Transatlantic Trade and Investment Partnership

Comments Submitted by:

Biotechnology Industry Organization (BIO)

Docket Number: USTR-2013-0019

Introduction

The Biotechnology Industry Organization (BIO) appreciates the opportunity to respond to the Request for Comments issued by the U.S. Trade Representative on objectives to be pursued in the negotiation of a Transatlantic Trade and Investment Partnership (TTIP) agreement. BIO applauds the U.S. and EU governments for their courage and ambition in launching an initiative that holds tremendous promise for the long-term competitiveness of the Transatlantic economy, and which can contribute specifically to shared U.S. and EU leadership with regard to innovative technologies.

BIO represents more than 1,100 companies, academic centers and research institutions involved in the research and development of innovative biotechnology products and services. Our members are primarily small- and medium-sized enterprises working to develop and commercialize cutting-edge products in the areas of healthcare, agriculture, energy, and the environment. Since its inception roughly 30 years ago, the biotechnology industry has spurred the creation of hundreds of thousands of jobs in the United States and Europe, and millions more through indirect employment.

The industry has developed 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 more than 325 million people worldwide who are suffering from cancer, HIV/AIDS, and numerous other serious diseases and conditions. Another 400 biotechnology medicines are in the pipeline. In the agricultural field, biotechnology innovations are growing the economy worldwide by simultaneously increasing food supplies, conserving natural resources of land, water and nutrients, and increasing farm income. Within the field of industrial biotechnology, biotech companies are leading the way in creating conventional biofuels, and next generation advanced biofuels, which can be produced from forest residues, algae, municipal solid waste, or other renewal sources of biomass, without compromising the environment. Renewable chemicals and biobased product platforms are providing real opportunities to create green jobs, reduce dependence on foreign oil, increase energy security, and reduce greenhouse gas emissions.

To fully appreciate the biotechnology perspective on TTIP, it is necessary to understand the nature of the biotechnology enterprise and the elements that enable biotechnology innovation. Biotechnology research and development is capital intensive. It is generally acknowledged that

it takes more than a decade and costs on average $1.2 billion to bring a biotechnology therapy to market[1]. The history of the industry is replete with anecdotes of meticulous, lengthy and expensive experiments that have failed. It is estimated that only one in 10,000 experimental compounds make it to market as successful medicines[2].

Yet because of its tremendous potential, the U.S. and most major European economies have invested significant capital resources in this industry. As such, U.S.- and EU-based innovators boast a tremendous number of scientific discoveries, many of which have the potential to yield the next cure for cancer, Alzheimer's, diabetes or other diseases. A concerted effort through the TTIP to unleash the potential of biotechnology in the Transatlantic economy and beyond will go a long way to bringing innovative products to consumers, create jobs, and improve economic prospects on both sides of the Atlantic.

Sustaining and building upon the innovative edge of U.S. and EU biotechnology leaders requires investment from the public and private sector; an efficient system leveraging university research through transfer from the public to the private sector; strong and predictable intellectual property protections and enforcement; and a science-based, streamlined regulatory system.

The TTIP represents a profoundly important opportunity to advance progress in these areas. The following comments represent BIO's initial suggestions for the formulation of negotiating objectives relevant to biotechnology. Through dialogue with negotiators, regulators, and other stakeholders, we expect to further refine and expand upon these suggestions as the TTIP process moves forward.

Regulatory Cooperation and Convergence – Bio-Pharmaceuticals

General Perspective

The prospect of significantly deeper regulatory cooperation and convergence related to bio-pharmaceuticals represents one of the most promising aspects of the TTIP. Such convergence will enhance Transatlantic innovative leadership in a sector that benefits the well-being of people in the U.S., the EU, and around the world. BIO requests that USTR pursue a distinct and targeted set of sectoral outcomes on bio-pharmaceuticals as part of the TTIP negotiations on regulatory convergence and cooperation.

A bio-pharmaceutical regulatory focus within TTIP will build on the considerable work that U.S. and EU regulatory authorities have undertaken in recent years. Under the framework of the Transatlantic Economic Council and the High Level Regulatory Cooperation Forum, the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have solidified relationships, collaborated on inspections, consulted on issues related to approval of pediatric therapies, and worked to streamline reporting requirements, among other initiatives.

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[1] Grabowski, Henry. "Follow-on Biologics: Data Exclusivity and the Balance Between Innovation and Competition" *Nature* 7 June 2008 Pg. 482

[2] Ernst & Young report, Beyond Borders 2009f

These efforts are producing real world results, and are helping to reduce costs and administrative burdens for many biotech innovators on both sides of the Atlantic. This is particularly important in light of the small size of many biotech companies, and the challenges they face in navigating regulatory systems.

However, much more can be done to minimize or eliminate unnecessary regulatory divergences or duplicative requirements. This can reduce the considerable cost of therapeutic innovation, and speed the development and delivery of safe, life-saving medicines to patients. Intensified regulatory cooperation and convergence has assumed particular importance in light of the challenges – in terms of cost and regulatory complexity – involved in development and approval of biologic drugs.

Specific Objectives

BIO urges USTR to work with the FDA and with European trade and regulatory counterparts to negotiate, within the TTIP, a specific, sustainable set of outcomes and mechanisms for bio-pharmaceutical regulatory cooperation and convergence.

