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March 23, 2012

Via Electronic Mail supplemental_examination@uspto.gov copy to Cynthia.Nessler@uspto.gov

The Honorable David J. Kappos
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office
Mail Stop Comments - Patents
P.O. Box 1450
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Attn: Cynthia L. Nessler, Sr. Legal Advisor

Re: Comments on Changes to Implement Supplemental Examination Provisions of the Leahy-Smith America Invents Act, 77 Fed. Reg. 3666 (Jan. 25,

2012)

Dear Under Secretary Kappos:

I am writing on behalf of the American Bar Association Section of Intellectual Property Law (the "Section") to provide comments in response to the request of the United States Patent and Trademark Office ("the Office") published in the Federal Register on January 25, 2012 (PTO-P-2011-0075). In particular, the Section submits the following comments on the *Changes to Implement Supplemental Examination Provisions of the Leahy-Smith America Invents Act*, 77 Fed. Reg. 3666 (the "Supplemental Examination Notice"). These comments have not been approved by the American Bar Association's House of Delegates or Board of Governors and should not be considered to be views of the American Bar Association.

The Section provides comments on the following four aspects of the Supplemental Examination Notice: (1) The 10-item limit for items of information cited in a request for supplemental examination, (2) the content requirements for a request for supplemental examination, (3) the Office's definition of "material fraud" and (4) certain discretionary aspects of the proposed rules implementing supplemental examination.

1. The Hard 10-Item Limit for Items of Information Cited in a Request for Supplemental Examination Should be Replaced by a Sliding Fee Scale for Additional Items of Information

The Leahy-Smith America Invents Act places no limits on the quantity of information that can be considered, reconsidered or corrected in a supplemental examination. The Section believes that placing a limitation on the number of items that can be considered in a single request for supplemental examination is both unworkable and unwise. To the extent such a limitation would necessitate that patent owners prepare and file multiple requests for supplemental examination concurrently in order to provide the Office a complete picture of potentially relevant information, the Office would be forced to examine these requests simultaneously, in a coordinated manner, in order to assure that any substantial new questions of patentability could be identified and, if so, a single reexamination proceeding to consider them could be commenced. Thus, placing a numerical limitation of this type on a single supplemental examination request can neither serve the interests of patent owners nor the Office.

Proposed 37 C.F.R. § 1.605(a), however, would permit "no more than ten items of information believed to be relevant to the patent" in a single request for supplemental examination, while expressly permitting multiple requests to be filed for the same patent to have additional items of information considered, reconsidered, or corrected. The Section urges that this ten-item limitation be removed in the final rulemaking in order to assure consistency with the new statute¹ and the greatest possible efficiency for both

¹ The Director is given broad authority under the AIA to require that requests for supplemental examination

be made "in accordance with such requirements as the Director may establish." The Section supports that the Director have wide discretion in implementing this new procedure in the public interest, consistent with the intent of Congress that it benefit the public by allowing the Director to reexamine issued patents and eliminate invalid claims from those patents, as well as assure patent owners that any patent claims surviving supplemental examination can be more reliably enforced. The 10-item limitation does, however, call into question whether the proposed rules would operate in such a proscriptive manner as to negate the express provisions in the statute that supplemental examination is to be available to patent owners. The only justification cited by the Office for the 10-item limit is that "inequitable conduct" allegations in the courts typically do not exceed 10 items of possible wrongdoing. The Office's assumption in this respect is both wrong and irrelevant. First, in many patent litigations, literally dozens of potential inequitable conduct allegations are pursued, particularly during discovery, in hopes of finding a subset of such issues to pursue and present at trial. Thus, a substantial minority of requests for supplemental examination may well exceed the 10-item limit. Second, even if a 10-item limit would suffice with respect to a numerical majority of patent prosecutions, the proposed rules should not be crafted to knowingly ignore a sizable minority of patent owners who may seek Office consideration of multiple items of prior art and multiple statements made during patent examination. As a loose analogy, a substantial majority of patent applicants would not, for example, exceed a 100-page limitation, were it to be imposed by rule on drafting applications for patent.

The Office, however, could not sensibly interpret its regulatory authority to require any disclosure in excess of a 100 page limit be placed in a separate patent filing simply on the ground that the vast majority of inventors would be unaffected by such a generous page limitation. The Office should, therefore, refrain from testing the reach of its statutory authority under the new law by imposing such a limitation on items

for consideration in a supplemental examination.

patent owners filing supplemental examination requests and the Office considering such requests.

