

From: Ryberg, Betty  
Sent: Friday, October 05, 2012 3:20 PM  
To: fitf\_guidance  
Subject: Novartis Comments on Examination of Guidelines for Implementing the First Inventor to File Provisions of the America Invents Act

Dear Senior Legal Advisor Till:

Please see the attached comments.

Respectfully submitted,

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-----Original Message-----

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Sent: Friday, October 05, 2012 2:30 PM  
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U.S. Patent and Trademark Office  
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P.O. Box 1450  
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Attn: Mary C. Till, Senior Legal Advisor  
Office of the Deputy Commissioner for Patent Examination Policy

Re: Novartis Comments on Examination Guidelines for Implementing the  
First Inventor to File Provisions of the America Invents Act

Dear Senior Legal Advisor Till:

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 Examination Guidelines related to the First Inventor to File (FITF) provisions of the AIA, which were published in the Federal Register on July 26, 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 these implementation rules and guidance. Please consider the below specific comments.

Disqualification of prior art under AIA 35 U.S.C. §102(b)(2)(C)

Novartis respectfully submits that the USPTO is incorrectly interpreting the common ownership disqualification provisions of AIA 35 U.S.C. §102(b)(2)(C) by reading the word “only” into the implementation of 35 U.S.C. §102(b)(2), and limiting the kind of commonly-owned prior art that may be excluded.

AIA §102(b)(2)(C) reads as follows:

(2) DISCLOSURES APPEARING IN APPLICATIONS AND PATENTS.—

A disclosure shall not be prior art to a claimed invention under subsection (a)(2) if

...

(C) the subject matter disclosed and the claimed invention, not later than the effective filing date of the claimed invention, were owned by the same person or subject to an obligation of assignment to the same person.

AIA, 35 U.S.C. §102(b)(2)(C).

Thus, from the clear terms of the statute, a disclosure that normally would be prior art under AIA 35 U.S.C. §102(a)(2) is disqualified as prior art

under AIA §102(a)(2) if the subject matter disclosed and the claimed invention, not later than the effective filing date of the claimed invention, were owned by the same person or subject to an obligation of assignment to the same person. There is no requirement in AIA §102(b)(2) that the prior art at issue ONLY qualify as prior art under AIA §102(a)(2), i.e., the prior art at issue may qualify as prior art under both AIA 35 U.S.C. §102(a)(1) and AIA §102(a)(2). This is not an uncommon situation, as a patent or patent publication that has published before the effective filing date of a claimed invention would qualify as both AIA §102(a)(1)- and AIA §102(a)(2)-type art (similar to a reference qualifying as prior art under current §102(a) and current §102(e)).

This is different than the common ownership provisions of current 35 U.S.C. §103(c), which state:

(1) Subject matter developed by another person, which qualifies as prior art **only** under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.

35 U.S.C. §103(c) (emphasis added).

Thus, under current law, an applicant for patent may remove commonly owned art for the purposes of an obviousness-type rejection if the prior art at issue qualifies as prior art only under one or more of current 35 U.S.C. §102(e), (f), or (g). As such, under the current law, if prior art at issue qualifies as prior art under, e.g., current §102(a) and current §102(e), an applicant may not remove such art using the common ownership exception unless the applicant FIRST disqualifies the art under current §102(a) (e.g., by showing the art is not by “another”, by showing derivation, etc.). This is due to the use of the term “only” in current §103(c) – a term that is explicitly absent from AIA §102(b)(2).

In several portions of the “Examination Guidelines for Implementing the First-Inventor-to-File Provisions of the Leahy-Smith America Invents Act”, 77 Fed. Reg. pp. 43759-773, the Office reads the term “only” into AIA §102(b)(2) (see, e.g., page 43672, stating “AIA 35 U.S.C. 102(b)(2)(C) provides an exception to prior art that qualifies **only** under 35 U.S.C. 102(a)(2) but that applies in the context of anticipation or obviousness to prior art that was commonly owned not later than the effective filing date of the claimed invention.” (emphasis added)). But, as shown above, this is incorrect because the term “only” does not appear in AIA §102(b)(2). Indeed, under AIA §102(b)(2), it is irrelevant whether the prior art at issue qualifies as prior art under AIA §102(a)(1), it need only qualify as art under AIA §102(a)(2) in

order to be removable as an AIA §102(a)(2)-type reference using AIA §102(b)(2)(C).

Novartis recognizes that, if a patent or patent publication qualifies as prior art under both AIA §102(a)(1) and AIA §102(a)(2), and the applicant removes the art under AIA §102(a)(2) using AIA §102(b)(2)(C), the applicant will nonetheless have to address the art as it remains under AIA §102(a)(1). However, it should be made clear that an applicant can choose the order in which to address this type of “dual qualifying” art, i.e., an applicant may first address the art under AIA §102(a)(2) and then AIA §102(a)(1) – or vice versa. Clarifying this issue now will undoubtedly remove issues that will arise during prosecution once AIA 35 U.S.C. §102 goes into effect in 2013.

