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PhRMA

March 5, 2012

VIA EMAIL: OED__SOL@uspto.gov

Mail Stop OED_Ethics Rules
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Attention: William R. Covey, Deputy General Counsel for Enrollment and Discipline and Director of the Office of Enrollment and Discipline

Dear Mr. Covey,

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 "Implementation of Statute of Limitations Provisions for Office Disciplinary Proceedings," 77 Fed. Reg. 457 [Docket No.: PTO-C-2011-0089]. 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,

David E. Korn

Enclosure

Comments of the Pharmaceutical Research and Manufacturers of America
Docket No: PTO-C-2011-0089
March 5, 2012

Comments of the Pharmaceutical Research and Manufacturers of America in Response to the PTO's Request for Comments on the Implementation of Statute of Limitations Provisions for Office Disciplinary Proceedings

The Pharmaceutical Research and Manufacturers of America ("PhRMA") appreciates the opportunity to submit comments in connection with the Patent and Trademark Office ("PTO" or "Office") Request for Comments on the Implementation of Statute of Limitations Provisions for Office Disciplinary Proceedings.[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 to recover their research investments. But patents are particularly important to pharmaceutical

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1/ 77 Fed. Reg. 457-61 (Jan. 5, 2012).

2/ Battelle Technology Partnership Practice, *The U.S. Biopharmaceuticals Sector: Economic Contribution to the Nation*, BATTELLE (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.

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 the PTO to uphold the integrity of the patent prosecution process. Many of PhRMA's member companies employ in-house attorneys and/or agents who work to prepare, file, and prosecute patent applications to protect intellectual property. As registered PTO attorneys or agents, these practitioners have demonstrated that they are of good moral character and possess the necessary qualifications to render valuable service, advice, and assistance in the presentation and prosecution of applications before the Office. PhRMA member companies and their attorneys/agents spend significant time and effort ensuring compliance with the PTO Rules of Ethics and Professionalism.[8/] PhRMA member companies and their attorneys/agents respect and rely on the PTO's prompt resolution of alleged misconduct through disciplinary proceedings to ensure the integrity of and respect for the Office.

In our view, the PTO's proposed rulemaking departs inappropriately and unnecessarily from the clear language of the Leahy-Smith America Invents Act (the "AIA"), which requires the commencement of disciplinary proceeding not later than one year after the date on which the alleged misconduct is "made known to an officer or employee of the Office."[9/] The PTO's principal stated rationale for in effect extending the one-year period specified by the statute is its need for a thorough investigation of the underlying conduct and fair consideration of the practitioner's defense. However, this concern can be addressed through tolling agreements between the PTO and the practitioner to extend the statute of limitations to allow for further investigation or consideration of issues as needed. Such an approach would allow the PTO to satisfy the statutory requirement that the one-year statute of limitations must commence once the misconduct forming the basis for the proceeding is made known to an officer or employee of the PTO, while at the same time permit the PTO to negotiate for more time as needed on a case-by-case basis. This approach also would help to ensure notice and fairness to the practitioner, and at the same time promote prompt resolution of an office disciplinary proceeding, upholding the integrity of the Office.

7/ *See* Claude Barfield and John Calfee. *Biotechnology and the Patent System: Balancing Innovation and Property Rights*, AEI PRESS, at 1-2 (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).

8/ These PTO rules can be found at 73 Fed. Reg. 47650-704 (effective Sept. 15, 2008).

9/ Leahy-Smith America Invents Act, Public Law No. 112-29, § 3(k)(1) (signed Sept. 16, 2011).

I. The PTO's Proposed Implementation of Statute of Limitations Provisions for Office Disciplinary Proceedings Is Not Consistent With The Plain Language of the Statute.

The PTO has requested comments on its proposed Implementation of Statute of Limitations Provisions for Office Disciplinary Proceedings, which, according to the PTO, is intended to "clarify[] when misconduct forming the basis for a disciplinary proceeding is made known to the Office."[10/] The PTO proposed that the one-year statute of limitations should commence as follows:

> (1) With respect to complaints under Section 11.32 predicated on the receipt of a probable cause determination from the Committee on Discipline, the date on which the Director, Office of Enrollment and Discipline ("OED Director") receives from the practitioner a complete, written response to a request for information and evidence;
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> (2) With respect to complaints under Section 11.24 based on reciprocal discipline, the date on which the OED Director receives a certified copy of the record or order regarding the practitioner being publicly censured, publicly reprimanded, subjected to probation, disbarred, suspended, or disciplinarily disqualified; and,
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> (3) With respect to complaints under Section 11.25 for interim suspension based on a serious crime conviction, the date on which the OED Director receives a certified copy of the record, docket entry, or judgment demonstrating that the practitioner has been convicted of a serious crime.[11/]

