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VIA EMAIL: supplemental_examination@uspto.gov

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

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

Dear Ms. Nessler,

I am writing on behalf of the Pharmaceutical Research and Manufacturers of America (“PhRMA”) to convey the views of PhRMA’s members in response to the notice on “Changes to Implement the Supplemental Examination Provisions of the Leahy-Smith America Invents Act and To Revise Reexamination Fees,” 77 Fed. Reg. 3666 [Docket No.: PTO-P-2011-0075]. PhRMA’s members are leading pharmaceutical research and biotechnology companies devoted to researching and developing new medicines to allow patients to live longer, healthier and more productive lives. PhRMA’s members lead the way in finding cures and new treatments as well as in developing critically important improvements in existing therapies. Patent protection is an important incentive to promote the innovative research necessary for such advances and to make available to society the benefits of that research.

The enclosed comments include views of PhRMA’s members on the subject matter discussed in the notice. PhRMA’s members appreciate the PTO seeking comments in the area, and would welcome further dialogue with the PTO on the issue.

Please feel free to contact me if you have any questions.

Sincerely,

A handwritten signature in black ink that reads 'David E. Korn'. The signature is written in a cursive, flowing style.

David E. Korn

Enclosure

Pharmaceutical Research and Manufacturers of America

Comments of the Pharmaceutical Research and Manufacturers of America in Response to the PTO's Request for Comments on Changes to Implement the Supplemental Examination Provisions of the Leahy-Smith America Invents Act and To Revise Reexamination Fees

The Pharmaceutical Research and Manufacturers of America (“PhRMA”) appreciates the opportunity to submit comments in response to the Patent and Trademark Office’s (“PTO” or “Office”) Request for Comments on Changes to Implement the Supplemental Examination Provisions of the Leahy-Smith America Invents Act and to Revise Reexamination Fees.^{1/}

PhRMA’s member companies are leading research-based pharmaceutical innovators devoted to developing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA’s membership ranges in size from small emerging companies to multi-national corporations that employ tens of thousands of Americans, and encompass both research-based pharmaceutical and biotechnology companies. A recent study by the Battelle Technology Partnership Practice reports that the U.S. biopharmaceutical sector supported a total of 4 million jobs throughout the economy, and directly employed more than 674,000 Americans in high-quality jobs that pay more than two times the average for U.S. private sector wages in 2009.^{2/} The industry’s direct economic output in 2009 was \$382.4 billion.^{3/}

Consistent with the Congressional Budget Office’s finding that the pharmaceutical sector is one of the nation’s most research-intensive sectors,^{4/} PhRMA member investment in discovering and developing new medicines reached nearly \$50 billion in 2010.^{5/} Medicines developed by the sector have produced large improvements in health across a broad range of diseases, with the rapid growth of biological knowledge creating growing opportunities for continued profound advances against our most complex and costly diseases. Developing a new medicine takes between 10 and 15 years of work and costs an average of over \$1 billion of investment in research and development.^{6/} Like innovators across the spectrum of American industries, pharmaceutical companies make the substantial R&D investments that yield new medicines in reliance on a legal regime that provides protection for any resulting intellectual property. Our companies rely on patents to protect their inventions and provide an opportunity

^{1/} 77 Fed. Reg. 3666-3681 (Jan. 25, 2012).

^{2/} Battelle Technology Partnership Practice, *The U.S. Biopharmaceuticals Sector: Economic Contribution to the Nation*, BATTLE (Washington, DC), July 2011, at 5, 8.

^{3/} *Id.* at 6.

^{4/} A CBO Study: Research and Development in the Pharmaceutical Industry, Pub. No. 2589, Cong. Budget Office, at 9 (Oct. 2006), *available at* <http://www.cbo.gov/ftpdocs/76xx/doc7615/10-02-DrugR-D.pdf>.

^{5/} PhRMA Annual Membership Survey, 2010.

^{6/} Joseph A. DiMasi and Henry G. Grabowski. *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 *MANAGERIAL & DECISION ECON.* 467-79, 470 (2007); *Drug Discovery and Development: Understanding the R&D Process*, INNOVATION.ORG (PhRMA, Washington, DC), Feb. 2007, at 1-2.