This submission outlines a number of focus areas for a bio-pharmaceutical chapter or annex within the TTIP's overall framework for regulatory convergence. These are intended to provide a non-exhaustive list of possible components. BIO looks forward to engaging directly with USTR, FDA, and other stakeholders in both the U.S. and EU to further refine and develop a robust approach to bio-pharmaceutical regulatory convergence.

A final TTIP agreement should directly incorporate the maximum possible number of concrete convergence outcomes. It is equally important that any negotiated text and related structures within the TTIP allow for adaptability and the ongoing integration of regulatory approaches, taking into account constantly evolving scientific and other factors surrounding the development of biologic drugs and other bio-pharmaceuticals.

Objectives with especially promising prospects for advancing innovation include:

- Mutual Recognition of Inspection Findings: The FDA and EMA have pursued pilot programs on coordination of inspections to assess compliance with Good Manufacturing Practices (GMP) and Good Clinical Practices (GCP). The agencies have a confidentiality agreement governing this cooperation. Based on this progress, TTIP should aim to produce agreement for mutual recognition of FDA and EMA GMP and GCP inspections. Under such an arrangement, regulatory authorities could also work to identify systematically high-risk sites and to coordinate inspection schedules.
- Parallel Scientific Advice Mechanisms: TTIP should aim to build on an existing FDA and EMA program to provide parallel scientific advice in order to remove remaining limitations on use of this program. Specifically, the EMA and FDA should amend the current program policy to expand its applicability to all medicines, and grant sponsors the right to receive parallel scientific advice upon request.
- Parallel Evaluation on Quality by Design (QbD) Applications: TTIP should aim to achieve formal adoption of current "pilot" efforts between FDA and EMA to conduct

parallel assessment of QbD applications. This will enable parallel evaluation of relevant development and manufacturing quality components submitted to both agencies.

- Data Field Requirements for Clinical Trial Disclosure: FDA and EMA could establish a harmonized list of clinical trial result data fields and agree on which of these data fields may be disclosed to the public.
- Collaboration in Developing Therapeutic Area Guidelines: FDA and EMA should establish a procedure for collaboration in developing scientific and other regulatory guidelines for specific therapeutic areas, in order to eliminate unnecessarily divergent requirements that are burdensome for innovators and delay the delivery of new treatments to market.
- Verification of Falsified Medicines: A TTIP bio-pharmaceutical work program could develop common national/regional coding systems for purposes of supply chain monitoring in connection with the control of falsified medicines. Work would focus on use of common standards for unique identifiers, developed using non-proprietary, harmonized international standards.

A number of additional components of regulatory cooperation can be built upon ongoing FDA-EMA collaboration under the auspices of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). These include:

- Pediatric Medicines: The FDA and EMA should work within the ICH framework to reduce divergences and achieve greater regulatory convergence in the scope, content, and timing of submission of pediatric investigation plans (PIP), so that companies are required to prepare only a single plan for submission in both territories. Such convergence could promote increased research efficiencies and result in more rapid completion of pediatric trials.
- Safety Reporting Requirements: Existing disparities between EU and U.S. safety reporting requirements should be targeted for intensified convergence work within the ICH. Specifically, the agencies should add an ICH "cluster" on pharmacovigilance issues to their existing slate of ICH priorities.
- Duplicative Testing Requirements: Existing ICH documents describe considerations for accepting foreign clinical trial data to support approval of the tested medicine in the EU or U.S. In practice, however, regulators from countries other than the U.S. and EU may require unnecessarily onerous bridging studies before a sponsor may gain approval of a medicine based on foreign test results. Additional work within the ICH could be useful in reducing the requirements of these bridging studies. FDA and EMA should also provide harmonized advice on the design of multi-regional clinical trials to support approval in both regions.
- Benefit-Risk Assessment: EMA and FDA should develop a harmonized structural framework and methodology for benefit-risk assessment, while retaining authority to make different risk-benefit judgments under their individual approval processes.
- Submissions Requiring Manufacturing Changes: EMA and FDA have similar requirements for submissions regarding manufacturing changes, but the details of these requirements can diverge. The agencies should work together to develop a harmonized approach to post-approval variation submissions for manufacturing changes.

Establishment of a "Working Group on Biopharmaceuticals" to oversee implementation of all aspects of regulatory cooperation foreseen under provisions of the TTIP.

Non-Disclosure of Data – An Issue Requiring Priority Attention

In addition to the regulatory objectives outlined above, BIO requests USTR to address, as a matter of priority, the need to ensure the non-disclosure of all personal data and other confidential commercial information (CCI) submitted to the EMA in connection with the marketing approval process. BIO is deeply concerned about recent indications by the EMA that it may disclose such information, including patient-level data, if requested by a third party, and its proposal to disclose such information proactively. This is inconsistent with the treatment of such information by the U.S. FDA, which appropriately applies a presumption that new drug applications and, indeed, marketing applications for all regulated products constitute confidential information that are generally not considered available for public release. If a dispute over release of particular information arises, FDA must, pursuant to regulations (21 CFR 20.47 & 20.55), consult with the owner of the information and provide that person the opportunity to explain and defend the confidential nature of the information, before the agency and in court if necessary, prior to any release of the information to the requestor. Moreover, failing to protect CCI in regulatory submissions threatens patient privacy; encourages second-guessing of EMA's expert regulatory decisions, thereby undermining patient trust in the safety and effectiveness of approved medicines; harms incentives to engage in biomedical research; and is not consistent with the EU's obligations under the TRIPS Agreement. While BIO supports responsible reporting and appropriate publication of clinical research and safety information, it is imperative that both the U.S. and the EU maintain uniform protection of patient privacy and confidential commercial information and trade secrets submitted in marketing approval applications. The EMA's current and proposed data disclosure policies are not consistent with these principles.

