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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: Final rule.

SUMMARY: The United States Patent and Trademark Office (Office) is revising the rules of practice in patent cases to implement the supplemental examination provisions of the Leahy-Smith America Invents Act (AIA). 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 adjusting the fee for filing a request for ex parte reexamination and setting a fee for petitions filed in ex parte and inter partes reexamination proceedings to more accurately reflect the cost of these processes.

DATES: EFFECTIVE DATE: The changes in this final rule take effect on September 16, 2012.

APPLICABILITY DATE: The changes in this final rule apply to any patent issued before, on, or after September 16, 2012.

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SUPPLEMENTARY INFORMATION:

Executive Summary: Purpose: Section 12 of the AIA amends the patent laws to provide that a patent owner may request supplemental examination of a patent to consider, reconsider, or correct information believed to be relevant to the patent. The supplemental examination will determine whether the information presented in the request raises a substantial new question of patentability. If the information presented in

the request raises a substantial new question of patentability, the Office will order ex parte reexamination of the patent. Section 12 of the AIA provides that, with certain 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 Office is also adjusting the fee for filing a request for ex parte reexamination and setting a fee for petitions filed in ex parte and inter partes reexamination proceedings to more accurately reflect the cost of these processes.

Summary of Major Provisions: This final rule specifies the requirements for a request for supplemental examination and the procedures for conducting supplemental examination.

A request for supplemental examination must contain: (1) a list of each item of information that is requested to be considered, reconsidered, or corrected; (2) an identification of each claim of the patent for which supplemental examination is requested; (3) a separate explanation of the relevance and manner of applying each item of information to each claim of the patent for which it was identified; and (4) a summary of the relevant portions of any submitted document, other than the request, that is over fifty pages in length.

This final rule requires the following supplemental examination fees: (1) a fee of \$5,140.00 for processing and treating a request for supplemental examination; (2) a fee of

\$16,120.00 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 pages in length, a fee of \$170.00 for a document of between 21 and 50 pages, and a fee of \$280.00 for each additional 50 pages or a fraction thereof.

This final rule also requires the following reexamination fees: (1) \$17,750.00 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) \$4,320.00 for a denied 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 cost calculations for these fees are described in “Cost Calculations for Supplemental Examination and Reexamination”, posted on the Office’s Internet Web site at www.uspto.gov.

Costs and Benefits: This rulemaking is not economically significant as that term is defined in Executive Order 12866 (Sept. 30, 1993).

Background: The AIA was enacted into law on September 16, 2011. See Pub. L. 112-29, 125 Stat. 284 (2011). The Office is revising the rules of practice in title 37 of the Code of Federal Regulations (CFR) to implement the supplemental examination provisions of section 12 of the AIA. 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 setting certain fees to implement supplemental examination, adjusting the fee for filing a request for ex parte reexamination, and setting a fee for petitions filed in ex parte and inter partes reexamination proceedings.

Section 12 of the AIA 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 supplemental examination certificate will indicate that ex parte reexamination will be 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) and any resulting ex parte reexamination under 35 U.S.C. 257(b) 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 a supplemental examination or any ex parte reexamination ordered under 35 U.S.C. 257, that a material fraud on the Office may have been committed in connection with the patent that is the subject of the supplemental examination, 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 anticipates that such instances will be rare. 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 AIA also indicates 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 AIA 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 and 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).

General Discussion Regarding Implementation: The Office must determine, within three months of the filing of a request for supplemental examination, whether a substantial new question of patentability affecting any claim of the patent is raised by the items of information in the 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 application which issued as 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. Moreover, the information permitted in a supplemental examination is anticipated to be more resource-intensive to process, review, and treat than the information permitted in an ex parte reexamination, because the patent owner may present, in supplemental examination, an item of information that raises multiple issues and not just the issues that are permitted to be raised in ex parte reexamination. For example, the patent owner may present one item of information that raises patent eligible subject matter issues under 35 U.S.C. 101 and written description or enablement issues under 35 U.S.C. 112 with respect to the original disclosure. For these reasons, the requirements set forth in this final rule 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.

The Office proposed changes to the rules of practice to implement the supplemental examination provisions in section 12 of the AIA and to set or adjust fees in ex parte and

inter partes reexamination proceedings in a notice of proposed rulemaking published in January of 2012. See Changes to Implement the Supplemental Examination Provisions of the Leahy-Smith America Invents Act and to Revise Reexamination Fees, 77 FR 3666-81 (Jan. 25, 2012) (notice of proposed rulemaking). The public submitted thirty-six comments in response to the notice of proposed rulemaking (discussed subsequently in greater detail). In view of the input from the public, the Office is making the following changes to the proposed rules of practice to implement the supplemental examination provisions of section 12 of the AIA.

Number of Items of Information Considered in a Request for Supplemental Examination:

The Office proposed to limit each request for supplemental examination to ten items of information. See Changes to Implement the Supplemental Examination Provisions of the Leahy-Smith Invents Act and to Revise Reexamination Fees, 77 FR at 3667. The Office received a number of comments requesting that there be a higher limit or no limit on the number of items of information contained in a request for supplemental examination. This final rule increases this proposed limit from ten to twelve, thus permitting a request for supplemental examination to contain up to twelve items of information. The Office must conclude a supplemental examination within three months of the date on which the request for supplemental examination is filed. See 35 U.S.C. 257(b). Thus, the Office must place a limit on the number of items of information that may be submitted with a request for supplemental examination. Ninety-three percent of the requests for ex parte reexamination filed in fiscal year 2011 included twelve or fewer documents. In addition, supplemental examination is designed to preempt allegations of inequitable conduct

being raised as a defense during patent litigation, which typically concern far fewer than twelve items of information. Further, if twelve items of information are not sufficient for a particular situation, more than one request for supplemental examination of the same patent may be filed at any time. Thus, the Office expects a limit of twelve items of information per request to accommodate the vast majority of patent owners.

Content Requirements for a Request for Supplemental Examination: The Office proposed a number of content requirements for a request for supplemental examination. See Changes to Implement the Supplemental Examination Provisions of the Leahy-Smith Invents Act and to Revise Reexamination Fees, 77 FR at 3667, 3670-71. The Office received a number of comments requesting that there be fewer and simpler content requirements for a request for supplemental examination. Thus, this final rule adopts content requirements for a request for supplemental examination that are comparable to the requirements for a request for ex parte reexamination (e.g., a list of each item of information to be considered, reconsidered, or corrected; an identification of each claim of the patent for which supplemental examination is requested; and a separate, detailed explanation of the relevance and manner of applying each item of information to each claim of the patent for which supplemental examination is requested). See 37 CFR 1.510. In addition, because the content requirements for a request for supplemental examination that are comparable to the requirements for a request for ex parte reexamination, this final rule does not implement the proposed requirement that a request for supplemental examination contain: (1) an identification of each item of information requiring consideration, reconsideration, or correction, and an explanation

why consideration or reconsideration of the item of information is being requested or how the item of information is being corrected; (2) 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), as amended by the AIA, in any claim to be examined; (3) an identification of each issue raised by each item of information; (4) an explanation of the support in the specification for each limitation of each claim identified for examination if an identified issue involves the application of 35 U.S.C. 101 (other than double patenting) or 35 U.S.C. 112; and (5) an explanation of how each limitation of each claim identified for examination is met, or is not met, by each item of information if an identified issue involves the application of 35 U.S.C. 102, 35 U.S.C. 103, or double patenting.

Filing Date Requirements: The Office proposed that a request for supplemental examination must comply with the applicable regulations in 37 CFR 1.605, 1.610, and 1.615 to be entitled to a filing date. See [Changes to Implement the Supplemental Examination Provisions of the Leahy-Smith Invents Act and to Revise Reexamination Fees](#), 77 FR at 3671. As discussed previously in this final rule, the Office must conclude a supplemental examination within three months of the date on which the request for supplemental examination was filed. However, it would absorb a considerable portion of the three-month period for conducting the supplemental examination for the Office to accord a filing date to a non-compliant request for supplemental examination, issue a notice of the defects in the request for supplemental examination, and await a corrected request for supplemental examination. Such a practice when applied in reexamination

proceedings repeatedly placed the Office in jeopardy of not meeting the three-month time frame in 35 U.S.C. 303 and 312. See Clarification of Filing Date Requirements for Ex parte and Inter Partes Reexamination Proceedings, 71 FR 44219, 44220 (Aug. 4, 2006). Therefore, the Office cannot adopt such a procedure in supplemental examination. A request for supplemental examination that does not comply with the requirements for a request for supplemental examination may not be granted a filing date. However, the Office is adopting content requirements for a request for supplemental examination that are comparable to the requirements for a request for ex parte reexamination, and thus has significantly streamlined the requirements for a request for supplemental examination to make the filing date requirements as simple and objective as possible. The Office has also eliminated the requirement for identification of the first-named inventor and the issue date of the patent for which supplemental examination is requested. Additionally, the Office has clarified that a cover sheet and a table of contents are not required in a request for supplemental examination.

A request for supplemental examination that is entitled to a filing date will be entered into the Office image file wrapper (IFW) and Patent Application Information Retrieval (PAIR) system, and will be viewable by the public via the Public PAIR system. The Office, however, is establishing a procedure in which the request, and any other papers or information submitted as part of or accompanying the request, will not be available in Public PAIR until the request meets the conditions to be entitled to a filing date.

A request for supplemental examination of a patent must be filed by the patent owner. The request for supplemental examination must be accompanied by the fee for filing a request for supplemental examination, the fee for ex parte reexamination ordered as a result of the supplemental examination proceeding under 35 U.S.C. 257, and any applicable document size fees. 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.

A supplemental examination proceeding is initiated by the filing of a request for supplemental examination that complies with 35 U.S.C. 257 and 37 CFR 1.601 et seq. and ends with the electronic issuance of the supplemental examination certificate. See 35 U.S.C. 257(a) (“Within 3 months after the date a request for supplemental examination meeting the requirements of this section is received, the Director shall conduct the supplemental examination and shall conclude such examination by issuing a certificate”). The supplemental examination certificate will state the result of the Office’s determination as to whether any of the items of information submitted as part of the request raises a substantial new question of patentability. 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. In other words, if the supplemental examination certificate states that a substantial new question of patentability is raised, an ex parte reexamination proceeding is initiated. The electronically issued supplemental examination certificate will remain as part of the public record for the patent. In addition,

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. If, however, the supplemental examination certificate states that no substantial new question of patentability is raised by one or more items of information in the request, then the electronically issued supplemental examination certificate, which remains as part of the public record for the patent, will also be published in due course as an attachment to the patent.

