



BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

December 10, 2003

The Honorable Robert Zoellick
United States Trade Representative
Executive Office of the President
600 17th Street, NW
Washington, DC 20506

Dear Ambassador Zoellick:

As you know, the Biotechnology Industry Organization (BIO) is a strong supporter of your efforts to negotiate free trade agreements with key trading partners of the United States. We firmly believe your efforts to liberalize trade will deliver benefits to patients, consumers and businesses abroad and in the United States.

We have previously communicated to you our member companies' priorities regarding free trade agreement negotiations. The highest is to establish standards to protect intellectual property to ensure that our innovations will be effectively and comprehensively protected in the markets of our trading partners. We believe the Administration and the Congress fully support this principle.

Recent reports regarding the state of negotiations on the Central American Free Trade Agreement (CAFTA) raise serious concerns within our organization. In particular, we have learned that the several of the nations that would be party to the CAFTA strongly oppose extending patent protection for transgenic crops and livestock, and strongly oppose extending plant variety protection using the standards set forth in the International Convention for the Protection of New Varieties of Plants (UPOV).

Frankly, we are puzzled by the opposition these nations have expressed to these protection standards. Central America is home to a biologically rich and diverse environment. Significant opportunities exist for the citizens of, and businesses in these

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countries to benefit from strengthening intellectual property protection for new plant technology and new crop varieties. Indeed, given the richness of resources in Central America, coupled with the capacity of plant breeders and many research institutions in the region, we find it difficult to understand why these countries would wish to *discourage* agricultural and other plant innovation. The opposition to UPOV is similarly puzzling, particularly in view of the fact that at least one nation is already a party to the UPOV Convention.

We also have learned that significant opposition exists to providing effective protection for the data our companies must generate to obtain marketing approval for new drugs, and for measures that will ensure effective patent protection for these products. Market exclusivity – which is delivered by patents and data protection measures – is the primary incentive that our companies have to invest in new drug development. Most of our members are small biotechnology enterprises that do not have products in the market. It is only the promise of market exclusivity that enables them to attract funding and enables them to continue their challenging drug development efforts. Standards in international agreements that effectively deny effective market exclusivity raise serious concerns with our members. Including such standards in Free Trade Agreements – which extend the most preferential access to our trading partners – would send a miserable message to our industry, which is based on innovation.

Simply stated, the opposition to effective and comprehensive intellectual property standards in the CAFTA will remove the primary incentive that these Agreements might present for BIO's members. Indeed, we believe that a CAFTA that enshrines inadequate standards – by failing to extend comprehensive patent eligibility to all biotechnology inventions (including transgenic plants and animals), by refusing to endorse globally accepted standards for plant variety protection, or by failing to extend workable and effective standards concerning data protection and patents associated with new and improved drugs – would fall far short of the requirements of the Trade Promotion Authority that Congress has granted to you, and would cause our members to oppose the implementation of the CAFTA.

We appreciate that you and your negotiators are working hard to deliver effective standards in the CAFTA. We hope these points will assist you in understanding our priorities for these negotiations, and will facilitate the completion of an effective agreement that our industry can support.

Sincerely,

A handwritten signature in black ink, appearing to read "Carl B. Feldbaum", with a long horizontal line extending to the right.

Carl B. Feldbaum
President
Biotechnology Industry Organization

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