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DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

37 CFR Part 1

[Docket No.: PTO-P-2011-0075]

RIN 0651-AC69

Changes to Implement the Supplemental Examination Provisions of the Leahy-Smith America Invents Act and to Revise Reexamination Fees

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice of proposed rulemaking.

SUMMARY: The United States Patent and Trademark Office (Office) is proposing to amend the rules of practice in patent cases to implement the supplemental examination provisions of the Leahy-Smith America Invents Act. The supplemental examination provisions permit a patent owner to request supplemental examination of a patent by the Office to consider, reconsider, or correct information believed to be relevant to the patent. These provisions could assist the patent owner in addressing certain challenges to the

enforceability of the patent during litigation. The Office is also proposing to adjust the fee for filing a request for ex parte reexamination and to set a fee for petitions filed in ex parte and inter partes reexamination proceedings to more accurately reflect the cost of these processes.

DATES: Written comments must be received on or before [Insert date 60 days after publication in the FEDERAL REGISTER].

ADDRESSES: Comments should be sent by electronic mail message over the Internet addressed to: supplemental_examination@uspto.gov. Comments may also be submitted by postal mail addressed to: Mail Stop Comments--Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA, 22313-1450, marked to the attention of Cynthia L. Nessler, Senior Legal Advisor, Office of Patent Legal Administration, Office of the Associate Commissioner for Patent Examination Policy.

Comments may also be sent by electronic mail message over the Internet via the Federal eRulemaking Portal. See the Federal eRulemaking Portal Web site (<http://www.regulations.gov>) for additional instructions on providing comments via the Federal eRulemaking Portal.

Although comments may be submitted by postal mail, the Office prefers to receive comments by electronic mail message over the Internet because sharing comments with the public is more easily accomplished. Electronic comments are preferred to be

submitted in plain text, but also may be submitted in ADOBE® portable document format or MICROSOFT WORD® format. Comments not submitted electronically should be submitted on paper in a format that facilitates convenient digital scanning into ADOBE® portable document format.

The comments will be available for public inspection at the Office of the Commissioner for Patents, currently located in Madison East, Tenth Floor, 600 Dulany Street, Alexandria, Virginia. Comments also will be available for viewing via the Office's Internet Web site (<http://www.uspto.gov>). Because comments will be made available for public inspection, information that the submitter does not desire to make public, such as an address or phone number, should not be included in the comments.

FOR FURTHER INFORMATION CONTACT: Cynthia L. Nessler, Senior Legal Advisor ((571) 272-7724), Kenneth M. Schor, Senior Legal Advisor ((571) 272-7710), or Pinchus M. Laufer, Senior Legal Advisor ((571) 272-7726), Office of Patent Legal Administration, Office of the Associate Commissioner for Patent Examination Policy.

SUPPLEMENTARY INFORMATION: The Leahy-Smith America Invents Act was enacted into law on September 16, 2011. See Pub. L. 112-29, 125 Stat. 284 (2011). The Office is proposing to amend the rules of practice in title 37 of the Code of Federal Regulation (CFR) to implement the supplemental examination provisions of section 12 of the Leahy-Smith America Invents Act. These provisions permit a patent owner to request supplemental examination of a patent by the Office to consider, reconsider, or correct

information believed to be relevant to the patent. The Office is also proposing to set certain fees to implement supplemental examination, to adjust the fee for filing a request for ex parte reexamination, and to set a fee for petitions filed in ex parte and inter partes reexamination proceedings.

Section 12 of the Leahy-Smith America Invents Act amends chapter 25 of title 35, United States Code, to add new 35 U.S.C. 257. 35 U.S.C. 257(a) provides for a proceeding titled “supplemental examination” that may be requested by the patent owner to consider, reconsider, or correct information believed to be relevant to the patent in accordance with requirements established by the Office. The information that may be presented in a request for supplemental examination is not limited to patents and printed publications, and may include, for example, issues of patentability under 35 U.S.C. 101 and 112.

Within three months of the receipt of a request for supplemental examination meeting the requirements of 35 U.S.C. 257, which include the requirements established by the Office, the Office shall conduct supplemental examination and shall conclude the examination (i.e., determine whether there is a substantial new question of patentability) by the issuance of a supplemental examination certificate. The supplemental examination certificate shall indicate whether the items of information presented in the request raise a substantial new question of patentability.

If the supplemental examination certificate, which is issued under 35 U.S.C. 257(a), indicates that a substantial new question of patentability is raised by one or more items of information in the request for supplemental examination, the certificate will indicate that

ex parte reexamination has been ordered by the Office. The resulting ex parte reexamination proceeding will be conducted according to ex parte reexamination procedures, except that the patent owner does not have the right to file a statement pursuant to 35 U.S.C. 304, and the basis of the ex parte reexamination is not limited to patents and printed publications. Each substantial new question of patentability identified during the supplemental examination proceeding will be addressed by the Office during the resulting ex parte reexamination proceeding. See 35 U.S.C. 257(b).

35 U.S.C. 257(c) specifies the effect of a supplemental examination under 35 U.S.C. 257(a) on the enforceability of the patent. 35 U.S.C. 257(c)(1) provides that, with two exceptions, 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. The first exception is that 35 U.S.C. 257(c)(1) shall not apply to an 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 under 35 U.S.C. 257(a) to consider, reconsider, or correct information forming the basis for the allegation (35 U.S.C. 257(c)(2)(A)). The second exception is that in an action brought under section 337(a) of the Tariff Act of 1930 (19 U.S.C. 1337(a)), or 35 U.S.C. 281, 35 U.S.C. 257(c)(1) shall not apply to any defense raised in the action that is based upon information that was considered, reconsidered, or corrected pursuant to a supplemental

examination request under 35 U.S.C. 257(a), unless the supplemental examination, and any ex parte reexamination ordered pursuant to the request, are concluded before the date on which the action is brought (35 U.S.C. 257(c)(2)(B)). 35 U.S.C. 257(c)(1) also provides that the making of a request for supplemental examination under 35 U.S.C. 257(a), or the absence thereof, shall not be relevant to enforceability of the patent under 35 U.S.C. 282.

35 U.S.C. 257(d)(1) provides the Director with authority to establish fees for filing a request for supplemental examination and for considering each item of information submitted with the request. If ex parte reexamination is ordered under 35 U.S.C. 257(b), 35 U.S.C. 257(d)(1) also establishes that the fees applicable to ex parte reexamination must be paid in addition to the fees for supplemental examination. 35 U.S.C. 257(d)(2) provides the Director with authority to establish regulations governing the requirements of a request for supplemental examination, including its form and content.

In accordance with 35 U.S.C. 257(e), if the Office becomes aware, during the course of supplemental examination or of any ex parte reexamination ordered under 35 U.S.C. 257, of a material fraud on the Office involving the patent requested to be examined, the Office shall refer the matter to the U.S. Attorney General, in addition to any other actions the Office is authorized to take, including the cancellation of any claims found to be invalid under 35 U.S.C. 307 as a result of ex parte reexamination ordered under 35 U.S.C. 257. The Office regards the term “material fraud” in 35 U.S.C. 257(e) to be narrower in scope than inequitable conduct as defined by the U.S. Court of Appeals for

the Federal Circuit in Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276 (Fed. Cir. 2011).

Section 12 of the Leahy-Smith America Invents Act also indicates, as discussed previously, that nothing in 35 U.S.C. 257 precludes the imposition of sanctions based upon criminal or antitrust laws (including 18 U.S.C. 1001(a)), the first section of the Clayton Act, and section 5 of the Federal Trade Commission Act to the extent that section relates to unfair methods of competition). See 35 U.S.C. 257(f)(1). Section 12 of the Leahy-Smith America Invents Act sets forth rules of construction, providing that 35 U.S.C. 257 shall not be construed to limit the authority of the Office to investigate issues of possible misconduct or impose sanctions for misconduct involving matters or proceedings before the Office, or to issue regulations under 35 U.S.C. 32 or 35 U.S.C. 33 relating to sanctions for misconduct by patent practitioners. See 35 U.S.C. 257(f)(2) and (f)(3).