Discussion of Specific Rules

The following is a discussion of the amendments to Title 37 of the Code of Federal Regulations, part 1, that are being implemented in this final rule:

Section 1.20: Section 1.20 is amended 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]”); see also 35 U.S.C. 257(d)(1).

Section 10(a) of the AIA provides that the Director 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 AIA 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 would 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 AIA). Therefore, the Office is setting these fees in this rulemaking pursuant to its authority under 35 U.S.C. 41(d)(2), 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 the respective processing, service, or material. 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 fee amounts will be convenient to patent users.

The Office is in the process of separately developing a proposed rulemaking to adjust and set patent fees under section 10 of the AIA. The fees set or adjusted in this notice will subsequently be revisited and may be proposed to be set or adjusted in a proposed rulemaking under section 10 of the AIA.

In this current rulemaking, as described further in materials posted on the Office's Internet Web site, the Office has estimated its fiscal year 2013 cost for processing and treating a request for supplemental examination to be \$5,180. The Office has also estimated that the document size fees will recover an average of \$40 per request for supplemental examination (discussed subsequently). Therefore, the Office is adding new § 1.20(k)(1) to set a fee of \$5,140 for processing and treating a request for supplemental examination (the estimated 2013 cost amount rounded to the nearest ten dollars minus \$40).

The Office has estimated 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 adding new § 1.20(k)(2) to set a fee of \$16,120 for conducting ex parte reexamination ordered as a result of a supplemental examination proceeding (the estimated 2013 cost amount 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 at the conclusion of the supplemental examination proceeding. See § 1.26(c).

The Office has also estimated its fiscal year 2013 cost for processing and treating non-patent documents over 20 pages in length that are submitted in a supplemental examination proceeding to be \$166 for each document between 21 and 50 pages in length, and \$282 for each additional 50-page increment or a fraction thereof. Therefore, the Office is also adding new §1.20(k)(3) to provide document size fees for any non-patent documents over 20 pages in length that are submitted in a supplemental examination proceeding, including (1) a fee of \$170 for each document between 21 and 50 pages in length; and (2) a fee of \$280 for each additional 50-page increment or a fraction thereof (the estimated 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, and may be directed to issues of patentability in addition to those permitted in ex parte reexamination, such as issues under 35 U.S.C. 101 and 112. 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

Office's analysis of the ex parte and inter partes reexamination costs revealed that the 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, in addition to setting fees for supplemental examination and resulting ex parte reexamination proceedings, the Office is adjusting the fee for ex parte reexamination proceedings, and setting 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 \$17,747. Therefore, § 1.20(c)(1) is amended to set a fee of \$17,750 for filing a request for ex parte reexamination under § 1.510(a) (the estimated 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 to be \$1,932. Consequently, the Office is adding new § 1.20(c)(6) to set 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 estimated 2013 cost amounts rounded to the nearest ten dollars). The 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 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 petitions enumerated in §§ 1.550(i) and 1.937(d), however, remain subject to any applicable fees other than the fee set forth in § 1.20(c)(6), including the fees required by the appropriate rule governing each petition.

The Office is also adding new § 1.20(c)(7) to set a fee of \$4,320 for a denied 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 denying 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 adjusting the inter partes reexamination filing fee as the Office is not authorized to 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 amended to provide that if the Director decides not to institute an ex parte reexamination proceeding (a denied 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 fee for ex parte reexamination resulting from a supplemental examination (\$16,120), as set forth in § 1.20(k)(2), will be made to the patent owner who requested the supplemental examination proceeding. The provision in § 1.26(c) 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 denial to institute an inter partes reexamination on or after September 16, 2012. 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 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 et seq. is added to provide regulations for the supplemental examination of patents. Section 1.601(a) is added 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. A request for supplemental examination may result in ex parte reexamination of the patent. The Office currently requires a patent owner requester of an ex parte reexamination to comply with the provisions of §§ 3.71 and 3.73 for establishing an assignee's right to take action when submitting a power of attorney. See Manual of Patent Examining Procedure §§ 2222 (Rev. 8, July 2010) (MPEP). This is because the terms of a patent may be changed (e.g., by cancellation or amendment of the claims) during a reexamination proceeding, and this change must be binding on all parties having an ownership interest in the patent. Furthermore, the Office has consistently required that all parties having an interest in a patent are deemed "a patent owner" as a composite entity and must act together in proceedings before the Office. See MPEP § 301 ("All parties having any portion of the ownership of the patent property must act together as a composite entity in patent matters before the Office."), and § 324 ("When an assignee seeks to take action in a matter before the Office with respect to a patent application, patent, or reexamination proceeding and the right, title, and interest therein is held by more than one assignee, each partial assignee must provide a submission under [former] 37 CFR 3.73(b). In each submission, the extent of each assignee's interest must be set forth so that the Office can determine whether it has obtained action by the entirety of the right, title, and interest holders (owners).").

Section 1.601(b) prohibits third parties from filing papers or otherwise participating in any manner in a supplemental examination proceeding. Section 12 of the AIA 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 only the patent owner can file the request for supplemental examination, 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 1.601(c) provides that a request for supplemental examination of a patent may be filed at any time during the period of enforceability of the patent. This time period is being specified in this final rule because the Office believes that Congress did not intend the Office to expend resources on the supplemental examination of a patent which cannot be enforced. The period of enforceability is determined by adding six years to the date that the patent expires. It is the responsibility of the patent owner to determine the expiration date of the patent for which supplemental examination is requested. The patent expiration date for a utility patent, for example, may be determined by taking into account the term of the patent, whether maintenance fees have been paid for the patent, whether any disclaimer was filed as to the patent to shorten its term, any patent term extensions or adjustments for delays within the Office under 35 U.S.C. 154, and any patent term extensions available under 35 U.S.C. 156 for premarket regulatory review. See MPEP §§ 2710 and 2750. Any other relevant information should also be taken into account. In addition, if litigation is instituted within the period of the statute of

limitations, requests for supplemental examination may be filed after the statute of limitations has expired, as long as the patent is still enforceable. This policy is consistent with ex parte reexamination practice. See § 1.510(a) and MPEP § 2211.

Section 1.605: Section 1.605(a) is added to require that each request for supplemental examination may include no more than twelve 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 for supplemental examination is limited to twelve (12). As discussed previously, 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) permits the filing of more than one request for supplemental examination of the same patent at any time during the period of enforceability of the patent. The patent owner is not precluded from obtaining review of any item of information despite the twelve-item limit because the patent owner may file multiple requests for supplemental examination of the same patent at any time during the period of enforceability of the patent.

Section 1.605(b) provides 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 requests the Office to consider claim 1 of the patent on the basis of 35 U.S.C. 101, and the discussion of any potential application of 35 U.S.C. 101 to claim 1 is wholly contained 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.

Similarly, a declaration or affidavit submitted as part of a request would be considered an item of information. If the declaration presents two distinct items of information, such as information relating to a potential ground under 35 U.S.C. 101 as to patent claim 1 that was not considered during the prior examination of the patent, and information relating to erroneous facts or data presented during the prior examination of the patent with respect

to an issue under 35 U.S.C. 103 as to patent claim 10, then each item of information contained within the declaration will be counted separately, resulting in two items of information. The patent owner may not avoid the counting of multiple items of information by inserting the multiple items within the body of a declaration or by presenting them as exhibits accompanying the declaration. Additionally, if the declaration presents one item of information, such as information regarding erroneous data presented during the prior examination of the patent with respect to an issue under 35 U.S.C. 103 as to patent claim 10, and relies upon a single exhibit, such as a new table of data, to support facts presented in the declaration, the Office is likely to count the declaration, including the supporting exhibit, as a single item of information. If, however, the declaration relies upon two separate and distinct exhibits, such as, for example, two separate and distinct sales receipts as evidence of a potential sale of the invention (e.g., a sales receipt dated March 2011 and a second, separate sales receipt dated October 2011, which provides evidence of a second, separate sale of the invention), then each additional sales receipt will be counted separately, resulting in two items of information (one item consisting of the declaration and one sales receipt, and the second item consisting of the second sales receipt).

Section 1.605(c) requires 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 video images.

Section 1.605(d) provides that if an item of information is combined in the request with one or more additional items of information, each item of information of the combination may be separately counted. If it is necessary to combine items of information in order to raise an issue, or to explain the relevance of the items of information to be considered, reconsidered, or corrected with respect to the identified claims, each item of information may be separately counted. 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)(8).

For example, if the patent owner requests consideration of claim 1 of a patent in light of references A and B, and explains that it is the combination of references A and B that is relevant to claim 1, reference A and reference B will be separately counted as items of information. Cumulative items of information will each be separately counted. If the patent owner believes that multiple items of information are cumulative to each other, the patent owner is encouraged to select one or two of them as the items of information that will be submitted as part of the request.

If, however, a single item of information, such as a reference patent, raises an issue under 35 U.S.C. 102 as to claim 1 and an issue under 35 U.S.C. 103 as to claim 2, the reference

patent will nevertheless be counted as a single item of information. The Office will count items of information, but will not count the number of issues raised by that item.

Section 1.610: Section 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).

Section 1.610(b) sets forth content requirements for a request for supplemental examination. Section 1.610(b)(1) requires that the request include an identification of the number of the patent for which supplemental examination is requested.

Section 1.610(b)(2) requires that the request include a list of the items of information that are requested to be considered, reconsidered, or corrected. Where appropriate, the list must meet the requirements of § 1.98(b). For example, the list must include a 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)(3) requires 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, 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. The type of proceeding may be, for example, an ex parte or inter partes reexamination proceeding, a reissue application, a supplemental examination proceeding, a post-grant review proceeding, or an inter partes review proceeding.

Section 1.610(b)(4) requires that the request include an identification of each claim of the patent for which supplemental examination is requested. The result of a supplemental examination is a determination of whether any of the items of information raises a substantial new question of patentability. Because patentability relates to the claims of the patent, the patent owner must identify the patent claims to be examined in order for the Office to determine whether a substantial new question of patentability as to those claims has been raised by an item of information. For example, if the information raises a question as to the adequacy of the written description portion of the specification, the substantial new question of patentability pertains to the question of whether the specification provides adequate support under 35 U.S.C. 112 for the identified claim. If the information raises a question as to a foreign priority or domestic benefit claim, the substantial new question of patentability pertains to the question of whether the patentability the identified claim under 35 U.S.C. 102 and 103 depends upon a foreign

priority or domestic benefit claim (e.g., where the claimed invention must be entitled to foreign priority or domestic benefit to be patentable under 35 U.S.C. 102 and 103 because there is an intervening references).

