By electronic submission
Chair of the Section 301 Committee
Office of the United States Trade Representative
Washington, D.C.

BIOTECHNOLOGY INNOVATION ORGANIZATION

Submission to the China Section 301 Investigation

September 28, 2017

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to submit comments to the Office of the United States Trade Representative (USTR) and the inter-agency Section 301 Committee regarding the investigation, initiated on August 18, 2017, by USTR under section 302(b) of the Trade Act of 1974, as amended, to determine whether acts, policies, and practices of the Government of China related to technology transfer, intellectual property, and innovation are unreasonable or discriminatory and burden or restrict U.S. commerce.

Biotechnology innovation models (for agriculture, biopharmaceuticals, and industrial applications) are built on collaborations between universities, small biotechnology companies, venture capital and larger private company partners. Increasingly, such collaborations are becoming cross-border in nature and require key market and policy conditions across economies to thrive, including intellectual property protection, a harmonized and science-based regulatory environment, fair and equitable technology transfer policies, as well as the rule of law.[1] A strong and robust innovation environment outside the United States not only supports growth of the U.S. biotech industry, but is, furthermore, a win-win situation for the United States and other economies.

In the 2017 Special 301 Report, USTR placed China in the Priority Watch List. According to USTR:

> China is home to widespread infringing activity, including trade secret theft, rampant online piracy and counterfeiting, and high levels of physical pirated and counterfeit exports to markets around the globe. China imposes requirements that U.S. firms develop their IP in China or transfer their IP to Chinese entities as a condition to accessing the Chinese market. China also requires that mandatory adverse terms be applied to foreign IP licensors, and requires that U.S. firms localize research and development activities. Structural impediments to civil and criminal intellectual property rights enforcement are also problematic, as are impediments to pharmaceutical innovation.

As noted in BIO's 2017 Special 301 submission, BIO supports placing China on the Priority Watch List. In addition to intellectual property rights (IPR) protection and enforcement, market access challenges, including indigenous innovation policies that discriminate against foreign companies; lack of transparency and meaningful industry engagement in the rules-making process; regulatory requirements and technical standards that are more trade restrictive than necessary; as well as

[1] *Building the Bioeconomy 4th Edition, 2017.* http://www.pugatch-consilium.com/reports/BIO_2017_report_US.pdf

restrictive pharmaceutical pricing policies have the effect of blunting innovation in the global bioscience industry and undermining access to innovative medicines, agricultural and industrial products in China.

BIO welcomes the opportunity to work with the U.S. Government to systematically address market barriers affecting the U.S. bioscience industry and to advocate for improvements in the innovation environment in China, including a strengthened IP regime. Driven by continued innovation and scientific breakthroughs, the U.S. biotechnology industry relies on a strong and stable global innovation ecosystem to facilitate collaborations between public and private stakeholders and to ensure trust and confidence between innovators and investors. The U.S.-China economic relationship is arguably the most important bilateral relationship in the world and BIO supports meaningful and results-driven engagements to assure mutual economic gain.

As a supplement to BIO's 2017 Special 301 submission, we highlight the following issues:

Biopharmaceuticals

The China Food and Drug Administration (CFDA), in May 2017, took initial steps to improve China's IP environment by proposing to establish new forms of regulatory data protection and patent linkage systems in China. However, without coordination with the State Intellectual Property Office (SIPO) to ensure corresponding revisions to China's Patent Law, the effectiveness of the patent linkage system to facilitate early resolution of patent disputes prior to market entry of the follow-on product may be undermined. In addition, BIO continues to advocate for China to align its patent administration practices with that of other patenting jurisdictions, including regarding the treatment of supplemental data submitted in support of pharmaceutical patent applications. Finally, while BIO welcomes CFDA's proposal to provide six, ten, and ten years of data protection for innovative drugs, new orphan and pediatric drugs, and innovative therapeutic biologics, respectively, it is important to ensure the implementing measures take into account industry recommendations for best practices and do not discriminate against foreign businesses, including small and medium-sized biopharmaceutical enterprises.

Onerous regulatory requirements or standards that effectively act as localization barriers to trade can compromise the global biopharmaceutical innovation ecosystem, and create economic inefficiencies as well as unnecessary burdens for enterprises. In this regard, BIO welcomes the draft measures announced by CFDA in May, 2017, including the proposal to accept overseas clinical trial data to support drug registration in China. Such policies, effectively implemented, would streamline and accelerate the drug evaluation and approval process in China and improve patient access. However, localized testing requirements in China, such as the biologics testing requirement and quality testing of imported commercial products, continue to add unnecessary burden and delay time-to-market of innovative therapies. Furthermore, China's clinical research requirements involving bio-samples and sampling materials, under the management of the Ministry of Science and Technology, restrict cross-border transport of materials and data for clinical studies and limit their applicability for future research. Finally, BIO continues to support harmonization of China's Pharmacopeia (ChP) requirements with international standards accepted by other regulators. In some instances, the ChP requirements, as applied, create conditions that favor domestic manufacturers and can result in unnecessary risks in the global drug supply chain.

Industrial Biotechnology

BIO members have been victims of intellectual property violations with respect to industrial microbes that produce commercially valuable proteins for various industries, including textiles and grain ethanol. Such instances have led to production of copycat products that have been rebranded and sold in China, undercutting competition from foreign innovators.

ABOUT BIO:

BIO is a non-profit organization with a membership of more than 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in almost all 50 States and a number of foreign countries. BIO's members research and develop health care, agricultural, industrial, and environmental biotechnology products.

The vast majority of BIO's members are small and medium-sized enterprises (SMEs) that currently do not have products on the market. Nonetheless, SMEs make up a critical innovation force in the bioscience industry. For example, emerging biopharmaceutical companies account for 70% of the global clinical pipeline between 2007 and 2016, and 84% of all Orphan-designated products in development in the same time period.[2] As such, BIO's members rely heavily on the strength and scope of their IP to generate investments needed to commercialize their technologies. More and more, BIO's members are looking abroad as they expand their R&D and commercialization efforts.

The U.S. bioscience industry employed 1.66 million people in 2014 across more than 77,000 U.S. business establishments. The broader employment impact of U.S. bioscience jobs is an additional 7.53 million jobs throughout the rest of the economy. Taken together, these direct, indirect, and induced bioscience jobs account for a total employment impact of 9.2 million jobs. The biotech industry continues to pay high wages, reflecting the high skills and education requirements of an innovative workforce, with the average U.S. bioscience worker earning nearly $95,000 per year, or 85% greater than the private sector average.

For additional details, please refer to BIO's submission to the USTR 2017 Special 301 Report: https://www.bio.org/sites/default/files/2017%20BIO%20301%20Report%20Submission.pdf

[2] *Emerging Therapeutic Company Investment and Deal Trends, 2017.* https://www.bio.org/sites/default/files/BIO%20Emerging%20Therapeutic%20Company%20Report%202007-2016.pdf