The Supplemental Examination Notice also proposes to set the base fee for filing a request for supplemental examination at \$21,300 (\$5,180 per 37 C.F.R. § 1.20(k)(1) plus \$16,120 per 37 C.F.R. § 1.20(k)(3)). Extra charges would be required for every non-patent-literature document over 20 pages included with the request. Thus, under the Office's proposed rules, a request for supplemental examination having 10 items of information would cost at least \$21,300. Should the patent owner have an eleventh item of information to submit for consideration, then a second request for supplemental examination would need to be filed with another fee of at least \$21,300, according to the proposed rules.

The Section believes that the fee structure exposes yet another defect in the 10-item limitation. The marginal cost of considering the 11th item of information is, in effect, set at 10 times the cost of considering each of the first 10 items of information. While the Section appreciates that the cost and time for the Office to evaluate a request for supplemental examination may depend, in part, on the number of items of information submitted (and, if so, the fees set should so reflect the cost and time), the Section believes that the 10-item limit is not only an arbitrary limit not justified statutorily, but *de facto* crosses the line by producing a disproportionate fee.

A more reasonable approach, which the Section is prepared to support, is to institute a sliding fee scale under which each additional item of information after the tenth requires payment of an additional fee. Further, the additional fee for each item should be significantly less than one-tenth the cost of filing a second proceeding, but reflect the cost and time that would need to be devoted to carefully consider all questions of patentability that might arise.

This approach of setting fees for a supplemental examination request at a level more closely approximating the cost to the Office of providing the service should benefit the Office to a much greater degree than the imposition of the arbitrary, 10-item limit. For example, if the Office is concerned that a sliding fee scale might result in a single supplemental examination request that would be much larger than a set of individual, 10-item requests all directed to the same patent, it is likely that the Office would be better positioned to evaluate a single (albeit larger) document within the three-month statutory time limit than it would to be able to evaluate multiple simultaneously filed requests. Since a patent owner, in requesting supplemental examination, would likely bring all items of information to the Office's attention at the same time, it would appear in everyone's interest that this be done in one document as part of one request.

The Section is also concerned that the magnitude of the proposed fees for supplemental examination may make the proceeding too costly for a majority of the potential users which, in turn, will frustrate congressional intent in creating such a proceeding. That said, the Section does not believe that supplemental examination should

be subsidized through other fees collected by the Office. The Section, therefore, is prepared to support a cost-recovery level of fee-setting for this new proceeding. To this end, fees would be set at a level no greater than required for the Office to recover in aggregate fee collections its reasonably estimated costs for performing the work it anticipates will be required to undertake supplemental examinations. In addition, the Section urges that the Office periodically revisit the fees for supplemental examination to assure that the aggregate fee collections continue to reflect the actual costs for the corresponding work performed by the Office.

The Section has earlier expressed its concerns that the Office would be making an inferior policy choice by attempting to discourage the use of supplemental examination by patent owners by charging fees in excess of costs. (The Section has written separately, in another letter to the Office, to express these concerns in more detail.) In situations where the original patent examination was incomplete or the record before the Office requires correction, the congressional intent was that patent owners should be encouraged to come forward voluntarily to complete or correct the examination record, with the Office then having the opportunity to fully reexamine any claims of the patent. Feesetting, consistent with this intent, can be achieved though a cost-recovery model.

2. The Office Should Simplify the Overly Complicated and Redundant Content Requirements for a Request for Supplemental Examination

As noted above, supplemental examination holds the promise of improving the quality of issued U.S. patents. If optimally implemented by the Office, it should provide assurance to the public that the Office has carefully considered all information that is necessary for an accurate and complete examination of each claimed invention in a patent for which a supplemental examination proceeding has been instituted.

In addition to appropriate fee-setting, a second means for encouraging patent owners to make appropriate use of supplemental examination is by limiting the content of any request for supplemental examination to information that is essential to assuring an accurate and complete examination with respect to the new or corrected information for which the examination is being sought. In other words, the rules for implementing supplemental examination should require that the request contain – and be substantially limited to – the information needed for the Office to readily identify a substantial new question of patentability presented through the new or corrected information contained in the request.

