Biotechnology Industry Organization

October 22, 2013

Douglas M. Bell
Chair, Trade Policy Staff Committee
Office of the U.S. Trade Representative
Executive Office of the President
601 17th Street, N.W.
Washington, D.C. 20508

Submitted via www.regulations.gov: Docket No. USTR-2013-0027

Dear Mr. Bell:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to provide comments to the U.S. Trade Representative's (USTR) 2014 National Trade Estimate (NTE) Report on Foreign Trade Barriers. BIO is hopeful that our contribution will assist the USTR's efforts in lowering trade barriers faced by United States' companies internationally. BIO appreciates the opportunity to comment pursuant to section 181 of the Trade Act of 1974, as amended (19 U.S.C. 2241).

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 research and develop health care, agricultural, industrial, and environmental biotechnology products. The U.S. life sciences industry 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.

The vast majority of BIO's members are small and medium sized enterprises that currently do not have products on the market. As such BIO's members rely heavily on the strength and scope of their patents to generate investment to take their technologies to commercialization. More and more, BIO's members are looking abroad as they expand their markets and R&D and commercialization efforts.

Biotechnology companies provide unique benefits to the United States and the world. In the health care sector alone, the industry has developed and commercialized more than 300 biotechnology drugs and diagnostics and there are over 400 products in the pipeline. In the agricultural field, biotechnology innovations are simultaneously increasing food supplies, reducing damage to the environment, conserving natural resources of land, water and nutrients, and increasing farm income and economies worldwide. In the energy and environmental sector, biotech innovation is cleaning our environment and fighting global climate change by reducing our dependence on petroleum and fossil fuels. Biotechnology innovation, if supported by appropriate public policies, has the potential to provide treatments for some of the world's most intractable diseases and address some

1201 Maryland Avenue SW
Suite 900
Washington DC 20024
202.962.9200 P
202.488.6301 F
bio.org

of the most pressing agricultural, energy, and environmental challenges facing our society today.

It is no surprise that the biotechnology industry relies heavily on intellectual property. The development of a single biotechnology product often takes more than a decade to be commercialized, and can require more than a billion dollars of capital investment, a significant amount of which comes from private sources. Biotechnology product development is also fraught with high risk as the vast majority of biotech products fail to ever reach the marketplace. In addition, while biotech health inventions are entitled to the same patent term as all other inventions – 20 years from the time they are filed – they have the additional hurdle of a rigorous pre-launch regulatory review process during which they may lose between 8 to 10 years of the patent life. Venture capital firms invest in capital-intensive, long-term, and high-risk research and development endeavors only if they believe there will be a return on their investment. Patents help provide this assurance. According to a patent survey conducted by researchers at the University of California Berkeley, 73% of the biotechnology entrepreneurs surveyed reported that potential funders, such as venture capitalists, angel investors, and commercial banks, etc. indicated patents were an important factor in their investment decisions.[1] Without strong and predictable patent protection, investors will shy away from investing in biotech innovation, and will simply put their money into projects or products that are less risky – without regard to the great societal value biotechnology can offer.

While we recognize that the National Trade Estimate takes into consideration many factors pertaining to many countries, and while BIO's members have significant interest in several markets, the following remarks will focus solely on issues pertaining to India. India is an important market to biotechnology companies and India is also viewed by as a leader in emerging markets by many emerging economies. We believe that India's actions have the potential to negatively impact the direction other emerging economies take as they develop regulations and legislation to meet their needs. We have witnessed this in recent months as South Africa for example, has incorporated many of India's policies in its proposed draft national IP policy.

INDIA

Difficulty in obtaining and enforcing intellectual property rights in India remains a barrier to biotechnology companies. In the past year, the Government of India has taken a number of very serious steps to revoke protection on widely-patented biopharmaceutical products. A full list of actions by the Indian Government is enclosed.

In the list are both patent revocations and a compulsory license on a patented product. While the justifications differ to some degree, these actions amount to what is

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[1]Graham, Stuart J. H. and Sichelman, Ted M., Why Do Start-Ups Patent? (September 6, 2008). Berkeley Technology Law Journal, Vol. 23, 2008. Available at SSRN: http://ssrn.com/abstract=1121224

"localization barriers to trade". By systematically curtailing the IP rights of innovative biotechnology and pharmaceutical companies – in at least one case justified because of the product is manufactured outside India –U.S. industry's R&D investment is negatively impacted. Beyond the short-term financial impact these actions have on U.S. companies operating in the Indian market, these actions have an extended impact on U.S. companies in other markets, as Indian companies are now in a position to legally export these medicines to third countries where U.S. companies do not normally seek patent protection, but would have otherwise turned to U.S. companies to meet their pharmaceutical needs.

