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March 6, 2012

VIA EMAIL: oath_declaration@uspto.gov

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

Attention: Hiram H. Bernstein, Senior Legal Advisor, Office of Patent Legal Administration

Dear Mr. Bernstein,

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 Inventor's Oath or Declaration Provisions of the Leahy-Smith America Invents Act," 77 Fed. Reg. 982 [Docket No.: PTO-P-2011-0074]. 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-P-2011-0074
March 6, 2012

Comments of the Pharmaceutical Research and Manufacturers of America in Response to the PTO's Request for Comments on Changes to Implement the Inventor's Oath or Declaration Provisions of the Leahy-Smith America Invents Act

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 Changes to Implement the Inventor's Oath or Declaration Provisions of the Leahy-Smith America Invents Act.[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. 982-1002 (Jan. 6, 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 improve the patent prosecution process and simplify the oath and declaration process.

Modern pharmaceutical research is often conducted as a team effort, on a global basis. The massive funding needed to undertake such research often requires funding by a global assignee. PhRMA companies are able to file in the name of the assignee around the world. The U.S. is an outlier in this regard. This is why PhRMA member companies welcomed the provisions of the Leahy-Smith America Invents Act (the "AIA") on simplifying the oath and declaration process and allowing assignee filing. However, in our view, the PTO's proposed rulemaking departs from the clear language of the AIA, which is aimed at allowing greater flexibility for applicants.

I. The PTO's Proposed Implementation of the Inventor's Oath or Declaration Provisions Is Not Consistent with the Intent of the AIA.

The AIA represents a sea change in patent law. It renders the patent law simpler, more transparent, more objective, and more predictable. Among the many reforms were changes to the law concerning applicable prior art and the handling of validity challenges.

Simplifying the oath or declaration provisions and facilitating assignee filings were also clearly part of the Congressional intent to modernize the patent process. The United States for many years has been an outlier with its requirement for filing patent applications in the name of the inventor only. We are not aware of any other Patent Cooperation Treaty ("PCT")[8/] member country that does not permit filing in the name of the assignee. As part of the sweeping reform enacted in the AIA, Congress clearly intended that, while it remained a requirement to name the inventor, filing of the patent application by the assignee will now be permitted. In addition, the AIA is clear that, while the naming of the inventors early in the patent process remains important

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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/ World Intellectual Property Organization, Patent Cooperation Treaty, June 19, 1970, amended Oct. 3, 2001, *available at* http://www.wipo.int/pct/en/texts/articles/atoc.htm.

in determining patentability, submission of an inventor's oath or declaration or substitute statement need only occur prior to the issuance of a Notice of Allowance.[9/]

Assignee filing, as practiced throughout the world recognizes the realities of modern innovative research. The beneficial owner of the technology is responsible for applying for the patent, while the inventor is recognized in the application. The clear intent of the AIA is to facilitate assignee filing in the United States, consistent with the practice in the rest of the world.

Unfortunately, the PTO's proposed rules are contrary to the intent of Congress in the areas of:

- Who may file the application
- The content of the oath or declaration or substitute statement
- The timing of filing of the oath or declaration or substitute statement

We urge that the PTO modify the proposed rules so that those rules faithfully carry out the Congressional intent, comport with the way research is conducted, and are consistent with global norms.

A. The PTO's Rules regarding Who May File an Application Should Be Consistent with the Intent of the AIA.

The intent of Congress to allow assignees to file patent applications is clearly reflected in the statutory changes made by the AIA to 35 U.S.C. §§ 115 and 118.

Prior to the AIA, 35 U.S.C. § 115 required that the ***applicant*** indicate in an oath his belief that he is "***the original and first inventor.***"[10/] Congress deleted that provision in favor of new statutory language noting that the "***application***" should include ***"the name of the inventor***."[11/] Amended Section 115 also states that the inventor needs to execute an oath or declaration with two required statements: (1) that the application was authorized to be made by the affiant or declarant; and (2) that the individual making the statement believes himself or herself to be the original inventor or joint inventor.[12/] These statements need to be made with an acknowledgement of the penalties for false statements.[13/] These statements can be included in the assignment document.[14/]

9/ Leahy-Smith America Invents Act, Pub. L. No. 112-29, sec. 4(a)(1), 35 U.S.C. § 115, 125 Stat. 284, 294 (2011) (to be codified at 35 U.S.C. § 115 (f)).

10/ 35 U.S.C. § 115 (emphasis added).

11/ Leahy-Smith America Invents Act, Pub. L. No. 112-29, sec. 4(a)(1), 35 U.S.C. § 115, 125 Stat. 284, 293 (2011) (to be codified at 35 U.S.C. § 115 (a)) (emphasis added).

12/ *Id.*, 125 Stat. 284, 294 (2011) (to be codified at 35 U.S.C. § 115 (b)).

13/ *Id.*, 125 Stat. 284, 295 (2011) (to be codified at 35 U.S.C. § 115 (i)).

