

March 11, 2009

James C. Greenwood  
President & CEO

**By electronic submission**

Gloria Blue, Executive Secretary  
Trade Policy Staff Committee  
Office of the United States Trade Representative  
Washington, D.C.

Submitted electronically to <http://www.regulations.gov>, docket number USTR-2009-0002

Re: *Request for Comments and Notice of Public Hearing Concerning Proposed Trans-Pacific Partnership Free Trade Agreement With Singapore, Chile, New Zealand, Brunei Darussalam, Australia, Peru and Vietnam, 74 FR 4480 (Jan. 26, 2009).*

Dear Ms. Blue:

The Biotechnology Industry Organization (BIO) is submitting this letter and the attached comments in response to the request by the United States Trade Representative (USTR) for comments concerning the proposed Trans-Pacific Partnership Free Trade Agreement (TPP FTA) with Singapore, Chile, New Zealand, Brunei Darussalam, Australia, Peru and Vietnam (TPP Countries). BIO is very pleased to have the opportunity to submit these comments, and respectfully requests that USTR consider the following remarks.

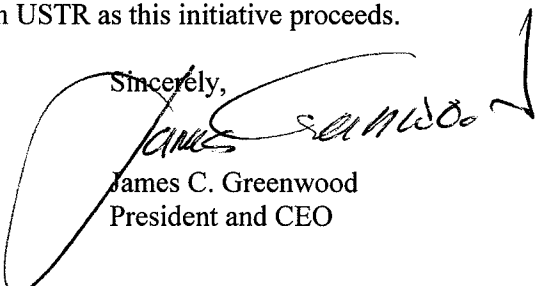
BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations in the United States and 33 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products and services.

BIO has been a consistent supporter of efforts to negotiate free trade agreements with key trading partners of the United States. We firmly believe that efforts to liberalize trade will deliver benefits to patients, consumers, producers and businesses in the United States. The Trans-Pacific region includes some of the world's fastest growing economies, and BIO members are active in this region. We urge USTR to take this opportunity to promulgate standards in the TPP FTA that provide the necessary enabling environment, including robust intellectual property standards, for a thriving biotechnology industry in the Trans-Pacific Region.

BIO will focus its comments on issues relating to (i) agricultural biotechnology and (ii) matters concerning intellectual property rights.

BIO appreciates this opportunity to comment on the proposed TPP FTA, and we look forward to working closely with USTR as this initiative proceeds.

Sincerely,

  
James C. Greenwood  
President and CEO

## **I. Agricultural Biotechnology**

The plant biotechnology sector marked a significant milestone in 2008, with the number of countries planting biotech crops reaching a historical milestone of 25 countries. Millions of small and resource-poor farmers around the world continued to plant more hectares of biotech crops in 2008, the thirteenth year of commercialization, with 13.3 million farmers worldwide growing 125 million hectares of biotech crops. The United States continues to lead the list of principal adopters of biotech crops globally, with 62.5 million hectares totaling 50% of global biotech area in 2008. The vast majority of these crops go into export markets, thus efforts to encourage foreign government support for these products are critical.

Also, on January 15, 2009 the Food and Drug Administration released a "Guidance for Industry 187, Regulation of Genetically Engineered Animals Containing Heritable rDNA Constructs." Now that this guidance has been issued and with the July 2008 approval of the Codex guidance on the risk assessment for genetically engineered animals, some countries may be starting to develop their own regulatory systems related to genetically engineered animals.

For these reasons, BIO requests that USTR consider the following in the proposed TPP FTA negotiations:

- A commitment from the TPP Countries to regulate products of agricultural (plant and animal) biotechnology in a transparent and predictable manner that is based on sound science and level of risk, consistent with their existing international obligations, and not unduly restrictive on trade of agricultural biotechnology products with the United States;
- Inclusion of language that the TPP Countries will only require labeling if the product has been significantly changed nutritionally or if there have been changes in other health-related characteristics of the food (allergenicity, toxicity, or composition);
- Inclusion of a commitment by the TPP Countries to support regulations which are science-based and risk-focused regarding the low-level presence of transgenic material in food or feed that has not received approval in these countries but has been approved in the country of cultivation. These regulations should be based on the guidance developed by the Codex Alimentarius Commission as found in the Annex on Food Safety Assessment in Situations of Low-level Presence of Recombinant-DNA Plant Material in Food;
- A recognition from the TPP Countries that no new approval process is necessary for stacked traits that have already been approved individually by national authorities;
- An agreement among the TPP Countries to coordinate on government positions in advance of multilateral governmental meetings, including the meetings of the Parties to the Cartagena Protocol on Biosafety; and

- A commitment from the TPP Countries to consult with the U.S. Government on possible trade disruptions related to products of agricultural biotechnology before any actual negative impact on trade occurs.