Section 1.610(b)(5) requires that the request include a separate, detailed explanation of the relevance and manner of applying each item of information to each claim of the patent for which supplemental examination is requested. In view of the fact that patent owners filing a request for supplemental examination may be contemplating future litigation, the Office recommends that, in order to meet this requirement, patent owners consider the guidance set forth in MPEP § 2214, which governs the content of a request for ex parte reexamination.

Section 1.610(b)(6) requires that the request include a copy of the patent for which supplemental examination is requested, and a copy of any disclaimer or certificate issued for the patent. A “certificate issued for the patent” includes, for example, a certificate of correction, a certificate of extension, a supplemental examination certificate, a post-grant review certificate, an inter partes review certificate, an ex parte reexamination certificate, and/or an inter partes reexamination certificate issued for the patent.

Section 1.610(b)(7) requires that the request include a copy of each item of information listed in § 1.610(b)(2), 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) are not required to be submitted. As discussed previously, 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, a copy of which is not required under § 1.610(b)(7) to be separately submitted. Copies of U.S. patents and U.S. patent application publications are also not required, but may be submitted.

Section 1.610(b)(8) requires 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)(9) requires that the request must include an identification of the owner(s) of the entire right, title, and interest in the patent requested to be examined, and a submission by the patent owner in compliance with § 3.73(c) establishing the entirety of the ownership in the patent requested to be examined. As discussed previously,

§ 1.601(a) requires that a request for supplemental examination of a patent must be filed by the owner(s) of the entire right.

Section 1.610(c) provides that the request may optionally include certain enumerated elements. Section 1.610(c)(1) permits the request to 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 or as part of the request. Section 1.610(c)(2) permits the request to include a table of contents for the request. Section 1.610(c)(3) provides that the request may include an explanation of how the claims patentably distinguish over the items of information. Section 1.610(c)(4) 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 this explanation, which will assist the Office in analyzing the request.

Section 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, 1.610, and 1.615, subject to the discretion of the Office. If the Office determines that the request, as originally submitted, is not entitled to a filing date, then 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, 1.610, 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) requires that all papers submitted in a supplemental examination proceeding must be formatted in accordance with § 1.52. Section 1.615(b) provides 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) requires 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 as part of the request raises a substantial new question of patentability will be the standard set forth in the 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.

The determination of whether an item of information submitted as part of the request raises a substantial new question of patentability (SNQ) will generally be limited to a review of the item(s) of information identified in the request with respect to the identified claim(s) of the patent. For example, a determination on a request that includes three items of information, where each item is requested to be considered 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 applying an item of information to multiple claims of the patent, the request for supplemental examination must include an identification of each claim to which the item of information is to be applied and the required detailed explanation with respect to each claim. For example, if the patent owner fails to request that the Office consider certain claims in view of an item of information, then the patent owner is not entitled to a determination for that item of information with respect to those 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 of whether a substantial new question of patentability was raised by one or more of the items of information submitted as part of the request, will become a part of the official record of the patent.

Section 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 for supplemental examination 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 raises 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.

Section 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) requires 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 notifying the Office 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 post-patent Office proceedings, including another supplemental examination proceeding. Knowledge of other proceedings is important to ensure a quality determination. In addition, notice is

required due to the statutory three-month period within which the Office must conclude the supplemental examination. The notice is limited to an identification of the post-patent Office 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 pursuant to § 1.620(c).

Section 1.620(e) prohibits 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. Interviews conducted in connection with any ex parte reexamination ordered under 35 U.S.C. 257 as a result of the supplemental examination proceeding are governed by the regulations governing ex parte reexamination proceedings. See, e.g., § 1.560.

Section 1.620(f) provides that no amendment may be filed in a supplemental examination proceeding. Amendments 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 § 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 because 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.

Section 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 as a result of the supplemental examination proceeding, that a material fraud on the Office may have been committed in connection with 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), as discussed previously.

Section 1.625: Section 1.625(a) provides that a supplemental examination proceeding will conclude with the electronic issuance of the supplemental examination certificate. The supplemental examination certificate will be electronically issued in the Office IFW system and will be visible in the Office 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 sufficient time to review the items of information submitted as part of the request. 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.

Section 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.

Section 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 fee for reexamination ordered as a result of supplemental examination, as set forth in § 1.20(k)(2), will be refunded in accordance with § 1.26(c).

Section 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 claim 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(a); (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, which differs from § 1.552(c); 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. The material to patentability standard (§ 1.56(b)) applicable to patent applications is also applicable to an ex parte reexamination proceeding under 35 U.S.C. 257 resulting from a supplemental examination proceeding because, like patent application examination, an ex parte reexamination proceeding under 35 U.S.C. 257 is not limited to patents and printed publications. In contrast, the material to patentability standard (§ 1.555(b)) applicable to ex parte reexaminations under 35 U.S.C. 302 is limited to patents and printed publications. Any reference to “applicant” in § 1.56(b) will be read as “patent owner” in the context of a supplemental examination proceeding and any resulting ex parte

reexamination proceeding under 35 U.S.C. 257, because these proceedings are only available to a patent owner.

Section 1.937: Section 1.937(d) is 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.

Comments and Responses to Comments: As discussed previously, the Office proposed changes to the rules of practice to implement section 12 of the AIA (supplemental examination) and to set or adjust fees in ex parte and inter partes reexamination proceedings in a notice of proposed rulemaking published in January of 2012. See Changes to Implement the Supplemental Examination Provisions of the Leahy-Smith Invents Act and to Revise Reexamination Fees, 77 FR at 3666-81. The Office received thirty-six comments in response to this notice from intellectual property organizations, industry, law firms, individual patent practitioners, and the general public. The comments and the Office's responses to the comments follow:

Fees:

Comment 1: A number of comments suggested that the fees for ex parte reexamination, and for supplemental examination and any ex parte reexamination ordered under

35 U.S.C. 257 as a result of the supplemental examination, are too high, and suggested a variety of alternative fee structures.

Response: The Office is adjusting the fee for filing a request for ex parte reexamination, and is setting the fees for filing supplemental examination and any resulting ex parte reexamination, to comply with 35 U.S.C. 41(d)(2). 35 U.S.C. 41(d)(2) permits the Office to set fees not otherwise specified in 35 U.S.C. 41. 35 U.S.C. 41(d)(2) specifies that such fees must be set at an amount that recovers the estimated average cost to the Office for the service.

Section 10 of the AIA also authorizes the Office to set or adjust fees, but unlike 35 U.S.C. 41(d)(2), permits fees to be set above or below cost recovery so long as the aggregate revenue equals the aggregate costs, including administrative costs. Section 10 of the AIA sets out a process that the Office must follow when setting or adjusting patent under that provision. The process set out in section 10 of the AIA, however, would 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 AIA. Therefore, the fee for filing an ex parte reexamination request is being adjusted, and the fees for filing supplemental examination and any resulting ex parte reexamination are being set, by this final rule under 35 U.S.C. 41(d)(2).

The Office has analyzed its ex parte and inter partes reexamination costs in order 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 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. This final rule sets these fees at amounts that more accurately reflect the estimated average cost to the Office for these processes or services. The Office's analysis of the estimated fiscal year 2013 costs for ex parte reexamination, supplemental examination and any resulting 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>). Separately, the Office is in the process of adjusting and setting all patent fees under section 10 of the AIA, and the fees set in this notice will be revisited and may be proposed to be set or adjusted in that rulemaking.

Comment 2: Several comments questioned why the cost calculations published by the Office to support the fees for ex parte reexamination and for supplemental examination are based on the cost of denying, rather than granting, ex parte reexamination.

Response: The cost calculations published by the Office, entitled "Cost Calculations for Supplemental Examination and Reexamination," are posted on the Office's Internet Web site at www.uspto.gov. These calculations are based on the costs incurred by the Office to process and analyze a request for reexamination, to draft an order granting or denying reexamination, and to conduct reexamination. The costs to process and analyze a request

for reexamination are the same regardless of whether the examiner grants the request and orders reexamination, or denies reexamination. This cost amount is specified as the fee for a denied request for ex parte reexamination because it is the fee amount retained by the Office if the Office decides not to institute reexamination.

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 printed publications, and may be directed to issues of patentability in addition to those permitted in ex parte reexamination, such as issues under 35 U.S.C. 101 and 112. For this reason, the estimated cost for processing and examining a request for supplemental examination is based on the Office's cost for processing and examining a request for ex parte reexamination up to the decision to grant or deny the request for reexamination.

Comment 3: Several comments requested clarification as to why there exists a significant difference between the proposed fee for treating certain petitions in reexamination proceedings and the fees for treating other petitions outside of reexamination.

Response: The Office is adjusting the fee for processing and treating certain petitions in reexamination proceedings to comply with 35 U.S.C. 41(d), which does not authorize the

Office to set the fee at an amount that is below the estimated average cost for the Office to process and treat the petition. As discussed previously, an analysis of the Office's ex parte and inter partes reexamination costs revealed that the Office's current fees for certain petitions in reexamination are not set at amounts that recover the Office's costs for these services. With the exception of certain types of reexamination petitions which are expressly excluded by the rules, petitions in reexamination proceedings involve issues of greater complexity, which require additional time to analyze and decide than other patent-related petitions. Reexamination petitions also tend to involve a greater number of issues than other patent-related petitions. Therefore, the fee for filing certain reexamination petitions is being adjusted, by this final rule, to an amount that more accurately reflects the estimated average costs to the Office to process and treat these petitions. As discussed previously, the Office's analysis of the estimated fiscal year 2013 costs for processing and treating petitions filed in ex parte and inter partes reexamination proceedings, as well as the Office's estimated fiscal year 2013 costs for supplemental examination and ex parte reexamination, are available via the Office's Internet Web site (<http://www.uspto.gov>).

Comment 4: A number of comments suggested that the Office should not charge fees for supplemental examination which are in excess of costs, as suggested by the Office's published executive summary of the patent fee proposal in accordance with section 10 of the AIA, submitted to the Patent Public Advisory Committee (PPAC) on February 7, 2012. A number of comments suggested the small and micro entity subsidies permitted under section 10 of the AIA be applied to supplemental examination and reexamination.

Several comments also suggested that the costs incurred by the Office for processing and analyzing a denied request for ex parte reexamination, on which the fee for filing a request for supplemental examination request is based, includes the costs for analyzing any non-patent documents submitted as part of the request which have a length greater than 20 pages. These comments suggested that the Office is inappropriately applying a surcharge for submitting these documents as part of a request for supplemental examination (the document size fee), without first reducing the fee for filing a supplemental examination request by an amount which reflects the average cost, per request, for analyzing these documents submitted with a denied request for ex parte reexamination.

