BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

February 3, 2012

L. Daniel Mullaney
Assistant U.S. Trade Representative for Europe and the Middle East
Office of the U.S. Trade Representative
600 17th Street NW
Washington, DC 20508

Re: U.S.-EU High Level Working Group on Jobs and Growth
Subject: Request for Comments
http://www.regulations.gov

Dear Mr. Mullaney:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to respond to the Request for Comments issued by the U.S. Trade Representative seeking input on identifying policies and measures to increase U.S. EU trade and investment to support mutually beneficial job creation, economic growth and international competitiveness. On behalf of BIO I would like to urge the working group to include in its high level dialogue, issues related to biotechnology.

BIO is a trade association representing 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 direct jobs in the United States and Europe and millions of indirect jobs. 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 renewable sources of biomass, without compromising the environment. Renewable chemicals and biobased product platforms are also providing real opportunities to create green jobs, reduce dependence on foreign oil, increase energy security, and reduce greenhouse gas emissions. In the U.S., states recognize the tremendous role that biotechnology can play in their economies. As such virtually all states have put into place bioscience initiatives.[1]

To fully appreciate the biotechnology perspective, it is necessary to clearly understand the nature of the biotechnology enterprise and the elements necessary to 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[2] to bring a biotechnology therapy to market. 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 ever make it to market as successful medicines.[3]

Yet because of its tremendous potential, the U.S. and most of the major European economies have invested significant capital resources in this industry. As such, these nations boast a tremendous number of scientific discoveries, many of which have potential to yield the next cure for cancer, Alzheimer's, diabetes or other diseases. A

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[1] http://www.bio.org/articles/battellebio-state-bioscience-initiatives-2010

[2] Grabowski, Henry. "Follow-on Biologics: Data Exclusivity and the Balance Between Innovation and Competition" *Nature* 7 June 2008 Pg 482
http://www.nature.com/nrd/journal/v7/n6/full/nrd2532.html

[3] Ernst & Young report, Beyond Borders 2009

concerted effort initiated by this high level working group to unleash the potential of biotechnology in the U.S. and EU will go a long way to bringing innovative products to consumers, creating jobs, and improving the economy of both regions. It is generally well accepted by policymakers that engendering a robust bioeconomy requires active support from government, policymakers, academia, the financial community, and other stakeholders. Creating an environment conducive to biotechnology requires investment from the public (through government funding and grants) and private sector (through VC investment, tax incentives, etc.); an efficient system leveraging university research through transfer from the public to the private sector; strong and predictable protections and enforcement for intellectual property, and a science-based, streamlined regulatory system. What follows is BIO's suggestion for areas around which that the U.S. and EU can generate a robust dialogue.

Opportunities for Enhancing the Compatibility of Regulations and Standards

The U.S. and Europe are the largest markets for biopharmaceutical products the cost of producing of which exceeds a billion dollars. While there is investment in the early R&D phase of product development, a significant portion of the cost of developing a biotech product goes towards taking the product through regulatory review process. In this regard, elimination of duplicative administrative requirements in the U.S. and EU will be helpful in bringing biopharmaceuticals to market. In 2007, the U.S. and EU began a dialogue on administrative simplification under the Transatlantic Economic Council which had as its key objective identification for simplification of the regulatory process at the level of administrative practices and guidelines[4]. BIO urges the USTR to consider reinvigorating this effort. Avoiding duplicative requirements would cut red tape, and save money for the industry, consumers, and regulators. Trade and investment on both sides of the Atlantic can be enhanced if the U.S. and EU eliminated duplicative testing and streamlined procedures which would ultimately also decrease the amount of time needed to bring new products to market.

[4]http://www.fda.gov/InternationalPrograms/FDABeyondOurBordersForeignOffices/EuropeanUnion/EuropeanUnion/EuropeanCommission/ucm114338.htm

Simplification and compatibility of requirements will also benefit the agricultural biotechnology sector. In this regard, I direct you to our comments filed in response to ITA-2011-0006 filed on August 8, 2011.[5] In the area of agriculture, the EU is a large export market for U.S. soybeans and soybean meal, in the U.S. importing $1.1 billion and $413 million respectively. However, unnecessary barriers that restrict trade remain. There are at least two areas where a high level U.S. EU dialogue that focuses on the role that agricultural biotechnology plays in the economy and job creation may be helpful. First, a World Trade Organization dispute panel found that the EU's moratorium on agricultural biotechnology product approvals and several member states bans on cultivation were inconsistent with their commitments under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS). Second, with regard to authorizations for new biotechnology products, the EU process is substantially slower than the U.S. and other important U.S. export markets. According to an analysis conducted by EuropaBio, the EC takes an average of 45 months to complete a review of an import product application. This burgeoning backlog represents a major barrier to trade.

