



BIOTECHNOLOGY  
INDUSTRY  
ORGANIZATION

November 27, 2002

The Honorable Robert B. Zoellick  
United States Trade Representative  
600 17<sup>th</sup> St. N.W.  
Washington DC 20508

Dear Ambassador Zoellick:

I am writing to express the serious concerns of the more than 1,100 members of the Biotechnology Industry Organization (BIO) over recent developments in Geneva concerning the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS).

BIO represents the interests of companies engaged in cutting-edge research that will provide innovative medicines, agricultural and environmental products to millions of people worldwide. The vast majority of our member companies are involved in research and development in the health care arena. In the developing world, biotechnology R&D can do its part by producing vaccines that do not require refrigeration and are nasally or orally delivered. Furthermore, biotechnology's innovative approaches can provide medicines for difficult to treat diseases such as malaria, tuberculosis and cholera. In a speech before a gathering of biotechnology leaders in June, I called on biotech health leaders to devise a comprehensive program for diseases of the developing world. The biotechnology industry is ready to do its share to combat the world's health problems.

But the reality is that the vast majority of our members are small start-up companies concentrating on research. In fact, more than 90 percent of biotechnology companies have yet to bring a product to market, and thus, they rely on patent portfolios as their only assets. What a biotech company owns and markets is essentially ideas: for example, the discovery of a potential point of intervention in a disease process or the identification of a gene or a regulatory compound that might affect that process. But earning a patent is only the beginning of the work. The ability of these companies to raise funding from the capital markets is linked directly to the availability, strength and

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security of their intellectual property rights. Without certainty in rights, our companies simply cannot raise funds to conduct their research and offer their products on the market. Without funding, products to treat unmet medical such as assistance to help patients suffering from HIV/AIDS and other intractable diseases will not be developed.

BIO supports the objectives of the Doha Declaration on the TRIPS Agreement and Public Health issued by the Doha Ministerial last November. We support the position because we appreciate that the intellectual property standards in the TRIPS Agreement permit countries to take action when faced with grave and immediate public health crises. We further support the Doha Ministerial's call for the WTO to devise a way for certain poor countries to gain access to alternative sources of pharmaceutical products if they cannot obtain them from the pioneer producer. The biotechnology industry is fully aware that there are special circumstances for which a legally secure mechanism should be developed to allow poor countries afflicted with epidemics of HIV/AIDS, tuberculosis and malaria to obtain drugs from alternative sources.

But we cannot support eliminating intellectual property protections throughout the developing world for all pharmaceutical products. This was never the intent of the Doha Ministerial. We are surprised and troubled therefore, that the draft legal text that recently emerged in Geneva after months of discussions deviates so dramatically from the mandate of Doha. The text that was widely circulated in the press last week would allow producers in large developing countries with significant manufacturing capabilities to manufacture any drug and to export it to any country to address any health-care situation. Such a "solution" would create a huge loophole in the protections guaranteed by the TRIPS Agreement and undermine the intellectual property protections that serve as incentives for investment in biotechnology research and development. If patent protection is uncertain, the biotechnology community cannot fulfill its promise of producing groundbreaking medicines for treating HIV/AIDS, malaria and tuberculosis, among others.

We are concerned that the tenor and direction of the current debate sends a very troubling and inaccurate message about the role of intellectual property protection and the steps our industry is taking to help these countries address their public health challenges. Next week BIO and the Bill and Melinda Gates Foundation will be hosting an unprecedented conference in Washington that will stimulate the formation of public-private partnerships to develop new drugs for diseases that are prevalent in the developing world. Preserving the essential market-based incentives for intellectual property is a critical component of these efforts.

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We urge the administration to act now to ensure that any agreement reached by negotiators in Geneva reflects accurately the mandate of the Doha Declaration.

Sincerely,

A handwritten signature in black ink, appearing to read "Carl B. Feldbaum". The signature is fluid and cursive, with the first name "Carl" and last name "Feldbaum" clearly distinguishable.

Carl B. Feldbaum  
President  
Biotechnology Industry Organization

CBF:lf

cc: Peter Allgeier Deputy United States Trade Representative  
Joe Papovich Assistant United States Trade Representative  
Linnett Deily U.S. Ambassador to World Trade Organization  
James E. Rogan Undersecretary of Commerce  
Gary Edson, Deputy Assistant to the President