Biotechnology Industry Organization

HEARING STATEMENT

United States House Ways and Means Subcommittee on Trade

U.S.- India Trade Relations: Opportunities and Challenges

March 13, 2013

Executive Summary

- The Biotechnology Industry Organization (BIO) represents more than 1,100 innovative biotechnology companies including many small and medium sized enterprises, and institutions in all 50 states, leading companies in the production of conventional and advanced biofuels, renewable chemicals and other sustainable energy and manufacturing solutions.

- Biotechnology is a capital- and time-intensive industry requiring hundreds of millions of dollars of investment and often more than a decade of development time.

- Accordingly, biotechnology companies are heavily reliant on intellectual property protection to generate the investment funding necessary to research, develop and commercialize innovative biotechnology products.

- India's recent actions relating to intellectual property are of significant concern to BIO. Specifically, the Indian government has revoked the patents of three medicines that are in force in over 100 countries, and it has issued a compulsory license for a fourth medicine. In January 2013, the government signaled its consideration of three additional compulsory licenses for three commonly used anti-cancer drugs. In March 2013, a petition for a compulsory license was filed with the Indian patent office on one of these drugs.

- BIO is concerned that these recent actions by India threaten economic growth in the U.S. biotechnology industry and the United States generally. Moreover, India's weakening of IP for biopharmaceuticals harms the competitiveness of the U.S. innovative pharmaceutical sector in India. But

even more harmful is the real possibility that other countries that view India as a leader and policy pioneer will follow in India's footsteps.

- BIO urges the U.S. government to review all available policy tools in light of India's deteriorating intellectual property environment and to send a strong signal to the Indian Government and to other governments that such actions are not condoned and will not be tolerated by the U.S. government.

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The Biotechnology Industry Organization (BIO) applauds the House Ways and Means Subcommittee on Trade on its review of U.S.- India trade relations, taking into consideration both the opportunities and challenges in India.

About BIO and the Biotechnology Industry

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 worldwide. BIO's members, which range from start-up businesses and university spin-offs to Fortune 500 corporations, are involved in the research and development of healthcare, agricultural, industrial, and environmental biotechnology products.

Since its inception roughly 30 years ago, the biotechnology industry has spurred the creation of 7.5 million direct and indirect jobs in the United States and hundreds of innovative products that are helping to heal, feed, and fuel the world. In the healthcare sector alone, the industry has developed and commercialized more than 300 biotechnology therapies, cures, vaccines, and diagnostics that are helping worldwide to prevent disease, and to aid those who are suffering from cancer, HIV/AIDS, and numerous other serious diseases and conditions; another 400 or so biotechnology medicines are in the pipeline. Synthetic insulin and human growth hormone are two examples of how biotechnology has changed human healthcare.

Prior to biotechnology, insulin, the hormone that regulates blood sugar levels, was once available only from the pancreases of slaughtered cows or pigs to treat diabetes. In the late 70's, through a biotechnology process, the first synthetic human insulin was produced in bacterial host cells[1]. Unlike pig and cow insulin, synthetic insulin does not cause allergic reactions in human patients and is available in abundant quantities. Human growth hormone (HGH) used to be extracted from the pituitary glands of human cadavers. Biotechnology processes enabled the production of this molecule in bacterial cultures and thus made it available for wider therapeutic applications. Recombinant HGH is now used to treat a variety of childhood and adult growth disorders.

In the agricultural field, researchers continue to work on ways to feed more people at lower cost and with less environmental impact by identifying and using genetic markers associated with natural resistance to insects and diseases, resistance to environmental stresses such as drought and temperature fluctuations, and improved characteristics such as lower nutrient use and higher yield. Biotechnology is also being used to drive improvements in food processing, food safety, and quality assurance. Biotechnology further holds great promise in combating food borne illness, a major public health issue affecting millions of people each year[2].

Biotechnology companies are also leading the way in creating alternative fuels from renewable sources without compromising the environment. Through biotechnology enzymes can be made to decrease energy use, replace harsh chemicals in industrial processing, and produce biofuels and green plastics without the use of petroleum, helping to reduce dependence on "dirty" energy sources and mitigate global climate

[1] Press Release, Genentech, *First Successful Laboratory Production of Human Insulin Announced* (Sept. 6, 1978).
[2] BIO, *Guide to Biotechnology* 37 (2008).

change. But we have yet to scratch the surface of the tremendous innovative potential that exists within the industry.

Intellectual Property Protection and Biotechnology

By its very nature, and because biotechnology springs from early-stage/hypothesis-driven research laboratories, developing biotechnology discoveries into products for the public is, even under the best of circumstances, a time-, risk-, and capital-intensive endeavor. 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[3] and a new biotechnology-derived plant product at $133 million.

