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**Sent:** Friday, October 05, 2012 3:35 PM  
**To:** fitf\_rules  
**Cc:** Hans Sauer  
**Subject:** Comments on FITF

To Susy Tsang-Foster:

Please find attached the comments of Hans Sauer, Deputy General Counsel for Intellectual Property at the Biotechnology Industry Organization on the proposed first to file rules. Thank you.

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RE: Docket No: PTO-P-2012-0015 (77 F.R. 43742-59) (Proposed Rules to Implement First-Inventor-to-File Standard)

The Biotechnology Industry Organization (BIO) respectfully submits these remarks in response to publication of proposed rules to implement the first-inventor-to-file provisions of the Leahy-Smith America Invents Act (AIA) that are the subject of the above-noted Docket and Federal Register notice. The proposed rules raise several concerns that, we believe, warrant reconsideration of the rules and/or practices of the Office under such rules. BIO's member companies continue to review these proposed rules as well as other, separately-published proposed rules and practice changes, and may, at a later time, identify additional concerns in supplementary comments.

**(a) Comments on Proposed 37 CFR 1.55 (regarding priority applications)**

Proposed 37 CFR 1.55 imposes a new deadline for an applicant to submit certified copies of foreign priority documents for U.S. applications that could prove unworkable in many circumstances and result in a loss of rights. Proposed 37 CFR 1.55(a)(2) provides that, for original applications filed under 35 U.S.C. 111(a), certified paper copies of the foreign priority applications must be filed within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior foreign application together with a claim for priority. An unintentional delay in filing the priority claim may be rectified by a petition; however, the proposed Rule provides no specific recourse for the applicant who is unable to timely provide a certified copy of the foreign priority document due to the failure of the foreign office to timely provide the certified copy of the priority application.<sup>1</sup>

Proposed Rule 1.55(d) would permit an applicant to meet this deadline through use of the electronic transmittal of priority documents via DAS or PDX, in lieu of submitting paper certified copies under proposed Rule 1.55(d). However, this option still requires the electronic transmission of the priority document to be complete by the deadline set in 37 CFR 1.55(a) or “by such later time as may be set by the Office.” Again, the proposed Rule provides no specific

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<sup>1</sup> The Office considers a petition under 37 CFR 1.55(c) not applicable to a situation where a delay occurs in submitting a certified copy of a foreign priority document.

recourse for the applicant in the situation where the electronic transmittal of the foreign priority document is untimely through no fault of his own (e.g., due to the failure of the foreign office to make available the electronic copy for transfer by the deadline specified by the Office or the Office's failure to retrieve the foreign priority document from the foreign patent office after a timely request has been made by applicant).

The electronic transmittal of priority documents also cannot be used as an alternative to providing a certified paper copy of a priority application from a foreign office in many situations. For example, participating Patent Offices to the DAS or PDS systems acknowledge they have difficulties in processing applications containing sequence listings, and recommend that paper certified copies of priority applications be provided instead.<sup>2</sup> Priority documents that contain about 1,000 pages or fewer are excluded from the PDX system.<sup>3</sup> Moreover, several large patent offices that are the first filing office for many applicants (e.g., the German patent office) do not participate in the PDX or DAS systems, which means that electronic transmittal of priority applications cannot be used with priority applications filed first in those offices. Compounding these problems is the Office's track record in processing priority document transmittal requests via PDX and DAS. As the Office acknowledges, the period of time it can take to complete priority document exchange can be several months or longer, and must occur after US formalities have been satisfied (e.g., no missing parts).<sup>4</sup> All of these factors show that there will be many circumstances in which electronic transmittal of a foreign priority application is not feasible, leaving as the only option the submission of certified copies on paper to satisfy the deadline specified in the proposed rule.

