



The Honorable David J. Kappos
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office

Via Electronic Mail to: oath_declaration@uspto.gov

Re: Notice of Proposed Rulemaking; USPTO Docket No. PTO-P-2011-0074
"Changes to Implement the Inventor's Oath or Declaration Provisions of the Leahy-Smith American Invents Act"

Washington, D.C., March 6, 2012

Dear Under Secretary Kappos,

The Biotechnology Industry Organization (BIO) thanks the United States Patent and Trademark Office (USPTO) for the opportunity to comment on the proposed rules implementing the Inventor's Oath or Declaration Provisions of the American Invents Act (AIA) as set forth at FR Vol. 77(4), 982 ff. (Friday, January 6, 2012).

BIO is a non-profit organization with a membership of more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in all 50 States and a number of foreign countries. BIO's members research and develop health care, agricultural, industrial, and environmental biotechnology products. The U.S. life sciences industry, fueled by the strength of the U.S. patent system, supports more than 7.5 million jobs in the United States, and has generated hundreds of drug products, medical diagnostic tests, biotech crops, and other environmentally-beneficial products such as renewable fuels and bio-based plastics.

The vast majority of BIO's members are small and medium sized enterprises that currently do not have products on the market. However, all of our members actively file for patents and often pursue both out-licensing and in-licensing business models. As such, the implementation of seemingly simple provisions such as the Oath or Declaration provisions can have a large impact on the day-to-day business of our members.

BIO supported passage of the American Invents Act with the understanding that the Act's amendments to Sections 115 and 118 would streamline and simplify existing USPTO processes and harmonize its procedures with those of other major developed

patent systems. Indeed, this understanding is echoed in the Act's legislative history, as, for example, in the Report on H.R. 1249 by the House Judiciary Committee Report to the House of Representatives:

Current law still reflects the antiquated notion that it is the inventor who files the application, not the company-assignee. ... [M]any have advocated that the statute be modernized to facilitate the filing of applications by assignees. The Act updates the patent system by facilitating the process by which an assignee may file and prosecute patent applications. It provides similar flexibility for a person to whom the inventor is obligated to assign, but has not assigned, rights to the invention

H.R. Report 112-98, p. 43-4. *See also Id.*, at 74 ("The section streamlines the requirement that the inventor submit an oath as part of a patent application, and makes it easier for patent owners to file applications.")¹

Unfortunately, BIO's members do not believe that the proposed Rules would result in an oath or declaration process that is significantly more flexible, simpler, or streamlined than current practice. Importantly, the USPTO's Federal Register notice also raises more fundamental questions about the Office's understanding of the conditions under which an assignee can be an applicant for patent. At page 983 of its FR notice, the USPTO explains that

[t]he changes to 35 U.S.C. 115 and 118 do not mean that a person to whom the inventor has assigned or is under an obligation to assign the invention may make an application for patent under all circumstances. They do, however, recognize that an assignee or a person to whom the inventor is obligated to assign can execute the oath or declaration. In those circumstances set forth in 35 USC 115(d)(2), an assignee ... is the applicant as is currently set forth in 37 CFR 1.41(b)."

It appears that the USPTO understands the AIA to authorize assignee filing only under the narrow exceptions of 35 USC 115(d)(2) - death, incapacity, absence, or refusal - i.e. under the very exceptions that already exist under current law. BIO does not believe the assignee's right to apply for patent to be constrained in this way. The USPTO's position (and the accompanying rule changes) would perpetuate the current system under which assignee filing would be a narrow, cumbersome exception to a general rule that only inventors can be applicants. BIO believes this to be contrary to Congressional intent and inconsistent with the language of the AIA. In new Section 118, Congress unambiguously departed from the previous statutory language, which permitted assignee filing only "on behalf of and as an agent for" an inventor who "refuses to execute an application for patent or cannot be found or reached after diligent effort." Even under these circumstances, the patent was to be granted only "to such inventor."

¹See http://www.uspto.gov/aia_implementation/crpt-112hrpt98-pt1.pdf

In new Section 118, in stark contrast, Congress plainly provides, in so many words, that an assignee “may make an application for patent.” Congress did so without reference to inventor absence or refusal. The only person required to make any showing by 35 USC § 118, as amended, is one who has a sufficient proprietary interest *other than* an assignment or an obligation to assign. Assignees who apply for patents no longer act on behalf of or as agents for the inventor. And the ensuing patents are granted to the assignee, not to “such inventor.” It is hard to imagine how Congress could have been any clearer in its intent to relax the constraints of the current system. Accordingly, BIO’s members are surprised to read that a separate oath or declaration, under cumbersome exceptions similar to those available today, will still be required in essentially every original case before an application can proceed to substantive examination.

BIO believes that the requirements of new section 115(a) would be met if an assignee who makes an application for patent identifies the inventor at the time of filing. The application should then proceed to substantive examination. The inventor oath or declaration need only be perfected prior to a notice of allowance, in compliance with the plain terms of new 35 USC 115(f). BIO believes that applicants would be unlikely to routinely delay filing the required inventor statements until the time the application is otherwise in condition for allowance. But the Office should provide the flexibility to file the statements later than contemplated by the proposed Rules, i.e. at a time when the claimed invention will be better defined through substantive examination, allowable subject matter is indicated, and inventorship is more ascertainable.