Most biotechnology innovation begins in the laboratory where a particular gene of interest is identified in association with some biological phenomenon. This gene may have some correlation with a specific disorder or disease or perhaps a new plant trait or enzyme. Further research and development of these promising discoveries can take years, even decades, and hundreds of millions of U.S. dollars to achieve. Biotechnology innovators generally patent these promising discoveries to (a) increase the likelihood of further research, development and commercialization of these discoveries by the innovators or on their behalf; (b) generate interest from investors to perform further research on these discoveries; and/or (c) license them to potential partners or developers. In these situations patents are critical as instruments to assure investors that their investment is secure, has the potential to be recouped, and is transferable. Thus it is no surprise that inadequate patent rights, or an absence of patent rights, will severely hinder

[3] J. A. DiMasi and H.G. Grabowski, "The Cost of Biopharmaceutical R&D: Is Biotech Different?," Managerial and Decision Economics 28 (2007): 469–479.

the development and commercialization and hence the availability of promising biotechnology discoveries.

Once a biotechnology product has been developed, unlike most other products, it must go through regulatory approval before it can be commercialized. This regulatory approval process, for example in the drug industry, can be the most cost-intensive portion of the drug development process. Generating the regulatory data package that is required by various regulatory authorities to demonstrate the safety and efficacy of a product comprises 90 percent or more of the cost of developing an individual drug all the way from laboratory to pharmacy.[4] Therefore, 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 the market. Under the best of circumstances biotechnology R&D and commercialization is risky. Today's economic and investment climate has only served to exacerbate this difficult process.

The Impact of India's Policies and Actions on Biotechnology

In India, BIO's members have partnered with Indian companies, built research facilities, and are collaborating with its research institutions. To its credit, India has recognized the benefits of biotechnology. It has invested billions of dollars into biotechnology and has developed a national strategy that calls for, among other things, predictability in the IP system.[5] India boasts over 350 biotechnology companies employing over 20,000 scientists and contributing over US$2 billion to the Indian economy.[6]

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[4] Stifling New Cures: The True Cost of Lengthy Clinical Drug Trials, Manhattan Institute Project FDA Report No. 5, March 2012

[5] India's "National Biotechnology Development Strategy" found at http://dbtindia.nic.in/biotech_strategy.htm.

[6] "Tenth Annual Biospectrum-ABLE Survey of Indian Biotech Industry", June 2012, found at http://www.ableindia.in/able_biospectrum_surveys.php.

However, the Indian Government's vision for biotechnology does not correspond with the anti-innovation policies it has implemented. In fact, rather than support its vision with innovation-friendly initiatives and policies, the Government of India has taken actions that have resulted in a serious deterioration of the environment for biotechnology, especially over the last 12 months. This environment not only impacts biotechnology innovation and R&D in India, but also has the potential to impact biotechnology innovation and R&D – and by extension, innovative life-saving products – in the United States and elsewhere.

BIO's members have witnessed, and been subject to, a growing trend of anti-IP developments in India that is creating significant uncertainty in the market and negatively impacting the biotechnology industry.[7] Despite being a member of the World Trade Organization, India has systematically failed to interpret and apply its intellectual property laws in a manner consistent with recognized global standards. As an example, India's Patents Act includes Section 3(d), which explicitly excludes from patentability new forms of a known substance that do not result in "enhancement of the known efficacy of that substance." [8] This requirement excludes from patentability many significant inventions in the pharmaceuticals area, e.g., new forms of known substances with improved heat stability for tropical climates, or having safety or other benefits that may not result in "enhanced efficacy" *per se*. India also has not yet implemented any meaningful protection for the regulatory data that must be generated to prove that pharmaceutical and agricultural chemical products are safe and effective. Under Article 39.3 of the TRIPS Agreement, protection must be extended against unfair commercial use of such data by makers of generic copies of innovator products.

[7] BIO's 2013 Special 301 Submission http://www.bio.org/sites/default/files/2013%20BIO%20Submission.pdf
[8] A court decision addressing this issue is expected to be released on April 1st.

More recently, the Indian government has revoked the patents of three medicines that are in force in over 100 countries, and it issued a compulsory license for a fourth medicine. In 2012, the Indian Patent Office (IPO) invalidated or revoked patents for AstraZeneca, Roche, Pfizer, and Merck. It also issued a compulsory license on a Bayer product, and in January 2013, the government signaled its consideration of three additional compulsory licenses for three commonly used anti-cancer drugs[9]. In March 2013, a petition for a compulsory license was filed with the Indian patent office on one of these drugs[10].

