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Via Electronic Mail

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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
Alexandria, VA 22313-1450

Attn.: Cynthia L. Nessler, Senior Legal Advisor, Office of Patent Legal Administration,
Office of the Associate Commissioner for Patent Examination Policy

Re: Eli Lilly and Company (Lilly) Comments to the United States Patent and Trademark Office (Office) Notice of Proposed Rulemaking Entitled: Changes to Implement the Supplemental Examination Provisions of the Leahy-Smith America Invents Act and To Revise Reexamination Fees (Federal Register/Vol. 77, No. 16/Wednesday, January 25, 2012/Proposed Rule 3666)

Dear Under Secretary Kappos:

Lilly appreciates the opportunity to comment on this Proposed Rule and commends the Office on its efforts to timely seek comments to ensure the Office's rulemaking effectively implements what is perhaps the single most extraordinary patent law reform resulting from the historic and remarkable comprehensive patent law reforms in the Leahy-Smith America Invents Act (AIA, Public Law 112-29, 125 Stat. 284 (2011)).

Lilly believes that in creating the new supplemental examination proceeding, Congress has made it possible for the Office to make significant patent quality and patent litigation enhancements that will greatly improve the U.S. patent system. However, these enhancements will only be realized upon implementation of rules that are carefully considered to encourage, not discourage, predictable, efficient and affordable use of the proceeding.

Supplemental examination provides for possible patent quality enhancements by encouraging patent owners who determine that errors or omissions may exist in the patent procurement record before the Office to take prompt action to remedy potential deficiencies by requesting that the Office consider, reconsider, or correct any information believed to be relevant to the patent.

Patent owners, potential competitors and the public benefit greatly from having a claimed invention undergo supplemental examination because the patent will have a more complete and accurate examination record, and the resulting patent will be limited only to claimed inventions that have been twice determined to be fully patentable by the Office. That is, the Office will have a second opportunity to eliminate invalid claims in the patent that should not have been issued, enabling better decision-making by patent owners and potential competitors and increasing public confidence in the validity of the patent and the patent system.

Supplemental examination also provides great potential to improve efficiencies in litigation by reining in the multi-decade “plague” of “inequitable conduct” allegations in patent litigation. As explained by the majority decision in *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1289-90 (Fed. Cir. 2011), inequitable conduct allegations resulting from the Office’s well intended “duty of candor and good faith,” have increased adjudication cost and complexity, complicated the ability to settle patent lawsuits, and cast huge burdens on the courts forced to deduce the “intent” behind allegedly missing or incorrect information in the patent examination record. The ever-present threat of having a patent held unenforceable for inequitable conduct has also strained Office resources from the well-documented “over disclosure” and “under explanation” that is engendered among patent practitioners, contributed to the backlog in patent examination that larger and less helpful submissions of information contribute to, and impaired overall patent quality.

Congress no doubt envisioned that the Office would implement rules for supplemental examination that advance the judicial efforts to stem the “plague” of inequitable conduct allegations in the courts:

Critics of the inequitable conduct defense, including the National Academies and the Federal Trade Commission, argue that our patent system is hampered by provisions that require courts to divine the difficult-to-prove subjective intent of individuals in patent disputes. And most defendants reflexively plead inequitable conduct as a defense to infringement, prompting the Federal Circuit to label the practice a ‘plague’ on the patent system.

The Act addresses the inequitable conduct doctrine by authorizing supplemental examination of a patent to correct errors or omissions in proceedings before the Office.
[AIA Committee Report, June 1, 2011 at pg. 50]

Supplemental examination, thus, provides patent owners an historic opportunity, and even the encouragement, to proactively address potential defects in patents that may otherwise be vulnerable to inequitable conduct allegations. The historic opportunity is for patent owners to seek a supplemental examination for a potential patent defect that in the past may have created too much risk for a would-be investor to invest based on the patent. The encouragement for the patent owner to pursue supplemental examination, in addition to having a patent emerging from the supplemental examination proceeding that is more reliably valid, is that the patent claims that survive the procedure, subject to two exceptions, will be more readily enforceable. This is because 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 proceeding.

For the patent owner to benefit from precluding use of the unenforceability defense, the supplemental examination request must at least be filed, and in some situations the entire proceeding must be completed, before an unenforceability allegation is asserted. *See*: 35 U.S.C. §257(c)(2). This requirement that the supplemental examination request be timely filed to ensure the information cannot be used as part of an unenforceability defense makes it very important that a patent owner be proactive in filing a request, and also that the Office's determination of what constitutes an effectively filed supplemental examination request not be overly burdensome.

The Office in its Proposed Rule understandably gave great consideration to the broad scope of information and patentability issues that may be presented in a supplemental examination request, as well as to the statutory requirement to conclude the proceeding within three months from the filing date of the supplemental examination request. Therefore, it is in consideration of the patent quality and litigation enhancement goals intended by Congress, as well as the broad scope of the proceeding and the limited time for the Office to complete the proceeding, that Lilly suggests the following changes to the Proposed Rules to better implement the supplemental examination provisions of the AIA:

1. Expressly provide that a supplemental examination request may be filed by an owner (one or more owner(s)) of the patent;
2. Provide the Office increased discretion to assign an original filing date for a substantially compliant supplemental examination request;
3. Remove the 10-item limit on the number of items of information that can be submitted in a single supplemental examination request;
4. Streamline the content requirements in a supplemental examination request to optimize Office and patent owner resources and maximize the usefulness of the proceeding; and
5. Clearly define the standard the Office will use to assess "material fraud."

