

March 26, 2012

The Honorable David J. Kappos Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office United States Patent and Trademark Office 600 Dulany Street Alexandria, VA 22314 Via email: (supplemental\_examination@uspto.gov)

# Re: Comments on Notice of Proposed Rulemaking – "Changes to Implement Supplemental Examination Provisions of the Leahy-Smith America Invents Act and To Revise Reexamination Fees," <u>77 Fed. Reg. 3666 (January 25, 2012)</u>

Dear Under Secretary Kappos:

The American Intellectual Property Law Association ("AIPLA") is pleased to have the opportunity to present its views with respect to the Notice of Proposed Rulemaking entitled "Changes to Implement Supplemental Examination Provisions of the Leahy-Smith America Invents Act" ("AIA") as published in the January 25, 2012, issue of the *Federal Register*, 77 Fed. Reg. 3666 (hereinafter the "Proposed Rule" or "Notice of Proposed Rule").

AIPLA is a U.S.-based national bar association whose approximately 15,000 members are primarily lawyers in private and corporate practice, government service, and the academic community. AIPLA represents a diverse spectrum of individuals, companies, and institutions involved directly and indirectly in the practice of patent, trademark, copyright, unfair competition, and trade secret law, as well as other fields of law affecting intellectual property. Our members practice or are otherwise involved in patent law and other intellectual property law in the United States and in jurisdictions throughout the world.

### **Executive Summary**

Section 12 of the AIA adds a new Section 257 to Title 35,<sup>1</sup> permitting a patent owner to request supplemental examination of a patent to consider, reconsider, or correct information believed to be relevant to the patent. Information that may be presented in a request for supplemental examination is not limited to patents and printed publications, and may include, for example, material raising issues of patentability under 35 U.S.C. §§ 101 and 112.

<sup>&</sup>lt;sup>1</sup> References to the statute will hereinafter refer to the newly added sections of Title 35.

<sup>241 18</sup>th Street, South · Suite 700 · Arlington, VA 22202 Phone: 703.415.0780 · Fax: 703.415.0786 · www.aipla.org · aipla@aipla.org

Furthermore, supplemental examination is not limited to issues concerning prior art and may be used to consider affidavits or declarations presented during a prior examination that contained incorrect information, irrespective of the reason. If a substantial new question of patentability is raised by one or more of the items of presented information, the supplemental examination is concluded by issuance of a supplemental examination certificate ordering *ex parte* reexamination conducted according to reexamination procedures, except that the reexamination is not limited to patents and printed publications, but rather, will consider any type of information submitted in the request that raises a substantial new question of patentability.<sup>2</sup> Notice of Proposed Rule, 77 Fed. Reg. at 3666.

The effect of a supplemental examination (35 U.S.C. § 257(c)) is that "with two exceptions,<sup>3</sup> a patent shall not be held unenforceable on the basis of conduct relating to information that had not been considered, was inadequately considered, or was incorrect in a prior examination of the patent if the information was considered, reconsidered, or corrected during a supplemental examination of the patent."<sup>4</sup> 77 Fed. Reg. at 3666.

If the Director of the USPTO becomes aware during the course of a supplemental examination or reexamination proceeding ordered under Section 257 that a "material fraud on the Office may have been committed in connection with the patent that is the subject of the supplemental examination," then in addition to any other actions the Director is authorized to take, including the cancellation of any claims found to be invalid under Section 307 as a result of a reexamination ordered, the Director "shall also refer<sup>5</sup> the matter to the Attorney General for such further action as the Attorney General may deem appropriate." 35 U.S.C. § 257(e).

<sup>&</sup>lt;sup>2</sup> A further exception is that the patent owner does not have the right to file a statement pursuant to 35 U.S.C. § 304. If the items of information in the request do not present a substantial new question of patentability, the certificate will so indicate, terminating any further proceedings. Proposed Rule, 77 Fed. Reg. at 3666.

