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June 22, 2007

The Honorable Jon W. Dudas
Undersecretary of Commerce and
Director of the United States Patent and Trademark Office
Office of International Relations
600 Dulany St. Madison West Building
Tenth floor,
Alexandria Va. 22313

ATTN: Mr. Jon Santamauro

Dear Undersecretary Dudas,

I am writing on behalf of the Biotechnology Industry Organization (BIO) in response to your invitation for public comments on questions pertaining to international efforts to harmonize substantive requirements of patent laws, dated May 3, 2007 ( 72 FR 24566). BIO is a trade association representing more than 1100 companies and entities focused on research, development and commercialization of inventions in the field of biotechnology.

## I. Introduction

BIO Members face significant practical problems in obtaining patent rights around the world. Perhaps the biggest problem is the high cost and procedural complexity of repetitious concurrent examination and registration procedure. The high costs also arise from a range of factors such as translations, local issuance fees, national annuity fees and mandatory use of local counsel in each jurisdiction for compliance with substantive prosecution and or registration procedures. Harmonization will have significant value to BIO members if it removes the sources of these unnecessary costs and complications.

Comprehensive harmonization, however, has failed each time it has been attempted. The difficulty of achieving true harmonization is attributable to the well-established but distinct nature of the world's patent systems, along with industries and practices that are grounded on those systems. Nevertheless, there are certain provisions of patent law that may be harmonized easier than others. For this reason BIO supports the PTO's effort to advance a limited package in substantive patent law with the Group B+ nations.

It has always been BIO's position, that in the absence of "total harmonization", a more realistic short-term target of harmonizing those elements of patent systems that are necessary to create a streamlined global patent granting system would serve the interests of the patent system's stakeholders. In this context, harmonization means a treaty that imposes identical standards on substantive patentability among all treaty signatories,

rather than a treaty that accommodates a range of options.[1] Patent systems based on such a treaty should capture the best elements of the U.S., European and Japanese patent systems. As noted below, in many respects, the "U.S" versions of the various elements of a harmonized patent system are, in the opinion of BIO Members, the "best" option and must be preserved. However, BIO also recognizes that in certain respects, the "best practice" may not be the version found in the United States patent system.

True harmonization will have little practical value if it does not enable BIO Members to obtain patents more efficiently and uniformly than is possible under existing world practice. Under a truly harmonized system patent eligible subject matter should include the full spectrum of man-made inventions which include medical devices, drugs, transgenic plants and animals. Furthermore, under a harmonized system, an applicant should, by right, be able to obtain a patent after a first substantive examination in a major examining office (i.e., the USPTO, the EPO or the JPO). The United States should therefore make it a priority to conclude a treaty that delivers true harmonization of those elements of patent systems necessary to implement the single examination model. Moreover, the United States should not move to conclude a treaty until it is clear that the treaty will yield true harmonization in a form compatible with U.S. interests.

**1) Priority of Invention**

BIO supports a change to a first-inventor-to-file or first-to-file system and believes this change is a prerequisite to any serious effort to harmonize substantive global patent law standards. The U.S. is the only country that retains a first-to-invent system, and BIO believes that a change to a first-to-file system will greatly reduce the complexity, delays, uncertainties, and costs associated with the U.S. first-to-invent system, including the complicated "interference" procedures currently employed in the U.S.

Although BIO supports a change to a first-inventor-to-file system, BIO believes such a change must be accompanied by two important safeguards. First, BIO believes that the law should be clear that the right to patent is the right of the inventor, and provisions must be adopted to protect, on a global basis, the interests of inventors against derivation of their inventions. Specifically, BIO supports retention of measures in the treaty and regulations that enable the "true inventor" from whom an invention has been improperly derived from negating the otherwise patent-defeating effect of an earlier filing by a party that has derived the invention. Second, BIO strongly supports a one-year grace period during which the inventor's own disclosure does not defeat the right to patent.

**2) Prior Art Effective Date of Published U.S. Patent Applications**

BIO supports reform, in the context of a first-inventor-to-file patent system, where patents and published applications that claim the benefit of an earlier filed foreign

[1] The 1991 exercise is a model of an "accommodation" treaty – such a model cannot be used going forward because it will make impossible a uniform patent granting treaty.

application are accorded the prior art status as of their Paris Convention priority filing date. The Paris Convention creates a so-called "right of priority" and, therefore, in determining whether a patent or published application for patent is earlier filed, the Paris Convention priority filing date must be used. In contrast, under existing section 102(e), Paris Convention priority filings are not accorded prior art status as of their filing dates. *See In re Hilmer*, 359 F.2d 859 (C.C.P.A. 1966). This aspect of U.S. law differs from most of the world and BIO believes that in a first-inventor-to-file context, this exclusion of Paris Convention priority filings from the corpus of prior art patents and patent applications should not be maintained, Therefore, BIO supports elimination of the *Hilmer* doctrine as found in Article 9(2) of the old style treaty.