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to recover their research investments. But patents are particularly important to pharmaceutical innovation given the research-intensive nature of this sector and the substantial investment required to discover and develop products that meet FDA approval requirements.^{7/}

Bringing new life-saving and life-improving products to people is the central role of our member companies. Because intellectual property is critical to carrying out this mission, PhRMA members particularly appreciate the efforts of Congress and the PTO to improve patent quality. PhRMA member companies welcomed the provisions of the Leahy-Smith America Invents Act (the “AIA”) introducing supplemental examination. Congress created the new supplemental examination procedure to improve patent quality by encouraging disclosure to the PTO of information bearing on issued patents:

[T]his bill also contains a very important new administrative proceeding available to patent owners, to help improve the quality of issued patents. This new “Supplemental Examination” procedure *encourages the voluntary and proactive disclosure of information that may be relevant to patent prosecution* for the Office to consider, reconsider, or correct. The voluntary disclosure by patentees serves to strengthen valid patents, while narrowing or eliminating patents or claims that should not have been issued. Both of these outcomes promote investment in innovation by removing uncertainty about the scope, validity or enforceability of patents, and thus the use of this new proceeding by patent owners is to be encouraged. ...

Supplemental Examination has the potential to play a powerful role in improving patent quality and boosting investment in innovation, economic growth, and job creation. *The Director should implement this new authority in a way that maximizes this potential.*

157 CONG. REC. E1182-01, at *1182 (daily ed. June 23, 2011) (statement of Rep. Smith) (emphasis added).

Unfortunately, in a number of important respects the PTO’s proposed rules fall short of this important mission. We urge the PTO to revise its rules so as to maximize the potential of the new supplemental examination proceeding to improve the quality of issued patents.

^{7/} See Claude Barfield & John E. Calfee, *Biotechnology and the Patent System: Balancing Innovation and Property Rights*, at 1-2 (AEI PRESS 2007). (“Without patent protection, potential investors would see little prospect of profits sufficient to recoup their investments and offset the accompanying financial risk.”); Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MGMT. SCI. 2, at 174-75, T.1 (Feb. 1986) at 173-181 (estimating that without patent protection, 65% of pharmaceutical products would never have been brought to market, while the average across all other industries was a mere 8%); see generally Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 J. OF INT’L ECONOMIC L. 849 (2002).

I. The PTO's Proposed Implementation of the Supplemental Examination Provisions Should Be Revised To Maximize the Potential To Improve the Quality of Issued Patents.

The AIA created a new administrative proceeding called supplemental examination^{8/} to help improve the quality of issued patents.^{9/} This proceeding allows patentees to request that the PTO consider, reconsider, or correct information believed to be relevant to a patent. Congress included a number of provisions designed to encourage patent owners to make use of supplemental examination. For example, Congress made clear that, if certain requirements are met, the information disclosed to the PTO cannot later be used against the patentee as part of a defense to infringement based on inequitable conduct.

Unfortunately, the PTO's proposed rules run against Congressional intent to maximize the utility of the supplemental examination proceeding in the areas of:

- Who may file a request for and participate in a supplemental examination;
- The required contents of the request for supplemental examination; and
- PTO interviews during the supplemental examination.

We urge that the PTO modify the proposed rules so that those rules faithfully carry out the Congressional intent for supplemental examination.

A. The PTO's Proposed Rules Are Too Onerous as to the Contents of a Supplemental Examination Request.

Congress intended to create a proceeding that would provide patent owners with the opportunity to correct errors or omissions in the original prosecution of the patent:

The America Invents Act provides a solution to [the inability under current law to resolve uncertainties regarding whether an aspect of prosecution was, in fact, inequitable conduct] by authorizing supplemental examination of patents. This new proceeding will allow inventors or patent purchasers to return to the Patent Office with additional material and have the Patent Office reevaluate the patent in light of that material. If the patent is invalid in light of the new material, the Patent Office will cancel the claims. But if the office finds that the patent is valid, the parties will have a patent that they can be legally certain will be upheld and enforced. The authorization of supplemental examination will result in path-

^{8/} Leahy-Smith America Invents Act, Pub. L. No. 112-29, sec. 12(a), 125 Stat. 284, 325-27 (2011) (to be codified at 35 U.S.C. § 257(a)-(f)).

^{9/} 157 CONG. REC. E1182-01, at *1182 (daily ed. June 23, 2011) (statement of Rep. Smith).

breaking inventions being developed and brought to market that otherwise would have lingered on the shelf because of legal uncertainty over the patent.

157 CONG. REC. S5319-03, at *S5319 (daily ed. Sept. 6, 2011) (statement of Sen. Kyl).

Unfortunately, the PTO has proposed rules that are extremely onerous and present many potential pitfalls for patentees, thereby undermining Congress' intent to maximize the supplemental examination proceeding to promote patent quality.