Proposed Rule 1.55 as cast thus has the potential to unfairly prejudice the ability of patent applicants to perfect legitimate claims to priority in circumstances that are beyond their control (i.e., where delays are attributable to the conduct of foreign intellectual property offices or the USPTO). Specifically, if the provision of the certified paper copy of a priority application is delayed by a foreign office, or the foreign office or the PTO fails to complete the electronic document exchange by the deadline specified in the Rule or by the Office, the only remedy available to a patent applicant is to file a petition under 37 CFR 1.183 seeking to waive application of the rules. This is not a viable solution for several reasons. First, the Office may construe the petition to be a delay attributable to the patent applicant, and could thereby reduce a patent term adjustment to which the patent applicant would otherwise be entitled. Second, the circumstances where the deadline cannot be met due to delays of a foreign office or the PTO will be a frequent, rather than, rare occurrence based on present experiences. It is thus improper to leave the resolution of these situations to an ad-hoc practice (i.e., a petition to waive the rules). Instead, proposed Rule 1.55 should expressly provide for a resolution of these late-perfected priority claims that are delayed due to actions beyond the control of the applicant. Doing so will be important to ensure a predictable resolution of these situations that are largely beyond the control of the patent applicant to influence.

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<sup>2</sup> <http://www.uspto.gov/patents/process/file/pdx/pdxfaqs.pdf> (fact 16)

<sup>3</sup> Id at fact 3.

<sup>4</sup> Id at fact 9.

Consequently, the Office should revise Rule 1.55 to specifically provide an exemption from the deadlines for providing a certified copy of the priority application in situations where the applicant has timely requested that certified copy or electronic transfer of that copy, but the foreign intellectual property office has not provided the copy by a time that permits the applicant to comply with the deadlines of proposed Rule 55(a)(2) or the foreign office or the PTO has not perfected the electronic transfer of the priority document. Proceeding under this rule should not be considered an “unintentional delay” attributable to the actions of the applicant, and should not affect patent term adjustment determinations made by the Office or the priority benefit due to the applicant. The proposed rule could impose reasonable requirements, such as that the applicant provide evidence that a certified copy (or suitable electronic copy) was requested in a timely manner from the foreign intellectual property office or that applicant requested in a timely manner the USPTO to retrieve a foreign priority document from a foreign patent office or from WIPO. The Office should also consider following the approach set forth in PCT Rule 17.1, which address scenarios where the timing of provision of the certified copy is affected by the actions of the patent offices, rather than solely the patent applicant.<sup>5</sup> The USPTO should adopt a procedure more similar to PCT rule 17.1.

Additionally, the Office should revise proposed Rule 55(d)(1) or provide a clarification of this clause of Rule 1.55 that makes clear that the Office will apply this authority to extend the deadline in scenarios where the certified copy has not been provided in a timely manner pursuant to a priority document exchange agreement. As presently stated in the rule, the Office will consider a priority claim timely if the certified copy is received by the Office “by such later time as may be set by the Office.” This manner in which this language provides the authority for the PTO to extend the deadline for receiving the certified copy is not clear or predictable for patent applicants. The language should be changed to provide that this deadline will be extended until actual receipt of the copy from the foreign office, if electronic transfer from patent office to patent office is used, or a reasonable time after applicants receive the copy from the foreign patent office. The Office should confirm that delays of a foreign office or the PTO will not prejudice the ability of the applicant to perfect its priority claim or cause a reduction in the patent term adjustment to which the applicant would otherwise be entitled.

In addition to these problems, Proposed Rule 1.55 as drafted raises a number of other concerns.

First, the language in Proposed Rule 1.55(a) is unclear with respect to applications that claim priority to multiple prior filed applications. As presently framed, proposed Rule 1.55(a)(2) provides that the claim for benefit and the certified copy the priority application must be received by the Office no later than the later of four months from the actual filing date of the application making the priority claim, or “sixteen months from the filing date of the prior foreign

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<sup>5</sup> PCT Rules 17.1(a)-(d) provide that “... any copy of the said earlier application which is received by the International Bureau after the expiration of that time (16 months after the priority) shall be considered to have been received by that Bureau on the last day of that time limit if it reaches it before the date of international publication”, (c) “...applicant given an opportunity to furnish priority document in a time limit reasonable under the circumstances” and (d) No ... disregard the priority claim under (c) if ... filed with it in its capacity as a national office or if the priority document is, in accordance with the Administrative Instructions available to it from a digital library.”

application.” In situations where multiple foreign applications have been filed before the U.S. filing date to which a claim of priority is warranted, the language of proposed Rule 1.55(a)(2) may be unclear. To rectify this problem, the Office should revise proposed Rule 1.55(a)(2) to clarify either that the deadline is sixteen months from the earliest priority application to which a claim for priority is made, or sixteen months from the filing date of any priority application to which a claim of priority is made.

