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Sent: Friday, October 05, 2012 2:36 PM
To: fitf_guidance
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Subject: Attached Comments from PhRMA for Docket PTO-P-2012-0024

Attached are comments from PhRMA regarding the PTO's Federal Register notice on "The Examination Guidelines for Implementing the First-Inventor-to-File Provisions of the Leahy-Smith America Invents Act." Please do not hesitate to contact me if you have any questions. Thanks.

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Comments of the Pharmaceutical Research and Manufacturers of America in Response to the PTO's Request for Comments on the Examination Guidelines for Implementing the First-Inventor-to-File Provisions of the Leahy-Smith America Invents Act

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 the Examination Guidelines for Implementing the First-Inventor-to-File 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

^{1/} 77 Fed. Reg. 43759-43773 (July 26, 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 appreciate the efforts of the PTO to implement the first-inventor-to-file provisions of the Leahy-Smith America Invents Act (“AIA”). PhRMA in particular appreciates the PTO’s request for comments on the extent to which public availability plays a role in “on sale” prior art defined in § 102(a)(1) of the AIA.^{8/} PhRMA urges the PTO to require “on sale” prior art to meet the public availability standard. PhRMA respectfully submits this is the only reasonable interpretation of the statute and its legislative history, and is the right outcome as a matter of public policy.

I. Public Availability Should Be Required for “On” Sale” Prior Art

The PTO has requested comments on the extent to which public availability plays a role in “on sale” prior art defined in the AIA’s § 102(a)(1).^{9/} PhRMA respectfully submits that the plain language of the statute, the legislative history of the AIA, other sections of the AIA, and public policy considerations all counsel towards “on sale” prior art being limited to activities that meet the public availability standard. Private offers for sale and private uses or secret processes, which increase litigation costs and reduce certainty of patent rights, should not be considered prior art under § 102(a)(1) of the AIA.

A. The Plain Language of the Statute Indicates that “On Sale” Prior Art Is Required to be Publicly Available

The plain language of the AIA’s 35 U.S.C. § 102(a)(1), as set out below, establishes that “on sale” prior art must be available to the public.

§ 102. Conditions for patentability; novelty

(a) NOVELTY; PRIOR ART.—A person shall be entitled to a patent unless—

^{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/} 77 Fed. Reg. at 43765.

^{9/} *Id.*

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(1) the claimed invention was patented, described in a printed publication, or in public use, *on sale, or otherwise available to the public* before the effective filing date of the claimed invention; or^{10/}

The AIA added the phrase “or otherwise available to the public” to § 102(a). This clause – and specifically the word “otherwise” – clearly limits the previously listed categories of prior art to those that are “available to the public.” This interpretation finds clear support in judicial construction of this phraseology. As explained in the legislative history, “[c]ourts have consistently found that when the words ‘or otherwise’ or ‘or other’ are used to add a modifier at the end of a string of clauses, the modifier thus added restricts the meaning of the preceding clauses.”^{11/}

For example, in *Strom v. Goldman, Sachs & Co.*, 202 F.3d 138 (2d Cir. 1999), in construing the phrase “may include...back pay, ...or any other equitable relief,” the court stated:

The position of the phrase “or any other equitable relief” in the sentence in which it appears indicates that it modifies one or both of the two specific remedies referred to just before it in the same sentence ... [T]he use of the word “other” immediately after the reference to back pay and before “equitable relief” demonstrated Congress’ understanding that the back pay remedy is equitable in nature.^{12/}

Similarly, in *Universal City Studios, Inc. v. Reimerdes*, 111 F.Supp.2d 294 (S.D.N.Y. 2000), in construing the phrase “offer to the public, provide, or otherwise traffic in any technology”, the court stated that the phrase “or otherwise traffic in modifies and gives meaning to the words ‘offer’ and ‘provide.’”^{13/} In addition, in *Williamson v. Southern Regional Council, Inc.* 154 S.E.2d 21 (Ga. 1967), in construing the phrase, “carrying on propaganda, or otherwise attempting to influence legislation,” the court stated:

The words ‘carrying on propaganda’ in this statute must be construed in connection with the words following it, ‘or otherwise attempting to influence legislation.’ The use of the word ‘otherwise’ indicates that ‘carrying on propaganda’ relates to ‘attempting to influence legislation.’^{14/}

¹⁰ Leahy-Smith America Invents Act, Pub. L. No. 112-29, sec. 3(b)(1), §102(a), 125 Stat. at 285-86 (2011) (emphasis added).