To implement the supplemental examination provisions of the Leahy-Smith America Invents Act, the Office is proposing to amend the rules of practice in patent cases as set forth herein. A request for supplemental examination of a patent must be filed by the patent owner. Each request for supplemental examination is limited to the presentation of ten items of information. Supplemental examination addresses allegations of inequitable conduct during patent litigation, which allegations typically concern far fewer than ten items of information. In addition, if a limit of ten items of information is not sufficient for a particular situation, more than one request for supplemental examination of the

same patent may be filed at any time. The request for supplemental examination must be accompanied by the fees for processing and treating an ex parte reexamination ordered under 35 U.S.C. 257, as well as any applicable document size fees. The request for supplemental examination must meet certain content requirements. Specifically, the request for supplemental examination must include an identification of the patent for which supplemental examination is requested; a list of each item of information and its publication date, if applicable; a list identifying any other prior or concurrent post patent Office proceedings involving the patent to be examined; an identification of each aspect of the patent to be examined; an identification of each issue raised by each item of information; a separate, detailed explanation for each identified issue; an explanation of how each item of information is relevant to each aspect of the patent to be examined and of how each item of information raises each identified issue; a copy of each item of information; and a summary of the relevant portions of any submitted document, other than the request, that is over 50 pages in length. A request for supplemental examination that does not comply with the content requirements may not be granted a filing date. 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.

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 the items of information presented and identified in the request. The supplemental examination certificate will state the result of this

determination. 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 as an attachment to the patent. The electronically issued supplemental examination certificate will also remain as part of the public record for the patent. If the supplemental examination certificate states that no substantial new question of patentability was found, and ex parte reexamination will not be ordered, then the electronically issued supplemental examination certificate will be published in due course as an attachment to the patent.

The Office must make its determination whether the items of information presented in the request raise a substantial new question of patentability within three months of the filing date of the supplemental examination request. Unlike a request for ex parte reexamination, the items of information presented in a request for supplemental examination are not limited to patents and printed publications. The items of information may include any information which the patent owner believes to be relevant to the patent, and which was not considered, was inadequately considered, or was incorrect during the prior examination of the patent. See 35 U.S.C. 257 (a) and (c). Thus, the variety of information that is permitted to be submitted in a request for supplemental examination, including, for example, transcripts of audio or video recordings, is more extensive than the information permitted to be submitted in an ex parte reexamination proceeding. The

information permitted in a supplemental examination is anticipated to be more resource-intensive than patents and printed publications to process, review, and treat, because the patent owner may present, in supplemental examination, an item of information that raises multiple issues in addition to those permitted to be raised in ex parte reexamination. For example, the patent owner may present one item of information that raises multiple issues of patentability, including issues under 35 U.S.C. 101 and issues under 35 U.S.C. 112 with respect to the original disclosure. For these reasons, the requirements set forth in the proposed rules are designed to permit efficient processing and treatment of each request for supplemental examination within the statutory three-month time period, and to complete any subsequent ex parte reexamination ordered as a result of the supplemental examination proceeding with special dispatch.

Discussion of Specific Rules

The following is a discussion of proposed amendments to Title 37 of the Code of Federal Regulations, Part 1.

Section 1.20: The Office is proposing to amend § 1.20 to set fees to implement supplemental examination, to adjust the fee for filing a request for ex parte reexamination, and to set a fee for petitions filed in ex parte and inter partes reexamination proceedings.

The authority to set fees for filing a request for supplemental examination and to consider each item of information submitted in the request is provided for in 35 U.S.C. 257(d)(1). See 35 U.S.C. 257(d)(1) (“[t]he Director shall by regulation establish fees for the submission of a request for supplemental examination of a patent, and to consider each item of information submitted in the request”). The authority to set fees for filing a request for ex parte reexamination is provided for in 35 U.S.C. 302. See 35 U.S.C. 302 (“[t]he request must be in writing and must be accompanied by payment of a reexamination fee established by the Director pursuant to the provisions of [35 U.S.C. 41]”).

Section 10(a) of the Leahy-Smith America Invents Act provides that the Office may set or adjust by rule any patent fee established, authorized, or charged under title 35, United States Code, provided that such fees only recover the aggregate estimated costs to the Office for processing, activities, services, and materials relating to patents (including administrative costs). See Pub. L. 112-29, 125 Stat. 283, 316 (2011).

Sections 10(d) and (e) of the Leahy-Smith America Invents Act set out a process that must be followed when the Office is using its authority under section 10(a) to set or adjust patent fees. See Pub. L. 112-29, 125 Stat. at 317-18. This process does not feasibly permit supplemental examination and the related ex parte and inter partes reexamination fees to be in place by September 16, 2012 (the effective date of the supplemental examination provisions of the Leahy-Smith America Invents Act). Therefore, the Office is setting these fees pursuant to its authority under 35 U.S.C.

41(d)(2) in this rulemaking, which provides that fees for all processing, services, or materials relating to patents not specified in 35 U.S.C. 41 are to be set at amounts to recover the estimated average cost to the Office of such processing, services, or materials. See 35 U.S.C. 41(d)(2). The Office's analysis of the estimated fiscal year 2013 costs for supplemental examination, ex parte reexamination, and petitions filed in ex parte and inter partes reexamination proceedings is available via the Office's Internet Web site (<http://www.uspto.gov>). The estimated fiscal year 2013 cost amounts are rounded to the nearest ten dollars by applying standard arithmetic rules so that the resulting proposed fee amounts will be convenient to patent users.

The Office is also in the process of developing a proposal to adjust patent fees under section 10 of the Leahy-Smith America Invents Act. The supplemental examination and ex parte and inter partes reexamination fees proposed in this notice will be revisited in furtherance of the Director's fee-setting efforts in this area.

The Office has estimated its fiscal year 2013 cost for processing and treating a request for supplemental examination to be \$5,180, and its fiscal year 2013 cost for conducting ex parte reexamination ordered as a result of a supplemental examination proceeding to be \$16,116. Therefore, the Office is proposing to add a new § 1.20(k)(1) to provide a fee of \$5,180 for processing and treating a request for supplemental examination, and a new § 1.20(k)(2) to provide a fee of \$16,120 for conducting ex parte reexamination ordered as a result of a supplemental examination proceeding (the 2013 cost amounts rounded to the nearest ten dollars). The \$16,120 fee for conducting an ex parte reexamination

ordered as a result of a supplemental examination proceeding will be returned if ex parte reexamination is not ordered. See § 1.26(c).

The Office has also estimated its fiscal year 2013 cost for processing and treating documents over 20 sheets in length that are submitted in a supplemental examination proceeding to be \$166 for each document between 21 and 50 sheets in length, and \$282 for each additional 50-sheet increment or a fraction thereof. Therefore, the Office is also proposing to add a new §1.20(k)(3) to provide document size fees for any documents over 20 sheets in length that are submitted in a supplemental examination proceeding, including (1) a fee of \$170 for each document between 21 and 50 sheets in length; and (2) a fee of \$280 for each additional 50-sheet increment or a fraction thereof (the 2013 cost amounts rounded to the nearest ten dollars).

The decision as to whether the information submitted in a request for supplemental examination raises a substantial new question of patentability is identical to the decision as to whether the information submitted in a request for ex parte reexamination raises a substantial new question of patentability, except that the information submitted in a request for supplemental examination is not limited to patents and publications. Thus, the Office has analyzed its ex parte and inter partes reexamination costs to estimate the cost of supplemental examination and resulting ex parte reexamination proceedings. The analysis of the Office's ex parte and inter partes reexamination costs also revealed that the Office's current ex parte and inter partes reexamination fees are not set at amounts that recover the Office's costs for these processes or services. Thus, the Office is

proposing to set fees for supplemental examination and resulting ex parte reexamination proceedings, adjust the fee for ex parte reexamination proceedings, and set a fee for petitions in ex parte and inter partes reexamination proceedings. The Office has estimated its fiscal year 2013 cost for conducting ex parte reexamination to be \$17,753. Therefore, the Office is proposing to amend § 1.20(c)(1) to change the fee for filing a request for ex parte reexamination (§ 1.510(a)) from \$2,520 to \$17,750 (the 2013 cost amounts rounded to the nearest ten dollars).

The Office is also proposing to add a new § 1.20(c)(6) to provide a fee of \$1,930 for filing a petition in an ex parte or inter partes reexamination proceeding, except for those specifically enumerated in §§ 1.550(i) and 1.937(d) (the 2013 cost amounts rounded to the nearest ten dollars). The Office has estimated its fiscal year 2013 cost for the processing and treatment of a petition in a reexamination proceeding is \$1,932. The proposed fee for treating a petition in a reexamination proceeding will apply to any petition filed in either an ex parte or an inter partes reexamination proceeding (except for those specifically enumerated in §§ 1.550(i) and 1.937(d)), including petitions under §§ 1.59, 1.181, 1.182, and 1.183. The proposed fee for treating a petition in an ex parte or inter partes reexamination proceeding will not apply to petitions specifically enumerated in §§ 1.550(i) and 1.937(d). The petitions enumerated in §§ 1.550(i) and 1.937(d) are petitions under §§ 1.550(c) and 1.956 to extend the period for response by a patent owner, petitions under §§ 1.550(e) and 1.958 to accept a delayed response by a patent owner, petitions under § 1.78 to accept an unintentionally delayed benefit claim,

and petitions under § 1.530(l) for correction of inventorship in ex parte or inter partes reexamination proceedings.