Market Access for Bio-Pharmaceuticals

General Perspective

Both the United States and the EU have recognized, in past free trade agreements, the particular challenges confronting market access for pharmaceuticals and medical devices. The product-specific chapters negotiated in respective U.S. and EU FTAs with Korea, for example, address the circumstances surrounding regulatory determinations on pricing and reimbursement of drugs and devices. The FTA chapters sought to surround these determinations with rules and disciplines that ensure procedural fairness, transparency, non-discrimination, and improved patient access to innovative medical products.

The experience of BIO members in the EU market has reinforced that addressing these issues in the TTIP will be critical to advancing meaningful improvements in market access for our industry's bio-pharmaceutical products. BIO recognizes the significant fiscal challenges faced by all governments, and stands ready to be a productive partner in finding solutions.

However, non-market-based pricing and reimbursement policies – including all pricing controls, whether in the form of reference pricing or demand-side controls, and whether a permanent aspect of national policy or in response to dynamic economic conditions – threaten timely access

by patients to the therapies that are most appropriate for them, and distort incentives for future innovation. These policies deny the ability of healthcare professionals to prescribe the most clinically appropriate medicines for patients. In addition, they negatively impact the progress of medical innovation, robbing patients of more advanced treatments in the future by inadequately valuing the investment that companies must make in generating those treatments. These impacts are amplified in the drive toward personalized medicine, as targeting smaller patient subgroups already increases the cost of clinical trials and other development costs. Pricing and reimbursement controls can also disproportionately disincentivize innovation in specific disease areas, stunting research succession and leading to long-term negative impacts on population health and economic productivity.

Consequently, the TTIP's ability to create a truly sustainable platform for long-term Transatlantic biotechnology innovation and competitiveness requires that progress be achieved with regard to the regulation of pricing and reimbursement of bio-pharmaceuticals. BIO requests USTR to pursue provisions in the TTIP that expand on those reflected in the KORUS FTA and the Korea-EU free trade agreement.

Specific Objectives

A bio-pharmaceutical market access component of the TTIP should address the following major issues. Implementation of these provisions should be overseen on an ongoing basis by a specialized committee or working group.

A. General Provisions/Principles

- Recognize the economic and social value of promoting the development of, and facilitating access to, pharmaceutical products and medical devices for U.S. and EU citizens;
- Ensure sound incentives that promote near-term access to pharmaceutical products and medical devices and foster an innovative environment capable of sustaining research and development investment and advancing medical science;
- Recognize that bio-pharmaceuticals have a role in reducing the need for other more costly medical expenditures and improving the lives of patients;
- Respect the right of physicians and other health care providers to prescribe the appropriate medicines for their patients based on clinical need;
- Recognize the value of ethical interactions between bio-pharmaceutical representatives and health care professionals; and
- Agree that any reimbursement controls/determinations should apply only to products dispensed and reimbursed in that Party.
- Identify specific international organizations/workstreams to foster further cooperation among the Parties to improve patient access to safe and effective medicines.

B. Access to Innovation

Beyond the general principles reflected above, the TTIP should reflect a common understanding that innovative medicines should be priced and reimbursed at levels that appropriately reward and recognize their value. The agreement should:

- Provide that during the patent term or term of regulatory exclusivity of a bio-pharmaceutical product, the government price for that product should be based on the value of that product and never be set by reference to prices for generic products. Stipulate that, in the framework of pricing and reimbursement decisions, the parties should not reassess the elements on which the market authorization for a product is based, which can include the quality, safety, efficacy or bioequivalence of the medicinal product based on specific national regulatory policies.
- Clarify that the negative impacts – to patient access and innovation – of a government entity establishing prices for bio-pharmaceuticals under patents or regulatory exclusivity mechanisms based on prices of the same product in other countries, are significantly exacerbated if the reference countries are dissimilar in terms of their socio-economic level, populations, disease burdens and health care systems. Government prices for patented bio-pharmaceuticals or bio-pharmaceuticals covered by regulatory mechanisms should be prohibited from being set by reference to prices for the same product in countries in economic or political crisis (for example, countries receiving aid from the International Monetary Fund or countries identified by the U.S. State Department as terrorist or unstable states); and
- Provide that a manufacturer should be permitted to apply for an increased amount of reimbursement and/or government price based on evidence of the safety and efficacy of its patented bio-pharmaceutical or bio-pharmaceutical protected by regulatory exclusivity mechanisms.
- Emphasize that a manufacturer should be permitted to apply for reimbursement for additional medical indications based <u>solely</u> on evidence of safety and efficacy.