Response: As discussed previously, the Office is separately in the process of adjusting and setting patent fees under section 10 of the AIA in a separate rulemaking, but that process would 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 AIA. Therefore, the fee for filing an ex parte reexamination request is being adjusted, and the fees for filing supplemental examination and any resulting ex parte reexamination are being set, by this final rule under 35 U.S.C. 41(d)(2). 35 U.S.C. 41(d)(2) does not provide for small or micro entity fee reductions. The fees set in this final rule will be revisited and may be proposed to be set or adjusted in the rulemaking under section 10 of the AIA.

To address the concern that the document size fees may result in a double recovery of fee revenue, the Office reviewed all requests for ex parte reexamination by a patent owner that met the requirements of 37 CFR 1.510 to be entitled to a filing date in fiscal year 2010 (59 requests) to determine: (1) the number of non-patent documents in these requests that were between 21 and 50 pages in length; and (2) the number of non-patent documents in these requests that were over 50 pages in length and the page length of each of these documents. In fiscal year 2010, patent owner-filed requests for ex parte reexamination contained three non-patent documents between 21 and 50 pages in length (which would have cost an additional \$510) and two non-patent documents which were over 50 pages in length: one between 100 and 150 pages in length (which would have cost an additional \$730), and one between 150 and 200 pages in length (which would have cost an additional \$1,010). Thus, the patent owner-filed requests for ex parte reexamination that received a filing date in fiscal year 2010 would, if submitted as requests for supplemental examination, have resulted in an additional \$2,250 in document size fees, which amounts to an average of \$38.14 per patent owner-filed request for ex parte reexamination ($\$2,250/59$), or \$40, when rounded to the nearest ten dollars. Accordingly, the fee for filing a request for supplemental examination, \$5,140, has been reduced from the originally proposed fee (\$5,180) by the Office's average cost, per request, for analyzing non-patent documents greater than 20 pages in length submitted as part of a patent owner-filed request for ex parte reexamination in fiscal year 2010 (\$40).

Comment 5: A number of comments suggested that payment of the fee for reexamination ordered under 35 U.S.C. 257 should not be required until after reexamination is ordered.

Response: 35 U.S.C. 257(b) provides that “reexamination shall be conducted according to procedures established by chapter 30” 35 U.S.C. 305 expressly provides that, after the order (and after the time period set for filing a patent owner statement under 35 U.S.C. 304, which is excluded by 35 U.S.C. 257(b)), “reexamination will be conducted . . . with special dispatch.” Therefore, once reexamination is ordered, the Office is required by statute to conduct the reexamination proceeding with special dispatch. To permit a delay in prosecution caused by any time period within which the patent owner would be permitted to pay the reexamination fee would be contrary to the Office’s mandate to conduct the reexamination with special dispatch. This final rule requires payment of the reexamination fee upon the filing of the request to permit the Office to commence any reexamination ordered under 35 U.S.C 257 in a timely manner. See § 1.610(a). If reexamination is not ordered, this final rule expressly provides that the patent owner will obtain a refund of the reexamination fee. See §§ 1.26(c)(3) and 1.625(c).

Comment 6: A number of comments suggested that if the patent owner cancels the claims within a set time period after reexamination is ordered under 35 U.S.C. 257, a significant portion of the reexamination fee should be refunded.

Response: 35 U.S.C. 257(b) expressly requires, if reexamination is ordered, that “fees established and applicable to ex parte reexamination proceedings under chapter 30 shall be paid.” 35 U.S.C. 257(b) does not provide for a refund due to claim cancellation during

the reexamination. Moreover, in ex parte reexamination, the only method by which the patent owner may file an amendment to cancel claims after the order and prior to a first Office action is by filing a patent owner's statement under 35 U.S.C. 304.

35 U.S.C. 257(b), however, expressly excludes the right of the patent owner to file a statement under 35 U.S.C. 304. Therefore, the filing of any amendment to cancel claims after the order granting reexamination under 35 U.S.C. 257 and before the initial Office action on the merits is statutorily precluded. Finally, there is no reason to believe that the processing and examination costs would be less for an ex parte reexamination in which an amendment has been filed (or claims have been canceled) than for an ex parte reexamination in which no amendment has been filed.

Comment 7: A number of comments suggested that the rule requiring document size fees be modified or eliminated for non-patent documents that are over 50 pages in length if a summary of the relevant portions is provided. Several comments alternatively suggested that the requirement to summarize non-patent documents over 50 pages in length be eliminated, and that the document size fees should be retained to recover the costs of reviewing lengthy documents in order to ensure the consideration of any relevant information contained in the documents.

Response: Even though a summary of the relevant portions of a document over 50 pages in length is provided, the examiner is still required to review the document. The document size fees, as set forth in this final rule, recover the Office's costs of reviewing lengthy documents. Additionally, the requirement for the summary directs the Office's

attention to the relevant information presented in lengthy documents. 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.

Item of Information Limit:

Comment 8: A number of comments suggested that the Office replace the limit on the number of items of information on which each request for supplemental examination may be based, with a sliding fee scale which would be based on, for example, a separate fee for each item of information submitted.

Response: The supplemental examination procedure was designed to enable patent owners to present items of information for consideration, reconsideration, or correction. The Office is required to conduct and conclude supplemental examination within three months after a request is filed. In order to meet this time frame, the Office is setting a limit of twelve items of information that a patent owner may submit to the Office in each request. The purpose of this limit is to strike a balance between the needs of the patent owner and the ability of the Office to timely conclude the proceeding. There is, however, no limit to the number of issues that these twelve items of information can raise, or to the number of separate requests for supplemental examination of the same patent that a patent owner can file at any time.

Even though the basis for most inequitable conduct allegations is typically far fewer than ten items of information, the Office has raised the limit to twelve items of information in response to the public's comments. A review of ex parte reexamination requests filed in fiscal year 2011 revealed that in at least ninety-three percent of the requests, the requester relied on twelve or fewer documents. In addition, the Office is very mindful of the time necessary for examiners to analyze the items of information submitted, particularly since the items are not limited to patents and printed publications, and since each item may raise multiple issues. This final rule limits the number of items of information to twelve to establish a procedure that not only is practical, but also enables an examiner to fully, comprehensively, and timely analyze all submitted items of information and issues to accurately determine whether there is a substantial new question of patentability.

Merger:

Comment 9: A number of comments questioned whether the Office will consider merging multiple requests for supplemental examination of the same patent and/or consolidating the reexamination proceedings resulting from these requests. These comments also questioned how any merger procedure contemplated by the Office will be conducted.

Response: A supplemental reexamination proceeding must conclude within three months from the filing date of the request. As a general rule, the Office will not merge a supplemental examination proceeding with any other supplemental examination proceeding. The Office, however, reserves its option to merge supplemental examination

proceedings as circumstances arise. The Office likewise does not anticipate that a supplemental examination proceeding or ex parte reexamination proceeding resulting from a supplemental examination proceeding will be merged with any other type of Office proceeding. The Office similarly reserves its option to merge reexamination proceedings that are ordered as a result of supplemental examination proceedings as circumstances arise.

Items of Information:

Comment 10: A number of comments requested that the method of counting the items of information be clarified. These comments questioned whether a reference which raises an issue of anticipation and also raises an issue of obviousness would be counted as one or two items. One comment suggested that a combination of references under 35 U.S.C. 103 be counted as a single item. One comment suggested that where multiple items of information can be deemed to be cumulative to each other, the cumulative items be counted as one item.

Response: When counting the number of items of information in a request for supplemental examination, the Office will tally the number of items of information, such as documents, presented. The Office will not count the number of issues raised by, or the number of grounds which the patent owner requests the Office to consider, when determining the number of items of information. A single reference that raises multiple issues under multiple grounds, for example, under 35 U.S.C. 102, 35 U.S.C. 103, and 35 U.S.C. 112, will be counted as a single item of information. However, if the patent

owner cites a combination of multiple references under 35 U.S.C. 103, then each reference of the combination will be counted as one item of information. For example, if the patent owner states that the claims are patentable under 35 U.S.C. 103 over the combination of reference A in view of reference B, then reference A and reference B must be separately listed as items of information, and will be counted as two items. Cumulative items of information will each be separately counted. For example, if the patent owner indicates that reference A is cumulative to reference B, reference A and reference B will be counted as two items of information. If the patent owner believes that multiple items of information are cumulative to each other, the patent owner is encouraged to select one or two documents as the items of information that will be submitted with the request.

Comment 11: One comment questioned whether a book of meeting abstracts constitutes one or more items of information. Several comments further questioned how supporting documents, such as declarations, dated sales receipts, marketing catalogs, and tables of data would be counted.

Response: An “item of information” is defined as a document, submitted as part of the request, that contains information believed to be relevant to the patent, and that the patent owner is requesting the Office to consider, reconsider, or correct. See § 1.605(b). If, for example, the patent owner relies upon different abstracts, bound together in a book of meeting abstracts, it is likely that the Office will treat each abstract as a separate item of information. In this example, the Office suggests that the patent owner cite to and rely

upon only the particular abstracts that are relevant to the patent and not cite to an entire book of meeting abstracts.

A declaration or affidavit would be considered an item of information. If the declaration presents two distinct items of information, such as information relating to a potential ground under 35 U.S.C. 101 as to patent claim 1 that was not considered during the prior examination of the patent, and information relating to erroneous facts or data presented during the prior examination of the patent with respect to an issue under 35 U.S.C. 103 as to patent claim 10, then each item of information contained within the declaration will be counted separately, resulting in two items of information. As another example, if the declaration presents one item of information, such as information regarding erroneous data presented during the prior examination of the patent with respect to an issue under 35 U.S.C. 103 as to patent claim 10, and relies upon a single exhibit, such as a new table of data, to support facts presented in the declaration, the Office is likely to count the declaration, including the supporting exhibit, as a single item of information. However, as a further example, if the declaration presents information relating to a potential sale of the invention and relies upon two separate and distinct sales receipts (e.g., a sales receipt dated March 2011 which provides evidence of the sale of the invention, and a second, separate sales receipt dated October 2011, which provides evidence of a second, separate sale of the invention), then each additional sales receipt will be counted separately, resulting in two items of information (one item consisting of the declaration and one sales receipt, and the second item consisting of the second sales receipt). As a final example, if the declaration relies not only upon a sales receipt as evidence of a sale of the invention

under 35 U.S.C. 102(b), but also upon a reference patent as evidence of a potential ground under 35 U.S.C. 103, then again, each additional exhibit will be counted separately. In this example, the reference patent will be counted as a second item of information.