<sup>&</sup>lt;sup>3</sup> The two exceptions occur where an item of information in a request is (1) prior to a supplemental examination request, contained in an allegation pled with particularity in a civil action or is set forth in a notice as provided by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)(2)(B)(iv)(II)), or (2) the basis of a defense in an action brought under Section 337(a) of the Tariff Act of 1930 (19 U.S.C. § 1337(a)), unless the supplemental examination and any *ex parte* reexamination ordered are concluded prior to the date on which the action is brought. 35 U.S.C. §§ 257(c)(2)(A)-(B).

<sup>&</sup>lt;sup>4</sup> This provides patent owners with the ability to bring back to the United States Patent and Trademark Office ("USPTO") any information that was for any reason not fully or adequately considered during a previous examination, and to ensure that the patent claims are either unaffected as to their patentability by such information, or that the claims are otherwise appropriately further amended to take the effect of such information into account. For example, a company acquiring a portfolio from a smaller entity which did not have sophisticated counsel might spend the time to go through the portfolio to make sure the USPTO had a chance to review everything which could potentially raise an issue (under *McKesson* for example) which might not have been expressly presented during the original prosecution. This is expected to have a beneficial effect in reducing the cost and complexity in litigation involving such patents, particularly since such circumstances often give rise to allegations of inequitable conduct. In addition to the other benefits noted above, as recognized by the USPTO, a further "benefit afforded to patent owners by supplemental examination is to potentially shield patent owners from a finding of unenforceability due to inequitable conduct for the information considered by the [USPTO]" during supplemental examination. 77 Fed. Reg. at 3675.

<sup>&</sup>lt;sup>5</sup> "Any such referral shall be treated as confidential, shall not be included in the file of the patent, and shall not be disclosed to the public unless the United States charges a person with a criminal offense in connection with such referral." 35 U.S.C. § 257(e).

AIPLA Comments on Supplemental Examination March 26, 2012 Page 3

Section 257(d)(1) provides the Director with the authority to establish fees for filing a request for supplemental examination and for requiring payment of the fees applicable to *ex parte* reexamination when ordered. Hence the Proposed Rule establishes supplemental examination fees and also revises reexamination fees.

While some have questioned whether supplemental examination is necessary as a means for reducing the number of cases in which inequitable conduct is pled as a defense, in light of the Federal Circuit's *en banc* decision in *Therasense, Inc. v. Becton, Dickinson, and Co.*, 649 F.3d 1276 (Fed.Cir. 2011),<sup>6</sup> AIPLA generally supports the availability of supplemental examination as a means for reducing the number of cases in which inequitable conduct is pled. However, AIPLA is concerned that the cost and complexity of supplemental examination under the Proposed Rule will seriously deter use of supplemental examination and will thus significantly limit its use as a helpful procedure for patent owners. AIPLA is also concerned that the Proposed Rule does not provide adequate safeguards for registered practitioners or others whose conduct may be called into question in the course of a request for supplemental examination.

With the foregoing in mind, AIPLA offers the following detailed comments to the Proposed Rules.

## **Detailed Comments in Response to the Proposed Rules**

### **Proposed § 1.601(a)-(b) – Filing by the Patent Owner**

The proposed Sections 1.601(a)–(b) would require that a request for supplemental examination of a patent be filed by the owner(s) of the entire right, title, and interest in the patent, and that ownership of the entirety of the ownership interest must be established as part of the request.

The language of the statute (35 U.S.C. § 257(a)) merely states that "A patent owner may request supplemental examination of a patent . . . ." (Emphasis added.) Thus, at least on its face, by using the phrase "A patent owner," the statute does not appear to require filing by one who owns the entirety of the ownership interest in the patent. Indeed, in some ways this seems at odds with the fact that if a substantial new question of patentability is found and reexamination is ordered, the procedure is then governed by the reexamination rules. Under the rules for "ordinary" reexamination (e.g., reexamination not related to a request for supplemental examination), an *ex parte* reexamination may be filed by "[a]ny person." 35 U.S.C. § 257.