BIO has long been concerned that if this behavior by the Indian government is left unchecked, other countries will follow in its footsteps, and this, in fact, seems to be happening. In late 2012 Indonesia issued compulsory licenses to seven pharmaceutical products,[11] and Greece is being urged to look at compulsory licensing as a means to reduce the cost of medicines[12]. If this trend continues, the investment that pharmaceutical companies make in biotechnology R&D as partners and as instigators of biotechnology research will diminish as these companies are forced to reassess their R&D investments. Moreover, investors are likely to look elsewhere for less risky investments as it becomes apparent that biotechnology products once successfully developed can potentially be subject to compulsory licenses in various markets. Consequently, early stage biotechnology companies may be forced to stop or significantly delay development of promising innovations and to cut back on R&D activities. This can in turn affect the creation of new, high-

[9] The Indian Express--http://www.indianexpress.com/news/govt-moves-to-make-three-key-cancer-drugs-cheaper/1058247/

[10] Reuters, March 18, 2013--http://www.reuters.com/article/2013/03/18/us-india-bdrpharma-drug-idUSBRE92H0F620130318

[11] Reuters, October 12, 2012--http://www.reuters.com/article/2012/10/12/us-indonesia-hiv-idUSBRE89B0O620121012

[12] Financial Times, March 17, 2013--http://www.ft.com/intl/cms/s/0/ade78168-8f3a-11e2-a39b-00144feabdc0.html#axzz2OEMg9hgE

value jobs and the availability of innovative products for those who need them most.

BIO is concerned that these recent actions by India threaten economic growth in the U.S. biotechnology industry and the United States generally. IP-intensive industries of which the biotechnology sector is a part, accounted for about $5 trillion in value added or 34.8% of the U.S. GDP in 2012 and supported 27 million jobs directly[13]. There is no question that India's weakening of IP for biopharmaceuticals harms the competitiveness of the U.S. innovative pharmaceutical sector in India. But even more harmful is the example India's actions provide for other countries that view India as a leader and policy pioneer. Without significant political pushback by the United States and like-minded governments, India may end up worsening the environment for U.S. IP throughout the developing world, restricting export opportunities for our innovative biotech companies, many of which are exactly the small companies U.S. policy should be encouraging to export. Such IP policies also jeopardize biotechnology R&D in the United States and advances in public health, as the revenues of today are funding the research necessary to develop new and innovative medicines of tomorrow. As we have also pointed out, it will have the effect of discouraging biotechnology innovation in India.

Finally, the anti-IP actions of the Government of India reflect industrial policy in the guise of health policy. The Government of India of India consistently under-spends on health care. In 2010, it spent only 1.19% of GDP on healthcare. This is well below the expenditure of other developing countries. For example, Brazil's government spent 4.23% of its GDP on healthcare, China 2.73%, and South Africa

[13] Intellectual Property and the U.S. Economy: Industries in Focus, A report prepared by The Economics and Statistics Administration and the United States Patent and Trademark Office. http://www.uspto.gov/news/publications/IP_Report_March_2012.pdf

3.9%. Even more telling, India's figure is significantly less even than many least developed countries, including Botswana, which spent 6% of its GDP on healthcare, Angola 2.39%, Burkina Faso 3.4%, Congo 3.35%, Gambia 2.89%, and Cameroon 1.5%.[14] In 2011-2012, the Government of India healthcare spending dropped even further to 1.04% of GDP.[15] Rather than increasing healthcare spending to an amount consistent with its level of development, India chooses instead to effectively shift costs to the very party that is developing new healthcare options.

Conclusion

Decisions to issue compulsory licenses and otherwise weaken U.S. biotechnology IP rights have been done in a manner that benefits Indian manufacturers and other domestic stakeholders to the detriment of U.S. innovators and exporters. India's actions have the potential to affect biotechnology R&D and innovation in the United States and elsewhere. BIO urges the U.S. government to review all available policy tools in light of India's deteriorating intellectual property environment and to send a strong signal to the Indian Government and to other governments that such actions are not condoned and will not be tolerated by the U.S. government.

[14] Data taken from the World Bank at http://data.worldbank.org/indicator/SH.XPD.TOTL.ZS/countries. Specific percentages given are a combination of the Health Expenditure, total (% of GDP) which measures public and private spending and the Health Expenditure, public (% of total health expenditure) to reflect public spending.
[15] http://forbesindia.com/article/universal-health-care/health-care-industry-captains-are-wary-of-newer-bets/34909/1