A complete set of proposed *Revisions to the Proposed Implementing Regulations* for Supplemental Examination are attached below.

1-Expressly provide that a supplemental examination request may be filed by an owner (one or more owner(s)) of the patent

35 U.S.C. §257(a) provides that “A *patent owner* may request supplemental examination of a patent in the Office to consider, reconsider, or correct information believed to be relevant to the patent, *in accordance with such requirements as the Director may establish.*” There is no statutory requirement or authorization for the requirement that *all* patent owners must join together or establish an entire interest in a patent to request supplemental examination of a patent.

Proposed Rule §1.601(a-c) states proposed requirements for establishing ownership and participation in supplemental examination - the request must be filed by *the owner(s)* of the entire right, title, and interest in the patent; *the patent owner* must establish the *entirety of the ownership interest* in the patent by filing a submission in compliance with the provisions of 35 U.S.C. §3.73(b); and third party participation is expressly prohibited in a supplemental examination proceeding. Proposed Rule §1.610(b)(12) would further require that *the patent owner* make a submission establishing the *entirety of the ownership interest* in the patent as part of the supplemental examination request.

Providing that a supplemental examination request may be filed by one or more patent owner(s) is not only consistent with the statutory text, it promotes the important policy objective of providing any patent owner the right to provide to the Office information believed to be relevant to the patent to ensure the patent is more reliably valid and will be more readily enforceable. Absent such a final rule, a patent owner having information believed to be relevant to a patent could be prohibited from making a supplemental examination request. Although a request for supplemental examination filed by one patent owner would result in a different patent owner that is not also making the particular request being considered a third party in the particular supplemental examination proceeding, such a third party patent owner may file one or more separate supplemental examination requests as provided for in Proposed Rule §1.605(a).

In addition to rendering the final rulemaking compliant with the statute by providing that a supplemental examination request may be filed by *an owner* of the patent, final rulemaking should also ensure that a supplemental examination request may be filed by an authorized representative of a patent owner (37 C.F.R. §1.32), and provide for correspondence between the Office and a patent owner that makes a request for supplemental examination (37 C.F.R. §1.33) and decides to correspond with the Office *pro se*.

It is within the Director’s authority to establish such implementing regulations, and in the interest of efficiency to make it clear in final rulemaking that a patent owner(s) that establishes *an ownership interest* in the patent in compliance with the provisions of §3.73(b), as required

by Proposed Rule §1.610(b)(12), may authorize a representative to act on the patent owner(s) behalf, or may elect to correspond with the Office *pro se*. Because the person making the supplemental examination request may be one or more (not necessarily all) of the patent owner(s), the term “requester” is preferred over “patent owner” to identify the party making the supplemental examination request. Note, however, that the use of “patent owner” in Proposed Rule §1.625(d)(1) is appropriate with respect to any *ex parte* reexamination ordered under 35 U.S.C. §257(b) and according to the procedures established by chapter 30.

2-Provide the Office increased discretion to assign an original filing date for a substantially compliant supplemental examination request

As previously noted and as acknowledged by the Office in its Proposed Rule, a critical incentive for a patent owner to request supplemental examination of a patent, and subject a patent to a second examination, is the potential to eliminate an enforceability defense 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 is considered, reconsidered, or corrected during a supplemental examination of the patent.

Prompt action in filing a supplemental examination request and receiving a timely filing date can be critical to the usefulness of the proceeding to a patent owner because an exception to this beneficial shield against an unenforceability defense occurs when there is a prior allegation pled with particularity in a civil action, or set forth with particularity in a notice received by the patent owner under section 505(j)(2)(B)(iv)(II) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)(B)(iv)(II)), before the date of a supplemental examination request if filed to consider, reconsider, or correct information forming the basis for the allegation.

Proposed Rule §1.610(d) and (e) addresses the requirements for a supplemental examination to receive a filing date from the Office that may be necessary to preclude an unenforceability allegation, and proposes to deny a filing date for a request that doesn't comply with most of the requirements in Proposed Rules §§1.605, 1.610, and 1.615, with the reservation by the Office of very limited discretion to grant an initial filing date for even minor filing defects under §1.610 (b)(1) or (b)(2). The Proposed Rule further states that the Office will notify the patent owner of a request that is not entitled to a filing date, and that the filing date of a supplemental examination request will be the receipt date of a corrected supplemental examination request. §1.610(e).

While the 3-month deadline for the Office to complete the supplemental examination proceeding requires that the Office receive information essential to conduct the supplemental examination in a timely manner, Lilly believes that at a minimum, the Office should reserve more discretion than exists in the Proposed Rule to award a substantially compliant supplemental examination request the filing date of an originally filed request, provided the Office is not precluded from commencing the supplemental examination proceeding.

The Proposed Rule is unnecessarily inflexible and prohibits the Office from granting what could be a very critical filing date based on an error in the supplemental examination request that in no way impairs the Office's ability to initiate, and even fully conduct, the supplemental examination proceeding. For example, compliance may be technically lacking with respect to §1.605(a) if the request includes an eleventh item of information and violates the proposed 10-item limit. If the 10-item limitation is retained in final rulemaking, the Office could simply conduct supplemental examination with respect to 10 items of information and notify the patent owner of the noncompliant request.

