumstances without an oath or declaration by the inventor(s). In addition, new 35 U.S.C. § 115(d) provides that a “substitute statement” may be filed in lieu of an oath or declaration by an applicant for patent under certain circumstances: death of the inventor, legal incapacity of the inventor, the inventor cannot be found or reached after diligent effort; or the inventor is under an obligation to assign the invention but has refused to execute the required oath or declaration. The Office proposes to amend 37 C.F.R. § 1.42 to provide a procedure to satisfy the oath or declaration requirement of 35 U.S.C. § 115(d) for deceased and legally incapacitated inventors, including providing for the oath to be executed by an

assignee, a party to whom the inventor is under an obligation to assign the invention, or a party who otherwise shows sufficient proprietary interest. The procedure in amended 37 C.F.R. § 1.47 would also apply in the situation where an inventor refuses to sign the oath or declaration or cannot be reached after diligent effort to sign the oath or declaration.

Under proposed 37 C.F.R. § 1.42(a), in the event of death or incapacity of an inventor or legal representative of the inventor, an assignee, a party to whom the inventor is under an obligation to assign the invention, or a party who otherwise shows sufficient proprietary interest in the matter may make an application for patent. However, in proposed 37 C.F.R. § 1.42(b)(1), the Office makes clear that, if the entity making an application for patent is one to whom the inventor is under an obligation to assign the invention, then the Office will require proof sufficient to establish that the deceased or incapacitated inventor is under an obligation to assign the invention to the entity. Similarly, under proposed 37 C.F.R. § 1.47(a), in the event that an inventor or the legal representative of the inventor refuses to execute an oath or declaration, or cannot be found or reached after diligent effort, an assignee, a party to whom the inventor is under an obligation to assign the invention, or a party who otherwise shows sufficient proprietary interest in the matter may make an application for patent. Again, in proposed 37 C.F.R. § 1.47(c)(4)(i), the Office makes clear that, if the entity making an application for patent is one to whom the inventor is under an obligation to assign the invention, then the Office will require proof sufficient to establish that non-signing inventor is under an obligation to assign the invention to the entity.

In light of the proposals to amend 37 C.F.R. § 1.42 and 37 C.F.R. § 1.47, the Office appears to interpret 35 U.S.C. § 115(d) in conjunction with 35 U.S.C. § 118 to require “proof” of an obligation to assign in the event that a juristic person (hereinafter “entity”) to whom an assignment is owed attempts to make an application for patent. Novartis agrees that 35 U.S.C. § 115(d) should be read in conjunction with 35 U.S.C. § 118 when establishing procedures for an assignee, a party to whom the inventor is under an obligation to assign the invention, or a party

who otherwise shows sufficient proprietary interest to execute the oath to make an application for patent. However, for the reasons discussed below, Novartis does not agree with the Office's interpretation that "proof" should be required where the application is filed by either of the first two types of entities (i.e. an assignee or a party to whom the inventor is under an obligation to assign), and requests the Office to reconsider their proposed amendments to 37 C.F.R. § 1.42 and 37 C.F.R. § 1.47 in light of the analysis below.

The first sentence of new 35 U.S.C. § 118 provides:

A person to whom the inventor has *assigned or is under obligation to assign* the invention may make an application for patent. . . .

The second sentence of new 35 U.S.C. § 118 provides:

... A person who otherwise shows *sufficient proprietary interest* in the matter may make an application for patent on behalf of and as agent for the inventor on *proof of the pertinent facts and a showing that such action is appropriate to preserve the rights of the parties*. . . .

35 U.S.C. §118 (emphasis added).

Implementation of 35 U.S.C. § 115(d), as it relates to an assignee, a party to whom the inventor is under an obligation to assign the invention, or a party who otherwise shows sufficient proprietary interest to execute the oath can be best achieved by paralleling the requirements and language of 35 U.S.C. § 118. Indeed, the Office appears to have taken this view already. However, it is notable that the first sentence of 35 U.S.C. § 118 indicates that an entity, when filing in lieu of an inventor(s) and using the criteria "... *assigned or is under obligation to assign* ..." need not submit any proof to establish entitlement to make the application for patent. The plain language of 35 U.S.C. § 118 seems to add a requirement for proof of pertinent facts and a showing of need to use the modified procedure only where the applicant is one with 'sufficient proprietary interest,' other than an assignee or party to whom assignment is owed by agreement. This understanding is supported by a comparison of the text of first sentence of new 35 U.S.C. § 118 (i.e., no requirement for proof)

with the text of the second sentence of new 35 U.S.C. § 118 (i.e., requirement for proof and a showing that such action is necessary to preserve the rights of the parties). The second sentence of new 35 U.S.C. § 118 relates to a party relying upon a ‘sufficient proprietary interest,’ rather than an assignment or obligation to assign, and requires “proof of pertinent facts and a showing that such action is appropriate to preserve the rights of the parties.” The first sentence of new 35 U.S.C. § 118 relates to assignees and parties to whom assignment is owed, includes no mandate for the proofs required in the second sentence.