A discussion within the body of the request will only be counted if the information to be considered, reconsidered, or corrected is not, at least in part, contained within or based on a supporting document. See § 1.605(b). If, for example, the discussion within the body of the request identifies a sales receipt supplied as an exhibit to the request as a potential ground under 35 U.S.C. 102(b), the discussion in the body of the request regarding a sales receipt will not be counted because the “information,” i.e., the sale, is at least in part, if not wholly, contained within or based on the sales receipt. Patent owners are encouraged to draft the request for supplemental examination in a manner that clearly and consistently sets forth the items of information which the patent owner wishes the Office to consider, reconsider, or correct.

Comment 12: A number of comments questioned whether a new reference cited in an information disclosure statement by the patent owner during a reexamination ordered under 35 U.S.C. 257 will be designated as “considered during the supplemental examination of the patent” within the meaning of 35 U.S.C. 257(c) for purposes of enforceability.

Response: 35 U.S.C. 257(c) specifies the effect of a supplemental examination proceeding on the enforceability of the patent. Specifically, 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.” A supplemental examination proceeding commences with the receipt of a request for supplemental examination, and concludes with the issuance of a supplemental examination certificate. See 35 U.S.C. 257(a). Reexamination is not ordered until after the supplemental examination certificate has issued. See 35 U.S.C. 257(b) (“[i]f the certificate issued under subsection (a) indicates that a substantial new question of patentability is raised . . . the Director shall order reexamination”). Thus, if the patent owner wishes to ensure that the benefits of 35 U.S.C. 257(c)(1) attach to an item of information, the patent owner should submit the item of information as part of the request for supplemental examination and not wait to submit it in an information disclosure statement during a reexamination.

Ownership Requirement:

Comment 13: A number of comments suggested that an owner of less than the entire right, title, and interest in the patent be permitted to file a request for supplemental examination. A number of comments suggested that filing by fewer than all of the owners be permitted when a joint owner is deceased, is legally incapacitated, refuses to

join, or cannot be found after diligent effort, or where one of the owners is an organization that is dissolved.

Response: 35 U.S.C. 257(a) only permits a patent owner to file a request for supplemental examination. All parties having an interest in a patent are deemed “a patent owner” as a composite entity and must act together in proceedings before the Office. See MPEP § 301 (“Ownership/Assignability of Patents and Applications”), which expressly states: “All parties having any portion of the ownership of the patent property must act together as a composite entity in patent matters before the Office.” See also MPEP § 324.

The Office’s practice for supplemental examination is consistent with ex parte reexamination practice, which requires a patent owner requester of an ex parte reexamination to comply with the provisions of §§ 3.71 and 3.73, and MPEP § 324 for establishing an assignee’s right to take action when submitting a power of attorney. See MPEP § 2222.

The Office may, under rare circumstances, permit less than all of the owners to file a request for supplemental examination if a grantable petition under § 1.183 requesting waiver of the provisions of §§ 3.71 and 3.73(c) is filed. For example, such a petition may be filed in the case of a deceased or legally incapacitated joint owner, or where the joint owner refuses to join or cannot be found after diligent effort. In the case of a deceased joint owner, the heirs, administrators, or executors of the joint owner may be permitted to

join in filing the request for supplemental examination. If one of the owners is legally incapacitated, the legal representative of the joint owner may be permitted to join in filing the request for supplemental examination. If a joint owner refuses to sign or cannot be found or reached after diligent effort, the remaining owners in the petition must include proof of the pertinent facts, a showing that such action is necessary to preserve the rights of the parties or to prevent irreparable damage, and the last known address of all of the joint owners. Finally, if an owner of all or a portion of the entire right, title, and interest of the patent is an organization that is dissolved, the Office may require that a determination of the ownership of the patent be obtained from a court of competent jurisdiction.

Comment 14: A number of comments suggested that a licensee, and in particular, an exclusive licensee, be permitted to file a request for supplemental examination. A number of comments also suggested that if an assignee or any person with sufficient proprietary interest, as authorized by 35 U.S.C. 118 as amended by the AIA, can apply for a patent, then the same assignee may file a request for supplemental examination. One comment questioned whether a legal representative of the patent owner may file a request and conduct prosecution.

Response: 35 U.S.C. 257(a) only permits a patent owner to file a request for supplemental examination. Accordingly, the Office is not authorized to permit a party who is not a patent owner, or a party who merely states that it is, for example, an

exclusive licensee or a person with sufficient proprietary interest under 35 U.S.C. 118, to file a request for supplemental examination.

A legal representative of the patent owner may file a request for supplemental examination on behalf of the patent owner. The request, however, may not be filed anonymously. The request must identify the owner(s) of the entire right, title, and interest in the patent to be examined, on whose behalf the legal representative is acting, as required by this final rule. See § 1.610(b)(9). Where an attorney or agent files a request on behalf of a patent owner, he or she may act under a power of attorney under § 1.32, or in a representative capacity under § 1.34. A patent owner may not be represented during a supplemental examination proceeding or the resulting ex parte reexamination proceeding by an attorney or other person who is not registered to practice before the Office. Any correspondence from the Office will be directed to the patent owner at the address indicated in the file of the patent for which supplemental examination is requested pursuant to § 1.33(c), regardless of the address of the person filing the request.

Content of Request:

Comment 15: A number of comments suggested that the content requirements for a supplemental examination request are overly burdensome, and suggested a variety of alternative and simplified requirements. A number of comments suggested that the detailed content requirements may potentially expose the patent owner to subsequent

allegations of inequitable conduct based on an omission, or a specific statement or characterization, made in a supplemental examination request.

Response: In response to the public's comments, the Office has revised the content requirements for a request for supplemental examination to include the following: (1) an identification of the number of the patent for which supplemental examination is requested; (2) a list of the items of information that are requested to be considered, reconsidered, or corrected; (3) a list identifying any other prior or concurrent post-patent Office proceedings involving the patent for which supplemental examination is being requested; (4) an identification of each claim of the patent for which supplemental examination is requested; (5) a separate, detailed explanation of the relevance and manner of applying each item of information to each claim of the patent for which supplemental examination is requested; (6) a copy of the patent for which supplemental examination is requested and a copy of any disclaimer or certificate issued for the patent; (7) a copy of each listed item of information, accompanied by a written English translation of all of the necessary and pertinent parts of any non-English language item of information (except for items of information that form part of the discussion within the body of the request, or copies of U.S. patents and U.S. patent application publications); (8) a summary of the relevant portions of any submitted document, other than the request, that is over 50 pages in length; and (9) an identification of the owner(s) of the entire right, title, and interest in the patent requested to be examined, and a submission by the patent owner in compliance with § 3.73(c) establishing the entirety of the ownership in the patent requested to be examined. See § 1.610(b). These requirements balance the

interests of the public with the Office's need to make an accurate and comprehensive determination, within the statutory three-month time period, whether any of the items of information submitted as part of the request raise a substantial new question of patentability.

Comment 16: A number of comments questioned whether permitting an explanation of how the claims distinguish over the items of information would be contrary to the spirit of 35 U.S.C. 257(b), which provides that "reexamination shall be conducted according to the procedures established by chapter 30, except that the patent owner shall not have the right to file a statement pursuant to section 304."

Response: Section 1.610(c) permits the patent owner to include, in the request, an explanation of how the claims patentably distinguish over the submitted items of information. Section 1.610(c) is consistent with established ex parte reexamination practice, which allows the patent owner to describe, in the request, how the claims distinguish over the cited prior art patents and printed publications (see MPEP § 2217). This provision is not contrary to the spirit of 35 U.S.C. 257(b), which removes the right of the patent owner to file a statement under 35 U.S.C. 304 during any subsequent reexamination. A patent owner's statement under 35 U.S.C. 304 is filed after the order granting reexamination and serves a different function. Specifically, patent owner's statement under 35 U.S.C. 304 addresses the Office's determination in the order granting reexamination that a substantial new question of patentability has been raised by the request. In contrast, a patent owner's explanation that may form part of the request for

supplemental examination under § 1.610 discusses how the claims may be distinguished over the items of information submitted as part of the request. Furthermore, § 1.610(c) is also consistent with established ex parte reexamination practice, which allows the patent owner to describe, in the request, how the claims distinguish over the cited prior art patents and printed publications (see MPEP § 2217).

Comment 17: A number of comments suggested that the requirements for a copy of the patent for which supplemental examination is requested, and for a copy of each item of information, are unnecessary because such copies would be available to the Office. One comment suggested that the Office may obtain copies of any items of information that are available through the Common Citation Document (CCD), which was launched by the Trilateral Offices.

Response: The requirement for a copy of the patent for which supplemental examination is requested assists in preventing an inadvertent misidentification by the patent owner of the patent, for example, by transposing some of the digits of the patent number in the transmittal sheet and/or in the body of the request. The requirement also assists the Office in quickly discovering such inadvertent errors upon the receipt of the request. This requirement likewise assists in preventing any similar misidentification by the Office, thus avoiding an erroneous supplemental examination of a patent that is not owned by the requester. A copy of each item of information is required for the same reasons; i.e., to prevent any inadvertent misidentification of the item of information in the list of items of information and/or in the body of the request by the patent owner or the Office.

However, copies of items of information that form part of the discussion within the body of the request as specified in § 1.605(b) are not required to be submitted. Copies of items of information which are U.S. patents and U.S. patent application publications are also not required, but may be submitted. See § 1.610(b)(7).

The Common Citation Document (CCD) is an effective work sharing tool developed by the Trilateral Offices. Use of the CCD to obtain copies of items of information would not be feasible. The Office is required by statute to make a determination on the request within three months from the filing date of the request. To receive a filing date, a request for supplemental examination must be in a condition which permits the Office to promptly initiate supplemental examination of the patent. For the Office to be able to promptly initiate supplemental examination, a copy of the subject patent and all items of information must be available for review. If a copy of an item of information identified in the request were not obtainable through the CCD tool due to, for example, an inadvertent misidentification of the identifying information by the patent owner, an inadvertent difficulty with the hyperlink or other form of browser-executable code that appears on the CCD Web site, or it being an inaccessible non-patent document, the Office would not be able to initiate supplemental examination, and the request would not be entitled to a filing date until the item could be obtained. Accordingly, the final rule requires that a copy of the patent for which supplemental examination is requested, and copies of each item of information identified in the request, must be submitted as part of the request.

Comment 18: A number of comments suggested that the requirement to identify any other prior or concurrent post-patent Office proceedings involving the patent for which supplemental examination is requested is unnecessary because this information may be obtained by the Office.