The Office also has provided itself no discretion to provide a supplemental examination request an initial filing date when any of the fees listed under §1.610(a) are deficient. Additionally, an initial filing date must be denied for noncompliance with many other requirements in §1.610, including for not identifying the patent number, date of issuance, or the first named inventor (§1.610(b)(3)) - even if a copy of the patent is provided under §1.610(b)(7). Likewise, an initial filing date must be denied if the request doesn't include a copy of the U.S. patent for which supplemental examination is requested (§1.610(b)(7)) - even if the patent number is provided (§1.610(b)(3)) and the Office can readily obtain a copy of the patent. An initial filing date must also be denied for not meeting even a minor formatting requirement under §1.615, for example, when a left side margin isn't precisely 2.5 cm.

Without reserving discretion to grant an initial filing date, even when the Office clearly has all information necessary to commence the supplemental examination, the Office will have no choice but to deny the initial filing date for even minor errors, to the great discouragement of patent owners making substantially compliant requests. Failure to strictly adhere to the rule would certainly result in later challenges to the filing dates for supplemental examination requests that the Office has the authority and opportunity to prevent. In addition, should the Office retain the detailed requirements in Proposed Rule §1.610(b), considerable time and resources will almost certainly be required in petitioning and litigating whether the Office appropriately determined a filing date for supplemental examination requests.

Therefore, Lilly proposes a revised procedure in the attached *Revisions to the Proposed Implementing Regulations* that would provide the Office more discretion than exists in the Proposed Rule to award a substantially compliant supplemental examination request the filing date of an originally filed request, provided the Office is not precluded from commencing the supplemental examination proceeding. This revised procedure would also obviate unnecessary filing date challenges.

According to the revised procedure, if the Office deems that a request for supplemental examination is materially incomplete and/or noncompliant, the Office may, within 30 days of the date of the request, notify the requester of the specific deficiencies in the request as originally filed and authorize the requester to file a supplemented request correcting or otherwise satisfactorily addressing each identified deficiency. Importantly, if no such notice is

provided within the 30-day period, the Office will waive any such deficiencies and complete the supplemental examination based on the request as originally filed. This waiver of any deficiencies by the Office would eliminate most third party challenges to whether an appropriate filing date was granted by the Office for a supplemental examination request.

If a supplemented request is filed by the requester that satisfactorily addresses the deficiencies in the original request, the supplemental examination would proceed based upon the request as supplemented. If no supplemented request is filed, or the supplemented request as filed by the requester fails to satisfactorily address the cited deficiencies, the request may be deemed by the Office not to meet the requirements for a properly filed supplemental examination request and no filing date would be accorded thereto. The filing date of a request for supplemental examination would be the date of the original filing of the supplemental examination request if the original request is determined by the Office to be in sufficient compliance with the regulations such that supplemental examination could meaningfully commence in the Office prior to receipt of additional information contained in the supplemented request.

3-Remove the 10-item limit on the number of items of information that can be submitted in a single supplemental examination request

The Office has proposed that each request for supplemental examination may request that the Office consider, reconsider, or correct no more than ten items of information believed to be relevant to the patent. §1.605(a). Although the Proposed Rule would allow for an unlimited number of supplemental examination filings, a separate supplemental examination filing would be required to have even a single additional item of information considered, reconsidered, or corrected beyond the 10-item limit. Without question, the 10-item limit is unprecedented in the patent examination process, could never have been intended by Congress, and would lead to unnecessary inefficiencies that will discourage use of the proceedings.

Section 257(a) in no way limits the number of items of information in a single supplemental examination request, stating that “[a] patent owner may request supplemental examination of a patent in the Office to consider, reconsider, or correct information believed to be relevant to the patent, in accordance with such requirements as the Director may establish.” Also, nowhere else in U.S. patent law, whether in the Patent Code or Office regulations, is there a comparable arbitrary limit on the number of items of prior art or information that may be submitted in patent examination or in a request for reexamination of a patent. *See e.g.*: 37 C.F.R. §1.104 (examination), §1.515(a) (*ex parte* reexamination), and §1.906(a) (*inter partes* reexamination). In view of the broad language in 35 U.S.C. §257(a), the absence of any precedent for such a limitation, and the absence of any hint of such a limitation in the AIA’s legislative history, it doesn’t appear even remotely possible that Congress intended to authorize the Office to require or conduct the fragmented supplemental examination proceedings proposed in §1.605(a).

In addition to increasing the likelihood a patent owner will not receive an important filing date for its request should an item of information be incorrectly counted, a few of many patent owner inefficiencies that would result from requiring multiple supplemental examination requests for the same patent include: having to file duplicate papers to establish ownership in the patent (§1.601) and the right of an assignee to take action under 35 U.S.C. §3.73(b); paying multiple fees, including relatively significant fees associated with the potential for multiple *ex parte* reexamination proceedings that may never be ordered or may be consolidated (§1.610(a)); submitting at least partially duplicative cover sheets itemizing each component submitted in the request and tables of contents (§1.610(b)(1) and (b)(2)); duplication in identifying the patent number, issue date, named inventors as well as providing copies of patents, any disclaimers, certificates of corrections, certificates of extensions, supplemental examination certificates, post grant review certificates, *inter partes* review certificates, or reexamination certificates (§1.610(b)); and the potential for filing duplicative petitions (§1.620(b)). All of this duplication unnecessarily increases the costs of the proceeding for the patent owner.