C. <u>Transparency</u>

A transparent, timely and predictable pricing and reimbursement process that provides applicants with meaningful due process is essential to ensure patient access to innovative medicines. USTR should pursue the following provisions within the TTIP:

- Clarify that <u>all</u> provisions in a TTIP bio-pharmaceutical chapter apply to laws, regulations, procedures, administrative rulings, and implementing guidelines concerning <u>all</u> aspects of the pricing and reimbursement process, including, but not limited to, health technology assessments or other medical assessments of the clinical effectiveness of a pharmaceutical, demand-side measures and "clawback" mechanisms.
- Clarify that the obligation to address substantive comments in writing and explain any substantive revisions made to proposed regulations should be completed before the proposed regulations are adopted.
- Include an obligation to ensure that all applications are processed within a reasonable, specified period, clarifying EU Member States should be subject to all applicable provisions associated with the timelines mandated in the EU Transparency Directive.

- Include language providing that if an application is inadequate or insufficient, the relevant authority must notify the applicant of what additional information is required to resume the application review process in a timely manner.
- Clarify that the relevant regulatory authority should not request any additional information which is not explicitly required under national legislation or administrative guidelines to complete the decision-making process.
- Detail the requirements for providing an applicant with a pricing and/or reimbursement decision (including a negative decision), including that the decision must specify the basis for the determination, with specific reference to objective and verifiable criteria.
- Require that the final reimbursement notice should advise the applicant of its rights and the relevant timelines for seeking an independent review of the reimbursement decision.
- Require each Party to ensure access for stakeholders with legitimate commercial interests to full information about each Party's pricing and reimbursement systems and processes, including to a positive list of products covered, if any, published at least annually, and a negative list, if any published at least every six months.
- Require that confidential information contained in agreements signed between private sector actors (e.g., bio-pharmaceutical companies) and government entities that were entered into with the explicit understanding that the details included in those agreements will be kept confidential.

D. Dissemination of Information to Patients and Health Care Professionals

In order to make informed, clinically appropriate decisions, health care professionals and patients need access to information concerning all of their health care options. This includes understanding the benefits and risks associated with a medicine deemed to be medically appropriate by a patient's physician or health care provider. The TTIP should include language permitting manufacturers to make information available to health professionals and patients about their approved medicines via their internet sites, predicated on such information being truthful, not misleading and balanced.

E. Other Barriers to Market Access/Patient Access

Reflecting on the experience of BIO member companies in the EU market for bio-pharmaceutical products, BIO requests USTR to supplement the foregoing provisions, which are largely based on provisions found in previous U.S. and EU trade agreements, with the following provisions intended to address additional, practical impediments to EU market access:

- Requirement to respect the payment terms established by U.S. law/the EU's Late Payments Directive, respectively.
- Requirement that any "clawback" or rebate tax levied in response to an economic crisis should not disproportionately burden pharmaceutical manufacturers temporarily holding an exclusive position (i.e., any tax should be borne by the entire supply chain), and should be subject to a transparent, annual review process that affords those subject to the tax the opportunity to comment on whether it remains necessary to continue the tax. Revenues raised by such taxes should be earmarked to cover healthcare expenditures.

Intellectual Property Rights

General Perspective

The viability of biotechnology innovation, in all of its aspects, rests extensively on the existence of strong frameworks for the protection and enforcement of intellectual property (IP) rights. The U.S. and EU are global leaders in biotechnology innovation in large measure due to the strength and predictability of their IP protection.

As TTIP negotiations move forward, the deeply shared and longstanding commitment of the U.S. and EU governments to strong IP protection represents a critical opportunity to signal that commitment through the negotiation of exceptionally high-standard rules, as well as through meaningful principles and cooperative mechanisms for achieving ever-deeper harmonization of IP policies and practices. Seizing this opportunity is important at a moment characterized by erosion of intellectual property protection – notably in patents and regulatory data protection – in significant markets around the world. Against this backdrop, BIO urges U.S. negotiators to approach the IP dimensions of the TTIP with a keen awareness of the value of precedent, and of the opportunity to further cement Transatlantic innovative biotechnology leadership through the strongest possible IP rules, principles, and cooperative mechanisms. In addition, harmonization of IP policies and procedures, if done properly, will reduce the financial burden associated with procuring patent protections for small and medium sized enterprises and will enable them to direct their limited resources to R&D.

The consideration of IP in the TTIP context will undoubtedly require approaches distinct in some ways from those adopted in past U.S. and EU free trade agreements. U.S. and EU IP laws and enforcement mechanisms are sophisticated and highly developed, and generally aim at achieving similar policy objectives, but sometimes arrive at those objectives by different legal pathways. Still, these approaches are sometimes duplicative and unnecessary, and at other times inefficient. Thus, while it may not be necessary for the TTIP to produce outcomes in which the detailed provisions of either U.S. or EU law will, in all cases, form the basis of final negotiated text, the TTIP should nonetheless be approached as a unique opportunity to explore ways to reach for the highest possible levels of IP protection in the Transatlantic economic space, and to promote harmonization and procedural streamlining in IP administration.

