

Mail Stop Comments – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attention: Cynthia L. Nesser
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner for Patent Examination Policy

RE: Response to PTO Docket No. PTO-P-2011-0075 (Changes to Implement Supplemental Examination Provisions of the Leahy-Smith America Invents Act)

Dear Ms. Nesser:

Genentech, Inc. (“Genentech”) submits the following comments in response to PTO Docket No. PTO-P-2011-0075¹ concerning proposed rules for implementing the supplemental examination procedure mandated by 35 U.S.C. § 257.

Genentech generally supports the proposed rules for implementing the supplemental examination procedure. However, Genentech believes certain of the rules should be revised to better reflect the statutory intent of the provisions and address practical considerations about use of the procedure.

The proposed rules that Genentech is addressing in this response are: (i) 37 CFR 1.601; (ii) 37 CFR 1.605 and (iii) 37 CFR 1.610.

A. Comments on Proposed Rule 601 (proposed 37 C.F.R. 1.601)

Proposed Rule 601(a) (37 CFR 1.601(a)) would provide that a request for supplemental examination may only be filed by the owner(s) of the entire right, title and interest in the patent. Proposed Rule 601(c) would provide that “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.”

Genentech submits that proposed Rule 601(a) is unduly restrictive as it precludes the exclusive licensee of a patent having the consent of the patent owner from requesting supplemental examination. Genentech fully agrees that a third party having no or even a partial interest in the patent does not have standing to request supplemental examination or to file comments during a supplemental examination proceeding. However, the exclusive licensee of

¹ See 77 Fed. Reg. 3666 (January 25, 2012).

all rights under the patent stands in a very different position relative to these other third parties; it has control of the beneficial rights of the patent and the authority to assert those rights.

Consequently, Genentech submits that proposed Rule 601(a) should be revised to permit the exclusive licensee of the patent having the consent of the patent owner to request supplemental examination of the patent. In particular, proposed Rule 601(a) should be revised to read as follows:

(a) A request for supplemental examination of a patent must be filed by (i) the owner(s) of the entire right, title and interest of the patent, or (ii) a person who is the exclusive licensee of the patent and who is authorized in writing by the owner(s) of the patent to request supplemental examination of the patent, or (iii) legal representatives on behalf of such owner or such authorized exclusive licensee.

If this amendment is adopted, Genentech believes that proposed Rule 601(c) also should be amended to specify that no parties other than the patent owner or the exclusive licensee of the patent, or legal representatives working on behalf of such owner or such authorized exclusive licensee, may participate in the supplemental examination of the patent. In particular, proposed Rule 601(c) should be revised to specify that:

(c) Any party other than one specified in paragraph (a)(i) or (ii) or (iii) the patent owner-(i.e., any a third party) is prohibited from filing papers or otherwise participating in any manner in a supplemental examination proceeding.

Genentech submits that these proposed revisions to proposed Rule 601(a) and (c) will make the supplemental examination proceeding more practical and efficient for patent owners and parties that own the full beneficial interests of the patent.

B. Comments on Proposed Rule 605 (proposed 37 C.F.R. 1.605)

In its proposed Rule 605(a), the Office is proposing to limit the number of items of information considered in a single request for supplemental examination to ten items. If a patent owner wishes to obtain supplemental examination for items of information in excess of ten, an additional request for supplemental examination must be filed, with a separate fee.

Genentech generally supports the approach the Office advances in its proposed Rule 605. However, Genentech believes additional clarifications are warranted.

First, a patent owner should be entitled as of right, if requested, to merger of multiple requests it has filed for supplemental examination. This approach would allow the Office to recover an appropriate amount of fees while avoiding the potential prejudice that can result

from an extended or disconnected review of multiple concurrent requests for supplemental examination.

Second, the Office should set the deadline for completing supplemental examination of a merged set of requests for reexamination to be the date that is three months from the last request submitted. The Office could, for example, require the patent owner to consent to the later date as a condition of merger of the requests for reexamination.

Third, the Office should permit a patent owner who has requested merger of two or more requests to request that the questions of patentability raised by the items of information in the merged request be subject to a single *ex parte* reexamination proceeding. Providing this procedural flexibility will avoid potential prejudice to the patent owner.