<sup>&</sup>lt;sup>6</sup> Those adopting this view typically argue that a request for supplemental examination is most likely to be prepared by an attorney representing the patent owner who did not prosecute the patent. This in turn will lead to portrayal of the prosecuting attorney's conduct in negative terms. This will detract (in terms of both time and resources of the USPTO) from the USPTO's core task of determining "but-for" materiality when a substantial new question of patentability has been raised by a submitted item of information. Thus, some believe that it would be better to simply rely on *Therasense*, rather than providing yet another forum where the prosecutor is not present and has little or no ability to defend his or her conduct, which will be judged and may result in OED or criminal fraud proceedings.

AIPLA realizes that there may be some circumstances where permitting a request by a patent owner holding less than the entirety of the ownership interest may give rise to more problematic circumstances.<sup>7</sup> Nevertheless, the USPTO in some circumstances should permit fewer than all owners of a patent to request supplemental examination in some circumstances. Consider, for example, circumstances where an inventor/joint owner is deceased or incapacitated, refuses to join or cannot be found after diligent effort, or where one of the owners is an organization that is dissolved. It seems that the Proposed Rule would deny to the owner/other joint owner the benefit of supplemental examination under those circumstances, with no valid justification for doing so.

AIPLA thus suggests that the USPTO revise the Proposed Rule so that fewer than all owners will still be able to request supplemental examination in appropriate circumstances such as those noted.

# <u>Proposed § 1.605(a) and (d) – Items of Information; Proposed §§ 1.610(a), 1.20(k)(1)-(2)</u> and 1.26 – Fee Provisions

Proposed Section 1.605(a) would require that a request for supplemental examination be limited to ten items of information. Section 1.605(d) of the Proposed Rule additionally requires that if two or more items of information must be combined in order to raise a substantial new question of patentability, each item will be separately counted as one of the ten submissions. Coupled with these provisions are the fee provisions under proposed Sections 1.20(k) and 1.26, which require *at the time of filing* a non-refundable request fee of \$5,180, and a reexamination fee of \$16,120 (refundable in the event there is no new substantial question of patentability and hence reexamination is not ordered), for a total fee at the time of filing of \$21,300.

The fee provisions noted above<sup>8</sup> provide context for why the ten-item limit under proposed Section 1.605(a) is troubling. Assume that there are eleven items of information that are believed to be required for consideration in a request for supplemental examination. Eight of the eleven items are believed to raise Section 102 anticipation questions of patentability. Two of the three remaining items are believed to raise questions of non-obviousness when combined with the third remaining (or eleventh) item. Notwithstanding that consideration of items nine through eleven would need to be handled in the same proceeding, the patent owner would be required under the Proposed Rule and fee provisions to file a second request for supplemental examination, separating these items and doubling the cost.

<sup>&</sup>lt;sup>7</sup> Given that at least one purpose of supplemental examination is to potentially shield patent owners from a finding of unenforceability due to inequitable conduct for the information considered, it would be problematic if one joint owner petitioned for supplemental examination to cure a fault for which he or she was blaming the other joint owner. AIPLA believes that such instances would likely be comparatively rare, and would not, as such, justify denial of supplemental examination in other settings such as those noted in these comments.

<sup>&</sup>lt;sup>8</sup> AIPLA has already addressed in some detail the concerns which it has regarding the proposed fees for supplemental examination. See, e.g., AIPLA's "Comments to the Patent Public Advisory Committee (PPAC) on the 'Proposed Patent Fee Schedule," Feb. 29, 2012, pp. 8-9. Those comments will not be restated in their entirety here, but are nonetheless reemphasized by the present comments and are incorporated herein by reference.