## II. Intellectual Property Rights

### General Comments:

The TPSC is requesting the views of stakeholders regarding, among other things, the “(h) [r]elevant trade-related intellectual property rights issues that should be addressed in the negotiations.”

BIO’s highest priority is to establish standards that protect intellectual property to ensure that our innovations will be effectively and comprehensively protected in the markets of our trading partners. Strong intellectual property protection is necessary to ensure the appropriate incentives exist to provide an enabling environment for the biotechnology industry. Such incentives are particularly critical for innovative companies in the current times of economic uncertainty and are fully consistent with other economic stimulus efforts geared toward innovative companies.

BIO is therefore supportive of the generally high level of intellectual property protection set forth in Free Trade Agreements (FTAs) to which the United States is a party and would urge USTR to continue to pursue such high standards in the TPP FTA. However, some recent agreements have included language that would permit the implementation of protection far below standards recognized in the United States and elsewhere as essential for providing an enabling environment for a thriving biotechnology industry. These provisions should be clarified to ensure that appropriate levels of protection are maintained in the TPP countries.

In addition, it is imperative that the TPP FTA not result in the weakening of any provision of existing FTAs with individual TPP countries. Obligations to adhere to existing international agreements on intellectual property, including UPOV 1991, as well as other obligations contained in these agreements, must be maintained. BIO members are firmly of the view that these provisions facilitate the development of an enabling environment for innovative industries and provide great benefits for stakeholders in the United States and its TPP trading partners.

### Specific Comments:

#### *Data Protection for Biopharmaceuticals and Agricultural Chemical Products*

Many countries require the submission of test and other data to prove that new pharmaceutical and agricultural chemical products are safe and effective. The generation of these data consumes enormous resources, and protection for these data is critical for BIO members. In respect of pharmaceutical products, this protection must provide for a period of marketing exclusivity for an innovator product so that a follow-on “generic” product is not approved for marketing on the basis of the data provided by the innovator for a fixed period of time necessary to prevent “unfair commercial use” of these data. For pharmaceutical products, standards in the U.S. and many

other countries provide that a period of no less than five years from the granting of marketing approval to the innovator is sufficient. In the case of agricultural chemical products, standards provide that a period of no less than ten years from the granting of marketing approval to the innovator is sufficient. These periods of time are necessary for companies to recoup the enormous investments made to bring a new product to market and to provide sufficient incentives for BIO members, many of which are small entities, to continue to develop these products. Many previous FTAs specifically require key trading partners to implement this protection of five years, in the case of pharmaceuticals, and ten years, in the case of agricultural chemicals, from the date of grant of marketing approval to the innovator product.

However, more recent FTAs, e.g., with Peru, Colombia, and Panama, have incorporated changes to these provisions that may be interpreted to permit standards of intellectual property protection significantly less than the comparable level of protection in the United States or other advanced markets. This is particularly the case with respect to pharmaceutical products.

In that light, BIO strongly urges that the text of Trans-Pacific Partnership FTA include language for these provisions to clarify that the level of protection in this FTA will require a minimum term of protection so that marketing approval is not granted to a generic pharmaceutical product on the basis of data submitted by the innovator for a period of no less than five years from the grant of the marketing approval in the market where generic approval is sought.

In addition, BIO members strongly support the inclusion of providing supplementary data protection for new formulations and new indications for pharmaceutical products. New formulations and indications provide enormous benefits in the form of improved treatments, reduced toxicity of existing medicines, heat-stable and other formulations for expanding treatments in tropical and other regions. These improvements may require extensive research, development and testing, thereby incurring significant costs, even though the underlying chemical product may have been previously approved in a different form or for a different indication. The ability to recoup these costs is essential to providing the incentives necessary to develop such innovative treatments. The TPP FTA should require that supplementary protection for new formulations and indications of previously approved pharmaceutical chemicals is provided.

