BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

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: *supplemental_examination@uspto.gov*

Re: Notice of Proposed Rulemaking; USPTO Docket No. PTO–P–2011–0075
"Changes To Implement the Supplemental Examination Provisions of the Leahy-Smith America Invents Act and To Revise Reexamination Fees"

Washington, D.C., March 26, 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 Supplemental Examination Provisions of the America Invents Act (AIA) as set forth at FR Vol. 77(16), 3666 ff. (Wednesday, January 25, 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 depend on their intellectual property for access to capital, and to make business decisions for product development and licensing of inventions that often require many years of sustained investment before reaching the marketplace. From BIO's perspective, Supplemental Examination may have significant benefits, because patents that undergo this process are expected to be stronger, clearer, and can be better relied on for investment, product development, and commerce.

In general, BIO believes that the PTO's proposed Rules put forward a basically sound framework. However, in a number of particulars BIO also believes that the proposed Rules create disincentives that could, in practice, severely limit the usefulness and actual utilization of the proceeding. The proposed proceeding carries a relatively high price tag, incorporates uncertain elements that generate unnecessary legal risk, and appears to require Supplemental Examination requests to be modeled along the the lines of what is required for an *ex parte* reexamination request without appreciating that the two types of request serve different purposes: While an *ex parte* reexamination request is designed to convince the PTO that a substantial new question does exist (see, e.g. MPEP 2214, "A requester must not, in a request for reexamination, argue that the submitted references do not raise a substantial new question of patentability"), a supplemental examination request is designed to determine whether a substantial new question exists.

Because BIO understood the Supplemental Examination request to be more in the nature of a "justified inquiry" as to the effect of the submitted information - rather than an advocacy document seeking invalidation or correction of the patent - it is unclear to BIO why the proposed Rules would require such a high degree of "spoon-feeding." The proposed Rules would require requesters to lay out exactly which legal issues the PTO should examine for exactly which part of the patent in light of the submitted information items. By limiting its review to only the legal issues as framed and presented by the requester, the PTO would incentivize applicants to be over-inclusive in the scope of their requests, and reduce the value of the proceeding to patentees who seek a truly independent, "blank-slate" look at the patent in light of the submitted information. Also, if the PTO's review of the submitted information were as highly limited and applicant-dependent as the proposed Rules set forth, BIO members would be concerned that the proceeding's effect on subsequent inequitable conduct allegations could be construed more narrowly in district court litigation than intended by Congress. Inequitable conduct allegations are weakened if the PTO took a fresh, unbiased look at the submitted information. They may actually be strengthened if the scope and substance of that review is confined to how the patentee framed (or was required to frame) the issues.

The proposed Rules would also require excerpting, summarizing and paraphrasing of information, and the making of numerous affirmative representations by requesters that go far beyond a simple patentee disclosure. Patentees who simply wished to disclose information for consideration or reconsideration would have to create a large body of affirmative representations about the submitted information and its applicability to the patent – these representations would not always seem necessary, and create new vulnerability under the *Therasense* "egregious, affirmative" prong.

Moreover, because the filing and completion dates of the Supplemental Examination proceeding are critical, the Office should provide more flexibility in its filing date determinations. In their proposed form, the current Rules are very unforgiving and deny a filing date for even small, formal errors. Also, because the Rules' requirements with respect to information "items," and the identification, mapping, and explanation of "issues" to "aspects" are difficult to meet, even patentees who make every effort at compliance may find themselves denied a critical filing date without the possibility of a quick decision on any petition relating thereto.

Finally, some member companies have raised questions over the standard that the PTO will utilize as to when it has found "material fraud" for referral to the Attorney General. Some members believe that the PTO should provide the general contours of the minimum standard to determine when conduct will be considered "material fraud."

Some observations on specific proposed Rules follow below:

Proposed 37 C.F.R. § 1.601: The proposed Rule states that only an owner or owners of the entire right, title, and interest in the patent may file a request for supplemental examination. Some BIO members seek clarification that attorneys or agents having a power of attorney or acting in a representative capacity can file requests and other papers in the proceeding, analogous to Rule 1.510(f) for *ex parte* reexamination requests.

Proposed 37 C.F.R. § 1.605: BIO believes that the limitation to 10 items may be too inflexible, especially since the definition of what constitutes an "information item" is necessarily somewhat open-ended. The same general information may be contained in multiple information "items" that all relate to one underlying potential issue of patentability that is sought to be clarified. For example, an instance of a possible public use may be documented by an exhibition catalogue, photograph, instruction pamphlet, newspaper article, and affidavit. In cases where multiple information items can be deemed merely cumulative to each other, BIO suggests that the PTO would not be unduly burdened if it were to consider an exemption from the 10-item limit.

