Biotechnology Industry Organization

August 17, 2012

Re: Treatment of Intellectual Property Rights in the U.S.- EU High Level Working Group on Jobs and Growth

The Biotechnology Industry Organization (BIO) appreciates the U.S. Trade Representative's (USTR) query about BIO's views on how intellectual property should be treated in any future agreement arising from the U.S.- EU High Level Dialogue. Given that both the U.S. and European economies have made significant investments in biotechnology, BIO appreciates that the USTR is considering including issues related to biotechnology in any future U.S. EU Agreement. For an overview of BIO's recommendation of elements that should be included in the dialogue and an explanation of the industry, we refer you to the comments BIO submitted on February 3 to the USTR. (see attached)

In brief, BIO is a trade association representing more than 1,100 companies, academic centers and research institutions involved in the research and development of innovative biotechnology products and services. Our members are primarily small- and medium-sized enterprises working to develop and commercialize cutting-edge products in the areas of healthcare, agriculture, energy, and the environment. Many of these companies have no products on the market and rely in large part of the strength of their patents to generate investment and develop partnerships and collaborations.

Biotechnology innovation requires predictable and effective upstream (early stage) and downstream (product) IP protection. Such innovation generally starts with an early laboratory discovery, and thus upstream protection helps to generate investment and interest in the further, applied research and development of the invention. Upstream protection includes broad patent eligibility for biotech innovations, consistent patent term, flexible licensing practices, and effective patent enforcement.

Downstream protection is just as important. In the area of healthcare for example, research and development of a biological product can take decades and cost more than a billion dollars to complete. A significant portion of this time and money goes towards developing the regulatory data package that is required by regulatory offices to approve the biotech product. Therefore, downstream protection for biotech products must include sufficient protection against foreign and domestic competitors relying on the innovator's data package to secure abbreviated approval of competitive products in such markets.

BIO believes that the US-EU dialogue should lead to substantive commitments on IP for two reasons: 1) it will help make clear that IP is central any state-of-the-art 21st century trade relationship; 2) as outlined below, there are substantive issues that need to be addressed. While these issues are not as fundamental as those that exist with some emerging economies, they are nonetheless important to the functioning of a modern, state-of-the-art IP regime. In addition, BIO is a strong proponent of patent law harmonization and to the extent possible, BIO urges that U.S. and EU harmonize their

patent laws. Attached is a document that reflects BIO's position on patent law harmonization.

BIO further urges that any future agreement should include already existing best practices in both the U.S. and EU. Examples of such best practices include the ability to obtain patents on plants and animals and second use claims, etc.

Admittedly, European intellectual property laws are in many ways comparable to US laws and as such require little adjustment. In the past, IP discussions between the two economies have focused on work programmes and third country issues. BIO supports work programmes to the extent that they result in positive outcomes for the industry. Such programmes include procedural changes in patenting and filing and requirements for data and information. In addition, BIO supports cooperative efforts that address IP issues in third countries. Examples of such issues include compulsory licensing challenges in India, ANVISA's pre-patent examination approval of pharmaceutical patents in Brazil, and data protection in China, Mexico and other countries. Moreover, BIO supports third country efforts to help preserve markets for the other trading partner. For example, heightened controls in each country to prevent entry of counterfeit medicines.

Further to the above cooperative activities, BIO urges full implementation of existing EU directives including the unitary patent. After nearly 40 years of debate the EU on June 29, 2012 adopted a unitary patent and litigation system. However, the agreement must still be ratified by at least 13 member states before becoming law across the EU. Ensuring ratification and appropriate implementation of

the unitary patent will help reduce enormous patent filing and litigation costs for our members. If appropriately implemented, biotechnology companies will no longer have to relitigate their claims in every EU country but rather they can redirect those resources back to the innovative process. Accordingly, BIO urges a cooperative transatlantic effort to ensure that the agreement is appropriately implemented in the EU countries.

In addition to the above, there are also areas of substantive concerns where the U.S. and EU can work together to improve the IP environment in Europe. Some of those areas are outlined below.

New EPO Rules and Their Affect on Patent Procurement

EPO rules implemented in April 2010 have had a negative effect on patent procurement in Europe.[1] These changes have resulted in biotech companies having to make intellectual property filing decisions much earlier requiring larger upfront investments before knowing whether their invention is commercially viable.