This proposed regulation represents a significant departure from the statutory mandate that the statute of limitations begins to run from when the conduct "is made known to an officer or employee of the Office." Instead, the PTO would have the statute of limitations run only when the misconduct is made known to the "OED Director" through carefully prescribed avenues. Specifically, the statute of limitations would be triggered only on (1) the date on which the OED Director receives a written response to a request for information from a practitioner for complaints under Section 11.32, or (2) when the OED Director receives a certified copy of the record providing the basis of reciprocal discipline (complaints under Section 11.24) or interim suspension based on conviction for a serious crime (complaints under Section 11.25). These additional requirements have the effect of delaying the statute of limitations expressly prescribed by Congress.

The PTO's proffered interpretation, which imputes knowledge to the Office only after the OED reaches a particular part of the investigative process, is not consistent with the statute. Nothing in 35 U.S.C. §§ 32 or 2(b)(2)(D) indicates such a narrow construction intended by Congress. And 35 U.S.C. § 3, the Patent Act provision governing "Officers and Employees,"

10/ 77 Fed. Reg. at 457.

11/ *Id*. at 457, 461.

indicates that Congress did not intend for such a narrow reading. Section 3 expressly defines such "officers and employees of the Office" more broadly than the "OED Director." Indeed, Section 3 identifies "officers and employees of the Office" as the Deputy Under Secretary and Deputy Director, Commissioners, employees such as attorneys, and agents of the Office.

The plain language of Congress's amendment to Section 32 indicates that once a responsible officer or employee of the PTO under Section 3 (*i.e.*, PTO Director, Commissioner, attorney or patent examiner) becomes aware of the potentially offending conduct, the Office has one year from that date to commence a disciplinary proceeding. This clearly expressed intent is consistent with Congress's and the PTO's interest of providing fairness to the practitioners and ensuring integrity of the process. In its current form, however, the PTO's proposed rule has the dual effect of allowing practitioners engaged in misconduct to continue their practice before the PTO and allowing a PTO officer or employee to ignore evidence of misconduct for an unspecified period of time before taking any action that would trigger the commencement of the one-year statute of limitations. Such results contravene Congress's intent that the one-year statute of limitations begins to run once the conduct forming the basis of a disciplinary proceeding is made known to an officer or employee of the PTO. These results also contravene the rationale for statutes of limitations in that a PTO officer or employee could ignore evidence of misconduct while memories fade and evidence disappears.

The plain language of the statute requires the proceeding to commence "not later than the earlier of either the date that is 10 years after the date on which the misconduct forming the basis for the proceeding occurred, or 1 year after the date on which the misconduct forming the basis for the proceeding is made known to an officer or employee of the Office as prescribed in the regulations established under section 2(b)(2)(D)."[12/] Congress's approach reflects careful balancing between the need to expand the time for allowing a disciplinary proceeding from five to ten years when the potential misconduct is not known, while at the same time limiting to one-year the time for initiating a disciplinary proceeding once the potential misconduct is known by a responsible PTO officer or employee.

The PTO's proposal to commence the one-year statute of limitations only after the OED Director receives a written response from the practitioner for complaints under Section 11.32 or a certified copy of the alleged misconduct under Sections 11.24 and 11.25 upends the second half of the balance. It circumvents the one-year statute of limitations by delaying the time the clock begins to run until after certain specified actions are taken by the OED Director. Further, the proposed rule creates perverse incentives to delay investigation and disciplinary action once alleged misconduct is made known to the Office. The narrowness of the PTO's proposed interpretation is extreme: (1) it is not sufficient for a patent examiner or other responsible employee of the PTO to have clear evidence of misconduct to trigger the statute of limitations; and (2) it is not sufficient even for the OED Director to have clear evidence of misconduct to trigger the statute of limitations. Rather, under the PTO's proposed rules, only if the OED has achieved specific, internal administrative guideposts that only the OED controls – namely, the timetable for requesting a certified copy of certain records from another jurisdiction or

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12/ Leahy-Smith America Invents Act, § 3(k)(1).

requesting a specific written response to allegations from the practitioner – is the statute of limitations triggered. The point of statutes of limitations is to ensure timely resolution of allegations, and that goal is not served if the agency can drive the timetable for invoking it.