In many aspects of IP, the TTIP may well reflect highly ambitious and detailed *principles* of protection and enforcement, while acknowledging the possibility of some variation in how those principles are implemented legally by each party to the agreement. Nonetheless, BIO urges USTR to supplement a "principles" approach with a "binding rules" approach, where doing so can advance the highest possible standards of protection or resolve unnecessary and correctable divergences in current U.S. and EU practice in a manner that can reinforce Transatlantic innovative leadership. BIO looks forward to remaining closely engaged with negotiators as they define potential new approaches to crafting the IP content of this unique free trade agreement.

Specific Objectives

Protection of Regulatory Data, Trade Secrets, and Commercial Confidential Information

The U.S. should seek 12 years of regulatory data protection for biologics, consistent with current U.S. law. The capital intensity of biotechnology development, the high rate of commercialization failures, and the uncertainties and expense surrounding biologics manufacturing combine to fully justify a 12-year protection period as essential to incentivizing innovation in these life-saving products.

With regard to regulatory data protection for non-biologic therapies (so-called "small molecules"), BIO urges USTR to engage with its EU counterparts to fully explore possibilities for maintaining the highest level of protection in the context of TTIP outcomes.

In addition, and as reflected in our comments above regarding regulatory cooperation, BIO urges U.S. negotiators to explore provisions to ensure the non-disclosure of all commercial confidential information (CCI) submitted to regulatory authorities in connection with regulatory approval of bio-pharmaceutical products. This is particularly important in light of recent EMA actions that would lead to the public disclosure of non-clinical and clinical study reports containing CCI. It is imperative that both the U.S. and the EU maintain uniform protection of patient privacy and CCI and trade secrets submitted in marketing approval applications. The EMA's current and proposed data disclosure policies are not consistent with these principles.

Patents – Advancing High-Standard Substantive Harmonization

With enactment of the America Invents Act in the United States and progressive implementation of an EU unitary patent system, there is a stronger-than-ever foundation for substantive patent harmonization between the U.S. and the EU. Negotiators should maximize possibilities for the TTIP to provide an important vehicle for advancing such harmonization, through both negotiated rules and structured cooperation mechanisms. This is an area with particularly important significance in terms of establishing high standards of patent protection that can, over time, assume greater global relevance and application.

Elements of focus for substantive patent harmonization should include:

- **12-Month Grace Period**: BIO regards the TTIP as an appropriate opportunity to advance towards a globalized grace period that would exclude public disclosures of a claimed invention emanating from an inventor from constituting prior art during a 12-month period prior to the effective filing date of the claimed invention. BIO supports a formulation that addresses both voluntary and unauthorized public disclosures, provided that the public disclosures emanate from inventors.
- **Standards of Patentability**: Given an unsettled international environment with regard to issues of patentability, it is essential that the TTIP encompass patentability provisions that are precise and unambiguous, and that promote greater substantive harmonization between the U.S. and EU. Specifically, BIO urges harmonization to clarify that a claimed invention will be considered novel if it is not part of the prior art. BIO also supports harmonization of criteria for determining "inventive step" and "non-obviousness" determinations – an area where BIO members have observed troubling variability across different jurisdictions. The establishment of harmonized U.S. and EU approaches to these issues will be meaningful in the development of more clearly applied standards on a global level.

- **Scope and Definition of Prior Art**: TTIP should aim to harmonize the definition and scope of "prior art." Provisions should clarify that prior art should consist of all information made available to the public anywhere in the world, in a form in which it is reasonably accessible by persons of ordinary skill, prior to the priority date of the claimed invention. The only additional category of prior art should consist of the disclosures in published applications and patents, as of their priority date. Such disclosures should have prior art effect as of their priority date for both novelty and non-obviousness/inventive step purposes.
- **Patent-Eligible Subject Matter**: Biotechnology inventions are unique in that they are derived from living organisms and biological materials, such as cell lines, nucleic acids, proteins, and transgenic plants and animals. Given certain weaknesses in the international rules framework with regard to patentable subject matter, the TTIP represents an opportunity for the U.S. and the EU, as global IP leaders, to establish a clear standard requiring broad patent eligibility for <u>all</u> inventions that are new, useful, and an inventive contribution over the prior art – including gene-based inventions, medical process inventions and plant or non-human animal inventions.
- **Protection for "Second Use" Inventions and Method of Treatment Claims**: It is equally important that the TTIP set a clear, high, and harmonized standard establishing that "second medical use" and *in vivo* diagnostic and "method of treatment" claims are protectable through patents.
- **Disclosure Issues**: The TTIP should clarify what constitutes adequate disclosure of the invention and the nature of what additional information can later be presented to support the patent application.
- **EU Unitary Patent System:** The recently adopted Unitary Patent System includes an exemption that states the unitary patent "…shall not extend to the use of biological material for the purpose of breeding or discovering other plant varieties." This exemption is inconsistent with the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), specifically the principles of exclusive rights to patent holders, and the fact that all exceptions to these exclusive rights need to be limited and specific, and non-discrimination. This exemption erodes patent protection and would undermined the value of effective patent protection for innovation in biotech and economic growth. Furthermore, this exemption would highly discriminate against innovative companies with operations in the European Union and the United States. Therefore, BIO recommends that TTIP should safeguard patent holders' rights consistent with principles under the TRIPS Agreement and those provided by the United States to European patent-holders.
- **Native Traits:** Over the past few years there have been efforts in the EU to restrict the granting of patents on "native traits" and to limit the form of intellectual property protection available for such traits to plant variety protection rights under UPOV. Although at this point legislation has not been introduced to impose these limitations, two matters pending before the European Patent Office Enlarged Board of Appeals squarely raise the issues of the patentability of these traits. Patent claims on native traits should neither have higher nor lower requirements on patentability than other inventions. The TTIP should provide a mechanism to ensure a robust dialogue between U.S. and EU patent authorities on these types of patents.