**3) Scope of Prior Art Effect of Published Patent Applications**

BIO supports a treaty provision that will confer a prior art effect for patents and published patent applications as from the effective filing date of the application for purposes of determinations of both novelty and nonobviousness.

BIO also opposes any treaty that does not preclude the possibility of "self-collision" of applications that would become prior art under only this standard but in which there is a common basis for ownership (e.g., where the applications are commonly owned or subject to a joint interest).

BIO believes that a satisfactory and workable "secret prior art" standard is a crucially important in an exercise that will harmonize priority of invention to follow the first-to-file standard. Secret prior art in systems that rely on an "absolute" novelty standard can give rise to a practice of "self-collision" (i.e., where the application giving rise to secret prior art is owned by the same applicant). This is an extremely undesirable aspect of the EPC system that is only partially addressed by the provision of a grace period (i.e., one year of the secret prior art, rather than the full 18 months). BIO thus believes it is essential that the treaty provide for no possibility of "self-collision" of applications in which there is a joint or common ownership (e.g., where both applications are owned by the same entity) during the period of time where secret prior art would otherwise cause such collision. Protection against self-collision should not be extended to unrelated filings that occur after publication of the first application.

**4) Grace period**

BIO strongly supports inclusion of a grace period for prior art determinations that is personal to the patent applicant (i.e., applies to disclosures arising from the applicant).

The inclusion of a grace period in a patent law harmonization treaty is a prerequisite for BIO support for treaty implementation in the United States. The significant question that remains to be determined is the form of the grace period. In this respect, three options exist:

- A personal grace period that requires proof that the disclosure that would otherwise constitute a patent-defeating disclosure had its origin with the applicant. Thus, a voluntary communication to the public by the patent applicant would be excused, as would an unauthorized disclosure (e.g., by a third party who has derived the information from the patent applicant).

- An absolute grace period that requires no proof of linkage between the information disclosed and the patent applicant. This standard would excuse any disclosures, including by third parties, that occur during the one year period of the grace period.

- Intervening disclosures in which both the "personal" and "absolute" conditions pertain should also be accorded a grace period. That is, a grace period should also be accorded for any subject matter first disclosed by the inventor as long as the inventor's personal disclosure precedes another disclosure during the 1-year grace period, i.e., an "absolute disclosure".

BIO supports a formulation for the grace period that would link the grace period to disclosures emanating from the applicant for the patent, rather than a formulation that would provide for an "absolute" grace period. A grace period linked to information emanating from the inventor or the applicant is more consistent with the first-to-file standard, and is a reasonable standard that will protect the inventor from what are in essence his own disclosures. In principle, BIO supports the formulation of the grace period which addresses voluntary and unauthorized disclosures, provided that the formulation be defined to encompass disclosures that emanate from individual inventors.

**5) Geographical Limitations in the Definition of Prior Art**

BIO supports in principle the definition of prior art as forwarded in either form of the treaty, provided that clarifications are made as to the form and characteristics of the information constituting the prior art disclosure. The clarifications in the treaty should define the attributes of the information that confer on it status as prior art.

The United States currently limits the scope of patent-defeating disclosures in a number of important respects. First, patents and printed publications confer an unrestricted prior art effect for novelty and non-obviousness purposes pursuant to 35 U.S.C. 102(a) and (b). Second, information not in the form of a patent or printed publication can have a patent defeating effect if it is publicly known in the United States (i.e., not outside the territories of the United States). Third, patents confer a patent-defeating effect during the period of their pendency as applications that BIO supports defining prior art to include information reasonably and effectively accessible to persons of ordinary skill in the art anywhere in the world. The "in this country" limitation that U.S. law imposes on non-published prior knowledge has become increasingly untenable as globalization and travel have removed geographic barriers to the location of persons skilled in the art and modern electronic

communication technologies have decimated information barriers. Thus, application of a more contemporary standard is essential to distinguish knowledge arising from some form of disclosure that ought to constitute prior art from knowledge whose character is such that an invention should nonetheless be regarded as novel and patentable.

The criteria for determining whether prior art is publicly accessible to persons of ordinary skill in the art is set forth in *Baxter Int'l, Inc. v. Cobe Lab., Inc.,* 88 F.3d 1054 (Fed. Cir. 1996); *Netscape Communications Corp. v. Konrad*, 295 F.3d 1315 (Fed. Cir. 2002); *Carella v. Starlight Archery,* 804 F.2d 135, 139 (Fed. Cir. 1986)("The statutory language, 'known or used ...' (35 U.S.C. §102(a)), means knowledge or use which is accessible to the public."); *In re Klopfenstein*, 380 F.3d 1345, 1350 (Fed. Cir. 2004). The present treaty formulations and rules do not provide sufficient structure for determining what information will qualify as "prior art." In this respect, several changes should be made to both the treaty language and the rules to establish the characteristics of information that will confer a patent defeating effect. In particular, to qualify as prior art under the treaty, the information should be required to be supported by evidence that establishes the date, scope and contents of the public disclosure and that the information is consistent with the existing case law.