Furthermore, the forced filing of multiple supplemental examination requests requires that the USPTO decide whether to merge the proceedings *sua sponte*. This type of outcome seems unwarranted and burdensome,<sup>9</sup> and does not seem to promote efficient use of USPTO resources. Rather, if merger is not undertaken, it would take up valuable examining resources to consider two proceedings which in all likelihood will have a common nucleus of facts.

AIPLA understands that a supplemental examination proceeding is likely, in some cases, to be more complicated than an ordinary reexamination proceeding, which is limited to consideration of patents and printed publications. Thus, it could be considered reasonable to restrict the number of documents in supplemental examination. Nevertheless AIPLA believes that the kind of burdensome outcome such as that suggested above will hurt the credibility of the USPTO, and in fact will act as a substantial deterrent to use of supplemental examination in the manner intended by the statute.<sup>10</sup>

AIPLA suggests that the USPTO consider adopting a fee structure, and revising proposed Sections 1.605(a) and (d), so as to facilitate consideration of all items submitted in a single supplemental examination proceeding, while at the same time providing a reasonable cost recovery basis for the proceeding. This could be done, for example, by charging a base fee for the request, coupled with a per document fee. The latter could include surcharges for greater numbers of documents, and for documents that are longer in length, as set forth in proposed Sections 1.20(k)(3)(i)-(ii).

AIPLA also believes that, while considerations of cost recovery may dictate higher fees than are currently in use for ordinary *ex parte* reexamination given the likely increased complexity of a reexamination based on supplemental examination, the appropriate charge for an ordered reexamination would be best determined once it is known *how many* of the submitted items will be considered in the reexamination.

<sup>&</sup>lt;sup>9</sup> As noted in the comments submitted to PPAC on the proposed patent fees (Feb. 29, 2012, p. 9), "Where . . . the explanation and justifications to date do not seem to be soundly based, it begs for a better explanation of the bases and assumptions if the USPTO is to build support for fees which seem significantly higher than might be anticipated. This simply illustrates the point that greater transparency and fuller explanations could lead to better collective insight and ultimately better numbers. AIPLA believes the goal is a collaborative process to get the USPTO the fees it needs to do its job and do it well."

<sup>&</sup>lt;sup>10</sup> As noted in AIPLA's comments to PPAC on the proposed patent fees (Feb. 29, 2012, p. 9), "AIPLA does not support raising the fees for Supplemental Examination as a disincentive to requesting it. The disincentive is perhaps underscored, for example, by the fact that the costs and procedures for filing a continuation application or a reissue application are substantially lower and simpler than those contemplated under the Proposed Rule. Applicants may well be motivated to keep continuation applications of granted patents alive and/or file *In re Tanaka* type reissue applications as a way of obtaining consideration (by submission in an [information disclosure statement 'IDS']) of information that would otherwise have been submitted in a supplemental examination request. By using these lower cost and simpler procedures, it will require an examiner to make a 'but-for' materiality determination, meaning that only where an examiner finally rejects the original patent claims on the information provided in the IDS and requires amendment of the claims to make them allowable, would the need to request supplemental examination arise. In such cases, the continuation or reissue application can then be abandoned in favor of filing a supplemental examination request."

For example, under the current proposal, it seems unlikely that the proposed \$16,120 cost would be the same for reexamination of a single item, which might be a patent or printed publication as for an ordered reexamination considering multiple items raising issues not only under Sections 102 and 103, but also Sections 101 and 112 based on non-prior art items of information. Thus, determination of the reexamination fee after reexamination is ordered, based on some type of base fee coupled with a per item fee, would seem more appropriate than attempting to assess fees for both stages up front.

As a final point relative to the proposed fees for supplemental examination and related reexamination, AIPLA offers the following comments on the decision of the USPTO not to adjust the fees for small entities. AIPLA is mindful of the USPTO's statement in the Notice of Proposed Rule that a fee reduction for small business concerns is not applicable to fees set under 35 U.S.C. § 41(d)(2), and that the USPTO considered but decided not to exempt small entities from a number of the content requirements due to the need for such information in order to promptly resolve a supplemental examination. 77 Fed. Reg. at 3676.