Other Market Barriers in India

Beyond their weak intellectual property system, India has systematically put in place other market barriers that make it difficult for U.S. companies to operate in the Indian marketplace. These include new or revised regulations impacting foreign direct investment, clinical research, biopharmaceutical price controls, and a moratorium on testing and evaluating genetically-modified crops.

Foreign Direct Investment (FDI) Rules: India has begun to put in place new rules restricting the type and amount of FDI in biotech and pharma companies. Previously, all FDI was automatically approved. Beginning in 2012, foreign investors wishing to invest in the biotech and pharma sector must now seek approval from the Government. Criteria for the approval of such proposals by the Government are not clear and both the Department of Industrial Policy and Promotion (DIPP) and the Health Ministry are currently circulating proposals within the government to curtail investment even further, for example limiting investment into existing ventures to 49 percent.[2] As a result of the confusion and fruitless debate, U.S. companies who wish to invest in the Indian market are forced to look elsewhere, denying India of both foreign capital and expertise.

Clinical Research: In order to receive marketing approval from regulatory authorities around the world, innovative biopharmaceutical companies must test their products for safety and efficacy through clinical trials involving human subjects. These trials take place around the world and companies (known as "sponsors") and those managing the clinical trials ("clinical research organizations" or CROs) are scrupulous to ensure that all regulations and widely accepted ethical standards are followed. India has gone through a necessary process to update its regulations for clinical research. While providing ample opportunity for industry to provide comments, the Government of India on January 30, 2013 issued new guidelines for clinical research that largely ignored industry's input.[3]

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[2] http://www.thehindu.com/business/Industry/cracks-in-govt-over-fdi-in-pharma/article5237540.ece
http://www.business-standard.com/article/companies/restricting-fdi-in-pharma-may-prove-counter-productive-113100101282_1.html

[3] "Notification, Ministry of Health and Welfare, 30th January 2013", the *Gazette of India*, Extraordinary, Part II, Section 3, Subsection (i).

The most controversial of these new guidelines were provisions regarding financial compensation to human subjects and their families in cases of death or injury. These guidelines were widely viewed to be impossible to implement given that compensation, including medical management, would be given even in cases where placebos were administered to the subject or the investigational drug did not have the intended therapeutic effect.

In response to industry concerns, the Government agreed to "refine" the regulations and established a new Expert Committee to make recommendations.[4] However, the Committee's report[5] does not adequately address the concerns of industry, and Government has yet to make any official changes to the regulations. Finally, since January 2013, approvals of all new clinical trials have been suspended pending reviews by the Government and the Supreme Court of India.[6] This suspension has brought the entire clinical research community to a standstill, and is preventing the Indian introduction of new, innovative medicines which must undergo clinical trials in India before receiving marketing approval.

Price Controls: After a long and protracted debate, the Government of India issued in early 2013 a new "Drug Price Control Order" which imposed new price controls on a wide range of biopharmaceutical products.[7] In this regard, we note that the Government of India has taken the positive step of moving from a cost and method of control to a market-based benefit. However, the policy while intended to make essential medicines more accessible to a greater number of Indian patients, has led to shortages of these medicines in certain regions as distributors are unwilling or unable to supply the medicines at the set price.[8] More of concern, the Indian Government is currently contemplating the imposition of additional price controls specifically on patented medicines, with several proposals being debated.

While BIO is very sympathetic to the Government's wishes to provide affordable medicines to its people, we are concerned about the long-term impact these policies will have on the ability for innovative biopharmaceutical companies to continue its investment in research and development, particularly Indian innovative companies which must consider India their primary market. Price controls have a negative impact on the

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[4] Notice DCG(I)/Misc/2013-16, Directorate General Health Services, Office of the Drugs-Controller General of India, dated March 13, 2013.

[5] "Report Of The Prof. Ranjit Roy Chaudhury Expert Committee To Formulate Policy And Guidelines For Approval Of New Drugs, Clinical Trials And Banning Of Drugs", July 2013.