¹¹ 157 CONG. REC. S1370 (daily ed. Mar. 8, 2011) (citing to *Strom v. Goldman, Sachs & Co.*, 202 F.3d 138, 146-147 (2d Cir. 1999), *Universal City Studios, Inc. v. Reimerdes*, 111 F.Supp.2d 294, 325 (S.D.N.Y. 2000), and *Williamson v. Southern Regional Council, Inc.* 154 S.E.2d 21, 25 (Ga. 1967)).

¹² *Strom*, 202 F.3d 138, 146-147.

¹³ *Universal City Studios*, 111 F.Supp.2d 294, 325.

¹⁴ *Williamson*, 154 S.E.2d 21, 25.

Furthermore, since the clause “or otherwise available to the public” is set off from the preceding clauses by a comma, it confirms that the clause applies to both “public use” and “on sale.”^{15/}

Therefore, the plain language of the statute clearly indicates that “on sale” prior art must be publicly available and the PTO should interpret it as such.

B. The Legislative History Establishes That Congress Intended the Public Availability Standard To Be Met For “On Sale” Prior Art

The legislative history repeatedly and consistently indicates that the intent of the phrase “or otherwise available to the public” was to clarify that all previously listed prior art had to be publicly available. The PTO should interpret this clause in a manner that is consistent with this expressed legislative intent.

The final Committee Report for the AIA states that “the phrase ‘available to the public’ is added to clarify the broad scope of relevant prior art, as well as to emphasize the fact that it must be publicly accessible.”^{16/} This same statement was included in the Committee Report for S. 1145^{17/}, the predecessor to the AIA, in which the “or otherwise available to the public” language was first added during a Judiciary Committee mark up of the bill.^{18/}

Statements from key congressional sponsors in the legislative history unambiguously express the intention of requiring public availability for all § 102(a)(1) prior art in contrast to pre-AIA precedent. For example, Senator Leahy, chief Senate sponsor of the Leahy-Smith America Invents Act, stated:

[S]ubsection 102(a) was drafted in part to do away with precedent under current law that private offers for sale or private uses or secret processes practiced in the United States that result in a product or service that is then made public may be deemed patent-defeating prior art. That will no longer be the case. In effect, the new paragraph 102(a)(1) imposes an overarching requirement for availability to the public, that is a public disclosure, which will limit paragraph 102(a)(1) prior art to subject matter meeting the

¹⁵ See *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1336 (Fed. Cir. 2008), which notes that “when a modifier is set off from a series of antecedents by a comma, the modifier should be read to apply to each of those antecedents.”

¹⁶ H.R. REP. NO. 112-98, at 43 (2011) (emphasis added).

¹⁷ S. REP. NO. 110-259, at 9 (2008). The Committee Report for S. 1145 also stated that the phrase “otherwise available to the public” was added to § 102 “to make clear that secret collaborative agreements, which are not available to the public, are not prior art.” *Id.* at 39.

¹⁸ See S. 1145, sec. 2., § 102(a)(1).

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public accessibility standard that is well-settled in current law, especially case law of the Federal Circuit.^{19/}

Similarly, Representative Lamar Smith, the Chairman of the House Judiciary Committee and lead sponsor of the AIA in the House of Representatives, stated that, “contrary to current precedent, in order to trigger the bar in the new 102(a) in our legislation, an action must make the patented subject matter ‘available to the public’ before the effective filing date.”^{20/}

In addition, the legislative history includes a discussion by Senator Kyl, another co-sponsor of the AIA, in which he explains that new section § 102(a)(1) is limited to prior art that is available to the public.^{21/} Some exemplary excerpts from this discussion are shown below:

[New section 102(a)(1)] limits all non-patent prior art to that which is available to the public.^{22/}

Thus new section 102(a)(1) imposes a public-availability standard on the definition of all prior art enumerated by the bill – an understanding on which the remainder of the bill is predicated.^{23/}

[T]he new definition of prior art will serve only one purpose: “to prevent the withdrawal by an inventor of that which was already in the possession of the public,” as noted in *Bruckelmyer v. Ground Heaters, Inc.*, [445] F.3d 1374, 1378, Fed. Cir. 2006. The new definition is “grounded on the principle that once an invention is in the public domain, it is no longer patentable by anyone,” as stated in *SRI International, Inc. v. Internet Security Systems, Inc.*, 511 F.3d 1186, 1194, Fed. Cir. 2008.^{24/}

Senator Kyl also cited to and plainly relied on the case law discussed in Section A above to support his choice of the word “otherwise” to require the public availability standard.^{25/}

¹⁹ 157 CONG. REC. S1496 (daily ed. Mar. 9, 2011) (statement of Sen. Leahy).

²⁰ 157 CONG. REC. H4429 (daily ed. June 22, 2011) (statement of Rep. Smith).