Novartis submits that, when an entity provides a substitute statement under 35 U.S.C. § 115(d) in lieu of an inventor(s) oath by using the criteria set forth in the first sentence of 35 U.S.C. § 118, i.e., “... *assigned or is under obligation to assign* ...”, the entity should not be required to submit any proof to establish entitlement to make the application for patent. However, the Office has added this “proof” requirement in their interpretation of 35 U.S.C. § 115(d) as it is proposed to be implemented in 37 C.F.R. §§ 1.42 and 1.47. To add requirements not found in the first sentence of 35 U.S.C. § 118 would contravene Congress’ intent for this portion of 35 U.S.C. § 118, i.e., to establish *simplified* procedures for filing in the name of an assignee or an entity to whom assignment is owed by the inventor(s). Requiring submission of “proof” that an inventor is under an obligation to assign will require further time and expenditures on the part of the entity making the application for patent, and will require additional review and analysis by the Office. Furthermore, the obligation to assign is often embedded in employment contracts, and the submission of employment contracts may raise privacy and confidentiality concerns. The Office should, instead, simply require the applying entity to aver that said entity is entitled to make an application for patent based on an assignment or obligation to assign. The operation of section 1001 of title 18, as well as the equitable law of inequitable conduct, will adequately ensure that this statement is effective only if made truthfully.

Novartis notes that proposed 37 C.F.R. § 1.42 and 37 C.F.R. § 1.47 contemplate requiring both proof and a showing that such action is necessary to

preserve the rights of the parties in the event that the entity is one who otherwise shows sufficient proprietary interest in the matter. 37 C.F.R. § 1.42(b)(2) and 37 C.F.R. § 1.47(c)(4)(ii). That is, while the Office reads the “proof” requirement from the second sentence of 35 U.S.C. § 118 into situations in which the entity making a substitute statement under 35 U.S.C. § 115(d) is either one to whom the inventor is under an obligation to assign the invention or one who otherwise shows sufficient proprietary interest in the matter, the Office only reads the “showing” requirement into situations in which the entity is one who otherwise shows sufficient proprietary interest in the matter. This is inconsistent with the rules of statutory construction, and provides further evidence that the Office’s proposals for 37 C.F.R. § 1.42(b)(1) and 37 C.F.R. § 1.47(a) are not reflective of congruent reading of 35 U.S.C. § 115(d) and 35 U.S.C. § 118.

Finally, given the confidential nature of proofs that may be used to establish compliance with the criteria of 35 U.S.C. § 115(d), Novartis requests that, if any confidential documents are used as “proof” for this purpose, the Office not include such documents in the public image file wrapper. Instead, for example, the Office could state in the file-wrapper that certain agreements were reviewed by the Office and found to fulfill the criteria set forth in 35 U.S.C. § 115(d).

Party Who Executes an Oath or Declaration

Proposed 37 C.F.R. § 1.42(a), relating to the procedures to be followed where an inventor is deceased or legally incapacitated, states that in the case of a deceased or incapacitated inventor the legal representative of the inventor, the assignee, or a party to whom the inventor is under an obligation to assign the invention or a party who otherwise shows sufficient proprietary interest in the matter may execute the oath or declaration. The final sentence of § 1.42(a) states that “a party who shows sufficient proprietary interest in the matter executes the oath or declaration on behalf of the deceased or incapacitated inventor.” This is somewhat confusing, however, because the first portion of § 1.42(a) refers to a legal representative, assignee, party to whom the inventor was obligated to assign, or a party who otherwise shows sufficient proprietary interest, while the last portion of § 1.42(a) merely states that it is the

“party who shows sufficient proprietary interest” that executes the oath or declaration on behalf of the deceased or incapacitated inventor. Novartis respectfully requests that the Office amend rule § 1.42(a) to make it clear that the party who “executes the oath or declaration on behalf of the deceased or incapacitated inventor” includes the legal representative, assignee, party to whom the inventor was obligated to assign, or the party who otherwise shows sufficient proprietary interest.

A similar issue exists in proposed rule § 1.47(a). Novartis respectfully requests that the Office amend the rule to make it clear that the party that “executes the oath or declaration on behalf of the non-signing inventor” includes the assignee, a party to whom the inventor has an obligation to assign, or a party who otherwise has a proprietary interest in the subject matter.

Respectfully submitted,



Betty Ryberg