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March 21, 2012

**VIA E-MAIL: [supplemental\\_examination@uspto.gov](mailto:supplemental_examination@uspto.gov)**

U.S. Patent and Trademark Office  
Mail Stop Comments—Patents  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Re: Comments of Eisai on AIA Implementation – Supplemental Examination

Dear Sir or Madam:

Eisai Co., Ltd. and Eisai Inc. ("Eisai") respectfully request that the United States Patent and Trademark Office ("PTO") consider the following comments in response to its request for comments on the implementation of the supplemental examination provisions of the America Invents Act ("AIA"). Eisai also submits, at the conclusion of this letter, amendments to the proposed rules which would resolve the issues that are raised by the comments herewith.

Eisai appreciates the PTO's decision to solicit comments on the provision's implementation in advance of rulemaking, and wishes to assist the PTO in developing its rules and guidance regarding its implementation. Eisai's specific comments and proposed changes to the rules at this time are as follows:

**Eisai's Background**

Eisai is an innovator pharmaceutical company of more than 15,000 employees, with offices in the United States, Japan and many other areas of the world, including the United Kingdom, Germany, France, China, and South Korea. Eisai's goal is to be a human health care company capable of making a meaningful contribution under any health care system while observing the highest legal and ethical standards in business activities. Eisai has been involved in several patent litigations in which inequitable conduct was accused, though in none was inequitable conduct found to have occurred. *Eisai Co., Ltd. v. Dr. Reddy's Labs., Ltd.*, 533 F.3d 1353 (Fed. Cir. 2008); *Eisai Co., Ltd. v. Teva Pharms. USA, Inc., C.A.* Nos. 05-5727 and 07-5489, 2008 U.S. Dist. LEXIS 33747 (March 28, 2008). Even though the allegations were ultimately found to be without merit in these cases, Eisai was forced to endure substantial expenditure of time, money, and resources defending against them. Eisai thus has direct experience with

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the wasteful nature of inequitable conduct litigation. Eisai recognizes that the Federal Circuit's decision in *Therasense* has tightened the substantive standards for proving inequitable conduct. Nonetheless, Eisai also understands the benefits to the patent system in having a procedure by which patentees may proactively make voluntary disclosure, post-issuance, of information so as to avoid later wasteful potential charges of inequitable conduct at all, even if the patentee does not believe that the information is, in fact, material to patentability.

**The Enactment and Importance of Supplemental Examination — 35 U.S.C. § 257**

The new supplemental examination provision of the AIA allows the patent owner proactively to submit additional information post-issuance to avoid the possibility that a defendant will try to create an inequitable conduct argument in a future litigation. Congress recognized that inequitable conduct arguments are often not successful but nonetheless involve unnecessary judicial resources and unjustified accusations and disparagement toward inventors, patent owners, and their patent agents and attorneys. Congress explained during the House Judiciary Committee markup session how the patent system would suffer without the supplemental examination process:

So many times, inequitable conduct is raised in a gotcha kind of situation when there really has been no inequitable conduct. There may have been a mistake.... To not have this new process, this supplemental examination process, would lead to inventors who have received patents leaving those patents on the table because there is some kind of a mistake that was made in acquiring the original patent. And this may be a lifesaving drug that could have been discovered if that patent had been exploited, but it was not because the patentee decided that he had more to lose than to gain by prosecuting that patent.

(Transcript of Markup with House of Representatives Committee on the Judiciary, p. 168, *available at* [http://www.uspto.gov/aia\\_implementation/20110414-house\\_judiciary\\_mark-up\\_transcript.pdf](http://www.uspto.gov/aia_implementation/20110414-house_judiciary_mark-up_transcript.pdf)).

The Senate likewise recognized the important purpose served by the supplemental examination process:

An investor would not risk spending hundreds of millions of dollars to develop a product if a potential inequitable conduct attack may wipe out the whole investment. Parties on both sides of these exchanges report that investors routinely walk away from inventions because of their inability under current law to resolve uncertainties whether a flaw in prosecution was, in fact, inequitable conduct.... The authorization of

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supplemental examination will result in path-breaking inventions being developed and brought to market that otherwise would have lingered on the shelf because of legal uncertainty over the patent. It will ensure that small and startup companies with important and valid patents will not be denied investment capital because of legal technicalities.