Response: The Office anticipates that a patent for which supplemental examination is requested may be involved in other post-patent Office proceedings, including another supplemental examination proceeding. Daily monitoring by the Office for the potential filing, in each and every supplemental examination proceeding, of any concurrent post-patent Office proceedings would not be feasible. The patent owner is in the best position to inform the Office of the existence of any other post-patent Office proceedings, whether the Office proceedings are prior or concurrent to the present supplemental examination proceeding. For these reasons, the final rule requires a list identifying any other prior or concurrent post-patent Office proceedings involving the patent for which supplemental examination is being requested. See § 1.610(b)(3).

Comment 19: A number of comments suggested that the requirement for a summary of the relevant portions of any submitted document, other than the request, that is over 50 pages in length be eliminated and/or replaced with an alternative requirement, such as a requirement for a summary of the entire document (rather than a summary of only the relevant portions) with citations to the particular pages believed to be relevant.

Response: As discussed previously, the requirement for the summary directs the Office's attention to the relevant information presented in lengthy documents. 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.

Comment 20: One comment questioned whether the required detailed explanation of the relevance and manner of applying each item of information will be available to the examiner during reexamination ordered as a result of the supplemental examination, and whether the required detailed explanation will be made part of the record.

Response: The entire contents of a request for supplemental examination, including the required detailed explanation of the relevance and manner of applying each item of information will be available to the examiner if a reexamination is ordered as a result of the supplemental examination. Also, the contents of a request for supplemental examination that has received a filing date will be made part of the official record of the patent, and will be available to the public.

Comment 21: One comment questioned how the Office will address a request to consider, reconsider, or correct an item of information based on a given document in view of "all existing prior art for the purposes of 35 U.S.C. 103."

Response: If a patent owner requests the Office to consider an item of information in view of “all existing prior art for the purposes of 35 U.S.C. 103” in a request for supplemental examination, the request will not be given a filing date, due to the failure to comply with the requirements of the request. See §1.610(d). The request may only be based on twelve items of information. If one item of information is combined in the request with one or more additional items of information, each item of information of the combination may be separately counted. See §§ 1.605(a) and (d). If an item of information is requested to be considered in view of all existing prior art under 35 U.S.C. 103, each piece of prior art would need to be provided and counted, and would presumably result in a number far greater than twelve. In addition, the request must include inter alia: (1) a list identifying each of the items of information that the patent owner requests the Office to consider, reconsider, or correct; and (2) a detailed explanation of the relevance and manner of applying each item of information to each claim of the patent for which supplemental examination is requested. See § 1.610(b). A request to consider, reconsider, or correct an item of information in view of “all existing prior art for the purposes of 35 U.S.C. 103” will not be deemed to meet these requirements.

Filing Date of Request:

Comment 22: A number of comments suggested that the procedure for determining the filing date of a request for supplemental examination is unduly strict, and suggested a variety of alternative procedures, such as a procedure in which a filing date is granted to a substantially complete request, or to any request that does not contain a gross deficiency.

These comments suggested that if an appropriately corrected request is timely filed in response to a notice by the Office of the defects, the request would retain the original filing date. A number of comments also suggested that a broader range of non-substantive or minimal defects, such as the mistakes in meeting format requirements, or a deficiency in a fee payment, be included in the exceptions to the requirement that the request be complete.

Response: The Office appreciates the importance of the filing date of a supplemental examination request. As discussed previously, the Office has simplified the content requirements for the request for supplemental examination to make it easier for a patent owner. See § 1.610(b). These requirements have been carefully formulated to address the concerns of the public, while providing the Office with the necessary information to make an accurate and comprehensive determination on the request for supplemental examination within the statutory three-month time period. As discussed previously, since the statutory three-month period commences with the filing date of the request, the final rule provides that a filing date will not be granted if the request is not in compliance with §§ 1.605, 1.610, and 1.615. The Office, however, has the discretion under § 1.610(d) to grant a filing date if the request contains only minor defects, such as improper margins or other format issues.

Comment 23: A number of comments suggested that the request not be made public until after a filing date is granted to avoid a “race to the court.” These comments suggested that a request that is not granted a filing date, due to the presence of one or more defects

in the request, could inform an accused infringer of the manner in which an inequitable conduct charge could be raised in court. These comments further suggested that such an inequitable conduct charge could be maintained in court notwithstanding a later-filed corrected request for supplemental examination that cures all of the defects of the originally filed request, but which is given a filing date that is later than the date on which the inequitable conduct charge is raised in court by the accused infringer.

Response: In response to the public’s comments, the Office does not intend to make a request for supplemental examination public until the request is granted a filing date. The Office is establishing a procedure in which the request, and any other papers or information submitted as part of or accompanying the request, would not be viewable in Public PAIR until a filing date is granted by the Office.

Comment 24: A number of comments suggested that the statute permits the filing date of the original request to be distinct from the date that starts the three-month period to conduct the supplemental examination when a corrected request is filed. These comments suggested that the original filing date may be granted upon correction of any defects, and that the date starting the three-month period may be separately determined to be the date of the corrected request.

Response: 35 U.S.C. 257(a) provides for a single date only— “the date a request for supplemental examination meeting the requirements of this section is received.” The statute does not authorize the Office to grant a date that is separate and distinct from the

date established by the statute as a filing date. Thus, the date specified in 35 U.S.C. 257(a) is both the filing date and the date that starts the three-month period to conduct the supplemental examination.

Conduct of Supplemental Examination:

Comment 25: A number of comments suggested that the review by the Office of the items of information presented in a request for supplemental examination should not be generally limited to a review of the issues identified in the request, but rather that the supplemental examination should entail a general reassessment of all issues of patentability. Several comments suggested that such a limitation is not authorized by 35 U.S.C. 257. These comments also suggested that this limitation would provide unwarranted unenforceability protection, because a patent owner could include in its request a discussion of some issues of patentability with respect to an item of information, while withholding comment as to other relevant issues of patentability, a court would be statutorily required to dismiss any allegations of inequitable conduct based on any conduct relating to the items of information.

Response: 35 U.S.C. 257(a) expressly authorizes the Office to set forth regulatory requirements governing supplemental examination: “A patent owner may request supplemental examination . . . in accordance with such requirements as the Director may establish.” See also 35 U.S.C. 257(d)(2) (“[t]he Director shall issue regulations governing the form, content, and other requirements of requests for supplemental examination, and establishing procedures for reviewing information submitted in such

requests”). In response to the public comments, this final rule has been clarified to state that the Office’s determination of whether a substantial new question of patentability affecting any claim of the patent has been raised by any of the items of information presented in the request will be generally limited to a review of the item(s) of information identified in the request with respect to the identified claim(s) of the patent.

35 U.S.C. 257(a) requires the Office to determine, within three months of the filing date of each request, whether any of the items of information on which the request is based raises a substantial new question of patentability. In order to ensure an accurate and comprehensive determination of whether the request raises a substantial new question of patentability within the statutory three-month period, it is reasonable to put the patent owner on notice that unless the patent owner identifies the particular claim(s) which the patent owner requests the Office to consider with respect to each item of information, the record may not reflect that these claim(s) were explicitly considered by the examiner. As to the level of unenforceability protection, the issue of whether a court would be statutorily required to dismiss all allegations of inequitable conduct involving a particular item of information is within the purview of the courts.

Comment 26: A number of comments suggested that the term “material fraud” be clarified. These comments suggested that the Office provide guidance as to the standard and the burden of proof that will be used for determining a threshold finding that is sufficient to justify a referral to the Office of Enrollment and Discipline (OED) and/or the Attorney General. A number of comments also suggested that any persons implicated by a potential material fraud be provided notice and opportunity to be heard prior to any

referral to OED or to the Attorney General, and that the patent owner be required to notify the person or practitioner as to the particular items of information and the alleged conduct pertaining to them.

Response: 35 U.S.C. 257 does not provide for the Office to make any definitive determination or finding of material fraud, nor does the statute provide for the Office to set up procedures to make such a determination. Moreover, the Office anticipates that such instances will be rare. Accordingly, the Office does not intend to create a unit to investigate instances of material fraud. If an employee of the Office, such as an examiner in the Central Reexamination Unit (CRU), becomes aware, during the course of supplemental examination or of any reexamination ordered under 35 U.S.C. 257, that a material fraud on the Office may have been committed in connection with the patent subject to a supplemental examination or resulting reexamination ordered under 35 U.S.C. 257, the employee would notify the supervisory official in charge of the section of the Office to which the employee is assigned, such as the Director of the CRU. The supplemental examination proceeding, or any reexamination proceeding ordered under 35 U.S.C. 257, would continue. If the supervisory official concurs, he or she would refer the matter to the Deputy Commissioner for Patent Examination Policy. If the Deputy Commissioner for Patent Examination Policy concurs, the matter would be referred to the Office's General Counsel.

Comment 27: One comment suggested that supplemental examination should be available after litigation is filed. A number of comments suggested that the Office

specifically retain the discretion to permit a supplemental examination proceeding to proceed concurrently with an action brought under Section 337(a) of the Tariff Act of 1930 (19 U.S.C. 1337(a)) in which a defense of inequitable conduct has been raised, if an ordered ex parte reexamination under 35 U.S.C. 257 has proceeded to a stage at which it is likely to be concluded prior to the trial proceeding. These comments suggested that if the ordered ex parte reexamination under 35 U.S.C. 257 has not proceeded to such a stage, then the Office should retain discretion to suspend the supplemental examination or any ordered ex parte reexamination until the merits of the defense are concluded in the trial proceeding.

Response: If the patent owner files a request for supplemental examination that is in compliance with 35 U.S.C. 257 and all applicable rules, the Office is required under 35 U.S.C. 257(a) to conduct the examination and conclude the proceeding within three months from the filing date of the request. Any reexamination proceeding resulting from the supplemental examination proceeding must, in accordance with 35 U.S.C. 257(b), be conducted “according to the procedures established by chapter 30,” which govern ex parte reexamination. If reexamination is ordered, the Office is required to proceed with the reexamination. 35 U.S.C. 304 requires the Office to resolve any substantial new question of patentability determined to be raised: “[i]f . . . the Director finds that a substantial new question of patentability affecting any claim of a patent is raised, the determination will include an order for reexamination of the patent for resolution of the question” (emphasis added). In addition, 35 U.S.C. 305 expressly provides that, after the order (and after the time period set for filing a patent owner statement under

35 U.S.C. 304, which is excluded by 35 U.S.C. 257(b)), “reexamination will be conducted.” Therefore, once reexamination is ordered, the Office is required by statute to conduct the reexamination. 35 U.S.C. 305 also requires that an ex parte reexamination proceeding “be conducted with special dispatch within the Office.” See Ethicon v. Quigg, 849 F.2d 1422 (Fed. Cir. 1988). For these reasons, any reexamination proceeding ordered under 35 U.S.C. 257 will generally not be suspended. The patent owner may wish to consider the provisions of 35 U.S.C. 257(c)(1) and (c)(2) on the effectiveness of any supplemental examination on already pending litigation when determining whether and when to file a request for supplemental examination.