The Office is also proposing to add a new § 1.20(c)(7) to provide a fee of \$4,320 for a refused request for ex parte reexamination (discussed below), which is included in the fee under § 1.20(c)(1) for filing a request for ex parte reexamination. The Office has estimated that its fiscal year 2013 cost of processing a request for ex parte reexamination up to the issuance of a decision refusing the request for reexamination is \$4,320. Under current practice, if the Office decides not to institute an ex parte reexamination proceeding, a portion of the ex parte reexamination filing fee paid by the reexamination requester is refunded. This section specifies the portion of the ex parte reexamination filing fee that is retained by the Office if the Office decides not to institute the ex parte reexamination proceeding.

The Office is not proposing changes to the inter partes reexamination filing fee as the Office cannot consider, or even accord a filing date to, a request for inter partes reexamination filed on or after September 16, 2012. See Revision of Standard for Granting an Inter Partes Reexamination Request, 76 FR 59055, 59056 (Sept. 23, 2011).

Section 1.26: Section 1.26(c) is proposed to be amended to provide that if the Director decides not to institute an ex parte reexamination proceeding (a refused reexamination), any fee for filing an ex parte reexamination request paid by the reexamination requester, less the fee set forth in § 1.20(c)(7), will be refunded to the reexamination requester. If

the Director decides not to institute an ex parte reexamination proceeding under § 1.625 as a result of a supplemental examination proceeding, a refund of the ex parte reexamination fee (\$16,120) for supplemental examination, as set forth in § 1.20(k)(2), will be made to the patent owner who requested the supplemental examination proceeding. The provision for a refund of \$7,970 to the inter partes reexamination requester, where the Director decides not to institute an inter partes reexamination proceeding, is being retained to address any remaining instances of a refusal to institute an inter partes reexamination. The reexamination requester or the patent owner who requested the supplemental examination proceeding, as appropriate, should indicate the form in which any refund should be made (e.g., by check, electronic funds transfer, credit to a deposit account). Generally, refunds will be issued in the form that the original payment was provided.

Section 1.550: Section 1.550(i) is proposed to be added to provide that a petition in an ex parte reexamination proceeding must be accompanied by the fee set forth in § 1.20(c)(6), except for petitions under § 1.550(c) to extend the period for response by a patent owner, petitions under § 1.550(e) to accept a delayed response by a patent owner, petitions under § 1.78 to accept an unintentionally delayed benefit claim, and petitions under § 1.530(l) for correction of inventorship in an ex parte reexamination proceeding.

Section 1.601: Section 1.601(a) is proposed to require that a request for supplemental examination of a patent must be filed by the owner(s) of the entire right, title, and interest in the patent. Section 1.601(b) is proposed to require that the patent owner must establish

an ownership interest in the patent as set forth in § 1.601(a) by filing, as part of the request, a submission in accordance with § 3.73(b).

Section 1.601(c) is proposed to prohibit third parties from filing papers or otherwise participating in any manner in a supplemental examination proceeding. Section 12 of the Leahy-Smith America Invents Act specifies that a request for supplemental examination may be filed by the patent owner. See 35 U.S.C. 257(a). There is no provision for participation in any manner by a third party in a supplemental examination proceeding. In addition, because the patent owner filed the request, third party participation is also prohibited in any ex parte reexamination ordered under 35 U.S.C. 257 and § 1.625, pursuant to ex parte reexamination practice.

Section 1.605: Section 1.605(a) is proposed to require 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. In other words, the number of items of information that may be submitted as part of each request is limited to ten (10). The amount of information that may be included with each request is limited in order to permit full and comprehensive treatment of each item of information within the three-month statutory time period. Section 1.605(a) is also proposed to permit the filing of more than one request for supplemental examination of the same patent at any time. The patent owner is not precluded from obtaining review of any item of information as a result of the ten-item limit, because the patent owner may file multiple requests for supplemental examination of the same patent at any time.

Section 1.605(b) is proposed to require that an “item of information” includes a supporting 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. Examples include a journal article, a patent, an affidavit or declaration, or a transcript of an audio or video recording, each of which may be considered an item of information. If the information to be considered, reconsidered, or corrected is not, at least in part, contained within or based on any supporting document submitted as part of the request, the discussion within the body of the request relative to the information will be considered as the item of information. For example, if the patent owner raises an issue under 35 U.S.C. 101, and the issue is wholly contained in a discussion within the body of the request and is not based, at least in part, on any supporting document, the discussion in the request will be considered as the item of information. If, however, the patent owner is presenting a copy of a supporting document within the body of the request, such as an image of an electronic mail message or other document, a separate copy of the supporting document must be provided, which will be considered as an item of information. The patent owner may not avoid the counting of an item of information by inserting the content of the supporting document within the body of the request. As another example, if the patent owner presents an argument in the request regarding an issue under 35 U.S.C. 102, such as a potential public use or sale of the claimed invention, and also submits a supporting document with the request as possible evidence of the public use or sale, or the lack thereof, the supporting document containing the possible evidence will be considered as the item of information.

Section 1.605(c) is proposed to require that an item of information must be in writing in accordance with § 1.2. The Office does not currently have the capability of retaining records in unwritten form. For this reason, any audio or video recording must be submitted in the form of a written transcript in order to be considered. A transcript of a video may be submitted together with copies of selected images of the video, and a discussion of the correlation between the transcript and the copies of the images.

Section 1.605(d) is proposed to require that if an 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 raise an issue to be considered, reconsidered, or corrected, each item of information of the combination may be separately counted. For example, if the patent owner requests consideration of a possible rejection of the claims under 35 U.S.C. 103(a) over a combination of reference A in view of reference B, reference A and reference B will be separately counted as items of information. Exceptions to this provision 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)(11).

Section 1.610: Proposed § 1.610 governs the content of the request for supplemental examination. Consistent with the requirement in 35 U.S.C. 257(d) to establish fees, § 1.610(a) requires that the request be accompanied by the fee for filing a request for supplemental examination as set forth in § 1.20(k)(1), the fee for ex parte reexamination

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).

Proposed § 1.610(b) sets forth content requirements for a request for supplemental examination. Section 1.610(b)(1) is proposed to require that the request include a cover sheet itemizing each component submitted as part of the request. A “component” may be a certificate of mailing, the request, the patent to be examined, an item of information, and any other separate document that is deposited with the request.

Section 1.610(b)(2) is proposed to require that the request include a table of contents for the request. Section 1.610(b)(3) is proposed to require that the request include an identification of the number, the date of issue, and the first named inventor of the patent for which supplemental examination is requested.

Section 1.610(b)(4) is proposed to require that the request include 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. This list must include each of the items of information on which the request is based. If the item of information is a discussion contained within the body of the request, as discussed previously, the pages of the request on which the discussion appears, and a brief description of the item of information, such as “discussion in request of why the claims are patentable under 35 U.S.C. 101, pages 7-11”, must be listed. Section 1.610(b)(4) is also proposed to require a statement that: (1) 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; (2) 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 (3) identifies each item of information that was incorrect in the prior examination of the patent, and explains how it is being corrected. For example, the patent owner may state that a declaration under § 1.132, which was presented during the prior examination of the patent as evidence of unexpected results, provided analytical data that was later determined to be erroneous or incorrect. The patent owner may present a corrected declaration under § 1.132 and explain how the previously submitted, erroneous data is being corrected. As another example, the patent owner may submit a patent with the request as an item of information, and explain that the patent was not considered (or was inadequately considered) during the prior examination, and that consideration (or reconsideration) of the patent is requested because it raises an issue under 35 U.S.C. 103 with respect to the claims of the patent for which supplemental examination has been requested. An amendment, however, is not an item of information. If the patent owner merely wishes, without more, to amend the claims or to add new claims, in order to further define the invention, the patent owner may file a reissue application. Similarly, a benefit claim may be corrected merely by filing an appropriate petition and/or a reissue application, as applicable. However, the patent owner may also, if desired, file the appropriate petition with the request for supplemental examination in order to correct the benefit claim.

Section 1.610(b)(5) is proposed to require that the request include a list identifying any other prior or concurrent post patent Office proceedings involving the patent for which the current supplemental examination is requested, including an identification of the type of proceeding (e.g., ex parte or inter partes reexamination, reissue, supplemental examination, post-grant review, inter partes review), the identifying number of any such proceeding (e.g., a control number or a reissue application number), and the filing date of any such proceeding.

