Comments of the Pharmaceutical Research and Manufacturers of America in Response to the PTO's Request for Comments on Matters Related to the Harmonization of Substantive Patent Law (Docket No: PTO-P-2013-0001)

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 Matters Related to the Harmonization of Substantive Patent Law.[1/]

PART I: Information about the Respondent

PhRMA's member companies are leading research-based biopharmaceutical 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 650,000 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 2011.[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/ 78 Fed. Reg. 7411-412 (February 1, 2013).

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, 2012.

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. Intellectual property is critical to carrying out this mission. PhRMA has a keen interest in harmonizing substantive patent law worldwide because PhRMA members file a large number of patent applications abroad. PhRMA appreciates the PTO's efforts in exploring international patent law harmonization.

Part II: Grace Period

PhRMA members believe that a grace period is a desirable and important part of the patent system. However, such a grace period should strike a fair balance in ensuring that an inventor will not lose rights to a patent as long as he or she is reasonably diligent in filing for it, while also ensuring that information that has been publically disclosed but not made the subject of a timely filed patent will be freely available. The one-year grace period afforded by the Leahy-Smith America Invents Act ("AIA") [8/] is reasonable and adequately strikes this balance. A grace period should also provide a safety net to inventors by protecting against breach of confidence and theft of ideas. Implementing a grace period is fundamentally important; and is more critical than is the harmonization of the duration of the grace period.

While a grace period is desirable, patent applicants should not have to declare entitlement to a grace period at the beginning of patent prosecution. Such a requirement would unnecessarily complicate the patent prosecution process and pose additional burdens on applicants. In some instances, applicants may not even be aware of the right to a grace period when filing and may inadvertently fail to declare entitlement. As such, requiring a declaration could be counter to the safety net function of the grace period. If there is any declaration requirement, it should only be to declare entitlement to a grace period if a reference falling within the grace period is brought to the applicant's attention during prosecution.

Below are answers to some of the questions regarding grace period from the PTO's questionnaire.

Questions:

8. Do you think that a grace period is an important feature of patent law?

   [**X**] Yes

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).

8/ AIA, 35 U.S.C. § 102(b).

[ ] No

9. In principle, are you in favor of a grace period?

[**X**] Yes

[ ] No

10. If "Yes" in Questions 8 and 9, please check the box next to each of the following statements that you agree with:

A grace period should:

[**X**] take account of and balance the goals of the patent system and the needs of the scientific community

[**X**] protect inventors against the consequences of breach of confidence and theft of information

[ ] allow inventors to test the marketability of their inventions and/or attract venture capital financing before undertaking the expense of pursuing patent protection for the innovation

[**X**] protect the inventor who first disclosed his invention from re-disclosure of his invention in the interval between first disclosure and filing, by third parties having derived knowledge of his invention from him

[ ] protect the inventor who first disclosed an invention against any interference from third parties in the interval between first disclosure and filing, including disclosures from independent inventors of their own inventions

[ ] *have a safety net function only, meaning that if inventors choose to disclose their invention prior to filing, they should bear the risk of such disclosures and the investments of third parties in good faith who adopt technology which appears to be freely available prior to the filing or priority date should be protected*

[ ] I agree with none of the above statements.

Please add any comments you deem necessary:

One important function of the grace period is to provide a safety net function against disclosures, including derived disclosures; however, this is not the only purpose of a grace

period. The italicized description above does not accurately describe the safety net function of the grace period.

11. Please check the box next to each of the following statements that you agree with:

[**X**] A good reason to implement a grace period is that it is user-friendly for those that may not be knowledgeable about the patent system, including small and medium enterprises (SMEs) and individual inventors.

[ ] A good reason not to implement a grace period is that it complicates the patent system.

[ ] A grace period diminishes the predictability and legal certainty of the patent system.