In defense of the high fees, some have made the point that supplemental examination is not a requirement to obtain a patent, but rather is a remedial provision that is optionally available to patent owners. Nevertheless, AIPLA believes that the level of proposed fees is especially burdensome for small entities and seems contrary to the spirit, if not the letter, of the AIA's intent as expressed in Section 10(b) ("The fees set or adjusted under subsection (a) for filing, searching, examining, issuing, appealing, and maintaining patent applications and patents *shall* be reduced by 50 percent with respect to . . . any small entity that qualifies . . . under section  $41(h)(1) \dots$ " (Emphasis added).)

For many small entities, an enforceable patent is essential to level the playing field and to compete with large, dominant corporations in a given market. The proposed fees, coupled with the complexity of filing a request for supplemental examination (discussed further below), will effectively foreclose many small entities from shielding themselves from a finding of unenforceability due to inequitable conduct, thus subjecting them to higher costs of litigation, which already mitigate heavily in favor of larger, better-funded corporations. Thus, AIPLA recommends that when the Section 10 fees are made final, the small- and micro-entity subsidies be applied to the supplemental examination and reexamination fees.

# **Proposed § 1.610(b)(1)-(12) – Content of the Request**

AIPLA is concerned that the complexity of the content required for a request for supplemental examination under proposed Section 1.610(b) is so burdensome that this will act as yet another significant deterrent to use of supplemental examination.<sup>11</sup> By raising the complexity of what must be submitted, it significantly increases costs for preparation of the document.

<sup>&</sup>lt;sup>11</sup> It seems almost certain that patent owners will opt for the alternative procedures noted above, *see, e.g.,* fn 10 *supra,* as a first choice, rather than using supplemental examination. This is especially the case, as the already high cost of the fees will be further exacerbated by the added complexity required in preparing the request under the Proposed Rule.

AIPLA Comments on Supplemental Examination March 26, 2012 Page 7

Proposed Section 610(b) requires, *inter alia*,

- A list of each item of information and its publication date, if applicable, with a statement (1.610(b)(4)) that
  - identifies each item that was not considered in the prior examination of the patent and explains why consideration of the item is requested,
  - identifies each item that was not adequately considered in the prior examination and explains why reconsideration of the item is requested, and
  - identifies each item of information that was incorrect in the prior examination of the patent and explains how it is being corrected.
- A list identifying any other prior or concurrent post patent office proceedings involving the patent (1.610(b)(5)).
- An identification of each aspect of the patent for which supplemental examination is sought, including an identification of the structure, material, or acts in the specification that correspond to each means-plus-function or step-plus-function element, in any claim to be examined (1.610(b)(6)).
- An identification of each issue raised by each item of information (1.610(b)(7)).
- A detailed explanation for each identified issue, discussing how each item of information is relevant to each aspect of the patent to be examined, and how each item of information raises each issue identified for examination, including (1.610(b)(8))
  - when an issue involves Section 101 or Section 112, an explanation discussing the support in the specification for each limitation of each claim to be examined, and
  - when an issue involves double patenting, Section 102 or Section 103, an explanation of how each limitation of each claim to be examined is met or is not met.
- A copy of each item of information with an English translation where appropriate (1.610(b)(10)) this also requires transcripts of audio or video recordings (1.615(a)).
- A summary of relevant portions of any document over 50 pages, including citations to the particular pages containing the relevant portions.
- A submission by the patent owner establishing the entirety of the ownership of the patent (1.610(b)(12)).