1. The Allowable Number of Items of Information for Review in Supplemental Examination is Too Limited.

The PTO's proposed Rule § 1.605(a) states that each request for supplemental examination may request consideration, reconsideration or correction of "no more than ten items of information believed to be relevant to the patent."^{10/} However, as with regular examination, reexamination, and reissue, the supplemental examination statute does not limit examination to a certain number of items. Therefore, the PTO's proposed rule conflicts with the plain language of the statute and its intent.

Addressing complex issues of patentability could easily require more than ten items of information to be considered. Compliance with the duty of disclosure may also require submission of more than ten items of information.^{11/} Although the proposed rule permits "[m]ore than one request for supplemental examination of the same patent [to] be filed at any time,"^{12/} multiple supplemental examination proceedings will not solve the problem if a single issue requires consideration of more than ten items of information. Also, consolidating issues into a single supplemental examination would be more efficient than conducting multiple concurrent or sequential proceedings. Furthermore, the submission of an eleventh item would result in the payment of the full fee for an entirely new request, which may have the unintended consequence of encouraging patent owners to limit information they present for review.

^{10/} 77 Fed. Reg. at 3679 (to be codified at 37 C.F.R. § 1.605(a)).

^{11/} In order to fulfill the duty of disclosure under 37 C.F.R. § 1.56, patentees are required to disclose many different categories of information such as articles (even if not prior art), sales demonstrations, clinical trial data, documents from ongoing litigations, information regarding co-pending U.S. applications, and documents cited by foreign patent offices. See Manual of Patent Examining Procedure § 2001.06 (8th ed. 2001) (Rev. 8, July 2010); see also *Avid Identification Sys., Inc. v. Crystal Import Corp.*, 603 F.3d 967, 973 (Fed. Cir. 2010), *Bayer Schering Pharma AG v. Barr Labs., Inc.*, Civ. A. No. 05-cv-2308 (PGS), 2008 WL 628592, at *46 (D.N.J. Mar. 3, 2008) (unpublished), *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1234 (Fed. Cir. 2003), *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1258-59 (Fed. Cir. 1997). Therefore, the number of items related to a single issue could easily exceed ten.

^{12/} 77 Fed. Reg. at 3679 (to be codified at 37 C.F.R. § 1.605(a)).

The statutory language of the AIA places no limits on the amount or type of information to be considered, reconsidered or corrected during a supplemental examination or reexamination ordered.^{13/} Absent clear statutory language to the contrary, the PTO's supplemental examination process and applicable regulations should mirror typical examination of a patent application in which there are no limits to the type or amount of information that may be presented to the PTO. The limited number of items of information and the scheme of having to request multiple supplemental examination proceedings, if more than ten items of information need to be considered, is contrary to the clear language of the AIA and Congressional intent that this is a "procedure [which] encourages the voluntary and proactive disclosure of information that may be relevant to patent prosecution for the Office to consider, reconsider, or correct."^{14/}

2. The Required Elements of the Request for Supplemental Examination Place Undue Burden on the Requestor.

The PTO's proposed Rules §§ 1.610(b)(4), (6)-(8) require the patent owner to "explain[] why consideration of the item of information is being requested,"^{15/} to identify "each aspect of the patent for which supplemental examination is sought,"^{16/} to identify "each issue raised by each item of information,"^{17/} and to provide 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."^{18/} The PTO indicated that it generally will limit its review to those matters identified by the owner.^{19/}

The detailed content requirement of the request undermines and conflicts with the language and intent of the AIA. As explained above, the statutory language places no limits on the amount or type of information to be considered, reconsidered or corrected. The proposed rules in essence shift the burden of supplemental examination onto the patent owner, who bears a significant risk of being wrong. Under the proposed rules, the patent owner is required to identify specific portions of documents to be examined,^{20/} and the specific statutory basis for patentability under which this information should be reviewed.^{21/} If the patent owner does not recognize or does not sufficiently raise a potential issue, the implication is that the patent will not be fully examined nor immunized against a subsequent inequitable conduct allegation on that issue. This is in contrast with regular examination, in which the PTO bears the burden of

^{13/} Leahy-Smith America Invents Act, Pub. L. No. 112-29, sec. 12(a), 125 Stat. 284, 325 (2011) (to be codified at 35 U.S.C. § 257(a)).