Office inefficiencies would also likely result from requiring multiple supplemental examination requests for the same patent under the Proposed Rule. For example, the Office would need to ensure separate requests are timely routed to the same examiner, which doesn't always happen today with related patent application filings. Absent routing requests to the same examiner, multiple examiners would need to devote resources to review the same patent and potentially overlapping information and issues, and coordinate their efforts to achieve consistent examination results. The Office would also need to carefully coordinate its decisions on whether to consolidate supplemental examination proceedings with another proceeding under 35 U.S.C. §325(d).

Also, even two supplemental examination requests filed on the same day by a patent owner may ultimately be granted very different filing dates, which alone may result in inefficiencies initiating and potentially consolidating any resulting *ex parte* reexamination(s). Such potential for delays in initiating and completing *ex parte* reexamination can further discourage use of the supplemental examination proceeding because of the potential negative impact on the patent owner's ability to timely assert the patent in litigation and preclude use of an unenforceability defense as afforded by a completed supplemental examination.

The proposed 10-item limitation would further discourage use of supplemental examination because it would significantly increase a patent owner's filing fees – fees that will double to even have one additional item of information considered, reconsidered or corrected by the Office. Even if the Office is authorized to charge a \$21,300 fee pursuant to 35 U.S.C. §41(d)(2) at the time of filing a supplemental examination request, when \$16,120 is earmarked for *ex parte* reexamination that may never be ordered, requiring double fees (\$42,600) seems excessive to have one additional item of information considered, reconsidered or corrected by the Office – particularly, when \$32,240 would be prepayment for two *ex parte* reexamination

proceedings, neither of which may ever be ordered, and if ordered, would presumably be consolidated for efficiency purposes.

Lilly believes that a more reasonable approach to setting fees for supplemental examination, that would eliminate many of the inefficiencies associated with requiring a multitude of requests, is to institute a sliding fee scale in which each additional item of information after the tenth item of information requires payment of an additional fee. The additional fee for each item of information should be set to allow the Office to recover all estimated costs to fully consider all patentability issues presented in a request within the three month statutory deadline.

Should the Office eliminate the proposed 10-item of information limit for a supplemental examination request, Lilly believes this change alone would considerably reduce, but not eliminate, the need for the Office to further explain and provide additional examples of what will be deemed to constitute “an item of information.” Proposed Rule 1.605(b) states in relevant part that an “item of information” includes a document submitted as part of the request that contains information, believed to be relevant to the patent, that the patent owner requests the Office to consider, reconsider, or correct. Although clearly impossible to shed light on how each item of information will be counted, Lilly believes that final rulemaking should further clarify and provide examples of what the Office considers to make up an item of information. For example, would a book of meeting abstracts constitute one or more items of information? What about supporting documents (declarations, marketing catalogs, tables of data) and any physical articles associated with the documents?

Requiring multiple supplemental examination requests and conducting multiple proceedings for the same patent will no doubt require increased patent owner and Office resources, lead to examination and reexamination inefficiencies, and frustrate the patent quality and litigation enhancements intended by Congress. Therefore, Lilly urges the Office in its final rulemaking to remove the proposed 10-item limitation and institute a sliding fee scale that enables the Office to set fees to fully recover its estimated costs.

4-Streamline the content requirements in a supplemental examination request to optimize Office and patent owner resources and maximize the usefulness of the proceeding

In view of the broad scope of information that may be submitted in a supplemental examination request, coupled with the three month statutory deadline to conclude the examination, the Proposed Rule seeks detailed information and analyses in a supplemental examination request to completely focus Office resources to the point that determining the existence of a substantial new question of patentability would amount to little more than a box checking exercise. 37 C.F.R. §1.610(b)(1)-(b)(12). Furthermore, the Office clearly states that there should be no expectation that any review of the patent by the Office will occur beyond the focused issues as stated and applied by the patent owner in the request as filed. 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.”)

On the flipside, a patent owner seeking to determine whether to undertake the expense and examination risks associated with supplemental examination will expect, similar to an initial examination of an application, that the Office will conduct a largely independent, thorough and cost-effective patent examination, and will undoubtedly be discouraged from using supplemental examination if the scope of preclusion against an unenforceability defense is unduly narrow, or if its scope is so uncertain to subject the issue and the filing date of an allegedly non-compliant request to expensive and unpredictable litigation.

Lilly believes that neither the Office’s current approach in its Proposed Rule, or merely lobbing information over the Office’s wall in a request, is appropriate and suggests a more balanced approach in the Office’s final rulemaking. In general, Lilly believes the Office’s final rulemaking should not require that a supplemental examination request include any unnecessary or redundant information, and the proposed content requirements must be streamlined considerably, to only require content the Office truly needs to readily determine whether a substantial new question of patentability is presented by the information contained in the request.

More specifically, it is Lilly’s view that an efficient final rule would retain the content requirements in Proposed Rule 37 C.F.R. §1.610(b)(1-3, 5, 9 and 10), but the content requirements in the remaining subparts of §1.610(b) should be amended or completely eliminated (*see* redacted 37 C.F.R. §1.610(b) below).