- ***The New Time Limit for Filing Divisional Applications Creates Filing Problems.*** Prior to the new rules, divisional applications relating to pending earlier European patent applications or "parent applications" could be filed at any stage of the grant procedure of that earlier application. The new rule restricts the filing of divisional applications to 24 months from either the first official Examining Division communication

[1] Amendment to the Guidelines for Examination in the European Patent Office. Press release accessed on February 10, 2011 at http://www.epo.org/patents/law/legaltexts/journal/informationEPO/archive/20100401.html?update

regarding the earliest application for which a communication has been issued (or sometimes called "voluntary" division) or from any communication in which a lack of unity objection has been raised for the first time in respect to the earlier application.

- ***The New Rule Impacts the Ability to File Divisional Applications.*** The new rule impacts the ability to address contentious issues in a parent application before the filing of a divisional. In effect, the divisional application filing deadline may arrive much earlier than the issue date of the parent application. This is problematic because the deadline arrives before an applicant knows what issues or rejections may be raised and thus whether or not they need to file a divisional application. The change completely alters patent prosecution strategy in Europe. Applicants may no longer have the opportunity to take narrow claims in a parent application and file a divisional application to pursue broader subject matter (which is available in the United States). Moreover, the ability under the previous laws to file a divisional application derived from an earlier divisional application is much more limited because the filing deadlines require earlier, less informed, filing decisions. This problem is particularly difficult in the drug development process where the large amounts of time required do not enable companies to make correct decisions when filing a divisional application.
- ***The New Rule Impacts Unity of Invention.*** As a result of the new rules, unity of invention rejection are issued earlier during the patent process. Prior to the rule change, the unity of invention rejection occurred during the examination phase. The new rule will likely result in the objection being raised earlier in the procedure, or in other words, before the issuance of the

European Search Report. While filers previously had the option to address the objections directly during the examination process, the new rule will result in applicants having to file precautionary divisional applications before the outcome of the arguments are known. The new rule seems to result in duplicative and probably unnecessary filings to protect from the possibility of a unity of invention objection.

- ***The New Rules Mandate a Response Earlier in the Application Process***. Prior to the new rules, the Examining Division advised applicants (without making it mandatory) to respond to the search report issued with a written opinion. Without a response from the applicant, the Examining Division would generally refer to the written opinion in the first official communication. The new Rule 70bis requires a response to the European Search Reports if the written opinion contains objections. The response must be made within the time period for requesting examination (6 months from the publication of the European Search Report) when examination has not yet been requested or within the period specified by the EPO for confirming the examination request when the examination has already been requested. If no response is filed, the application will be deemed withdrawn. Applicants are forced to respond and put statements on the record to objections raised in the search opinion long before the applicants know what is important to pursue in prosecution.

Implementation of the Nagoya Protocol

Currently, the EU is in the process of implementing their obligations under the Nagoya Protocol. In doing so, the EU should not include

trade impeding provisions for access and benefit sharing that would include intellectual property offices or marketing authorities as checkpoints. BIO supports a single check point, which could be the competent (national) authority, preferably one at the EU level. Other checkpoints which have been suggested - such as customs, IP offices, or marketing approval authorities - would not be appropriate as they would create legal uncertainty and/or trade blockages for companies that would severely hamper business operations.

Heightened Standards for Patentability

The European Patent Office is implementing increasingly heightened standards of patentability. For example, with respect to antibodies, the European Patent Office is requiring that patent applications include data demonstrating utility for each species of antibody described in the patent specification. This requirement goes beyond a fair and reasonable showing of possession and enablement of the invention and weakens the scope of meaningful IP protection especially against future biosimilars.

The Need for a Dispute Mechanism for Patent Disputes Prior to Generic and Biosimilar Product Launch

BIO also supports a mechanism to resolve patent disputes before generic products are launched. Some form of patent linkage where notice is provided to the innovator of regulatory approval and subsequent infringement would ensure patent issues are resolved prior to infringement.

Conclusion

In conclusion, BIO urges that any future bilateral agreement with Europe include a substantive IP chapter which addresses direct US EU

concerns as well as third country concerns. We believe that consistent requirements for patent protections on both sides of the Atlantic would go a long way to spurring biotechnology innovation and commercialization. We further urge the Administration to continue its consultative process as the high level working group continues its efforts.

We appreciate the opportunity to provide our views on this important topic. For additional information please contact, Lila Feisee, BIO's vice president for international affairs, at 202-962-9502.