Section 1.610(b)(6) is proposed to require that the request include an identification of each aspect of the patent to be examined. Examples of an “aspect of the patent” include the abstract, any drawing, specification, patent claims, or benefit claims. If any of the claims identified for examination include one or more means-plus-function or step-plus-function elements as set forth in 35 U.S.C. 112(f), as amended by the Leahy-Smith America Invents Act, the request must include an identification of the structure, material, or acts in the specification that correspond to each means-plus-function or step-plus-function element of each claim to be examined.

Section 1.610(b)(7) is proposed to require that the request include an identification of each issue of patentability raised by each item of information. An item of information may raise more than one issue of patentability. For example, a journal article or reference patent may raise an issue under 35 U.S.C. 102, 35 U.S.C. 103, 35 U.S.C. 112, or obviousness-type double patenting, as appropriate. A discussion in the body of the

request may raise an issue under 35 U.S.C. 101. A sales invoice or advertisement may raise an issue under 35 U.S.C. 102.

Section 1.610(b)(8) is proposed to require that the request include a separate, detailed explanation for each identified issue of patentability, in order to determine whether the submitted items of information are appropriate for supplemental examination, and to better analyze the information submitted with the request. The explanation must also discuss how each item of information is relevant to each aspect of the patent identified for examination. In addition, the explanation must discuss how each item of information raises each issue identified for examination. For example, the explanation must discuss how each claim limitation is met, or is not met, by an item of information, such as a patent which qualifies as prior art under 35 U.S.C. 102.

Section 1.610(b)(8)(i) is proposed to require that, where an identified issue involves the application of 35 U.S.C. 101 (other than double patenting) or 35 U.S.C. 112, the explanation must discuss the support in the specification for each limitation of each claim identified for examination with respect to this issue. Section 1.610(b)(8)(ii) is proposed to require that, where an identified issue involves the application of 35 U.S.C. 102, 35 U.S.C. 103, or double patenting, the explanation must discuss 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. For example, for an item of information that is identified as raising an issue under 35 U.S.C. 102 with respect to

claims 1 through 10, such as a patent which qualifies as prior art under 35 U.S.C. 102, the explanation must discuss how each claim limitation in each of claims 1 through 10 is met, or is not met, by the item of information. Preferably, the explanation employs a claim chart that matches each claim limitation to cited portions of the item of information, as applicable. The requirements for this explanation are anticipated to be substantially similar to the requirements for a detailed explanation under § 1.510(b)(2) in a request for ex parte reexamination, for items of information that raise issues that are relevant to the patent claims. In other words, this explanation must state, in sufficient detail, for each identified issue, how an item of information is applied to the patent.

Section 1.610(b)(9) is proposed to require that the request include 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 ex parte or inter partes reexamination certificate issued for the patent.

Section 1.610(b)(10) is proposed to require that the request include a copy of each item of information listed in § 1.610(b)(4), 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.

Section 1.610(b)(11) is proposed to require that the request include a summary of the relevant portions of any submitted document (including patent documents), other than the request, that is over 50 pages in length. The summary must include citations to the particular pages containing the relevant portions. This summary may be similar to the requirement, for information disclosure statements, of a discussion of the relevant and pertinent parts of a non-English language document. This requirement will assist the Office in treating information presented in lengthy documents within the statutory three-month time period. Patent owners are encouraged to redact lengthy documents to include only the relevant portions, unless the redaction would remove context such that the examiner would not be provided with a full indication of the relevance of the information.

Section 1.610(b)(12) is proposed to require that the request must include a submission by the patent owner in compliance with § 3.73(b) establishing the entirety of the ownership in the patent requested to be examined, as set forth in § 1.601(b).

Proposed § 1.610(c) provides that the request may include an explanation why each item of information does or does not raise a substantial new question of patentability. Patent owners are strongly encouraged to submit such explanation, which will assist the Office in analyzing the request.

Proposed § 1.610(d) provides that the filing date of a request for supplemental examination will not be granted if the request is not in compliance with §§ 1.605, 1.615,

and 1.610(a) and (b). A defective request may be granted a filing date if the defects are limited to the omission of one or more of the requirements set forth in § 1.610(b)(1) or (b)(2), subject to the discretion of the Office.

Proposed § 1.610(e) provides that if the Office determines that the request, as originally submitted, is not entitled to a filing date pursuant to § 1.610(d), then the patent owner will be so notified and will generally 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 ex parte 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, 1.610 and 1.615, the filing date of the supplemental examination request will be the receipt date of the corrected request.

Section 1.615. Section 1.615(a) is proposed to require that all papers submitted in a supplemental examination proceeding must be formatted in accordance with § 1.52, including the request 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)(11). 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. However, such 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.

Section 1.615(b) is proposed to require that 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.

Section 1.620: Section 1.620(a) is proposed to require that, 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 properly presented in the request. The standard for determining whether an item of information submitted with the request raises a substantial new question of patentability will be the standard set forth in the Manual of Patent Examining Procedure (MPEP): *i.e.*, whether there is a substantial likelihood that a reasonable examiner would consider the item of information important in determining patentability. See MPEP § 2242 (8th ed. 2001) (Rev. 8, July 2010). This determination will generally be limited to a review of the issues identified in the request as applied to

the identified aspect(s) of the patent. For example, a determination on a request that includes three items of information, wherein each item is identified as raising an issue under 35 U.S.C. 102 with regard to claim 1, will generally be limited to whether any of the three items of information raise a substantial new question of patentability with respect to claim 1. If the patent owner is interested in having more issues addressed for an item of information, the patent owner must identify every issue and provide the required explanation(s) in the request for supplemental examination. Similarly, if the patent owner is interested in applying an item of information to more aspects of the patent (e.g., to more claims), the request for supplemental examination must include an identification of each aspect to which the item of information is to be applied and the required explanation(s). For example, if the patent owner fails to apply an item of information to certain claims, then the patent owner is not entitled to a determination for that item of information as applied to such claims. The determination will be based on the claims in effect at the time of the determination. The supplemental examination certificate, which contains the determination, will become a part of the official record of the patent.

Proposed § 1.620(b) provides that the Office may hold in abeyance an 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. The only actions by the Office on the request are: (1) a determination of whether the request is entitled to a filing date; and (2) a determination of whether any of the items of information submitted with the request raise a substantial

new question of patentability. The only relevant type of petition that the Office anticipates will be filed in a supplemental examination proceeding would involve the filing date of the request, which is not relevant to the determination of whether any of the items of information submitted with the request raises a substantial new question of patentability. Holding in abeyance a decision on such a petition will assist the Office in making the determination regarding the substantial new question within the three-month statutory period.

Proposed § 1.620(c) provides that 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.

Section 1.620(d) is proposed to require that the patent owner must, as soon as possible upon the discovery of any other prior or concurrent post patent Office proceeding involving the patent for which the current supplemental examination is requested, file a paper limited to bare notice of the post patent Office proceeding, if such notice has not been previously provided with the request. The Office anticipates that a patent for which supplemental examination is requested is likely to be involved in other Office post patent proceedings, including another supplemental examination proceeding. Knowledge of other proceedings is important to ensure a quality determination. In addition, bare notice is required due to the statutory three-month period within which the Office must process the information. The notice is 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), an identifying number, such as a control number or reissue application number, and the filing date of the post patent Office proceeding. The notice may not include any discussion of the issues present in the current supplemental examination proceeding or in the identified post patent Office proceeding(s). If the paper containing the notice is not so limited, the paper will be held to be improper, and will be processed as an unauthorized paper.

Section 1.620(e) is proposed to prohibit interviews in a supplemental examination proceeding. This requirement will assist the Office to process the request for supplemental examination within the three-month statutory period. A telephone call to the Office to confirm receipt of a request for supplemental examination, or to discuss general procedural questions, is not considered to be an interview for the purposes of this provision. This prohibition against interviews applies only to supplemental examination proceedings. As to any ex parte reexamination ordered as a result of the supplemental examination proceeding, interview practice is governed by the regulations governing ex parte reexamination proceedings. See, e.g., § 1.560.

Proposed § 1.620(f) provides that no amendment to any aspect of the patent may be filed in a supplemental examination proceeding. Amendments to any aspect of the patent are not items of information, and are not appropriate in a supplemental examination proceeding. As specified in 35 U.S.C. 257(b), the patent owner does not have the right to file a statement under 35 U.S.C. 304. See proposed § 1.625(d)(1). 35 U.S.C. 304 permits a patent owner to file an amendment by including the amendment with the patent owner's

statement prior to an initial Office action. However, because the ex parte reexamination proceeding does not exist prior to the order under 35 U.S.C. 257 and the patent owner is precluded from filing a statement under 35 U.S.C. 304, no amendment may be filed from the time the request for supplemental examination is filed, until after the issuance of an initial Office action on the merits in any ex parte reexamination proceeding ordered under 35 U.S.C. 257.