Comment 28: One comment suggested that the rules make clear whether the Office will hold in abeyance any petition or paper filed by a third party in a supplemental examination proceeding until after the proceeding is concluded.

Response: In accordance with 35 U.S.C. 257(a), which only permits a patent owner to file a request for supplemental examination, this final rule expressly prohibits any party other than the patent owner from filing papers or otherwise participating in any manner in the supplemental examination proceeding. See § 1.601(b). If a third party files any petition or other paper in a supplemental examination proceeding, it will not be entered into the official file or considered. If such papers are inadvertently entered, they will be expunged. See § 1.620(c).

Interviews:

Comment 29: A number of comments suggested that interviews be permitted at the discretion of the examiner during the time period prior to the issuance of a supplemental examination certificate. Several comments suggested interviews be permitted as a matter of right during this time period.

Response: The Office must make a determination on the request within the three-month statutory period, which limits the amount of time that an examiner can devote to any one request. The prohibition of interviews, as implemented in this final rule, will assist the Office in meeting the statutory deadline. See § 1.620(e). A telephone call to the Office to confirm the receipt of a request, or to discuss general procedural questions, is not considered to be an interview for the purposes of this provision. Additionally, the prohibition applies only to supplemental examination proceedings. Interviews will be permitted in any ex parte reexamination proceeding ordered as a result of the supplemental examination proceeding, in accordance with the regulations governing ex parte reexamination. Further, interviews are generally permitted to discuss issues of patentability, which are directly addressed during any reexamination proceeding ordered under 35 U.S.C. 257, and not during the supplemental examination proceeding. Finally, the only determination made in a supplemental examination proceeding is whether a substantial new question of patentability is raised by any of the items of information submitted as part of the request. The prohibition of interviews in a supplemental examination proceeding, as implemented in this final rule, is consistent with established

ex parte reexamination practice, which prohibits interviews involving a discussion of the patentability of the claims prior to a first Office action on the merits. See § 1.560(a).

Amendments:

Comment 30: Several comments suggested that amendments be permitted to be filed with the request for supplemental examination. These comments suggested that permitting amendments to be filed with the request would prevent the examiner from unnecessarily applying, in any reexamination ordered under 35 U.S.C. 257, a rejection to a claim which the patent owner intends to amend or cancel. One comment questioned whether a discussion of proposed alternative claim language in the request will be considered to be a prohibited proposed amendment.

Response: 35 U.S.C. 257(a) permits a patent owner to present only items of information in a request for supplemental examination. An amendment is not an item of information and therefore the final rule provides that no amendment may be filed in a supplemental examination proceeding. See § 1.620(f). Any proposed amendment included with a request for supplemental examination would not be considered by the Office in making the determination of whether a substantial new question of patentability is raised by any of the items of information. Furthermore, if the Office makes the determination that no substantial new question of patentability is raised, any amendment filed with the request would remain in the file, and may create a cloud on the patent.

An amendment may be submitted during a reexamination ordered under 35 U.S.C. 257. Patent owners, however, are reminded that 35 U.S.C. 257(b) expressly removes the right of the patent owner to file a statement under 35 U.S.C. 304, which includes any amendment that the patent owner may wish to file prior to an initial Office action on the merits. As the patent owner is prohibited from filing a statement under 35 U.S.C. 304, no amendment may be filed, in any reexamination proceeding ordered under 35 U.S.C. 257, until after the initial Office action on the merits. As discussed previously, a patent owner may file a statutory disclaimer under 35 U.S.C. 253 and § 1.321(a) prior to filing any request for supplemental examination. See MPEP § 1490. Moreover, if the patent owner merely wishes to amend the patent claims, the patent owner may file a reissue application instead of a request for supplemental examination.

Supplemental Examination Certificate:

Comment 31: A number of comments suggested that the Office specify that the electronically issued supplemental examination certificate will display the filing date of the request. These comments also suggested that the Office consider whether any ex parte reexamination certificate published as a result of an ex parte reexamination ordered under 35 U.S.C. 257 will be issued electronically, in the same manner as the supplemental examination certificate. A number of comments requested that the supplemental examination certificate list each item of information presented by the request, and expressly state that the item was considered during the supplemental examination of the patent even if the item is determined not to raise a substantial new question of patentability.

Response: The electronically issued supplemental examination certificate will display the filing date of the request. The Office is mindful of the importance of the filing date in determining the effect under 35 U.S.C. 257(c) of the supplemental examination proceeding. The electronically issued supplemental examination certificate will also list each of the items of information properly submitted as part of the request, and state whether each of these items raises a substantial new question of patentability affecting the identified claims of the patent. Any ex parte reexamination certificate resulting from a reexamination ordered under 35 U.S.C. 257 will be published in accordance with established ex parte reexamination practice (see § 1.570) since 35 U.S.C. 257(b) requires that any resulting reexamination be conducted according to procedures established for ex parte reexamination.

Comment 32: One comment suggested that supplemental examination proceedings do not conclude with the issuance of the initial (supplemental examination) certificate. This comment suggested that the (ex parte reexamination) certificate, which is issued at the conclusion of any reexamination ordered under 35 U.S.C. 257, should be designated as the supplemental examination certificate.

Response: 35 U.S.C. 257(a) requires that supplemental examination “shall conclude with the issuance of a certificate indicating whether the information presented in the request raises a substantial new question of patentability.” An ex parte reexamination certificate does not indicate whether the information presented in the request raises a substantial

new question of patentability. Instead, it provides the results of the Office's later determination, in any reexamination ordered as a result of the supplemental examination proceeding, whether the claims are patentable. In addition, if the Office determines in a supplemental examination proceeding that none of the items of information raise a substantial question of patentability, then reexamination would not be ordered, and no reexamination certificate would issue that could be designated as a supplemental examination certificate. For these reasons, a supplemental examination proceeding will conclude with the electronic issuance of a supplemental examination certificate, which is separate and distinct from an ex parte reexamination certificate. See § 1.625(a).

Comment 33: One comment suggested that the order for reexamination be published in the Official Gazette so as to put third parties on notice that they are prohibited from making a submission or otherwise participating in the reexamination.

Response: The final rule specifically provides that no party other than the patent owner may file any papers or otherwise participate in any manner in a supplemental examination proceeding. See § 1.601(b). Accordingly, third parties are on notice that they have no participatory rights in a supplemental examination proceeding. Furthermore, even in ex parte reexamination practice, third party participation is limited. After the request has been filed by the third party, there is no opportunity for the third party to participate, other than to file a reply in response to any statement under 35 U.S.C. 304 filed by the patent owner prior to the first Office action. In any reexamination resulting from a supplemental examination proceeding, however, there is

no request for reexamination filed by a third party. For this reason, third parties have no participatory rights in any ex parte reexamination proceeding ordered under 35 U.S.C. 257.

Miscellaneous:

Comment 34: A number of comments suggested the rules be amended to specify that a request for supplemental examination may be filed at any time during the enforceability of the patent for which supplemental examination is requested.

Response: In response to the public's comments, § 1.601(c) now provides that a request for supplemental examination of a patent may be filed at any time during the period of enforceability of the patent. This policy is consistent with ex parte reexamination practice. See § 1.510(a). If the patent is not enforceable, then the Office believes that the benefits of 35 U.S.C. 257 will have no effect.

Comment 35: One comment suggested that the rules should require the patent owner to make a statement regarding why an item is not material.

Response: The Office must determine whether any of the items of information raises a substantial new question of patentability, not whether any of the items of information is "material." Therefore, the Office is not adopting a requirement that the patent owner state whether or why an item of information is or is not material.

Comment 36: One comment questioned whether the supplemental examination request is subject to a page limit. This comment also questioned whether the determination of a substantial new question of patentability will be decided by the same or a different examiner from the examiner in charge of the original prosecution of the patent. This comment also questioned which post-patent proceeding would proceed first if multiple post-patent proceedings are filed, such as a supplemental examination proceeding, an ex parte reexamination proceeding, and a post-grant review proceeding.

Response: A request for supplemental examination is not subject to a page limit requirement. However, if any document, other than the request, is over 50 pages in length, then the patent owner must provide a summary of the relevant portions of the document with citations to the particular pages containing the relevant portions. See § 1.610(b)(8). In addition, any non-patent document that is submitted as part of the request is subject to document size fees, if the document is over 20 pages in length. See § 1.20(k)(3). The determination of the substantial new question of patentability will not generally be decided by the same examiner who examined the original patent application, since the Office intends for supplemental examination proceedings to be examined by the Central Reexamination Unit. If multiple post-patent proceedings are simultaneously filed, any determination of which proceedings to initiate, and the order in which to initiate them, will be made on a case-by-case basis. Because a supplemental reexamination proceeding must conclude within three months from the filing date of the request, a supplemental examination proceeding will not be suspended, as a general rule.

The Office, however, reserves its option to suspend a supplemental examination proceeding as circumstances arise.

Comment 37: One comment suggested the use of the term “ex parte reexamination” to refer to reexamination under 35 U.S.C. 257 is confusingly similar to the use of the same term when referring to ex parte reexamination ordered under 35 U.S.C. 302. This comment suggests the term “reexamination under 35 U.S.C. 257” be used to refer to reexamination ordered as a result of a supplemental examination proceeding, and that “ex parte reexamination” only be used to refer to ex parte reexamination ordered under 35 U.S.C. 302.

Response: When it is necessary to distinguish ex parte reexamination ordered under 35 U.S.C. 257 from ex parte reexamination ordered under 35 U.S.C. 302, the Office will utilize language such as “reexamination resulting from a supplemental examination proceeding” or “ex parte reexamination ordered under 35 U.S.C. 257” to avoid confusion.

Rulemaking Considerations:

A. Administrative Procedure Act: This final rule amends the rules of practice in patent cases to implement the supplemental examination provisions of the AIA. The Office is also adjusting 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 in this rulemaking do not change the substantive criteria of patentability. These 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 342, 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). 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, published proposed changes and an Initial Regulatory Flexibility Act (IRFA) analysis for comment as it sought the benefit of the public's views on the Office's proposed implementation of this provision of the AIA. The Office provides the Final Regulatory Flexibility Analysis as follows.