Patents – Procedural Aspects

- **Post-Grant Review, Reexamination, Opposition, and Correction Procedures**: BIO urges U.S. negotiators to engage with their EU counterparts in discussing ways to advance harmonization and high standards on a range of procedural issues that are critical to the sound functioning of patent systems around the world. The U.S. and the EU should, for example, explore ways to encourage harmonized post-grant patent review procedures that will encourage early challenge on best available evidence, include protections against serial challenges, and ensure efficient and quick resolution. The TTIP negotiators should also explore the establishment of benchmarks surrounding pre-grant patent opposition proceedings in order to address the misuse of such procedures that has occurred in some jurisdictions around the world. Work on harmonization of patent procedures should also advance acceptance of *ex parte* mechanisms allowing patentees to seek correction or reexamination of their issued patents. BIO urges U.S. negotiators to advocate for uniform mechanisms between the U.S. and the EU allowing patent owners to have recourse to simple, inexpensive procedures to enable substantive reexamination of their issued original or amended claims when they deem necessary.
- **Patent Term Adjustment and Patent Term Extension for Patent Office and Regulatory Delays**: Both the U.S. and the EU have mechanisms enabling the adjustment of patent terms to account for administrative delays by patent offices and regulatory authorities. It is important that the TTIP directly address the importance of patent term adjustment and patent term extension as a critical elements in a strong overall patent system. While the precise elements of the U.S. and EU adjustment systems differ in some respects, both sides should aim within TTIP to reach maximum uniformity in criteria of applicability and length of adjustment, and to reflect the importance of patent adjustment as part of a final set of TTIP IP outcomes.
- **Patent Enforcement Mechanisms**: The U.S. and EU have adopted somewhat different legal and procedural mechanisms aimed at guarding against market entry by patent-infringing products. The existence of such mechanisms is essential in ensuring the early resolution of patent disputes before an infringing product is launched on the market. BIO considers it important that the TTIP negotiators engage on this issue, and that the importance of effective patent enforcement tools be reflected as part of a final set of TTIP IP outcomes.

Trademarks

The TTIP should prohibit limitations on the use of trademarks, other than limitations necessary to protect public health. BIO urges U.S. negotiators to address provisions in EU (and EU member state) law that provide privileges or exclusivity to generic names over proprietary names.

Third-Country/International Cooperation

The TTIP should set up enduring structures to foster continued, and intensified, U.S.-EU cooperation on international IP policy issues, including efforts to address IP protection or enforcement problems in third countries.

Agricultural Biotechnology

General Perspective

Comments in this section build upon previous submissions from both BIO and its partner EuropaBio. We encourage the U.S. and the EU to find a long-term solution to normalize trade in products derived through agricultural biotechnology. BIO believes that this can be accomplished within the existing legal and regulatory framework. Doing so would be to the mutual benefit to consumers, farmers and the economies of the United States and the European Union.

Agricultural biotechnology is an important tool that is being embraced globally to help address challenges such as food and energy security, environmental sustainability, and changing climactic conditions. With that promise in mind, it is critical that the US and EU take full advantage of the TTIP to forge a new trading relationship that can keep pace with the rapid adoption of agricultural biotechnology globally.

Most significantly, the TTIP should result in increased predictability and implementation of existing EU laws and regulations consistent with legislated timelines, and should also seek to incorporate internationally recognized approaches to risk assessment. The TTIP should provide for a mechanism to reduce risk of trade disruption resulting from gaps between the approval in the U.S. and EU. The TTIP should also establish improved dialogue and greater accountability at the ministerial and technical levels to address both existing trade issues, as well as promote cooperation as innovation in agriculture continues to evolve.

Additional Background and Related Specific Objectives

1. *Increased production and demand for grains and oilseeds requires functioning regulatory systems to ensure important trade flow*

The pipeline of new agricultural biotechnology products in the major agricultural exporting nations of the Americas continues to increase, as does demand for grains and oilseeds in importing countries. In addition, public institutions, globally, are advancing many new innovative products towards commercialization in major crops such as rice as well as minor (small acreage) fruit and vegetable crops. The International Service for the Acquisition of Agri-Biotech Applications (ISAAA) states that biotech crop hectares have increased from 1.7 million hectares in 1996, to over 170 million in 2012. There are now 28 countries cultivating biotechnology crops; of that number 20 are developing countries, and over 90 percent are small resource poor farmers[3]. While the United States remains the leading producer of biotechnology crops, countries outside the industrialized world are closing the gap, and adoption rates among developing countries are outpacing industrialized countries. This has been accomplished because of the benefits of this technology and the proven safety of agricultural biotechnology. Moreover, the European Union has funded research for over 25 years, involving more than 500

[3] Global Status of Commercialized Biotech/GM Crops 2012, Top Ten Facts about Biotech/GM Crops, International Service for the Acquisition of Agri-Biotech Applications, ISAAA.org

independent research groups concluding "that biotechnology, and in particular GMOs, are not *per se* more risky than the e.g. conventional plant breeding technology[4]."