Proposed § 1.620(g) provides that, if the Office becomes aware, during the course of a supplemental examination or of any ex parte 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 ex parte reexamination proceeding ordered under 35 U.S.C. 257 will continue. The matter will be referred to the U.S. Attorney General in accordance with 35 U.S.C. 257(e).

Section 1.625: Proposed § 1.625(a) provides that a supplemental examination proceeding will conclude when the supplemental examination certificate is electronically issued. The supplemental examination certificate will be electronically issued in the Office image file wrapper (IFW) system and the Patent Application Information Retrieval (PAIR) system within three months of the filing date of the request. Electronic issuance of the supplemental examination certificate will permit the Office to issue the certificate within the three-month statutory period and will permit additional time to review the items of information provided by the request, which would otherwise not be available if the certificate were to go through the Office's publication process, which currently takes

approximately eight weeks to complete. The certificate will be viewable by the public in Public PAIR. 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.

Proposed § 1.625(b) provides that, if the supplemental examination certificate indicates 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 as an attachment to the patent by the Office's patent publication process. The electronically issued supplemental examination certificate will also remain as part of the public record for the patent.

Proposed § 1.625(c) provides that, 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 by the Office's patent publication process as an attachment to the patent. The reexamination fee for supplemental examination, as set forth in § 1.20(k)(2), will be refunded in accordance with § 1.26(c).

Proposed § 1.625(d) provides that 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) ex parte 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 a reexamination proceeding, which differs from the provisions of § 1.552; (3) issues in addition to those raised by patents and printed publications and by subject matter added or deleted during an ex parte reexamination proceeding may be considered and resolved; and (4) information material to patentability will be defined by § 1.56(b) for the purposes of a supplemental examination proceeding, and any resulting ex parte reexamination proceeding. Because supplemental examination is not limited to patents and printed publications, any aspect of the patent, including the original specification, may be examined. The material to patentability standard applicable to patent applications (§ 1.56(b)) is proposed for ex parte reexamination resulting from a supplemental examination because the material to patentability standard applicable to ex parte reexaminations (§ 1.555(b)) is limited to patents and printed publications, and an ex parte reexamination resulting from supplemental examination is not limited to patents and printed publications. Any reference to “applicant” in § 1.56(b) will be read as “patent owner.”

Section 1.937: Section 1.937(d) is proposed to be added to provide that a petition in an inter partes reexamination proceeding must be accompanied by the fee set forth in § 1.20(c)(6), except for petitions under § 1.956 to extend the period for response by a patent owner, petitions under § 1.958 to accept a delayed response by a patent owner, petitions under § 1.78 to accept an unintentionally delayed benefit claim, and petitions under § 1.530(l) for correction of inventorship in an inter partes reexamination proceeding.

The Office would also make appropriate reference to supplemental examination in title 37 CFR (e.g., §§ 3.71, 3.73).

Rulemaking Considerations:

A. Administrative Procedure Act: This notice proposes to amend the rules of practice in patent cases to implement the supplemental examination provisions of the Leahy-Smith America Invents Act. The Office is also proposing to adjust the fee for filing a request for ex parte reexamination and to set a fee for petitions filed in ex parte and inter partes reexamination proceedings to more accurately reflect the cost of these processes. The changes being proposed in this notice do not change the substantive criteria of patentability. These proposed changes involve rules of agency practice and procedure and/or interpretive rules. See Bachow Commc'ns Inc. v. FCC, 237 F.3d 683, 690 (D.C. Cir. 2001) (rules governing an application process are procedural under the Administrative Procedure Act); Inova Alexandria Hosp. v. Shalala, 244 F.3d 242, 350

(4th Cir. 2001) (rules for handling appeals were procedural where they did not change the substantive standard for reviewing claims); Nat'l Org. of Veterans' Advocates v. Sec'y of Veterans Affairs, 260 F.3d 1365, 1375 (Fed. Cir. 2001) (rule that clarifies interpretation of a statute is interpretive).

Accordingly, prior notice and opportunity for public comment are not required pursuant to 5 U.S.C. 553(b) or (c) (or any other law) and thirty-day advance publication is not required pursuant to 5 U.S.C. 553(d) (or any other law). See Cooper Techs. Co. v. Dudas, 536 F.3d 1330, 1336-37 (Fed. Cir. 2008) (stating that 5 U.S.C. 553, and thus 35 U.S.C. 2(b)(2)(B), does not require notice and comment rulemaking for “interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice”) (quoting 5 U.S.C. 553(b)(A)). The Office, however, is publishing these proposed changes and the Initial Regulatory Flexibility Act analysis, below, for comment as it seeks the benefit of the public’s views on the Office’s proposed implementation of these provisions of the Leahy-Smith America Invents Act.

B. Initial Regulatory Flexibility Analysis:

1. Description of the reasons that action by the agency is being considered: The Office is proposing to amend the rules of patent practice to implement the supplemental examination provisions of the Leahy-Smith America Invents Act, which take effect September 16, 2012. The Office is also proposing to adjust the fee for filing a request for ex parte reexamination, and to set a fee for petitions filed in ex parte and inter partes reexamination proceedings, to more accurately reflect the cost of these processes.

2. Succinct statement of the objectives of, and legal basis for, the proposed rules: The objective of the proposed rules to implement the supplemental examination provisions of the Leahy-Smith America Invents Act is to establish a process which allows: (1) patent owners to exercise their statutory right to request supplemental examination to consider, reconsider, or correct information believed to be relevant to a patent; and (2) the Office to make its determination whether the information presented in the request raises a substantial new question of patentability within three months of the filing date of the supplemental examination request. The objective of the proposed rules to adjust the fee for filing a request for ex parte reexamination, and to set a fee for petitions filed in ex parte and inter partes reexamination proceedings, is to recover the estimated average cost to the Office of ex parte reexamination proceedings and petitions filed in ex parte and inter partes reexamination proceedings.

Section 12 of the Leahy-Smith America Invents Act provides a legal basis for the proposed rules to implement supplemental examination. 35 U.S.C. 41(d)(2) provides a

legal basis for the proposed rules to set the fee for supplemental examination, to adjust the fee for filing a request for ex parte reexamination, and to set a fee for petitions filed in ex parte and inter partes reexamination proceedings. Specifically, 35 U.S.C. 41(d)(2) provides that fees for all processing, services, or materials relating to patents not specified in 35 U.S.C. 41 are to be set at amounts to recover the estimated average cost to the Office of such processing, services, or materials.

3. Description and estimate of the number of affected small entities:

a. Size Standard and Description of Entities Affected. The Small Business Administration (SBA) small business size standards applicable to most analyses conducted to comply with the Regulatory Flexibility Act are set forth in 13 CFR 121.201. These regulations generally define small businesses as those with fewer than a specified maximum number of employees or less than a specified level of annual receipts for the entity's industrial sector or North American Industry Classification System (NAICS) code. As provided by the Regulatory Flexibility Act, and after consultation with the Small Business Administration, the Office formally adopted an alternate size standard as the size standard for the purpose of conducting an analysis or making a certification under the Regulatory Flexibility Act for patent-related regulations. See Business Size Standard for Purposes of United States Patent and Trademark Office Regulatory Flexibility Analysis for Patent-Related Regulations, 71 FR 67109 (Nov. 20, 2006), 1313 Off. Gaz. Pat. Office 60 (Dec. 12, 2006). This alternate small business size standard is SBA's previously established size standard that identifies the criteria entities must meet to be entitled to pay reduced patent fees. See 13 CFR 121.802. If patent applicants

identify themselves on a patent application as qualifying for reduced patent fees, the Office captures this data in the Patent Application Location and Monitoring (PALM) database system, which tracks information on each patent application submitted to the Office.