Congress clearly recognized the balance it struck may preclude disciplinary proceedings in certain cases. Congress included a new sub-paragraph requiring the PTO Director to report to Congress every two years the incidents of misconduct of which the Office becomes aware and would have investigated but for the statute's prohibition of a proceeding commencing the shorter of the 10 years from the date the misconduct occurred or one year from the date on which the misconduct was made known to a PTO officer or employee.[13/] This new required report reflects Congress's understanding that the new statute of limitations may have the effect of barring certain disciplinary proceedings. The PTO's required report could allow Congress to consider whether further amendments of the statute are necessary. Such a future policy choice should remain in the legislative domain of Congress.

Based on the plain language of the statute, the one-year statute of limitations for these proceedings should commence when any officer or employee of the PTO who is empowered to act learns of the potential misconduct. This satisfies the "goal of commencing section 32 proceedings without undue delay,"[14/] while at the same time promoting the basic notions of fairness to the practitioner and integrity of the process.

II. Implementing the Statute of Limitations Provisions for Office Disciplinary Proceedings Based on the Clear and Unambiguous Statutory Language.

The PTO's principal rationale for its interpretation of the statute is the need for a thorough and fair investigation before commencing a disciplinary proceeding.[15/] PhRMA agrees with these goals but believes they can be served while also following Congress's clear statutory directive.

PhRMA member companies understand the PTO's OED Director takes four steps before filing a Section 11.32 disciplinary complaint against a practitioner.[16/] In cases where time beyond the one-year trigger is needed to allow the PTO to complete its process, the PTO can, on a case-by-case basis, rely on agreements between the PTO and the practitioner to toll the statute. Other agencies successfully rely on tolling agreements for these purposes,[17/] and there is no

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13/ Leahy-Smith America Invents Act, § 3(k)(2).

14/ 77 Fed. Reg. at 458.

15/ *Id*. at 459 ("Under the proposed regulation, the OED Director is able to continue to afford a practitioner a reasonable period of time [through extensions] to address allegations of ethical violations because the limitation period would not commence until after the practitioner provides a complete, written response."); *id.* ("The proposed regulation reflects that a complete response to [a request for information relating to the conduct] usually is a significant step in making a practitioner's misconduct known to the OED Director in an informed and meaningful way.").

16/ *Id*. at 458.

17/ *See, e.g.*, 24 C.F.R. § 28.35(b) (Department of Housing and Urban Development authorizes tolling agreements during civil fraud investigations); 33 C.F.R. § 326.3(e)(v)

reason tolling agreements would not serve the PTO as well. Where additional time is necessary, a tolling agreement could enable the OED Director to "afford a practitioner a reasonable period of time to address allegations of ethical violations" levied against him or her without fear of encouraging dilatory responses or other tactical delays by practitioners.[18/]

Tolling agreements also can be used to address additional time that may be needed for commencing reciprocal disciplinary complaints under Section 11.24 and complaints for interim suspension predicated upon conviction of a serious crime under Section 11.25. In its proposed rulemaking, the PTO explained that the OED has a "practice to request a certified copy of the requisite records within 60 calendar days of receiving information suggesting that a practitioner has been disciplined by another authority or has been convicted of a serious crime."[19/] During that same time period, the OED "contact[s] the practitioner" to "provid[e] the practitioner an opportunity to explain whether he or she is the same person who was disciplined by another licensing authority or convicted of a serious crime."[20/] As a result, for complaints under Sections 11.24 and 11.25, the PTO can enter into an agreement if necessary to toll the statute of limitations for commencing a disciplinary hearing from the time it notifies the practitioner of its pending investigation until the investigation is complete.

III. Conclusion

PhRMA appreciates the opportunity to comment on the PTO's proposed implementation of regulations concerning the statute of limitations for Office disciplinary proceedings. PhRMA respectfully submits that the Office should revise its interpretation to heed the plain language of the statute, which requires the commencement of disciplinary proceedings no later than one year after a responsible officer or employee of the PTO under Section 3 (*i.e.*, PTO Director, a Commissioner, attorney or patent examiner) becomes aware of the offending conduct. It is in the interest of the Office, PTO practitioners, and the public to ensure prompt disciplinary action for any purported misconduct before the Office. If necessary, negotiation of a tolling agreement on a case-by-case basis after notice of a pending investigation would allow the OED to conduct further investigation as needed and file a disciplinary proceeding outside the one-year period.

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.

(Department of the Army Corps of Engineers permits tolling agreements during investigations of unauthorized activities); Enforcement Manual, Securities & Exchange Comm'n, Division of Enforcement, pp.46-49 (Aug. 2, 2011), *available at* www.sec.gov/divisions/enforce/enforcementmanual.pdf (sample Securities and Exchange Commission tolling agreements).

[18/] 77 Fed. Reg. at 459.

[19/] *Id*.

[20/] *Id*. at 459-50.