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Written Testimony of the Biotechnology Industry Organization

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COMMITTEE ON THE JUDICIARY

SUBCOMMITTEE ON INTELLECTUAL PROPERTY, COMPETITION

AND THE INTERNET

**Hearing on: International IP Enforcement: Protecting Patents, Trade Secrets
and Market Access**

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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 generate 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 approximately \$136 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 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 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.

IP Attaché Program

The U.S. Intellectual Property Rights Attaché Program has had significant success and holds immense promise in helping to enhance IP protection abroad for U.S. interests. This international focus is imperative, given that more than 60% of U.S. merchandise exports are from IP-intensive industries.¹ IP Attachés located in America's most important trading markets are crucial for the continued vitality of the U.S. economy and to preserve America's global competitive advantage.

For example, BIO has worked with IP Attachés to organize roundtable discussions and other meetings with officials and examiners in foreign patent offices, during which our member company IP experts can educate on biotechnology patenting and can raise general technical or policy challenges in securing sufficient IP protection for biotechnology-related inventions in those countries. Such opportunities are incredibly valuable in fostering greater understanding and awareness amongst both parties.

While the IP Attaché Program has been beneficial to date, several enhancements are necessary for the program to fully achieve its critical mission. First, more resources are needed to hire additional IP Attachés to serve in key export markets around the world. Such

¹ *Intellectual property and the U.S. Economy: Industries in Focus*. Prepared by the Economics and Statistics Administration and the United States Patent and Trademark Office (2012). Accessed at http://www.uspto.gov/news/publications/IP_Report_March_2012.pdf



an expansion would serve as a powerful signal to these foreign nations that the United States government considers protecting the intellectual property and economic interests of American inventors a major economic priority.

Second, the U.S. government needs to broaden its international IP focus from “enforcement” to include the scope of current and future protection. Put more simply, patent infringement and “knock offs” can become problems only if American inventions are granted patents by these countries in the first instance. Protecting U.S. technology in its early stages will help to ensure that Americans can reap the rewards of their massive investments in research and development. Furthermore, plants and seeds are often denied patent protection by statute in many foreign countries and the Plant Variety Protection laws are often adverse to innovators. There is a critical need for broadening the scope of patent protection in many foreign countries where BIO member products are not patent eligible, to expand U.S. market access and avoid the legal piracy created when products are not patent eligible. The U.S. IP Attachés should be on the front lines advocating with our trading partners that America’s current and future economic interests should be more greatly protected.

Finally, the IP Attaché Program would benefit from greater coordination with the United States Patent & Trademark Office’s other international IP programs and offices, consistent with this agency’s stated mission of “... guiding domestic and international intellectual property policy, and delivering intellectual property information and education worldwide.”

BIO thanks the Subcommittee Chairman and Ranking Member for the opportunity to submit this written testimony for the record. BIO urges that this Subcommittee and the United States Congress as a whole continue its efforts to improve IP protection abroad for American innovation, and to encourage greater predictability of patent rights across multiple foreign jurisdictions.