More flexibility may also be needed if the underlying information is not of a simple, written nature. If information is contained in photographs, videos, samples, software, or articles, the information will likely need to be accompanied by supporting documentation in the form of, e.g., dated sales receipts, analytical reports, exhibition catalogues, and expert declarations. If such supporting documentation counts as separate "items," the item limit could quickly be exceeded.

Finally, more flexibility is needed because inadvertent failure to adhere to the 10-item limit can lead to a denial of the filing date under proposed Rule 610(d).

Proposed 37 C.F.R. § 1.610(b)(4): This proposed Rule would require a list of information items, and a statement explaining why consideration or reconsideration of each item is requested, or how correction is being made. BIO's members seek further clarification of the need for the justifications required by subparagraphs (i) and (ii). For subparagraph (i), a simple statement that the requester believes the information to not have been previously considered should be sufficient – what else need the requester say? For subparagraph (ii), does the PTO want an explanation why the information was not adequately considered, or how exactly the prior consideration was inadequate?

Proposed 37 C.F.R. § 1.610(b)(5): This proposed Rule would require a list of any prior or concurrent PTO proceeding involving the patent and related information. The information requested is readily and easily available to the PTO. To require this

information by Rule would seem to accomplish little other than to create a potential source of error and defective requests.

Proposed 37 C.F.R. § 1.610(b)(8): This proposed Rule would require detailed explanations of all issues of patentability raised by the request. Detailed mapping of information "items" to particular parts of the patent, and to particular legal issues, would need to be provided by the requester. BIO's general concerns with this proposed Rule are set forth above. BIO believes that this Rule would be burdensome for requesters and the PTO alike. Because the PTO would generally limit its review to the "issues" as identified and framed by the requester (see proposed Rule 1.620(a)), requesters would be systematically incentivized to raise every conceivable legal issue, no matter how strained its applicability.

Proposed 37 C.F.R. § 1.610(b)(11): This proposed Rule would require summaries of documents over 50 pages in length. BIO believes that, at most, highlighting should be sufficient. The need for a separate summary is unclear, especially since the patentee is already required to pay excess document fees for such documents. Some BIO members have expressed concern that the proposed requirement to not just submit, but to affirmatively extract "relevant portions" of documents creates unnecessary legal risk under the "affirmative" prong of the *Therasense* standard without greatly aiding independent review by the examiner.

Proposed 37 C.F.R. § 1.610(c): This proposed Rule would permit the filing of an explanation why or why not each information item raises a substantial new question of patentability. While this provision is appropriately voluntary, it is unclear how this explanation differs meaningfully from the required explanation of proposed Rule 1.610(b)(8). BIO's members would benefit from further guidance as to how an "issue of patentability" differs from a "substantial new question of patentability."

Proposed 37 C.F.R. § 1.610(d): Filing dates can be critically important under 35 U.S.C. § 257(c). With the exception of errors in the table of contents or coversheet ("at the discretion of the Office"), this proposed subsection would cause requesters to lose their filing date for noncompliance with formalities under proposed Rule 1.615 or for arguable noncompliance with the requirements of proposed Rule 1.610. As discussed above, it will not always be clear to a requester whether all requirements of proposed Rule 1.610 are met by a request, as the Rule's requirements are not very clear. What happens, for example, if the PTO sees an insufficiency in the mapping of "items" to "aspects" and "issues" under proposed Rule 1.610 (b)(6)-(8)? What if the PTO's count of "information items" in the request differs from the requester's count? It seems very easy for a patentee to inadvertently lose the filing date of a request. This concern is aggravated by an inability to obtain a quick decision on a petition relating to the denial of a filing date (see PTO's commentary to proposed Rule 1.620 (petitions held in abeyance)).

Proposed 37 C.F.R. § 1.620: The proposed Rule states that the PTO's determination of a substantial new question of patentability will generally be limited to the identified aspects of the patent. BIO's concerns with the proposed "passive" review

process have been discussed above. BIO does not believe the PTO should require patentees to explain and frame the legal issues for review, and then limit its determination to only the issues identified by the patentee, and in the form in which they were presented by the patentee. Doing so would limit the value of the proceeding as an independent Patent Office assessment of the information and its relevance for patentability.

Proposed 37 C.F.R. § 1.625: The PTO should specify that the electronically-issued supplemental examination certificate will also display the filing date of the request. The PTO should also consider whether any *ex parte* reexamination certificate in an *ex parte* reexamination ordered under 35 U.S.C. 257 should be issued electronically.

Respectfully submitted,

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Biotechnology Industry Organization