AIPLA recognizes that the USPTO requires sufficient information to permit it to make a reasoned determination as to each new question of patentability. Nevertheless, much of the information required to be included in the request under the proposed rule does not seem to be reasonably necessary or required in order for the USPTO to make that determination. For example, proposed Section 1.610(b)(4)(i)–(iii) requires a statement that sets out the nature of each item of information (e.g., whether it was not considered, inadequately considered, or incorrect), as well as a detailed statement as to *why* consideration or reconsideration is being requested. That kind of requirement seems wholly unnecessary once it is established that one or more items of information were not adequately considered in the original examination and that such items give rise to what appears to be a substantial new question of patentability. That should be sufficient to justify the submitted request. Further, such a request goes far beyond what Congress required in the language of the AIA.

Because supplemental examination can potentially benefit the patent owner in later litigation, the patent owner already has a strong incentive to indicate in the request which issues need to be addressed by the Office. For this reason, AIPLA believes that the list of requirements in the request can be significantly simplified. A shortened list of requirements would remove the unreasonable and unnecessary burden on the requester, without causing any adverse impact to the proceedings. The following represents what AIPLA believes would be a more reasonable middle ground for the list of requirements:

- A list of each item of information and its publication date, if applicable.
- A statement that each item of information was not considered in the prior examination, was not adequately considered or was incorrect, and may be relevant to the patent, including
  - when the issue relates to Section 101 or Section 112, an explanation discussing the support in the specification for each limitation of each claim to be examined, and
  - when the issue relates to double patenting, Section 102 or Section 103, an explanation of the relevance of each reference.
- A list identifying any other prior or concurrent post patent office proceedings involving the patent.
- A copy of each item of information, with an English translation where appropriate, and an indication of the relevant portions of any document over 50 pages, including citations to the particular pages containing the relevant portions.
- A submission by the patent owner establishing the entirety of the ownership on the patent.

## Proposed § 1.610(d)-(e) – Failure to Receive A Filing Date for A Request

Proposed Section 1.610(d) provides that, with two exceptions, a filing date will not be granted if the request is not in compliance with Section 1.605 (requirements for submitted items of information), Section 1.615 (format of papers filed), and the content requirements of Section 1.610 (a)–(c). The two exceptions are where the defects are limited to omission of the requirements in Section 1.610(b)(1) (the cover sheet) and/or Section 1.610(b)(2) (the table of contents). Proposed Section 1.610(e) goes on to provide that, where a request for supplemental examination is not given a filing date, the patent owner will be notified and given a specified time in which to comply with the notice. If a corrected request is timely filed in response to the notice, the filing date will be the receipt date of the *corrected* request.

AIPLA believes that denying a filing date to a defective submission is unduly harsh and is not mandated by the AIA. While the Notice of Proposed Rule does not explicitly state why the USPTO proposes to adopt this harsh result, presumably it is because of the requirement to conclude a request for supplemental examination within three months from the filing date. However, the language of the AIA states that "Within 3 months after the date a request for supplemental examination and shall conclude such examination." (Emphasis added.) The AIA's language seems to suggest that the intent of the AIA is to simply permit the three-month period for concluding the request to run from the time of the *corrected* request, rather than the original submission date, where defective. This does not necessarily mandate a denial of the original date, only that the submission be timely corrected. Once that is done, the supplemental examination must then be concluded by the issuance of the certificate within three months from that date.

AIPLA believes that there are sound reasons why denial of a filing date for an original submission should not be required where the noted minor defects are timely corrected. For example, the effect of a supplemental examination is not obtained where an item of information in a request is, *prior to a supplemental examination request*, contained in an allegation pled with particularity in a civil action or is set forth in a notice as provided by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)(2)(B)(iv)(II)). 35 U.S.C. § 257(c)(2)(A). Thus, in the case where a request for supplemental examination is filed but is defective, even if timely corrected, the result may be a loss of the right to supplemental examination in the event that prior to correction, a Section 257(c)(2)(A) proceeding is filed. In other words, the Proposed Rule simply encourages a race to the court. This should be eliminated by granting the filing date of the original request upon timely correction, and starting the three-month period for concluding the supplemental examination from the date of the corrected request.<sup>12</sup>