The ‘Grace Period’ for Public Disclosures: 35 U.S.C. §102(b)

With regard to the so-called ‘Grace Period’ created by new 35 U.S.C. § 102(b)(1), Novartis believes the position described in the Examination Guidelines is inconsistent with the statute. The AIA creates a twelve-month grace period during which an inventor who has publicly disclosed an invention can file a patent application without having her own disclosure treated as prior art against the application. The relevant portion of the statute relates to the prior art status of a disclosure by a third party that occurs after the Inventor’s public disclosure but before the Inventor files a patent application: this third-

party disclosure is referred to herein as an “intervening reference.” The statute provides that the disclosure of an intervening reference shall not be prior art if “the subject matter disclosed” in the intervening reference had “been publicly disclosed by the inventor or a joint inventor,” either directly or indirectly, “before such subject matter was effectively filed” as a patent application. Thus where the Inventor publicly discloses certain subject matter before an intervening reference discloses the same subject matter, and the Inventor subsequently files a patent application directed to the same subject matter within 12 months, the intervening reference does not qualify as prior art against the Inventor’s application.

In the proposed Examination Guidelines, the Office says this exception requires that the subject matter in the intervening reference must be the ‘same’ as that in the Inventor’s public disclosure. The Examination Guidelines says the grace period protection would not apply to an intervening reference that contains “mere insubstantial changes, or only trivial or obvious variations” of the Inventor’s original disclosure. FR 77 (144), 43769, col. 3. This can be read to mean that the Office would view an intervening reference as prior art in its entirety unless the Inventor’s public disclosure is virtually identical to the intervening reference, without even insubstantial differences.

Under this interpretation, an intervening reference would almost never be disqualified as prior art by the grace period provision, because an intervening reference by a third party will rarely if ever have ‘the same’ disclosure as that of the Inventor’s independent public disclosure. Indeed, this interpretation seems to invite the illogical result that an intervening reference could disclose *less* than the Inventor’s public disclosure, and yet it could defeat the protection intended by the AIA because the disclosures were not ‘the same’.

Novartis believes this interpretation is contrary to the intent of the AIA statute. The legislative history of this part of the statute, as summarized by Joe Matal and published by the USPTO, <<[www.uspto.gov/aia\\_implementation/guide-to-aia-p1.pdf](http://www.uspto.gov/aia_implementation/guide-to-aia-p1.pdf)>>, provides that a disclosing Inventor would be “fully protected during the grace period ... not only from the inventor’s own disclosure being prior art against the inventor’s claimed invention, but also against the disclosures of any of the same subject matter in disclosures made by others ...”.

Novartis does not believe that the entirety of an intervening reference should be viewed as prior art merely because the Inventor’s public disclosure does not anticipate every detail in the intervening reference. In our view, the Grace Period should apply to subject matter in an intervening reference to the extent the subject matter in the reference is within the scope of the Inventor’s

public disclosure: it should not provide an ‘all or nothing’ protection that excludes only references that are virtually identical to the Inventor’s public disclosure. Any subject matter publicly disclosed by the Inventor that is found in an intervening reference should be disqualified as prior art, while any subject matter in the intervening reference that is NOT found in the Inventor’s public disclosure would qualify as prior art.

Examiners routinely make this analysis when assessing priority claims to determine whether a provisional application provides priority for a later-filed claim in view of an intervening reference published after the provisional filing date. The provisional application negates the effect of any content in an intervening reference that was disclosed by the earlier provisional application, but does not protect claims against intervening reference disclosures that exceed the content of the provisional application. Thus a claim that was fully supported by the Inventor’s public disclosure would be patentable to the Inventor *regardless of the content of any intervening references*, but an intervening reference would constitute prior art against claims in the later application that were not supported by the Inventor’s public disclosure. The legislative history even refers to the Inventor’s original disclosure as providing priority, stating that the Inventor’s public disclosure “preserves his priority to the invention even if there is intervening prior art between the inventor’s public

disclosure and the inventor's application for patent, provided that the application is made 1 year or less after the initial disclosure." Matal, at 477.

From the legislative history, it seems clear that the grace period in 35 U.S.C. §102(b) was intended to be robust and meaningful. The summary of the relevant legislative history mentions a Committee Report summarizing the new section of 102(b), stating that the grace period was important to small inventors and universities, and "encouraged early disclosure ...". An interpretation of the statute that allows an Inventor's public disclosure to provide protection against an intervening disclosure only if that intervening disclosure is virtually identical to the Inventor's public disclosure would be neither robust nor meaningful, and would strongly discourage the kind of early public disclosures that the AIA intends to protect and even encourage.

In order to achieve the objectives of the AIA as revealed by the legislative history, a robust grace period is needed. Thus, references to the 'same subject matter' in an intervening disclosure should be understood to mean that any material disclosed in an intervening reference that is the same as material in the Inventor's earlier public disclosure does not qualify as prior art.

Novartis encourages the Office to clarify its position on the scope of the exclusion of intervening references under 35 U.S.C. §102(b) consistent with these comments. Novartis believes the Office should adopt an interpretation

that allows an Inventor's public disclosure to protect the disclosed subject matter against intervening references to the extent the intervening reference contains the same subject matter (or less), even if the intervening reference also discloses modifications or additions not found in (and thus not protected by) the Inventor's public disclosure. This interpretation would ensure that a public disclosure would "fully protect" the Inventor against intervening disclosures to the extent of the Inventor's early public disclosure while maintaining incentives to file soon after a public disclosure, since the Inventor's right to claim variations and improvements is put at risk by the public disclosure.

Respectfully submitted,



Betty Ryberg