Second, the Office should revise Rule 1.55 and/or provide clarifications as to its application to in situations where an applicant files a U.S. continuation application claiming benefit of a PCT application designating the United States, rather than simply entering the U.S. national phase under the PCT (so called “by-pass” applications). In particular, proposed Rule 1.55 should be revised to make clear that an applicant who files a U.S. application under 35 U.S.C. § 111(a) claiming the benefit under § 120 of an earlier filed international application designating the United States may establish compliance with Rule 1.55 either by complying with Rule 1.55(a)(2) (applicable to “original” applications) or by establishing compliance with Rule 1.55(a)(3) (applicable to PCT national stage applications) during the international phase of the parent PCT application. Doing so will provide applicants the greatest flexibility to choose the path of entry into the U.S. for an application filed under the PCT, without prejudice to the Office or the public. In this respect, we note that in bypass applications in which the parent international application has published, submission of certified copies of parent international applications, and foreign priority documents from which the international applications claim benefit, will be available to the public from WIPO (e.g., through the WIPO website). To ensure that such priority documents are available whether the international application has published or not, applicants can attest to the fact that copies of the originally filed parent international application and true copies of all the foreign priority documents were submitted to the PCT by a given date. If such priority documents were available to the public through WIPO when the US patent application published, the Rule should not automatically require the submission of certified copies, unless specifically requested by the PTO. If such priority documents are not available to the public through WIPO when the US patent application publishes, then applicant can be required to provide such copies to the USPTO pursuant to Rule 1.55(a)(2).

Third, proposed 37 CFR 1.55(a)(3), which relates to § 371 applications, has been amended to require that a certified copy of the foreign application be filed within the time limit set forth in the PCT and the Regulations under the PCT. The PTO should clarify that this new requirement refers to the filing of a certified copy during the international phase, not the national phase. Again, the proposed Rule provides no recourse if, through no fault of applicant, copies of priority documents were not timely transmitted to the PCT receiving office from another national office or certified copies of the priority documents were not available for submission. The implication is that if copies of priority documents are not timely filed during the international phase, then loss of priority rights would occur.

**(b) Comments on Proposed 37 CFR 1.104 (concerning joint research agreements)**

Proposed 37 CFR 1.104 (c)(5)(i) and (ii) relates to joint research agreements and subject matter that would be considered prior art under 35 U.S.C. 102(e), (f) or (g) in effect prior to

March 13, 2013. BIO believes that (i) and (ii) should be clarified by changes that explain that those sections apply to a claimed invention in an application “pending” . . . on or after December 10, 2004.

**(c) Comments on Proposed 37 CFR 1.130**

Proposed 37 CFR 1.130 governs the practice of invoking the grace period to overcome a prior disclosure of subject matter that is used to reject a patent claim. In general, BIO believes the use of declarations to overcome rejections based on prior art is appropriate, but notes that expression of one aspect of this authority in the proposed Rule is imprecise and should be changed.

To be proper under proposed 37 CFR 1.130(b), (c), (d) or (e), a declaration “must provide a satisfactory showing that the inventor or a joint inventor is in fact the inventor of the subject matter of the disclosure.” The rules thus appear to require that the subject matter of a disclosure being applied in a rejection against a claim be an invention. This may not be the case – a disclosure may only disclose information conveyed by an inventor that is later published and thereafter used in conjunction with other information to reject a claimed in an application (e.g., as being obvious under 35 U.S.C. § 103).

The proposed rule should be revised to remove the requirement that the “subject matter disclosed” be shown to have been “invented” by one of the inventors of the application. Instead, the rule should conform to the statute, and require merely that the declaration establish that the subject matter that is disclosed was obtained directly or indirectly from an inventor of the invention that is claimed. In this respect, the Office may properly require a showing that the individual from whom the disclosed subject matter was obtained is an inventor of the claimed invention; however, as presently cast, it is improper to require a showing that such person “invented the subject matter disclosed,” as such subject matter may not necessarily correspond to the claimed invention.

As noted above, this requirement is imposed in several paragraphs of the proposed rule. A suitable change to each of these paragraphs of proposed Rule 1.130 should be made.

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BIO respectfully requests the Office to revise the rules and clarify its practice under the rules as noted above.

Sincerely,

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