Unlike the SBA small business size standards set forth in 13 CFR 121.201, the size standard for USPTO is not industry-specific. Specifically, the Office's definition of small business concern for Regulatory Flexibility Act purposes is a business or other concern that: (1) meets the SBA's definition of a "business concern or concern" set forth in 13 CFR 121.105; and (2) meets the size standards set forth in 13 CFR 121.802 for the purpose of paying reduced patent fees, namely, an entity: (a) whose number of employees, including affiliates, does not exceed 500 persons; and (b) which has not assigned, granted, conveyed, or licensed (and is under no obligation to do so) any rights in the invention to any person who made it and could not be classified as an independent inventor, or to any concern which would not qualify as a non-profit organization or a small business concern under this definition. See Business Size Standard for Purposes of United States Patent and Trademark Office Regulatory Flexibility Analysis for Patent-Related Regulations, 71 FR at 67112 (Nov 20, 2006), 1313 Off. Gaz. Pat. Office at 63 (Dec. 12, 2006).

b. Overview of Estimates of Number of Entities Affected. The proposed rules will apply to any small entity that files a request for supplemental examination, a request for ex parte reexamination, or a petition in an ex parte and inter partes reexamination

proceeding. To estimate the number of requests for supplemental examination, ex parte reexamination, and petitions filed in ex parte and inter partes reexamination expected to be submitted annually by small entities, the Office considered the information concerning ex parte reexamination filings published in the United States Patent and Trademark Office Performance and Accountability Report, Fiscal Year 2011. The Office received 758 requests for ex parte reexamination in fiscal year 2011, of which 104 (14 percent) were by the patent owner and 654 (86 percent) were by a third party. See United States Patent and Trademark Office Performance and Accountability Report, Fiscal Year 2011, at 171 (table 14A) (2011). Based upon that information, the Office estimates that it will receive about 800 (758 rounded to be nearest 100) requests for ex parte reexamination annually and that about 14 percent of all requests for ex parte reexamination are filed by patent owners.

c. Number of Entities Filing Requests for Ex Parte Reexamination. As discussed previously, the Office estimates that it will receive about 800 requests for ex parte reexamination annually and about 14 percent of all requests for ex parte reexamination are filed by patent owners. Thus, the Office estimates that it receives approximately 110 (14 percent of 800 rounded to the nearest 10) requests for ex parte reexamination filed by patent owners annually. Due to the availability of supplemental examination beginning in fiscal year 2013, the Office estimates that all 110 requests for ex parte reexamination that would have been filed annually by patent owners will instead be filed as requests for supplemental examination. Therefore, the Office estimates that a total of approximately

690 (86 percent of 800 rounded to the nearest 10) requests for ex parte reexamination (all by third parties) will be filed annually.

Reexamination requesters are not required to identify their small entity status. Therefore, the Office does not have precise data on the number of requests for ex parte reexamination submitted annually by small entities. However, the Office tracks the number of requests for ex parte reexamination that are filed in which the patent that is the subject of the reexamination was prosecuted under small entity status. For fiscal year 2011, approximately 36 percent of the requests for ex parte reexamination that were filed sought reexamination of a patent that was prosecuted under small entity status.

It is difficult to estimate what fraction of the anticipated 690 requests for ex parte reexamination submitted annually will be by small entities, because reexamination requesters are not required to identify their small entity status. The data that the Office keeps regarding the number of requests for ex parte reexamination that are filed in which the patent that is the subject of the reexamination was prosecuted under small entity status provides no insight into the number of requests for ex parte reexamination submitted by small entity third party requesters. Therefore, for purposes of this analysis, the Office is considering all 690 requests for ex parte reexamination expected to be submitted annually as being submitted by small entities.

d. Number of Entities Filing Petitions in Ex Parte Reexamination Proceedings. The proposed rule to set a fee for petitions filed in reexamination proceedings (except for

those petitions specifically enumerated in 37 CFR 1.550(i) and 1.937(d)) will apply to any small entity that files a petition in a reexamination proceeding. The Office decided 832 petitions in reexamination proceedings (ex parte and inter partes) in fiscal year 2010. In view of the statutory mandate to conduct reexamination proceedings with special dispatch, the Office estimates that the 832 petitions decided in reexamination proceedings in fiscal year 2010 reasonably approximates the number of petitions filed in reexamination proceedings in fiscal year 2010. In view of the proposed fee for petitions filed in reexamination proceedings, the Office estimates that no more than 850 (832 rounded to the nearest 50) will be filed annually in reexamination proceedings. The data that the Office keeps regarding petitions filed in reexamination proceedings does not indicate the number of petitions submitted by unique small entities. Therefore, for purposes of this analysis, the Office is considering all 850 petitions expected to be submitted annually in a reexamination proceeding as being submitted by small entities. Hence, the Office estimates that no more than 850 small entities will file a petition in a reexamination proceeding annually.

e. Number of Entities Filing Request for Supplemental Examination. In view of the benefits to patent owners afforded by supplemental examination at 35 U.S.C. 257(c), the Office is estimating that all 110 requests for ex parte reexamination that would have been filed annually by patent owners will instead be filed as requests for supplemental examination. However, the Office is also estimating that more than 110 requests for supplemental examination will be filed annually due to a combination of: (1) the benefits to patent owners afforded by supplemental examination; (2) the fact that the

“information” that may form the basis of a request for supplemental examination is not limited to patents and printed publications; and (3) the fact that the issues that may be raised during supplemental examination may include issues in addition to those permitted to be raised in ex parte reexamination, e.g., issues under 35 U.S.C. 112.

Because a main 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 Office and subject to a written decision by the Office, the Office estimates that the number of cases annually in which inequitable conduct is pled in the United States district courts represents a reasonable approximation of the number of annual requests for supplemental examination that the Office will receive. Data from the United States district courts reveals that between 2,900 and 3,301 patent cases were filed each year during the period between 2006 and 2010. See U.S. Courts, Judicial Business of the United States Courts, www.uscourts.gov/uscourts/Statistics/JudicialBusiness/2010/appendices/C02ASep10.pdf (last visited Nov. 11, 2011) (hosting annual reports for 1997 through 2010). Thus, the Office projects that no more than 3,300 (the highest number of yearly filings between 2006 and 2010 rounded to the nearest 100) patent cases are likely to be filed annually. Note that inequitable conduct is pled in approximately 40 percent of the patent cases filed annually in U.S. District Courts. See Christian E. Mammen, Controlling the “Plague”: Reforming the Doctrine of Inequitable Conduct, 24 Berkeley Tech. L.J. 1329, 1358–60 (2010) (displaying a chart estimating the steady increase in assertions of the inequitable conduct defense). However, the number of patent cases in which a finding of inequitable

conduct is upheld by the U.S. Court of Appeals for the Federal Circuit (Federal Circuit) is only a fraction of a percent. See id. The Office also anticipates that the percentage of patent cases in which inequitable conduct is pled and in which a finding of inequitable conduct is upheld by the Federal Circuit will begin to decline due to the May 2011 en banc decision by the Federal Circuit in Therasense, Inc. v. Becton, Dickinson, and Co., 649 F.3d 1276 (Fed. Cir. 2011).

The Office also anticipates that supplemental examination will lead to a reduction in the number of district court patent infringement cases in which inequitable conduct is pled as a defense. See H.R. Rep. No. 112-98, Part 1 at pages 50 and 78 (2011) (the information submitted in a request for supplemental examination cannot later be used to hold the patent unenforceable or invalid on the basis of inequitable conduct during civil litigation).

The Office understands that the costs related to inequitable conduct (e.g., discovery related to inequitable conduct) are a significant portion of litigation costs. See e.g., Mammen, Controlling the “Plague”: Reforming the Doctrine of Inequitable Conduct, 24 Berkeley Tech. L.J. at 1347. The Office is specifically interested in receiving comments on litigation cost savings and other benefits the public may expect to realize from implementation of rules on supplemental examination.

Therefore, the Office estimates that it will receive about 1,430 (40 percent of 3,300 plus 110) requests for supplemental examination annually. Assuming that requests for supplemental examination will be filed by small entities in roughly the same percentage that requests for ex parte reexamination are currently filed by small entities (36 percent),

the Office estimates that about 500 (36 percent of 1,430 (515) rounded to the nearest 100) requests for supplemental examination will be submitted annually by small entities.

4. Description of the projected reporting, recordkeeping and other compliance requirements of the proposed rules, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record: The proposed rules will apply to any small entity that files a request for supplemental examination, a request for ex parte reexamination, or a petition in an ex parte or inter partes reexamination proceeding. The proposed rules to implement the supplemental examination provisions of the Leahy-Smith America Invents Act will impose compliance requirements on patent owners who request supplemental examination to consider, reconsider, or correct information believed to be relevant to a patent. The proposed rules will charge a fee to any patent owner who requests supplemental examination, and change the fee applicable to any entity that files a request for ex parte reexamination or a petition in an ex parte or inter partes reexamination proceeding.

All papers in a supplemental examination proceeding must be filed in accordance with the requirements set forth in 37 CFR 1.601 and must be formatted in accordance with the requirements set forth in 37 CFR 1.615. All “items of information” submitted as part of the request must meet the requirements of 37 CFR 1.605. The request itself must include the items set forth in 37 CFR 1.610. The proposed rules to implement the supplemental examination provisions of the Leahy-Smith America Invents Act also require: (1) a fee

of \$5,120.00 for processing and treating a request for supplemental examination; (2) a fee of \$15,930.00 for an ex parte reexamination ordered as a result of a supplemental examination proceeding; and (3) for processing and treating, in a supplemental examination proceeding, a non-patent document over 20 sheets in length, a fee of \$170.00 for a document of between 21 and 50 sheets, and a fee of \$280.00 for each additional 50 sheets or a fraction thereof.