^{14/} 157 CONG. REC. E1182-01, at *1182 (daily ed. June 23, 2011) (statement of Rep. Smith).

^{15/} 77 Fed. Reg. at 3679 (to be codified at 37 C.F.R. § 1.610(b)(4)(i)).

^{16/} *Id.* (to be codified at 37 C.F.R. § 1.610(b)(6)).

^{17/} *Id.* (to be codified at 37 C.F.R. § 1.610(b)(7)).

^{18/} *Id.* (to be codified at 37 C.F.R. § 1.610(b)(8)).

^{19/} 77 Fed. Reg. at 3672.

^{20/} *Id.* at 3667, 3671.

^{21/} *Id.* at 3670-71.

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conducting a complete examination -- at much lower cost than supplemental examination. When the PTO considers an item of information during regular examination, it is presumed to have fully considered that item and all issues potentially raised by the item. Under the proposed rules, the patent owner also bears a risk of creating fodder for future inequitable conduct charges -- charges that the owner failed to raise an issue or mischaracterized an issue (even if such actions were unintentional). This result would be inconsistent with Congress' intent of implementing supplemental examination in order to reduce the plague of inequitable conduct challenges^{22/} and could also provide disincentives to using the procedure.

Consistent with Congressional intent, each new item of information presented for the first time should be fully considered and a full examination based on those items should be conducted by the PTO. For items of information that are being reconsidered or corrected in supplemental examination, it may be appropriate for the PTO to limit the review to the specific items being reconsidered or corrected, but the PTO should conduct a full examination based on this request.

The requirements for receiving a supplemental examination filing date are also problematic and could discourage use of the process. According to proposed Rules §§ 1.610(d) and (e), the supplemental examination request will not be granted a filing date until the PTO deems the request as having fulfilled the detailed and onerous requirements set forth in the proposed regulations.^{23/} Therefore, a patentee could submit a request in which the details of the issues to be considered are clearly laid out; however, if the PTO determines that the request does not satisfy all of its requirements (*e.g.*, if a foreign document is submitted without a translation), the patentee will not receive a supplemental examination filing date until a corrected request is received. Since supplemental examination is a new process, it is very likely that a misinterpretation of the rules could result in a request being deemed deficient. If the initial request is publicly available (which is not clear from the proposed regulations), an alleged infringer could see the detailed request and craft an inequitable conduct charge that could be pled in a civil action or set forth in a Paragraph IV notice letter before the patentee files a corrected request. This could serve as a trap to patentees and would provide a further disincentive to using the supplemental examination process.

In order to avoid this problem and encourage use of the supplemental examination process, the PTO could clarify that a supplemental examination request does not become publicly available until a filing date is accorded. Alternatively, the PTO could accord a filing date to a supplemental examination request, contingent upon the requirements being fulfilled within a set, non-extendible period of time (along with the payment of a fee), as is done when a patent application is filed without an oath or declaration and the PTO mails a Notice to File Missing Parts. In this scenario, the supplemental examination request would be accorded its original filing date as long as the requirements of such a request are subsequently fulfilled within a set amount of time. Given the importance of the timing of supplemental examination to the ability of an alleged infringer to use information against the patentee as part of an inequitable

^{22/} H.R. Rep. No. 112-98, at 50 (2011).

^{23/} 77 Fed. Reg. at 3680 (to be codified at 37 C.F.R. §§ 1.610(d) and (e)).

conduct claim, it is reasonable (and only fair) that a patentee not be penalized if he has attempted to utilize the supplemental examination process.

B. The PTO's Proposed Rules Too Narrowly Limit Who May Request and Participate in Supplemental Examination.

Section 12(a) of the AIA 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, in accordance with such requirements as the Director may establish."^{24/} The PTO's proposed Rule § 1.601(a) narrowly construes who is "a patent owner" under the statute and states that "owner(s) of the entire right, title and interest in the patent" may request supplemental examination of a patent.^{25/} Similarly, proposed Rule § 1.601(c) states that "[a]ny party other than the patent owner . . . is prohibited from . . . participating in any manner in a supplemental examination proceeding."^{26/}

Under these proposed rules, it appears that a supplemental examination may only be requested by all the owners of the patent. This appears to limit the ability of a co-owner of a partial interest or an exclusive licensee to request a supplemental examination when an owner unreasonably withholds support for the request or is unavailable. The rights of co-owners or exclusive licensees should not be undermined by unreasonable or unavailable co-owners or owners. Also, under the proposed rules, exclusive licensees of a patent may not request or participate in supplemental examination even though they have a significant legal interest in the patent including, in many cases, the ability to enforce the patent.