(154 Cong. Rec. S5319).

As explained below, the PTO's proposed implementation guidance is in tension with Congressional goals because it renders supplemental examination a process that patentees likely will avoid using entirely. In accordance with the discussion below, Eisai respectfully requests that the PTO reconsider the proposed regulations.

#### **Difficulties With the Proposed Rules For Supplemental Examination**

The proposed regulations require not only that the patent owner describe items of information he or she would like the PTO to consider in the supplemental examination and a basic explanation of why supplemental examination is being requested for those items of information, but goes further than even a request for *ex parte* reexamination by requiring that the patent owner describe in detail how each item raises an issue with regard to patentability of specific aspects of the patent. See proposed rules 1.610(b) and 1.620(a). These proposed requirements place patentees in the undesired position of having to criticize their own patents in the way that they believe an aggressive litigant might in the future, even if the patentee does not believe the information should affect patentability. Nor would a patentee wish to describe publicly its opinions concerning possible approaches of an aggressive opponent to the patent, opinions potentially developed with the assistance of in-house and/or outside attorney counsel. In addition, requiring that the relevance of the material be described by the patentee to meet three separate requirements only makes more complex the document being presented to the Patent Office and makes the Patent Office review of the document more difficult and time-consuming than necessary.

The information required under the proposed regulations also goes beyond what is contemplated in the legislation. Section 257 of the statute allows the patent owner to "request supplemental examination of a patent in the Office to consider, reconsider, or correct information believed to be relevant to the patent." The statute does not require the level of detail provided for in the proposed regulations.

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Moreover, if the patent owner does not in fact believe that the submitted information should affect patentability, that patent owner would have great difficulty complying with the proposed rules as written. In addition, we are concerned that the requirement that a patent owner make statements to the PTO in such detail about these issues in fact creates more risk of additional future litigation. For example, the regulations create incentives for potential infringers to accuse the patent owner of misstatements during the supplemental examination, or to seek to discover the patentee's state of mind in asserting that information was or was not material. The AIA is intended to eliminate wasteful inequitable conduct allegations relating to a piece of information presented during the supplemental examination, not potentially create a source of more litigation. The supplemental examination submission should thus be seen as more akin to an information disclosure statement than to a request for reexamination.<sup>1</sup>

#### **Timing Difficulties Raised by the Proposed Regulations**

To obtain the benefits of supplemental examination and prevent arguments of inequitable conduct, a supplemental examination as well as any resulting reexamination must be concluded before a civil action is brought requesting that the patent be declared invalid or unenforceable. 35 U.S.C. § 257(c)(2). Thus, to use this procedure, patentees must make judgments about how long the process will take and the risk of litigation prior to its use. This further creates incentives for a proactive approach. The PTO's proposed rules state that a request for supplemental examination will not be granted a filing date if the patent owner does not meet the requirements of Section 1.610, among others. See proposed rule 1.610(d), (e). Given the onerous burden on the patentee, the risk that the PTO will find a deficiency in complying and fail to accord a filing date is substantial. If there is substantial uncertainty and risk that a filing date will not be given, patentees cannot reasonably estimate the overall time frame for the procedure. This uncertainty will create further disincentives for any use of supplemental examination.

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<sup>1</sup> The reexamination *statute* expressly requires that a person making a request for reexamination "set forth the pertinency and manner of applying cited prior art to every claim for which reexamination is requested." 35 U.S.C. § 302. The supplemental examination statute contains no such provision. 35 U.S.C. § 257. Reexamination is specifically for the purpose of raising substantial new questions of patentability. Supplemental examination is for a different purpose – providing information that the patentee believes might in the future potentially be a source of aggressive and wasteful litigation, but which may or may not in fact raise any substantial questions of patentability.