A patent practitioner would have the type of professional skills necessary for preparation of request for supplemental examination. Office staff with experience and expertise in a wide range of patent prosecution matters as a patent practitioner estimate that preparing and filing a request for supplemental examination will require about 25 patent practitioner hours, costing \$8,500 (25 hours at the \$340 per hour median rate for attorneys reported in the American Intellectual Property Law Association (AIPLA) Report of the Economic Survey 2011. As discussed previously, a request for supplemental examination is comparable to a request for ex parte reexamination, in that both present information to the Office for evaluation as to whether the information raises a substantial new question of patentability). The American Intellectual Property Law Association (AIPLA) Report of the Economic Survey 2011 indicates that the average cost of preparing and filing a request for ex parte reexamination (the current Office proceeding most similar to a request for supplemental examination) is \$19,000. The Office staff estimate for preparing a supplemental examination is lower than the comparable ex parte reexamination cost because a patentee in supplemental examination would simply be preparing a supplemental examination request in compliance with the

applicable statutes and regulations with information already at hand, whereas a third party requester in an ex parte reexamination (the majority of ex parte reexamination requests being by third parties) is not merely preparing an ex parte reexamination request in compliance with the applicable statutes and regulations, but is also seeking to convince the Office that the claims in the patent for which reexamination is sought are unpatentable with patents and printed publications that the third party must uncover as part of the process.

The proposed rules to adjust or set fees in ex parte reexamination are as follows:

(1) \$17,550.00 for filing a request for ex parte reexamination; (2) \$1,930.00 for filing a petition in an ex parte or inter partes reexamination proceeding, except for those specifically enumerated in 37 CFR 1.550(i) and 1.937(d); and (3) for a refused request for ex parte reexamination under 37 CFR 1.510 (this amount is included in the request for ex parte reexamination fee, and is the portion not refunded if the request for reexamination is denied). The proposed rules to adjust the fee for filing a request for ex parte reexamination, and to set a fee for petitions filed in ex parte and inter partes reexamination proceedings, do not impose any discernible reporting, recordkeeping, or other compliance requirements. The proposed rules to adjust the fee for filing a request for ex parte reexamination, and to set a fee for petitions filed in ex parte and inter partes reexamination proceedings, only adjust or establish certain fees (as discussed previously) to more accurately reflect the cost of the process or service.

5. Description of any significant alternatives to the proposed rules which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rules on small entities: This analysis considered significant alternatives such as: (1) the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities; (3) the use of performance rather than design standards; and (4) an exemption from coverage of the rule, or any part thereof, for such small entities. See 5 U.S.C. 603; see also 35 U.S.C. 41(h) (fee reduction for small business concerns not applicable to fees set under 35 U.S.C. 41(d)(2)).

With respect to the proposed rules to implement the supplemental examination provisions of the Leahy-Smith America Invents Act, the Office considered requiring less than, or exempting small entities from, what is currently set forth at proposed 37 CFR 1.601, 1.605, 1.610, and 1.615. Specifically, the Office considered not requiring any or all of, or exempting small entities from, the following content requirement of proposed 37 CFR 1.610: (1) a list of each item of information that is requested to be considered, reconsidered, or corrected, identifying each item of information that was not considered, adequately considered, or correctly considered in the prior examination of the patent, and explaining why consideration or reconsideration of the item of information is being requested or how the item of information it is being corrected; (2) 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; (3) an identification of each issue raised by each item of information; and (4) 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 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 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.

However, it is in the patent owner's interest to have the supplemental examination proceeding, and any reexamination proceeding ordered pursuant to the supplemental examination request, concluded as soon as possible. See 35 U.S.C. 257(c)(2)(B) (stating that the potential benefits to patent owners afforded by 35 U.S.C. 257(c)(1) shall not apply "unless the supplemental examination, and any reexamination ordered pursuant to the request, are concluded before the date on which [a patent infringement action] is brought"). The information that may be submitted in a supplemental examination is more extensive than the information permitted in an ex parte reexamination proceeding, and the issues that may be raised during supplemental examination include issues that are not permitted to be raised in ex parte reexamination, e.g., issues under 35 U.S.C. 101 and

112. The Office needs to require this information to promptly resolve a supplemental examination proceeding, and any reexamination proceeding ordered pursuant to the supplemental examination request. Finally, it is in the patent owner's interest to have the supplemental examination request be as complete as possible. With these factors in mind, the Office designed the requirements set forth in the proposed rules to permit: (1) efficient processing and treatment of each request for supplemental examination within the statutory three-month time period; and (2) completion of any reexamination ordered as a result of the supplemental examination proceeding with special dispatch.

With respect to the proposed rules to adjust the fee for filing a request for ex parte reexamination, and to set a fee for petitions filed in reexamination proceedings, the alternative of not adjusting or setting the fees would have a lesser economic impact on small entities, but would not accomplish the stated objectives of applicable statutes. See 35 U.S.C. 41(d)(2) (provides that fees set by the Office recover the estimated average cost to the Office of the processing, services, or materials); see also 35 U.S.C. 41(h) (fee reduction for small business concerns not applicable to fees set under 35 U.S.C.

41(d)(2)). In addition, a decision to forego this fee adjustment and fee setting would have a negative impact on Office funding, which in turn would have a negative impact on the ability of the Office to meet the statutory mandate to conduct reexamination proceedings with special dispatch.

A request for supplemental examination is a unique submission (the proposed rule does not involve periodic reporting requirements), thus the establishment of timetables that

take into account the resources available to small entities and consolidation of compliance and reporting requirements is inapplicable. In addition, the use of performance rather than design standards is also inapplicable to a request for supplemental examination.

6. Identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap or conflict with the proposed rules: The Office is the sole agency of the United States Government responsible for administering the provisions of title 35, United States Code, pertaining to examination and granting patents. Therefore, no other federal, state, or local entity shares jurisdiction over the examination and granting of patents.

Other countries, however, have their own patent laws, and an entity desiring a patent in a particular country must make an application for patent in that country, in accordance with the applicable law. Although the potential for overlap exists internationally, this cannot be avoided except by treaty (such as the Paris Convention for the Protection of Industrial Property, or the Patent Cooperation Treaty (PCT)). Nevertheless, the Office believes that there are no other duplicative or overlapping rules.

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C. Executive Order 12866 (Regulatory Planning and Review): This rulemaking has been determined to be significant for purposes of Executive Order 12866 (Sept. 30, 1993).

D. Executive Order 13563 (Improving Regulation and Regulatory Review): The Office has complied with Executive Order 13563. Specifically, the Office has, to the extent feasible and applicable: (1) made a reasoned determination that the benefits justify the costs of the rule; (2) tailored the rule to impose the least burden on society consistent with obtaining the regulatory objectives; (3) selected a regulatory approach that maximizes net benefits; (4) specified performance objectives; (5) identified and assessed available alternatives; (6) involved the public in an open exchange of information and perspectives among experts in relevant disciplines, affected stakeholders in the private sector and the public as a whole, and provided on-line access to the rulemaking docket; (7) attempted to promote coordination, simplification and harmonization across government agencies and identified goals designed to promote innovation; (8) considered approaches that reduce burdens and maintain flexibility and freedom of choice for the public; and (9) ensured the objectivity of scientific and technological information and processes.

E. Executive Order 13132 (Federalism): This rulemaking does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (Aug. 4, 1999).

F. Executive Order 13175 (Tribal Consultation): This rulemaking will not: (1) have substantial direct effects on one or more Indian tribes; (2) impose substantial direct compliance costs on Indian tribal governments; or (3) preempt tribal law. Therefore, a

tribal summary impact statement is not required under Executive Order 13175 (Nov. 6, 2000).

G. Executive Order 13211 (Energy Effects): This rulemaking is not a significant energy action under Executive Order 13211 because this rulemaking is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required under Executive Order 13211 (May 18, 2001).

H. Executive Order 12988 (Civil Justice Reform): This rulemaking meets applicable standards to minimize litigation, eliminate ambiguity, and reduce burden as set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 (Feb. 5, 1996). The rulemaking carries out a statute designed to lessen litigation. See, e.g., H.R. Rep. No. 112-98, Part 1 at pages 50 and 78 (2011) (information submitted in a request for supplemental examination cannot later be used to hold the patent unenforceable or invalid on the basis of inequitable conduct during civil litigation).

I. Executive Order 13045 (Protection of Children): This rulemaking does not concern an environmental risk to health or safety that may disproportionately affect children under Executive Order 13045 (Apr. 21, 1997).