[**X**] A grace period allows early publication of research results, which not only addresses the needs of academics but advances the interests of the public by promoting earlier dissemination of new technical information

[ ] Other – please specify: _____

12. Some patent systems require applicants to declare entitlement to the grace period by providing certain information about any pre-filing disclosures they are aware of within a prescribed period of time after filing the application. In other systems, the grace period arises by operation of law, i.e., no formal procedures for obtaining its benefits are required. Do you believe declarations or similar prescribed procedures should be mandatory for invoking the grace period?

[ ] Yes

[**X**] No.

b. If you answered "No" in Question 12, please indicate for which of the following reason(s) (check all that apply):

[**X**] You are concerned that failure to identify or misidentification of a disclosure in the declaration, even due to an honest mistake or oversight, might result in the disclosure not being graced

[ ] You are concerned that it will lead to applicants trying to manipulate the system

[**X**] It imposes an additional burden on applicants.

[**X**] It imposes an additional burden on patent offices.

[ ] Other – please specify: _____

13. The duration of the grace period reflects a balance between affording a reasonable amount of time to the inventor/applicant to disclose the invention prior to filing the application on the one hand, and the interests of third parties in knowing within a reasonable period of time whether an application has been filed for an invention that has been revealed to the public on the other. Some patent systems provide a grace period of 6 months before filing, and others provide 12 months. What length of time (in months) do you believe is appropriate for the grace period?

    [ ] 6 months

    [**X**] 12 months. However, as explained above, the key is to have a grace period available and the harmonization of the duration of the grace period is less critical.

    [ ] Other – please specify and explain:

14. Regardless of the duration of the grace period, from which date should the term of the grace period be computed:

    [ ] The filing date only

    [**X**] The filing date, or, if applicable, the priority date

    [ ] Other – please specify: _____

15. Do you think the grace period should be internationally harmonized?

    [**X**] Yes, with the additional considerations noted above in Question 13.

    [ ] No

    [ ] No opinion/Don't know

    Please explain your answer. _____

Part III: Publication of Application ("18-Month Publication")

PhRMA members are in favor of publication of patent applications at 18 months and do not object to a requirement that all patent applications must publish at 18 months. However, to the extent that there are a small (and diminishing) number of U.S. patent applications that do not publish at 18 months, PhRMA does not believe it is critical to require international harmonization in this regard.

Below are answers to some of the questions regarding 18-month publication from the PTO's questionnaire.

Questions:

1. Considering the issue from the perspective of patent applicants, is 18 months from the earlier of the filing date or the priority date of the application:

   [ ] Too long

   [ ] Too short

   [**X**] Reasonable

2. Considering the issue from the perspective of third parties, including the public, is 18 months from the earlier of the filing date or the priority date of the application:

   [ ] Too long

   [ ] Too short

   [**X**] Reasonable

3. Should all applications not otherwise withdrawn, abandoned or subjected to secrecy orders or similar proceedings be published at 18 months from the earlier of the filing date or the priority date, assuming 18 months is a reasonable period of time considering the interests of applicants and third parties?

   [**X**] Yes. This answer is tied to question #10 below. PhRMA is not opposed to a requirement that all patent applications must publish at 18 months but a small (and diminishing) amount of applications that do not publish at 18 months may not require international harmonization.

   [ ] No

4. If a jurisdiction requires publication of all applications at 18 months, should that jurisdiction also require the competent authority to make search and/or examination results available to the applicant sufficiently in advance of the 18 month date under certain conditions so that the applicant can make an informed decision whether to withdraw or abandon their application before publication?

   [**X**] Yes

   [ ] No

   Please provide additional details/explanation as appropriate. _____

10. Considering that the publication opt-out rate in the United States has been declining for the last several years and is currently at approximately 6% of applications filed per year (equating to about 22,000 non-publication requests in 2011), and further taking account of USPTO strategic plans that call for reaching 10 months pendency to first office action by 2014, do you consider the United States' 18-month publication regime to be effectively aligned with regimes in other jurisdictions that require all applications to be published at 18 months?