Proposed Rule §1.610(b)(4). Proposed Rule §1.610(b)(4) appropriately seeks a list of each item of information that is requested to be considered, reconsidered, or corrected, and as applicable, the publication date for each item of information. As Lilly proposes below in the *Revisions to the Proposed Implementing Regulations for Supplemental Examination*, this subpart would also require a concise explanation of why each item of information to be considered or reconsidered or corrected is believed to be relevant to the patent. Other aspects of §1.610(b)(4) appear either completely unnecessary, redundant or vague. For example, while the required concise explanation would nearly always require an explanation of why the information is believed relevant in view of a drawing, specification, certain patent claims, or benefit claims, etc., the “aspect of the patent” terminology appears to be overly vague and also does not appear anywhere in the actual text of the Proposed Rule. Should this “aspect of the patent” terminology be retained in final rulemaking, it preferably would be defined in the rule to provide necessary clarity.

Proposed Rule §1.610(b)(6)-(b)(8). Proposed Rule §1.610(b)(6)-(b)(8) simply goes too far in requiring that a patent owner examine its own patent for the Office, and appears in some respects to represent a misunderstanding of the supplemental examination proceeding. If the

request includes a statement that, for each such item of information, separately and concisely explains why the information to be considered or reconsidered or being corrected is believed to be relevant to the patent, the Office should devote the resources and expertise to examine the patent as requested. Not only are the requirements in these subparts that Lilly proposes be deleted onerous to comply with, they may result in unnecessary challenges to compliance with the Office's rules and simply go too far to discourage use of the supplemental examination proceeding.

Furthermore, requiring the identification of the legal issues presented by each item of information, a detailed explanation for each identified issue of patentability (e.g., under 35 U.S.C. §§102, 103, 112, or obviousness-type double patenting), and an explanation of how the Office should apply each item of information that *is relevant to each aspect of the patent* identified for examination, appears to go beyond what is authorized by the statute. The statute does not require that information submitted in a supplemental examination request identify or even necessarily raise an issue of patentability, or that information submitted as part of a request be material or even relevant to patentability – the statute authorizes submission of information *believed to be relevant* to the patent by a patent owner. Final rulemaking should be consistent with this important aspect of the statute.

Proposed Rule §1.610 (b)(11). Again, according to 35 U.S.C. §257(a), a patent owner need only submit information that he or she subjectively believes to be relevant to a patent. Therefore, Proposed Rule §1.610(b)(11) has been amended to delete inappropriate statements about the aspects of a document that are deemed “relevant.”

Proposed Rule §1.610 (b)(12). Proposed Rule §1.610(b)(12) requires that the patent owner make a submission establishing the entirety of the ownership interest in the patent as part of the supplemental examination request. As mentioned above, the Proposed Rule should reflect that a supplemental examination request may be filed by *an owner* of the patent or an authorized representative of an owner of a patent. Accordingly, this subpart should clearly state that a requester need only establish *its ownership* in the patent.

Proposed Rule §1.620(e). Although as stated above, Lilly believes the Office's final rulemaking should not require that a supplemental examination request include any unnecessary or redundant information, and the proposed content requirements must be streamlined considerably, the Office may want to consider in final rulemaking whether to retain discretion to conduct interviews in a supplemental examination proceeding. §1.620(e). Interviews, at the complete discretion of the Office, may enable more efficient supplemental examination proceedings.

5-Clearly define the standard the office will use to assess “material fraud”

According to 35 U.S.C. §257(e), if the Office becomes aware, at any time during a supplemental examination proceeding or any *ex parte* reexamination, of a *material fraud* involving the patent for which supplemental examination has been requested, the Office is required to refer the matter to the U.S. Attorney General. The commentary to the Proposed Rule appropriately states that the Office regards the term *material fraud* in 35 U.S.C. §257(e) to be narrower in scope than the inequitable conduct standard articulated in *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011); however, the Office does not clearly state what standard it intends to use in assessing material fraud.

As the Office is well aware, uncertainty around the threshold level of intent or applicable materiality standard, and how intent and materiality may be played off each other, have caused considerable problems in the patent system and led to widespread public support for enacting supplemental examination. Therefore, Lilly believes it is very important for the Office to clearly state in its final rulemaking that the Office will adopt a strict, common law, “knowing and willful” fraud standard to assess “material fraud” under Section 257(e). That is, material fraud on the Office should be defined in final rulemaking to require: (1) misrepresenting to or withholding material information from the Office; (2) with specific intent to deceive the Office; (3) a justifiable reliance upon the misrepresentation or the withholding of the material information by the Office in granting the patent; and (4) absent misrepresenting or withholding material information, the Office would not have issued a claim in the patent.

This degree of certainty, Lilly believes will benefit the Office in its relatively rare referral of matters to the Attorney General based on “material fraud,” and will ensure patent owners considering whether to request supplemental examination that the horrors associated with the inequitable conduct doctrine’s varying levels of intent, shifting standards for materiality, and juxtaposing degrees of intent and materiality, won’t creep back into any equation used by the Office in considering whether to make a referral to the Attorney General.

Lilly appreciates the Office’s efforts to seek public comment regarding new regulations relating to supplemental examination proceedings. In creating this proceeding, Congress has made it possible for the Office to greatly improve patent quality by encouraging patent owners to seek a more complete and accurate review of their patents, patent litigation efficiencies by reining in “inequitable conduct” allegations that discourage innovation and “plague” the patent system, and overall confidence in the U.S. patent system. Lilly firmly believes the Office’s consideration in its final rulemaking of Lilly’s comments and the *Revisions to the Proposed Implementing Regulations* for Supplemental Examination attached below will result in encouraging patent owners to take full advantage of a more predictable, efficient and affordable supplemental examination proceeding.