As a practical matter, BIO believes that assignee filing under the AIA would quickly become the norm, and that corporate assignees in particular would be very interested in using the assignment process under new 35 USC 115(e) to make the statutorily required inventor statements of record. At the time of filing, the PTO could require assignee-applicants to identify the inventors and to affirm that the statements required by 35 USC 115(b) were filed or will be filed prior to a notice of allowance. If an assignment is used to make the required statements, proper recordation at the PTO should be sufficient without having to make the assignment of record in the prosecution history of the application. A recorded assignment in the USPTO should also mitigate any need for additional requirements made by the Director outside the statutory requirements. An assignment should be deemed sufficient to meet the requirements of Section 115 if it contains an inventor assertion of her or his status as the original inventor, and makes clear that the inventor has transferred all right, title, and interest in the application. The fact that the inventor has no remaining proprietary interest in the application whatsoever should be deemed sufficient to meet the authorization requirement of paragraph (b)(1). While Section 115(c) allows for “Additional Requirements” promulgated by the Director, we see no policy or procedural reason why additional regulatory burdens must be in place. In fact, additional requirements would encumber the usefulness of the assignment route under subsection 115(e) especially for domestic applicants who obtain inventor assignments early. For example, if an assignment is obtained prior to filing a provisional application, the PTO’s proposed required statement that the inventor has reviewed and understands the application and claims would effectively force the applicant to obtain and

record a new assignment or a separate oath at the time of filing a nonprovisional application.

Other proposed required statements, such as an acknowledgement of the inventor's obligation to provide the PTO with material information under Rule 56, go beyond what is required by statute and have no place in an assignment document that binds, by its nature, only the assignor and assignee. They also create incongruities between direct-filed applications and those that enter the U.S. through the PCT route. For example, proposed Rule 1.63(a)(6) requires the inventor to state that she or he has reviewed and understands the contents of the application and the claims, and proposed Rule 1.63(a)(7) requires an inventor acknowledgement of the duty to disclose. The same is not required under proposed Rule 1.497 at the time of entering the national stage under 35 U.S.C. 371. This differential treatment creates complexity that doesn't seem to be warranted. A non-U.S. national would apparently not have to make these statements at the time a PCT application enters the U.S. national stage, and a U.S. inventor could likewise at least defer making these statements by going through the PCT to file a U.S. application rather than filing under 35 U.S.C. 111(a).

Some BIO members have also suggested that proposed Rule 1.311 should be amended to delete the required notification "of any change in ownership for the application no later than payment of the issue fee." This new addition is not required by the statute, and, for many of the reasons suggested in response to the Office's previous "Request for Comments on Eliciting More Complete Patent Assignment Information," is not necessary and could create unnecessary complexity for applicants. Ownership can change at any time, including just before or just after patent issuance, such that the information may not be up to date at the time the patent issues. The consequences of failure to report such a change are also not spelled out.

BIO also urges the USPTO to consider the importance of an existing assignment for an applicant-assignee's ability to meet the required showing for a substitute statement under 35 USC 115 (d)(1). Subsection 115 (d) allows a "substitute statement" in circumstances where the inventor is unable to execute the oath, or unwilling to do so while under an obligation to assign, or under the Director's broad authority to define additional circumstances by regulation. The required contents of the substitute statement under Section 115 (d)(3) are the identity of the "individual with respect to whom the statement applies", "...the circumstances representing the permitted basis" for filing it, and "any additional information, including any showing, required by the Director." BIO believes that an executed assignment document would provide the statutorily-required information to the PTO: the inventor would be identified, the showing of circumstances would be satisfied by proof of the inventor's obligation, and little further evidence would seem to be required. Additional requirements listed in proposed rule 1.47, for example "proof of the pertinent facts" that the inventor could not be reached or has affirmatively refused to make an oath, goes beyond what is necessary to fulfill the statutory objective.

If the USPTO is concerned about fraud conducted on the office there are other mechanisms to address this problem. Indeed, the House Judiciary Committee report quoted above directly references possible concerns the USPTO may have. It states that

“If an error is discovered, the statement may later be corrected. A savings clause is included to prevent an invalidity or unenforceability challenge to the patent based on failure to comply with these requirements, provided that any error has been remedied. Willful false statements remain punishable, however, under Federal criminal laws. (See 18 U.S.C. § 1001).”²

To BIO members, this indicates that Congress contemplated particular concerns that might arise but believed them to be adequately addressed by the provisions of the bill and already-existing law. Surely, in light of the AIA, the USPTO need no longer engage in inquiries that attempt to measure the sufficiency of assignee effort, and could instead rely on the assignment document as objective proof of the assignee’s plenary right to “make an application for patent.”

BIO appreciates the magnitude of the PTO’s task of implementing the America Invents Act, and applauds the transparency and consistency of its outreach efforts since the day the Act was signed into law. While BIO is reluctant to embrace the proposed Oath and Declaration Rules in their current form for the reasons stated above, we optimistically look forward to continued dialogue on the matter.

Respectfully submitted,

/s/ Hans Sauer
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Biotechnology Industry Organization

² *Id.* at 44