July 26, 2010

Trade Promotion Coordinating Committee
U.S. Department of Commerce, Room C102
1401 Constitution Ave. NW,
Washington, DC 20230

Attn.: NEI Comments

Dear Sir/Madam,

I am writing on behalf of the Biotechnology Industry Organization (BIO), in response to the request by the Trade Promotion Coordinating Committee for comments on the Administration's plan to develop a National Export Initiative [Federal Register Doc. 100624279-0279-01].

BIO represents companies, universities and research institutions that focus on cutting-edge research and development of biotechnology products and technologies, specifically with respect to healthcare, agriculture and environmental applications. The majority of BIO's members are small- and medium-sized enterprises that, for a variety of reasons, are expanding their reach globally. Our members are among the most innovative in the U.S. economy, with products and technologies that have the potential to address many of today's global challenges, including hunger and malnutrition, climate change, and access to healthcare. For example, some biotechnology companies are developing technologies that can convert biological resources such as algae and switch grass into non-carbon-based fuels. Other companies are developing products and technologies with the potential for managing or defeating chronic and infectious diseases. And still other

companies are developing genetically-engineered crops and climate-friendly technologies to help feed the world's population. We believe that our members' products and technologies have global application, and as such BIO supports the Administration's efforts to develop a strategy for stimulating U.S. exports.

As previously mentioned, our members are primarily small-and medium-sized enterprises, many of which are developing technologies that are five to 10 years away from a commercializable product. They need investment capital to move the research and development process further towards commercialization, and the availability of such capital is highly dependent on transparent and effective regulatory and intellectual property (IP) regimes.

BIO's members have identified certain key markets, including China and India, and countries within our own hemisphere such as Brazil and Mexico, as potential regions for collaborations. These countries have shown through various initiatives and policies that they appreciate the role that biotechnology can play in their economies. They also have demonstrated varying degrees of appreciation for the complexity of biotechnology product development, which includes the need for coherent and investment-friendly regulatory and IP environments. Several of our companies have set up facilities in these countries and others have begun collaborative discussions with entities within these countries. These collaborative endeavors have the potential to benefit not only the countries mentioned above, but also the U.S. economy.

Yet even in these fairly sophisticated regions, our companies have encountered obstacles in the regulatory and IP arena that can hinder export of products and technologies in the biotech space. For example, in India and China, certain types of basic biotech inventions such as cell lines, plants and animals are not patentable and can therefore be expropriated. Further, it remains unclear whether polypeptides, nucleic acids, and other biomolecules are eligible for patents under these patent laws. This is compounded by the lack of meaningful protection for the data that must be generated to prove that pharmaceutical and agricultural chemical products are safe and effective. Under Article 39.3 of the

TRIPS Agreement, protection must be extended against unfair commercial use of such data by makers of generic copies of innovator products (i.e., novel products that must be shown to be safe and effective or to not cause significant risk to the environment). Because biotechnology products require regulatory approval, any data generated that is not protected can serve as a blueprint for the production of unauthorized copies. Biotechnology companies would be less likely to export their products into countries that do not provide meaningful IP and data protections.

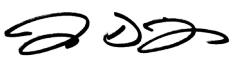
Agriculture biotechnology adds substantial value to U.S. agriculture. Fourteen years after the first product was commercialized, agricultural biotechnology has been proven safe and effective in increasing agricultural productivity and reducing pesticide use globally. Yet, U.S. exports of food and feed products derived from modern biotechnology and global adoption of biotechnology face a number of arbitrary and non-science based barriers globally. U.S. exports for the three main crops (maize, soy and cotton) and their products account for over $30 billion. Global barriers not only keep this number from increasing, but they also stifle innovation and increase research and development costs. In turn, these barriers delay the commercialization of next generation technology that keeps U.S. farmers competitive in the global marketplace. In an effort to remove these barriers and to help limit trade disruption, BIO's members are seeking global approval for products, including next generation traits that have proven effective against environmental stress, enhanced nutrition and increase nutrient efficiency. BIO urges the Administration to work with its current and potential trading partners to eliminate these barriers, and to implement, science-based regulatory schemes for biotechnology products.

The United States is currently the global leader in biotechnology. However, efforts abroad to undermine the IP rights of our members and regulations that restrict their market access, coupled with a desire by other trade partners to cultivate domestic industries, may threaten that status. As such, BIO urges this Administration to not only work to increase access to financing for innovators in these regions, but also to work to reduce regulatory barriers and strengthen IP protections in these key markets. In

addition, BIO urges the Administration to develop a more comprehensive regional approach to trade with respect to countries within our own hemisphere, including Brazil and Mexico, and to work to ratify pending free-trade agreements that will open additional markets to U.S. exports and thereby generate more U.S. jobs.

BIO stands ready to work with the Administration in this endeavor and we would like the opportunity to discuss these issues in more detail with the appropriate personnel.

Sincerely,



Tom DiLenge
General Counsel and Senior Vice President
Legal & Intellectual Property