[6] According to unofficial reports, the Supreme Court on October 21, 2013 allowed five clinical trials to go forward and the government agreed to one of the recommendations of the Expert Committee.

[7] "Drug Price Control Order, 2013" published in the *Gazette of India*, Extraordinary, Part II, Section 3, Sub-section(ii) dated 15th May 2013.

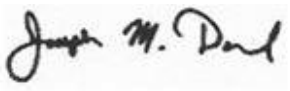
[8] http://timesofindia.indiatimes.com/business/india-business/Govt-steps-in-to-end-impasse-in-pharmaceutical-industry/articleshow/23664764.cms

ability of innovative companies to receive a return on their R&D investment. Without adequate return on their investment, these companies will have fewer incentives to conduct the expensive research and testing of new products. Pricing policies, should as a general rule, be transparent and predictable mechanisms which reward innovation. Furthermore, merely introducing price controls on biopharmaceutical products may not substantially improve citizens' access to health care, since there are many other barriers to health care, particularly inadequate health infrastructure, lack of qualified health professionals, and the absence of health financing, i.e. insurance.

Genetically-modified Crops: Both U.S. companies and Indian scientists have developed a long list of new, genetically-modified (GM) crops with a variety of commercially-valuable traits. However, the Indian government has placed a moratorium on the testing and evaluation of these GM varieties, and thus none of these GM crops will be able to receive final regulatory approval from the Indian Government.

Thank you for the opportunity to make comments. If you have additional questions or follow-up we would be happy to respond.

Respectfully Submitted,



Joseph M. Damond
Senior Vice President for International Affairs

enclosure

Intellectual Property Concerns in India

Compulsory Licenses	Patent Revocations	Patent Denials	Patent Infringements
Sept 2013: Indian Health Ministry petitions the Indian Commerce Ministry to issue a compulsory license for BMS' Sprycel under Section 92 of the Indian Patents Act. Commerce Ministry said to make a decision shortly.	Aug 2013: India's Intellectual Property Appellate Board (IPAB) revoked patents on two Allergan products to treat glaucoma, Ganfort and Combigan.	July 2013: IPAB denied Monsanto's patent application for a genetically-engineered method of increasing climate resilience in plants, the first such denial for a patent not related to pharmaceuticals.	June 2013: Merck is provided a preliminary injunction by the Indian courts in a alleged patent infringement case involving Merck's Januvia, an anti-diabetes treatment.
Aug 2013: Roche decides to drop patent covering Herceptin, rather than risk losing patent rights through a CL. BMS' Ixempra is dropped from CL consideration by Health Ministry.		April 2013: The Indian Supreme Court denied a patent on a Novartis cancer drug, Glivec, even though the patent is recognized and valid in 40 other countries.	April 2013: Merck is refused a preliminary injunction in regards to an alleged patent infringement of Januvia by Glenmark Pharmaceuticals. [In all, Merck's Januvia for has been infringed by 4 different generic companies, and has received preliminary injunctions in all but one case.]
Feb 2012: BDR Pharmaceuticals files petition for Section 84 compulsory license on BMS' Sprycel.	Dec 2012: IPAB revokes patent on Merck asthma drug	Nov 2012: IPAB rejected a patent application for a well-known Astra-Zeneca anti-cancer drug, Iressa.	Dec 2012: BMS files suit in
January 2013: Media reports that the Govt of India has begun a process to	Nov 2012: IPAB revokes patent on Roche's hepatitis C drug, Pegasys. Pegasys was the first		Sept 2012: The Delhi High Courts ruled in favor of Cipla, a generic, that they

compulsorily license three anti-cancer drugs, BMS' Sprycel and Ixempra, and Roche's Herceptin	drug to receive patent protection in India under 2005 patent amendments.		did not infringe the patent rights of a Roche cancer drug, Tarceva, even though the active ingredients were the same.
March 2012: India issued its first ever compulsory license on Nexavar, a Bayer drug used for cancer treatment, in part, because the product was imported and not manufactured locally, which is not a condition for issuing a compulsory license in TRIPS.	Oct 2012: A Pfizer cancer drug, Sutent, had its patent revoked from the Indian patent board, even though it has a valid patent, without challenge, in 90 other countries.		June 2012: Natco Pharmaceuticals obtains Health Ministry marketing approval to market a generic version of BMS' Sprycel
2011: BMS successfully blocks an application by Natco for a compulsory license on Sprycel.			