#### *Measure to Prevent Granting of Marketing Approval for Generic Versions of Products Still Under Patent Protection*

Recent FTAs have also provided optional provisions in respect of measures needed to ensure that government agencies do not grant marketing approval to generic products that, if put on the market, would infringe a valid and enforceable patent. As noted, patent protection is critical to the efforts of BIO members to create new and innovative biopharmaceutical products. Agencies granting marketing approval should not facilitate patent infringement by permitting the marketing of products that would infringe when made, used, sold, or otherwise exploited in the relevant market. In that light, the TPP FTA should include language that would require parties to adopt measures that prevent third parties from marketing a product covered by an innovator's patent and should further provide the patent owner notice of the identity of any party who requests marketing approval to enter the market during the term of patent protection.

### *Protection for Transgenic Plants and Animals, including Transgenic Crops*

Patent protection for biotechnology inventions is critical for attracting private investment funding. The governments in the TPP countries provide varying levels of protection for biotechnology inventions. Some of these countries currently exclude transgenic plants and other valuable inventions from patent protection. Without such protection, competitors may free ride on the innovator's work and thereby undermine incentives required for a thriving industry sector. The TPP should provide for patent protection, including new and inventive uses of existing products, consistent with the robust protection of biotechnology inventions in the United States. Most importantly, it should specifically articulate that transgenic crops, which are of great importance to the agricultural biotechnology sector, are susceptible of patent protection. Requiring patent eligibility for transgenic plants and animals would help to provide protection for a wide array of important biotechnology-related inventions.

### *Special Patent Disclosure Requirements*

In addition, we also note that certain developing countries in the Pacific region have enacted laws requiring special disclosure of source and/or origin of genetic resources as part of patent applications; these requirements are onerous and are fraught with uncertainty for patent applicants. If unchallenged, such special requirements may permit countries to deny patent applications on grounds unrelated to the merits of the invention, and may permit competitors to launch unjustified attacks on BIO members' patents. We urge USTR to ensure that such special requirements for biotechnology inventions are not adopted in TPP countries, and that FTA terms strictly circumscribe patent disclosure requirements on applicants to international standards such as those articulated in Article 29 of the TRIPS Agreement.

### *Patent Term Extension for Regulatory Delays*

Pharmaceutical products require extensive regulatory reviews prior to marketing an innovative new biopharmaceutical product. This causes delays that prevent an innovator from the benefiting from the term of protection provided by a patent for an innovative product and thereby undermines the incentives provided by the patent system for the development of new pharmaceutical products. In order to ensure that an appropriate period of protection is enjoyed, the United States and many other systems provide for extension of the patent term to compensate for these delays.

Some recent FTAs have provided that such extensions of patent term are optional for parties. Further, these provisions exempt pharmaceutical products from patent term restoration to remedy delays in processing of patent applications. This leads to highly inequitable situation where protection for deserving pharmaceutical inventions is undermined. The TPP FTA should include provisions that require all parties to the Agreement to provide for restoration and extension of patent terms to compensate for delays in patent office procedures and in regulatory delays in order to ensure that the full term of protection is enjoyed for each deserving invention.

*Doha Declaration on TRIPS and Public Health*

BIO supports the Doha Declaration on TRIPS and Public Health, adopted by Ministers of WTO countries in Doha, Qatar on 2001. The Declaration recognizes the importance of intellectual property protection to the development of new medicines while also affirming that the Agreement should be interpreted in a manner to promote access to medicines for all. In doing so, it discusses a number of “flexibilities” included in the TRIPS Agreement to meet urgent public health needs, and also recognizes that public health crises, including those related to HIV/AIDS, malaria and other epidemics, may represent a national emergency or other circumstance of extreme urgency. BIO supports the letter and spirit of the Doha Declaration. However, language inserted into some recent FTAs in Peru, Panama and others, may be interpreted by certain parties in a manner to permit systematic derogations from important intellectual property rights essential for the continued flow of new medicines essential to addressing diseases that continue to plague the world.

BIO urges the USTR to work toward ensuring that the TPP FTA would more clearly permit nations to adopt certain measures to address public health crises in line with the letter and spirit of the Doha Declaration, but not permit derogation of critical intellectual property rights, including patent and data protection, that are essential incentives for the creation of new medicines. BIO continues to believe that the most effective global solutions will result from policies that respect and encourage innovation.