BIO

BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

January 29, 2003

The Honorable Robert Zoellick
U.S. Trade Representative
600 17th Street, NW
Washington, DC 20508

Dear Ambassador Zoellick:

I am writing on behalf of the Biotechnology Industry Organization (BIO) with regard to your efforts to negotiate free trade agreements with Australia, Morocco, the South African Development Community and five countries in Central America. BIO represents the interests of more than 1,100 companies and research organizations engaged in cutting-edge research that will provide innovative medical, agricultural and environmental products to millions of people worldwide.

The biotechnology industry is ready and well positioned to do its share to contribute to international efforts to combat disease. In reality, however, the vast majority of our companies are small businesses that have no revenue and are facing significant developmental, market, regulatory and commercial challenges. For example, bringing a single biotechnology product to market can take 14 years and half a billion dollars. Investors here and abroad must have reasonable assurance that their capital investment will bring some returns. They look to biotechnology companies' assets to determine the value of their investment.

In many instances, the only asset our companies have is their intellectual property. Thus, the ability of our companies to obtain strong intellectual property rights globally and use them effectively in the United States and abroad is crucial to the long-term survival of our industry.

The United States' intellectual property system is the best in the world, and BIO advocates the establishment of global standards protecting intellectual property comparable to those in the United States. Unfortunately, existing international

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agreements governing intellectual property, including the WTO TRIPS Agreement, fail to meet this goal. Recent agreements with Jordan, Chile and Singapore were built somewhat upon the TRIPS standards, but these agreements also fall short of our industry's needs. We were however, pleased to see that the mandate for trade negotiations set forth in the Trade Promotion Authority passed last year by Congress calls for agreements that require our trading partners to establish levels of protection comparable to those found in the United States.

We have identified several issues that will help the biotechnology industry fulfill its promise, and we encourage you to make it a priority to resolve these issues in the upcoming negotiations.

First, new agreements must require our trading partners to grant patents on all types of biotechnology inventions, as in the United States. In particular, future agreements must close the loophole of Article 27.3(b) of the TRIPS Agreement by requiring Agreement signatories to grant patents on new, useful and nonobvious transgenic plant and animal inventions. We also are concerned that certain countries will reinterpret their TRIPS obligations to justify refusing to grant patents on nucleic acid, protein and cell line inventions. These types of products are the most common commercial embodiments of our intellectual property, and any limits on their patent eligibility will have serious commercial consequences for our companies. The language of these agreements must explicitly and clearly require parties to the agreement to grant patents on all classes of biotechnology inventions—including plant and animal inventions—that are protected under U.S. law.

Second, new agreements must prohibit our trading partners from imposing special patent application requirements for biotechnology inventions, such as to disclose the genetic origin of living materials used to make biotechnology inventions. Certain countries have passed laws demanding that we include this information in our patent applications; these requirements are onerous and nearly impossible to fulfill. Such special requirements, if unchallenged, will allow countries to deny our patent applications on grounds unrelated to the merits of the invention, and they will allow our competitors to mount unjustified attacks on our patents. U.S. trade negotiators must vehemently oppose disclosure requirements other than those specified in Article 29 of the TRIPS Agreement.

Additional issues that require your attention include a) requiring our trading partners to grant patents in a timely manner with the provision that patent terms be extended to compensate our companies for delays in patent approvals and b) requiring our trading partners to protect test and other data at the same level as these data are protected in the United States. With respect to the latter, trade provisions must explicitly prohibit countries from approving generic copies of new products for at least five years (for drugs) or 10 years (for agricultural products) following the approval date of the product in *each* market. These agreements must also prohibit the regulatory authorities in each country from approving generic copies of products for marketing while patents remain in force that cover the product. Market exclusivity must also be extended to "orphan drugs" in the same way such protection is extended in the U.S. regime. And, as is the case in the United States, periods of regulatory approval should be added to the term of a patent in each market.

BIO strongly supports your efforts to negotiate new agreements that create intellectual property systems in the markets of our significant trading partners that are comparable to those in the United States. We would be pleased to work with you and your staff on the appropriate resolution of these issues and other issues that affect our industry and the public.

Sincerely,

Carl B. Feldbaum
President
Biotechnology Industry Organization

CBFlf

cc: The Honorable Donald Evans, Secretary of Commerce
The Honorable James E. Rogan, Under Secretary for Intellectual Property and Director of the U.S. Patent and Trademark Office