The AIA states clearly that "*a patent owner*" may request a supplemental examination.^{27/} The statute does not provide or suggest that a request must be made by a patent owner of the entire interest. Had Congress intended to limit the right to request a supplemental examination to patent owner(s) of the entire interest, Congress could have specified this in the statute, as it has done in other contexts. For example, in the context of reissue applications, an "application for reissue may be made and sworn to by the *assignee of the entire interest . . .*"^{28/} In addition, in the context of patent application filings, in cases where a joint inventor is unwilling or unavailable to join in a patent application, 35 U.S.C. § 116(b) permits a joint inventor to file the patent application on behalf of himself and the other inventor.^{29/}

Permitting a co-assignee or any other person with "sufficient proprietary interest," such as an exclusive licensee, to seek supplemental examination is consistent with the AIA

^{24/} Leahy-Smith America Invents Act, Pub. L. No. 112-29, sec. 12(a), 125 Stat. 284, 325 (2011) (to be codified at 35 U.S.C. § 257(a)).

^{25/} 77 Fed. Reg. at 3679 (to be codified at 37 C.F.R. § 1.601(a)).

^{26/} *Id.* (to be codified at 37 C.F.R. § 1.601(c)).

^{27/} Leahy-Smith America Invents Act, Pub. L. No. 112-29, sec. 12(a), 125 Stat. 284, 325 (2011) (to be codified at 35 U.S.C. § 257(a)) (emphasis added).

^{28/} 35 U.S.C. § 251 (emphasis added).

^{29/} 35 U.S.C. § 116(b).

amendments to Section 118. Revised Section 118 allows an assignee, and any person with “sufficient proprietary interest,” to file a patent application upon “proof of the pertinent facts and a showing that such action is appropriate to preserve the rights of the parties.”^{30/} If an assignee or any person with “sufficient proprietary interest,” can apply for a patent, there is no reason not to allow the same assignee to also seek a supplemental examination. A similar approach with regard to supplemental examination would permit co-owners or exclusive licensees to request supplemental examination, which would support the public interest in improving patent quality, consistent with the Congressional intent.

Alternatively, exclusive licensees could be allowed to file and participate in supplemental examinations in circumstances in which the patent owner has, by contract, given control of the prosecution of the application to the licensee. In those circumstances the patent owner has effectively appointed the licensee its agent for dealing with PTO matters and the licensee should, therefore, be allowed to file and participate in supplemental examination. This would be akin to an exclusive licensee’s ability to enforce a patent when the license agreement transfers such rights to the licensee.^{31/}

C. The PTO Should Permit Interviews during the Supplemental Examination.

The PTO’s proposed Rule § 1.620(e) prohibits interviews in a supplemental examination proceeding. This is not based on sound policy because examiner interviews play a critical role in fostering patent quality. Interviews facilitate constructive dialogue between the Examiner and the applicant, thereby aiding in the understanding and resolution of the relevant issues in a more efficient manner.

PhRMA believes that, in order to facilitate the PTO’s compliance with the statutory mandate to complete supplemental examination within three months,^{32/} the Office should permit interviews, if not as a matter of right, then at least at the Examiner’s discretion.

II. Conclusion

PhRMA appreciates the PTO’s efforts to implement the AIA and the opportunity to offer its perspective on the PTO’s proposals. PhRMA and its member companies are committed to helping the PTO find solutions to the many challenges it faces today and in the years to come.

^{30/} Leahy-Smith America Invents Act, Pub. L. No. 112-29, sec. 4(b), 35 U.S.C. § 118, 125 Stat. 284, 296-97 (2011) (to be codified at 35 U.S.C. § 118).

^{31/} See *ASM America, Inc. v. Genus, Inc.*, 401 F.3d 1340, 1341 (Fed. Cir. 2005); see also *Adelberg Laboratories, Inc. v. Miles, Inc.*, 921 F.2d 1267, 1269 (Fed. Cir. 1990). Similar to the AIA’s provisions on supplemental examination, which refers to a “patent owner,” 35 U.S.C. § 281 provides that “A patentee shall have remedy by civil action for infringement of his patent.”

^{32/} Leahy-Smith America Invents Act, Pub. L. No. 112-29, sec. 12(a), 125 Stat. 284, 325 (2011) (to be codified at 35 U.S.C. § 257(a)).