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Alternatively, a patent owner will be forced to include even more information in a supplemental examination request than he or she believes is necessary, including information that he or she may not even consider relevant, in order to have a completed request as soon as possible so that there is no delay in finishing the process. This only exacerbates the problems discussed previously. It also may result in overburdening of patent examiners with extraneous information.

### **The PTO's Overestimation of the Number of Likely Applications**

The PTO has estimated the number of patent owners who will request supplemental examination by using the number of original applications filed per year and relating that to a statistic about the rate at which patents historically have been subject to inequitable conduct charges, essentially assuming that every application filed per year that could be subject to an inequitable conduct charge will be the subject of a request for supplemental examination. We believe that this number is overestimated, given the burdens and risks described above inherent in filing a supplemental examination request when one already possesses an issued patent. In addition, because the PTO is charging significant fees for each supplemental examination, this also disincentivizes some applicants who would otherwise file without an expense. Supplemental examination most likely would be considered only for important patents where even the possibility of an inequitable conduct charge in the future is deemed a risk that is unacceptable, making it worth the risk of exposing the patent to further examination.

### **Suggested Changes to the Proposed Guidance and Rules for Implementation**

We respectfully suggest that, to minimize the burdens and risks as described above, the implementation regulations be changed in the following ways consistent with the above comments. We present below both a showing of the proposed revisions and a clean version incorporating those comments. We take no position with respect to other aspects of the rules that do not relate to the comments raised above:

#### **Markup Showing Requested Changes**

##### **§ 1.610 Content of request for supplemental examination.**

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

(b) A request for supplemental examination must include each of the elements set forth in paragraphs (b)(1) through (b)(4) of this section.

- (1) A cover sheet itemizing each component submitted as part of the request.
- (2) A table of contents for the request.

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

(4) A list of each item of information that is requested to be considered, reconsidered, or corrected, and the publication date for each item of information, if applicable; and a statement that: identifies each item of information and whether the information is being submitted for consideration, reconsideration or correction.

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

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

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

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

(6) An ~~identification of each aspect of the patent for which supplemental examination is sought, including an~~ identification of the structure, material, or acts in the specification that correspond to each means-plus-function or step-plus-function element, as set forth in 35 U.S.C. 112(f), in any claim to be examined.

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

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

~~(i) Where an identified issue involves the application of 35 U.S.C. 101 (other than double patenting) or 35 U.S.C. 112, an explanation discussing the support in the specification for each limitation of each claim identified for examination with respect to this issue; and~~

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

~~(7) (9)~~ A copy of the patent for which supplemental examination is requested and a copy of any disclaimer, certificate of correction, certificate of extension, supplemental examination certificate, post grant review certificate, *inter partes* review certificate, or reexamination certificate issued for the patent.

~~(8) (10)~~ A copy of each item of information listed in paragraph (b)(34) of this section, accompanied by a written English translation of all of the necessary and pertinent parts of any non-English language document. Items of information that form part of the discussion within the body of the request as specified in § 1.605(b), and copies of U.S. patents and U.S. patent application publications, are not required to be submitted.

~~(9) (11)~~ A summary of the relevant portions of any submitted document, other than the request, that is over 50 pages in length. The summary must include citations to the An identification of particular pages containing the relevant portions of information to be considered, reconsidered or corrected, along with the entirety of the document, in any document which is over 50 pages.

~~(10) (12)~~ A submission by the patent owner in compliance with § 3.73(b) of this chapter establishing the entirety of the ownership in the patent requested to be examined as set forth in § 1.601(b).

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

(d) The filing date of a request for supplemental examination will ~~not~~ be granted conditionally if the request is not in compliance with § 1.605, § 1.615, and this section. ~~A defective request may receive a filing date if the defects are limited to the omission of one or more of the requirements set forth in paragraph (b)(1) or (b)(2) of this section, subject to the discretion of the Office.~~

(e) If the Office determines that the request, as originally submitted, does not meet the requirements of paragraph (d) of this section ~~to be entitled to a filing date~~, the patent owner will be so notified, and the request will be granted only conditionally while the patent owner is given an opportunity to complete the request within a specified time. Such notification shall be sent within 10 days of the receipt by the Office of the request for supplemental examination.

