Biotechnology Industry Organization

Office of the United States Trade Representative
600 17th Street NW
Washington, DC 20508

4 September 2012 (Submitted on-line at *www.regulations.gov*)

Re: *Request for Comments on Negotiating Objectives with Respect to Mexico's Participation in the Proposed Trans-Pacific Partnership Trade Agreement*, 77 Federal Register 141 (July 23, 2012).

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to provide the views of its members on negotiating objectives implicated by Mexico's participation in the Trans-Pacific Partnership Trade Agreement (TPP). BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare and agricultural and environmental biotechnology products, thereby expanding the boundaries of science by providing better medicines, enhanced agriculture, and a cleaner and safer environment.

As a representative of America's leading research-based biotechnology companies, BIO supports USTR's stated goal of making the TPP a "21st Century Trade Agreement" and urges USTR to develop a framework of commitments that will serve as a gold standard for protecting biotechnological inventions throughout the world. BIO supports the inclusion of an intellectual property chapter in the TPP that establishes adequate and effective standards for patent and data exclusivity, and which would facilitate the issuance and enforcement of such rights. The essential elements of such a chapter should build upon and enhance the standards established by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and recent trade agreements between the United States and other nations.

Of critical importance to BIO, the TPP must include measures that provide exclusivity for the clinical and test data that are generated and submitted to regulatory authorities to support the approval of biological pharmaceutical products.

Data exclusivity for clinical and test data submitted to health authorities for marketing approval of all pharmaceutical products is a cornerstone of the intellectual property chapters of the North American Free Trade Agreement

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(NAFTA), the TRIPS Agreement, and subsequent US trade agreements. These agreements recognize the importance of providing data exclusivity for all safety and efficacy information generated and submitted to relevant authorities in connection with obtaining marketing approval of all new pharmaceutical products. During this time period, a third party, i.e., a generic or biosimilar manufacture, is not permitted to enter the market by relying on the innovator's data or marketing approval. The purpose of test data exclusivity is to provide incentives for manufacturers of pharmaceutical products to perform the difficult, time consuming, and expensive clinical trials needed to establish that a new pharmaceutical compound is safe and effective.

Confirmation in the TPP trade agreement that data exclusivity measures apply to biological pharmaceutical products is necessary to ensure that Mexico complies with existing international obligations to provide data exclusivity for all new pharmaceutical products. Our understanding is that the relevant health authorities in Mexico are of the view that the data exclusivity obligations of NAFTA may be limited to non-biological drug products. It is deeply concerning that the Government of Mexico could be misinterpreting its international obligations so as to not extend data exclusivity to biological medicines. For the reasons explained below, negotiations with Mexico should be conducted in a manner that ensures that Mexico will be obligated to provide data exclusivity for biological products.

To clarify and make more permanent Mexico's obligations it is necessary to incorporate data exclusivity in secondary legislation (law or regulation), in accordance with Mexico's administrative procedures. Such law or regulation must be fully consistent with Mexico's obligations under NAFTA Article 17.11 to protect clinical data of all types of medicines regardless of their molecular properties. Importantly, the terminology used in any such law or regulation must also be consistent with the concepts provided in the General Health Law and the Regulations for Health Supplied ("RIS"), including RIS 167 and 177. The law or regulation must be in compliance with the outcome of TPP.

<u>The data exclusivity obligations of the TRIPS Agreement and NAFTA unequivocally apply to biological medicines.</u>

Mexico has obligations under Article 39 (3) of the TRIPS Agreement to provide data exclusivity for pharmaceutical products against unfair commercial use and under Article 1711 (5)–(7) of NAFTA to provide a five-year period of data exclusivity for pharmaceutical products against reliance by third parties on the data supplied by the innovator. Both Agreements explicitly require governments to protect clinical and test data submitted to regulatory authorities for all "pharmaceutical products which utilize new chemical entities." The plain

language of TRIPS and NAFTA does not distinguish between biological and non-biological pharmaceutical products for purposes of determining eligibility for data exclusivity. Most importantly, the language does not include any restriction as to the source, origin, or chemical composition of the pharmaceutical product.

By definition, the expression "pharmaceutical products which utilize new chemical entities" includes biological pharmaceutical products.

Like their small molecule counterparts, biological medicines are chemical compounds used for the treatment, prevention, and cure of human disease, including serious and life-threatening conditions such as diabetes, cancer, and heart disease. The primary distinction between biological pharmaceutical products and other types of pharmaceutical products is how the product is made. Active ingredients of biological medicines typically involve the use of genetically engineered cells to synthesize therapeutically valuable products, while active ingredients of small molecule drugs are generally produced using chemical syntheses outside a cell. Regardless of how biologics are prepared, a new biological pharmaceutical product that was not previously approved in Mexico qualifies for data exclusivity under TRIPS and NAFTA because it (i) is a pharmaceutical product (i.e., it is used to treat human disease) and (ii) it utilizes a new chemical entity, such as a protein, which is a chemical compound. Accordingly, there is no logical basis to justify a restrictive interpretation of "pharmaceutical product" or "chemical entity" so as to exclude biological pharmaceutical products.

Effective data exclusivity measures support the objectives of fostering the innovation of new biological medicines.

The effectiveness of the intellectual property incentives that exist today for developing new biological pharmaceutical products is linked to the regulatory systems that govern these products. Data exclusivity promotes the development and commercialization of new medicines by encouraging innovative companies to conduct safety and efficacy studies on new products so that they can be brought to the market to treat patients. Because data exclusivity is implemented by the health authorities, once an innovator's information is entitled to protection, it offers the innovator certainty and predictability regarding exclusivity in the marketplace. Any interpretation of NAFTA or TRIPS that excludes biological products from data exclusivity will compromise incentives to bring new biologics to the marketplace, translating into fewer drug products and therapies to the detriment of patients with unmet needs.

The justification for providing exclusivity for test data generated for biological pharmaceuticals is just as strong as it is for any other type of new

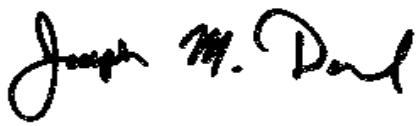
pharmaceutical product. In fact, biological products typically must satisfy more regulatory requirements than pharmaceutical products made by traditional chemical synthetic methods. One reason for this is that biological products cannot be completely characterized. Consequently, the manufacturing processes used to produce biological products are regulated, with any significant changes to these manufacturing processes requiring additional review by regulators. In contrast, the manufacturing processes used to make chemically synthesized pharmaceutical products are not typically regulated; instead, regulators rely on comparisons of each batch of a product to an earlier produced referenced product.

Mexico's trading partners provide exclusivity for test data generated for biologics.

Nearly all OECD members (of which Mexico is a member), including the United States and Europe, recognize that biological pharmaceutical products are deserving of data exclusivity. In the United States, biosimilar products cannot be approved until 12 years after the innovative biological product was approved. Comparably, Europe provides 10-11 years of data and market exclusivity for innovative pharmaceutical products. Japan and Canada provide 8 years of data exclusivity for biologics while Korea and Australia provide 6 and 5 years of exclusivity for biologics, respectively. Thus, there is a consistent global practice of providing exclusivity for test data generated for biological products.

In conclusion, BIO supports the President's decision to include Mexico in the TPP trade negotiations. Providing effective intellectual property protection for biological products is a central focus for BIO and its members. The TPP provides an excellent opportunity for the US Government to preserve the incentives for the development of new biological medicines. With this goal in mind, we urge USTR to ensure that the TPP trade agreement expressly include measures that provide adequate and effective exclusivity and enforcement of data exclusivity for biological products.

Respectfully submitted,



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