J. Executive Order 12630 (Taking of Private Property): This rulemaking will not effect a taking of private property or otherwise have taking implications under Executive Order 12630 (Mar. 15, 1988).

K. Congressional Review Act: Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.), prior to issuing any final rule, the United States Patent and Trademark Office will submit a report containing the final rule and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the Government Accountability Office. The changes in this notice are not expected to result in an annual effect on the economy of 100 million dollars or more, a major increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. Therefore, this notice is not expected to result in a “major rule” as defined in 5 U.S.C. 804(2).

L. Unfunded Mandates Reform Act of 1995: The changes set forth in this rulemaking do not involve a Federal intergovernmental mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, of 100 million dollars (as adjusted) or more in any one year, or a Federal private sector mandate that will result in the expenditure by the private sector of 100 million dollars (as adjusted) or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no

actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995. See 2 U.S.C. 1501 et seq.

M. National Environmental Policy Act: This rulemaking will not have any effect on the quality of the environment and is thus categorically excluded from review under the National Environmental Policy Act of 1969. See 42 U.S.C. 4321 et seq.

N. National Technology Transfer and Advancement Act: The requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) are not applicable because this rulemaking does not contain provisions which involve the use of technical standards.

O. Paperwork Reduction Act: The Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) requires that the USPTO consider the impact of paperwork and other information collection burdens imposed on the public. This notice proposes changes to the rules of practice that would impose new information collection requirements and impact existing information collection requirements previously approved by the Office of Management and Budget (OMB) under OMB Control Number 0651-0064. Accordingly, the USPTO will submit to the OMB a proposed revision to the information collection requirements under 0651-0064. The proposed revision will be available at the OMB's Information Collection Review Web site (www.reginfo.gov/public/do/PRAMain).

Needs and Uses: This information collection is necessary so that a patent owner may file a request for supplemental examination of the patent. The Office will use this information to determine whether the information submitted with the supplemental examination request raises a substantial new question of patentability.

Title of Collection: Patent Reexaminations and Supplemental Examination (formerly Patent Reexaminations).

OMB Control Number: 0651-0064.

Method of Collection: By mail, facsimile, hand delivery, or electronically to the USPTO.

Affected Public: Individuals or households; businesses or other for-profits; and not-for-profit institutions.

Estimated Number of Respondents: 9,560 responses per year.

Estimated Time Per Response: The USPTO estimates that it will take the public from 18 minutes (0.3 hours) to 135 hours to gather the necessary information, prepare the appropriate form or other documents, and submit the information to the USPTO.

Estimated Total Annual Respondent Burden Hours: 235,365 hours per year. In addition, the USPTO anticipates that supplemental examination will produce significant benefits

by leading to a reduction in the number of district court patent infringement cases in which inequitable conduct is pled as a defense.

Estimated Total Annual Respondent Cost Burden: \$80,024,100 per year.

Estimated Total Annual Non-hour Respondent Cost Burden: \$35,283,875 per year in the form of fees and postage costs.

The agency is soliciting comments to: (1) evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of collecting the information on those who are to respond, including by using appropriate automated, electronic, mechanical or other technological collection techniques or other forms of information technology.

Please send comments on or before [Insert date 60 days after publication in the FEDERAL REGISTER] to Mail Stop Comments--Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA, 22313-1450, marked to the attention of Raul Tamayo, Legal Advisor, Office of Patent Legal Administration, Office of the Associate Commissioner for Patent Examination Policy. Comments should also be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget, New

Executive Office Building, Room 10202, 725 17th Street, N.W., Washington, DC 20503,
Attention: Desk Officer for the Patent and Trademark Office, or via email at
OIRA_submission@omb.eop.gov.

Notwithstanding any other provision of law, no person is required to respond to, nor shall a person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act, unless that collection of information displays a currently valid OMB control number.

List of Subjects in 37 CFR Part 1

Administrative practice and procedure, Courts, Freedom of Information, Inventions and patents, Reporting and record keeping requirements, Small Businesses.

For the reasons discussed in the preamble, the United States Patent and Trademark Office proposes to amend 37 CFR part 1 as follows:

PART 1 - RULES OF PRACTICE IN PATENT CASES

1. The authority citation for 37 CFR Part 1 continues to read as follows:

Authority: 35 U.S.C. 2(b)(2).

2. Section 1.20 is amended by revising paragraph (c)(1) and by adding paragraphs (c)(6), (c)(7), and (k) to read as follows:

§ 1.20 Post issuance fees.

* * * * *

(c) * * *

(1) For filing a request for ex parte reexamination (§ 1.510(a)) \$17,750.00

* * * * *

(6) For filing a petition in a reexamination proceeding, except for those specifically enumerated in §§ 1.550(i) and 1.937(d) \$1,930.00

(7) For a refused request for ex parte reexamination under § 1.510 (included in the request for ex parte reexamination fee) \$4,320.00

* * * * *

(k) In supplemental examination proceedings:

(1) For processing and treating a request for supplemental examination..... \$5,180.00

(2) For ex parte reexamination ordered as a result of a supplemental examination proceeding \$16,120.00

(3) For processing and treating, in a supplemental examination proceeding, a non-patent document over 20 sheets in length, per document:

(i) Between 21 and 50 sheets \$170.00

(ii) For each additional 50 sheets or a fraction thereof \$280.00

3. Section 1.26 is amended by revising paragraph (c) to read as follows:

§ 1.26 Refunds.

* * * * *

(c) If the Director decides not to institute a reexamination proceeding in response to a request for reexamination or supplemental examination, fees paid with the request for reexamination or supplemental examination will be refunded or returned in accordance with paragraphs (c)(1) through (c)(3) of this section. The reexamination requester or the patent owner who requested a supplemental examination proceeding, as appropriate, should indicate the form in which any refund should be made (e.g., by check, electronic funds transfer, credit to a deposit account). Generally, refunds will be issued in the form that the original payment was provided.

(1) For an ex parte reexamination request, the ex parte reexamination filing fee paid by the reexamination requester, less the fee set forth in § 1.20(c)(7), will be refunded to the requester if the Director decides not to institute an ex parte reexamination proceeding.

(2) For an inter partes reexamination request, a refund of \$7,970 will be made to the reexamination requester if the Director decides not to institute an inter partes reexamination proceeding.

(3) For a supplemental examination request, the fee for reexamination ordered as a result of supplemental examination, as set forth in § 1.20(k)(2), will be returned to the patent owner who requested the supplemental examination proceeding if the Director decides not to institute a reexamination proceeding.

4. Section 1.550 is amended by adding a new paragraph (i) to read as follows:

§ 1.550 Conduct of ex parte reexamination proceedings.

* * * * *

(i) A petition in an ex parte reexamination proceeding must be accompanied by the fee set forth in § 1.20(c)(6), except for petitions under paragraph (c) of this section to extend the period for response by a patent owner, petitions under paragraph (e) of this section to accept a delayed response by a patent owner, petitions under § 1.78 to accept an unintentionally delayed benefit claim, and petitions under § 1.530(l) for correction of inventorship in a reexamination proceeding.

5. Subpart E, consisting of §§ 1.601, 1.605, 1.610, 1.615, 1.620, and 1.625, is added to read as follows:

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 by the owner(s) of the entire right, title, and interest in the patent.

(b) The patent owner must establish the entirety of the 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 (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 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.

(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 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 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)(11).

§ 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 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).

(b) A request for supplemental examination must include each of the elements set forth in paragraphs (b)(1) through (b)(12) 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:

(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.

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

(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:

(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.

(9) 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.

(10) A copy of each item of information listed in paragraph (b)(3) 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.

(11) A summary of the relevant portions of any submitted document, other than the request, that is over 50 pages in length. The summary must include citations to the particular pages containing the relevant portions.

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

(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) The filing date of a request for supplemental examination will not be granted if the request is not in compliance with § 1.605, § 1.615, and this 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, does not meet the requirements of paragraph (d) of this section to be entitled to a filing date, the 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.

§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)(11). 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 will generally be limited to a review of the issues 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.

(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 must, as soon as possible upon the discovery of any other prior or concurrent post patent Office proceeding involving 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 prohibited in a supplemental examination proceeding.

(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).

6. Section 1.937 is amended by adding a new paragraph (d) to read as follows:

§ 1.937 Conduct of inter partes reexamination.

* * * * *

(d) A petition in an inter partes reexamination proceeding must be accompanied by the fee set forth in § 1.20(c)(6), except for petitions under § 1.956 to extend the period for response by a patent owner, petitions under § 1.958 to accept a delayed response by a patent owner, petitions under § 1.78 to accept an unintentionally delayed benefit claim, and petitions under § 1.530(l) for correction of inventorship in a reexamination proceeding.

Date: January 19, 2012

David J. Kappos
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

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