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Patent Reform: Changes to Reissues and the New Supplemental Examination Procedure

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The Leahy-Smith America Invents Act of 2011 ("AIA") was signed into law by President Obama on September 16, 2011. The first significant overhaul of the U.S. patent system in nearly 60 years, this new patent reform measure ushers in considerable changes in how companies and individuals may obtain and enforce patents in the United States. This is the seventh in a series of articles on the AIA (the earlier articles can be accessed <u>here</u>).

Currently, Chapter 25 of 35 U.S.C. provides patent owners with two primary means for amending and correcting issued patents: certificates of correction and reissue. (35 U.S.C. §§ 251-256). Both of these options were limiting in the types of information and/or issues they allowed the patent owner to address. The AIA removed many of these prior limitations and has given more strength to these procedures by amending 35 U.S.C. § 251, governing reissue of defective patents, and by creating a new Supplemental Examination procedure. (35 U.S.C. § 257).

How Did the AIA Change the Reissue Option?

The AIA amended 35 U.S.C. § 251 to remove the language "without any deceptive intention," thereby removing a significant limitation on the types of errors that may be corrected through the reissue process. Section 251(a) now reads as follows:

(a) In General. – Whenever any patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, the Director shall, on surrender of such patent and the payment of the fee required by law, reissue the patent for the invention disclosed in the original patent, and in accordance with new and amended application, for the unexpired part of the term of the original patent. No new matter shall be introduced into the application for reissue.

What Is the New Supplemental Examination Option?

Under new 35 U.S.C. § 257, "[a] patent owner may request supplemental examination of a patent in the Office to consider, reconsider, or correct information believed to be relevant to the

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patent." (§ 257(a)). Within three months after receiving a request for supplemental examination, the Patent Office must conduct the supplemental examination and must issue a certificate indicating whether the information presented in that request "raises a substantial new question of patentability." (§ 257(a)). If the Patent Office determines that the supplemental examination request raises a substantial new question of patentability, then an ex parte reexamination of the patent will be conducted in which the Patent Office will address each substantial new question of patentability identified during the supplemental examination. (§ 257(b)).

The AIA does not specify or limit the type of information that may be corrected through this supplemental examination procedure. The only requirement is that the information must be "believed to be relevant to the patent." (§ 257(a)). Thus, while the patent owner may submit any information they believe to be relevant to the patent, the Patent Office will only act further if it determines that the information raises a substantial new question of patentability. Additionally, the AIA specifically states that the resulting reexamination is not limited to patents and printed publications as required under the ex parte reexamination rules of chapter 30. (§ 257(b)). Therefore, a patent owner may have issues relating to 35 U.S.C. §§ 101, 112, or inequitable conduct addressed through the reexamination process via a supplemental examination request.

One of the strengths of the supplemental examination procedure for patent owners is that the AIA specifically states that a patent cannot be held unenforceable based upon information that was "considered, reconsidered, or corrected during a supplemental examination of the patent." ($\S 257(c)(1)$). So, unlike the prior options for amending and/or correcting a patent, the supplemental examination provides a process for essentially absolving a prior sin regarding that patent.

Because supplemental examination can negate a future unenforceability argument against a patent, the AIA provides some limitations with respect to the use of the supplemental examination process to address issues raised in a litigation context. For example, the provision that a patent cannot be held unenforceable based upon information that was considered, reconsidered, or corrected during a supplemental examination does not apply if the issues raised in the supplemental examination were pled with particularity in a civil action or described in a paragraph IV certification letter received by the patentee under the provisions of the Hatch-Waxman Act (§ 505(j)(2)(B)(iv)(II) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(i)(2)(B)(iv)(II) prior to the filing of the supplemental examination request. (§ 257(c)(2)(A)). Thus, the statute prevents a patent owner from using the supplemental examination procedure as a means to move an issue of unenforceability from the Court to the Patent Office when a litigation is ongoing or, in the case of paragraph IV situations, is imminent. Similarly, the provision that a patent cannot be held unenforceable based upon information that was considered, reconsidered, or corrected during a supplemental examination does not apply to a defense raised in a section 337(a) action before the International Trade Commission ("ITC") unless the supplemental examination and any resulting reexamination are concluded before the date on which the action is brought in the ITC. (§ 257(c)(2)(B)). Finally, "[t]he making of a request under subsection (a), or the absence thereof, shall not be relevant to enforceability of the patent under section 282" (which provides for the presumption of validity of a patent and the defenses thereto). (§ 257(c)(1)).

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Effective Date of These Changes

The changes to 35 U.S.C. § 251 and the new supplemental examination procedure under 35 U.S.C. § 257 will take effect on September 16, 2012 (1-year from the date of enactment of the AIA) and shall apply to every patent issued before or after that effective date.

During the next few months, it is anticipated that the Patent Office will issue proposed regulations governing the form and content of, and other requirements for, requests for supplemental examination, and establishing procedures for reviewing information submitted in such requests. (§ 257(d)(2)). *snippets* will cover those regulations in future issues.

Alison J. Baldwin, an MBHB partner, has over a decade of experience in handling complex litigation matters. This litigation experience includes both jury and bench trials in federal district court, as well as advocacy in forums such as the International Trade Commission and private arbitration proceedings. Ms. Baldwin also has considerable experience in counseling clients in all aspects of intellectual property, particularly focusing on new business ventures and due diligence. Her litigation experience crosses over into many other strategic applications for her clients, such as reexaminations, FTOs and patent portfolio analysis.

MBHB attorneys are well versed on the Leahy-Smith America Invents Act patent law changes and how the changes will impact prosecuting and enforcing patents in the U.S. Please contact an MBHB attorney should you have any questions about the Act or to arrange an in-house seminar about the Leahy-Smith America Invents Act. For more general information about the Act, and its impact on the patent laws, <u>view our Summer 2011 edition of *snippets*</u>.

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