In Asia and elsewhere, demand for imported grain and oilseeds is increasing at a staggering pace, placing increased pressure for improved crop yields and for new technology that can tolerate agronomic stress, such as drought. Urbanization, increasing incomes and limited land and water resources are driving demand for animal protein and increase the need for imported grains and oilseeds for livestock feed.

As demand increases globally and farmers respond through adopting the latest in biotech innovations, countries with regulatory regimes that are not in-line with international standards, or those that are unable to implement regulatory regimes in a predictable and consistent manner will be increasingly vulnerable to severe trade impacts. The TTIP offers a valuable opportunity to reduce this risk and develop practical measures consistent with international guidelines that will ensure a growing US and EU trading relationship.

In light of these factors, BIO urges USTR to pursue the following as a specific objective for the TTIP:

- Obtain a TTIP outcome that will ensure full and consistent implementation of existing EU legislation governing approval of agricultural biotechnology products, including a means to predictably achieve approvals of agricultural biotechnology products within the timeframes established by European laws and regulation. Respecting science and legislated timelines would dramatically reduce the threat of trade disruption, not only between the United States and EU, but also other major exporting nations within the Americas.

2. *Need for Alignment of Risk Assessment Requirements and Adherence to Legislated Timelines*

The primary concern affecting U.S.-EU trade in commodities derived from agricultural biotechnology is the significant and growing gap between the deregulation of a new biotechnology product in the United States and the approval of those products in the EU. This "asynchronous approval" is caused by lack of alignment of risk assessment guidelines and delays in product approvals that are based on factors other than science. Even after products receive a safety endorsement by the European Food Safety Authority (EFSA), they can linger in the EU political review process for months and even years. As stated by DG Agriculture, "fast approvals of new GMOs that have received clearance from the European Food Safety Authority cannot be guaranteed in the EU, given the persistent disagreement among Members States in the

[4] A Decade of EU-funded GMO research; Directorate General for Research and Innovation

Biotechnologies, Agriculture and Food, European Commission, 2010,
http://ec.europa.eu/research/biosociety/pdf/a_decade_of_eu-funded_gmo_research.pdf

respective Regulatory Committees and in the Council. So far, not a single GMO has been approved by a qualified majority.[5]"

The elimination of these undue delays in processing new product applications is critical. Timelines set by EU legislation are consistently missed. These delays cause a significant gap between the regulatory approval in the US and EU, increasing the potential for trade disruption due to low-level presence (LLP) of new agricultural biotechnology products in commodity shipments or other agricultural products.

As of May 2013, 74 applications are queued in the approval process in the EU. Of these, 52 products are in the EFSA process, and 22 have received a positive opinion from EFSA and are awaiting Commission/Member State action. Of the 22 products, many are simply awaiting renewal, yet the political process has delayed the decision from between 1 and 3.5 years.

Article 7 of Regulation 1829/2003 states that after EFSA issues a positive opinion on a biotechnology product, the European Commission must act within three months after receiving the positive opinion from EFSA. In the case of a non-decision vote, which is the most common outcome, the Commission must submit a proposal for a second vote within a maximum of two months according to Article 5 of Regulation 182/2011. Rarely have these deadlines been met.

While the delays in the political decision-making process are cause for significant concern, so is the political interference in the EFSA risk assessment process. For example, recently revised risk assessment guidelines remove EFSA's flexibility to approach its assessments on a case-by-case basis, including the requirement for a 90-day rat study even when considered unnecessary by EFSA.

The TTIP is also an opportunity to address the EU's approach to regulating stacked events. An increasing amount of new agricultural biotechnology products will take the form of combined event products or 'stacks'. The EU requires a risk assessment for each stack, in addition to a separate risk assessment for each individual component of a stack, even if a single component has previously been authorized or never commercialized. Furthermore, the review of the stacks cannot begin until after the risk assessment on the single component is completed. This practice will become increasingly burdensome and will substantially increase delays as stacked products become more prevalent in the marketplace.

Also, the U.S. and EU should use the TTIP to address product renewals, which are required every ten years. As stated above, many of the products delayed in the decision making process are products awaiting renewed authorizations and have an extensive history of safe use. As the agricultural biotechnology industry matures, the cost of maintaining authorizations for older products will become increasingly disproportionate, and will have a negative impact on the

[5] Directorate General for Agriculture and Rural Development: Economic Impacts of Unapproved GMOs on EU Feed Imports and Livestock Production http://ec.europa.eu/agriculture/envir/gmo/economic_impactGMOs_en.pdf

development of a 'generic' marketplace, as we approach off patent status in the United States for the first agricultural biotechnology product in 2014.

In light of these factors, BIO urges USTR to pursue the following as specific objectives for the TTIP:

- Obtain a TTIP outcome that will advance incorporation within EU risk assessment processes of regulatory experience and familiarity with biotech events, including a revised, risk-appropriate approach to the review of stacked products. Doing so will align the EU more closely with international guidelines and the risk assessment approaches of trading partners, including the United States, and in turn reduce regulatory burden at EFSA.