If there are questions regarding our comments, or if further explanation of any of our comments is desired, please feel free to contact the undersigned.

Respectfully submitted,

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America Invents Act (AIA) Section 12
Revisions to the Proposed Implementing Regulations

Supplemental Examination Rules

Proposed Rules (January 25, 2012; 77 Federal Register 3,666)

Subpart E—Supplemental Examination of Patents

Sec.

1.601 Filing of papers in supplemental examination.

1.605 Items of information.

1.610 Content of request for supplemental examination.

1.615 Format of papers filed in a supplemental examination proceeding.

1.620 Conduct of supplemental examination proceeding.

1.625 Conclusion of supplemental examination; publication of supplemental examination certificate; procedure after conclusion.

Subpart E—Supplemental Examination of Patents

§ 1.601 Filing of papers in supplemental examination.

(a) A request for supplemental examination of a patent must be **filed made by the an** owner(s) of ~~the entire right, title, and interest in~~ the patent.

(b) The ~~patent owner~~ **requester** must establish ~~the entirety of the its~~ ownership interest in the patent of paragraph (a) by filing, as part of the request, a submission in compliance with the provisions of § 3.73(b) of this chapter.

(c) Any party other than the ~~patent owner~~ **requester** (*i.e.*, any third party) is prohibited from filing papers or otherwise participating in any manner in a supplemental examination proceeding.

§ 1.605 Items of information.

(a) Each request for supplemental examination may request that the Office consider, reconsider, or correct ~~one or no~~ more ~~than ten~~ items of information believed to be relevant to the patent. More than one request for supplemental examination of the same patent may be filed at any time.

Comment [A1]: §257 specifically provides that "A patent owner" may petition; there is no statutory requirement that all owners must join in the request, *i.e.*, that "The patent owner" must file the request.

Comment [A2]: The statute gives the requester the right to seek supplemental examination without regard to the number of individual items of information.

(b) An “item of information” includes a document submitted as part of the request that contains information, believed to be relevant to the patent, that the **requester** ~~patent owner~~ requests the Office to consider, reconsider, or correct. If the information to be considered, reconsidered, or corrected is not, at least in part, contained within or based on any document submitted as part of the request, the discussion within the body of the request relative to the information will be considered as an item of information.

(c) An item of information must be in writing in accordance with § 1.2. To be considered, any audio or video recording must be submitted in the form of a written transcript.

(d) If one item of information is combined in the request with one or more additional items of information, including instances where it may be necessary to combine items of information in order to **consider, reconsider or correct information believed to be relevant to the patent** ~~raise an issue to be considered, reconsidered, or corrected~~, each item of information of the combination may be separately counted. Exceptions include the combination of a non-English language document and its translation, and the combination of a document that is over 50 pages in length and its summary pursuant to § 1.610(b)(~~118~~).

Comment [A3]: The request, under the statute, is for information to be considered, reconsidered, or corrected, not “issues.” Thus, the revised language renders the rule consistent with the statute.

§ 1.610 Content of request for supplemental examination.

(a) The request must be accompanied by the fee for filing a request for supplemental examination as set forth in § 1.20(k)(1), the fee for reexamination **that may be** ordered as a result of a supplemental examination proceeding as set forth in § 1.20(k)(2), and any applicable document size fees as set forth in § 1.20(k)(3).

Comment [A4]: The statute provides only that a reexamination may be ordered. The revised language avoids any implication that reexamination must be or typically would be ordered.

(b) A request for supplemental examination must include each of the elements set forth in paragraphs (b)(1) through (b)(~~129~~) of this section.

(1) A cover sheet itemizing each component submitted as part of the request.

(2) A table of contents for the request.

(3) An identification of the number, the date of issue, and the first named inventor of the patent for which supplemental examination is requested.

~~(4) A list of each item of information that is requested to be considered, reconsidered, or corrected, and the publication date for each item of information, if applicable; and a statement that, **for each such item of information, separately and concisely explains why the information to be considered or reconsidered or being corrected is believed to be relevant to the patent.**~~

Comment [A5]: The statute contains no requirement that the requester provide an explanation of why the information in question is believed to be relevant to the patent, but permits the Office to provide by rule such a requirement. The revised language should be sufficient to allow a requester to provide concise explanations that will be useful for the Office to determine if the information creates a substantial new question of patentability. The revised language replaces the more open-ended requirement to address “why consideration ... is being requested.”

~~(i) Identifies each item of information that was not considered in the prior examination of the patent, and explains why consideration of the item of information is being requested;~~

~~(ii) Identifies each item of information that was not adequately considered in the prior examination of the patent, and explains why reconsideration of the item of information is being requested; and~~

~~(iii) Identifies each item of information that was incorrect in the prior examination of the patent, and explains how it is being corrected.~~

(5) A list identifying any other prior or concurrent post patent Office proceedings involving the patent for which supplemental examination is being requested, including an identification of the type of proceeding (e.g., *ex parte* or *inter partes* reexamination, reissue, supplemental examination, post-grant review, or *inter partes* review), the identifying number of any such proceeding (e.g., a control number or reissue application number), and the filing date of any such proceeding.