Genentech encourages the Office to provide for the possibility of merger of requests for supplemental examination consistent with these recommendations.

C. Comments on Proposed Rule 610 (proposed 37 C.F.R. 1.610)

Proposed Rule 610 seeks to define the requirements for requests for supplemental examination. Genentech believes there are several issues of concern with this proposed Rule.

Proposed Rule 610 would require patent owners to provide redundant and unnecessary explanations of the items of information being provided for review. Specifically:

- proposed Rule 610(b)(4) would require the patent owner to provide a list of the items of information for which supplemental examination is desired, and to then, for each item, explain why consideration or reconsideration of the information is being requested or how the information is being corrected;
- proposed Rule 610(b)(7) would require the patent owner to “include an identification of each issue of patentability raised by each item of information”;
- proposed Rule 610(b)(8) would require a “separate, detailed explanation for each identified issue of patentability” raised by each item of information; and
- proposed Rule 610(c) would permit a patent owner to provide a response to possible substantial new questions of patentability.

Genentech respectfully submits that proposed Rules 610 would impose redundant requirements to describe the information for which supplemental examination is sought.

35 U.S.C. § 257 allows patent owners to request supplemental examination without identifying a specific patentability issue associated with each item of information being presented for review. As 35 U.S.C. § 257 provides, a patent owner may “request supplemental examination of a patent in the Office to *consider, reconsider, or correct information believed to*

be relevant to the patent ...” Information may be considered relevant by the patent owner if, for example, the patent owner believes that an adverse party in future litigation could assert that the information is material to the patent. The requirements in the proposed rules that demand an explanation of specific patentability issues raised by the information, thus, impose requirements going beyond those envisioned within or authorized by § 257.

Genentech does not oppose rules that require a patent owner to assist the Office in its efficient evaluation of information provided for supplemental examination. For example, Genentech does not oppose provisions within proposed Rules 610(b)(4) or (7) that would require a patent owner to list the items of information. Genentech also does not oppose elements of the proposed Rules that would require a patent owner to identify portions of a document having more than 50 pages that should be reviewed by the Office. Nor does Genentech oppose a requirement that the patent owner provide a brief explanation as to why the information is being provided for supplemental examination (e.g., to bring to the attention of the Office a reference that was not considered in an earlier examination, to identify portions of a document that were not apparently considered by the Office, or to correct information that was incorrect as originally presented to the Office). In the last example, the Office could reasonably require a patent owner to present the corrected information in a form that readily identifies what has been corrected.

Genentech also does not oppose those provisions of the proposed rules that permit, but do not require, a patent owner to provide an explanation of possible patentability issues raised by one or more items of information being presented. Thus, for example, Genentech supports retention of Rule 610(c), which permits a patent owner to voluntarily provide a summary of why the information provided does not raise a substantial new question of patentability.

Genentech thus submits that proposed Rules 610(b)(4), (7), (8) and 610(c) should be revised and consolidated. In particular:

- (i) Proposed Rule 610(b)(4) should simply require a descriptive list of the items of information for which supplemental examinations is requested.
- (ii) Proposed Rule 610(b)(7) and (8) should be consolidated into a single Rule that specifies that a patent owner must provide a brief explanation of why each item of information is being provided. The revised Rule should specify that a patent owner can satisfy this requirement, for example, by stating that a reference was not submitted, by explaining that a portion of an item of information previously provided may not have been fully considered by the Examiner, or by identifying an incorrect portion of an item of information submitted during an earlier examination of the patent.
- (iii) Proposed Rule 610(c) should be preserved as an optional element of the request for supplemental examination.

Finally, Genentech submits that proposed Rules should permit an applicant to indicate that several items of information may be related and/or cumulative. For example, a patent owner could explain that several patents or published applications are members of a patent family and have an identical disclosure. In such cases, the patent owner could satisfy the form requirements by referencing a single member of the group of related items of information.

Genentech respectfully urges the Office to consider the remarks, and to make appropriate revisions to Rules 601, 605 and 610 as proposed above.

Sincerely,



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Genentech, Inc.