**6) Loss of Right Provisions**

BIO supports the current treaty structure that reduces the number of "loss of right" conditions as compared to U.S. law and practice. Various proposals being discussed in international forums would establish a patent system that is based on the first-to-file concept and extends the effect of prior art beyond national boundaries. In light of these two significant changes, many of the "loss of right" provisions in U.S. law either would not longer be relevant or would not be necessary to protect the public interest served by the relevant loss of right provision.

In particular, under the proposed treaty in either formulation, there would be no possibility of losing the right to a patent due solely to the (i) abandonment of the invention or (ii) public use or sale of the invention. Instead, under the liberalized prior art definition, public disclosures, including in the form of proof of public knowledge of the invention, would operate to preclude the patentability of the invention. There would be no sanction for abandonment of the invention, presumably because under a first-to-file system, there is sufficient motivation for early filing of patent applications after an invention has been made.

**7) "Experimental Use Exception" to Prior Art**

Under U.S. patent law, a prior public use or sale can be exempt from the prior art if such public use or sale was experimental. For example, a commercial offer for sale of the invention is not considered prior art if the invention was not sufficiently developed or

tested so as to be ready for patenting. The experimental use exemption applies to a prior use in public if it can be shown that the use was for the purpose of testing, or performing research or experiments, on a claimed feature of the invention. Some of the factors considered in determining whether a prior public use is experimental include the degree of control over the testing exerted by the inventor or patent holder, for example in the form of prescribed research protocols or other restrictions on the users' activities involving the invention, or the existence of confidentiality agreements or obligations to report test results to the inventor or patent holder, and whether or not the use was performed to perfect the invention.

Biotechnology inventions not infrequently require such testing in settings which are arguably public. For example, clinical studies of experimental treatments often involve large numbers of well-informed third party clinical investigators at many medical centers, as well as volunteers and patients. Field trials of agricultural biotechnology inventions sometimes must be undertaken on a significant scale which makes it difficult to maintain a level of security. There are important inventions which cannot reasonably be made or perfected without such testing. For example, finding the ideal dose level and administration paradigm for an experimental treatment, and the most responsive patient population, often cannot be achieved without large-scale testing in patients of different gender, age, ethnicity, or health status. Accordingly, BIO believes that in order for prior art to be patent defeating, it must meet criteria as set for in existing case law (supra). Therefore, an inventor's non-accessible use or sale of an invention, such as those mentioned above, should not qualify as prior art.

Accordingly, to the biotechnology industry the experimental use exception to prior art under U.S. patent law is an important doctrine that allows biotechnology inventors to make inventions under "real-world" conditions, and in settings in which confidentiality often cannot reasonably be maintained to a degree that would decidedly qualify as non-public. If the very testing required today to make such inventions were given prior art effect, it would in the future be impossible to perfect many important biotechnology inventions. Accordingly, BIO believes the experimental use doctrine should be preserved in the context of substantive patent law harmonization.

**8) Prior User Rights**

Section 273 was enacted in 1999 to provide a so-called "prior user right" defense that exempts certain activities from infringement of a patent when based upon commercial use of certain "method" inventions before the patent owner's applicable effective filing date. The prior user right defense applies in certain situations where an inventor has reduced an invention to practice, placed the invention into commercial use in the United States (or made substantial preparations for doing so) before the effective filing date of a later-filed patent, and seeks to continue the commercial activity notwithstanding the later-filed patent. As noted above, in the U.S., unlike in many other countries, prior user rights are limited to certain "methods." BIO supports a prior user right which expands the defense

beyond methods to all statutory subject matter where prior to the effective filing date of a later-filed invention, the prior user has commercially used the invention or made substantial preparation for such a commercial use.

**9) Filing by Assignees**

BIO supports conferring on assignees the right to file patent applications owned by those entities. The issue of assignee filing is currently before Congress in patent reform legislation. Assignee filing would facilitate the filing of patent applications by obviating the need for each application to comply with formalities of inventor signatures and the like in filing applications. Given that this measure would simplify the process of filing applications already owned by the assignee, it is supported by BIO. In this situation, filing by individuals would not be affected, since the individual him or herself would be the Assignee.

**10) 18 Month Publication**

This issue is currently before Congress in patent reform legislation. BIO supports 18 month publication of all patent applications.

**Concluding Remarks**

BIO applauds the USPTO for working with like-minded countries to advance patent law harmonization. We look forward to working with you as progress through this process.

Sincerely,

Lila Feisee

Managing Director for Intellectual Property