~~(6) 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, as set forth in 35 U.S.C. 112(f), in any claim to be examined.~~

Comment [A6]: The requirement to identify an “aspect” of a patent is unduly vague. The requirement with respect to means-plus-function claiming appears to be overly broad—applying to every such claim of the patent.

~~(7) An identification of each issue raised by each item of information.~~

Comment [A7]: The requirement to identify issues is vague, open-ended, and could potentially be so burdensome to a requester and the Office that it would be wasteful and inefficient.

~~(8) A separate, detailed explanation for each identified issue, discussing how each item of information is relevant to each aspect of the patent identified for examination, and how each item of information raises each issue identified for examination, including:~~

Comment [A8]: This further requirement greatly compounds the problematic nature of the earlier requirements.

~~(i) Where an identified issue involves the application of 35 U.S.C. 101 (other than double patenting) or 35 U.S.C. 112, an explanation discussing the~~

~~support in the specification for each limitation of each claim identified for examination with respect to this issue; and~~

~~(ii) Where an identified issue involves the application of 35 U.S.C. 102, 35 U.S.C. 103, or double patenting, an explanation of how each limitation of each claim identified for examination with respect to this issue is met, or is not met, by each item of information. The detailed explanation may also include an explanation of how the claims distinguish over the items of information.~~

(96) A copy of the patent for which supplemental examination is requested and a copy of any disclaimer, certificate of correction, certificate of extension, supplemental examination certificate, post grant review certificate, *inter partes* review certificate, or reexamination certificate issued for the patent.

(107) A copy of each item of information listed in paragraph (b)(34) of this section, accompanied by a written English translation of all of the necessary and pertinent parts of any non-English language document. Items of information that form part of the discussion within the body of the request as specified in § 1.605(b), and copies of U.S. patents and U.S. patent application publications, are not required to be submitted.

(118) A summary of ~~the relevant portions of~~ any submitted document, other than the request, that is over 50 pages in length. If only portions of the document are believed to be relevant, the ~~The~~ summary must include citations to the particular pages believed to be relevant containing the relevant portions.

Comment [A9]: The revised language provides for a summary of the entire document as well as the portion believed to be relevant. This formulation is consistent with the statutory language permitting requests to be made with respect to information believed to be relevant, whether relevant in fact or not.

(129) A submission by the requester patent owner in compliance with § 3.73(b) of this chapter establishing its the entirety of the ownership in the patent requested to be examined, as set forth in § 1.601(b).

Comment [A10]: The revised language conforms the paragraph to the revisions above.

(c) The request may also include an explanation of why each item of information submitted with the request does or does not raise a substantial new question of patentability.

(d) If the Office deems that a request for supplemental examination is materially incomplete or otherwise fails to comply with the requirements of this subpart, the Office may, within 30 days of the date of the request, notify the requester of the specific deficiencies in the request as originally filed and authorize the requester to file a supplemented request correcting or otherwise satisfactorily addressing each identified deficiency. If no such notice is

Comment [A11]: The new text offers a revised procedure for addressing deficiencies in supplemental examination requests that would permit the requester to file a supplemented request to cure any deficiencies. Whether the date of the original request or the supplemented request would determine the start of the 3-month period for supplemental examination would be determined on the basis of whether the supplemental examination could not commence prior to the receipt of the information contained in the supplemental request.

provided within such 30-day period, the Office will waive any such deficiencies and complete the supplemental examination based on the request as originally filed. If a supplemented request filed by the requester, pursuant to a notice issued under the preceding sentence, satisfactorily addresses the deficiencies in the original request, the supplemental examination will proceed based upon the request as supplemented. If no supplemental request is filed, or the supplemented request as filed by the requester fails to satisfactorily address the cited deficiencies, the request may be deemed by the Office not to meet the requirements of this subpart and supplemental examination shall not proceed based upon the original or supplemented request and no filing date will be accorded thereto. The filing date of a request for supplemental examination will ~~not be granted~~ be deemed the date of the original filing of the supplemental examination request under this paragraph if the original request is determined by the Office not to be in sufficient compliance with ~~§ 1.605, § 1.615, and this subpart such that supplemental examination could meaningfully commence in the Office prior to receipt of additional information contained in the supplemented request.~~ section. 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.

(e) If the Office determines that the request, as originally submitted or as supplemented under, does not meet the requirements of paragraph (d) of this section, is not to be entitled to a filing date, the requester/patent owner will be so notified and will be given an opportunity to complete the request within a specified time. If the patent owner does not timely comply with the notice, the request for supplemental examination will not be granted a filing date and the fee for reexamination as set forth in § 1.20(k)(2) will be refunded. If the patent owner timely files a corrected request in response to the notice that properly addresses all of the defects set forth in the notice and that otherwise complies with all of the requirements of §§ 1.605, 1.615 and of this section, the filing date of the supplemental examination request will be the receipt date of the corrected request.

Comment [A12]: The revised language conforms this subsection to the new procedure in the preceding subsection. It now merely authorizes return of the reexamination fee in the situation where the request (or supplemental request) is not sufficient to proceed with a supplemental examination and no filing date is accorded.

§ 1.615 Format of papers filed in a supplemental examination proceeding.