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~~If the patent owner does not timely comply with the notice, the request for supplemental examination will not be granted a filing date and the fee for reexamination as set forth in § 1.20(k)(2) will be refunded.~~ If the patent owner timely files a corrected request in response to the notice that properly addresses all of the defects set forth in the notice and that otherwise complies with all of the requirements of §§ 1.605, 1.615 and of this section, the filing date of the supplemental examination request will be the receipt date of the ~~corrected request.~~ original request. ~~If the patent owner does not timely comply with the notice, the conditional grant of a filing date will be withdrawn, 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.~~

**§ 1.620 Conduct of supplemental examination proceeding.**

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

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

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

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

(e) Interviews are prohibited in a supplemental examination proceeding.

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

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

**Proposed Regulation Incorporating Requested Changes**

**§ 1.610 Content of request for supplemental examination.**

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

(b) A request for supplemental examination must include each of the elements set forth in paragraphs (b)(1) through (b)(10) of this section.

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

(2) A table of contents for the request.

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

(4) A list of each item of information that is requested to be considered, reconsidered, or corrected, and the publication date for each item of information, if applicable; and a statement that identifies each item of information and whether the information is being submitted for consideration, reconsideration or correction.

(5) A list identifying any other prior or concurrent post-patent Office proceedings involving the patent for which supplemental examination is being requested, including an identification of the type of proceeding (*e.g.*, *ex parte* or

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*inter partes* reexamination, reissue, supplemental examination, post-grant review, or *inter partes* review), the identifying number of any such proceeding (e.g., a control number or reissue application number), and the filing date of any such proceeding.

(6) An identification of the structure, material, or acts in the specification that correspond to each means-plus-function or step-plus-function element, as set forth in 35 U.S.C. 112(f), in any claim to be examined.

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

(8) A copy of each item of information listed in paragraph (b)(4) of this section, accompanied by a written English translation of all of the necessary and pertinent parts of any non-English language document. Items of information that form part of the discussion within the body of the request as specified in § 1.605(b), and copies of U.S. patents and U.S. patent application publications, are not required to be submitted.

(9) An identification of particular pages containing information to be considered, reconsidered or corrected, along with the entirety of the document, in any document which is over 50 pages.

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

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

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

(e) If the Office determines that the request, as originally submitted, does not meet the requirements of paragraph (d) of this section, the patent owner will be so notified, and the request will be granted only conditionally while the patent owner is given an opportunity to complete the request within a specified time. Such notification shall be sent within 10 days of the receipt by the Office of the request for supplemental examination. If the patent owner timely files a corrected request in response to the notice that properly addresses all of the defects set forth in the notice and that otherwise complies with all of the requirements of §§ 1.605, 1.615 and of this section, the filing date of the supplemental examination request will be the receipt date of the original request. If the patent owner does not timely comply with the notice, the conditional grant of a filing date will be withdrawn, 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.

#### **§ 1.620 Conduct of supplemental examination proceeding.**

(a) Within three months following the filing date of a request for supplemental examination, the Office will determine whether a substantial new question of patentability affecting any claim of the patent is raised by any of the items of information presented in the request. The determination will be based on the claims in effect at the time of the determination and will become a part of the official record of the patent.

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

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

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

(e) Interviews are prohibited in a supplemental examination proceeding.

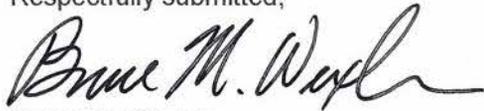
(f) No amendment to any aspect of the patent may be filed in a supplemental examination proceeding.

(g) If the Office becomes aware, during the course of supplemental examination or of any reexamination ordered under 35 U.S.C. 257, of a material fraud on the Office involving the patent requested to be examined, the

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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).

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Bruce M. Wexler". The signature is fluid and cursive, with a long horizontal stroke at the end.

Bruce M. Wexler  
PAUL HASTINGS LLP

ATTORNEYS FOR EISAI CO., LTD. AND EISAI INC.