Given this objective, to the extent that the proposed rules are too vague in laying out the requirements for a complete request, are overly broad in specifying the information to be included in the request, or are open-ended in stating the content required for a complete request for supplemental examination, the Office could easily defeat the congressional purpose in enacting this new procedure. The Section is concerned that, as drafted, the proposed rules are unworkable for both requesters and the Office.

The Office's proposed 37 C.F.R. § 1.610(b) contains twelve separate subparts specifying in elaborate detail the required components of a request for supplemental examination. The Section respectfully submits that these requirements are (or, at a minimum, could be interpreted to be) vague, overly broad, overly complicated, unduly open-ended, and – in material respects – redundant.

For example, under the proposed rules, a petition for supplemental examination must include:

- 1. A list of each item of information to be considered.
- 2. An explanation of why consideration, reconsideration, or a correction is being requested for each item of information.
- 3. An identification of each aspect of the patent for which supplemental examination is sought.
- 4. An identification of each issue raised by each item of information.
- 5. A detailed explanation for each identified issue, discussing how each item of information is relevant to each aspect of the patent identified, and how each item of information raises each issue identified.
- 6. Optionally, an explanation of why each item of information does or does not raise a substantial new question of patentability.

37 C.F.R. § 1.610(b)(4), (b)(6), (b)(7), (b)(8), (c).

The Section submits that items 3-6 on the list above are either wholly or partially redundant with items 1 and 2. Furthermore, the requirements are overly complicated insofar as they require the open-ended identification of "each issue raised by each item of information" and "each aspect of the patent for which supplemental examination is sought."

As a practical matter, this "each-each" requirement poses virtually impossible compliance obligations on the patent owner and, thus, creates an unmanageable burden on the Office. What is an "aspect of a patent"? Is the term "issue" used in the context of "issue-spotting" (i.e., as might be appropriate in the context of a law-school examination) or is the term merely used to reference a statutory "issue" of patentability (i.e., such that a general averment that an "issue of novelty or non-obviousness" may be presented)? Of even greater concern, if the applicant spots 100 separate law-school "issues," but the Office identifies a 101^{st} issue of patentability, is the supplemental examination request defective for failure to delineate "each issue"?

The Section submits that the core of the request should be a simple explanation called for in item 2 ("why consideration, reconsideration, or a correction is being

requested for each item of information."). A simple identification of each item, along with an explanation for why consideration of that item is sought, should be sufficient for the Office to review a request and get to the merits of any substantial new question of patentability.

Thus, absent a significant simplification of the proposed rules, there is likely to be confusion over the distinction between these many separate requirements and how they should be presented in the request. This will likely lead to lengthy requests containing significant repetition, as requesters attempt to fit explanations into the required categories. The Office might be *less likely* rather than *more likely* to identify questions of patentability simply because of the bulk of utterly irrelevant information that the proposed rules would require in order for a request to be assured of being complete.

The Section is also concerned that patent owners will be routinely second-guessed as to whether "each issue" was identified. It is much easier to inadvertently fail to comply with more complicated and detailed requirements. Thus, rather than encouraging use of supplemental examination, the proposed rules have the potential to chill uses that would otherwise have been clearly within the public interest and the congressional intent in enacting the new statute.

For example, because the benefit of supplemental examination against charges of inequitable conduct does not apply to allegations pled before the date of the request, a patent owner's request that is not granted a filing date (because of noncompliance with the rules) could inform an accused infringer how better to raise an inequitable conduct charge. And this inequitable conduct charge could go forward notwithstanding a later filed supplemental examination request that cures the infirmities in the earlier noncompliant request. *See* discussion of proposed 37 C.F.R. § 1.610(d) *infra* under heading 4 of this letter. Such a result is not what Congress intended when it enacted supplemental examination as a mechanism to reduce the number of inequitable conduct charges faced by patent owners.²