Consistent requirements for patent protections on both sides of the Atlantic would go a long way to reducing the cost of biotech innovation and commercialization. Intellectual property is the linchpin of biotechnology innovation. The ability to obtain IP protection both upstream and downstream of the biotechnology R&D enterprise is critical to investment. As a first step, adoption in Europe of a unitary patent would help mitigate the high patent filing costs of applying in multiple EU countries (mostly due to translation requirements). Lowering these patent filing costs would result in more capital flowing to the research and development process and result in job creation. In addition, a Unitary Patent Court has the promise of lowering litigation costs and enforcement across European countries. Biotechnology companies will no longer have to relitigate their claims in every EU country but rather they can redirect those resources back to the

[5] http://www.bio.org/category/41

innovative process. Finally, any further harmonization (both procedural and substantive) between the United States and European Patent Offices would further reduce patent filing costs.

Enhanced Cooperation for the Development of Rules and Principles on Global Issues of Common Concern and also for the Achievement of Shared Economic Goals Relating to Third Countries

Bringing innovative medicines and technologies to the public at large is arguably one of the greatest global challenges of our time. Yet, these difficult economic times have made moving products along the research and development continuum even more challenging. In particular, today's economic downturn has created a gap in the investment required to take promising discovery to a stage where investors, collaborators and larger biotech firms are willing to invest their resources. While conventional upstream initiatives in research and development continue to be important for biotechnology innovation, it has become all too clear that without robust translational programs, promising biotechnology products may not be developed. This is because many such early stage discoveries are just that-- discoveries which entail significant investment to develop them into products. Traditional biotech models include investors and VCs as significant funders of early technologies. Once these technologies are suitably developed, they are transferred to, or acquired by, a larger company. Today's economic down turn has made VC and company backing of these risky, early stage technologies less desirable. As such many potential products and technologies never get developed to the point of being attractive to larger firms. Advancing science through what has been called the "valley of death" has never been more important than it is right now, as numerous small biotechnology companies are being forced to shelve promising therapies as a result of the current economic crisis and restrictive capital market. The impact of the current economic crises on small biotechnology companies has been and continues to be severe. In fact, since 2008, at least 47 U.S. public biotech companies have either placed drug development programs on hold or cut programs all together. These programs include therapies for HIV/AIDS, cervical cancer, multiple sclerosis, and diabetes. According to the latest available data, 24 percent of small, publicly-traded biotechnology companies are now operating with less than six

months of cash on hand, and 38 percent of these companies have less than one year of cash remaining. The total capital raised by the industry saw a 25 percent decline between 2007 and with venture capital funding dropping 30 percent. Coordinated efforts across the Atlantic on translational research initiatives to fill these gaps could benefit biotechnology innovation and bring more products into the hands of consumers.

A second area of global concern relates to incentivizing the development of climate friendly technologies in particular biofuels. Combustion of fossil fuels permanently and irreversibly leads to increased concentrations of CO2 in the atmosphere. Combustion of biofuels and other biogenic energy sources recycles CO2 emissions through renewable biomass feedstocks. If sustainably sourced, such combustion does not result in lasting increases in CO2 concentrations in the atmosphere. Other uses of biogenic carbon, such as biochemicals and bioplastics, may even sequester CO2, reducing atmospheric GHG concentrations. These inherent benefits of utilizing renewable biomass feedstocks versus traditional fossil fuel consumption should be recognized on a global scale.

There is perhaps no better time than now for the U.S. and EU to discuss the timing for building a biobased economy to provide fuels, chemicals, materials and energy sustainably for the long term future. A high level dialogue that includes discussions of how to further these technologies on a global scale would not only benefit the biotechnology sector, but would also help bring innovative alternative sources of energy into the market place.

Conclusion

We applaud the Administration for exploring trade focused ways to stimulate innovation and job creation in the U.S. and EU. BIO believes that the suggestions outlined in this paper can have both a short- and medium term impact on economic growth, job creation and competitiveness but unleashing the potential of biotechnology. The suggested topics are not only feasible in the short term, but also have significant implications for and consistency with bilateral and multilateral trade obligations. We urge the Administration to continue its consultative process as the high level working group continues its efforts.

We appreciate the opportunity to provide our views on this important topic. Please do not hesitate to contact me or Joseph Damond, BIO's senior vice president for international affairs, at 202-962-9200, for additional information.

Sincerely,

James C. Greenwood
President and CEO