14/ *Id.*, 125 Stat. 284, 294 (2011) (to be codified at 35 U.S.C. § 115 (e)).

Revised 35 U.S.C. § 118 expressly states that "[a] person to whom the inventor has assigned or is under an obligation to assign the invention may make an application for patent."[15/] The provision goes on to note that persons who otherwise show sufficient proprietary interest in the matter may ***also*** make an application on behalf of an inventor.[16/] This new statutory language in Section 118 replaced a provision that had limited such filings to situations where the inventor was unwilling or unavailable to file the application.[17/] By replacing the prior, narrow provision with the broader language, Congress plainly did not intend to ***limit*** the situations in which an assignee of the subject matter could file a patent application to those that existed previously.

Taken together, the amendments to Sections 115 and 118 clearly indicate that Congress intended a simplified process, as exists in most of the patent world, allowing for filing by an assignee who names the inventors. This comports with the legislative history of the AIA. Indeed, as noted in House Judiciary Committee Report 112-98:

> The U.S. patent system, when first adopted in 1790, contemplated that individual inventors would file their own patent applications, or would have a patent practitioner do so on their behalf. It has become increasingly common for patent applications to be assigned to corporate entities, most commonly the employer of the inventor. [Citing studies showing an 85% assignment rate.]…
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> Current law still reflects the antiquated notion that it is the inventor who files the application, not the company-assignee. For example, every inventor must sign an oath as part of the patent application stating that the inventor believes he or she is the true inventor of the invention claimed in the application. By the time an application is eventually filed, however, the applicant filing as an assignee may have difficulty locating and obtaining every inventor's signature for the statutorily required oath. **Although the USPTO has adopted certain regulations to allow filing of an application when the inventor's signature is unobtainable, many have advocated that the statute be modernized to facilitate the filing of applications by assignees.**
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> **The Act updates the patent system by facilitating the process by which an assignee may file and prosecute patent applications.** It provides similar flexibility for a person to whom the inventor is obligated to assign, but has not assigned, rights to the invention (the ''obligated assignee'').

H.R. Rep. No. 112-98, pt. 1, at 43-44 (2011) (emphasis added) (footnotes omitted).

15/ 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).

16/ *Id*.

17/ 35 U.S.C. § 118.

In contrast, the background section of the PTO's Notice of Proposed Rulemaking (the "Notice") states that:

> The changes to 35 U.S.C. 115 and 118 do not mean that a person to whom the inventor has assigned or is under an obligation to assign the invention may make an application for patent in all circumstances.[18/]

This statement is inconsistent with the statutory language of the AIA, as well as the legislative history. There is no exception indicated in amended Section 118 that limits the right of an assignee to file an application in all circumstances. The Notice suggests that an assignee can only file an application when an inventor is unwilling or unavailable to file the application.[19/] However, such an implementation would not be a change from current law[20/] and would render the AIA's amendment to Section 118 moot.

B. The PTO's Rules regarding the Content of the Oath or Declaration Should Be Consistent with the Intent of the AIA.

As noted above, amended 35 U.S.C. § 115 (b) requires two statements to be made in the oath or declaration (or alternatively in the assignment as provided in Section 115 (e)):

1. That the application was made or authorized to be made by the affiant or declarant, and
2. That the individual believes himself or herself to be the original inventor or joint inventor of a claimed invention in the application.[21/]

35 U.S.C. § 115(c) notes that the Director may specify additional requirements for the oath or declaration. The Office has proposed adding requirements for a statement that the person making the oath or declaration has reviewed and understands the application and a statement regarding obligations under current 37 CFR § 1.56.[22/] However, no explanation of the need for these additional statements is provided in the Notice. Indeed, in light of the purpose of the legislative changes, requiring these latter two statements is not warranted. In a patent system in which the vast majority of applications are anticipated to be filed by assignees, the most important statements are that the application was authorized by the named inventor and that the individual believes he or she is an original inventor or co-inventor. The applicant, through a registered practitioner, can handle the concerns embodied in the additional requirements.

18/ 77 Fed. Reg. at 983.

19/ *See id.*

20/ 35 U.S.C. § 118.

21/ Leahy-Smith America Invents Act, Pub. L. No. 112-29, sec. 4(a)(1), 35 U.S.C. § 115, 125 Stat. 284, 294 (2011) (to be codified at 35 U.S.C. § 115(b)).

22/ 77 Fed. Reg. at 990, 1000.

C. The PTO's Rules regarding the Timing of Filing of the Oath or Declaration Should Be Consistent with the Intent of the AIA.

The Office states in the background of the Notice that "the change to 35 U.S.C. 115 does not alter the statutory authorization in 35 U.S.C. 111(a) and 371 for requiring the oath or declaration to be submitted prior to examination of the application."[23/]

However, the statute clearly states that the declaration or oath is only required to be filed before a Notice of Allowance is provided.[24/] Thus, while the statements required by 35 U.S.C. § 115(b), or as put in the assignment, are required to be filed before a Notice of Allowance is provided to the applicant, if the proper inventors are named by a registered patent attorney or agent, the Office can begin examination.