<sup>&</sup>lt;sup>12</sup> As noted above, proposed Section 1.610(d) already provides two exceptions to a loss of right due to a defective submission: (i) where the defects result from omission of the requirements in Section 1.610(b)(1) (the cover sheet) and/or (ii) where the defects result from omission of the requirements of Section 1.610(b)(2) (the table of contents). Perhaps as an alternative or middle ground, proposed Section 1.610(d) could expand the kinds of exceptions so that they would include a broader range of non-substantive or minimal defects, such as failure to include the correct fee, mistakes in meeting format requirements (proposed Section 1.615) or similar defects that are more formalistic as opposed to substantive in nature.

## Proposed § 1.620(g) – Conduct of Proceedings – Referral of A Material Fraud

Proposed Section 1.620(g) states that "if the Office *becomes aware*, during the course of supplemental examination or any reexamination ordered . . . *of a material fraud on the Office involving the patent* . . . the supplemental examination proceeding or any reexamination proceeding ordered . . . will continue, and the matter will be referred to the U.S. Attorney General in accordance with 35 U.S.C. 257(e)." (Emphasis added.)

AIPLA is concerned with the language of the proposed section for several reasons. First, the Proposed Rule provides no guidance as to either the standard or the burden of proof that is to be used for 1) determining what is required by way of a threshold finding that is sufficient to justify a referral to either the Office of Enrollment and Discipline ("OED") and/or the Attorney General; and 2) supporting a finding of material fraud in the case of disciplinary proceedings conducted by the USPTO. Second, there are no safeguards in the Proposed Rule designed to protect registered practitioners or other persons implicated by a potential "material fraud" by giving them any kind of notice and opportunity to be heard.<sup>13</sup> These two points are addressed in detail below.

The rules should clearly define what standard and burden of proof will apply to the statutory term "material fraud." AIPLA believes that this term refers not to simple fraud, but rather to the "affirmative egregious misconduct" identified in *Therasense*, 649 F. 3d 1276, *supra*. In that case, the Federal Circuit referred to "deliberately planned and carefully executed scheme[s] to defraud the USPTO and the courts." *Id.* at 1292-93. This is the standard that should apply, whether in the context of a referral to OED, a referral to the Attorney General, or a disciplinary proceeding before OED.

The USPTO should also adopt appropriate burdens of proof given the different stages required for handling matters that may involve material fraud. For example, the USPTO should define the standard for the burden of proof for a threshold finding that a "material fraud on the Office *may* have been committed" so as to require referral to the Attorney General. 35 U.S.C. § 257(e). AIPLA recommends that the USPTO not undertake further investigation by OED or referral if the evidence pertaining to an item of information submitted in the supplemental examination or being reviewed in an ordered reexamination does not clearly indicate a knowing and willful misrepresentation (37 CFR § 11.18(b)(1)), withholding or non-disclosure of the material information, with some indication of specific intent to deceive or mislead (e.g., the single most reasonable inference to be drawn from the facts must be an intent to deceive or mislead the Office).

<sup>&</sup>lt;sup>13</sup> It is clear that the USPTO has no jurisdiction concerning persons who are not registered practitioners, other than to refer such matters to the U.S. Attorney where a "material fraud" may justify a criminal proceeding. On the other hand, there is no reason why, at the very least, such persons, like registered practitioners, cannot and should not be given at least some notice and opportunity to respond prior to making such a referral.

AIPLA believes that referral for criminal investigation should be made only *after* a *finding* of material fraud by OED under a clear and convincing evidence standard, or, at the very least, a referral should not be made to the Attorney General without a probable cause determination being made by the Committee on Discipline and review and approval by the General Counsel and Director of the USPTO.