B. Final Regulatory Flexibility Analysis:

1. Description of the reasons that action by the agency is being considered: The Office is revising the rules of patent practice to implement the supplemental examination

provisions of the AIA, which take effect September 16, 2012. The Office is also adjusting the fee for filing a request for ex parte reexamination, and setting a fee for petitions filed in ex parte and inter partes reexamination proceedings, to more accurately reflect the cost of these processes.

2. Statement of the objectives of, and legal basis for, the final rules: The objective of the rules is to implement the supplemental examination provisions of the AIA by establishing 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 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 AIA provides a legal basis for the rules to implement supplemental examination. 35 U.S.C. 41(d)(2) provides a legal basis for the 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. Statement of significant issues raised by the public comments in response to the IRFA and the Office's response to such issues: The Office published an IRFA analysis to consider the economic impact of the proposed rules on small entities. See Changes to Implement the Supplemental Examination Provisions of the Leahy-Smith Invents Act and to Revise Reexamination Fees, 77 FR at 3675-76. The Office did not receive any comments that specifically referenced the IRFA or cited to the Regulatory Flexibility Act.

The Office received a few comments indicating that the Office may be overestimating the number requests for supplemental examination that will be submitted annually. The Office, however, did not receive any comments indicating that the Office was understating the number of requests for supplemental examination that will be submitted annually by small entities. No change has been made in response to these comments because the Office's estimates as to the impact on small entities are conservative.

No comments asserted that the Office's estimates concerning the projected reporting, recordkeeping and other compliance requirements were inaccurate.

In response to general public comments, this final rule reduces the number of procedural requirements for requesting supplemental examination, which may have the effect of

reducing the impact on all entities requesting supplemental examination. In particular, the Office has determined to not implement in this final rule the following proposed requirements for a request for supplemental examination to contain: (1) an identification of each item of information requiring consideration, reconsideration, or correction, 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 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; (4) an explanation of the support in the specification for each limitation of each claim identified for examination if an identified issue involves the application of 35 U.S.C. 101 (other than double patenting) or 35 U.S.C. 112; and (5) an explanation of how each limitation of each claim identified for examination is met, or is not met, by each item of information if an identified issue involves the application of 35 U.S.C. 102, 35 U.S.C. 103, or double patenting. In addition, the Office reduced the fee for requesting supplemental examination by \$40, to \$5140.

4. 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 the 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 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 that about 14 percent of all requests for ex parte reexamination are filed by patent owners and 86 percent of all requests for ex parte reexamination are filed by a third party. 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 and approximately 690 (86 percent of 800 rounded to the nearest 10) requests for ex parte reexamination filed by third parties 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.

As discussed previously, the Office estimates that approximately 690 requests for ex parte reexamination are filed by third parties 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 requested 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 the entity status of the third party requester is not necessarily the same as the entity status of the patentee and reexamination requesters currently have no reason to identify whether they are a small entity. 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 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 number of petitions decided in reexamination proceedings in fiscal year 2010 (i.e., 832) reasonably approximates the number of petitions filed in reexamination proceedings that year. 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. As discussed previously, the Office estimates that it receives approximately 110 requests for ex parte reexamination filed by patent owners annually. In view of the benefits to patent owners afforded by supplemental examination under 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 an approximation of the upper limit 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 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.

Therefore, the Office estimated that it will receive about 1,430 (40 percent of 3,300 plus the 110 requests for ex parte reexamination filed by patent owners annually as discussed previously) requests for supplemental examination annually. Assuming that requests for supplemental examination will be filed by small entities in roughly the same percentage as requests for ex parte reexamination where a small entity prosecuted the underlying patent (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.

5. Description of the projected reporting, recordkeeping, and other compliance requirements of the 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 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 rules to implement the

supplemental examination provisions of the AIA will impose procedural requirements on patent owners who request supplemental examination to consider, reconsider, or correct information believed to be relevant to a patent. The 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 rules to implement the supplemental examination provisions of the AIA also require: (1) a fee of \$5,140.00 for processing and treating a request for supplemental examination; (2) a fee of \$16,120.00 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 pages in length, a fee of \$170.00 for a document of between 21 and 50 pages, and a fee of \$280.00 for each additional 50 pages or a fraction thereof.

A patent practitioner would have the type of professional skills necessary for preparation of a 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 \$9,275 (25 hours at the \$371 per hour mean 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 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 Office estimates \$19,000 for the cost to prepare and file a request for supplemental examination even though many of the requirements initially proposed have been eliminated in this final rule because the requirements in this final rule closely track the requirements for ex parte examination.

The rules to adjust or set fees in ex parte reexamination are as follows: (1) \$17,750.00 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) \$ 4,320.00 for a denied 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 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 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.

6. Description of any significant alternatives to the rules which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the 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 rules to implement the supplemental examination provisions of the AIA, the Office considered requiring less than, or exempting small entities from, what is currently set forth at 37 CFR 1.601, 1.605, 1.610, and 1.615. As discussed previously, this final rule adopts content requirements for a request for supplemental examination that are comparable to the requirements for a request for ex parte reexamination (e.g., list of each item of information to be considered, reconsidered, or corrected, an identification of each claim of the patent for which supplemental examination is requested, and a separate, detailed explanation of the relevance and manner of applying each item of information to each claim of the patent for which supplemental examination is requested). See 37 CFR 1.510.

One alternative the Office considered was proposed in the NPRM. Namely, the Office considered, and proposed, to require that a request for supplemental examination contain: (1) an identification of each item of information requiring consideration, reconsideration, or correction, explaining why consideration or reconsideration of the item of information is being requested or how the item of information is being corrected; (2) 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; (4) an explanation of the support in the specification for each limitation of each claim identified

for examination if an identified issue involves the application of 35 U.S.C. 101 (other than double patenting) or 35 U.S.C. 112; and (5) an explanation of how each limitation of each claim identified for examination is met, or is not met, by each item of information if an identified issue involves the application of 35 U.S.C. 102, 35 U.S.C. 103, or double patenting. These proposed requirements were not included in this final rule in response to public comments and because the Office decided to make the requirements for requesting supplemental examination closely track the requirements for requesting reexamination.

The Office adopted the requirements in this final rule because 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 final 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 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 Office considered the alternative of not adjusting or setting the fees, which would have reduced the economic impact on small entities, but this alternative 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 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.

7. Identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap or conflict with the 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.), the United States Patent and Trademark Office will submit a report containing this 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 final rule 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 final rule is not 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 final rule 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 final rule makes 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 Office submitted a proposed revision to the information collection requirements under 0651-0064 to OMB for its review and approval when the notice of proposed rulemaking was published. The Office also published the title, description, and respondent description of the information collection, with an estimate of the annual reporting burdens, in the notice of proposed rulemaking (See Changes to Implement the Supplemental Examination Provisions of the Leahy-Smith Invents Act and to Revise Reexamination Fees, 77 FR at 3678). The Office did not receive any comments on the proposed revision to the information collection requirements under 0651-0064.

As discussed previously, however, this final rule adopts content requirements for a request for supplemental examination that are comparable to the requirements for a request for ex parte reexamination (e.g., list of each item of information to be considered, reconsidered, or corrected, an identification of each claim of the patent for which supplemental examination is requested, and a separate, detailed explanation of the

relevance and manner of applying each item of information to each claim of the patent for which supplemental examination is requested). See 37 CFR 1.510. Thus, this final rule does not adopt the proposed requirements that a request for supplemental examination contain: (1) an identification of each item of information requiring consideration, reconsideration, or correction, 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 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; (4) an explanation of the support in the specification for each limitation of each claim identified for examination if an identified issue involves the application of 35 U.S.C. 101 (other than double patenting) or 35 U.S.C. 112; and (5) an explanation of how each limitation of each claim identified for examination is met, or is not met, by each item of information if an identified issue involves the application of 35 U.S.C. 102, 35 U.S.C. 103, or double patenting. This final rule also adopts a fee for a request for supplemental examination that is \$40 less than the proposed fee.

The Office has resubmitted the proposed revision to the information collection requirements under 0651-0064 to OMB. The proposed revision to the information collection requirements under 0651-0064 is available at the OMB's Information Collection Review Web site (www.reginfo.gov/public/do/PRAMain).

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 recordkeeping requirements, Small businesses.

For the reasons set forth in the preamble, 37 CFR part 1 is amended 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 denied 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.....\$5,140.00

(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 pages in length, per document:

(i) Between 21 and 50 pages \$170.00

(ii) For each additional 50 pages or a fraction thereof, in addition to the fee specified in paragraph (k)(3)(i) of this section \$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 Part 1 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) 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.

(c) A request for supplemental examination of a patent may be filed at any time during the period of enforceability of the patent.

§ 1.605 Items of information.

(a) Each request for supplemental examination may include no more than twelve 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 during the period of enforceability of the patent.

(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, 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)(8).

§ 1.610 Content of request for supplemental examination.

(a) A request for supplemental examination 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:

(1) An identification of the number of the patent for which supplemental examination is requested.

(2) A list of the items of information that are requested to be considered, reconsidered, or corrected. Where appropriate, the list must meet the requirements of § 1.98(b).

(3) 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, the identifying number of any such proceeding (e.g., a control number or reissue application number), and the filing date of any such proceeding.

(4) An identification of each claim of the patent for which supplemental examination is requested.

(5) A separate, detailed explanation of the relevance and manner of applying each item of information to each claim of the patent for which supplemental examination is requested.

(6) A copy of the patent for which supplemental examination is requested and a copy of any disclaimer or certificate issued for the patent.

(7) A copy of each item of information listed in paragraph (b)(2) of this section, accompanied by a written English translation of all of the necessary and pertinent parts of any non-English language item of information. The patent owner is not required to submit copies of items of information that form part of the discussion within the body of the request as specified in § 1.605(b), or copies of U.S. patents and U.S. patent application publications.

(8) 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.

(9) An identification of the owner(s) of the entire right, title, and interest in the patent requested to be examined, and a submission by the patent owner in compliance with § 3.73(c) of this chapter establishing the entirety of the ownership in the patent requested to be examined.

(c) The request may also include:

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

(2) A table of contents for the request;

(3) An explanation of how the claims patentably distinguish over the items of information; and

(4) 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, subject to the discretion of the Office. If the Office determines that the request, as originally submitted, is not 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 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.

(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 after 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 item(s) of information identified in the request as applied to the identified claim(s) 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 notifying the Office 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 Office

proceeding, including the type of proceeding, 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 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 as a result of the supplemental examination proceeding, that a material fraud on the Office may have been committed in connection with 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 with the electronic issuance of a supplemental examination certificate. 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 fee for reexamination ordered as a result of 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 claim 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: July 17, 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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