Biotechnology Industry Organization

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Re: Request of the U.S. Intellectual Property Enforcement Coordinator for Public Comments: Development of the Joint Strategic Plan on Intellectual Property Enforcement

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The Biotechnology Industry Organization (BIO) is a non-profit organization with a membership of more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in all 50 States and a number of foreign countries. BIO's members are involved in the research and development of health care, agricultural, industrial, and environmental biotechnology products. The U.S. life sciences industry, fueled by the strength of the U.S. patent system, supports more than 7.5 million jobs in the United States, and has generated hundreds of drug products, medical diagnostic tests, biotech crops, and other environmentally-beneficial products such as renewable fuels and bio-based plastics. These products are literally helping to feed, fuel and heal the world.

The majority of BIO's members are small companies that currently do not have products on the market. As such, BIO's members rely heavily on the strength and scope of their patents, both domestically and internationally, to recoup the investment necessary to sustain their long product development cycle. On average, it takes more than 10 years to develop a biotech medicine or a plant improved through agricultural biotechnology from its inception to regulatory approval and finally to market launch. The average, fully capitalized cost of developing a new medicine has been estimated at $1.2 billion and a new biotechnology derived plant product at $133 million.

To fully understand what is needed to level the playing field for the biotechnology sector in international markets, one must understand the intellectual property (IP) needs of the biotechnology sector. Biotechnology innovation requires predictable and effective IP protection throughout the research, development and commercialization process, including upstream (early stage) and downstream (product) IP protection. Biotechnology 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. As mentioned above, the 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 the FDA, USDA, or similar foreign regulatory offices to approve the biotech product. Therefore, downstream

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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.

I. Judicial Enforcement

The United States Patent and Trademark Office (USPTO) has led the world in providing technical expertise and training to various patent and trademark offices around the world. However, when the judiciary in the markets of important trading partners fails to grasp patent law or the technology in question, this undermines the USPTO's investment in increasing the quality of examination around the world. The Office of the U.S. Intellectual Property Enforcement Coordinator (The Office) can lead the way in intellectual property enforcement by increasing efforts to elevate the expertise of the judiciary that handles patent cases in the markets of important trading partners.

BIO has commented on specific enforcement problems around the world in our Special 301 submission to the United States Trade Representative.[1] BIO has also specifically commented to the USPTO on specific judicial challenges regarding intellectual property in China.[2] However, common issues found in important markets include:

a) Patentability – Courts around the world struggle with applying the legal principles of patentability to various technology areas. The USPTO understands this complexity by hiring patent examiners with advanced degrees in biotechnology. The U.S. created a specialized court, the Court of Appeals for the Federal Circuit, to handle patent cases so that judges could develop the expertise needed to handle this complicated area of the law. Many of these judges hold science degrees in addition to the typical legal training required of a judge. However, such expertise is unique to the United States.

The Office can utilize various agency resources to provide this much needed technical training to our trading partners. The Office may also encourage countries to set up specialized patent courts to help develop the judicial expertise to handle these complicated cases.

b) Injunctions – The significant amount of capital and investment that goes into creating and commercializing biotechnology inventions requires that inventors have the ability to seek injunctive relief from the courts. However, obtaining injunctive relief in many countries is difficult. In a short period of time, patent owners must try to explain to judges with little scientific expertise the complicated biotechnology that underpins the patented invention and the infringer's activities.

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[1] 2012 Special 301 Report: Biotech's International IP Issues
[2] China Patent Enforcement Comments to USPTO

Other procedural rules complicate the process. For example, in China inventors are denied preliminary injunctions on the basis that the judges cannot assess the technology in the 48 hour window required. In other countries like India, the courts have no standards for issuing injunctions making it difficult to enforce a patent.

The Office can utilize the resources of the various agencies within the Administration to provide the necessary training that judges in other countries need to adequately address challenges inventors face when trying to obtain injunctions.

II. Compulsory License Abuse

BIO remains concerned that compulsory licensing exceptions to patent law will be abused by our trading partners to enhance their own economic development to the detriment of US companies. While rhetoric would suggest that the fast growing economies in the world (like India, Brazil and China) are only using or threatening the use of compulsory licenses for the public health, a simple review of the rules and regulations for a compulsory license reveals much more.

The recent compulsory licensing decision in India is a prime example of how the laws are set up in countries to abuse this exception. One of the provisions that India granted the compulsory license to Natco was based on a lack of 'working in India.' In the decision, the Patent Controller defines working as "manufactured to a reasonable extent in India."[3] This patent requirement applies to all technologies and, according to this decision, requires iPads, John Deere tractors, medicine, and every other patented product to be "manufactured to a reasonable extent in India" or suffer a compulsory license. This provision clearly goes well beyond addressing emergency situations and public health and appears inconsistent with India's obligations under the TRIPS Agreement which prohibits discrimination concerning enjoyment or availability of patent rights based on whether products are imported or locally produced. Finally, the Office should also ensure that any products produced through the compulsory licensing process meet strict safety and IP requirements prior to being introduced into the market.

Compulsory licensing is available for use in accordance with TRIPS and other trade agreements. However, the Office should ensure that countries do not expand this limited exception to patent law for their own economic development and competitive interests to the detriment of the United States.

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[3] See http://www.ipindia.nic.in/ipoNew/compulsory_License_12032012.pdf at pg. 45

III. Resource and Patentability Restrictions

BIO understands the Office's focus on post product patent issues. However, the Office should consider expanding that focus to include pre-product patent issues that affect enforcement. These issues are wide ranging and include foreign office administrative capacity issues (patent backlogs, etc) which effectively run out the clock on complicated biotechnology patents before they can be enforced.

Other examples may fit more squarely within the Office's mandate. The Office could focus on ensuring country compliance with international obligations, including obligations under the TRIPS Agreement. This could include the compulsory license issue discussed above. In addition, certain countries are now implementing and/or considering restrictions on patent-eligible subject matter (e.g., new formulations) that are targeted at pharmaceutical products in a manner contrary to "best practices" adapted in most jurisdictions and that do not appear consistent with the TRIPS Agreement. These restrictions, if fully implemented, would prevent the availability and enforcement of patents for deserving inventions in a specific field of technology, and thereby harm U.S.-based innovators and their ability to compete in these markets.

IV. Conclusion

BIO urges the Office to consider expanding the resources and scope of the mission to include judicial training, compulsory license abuse, foreign office resource issues, and other TRIPS noncompliant activities.

Sincerely,

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Biotechnology Industry Organization