Lastly, AIPLA strongly recommends that the Proposed Rule should be revised to include at least some level of safeguard for registered practitioners, or any other person who may be implicated by a material fraud, that will provide notice and some opportunity for response when the practitioner's (or other person's) conduct is drawn into question in a request for supplemental examination.<sup>14</sup> To that end, the Proposed Rule should be revised to require that when the conduct of a particular practitioner or other person is drawn into question by reason of circumstances pertaining to one or more items of information referred to in a request for supplemental examination, the patent owner notify the practitioner or other person as to the particular items of information and the alleged conduct pertaining to them. The practitioner or other person should be permitted by rule to prepare an affidavit or declaration on his or her own behalf that can be sent within a reasonable time after such notification to the patent owner for submission in an IDS during the *ex parte* reexamination phase of the proceedings should *ex parte* reexamination be ordered.

# **Other Matters Not Addressed in the Proposed Rule**

Where an item of information in a request is the basis of a defense in an action brought under Section 337(a) of the Tariff Act of 1930 (19 U.S.C. §1337(a)), unless the supplemental examination and any *ex parte* reexamination ordered are concluded prior to the date on which the action is brought, 35 U.S.C. § 257(c)(2)(B) provides that the effect of a supplemental examination (e.g., that the patent shall not be held unenforceable on the basis of conduct relating to the information) is excepted. Thus, in this instance the potential benefit afforded to patent owners by supplemental examination of shielding the patent owner from a finding of unenforceability due to inequitable conduct for the information considered is defeated.

In an effort to remedy this, AIPLA recommends that the Office expedite the handling of supplemental examination requests and subsequent reexaminations to ensure that they can be promptly concluded.

<sup>&</sup>lt;sup>14</sup> The USPTO should also adopt the view that when a registered practitioner's conduct is drawn into question in a request for supplemental examination filed by a patent owner, this should commence the one-year statute of limitations provided under 35 U.S.C. § 32 (as amended by the Leahy-Smith America Invents Act). This would seem to be fully consistent with the requirement of the statute that the misconduct forming the basis of the proceeding has been made known to an officer or employee of the USPTO. Moreover, while the USPTO argued in its Notice of Proposed Rule ("Implementation of Statute of Limitations Provisions for Office Disciplinary Proceedings," 77 Fed. Reg. 457 (Jan. 5, 2012)) that the clock should start *after* the practitioner's response because of the time this might take out of the one-year period, AIPLA stated in its comments (Mar. 5, 2012, p. 3) in response to the Proposed Rule that "the answer is not to change the date for starting the clock, but rather to grant extensions of time only if the practitioner agrees to toll the statutory period by an amount equal to the requested extension of time to respond."

AIPLA Comments on Supplemental Examination March 26, 2012 Page 12

Furthermore, Section 257(c)(2)(B) of the AIA precludes paragraph (a) from applying to any defense raised in such an action. The Director should retain the discretion to permit the supplemental examination to proceed concurrently with the action, if an ordered *ex parte* reexamination has proceeded far enough that it is likely to be concluded prior to trial of the action, or, if not, to stay the supplemental examination or any ordered *ex parte* reexamination until the merits of the defense are concluded in the action. This could avoid unnecessary or inconsistent outcomes.

Lastly, AIPLA believes that clarification of the Proposed Rule by the USPTO would also be helpful regarding whether and how supplemental examination can be used to consider issues that do not by their nature raise a substantial new question of patentability, but may nevertheless be the subject of an inequitable conduct charge (e.g., a large entity claiming small entity status or under-listing the number of total and/or independent claims on an application or transmittal form or amendment document and then under-paying for excess claim fees).

AIPLA appreciates the opportunity to provide these comments on the subject Notice of Proposed Rulemaking. We would be pleased to answer any questions these comments may raise and look forward to participation in the continuing development of rules appropriate for patent practice and for implementation of the AIA.

Sincerely,

Willin S. Ben

William G. Barber AIPLA President