    [**X**] Yes. To the extent that there is only a small (and diminishing) amount of patent applications in the U.S. that do not publish at 18 months, the U.S. is effectively aligned with other jurisdictions that require all applications to be published at 18 months.

    [ ] No

11. How important do you consider international harmonization of publication of applications to be?

    [ ] Critical

    [**X**] Important, but not critical

    [ ] Not important

12. Does your answer to question 11 change if a grace period is included along with publication of applications among the issues to be considered for international harmonization?

    [**X**] Yes

[ ] No

Please provide additional details/explanation as appropriate.

While PhRMA members do not see a substantive link between the grace period and 18-month patent application publication, any international treaty would have to be viewed in its entirety and all provisions would have to be viewed in context.

Part IV: Treatment of Conflicting Application

PhRMA members believe that the current U.S. approach with respect to conflicting applications and anti-self-collision is the correct one for the U.S. system; however, while this issue is important, it is not critical to patent harmonization.

Below are answers to some of the questions regarding treatment of conflicting application from the PTO's questionnaire.

Questions:

7. How important do you consider international harmonization of the treatment of conflicting applications to be?

   [ ] Critical

   [**X**] Important, but not critical

   [ ] Not important

   Please provide a reason for your answer: _____

8. Which of the following approaches do you believe strikes the best balance among the competing interests involved in the treatment of conflicting applications (please choose one)?

   [ ] Conflicting applications should be relevant for the examination of novelty only with no consideration of who filed the application (no anti-self-collision).

   [ ] Conflicting applications should be relevant for the examination of novelty only, a concept encompassing minor differences, provided the inventions are "substantially the same" but not where applications were filed by the same applicant (anti-self-collision applies).

[**X**] Conflicting applications should be relevant for the examination of novelty and inventive step/obviousness, but not where applications were filed by the same applicant (anti-self-collision applies).

[ ] Other (please briefly describe the approach or name a country operating on that basis) _____

Please provide a reason for your answer:

PhRMA members believe that the current U.S. approach is the correct one in the context of the U.S. system; however, any international agreement would have to be viewed in its entirety in order to determine how critical this issue is to harmonization.

9. For conflicting applications filed under the Patent Cooperation Treaty (PCT), which of the following do you believe constitutes an international best practice?

[ ] The prior art effective date of the conflicting PCT application should be the international filing date or the priority date, if claimed, only if the application enters the national/regional phase in the country/region in question. One consequence would be that PCT applications would only become "secret" prior art once they have been translated into the prescribed language(s), making examination easier; another would be to limit the prior art effect of such applications only to that necessary to prevent two or more patents from issuing on the same subject matter, i.e., to prevent double-patenting, since the PCT application cannot mature into a patent if it does not enter the national/regional phase.

[**X**] The prior art effective date of the conflicting PCT application should be the international filing date or the priority date, if claimed, upon designation of the country or region in question and provided the application was published under the PCT. One consequence would be to enable a much earlier determination of the patentability of an invention contained in a subsequent application, another would be to allow the creation of an international pool of "secret" prior art applicable to all applications (PCT and national) worldwide.

[ ] Other - please explain _____

Part V: Prior User Rights

While it would simplify worldwide patent enforcement if prior user rights were harmonized, such rights vary worldwide to a great extent (*see, e.g.*, Report on the Prior User Rights Defense).[9/] Therefore, such harmonization should not be the current focus as there are more critical issues. Further study on this issue is welcome.

Below are answers to some of the questions regarding prior user rights from the PTO's questionnaire.

Questions:

3. How important do you consider international harmonization of prior user rights regimes to be?

   [ ] Critical

   [ ] Important, but not critical

   [**X**] Not important. Although there could be some value to harmonization, PhRMA members view this issue as the least important of the four presented in this survey to harmonize in the short term.

VI. Conclusion

PhRMA appreciates the PTO's efforts to harmonize substantive patent law and the opportunity to offer its perspective. 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.

9/ Report on the Prior User Rights Defense, The United States Patent and Trademark Office, Report to Congress (Jan. 2012) at p. 60.