²¹ 157 CONG. REC. S1370-71 (daily ed. Mar. 9, 2011) (statement of Sen. Kyl).

²² *Id.* at S1370.

²³ *Id.*

²⁴ *Id.* at S1371.

²⁵ *See id.* at S1370. (citing to *Strom v. Goldman, Sachs & Co.*, 202 F.3d 138, 146-147 (2d Cir. 1999), *Universal City Studios, Inc. v. Reimerdes*, 111 F.Supp.2d 294, 325 (S.D.N.Y. 2000), *Williamson v. Southern Regional Council, Inc.* 154 S.E.2d 21, 25 (Ga. 1967), and *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1336 (Fed. Cir. 2008)).

The legislative history of the AIA clearly shows that Congress' intent was to require § 102(a)(1) prior art to meet the public availability requirements. The PTO should interpret the statute consistent with the plain language of the statute and the clear legislative intent.

C. Other Provisions of the AIA Indicate That “On Sale” Prior Art Is Limited to That Which is Publicly Available

Further support that § 102(a)(1) requires public availability is found in other sections of the AIA. Consistent with a first-inventor-to-file system, the AIA removed other sources of “secret” prior art such as prior invention under § 102(g) and derivation under § 102(f).

As another example, the AIA's transitional program for covered business method patents limits the prior art that can be raised against *first-to-invent* business method patents to pre-AIA § 102(a) art (which has a public availability limitation), and old § 102(b) art that is limited to the old § 102(a)'s publicly-available prior-art scope.^{26/} No parallel change was made to the art that can be asserted against *first-inventor-to-file* patents, presumably because it was understood that public-availability is already a requirement under new § 102(a)(1).

Similarly, Congress limited the AIA's new post-grant review procedures to first-inventor-to-file patents because “[first-to-invent] patents raise discovery-intensive invention-date and secret-prior-art issues that would be difficult to address in an administrative proceeding.”^{27/} This statement implicitly acknowledges that first-inventor-to-file patents, governed by the new § 102(a)(1), do not have these types of discovery issues because there is no “secret” prior art to uncover.

These examples illustrate the manner in which other sections of the AIA are predicated on the understanding that new § 102(a)(1) requires prior art to meet the public availability standard. A contrary interpretation would affect not only § 102(a)(1) but other sections of the AIA that assume such public availability. The PTO should, therefore, interpret § 102(a)(1) in a manner that is consistent with the entirety of the AIA to require that § 102(a)(1) prior art must be available to the public.

D. For Public Policy Reasons, “On Sale” Prior Art Should Meet the Public Availability Standard

The plain reading of the statute and legislative history leave no question that Congress intended for “on sale” prior art to meet the public availability standard. In addition, there are several public policy reasons supporting the requirement that prior art under § 102(a)(1) be publicly available. For example, the public availability requirement will reduce litigation discovery costs. Under this new standard, there will no longer be a need for discovery on an inventor's private dealings to determine if a “secret” sale or offer for sale occurred. This is

²⁶ See Leahy-Smith America Invents Act, sec. 18, 125 Stat. at 329-31.

²⁷ 157 CONG. REC. S1366 (daily ed. Mar. 8, 2011).

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particularly important given the AIA's provision that a prior art sale under § 102(a)(1) can occur anywhere in the world, in contrast to the current law's requirement that the activity be in the United States. If secret sales or offers for sale were to be considered prior art under the AIA, additional required discovery into foreign activity could be difficult and would lead to further increases in the cost of litigation.

A reading of new § 102(a)(1) that allows private sales or offers for sale to constitute invalidating prior art would also make the new post-grant review proceedings unmanageable. It would require discovery-intensive searches for secret sales or offers for sale in order to determine the validity of the patents under review. Such a system would be inefficient and unworkable.

Requiring public availability for sales is also preferable because it removes pitfalls for inventors who are unaware of the patent forfeiture provisions. Under the current law, inventors unfamiliar with the "secret" sale or offer for sale doctrine can inadvertently forfeit their rights to a patent even if there has been no public disclosure.^{28/} The adoption of a first-inventor-to-file system encourages inventors to file patent applications quickly; therefore, there is no need also to require forfeiture of patents simply because the inventor made some use of the invention that was not publicly accessible.

Lastly, limiting "on sale" prior art to activities that are public is consistent with the AIA's intended purpose of international patent law harmonization. Removing the forfeiture of patent rights through "secret" sales or offers for sale, a provision which is not present in foreign patent jurisprudence, goes hand in hand with moving to a first-inventor-to-file system in promoting international patent law harmonization, which will lead to the more efficient functioning of patent systems.

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.

²⁸ See, e.g., *Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516 (2d Cir. 1946).