(a) All papers submitted in a supplemental examination proceeding must be formatted in accordance with § 1.52, including the request for supplemental examination and any other documents generated by the patent owner/requester, such as translations of non-English language documents, transcripts of audio or

video recordings, affidavits or declarations, and summaries of documents over 50 pages in length pursuant to §1.610(b)(~~811~~). Exceptions include tables of contents, curriculum vitae, claim charts, court documents, third-party generated affidavits or declarations, and any other document generated by a third party, including patents, patent application publications, and non-patent literature. All documents must be presented in a form having sufficient clarity and contrast between the paper and the text or image to permit the direct reproduction of readily legible copies by use of digital imaging and optical character recognition.

(b) Court documents and non-patent literature may be redacted, but must otherwise be identical both in content and in format to the original documents, and, if a court document, to the document submitted in court, and must not otherwise be reduced in size or modified, particularly in terms of font type, font size, line spacing, and margins. Patents, patent application publications, and third-party-generated affidavits or declarations must not be reduced in size or otherwise modified in the manner described in this paragraph.

§ 1.620 Conduct of supplemental examination proceeding.

(a) Within three months following the filing date of a request for supplemental examination, the Office will determine whether a substantial new question of patentability affecting any claim of the patent is raised by any of the items of information presented in the request. The determination **of the existence of a substantial new question of patentability** will ~~generally be based upon limited to~~ a review of the **issues information** identified in the request ~~as applied to the identified aspects of the patent~~. The determination will be based on the claims in effect at the time of the determination and will become a part of the official record of the patent.

Comment [A13]: The revised language better conforms the proposed rule to the statute, which limits a substantial new question of patentability to those "raised by 1 or more items of information in the request." 35 U.S.C. §257(b).

(b) The Office may hold in abeyance action on any petition or other paper filed in a supplemental examination proceeding until after the proceeding is concluded by the electronic issuance of the supplemental examination certificate as set forth in §1.625.

(c) If an unauthorized or otherwise improper paper is filed in a supplemental examination proceeding, it will not be entered into the official file or considered, or if inadvertently entered, it will be expunged.

(d) The ~~patent owner requester~~ must, **promptly as soon as possible** upon the discovery of any other prior or concurrent post patent Office proceeding involving

Comment [A14]: A requirement for promptness should address the need for a timely reporting. The "as soon as possible" standard ignores a delay resulting from impracticability and potentially opens the patent owner to allegations that even a meaningless delay before acting failed to comply with the requirements set out in the regulation.

the patent for which the current supplemental examination is requested, file a paper limited to notice of the post patent Office proceeding, if such notice has not been previously provided with the request. The notice shall be limited to an identification of the post patent proceeding, including the type (*e.g.*, *ex parte* or *inter partes* reexamination, reissue, supplemental examination, post-grant review, or *inter partes* review), the identifying number of any such proceeding (*e.g.*, a control number or reissue application number), and the filing date of any such proceeding, without any discussion of the issues of the current supplemental examination proceeding or of the identified post patent Office proceeding(s).

(e) Interviews are **subject to the discretion of the Office prohibited** in a supplemental examination proceeding.

Comment [A15]: The revised language affords the USPTO more discretion in administering the statute. In certain situations, an interview might be sought by the USPTO itself to assure an efficient and timely disposition of the supplemental examination.

(f) No amendment to any aspect of the patent may be filed in a supplemental examination proceeding.

(g) If the Office becomes aware, during the course of supplemental examination or of any reexamination ordered under 35 U.S.C. 257, of a material fraud on the Office involving the patent requested to be examined, the supplemental examination proceeding or any reexamination proceeding ordered under 35 U.S.C. 257 will continue, and the matter will be referred to the U.S. Attorney General in accordance with 35 U.S.C. 257(e).

§ 1.625 Conclusion of supplemental examination; publication of supplemental examination certificate; procedure after conclusion.

(a) A supplemental examination proceeding will conclude when the supplemental examination certificate is electronically issued. The supplemental examination certificate will indicate the result of the determination whether any of the items of information presented in the request raised a substantial new question of patentability.

(b) If the supplemental examination certificate states that a substantial new question of patentability is raised by one or more items of information in the request, *ex parte* reexamination of the patent will be ordered under 35 U.S.C. 257. Upon the conclusion of the *ex parte* reexamination proceeding, an *ex parte* reexamination certificate, which will include a statement specifying that *ex parte* reexamination was ordered under 35 U.S.C. 257, will be published. The electronically issued supplemental examination certificate will remain as part of the public record of the patent.

(c) If the supplemental examination certificate indicates that no substantial new question of patentability is raised by any of the items of information in the request, and *ex parte* reexamination is not ordered under 35 U.S.C. 257, the electronically issued supplemental examination certificate will be published in due course. The reexamination fee for supplemental examination, as set forth in § 1.20(k)(2), will be refunded in accordance with § 1.26(c).

(d) Any *ex parte* reexamination ordered under 35 U.S.C. 257 will be conducted in accordance with §§ 1.530 through 1.570, which govern *ex parte* reexamination, except that:

(1) The patent owner will not have the right to file a statement pursuant to §1.530, and the order will not set a time period within which to file such a statement;

(2) Reexamination of any aspect of the patent may be conducted on the basis of any item of information as set forth in §1.605, and is not limited to patents and printed publications or to subject matter that has been added or deleted during the reexamination proceeding, notwithstanding § 1.552(a);

(3) Issues in addition to those raised by patents and printed publications, and by subject matter added or deleted during a reexamination proceeding, may be considered and resolved, notwithstanding § 1.552(c); and

(4) Information material to patentability will be defined by § 1.56(b), notwithstanding § 1.555(b).