- The TTIP should also address the requirement to renew authorizations every ten years by creating a mechanism to recognize when a product has established a history of safe use, and would therefore no longer require renewed approvals.

3. Importance of Commercially Viable Low-Level Presence Policy

The EU is a significant importer of soy and soy meal from the United States and other major exporters within the Americas, as well as a traditional importer of corn and corn by-products. Due to the significant gap between deregulation of a new biotechnology product in the United States (Americas) and approval in the EU, bilateral trade of grains and oilseeds is consistently threatened. This is exacerbated by the fact that Europe has not adopted a commercially viable LLP policy. LLP is defined by Codex Alimentarius as low levels of recombinant DNA plant materials that have passed a food safety assessment according to the Codex Plant Guideline in one or more countries but not in the importing country.

Predictability and legal certainty are needed for grain and oilseed exports to the EU. While the EU has adopted a "technical solution" to enable trade when trace amounts of unapproved biotechnology events are found in shipments intended for feed, this policy simply re-defines "zero tolerance" and is not comprehensive, as it does not apply to food or seed. Analysis prepared by the DG Agriculture concludes that the impact of LLP in soy meal on the EU from major soybean exporters would be severe, as EU pork and poultry production would drop substantially and cause the EU to become a net importer of pork[6]. The same analysis suggests that the worst case scenario (widespread disruption in imports from the Americas) would trigger a sharp increase in beef meet prices and EU exports would be eliminated.

In light of these factors, BIO urges USTR to pursue the following as specific objectives for the TTIP:

- Extend the existing technical solution to both food and seed, as currently it applies only to feed.

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[6] Directorate General for Agriculture and Rural Development: Economic Impacts of Unapproved GMOs on EU Feed Imports and Livestock Production http://ec.europa.eu/agriculture/envir/gmo/economic_impactGMOs_en.pdf

- Address LLP in a commercially meaningful way. In this context, practical solutions should be developed to ensure that trade is not stopped for products that have received a positive safety opinion from EFSA and the product has completed the full approval process, consistent with international standards, in the one or more of the major exporting countries in the Americas.

- Implementation of limited, harmonized and practical sampling and identification of crop biotechnology events in commodity shipments intended for feed, feed and processing should be part of the TTIP. For example, when biotech corn content must be identified, grains drawn from existing processes that sample for quality and safety should be used and final identification should occur in country of origin prior to shipment.

4. Need for Improved Dialogue and Establishment of Accountability

The U.S.-EU relationship related to agricultural biotechnology has been complex. The TTIP is an opportunity to learn from past exchanges and chart a new course for the relationship as the agricultural industry continues to evolve to address global challenges such as food and energy security, environmental sustainability, and changing climatic conditions.

- BIO recommends the US and EU create a Sanitary and Phytosanitary (SPS) Committee that is charged with avoiding bilateral trade disruption and disputes on SPS issues, and which commits both the US and EU to the application of sound science and to promptly resolve issues should they occur.

- The Committee should establish working groups across the various areas of agriculture. One such working group should be focused on innovative agricultural technologies, including plant and animal biotechnology. This working group should focus on regulatory convergence in the area of innovative plant and animal production techniques and technologies. The working groups should commit to a dialogue regarding the development of any new regulations with a view to avoiding regulatory divergence as techniques and technology evolves. These working groups should be science-based, transparent and enable industry to provide technical expertise, when appropriate.

- In addition, to improve accountability with regard to avoiding and resolving disputes, trade and agriculture ministers from the US and EU should commit to annual bilateral meetings focused on SPS issues.

Additional Areas of Interest

The foregoing information summarizes the TTIP negotiating objectives of most direct interest to BIO member companies. However, BIO wishes to signal its interest in the following additional issues, and its desire to remain engaged with USTR as approaches on these issues are developed:

Professional Mobility: BIO shares with many other technology-based industries a strong interest in enabling the freer movement of professionals and technical experts across borders, as a means of facilitating trade and innovation. Biotechnology development benefits from the extensive technical expertise of individuals of many nationalities, and innovative capacity depends

importantly on the availability of immigration status enabling non-U.S. workers to apply their skills within the U.S. We hope that the TTIP can ease the mobility of workers and researchers between the U.S. and the EU.

Trade Facilitation: The interplay of customs enforcement and product regulatory authority is becoming increasingly relevant to trade in regulated products of all types, including in the biotechnology field. TTIP negotiations on trade facilitation should explore mechanisms to bring about enhanced coordination between these functions of government in both the U.S. and the EU.

Investment: Venture capital and other forms of cross-border investment are critical to biotechnology research, development, and commercialization. BIO will consequently be interested in the development of strong investment rules in the TTIP, including provisions allowing for investor-state dispute settlement.

Tariffs: While negotiations at the World Trade Organization level have substantially eliminated tariffs for most bio-pharmaceutical products among a participating group of WTO members, including the U.S. and EU, the application of duties is still relevant with regard to certain compounds used for research and development purposes. TTIP should address these residual tariff barriers, and should also explore procedural mechanisms to facilitate the addition of new products to those covered under the WTO's plurilateral Agreement on Trade in Pharmaceutical Products.

Government Procurement: TTIP provisions concerning government procurement should prohibit tenders based on reference to the price of generic pharmaceutical products, during the period in which a patent on such products remains valid.