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² If the rules were reconstituted to provide a *simple and straightforward* set of statements from the patent owner with respect to each item of information being submitted for consideration, there should be little, if any, justification for failing to grant a filing date to a request for supplemental examination. Thus, the Office should consider dispensing altogether with a mechanism for denying any supplemental request a filing date. If any vestige of this authority is to be retained, then it should be applied only in specified situations where the Office detects a gross deficiency in the request as filed, sufficient to justify an exercise of discretion to deny a filing date. Even in the case of a gross deficiency in the original request, the decision to deny a filing date should be done expeditiously, such that the patent owner is on notice of the manifest deficiency and, thus, has the opportunity to file a renewed request promptly. For this purpose, it would seem appropriate for the Office to set a 30-day time period in which the Office would affirmatively notify the patent owner that a supplemental examination request has been accepted, and thus accorded a filing date, or rejected as containing one or more gross deficiencies. For a request containing any other types of deficiencies, *i.e.*, ones that are deemed not to unduly impair the ability of the Office to process the request in order to proceed with the supplemental examination itself, such issues could be readily handled by the Office by *instituting a reexamination* in which the Office would presumptively treat each such deficiency

For these reasons, the Section urges the Office to streamline and simplify the rules regarding the content of a request, and, in particular, to remove requirements that can be regarded as overly complicated, overly broad, too vague, unnecessarily open-ended and ultimately redundant relative to the information actually needed by the Office to assure the most efficient identification of a substantial new question of patentability.

3. Definition of "Material Fraud"

Subsection (e) of section 257, the new supplemental examination statute, requires the Director to refer to the Attorney General any matters arising as a result of a supplemental examination in which the Director becomes aware of "material fraud" in connection with the patent. Proposed 37 C.F.R. § 1.620(g) reflects this duty. The Supplemental Examination Notice notes that the Office considers "material fraud" to be narrower in scope than inequitable conduct as defined in *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011) (en banc), but does not otherwise indicate a definition or standard for "material fraud."

Given the serious consequences that can follow from the Office's determination that material fraud has occurred, the Section encourages the Office to clarify what it will consider to constitute "material fraud."

4. Discretionary Aspects of the Supplemental Examination Rules

The Section encourages the Office to more definitely state the Office's policies regarding a number of matters for which the proposed rules leave discretion to the Office.

For example, if a request for supplemental examination does not comply with the requirements of proposed Rule 610(b) but those infirmities are later cured, then the Office would retain unfettered discretion to accord the request either the earlier or the later filing date. *See* proposed 37 C.F.R. § 1.610(d) ("A defective request *may* receive a filing date if the defects are limited to the omission of one or more of the requirements set forth in paragraph (b)(1) or (b)(2) of this section, *subject to the discretion of the Office*." (emphases added)). As noted above, the granting of a filing date to a request for supplemental examination can have repercussions in related litigation and should not be left to chance.

in the information provided in the request as raising a "substantial new question of patentability." The Office would provide notice to the patent owner that reexamination raised substantial new questions of patentability because further information from the patent owner was needed in order for the Office to resolve such questions.. By limiting the denial of a filing date to a supplemental examination request solely to the circumstance where the Office identified gross deficiencies – and by addressing any other deficiencies in the information provided in the request as issues to be resolved in a Director-ordered reexamination – the Office would encourage patent owners to provide requests that were in full compliance with the rules in order to reduce the costs and delays associated with any reexamination of the patent that would otherwise be necessitated.

Other examples where the proposed rules leave matters to the discretion of the Office include the following proposed rules (with emphases added):

37 C.F.R. § 1.605(d) ("where it may be necessary to combine items of information in order to raise an issue to be considered, reconsidered, or corrected, each item of information of the combination *may be* separately counted.")

37 C.F.R. § 1.620(a) ("The determination [whether a substantial new question of patentability is raised] will *generally* be limited to a review of the issues identified in the request as applied to the identified aspects of the patent.")

In each case identified above, the Section is concerned that the uncertainty created by the permissive language in the proposed rules would be detrimental to patent owners and the public. The Section therefore encourages the Office to revise these rules to replace all unnecessary discretionary language with a more definitive explanation of the Office's policy.

In closing, the Section recognizes and appreciates the Office's efforts to solicit public opinions regarding rules proposed in the Supplemental Examination Notice and offers the foregoing comments in an effort to help the Office implement rules that best serve the interests of the users of the patent system and the public.

If you have any questions on our comments or would wish for us to further explain any of our comments, please feel free to contact me. Either I or another member of the leadership of the Section will respond to any inquiry.

Very truly yours,

Robert A. Armitage Section Chairperson

American Bar Association

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Section of Intellectual Property Law