The PTO's Notice indicates that the Office considered allowing later filing of the oath or declaration until the case is in condition for allowance, but "considers it better for the examination process and patent pendency to continue to require the oath or declaration during pre-examination."[25/]

The Office's rationale for requiring an early filing (during pre-examination) of the statements includes the following:

1. The Office needs to know who the inventors are to prepare patent application publications and publish applications at eighteen months. [26/]

2. The Office needs to know the inventors to conduct examination (e.g., to determine what prior art applies, for both current law and prior art effects after the AIA, and for possible double patent rejections.) [27/]

3. Delaying the filing would add to patent application pendency.[28/]

As for the first two concerns, naming of the inventors in the Application Data Sheet ("ADS") by a registered patent attorney or agent acting on behalf of the applicant (assignee) would be sufficient. Indeed, as claims are amended, the registered patent attorney will be in the best position to inform the Office of the proper inventorship. While the Office indicated that, under 37 CFR § 1.41, inventorship in an application is not set until an oath or declaration is filed,[29/] that is not the requirement of the law, but an Office rule. Clearly, in a system with assignee filing, inventorship is set when the applicant names the inventors.

23/ 77 Fed. Reg. at 983 (emphasis added).

24/ Leahy-Smith America Invents Act, Pub. L. No. 112-29, sec. 4(a)(1), 125 Stat. 284, 294 (2011) (to be codified at 35 U.S.C. § 115 (f)).

25/ 77 Fed. Reg. at 984.

26/ *Id.*

27/ *Id.*

28/ *Id.*

29/ *Id.*

As for application pendency, applicants already have incentives to file assignments upon application filing, or shortly thereafter, and preferably prior to PCT filing or national entry for PCT applications.[30/] Thus, if the required statements are included in the assignment, this can be filed well in advance of the Notice of Allowance, thus avoiding any need for correcting formalities after prosecution on the merits is closed (*e.g.*, in response to an *Ex parte Quayle* action).[31/] In addition, the Office has the ability to issue a Notice of Allowance with additional formality requirements with deadlines that do not extend beyond the payment of the issue fee.[32/] Moreover, formality delays in pendency caused by the applicant can be excluded from any patent term adjustment the patent may otherwise receive.[33/] All of these factors provide additional powerful incentives for the applicant to submit the required statements in a timely fashion.

Thus, as long as the inventors are named at the time of filing, there need be no delay in examination or processing of the application.

II. Implementing the Oath and Declaration Provisions Consistent with the Legislative Intent.

We suggest that the Office implement a revised process for the submission of oaths/declarations and filing of applications that is consistent with Congress' intent of simplifying the process and providing more flexibility for applicants. This revised process could include the following elements:

1. An applicant, which in the majority of cases would be an assignee of a claimed invention, could file a patent application with the Office;

2. The inventors would be named on the ADS; and

3. The applicant could provide the Office the required substitute statement or oath or declaration containing two required statements (that the application was made or was authorized to be made by the affiant or declarant; and such individual believes himself or herself to be the original inventor or an original joint inventor

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30/ One incentive arises because, under the law of many European countries, there needs to be a direct chain of title (i.e., an assignment needs to be executed) from all the applicants on the priority application to the applicants named on a subsequent application in order for the priority claim to be valid. *See*, *e.g.*, McNeill R., Murphy A., and Rinne B., "Late-Executed Assignments in PCT Applications Can Impact Rights Across Different Jurisdictions," BNA's World Intellectual Property Report, 25 WIPR 50, Sept. 2011.

31/ 25 U.S.P.Q. 74, 1935 C.D. 11; 453 O.G. 213 (Comm'r Pat. 1935). An *Ex parte Quayle* action is issued by the PTO when prosecution on the merits is closed but formal matters still need to be corrected (i.e., the filing of a new oath). *See* Manual of Patent Examining Procedure §§ 710.02(b), 714.14 (8th ed. 2001) (Rev. 8, July 2010).

32/ *See id.*, § 710.02(e)III.

33/ *See id.*, § 2731-32; *see also* 37 C.F.R. §§ 1.703, 1.704.

of a claimed invention in the application), with an acknowledgement of penalties for making willful false statements. The required statements could also be included in an assignment in lieu of an oath or declaration. This could be filed at any time prior to receiving a Notice of Allowance, and could be submitted well in advance of this event.

4. The Office could then scan the Inventor's statements or assignment containing the statements into the Image File Wrapper ("IFW") system, and a copy of any previously filed statements or assignment would not be required in any later-filed patent application naming an inventor or a joint inventor and claiming benefit to the earlier-filed application under Sections 120, 121, or 365(c).

Thus, we urge the PTO to modify the proposed rules to carry out the legislative intent as described above.

III. 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.