

August 16, 2007

Kimberly Halamar  
Manager: EU, China, APEC, Food & Agriculture  
United States Council for International Business  
1212 Avenue of the Americas  
New York, NY 10036

Dear Ms. Halamar:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to provide comments on the U.S. Council for International Business's response to the U.S. Trade Representative's Federal Register notice of July 25, 2007, requesting information on China's compliance with its WTO commitments.

BIO is a trade association representing over 1,100 companies, research institutions and affiliated groups with an interest in promoting biotechnology. Our members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products. The majority of our members are small biotechnology companies who are five to ten years from commercialization of their products, but whose innovative research holds promise for addressing diseases of the developing world, hunger and energy concerns. These companies rely on strong intellectual property (IP) rights to garner investment from venture capital markets, large companies and other financial sources. Strong intellectual property protection provides investors the needed assurance that their investment will yield a return. Weakened IP rights, on the other hand, will drive investment away from the biotech sector, which needs decades and hundreds of millions of dollars to bring a product to market, and toward less risky and potentially less beneficial, short-term investments.

Our members view China as one of the largest markets for biotechnology products. However, China's IP system is less than amenable to the growth and development of biotechnology within China's borders, and indeed poses a threat to the progress of the U.S. biotechnology industry. We ask that you consider the following issues as potential elements for inclusion in the USCIB submission on China's WTO compliance.

While China has made strides toward strengthening its IP protections, biotechnology companies continue to experience problems with counterfeiting and effective enforcement of intellectual property in certain provinces. BIO Members have noted an increase in the trafficking of counterfeit pharmaceuticals and biopharmaceuticals in China. Such counterfeits are troubling to our industry for several reasons. Of course, counterfeiting improperly deprives the owners of intellectual property of the value of their assets. However, the threat to public health, together with the economic costs of responding to clinical emergencies associated with the use of impure



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or ineffective pharmaceuticals, are of greater concern. Counterfeit medications place the public at unnecessary risk, and they divert the resources of industry and government agencies from productive uses. In this regard, BIO also notes that Chinese government agencies and municipalities lack the coordination and cooperation necessary to address enforcement issues. BIO urges more effective interdiction and enforcement against traffickers and distributors of counterfeit biopharmaceuticals. A reliable dispute resolution system that produces objective decisions and enforcement coupled with a public record of precedent would greatly enhance China's IP rights regime.

China has continued its progress toward establishing a comprehensive statutory scheme of intellectual property protection. BIO commends China in this regard. However, significant gaps in existing law remain. Additionally, as BIO has previously noted, ambiguities in China's intellectual property laws hinder patent procurement and enforcement. In the experience of BIO Members, such deficiencies in the legal framework contribute to a failure of the Chinese system to provide adequate and effective protection for intellectual property rights.

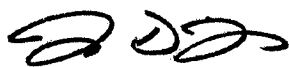
Specifically, some recent Chinese patent law amendments (Articles 48 and 49) may pose unique problems for the biotechnology sector. Chinese patent law currently provides for compulsory licensing, but the considerations that would trigger compulsory licensing as well as the scope and duration on the license need significant clarification.

We also note that new Article 63(5) provides a "Bolar exemption" to patent infringement for pharmaceutical products. However, unlike the law of most countries, this exemption is not balanced by any provision for extending the terms of pharmaceutical patents to compensate patent owners for delays encountered in the regulatory approval process. In the absence of such a provision, the Chinese patent law fails to provide adequate and equitable treatment to the owners of intellectual property relating to pharmaceutical inventions.

With respect to the provisions relating to agricultural biotechnology in the draft USCIB letter, BIO believes it is important to note that the examples provided are indicative of the types of problems experienced by the agricultural biotechnology industry in China. They are provided as illustrative examples and are not an exhaustive list.

Thank you for your consideration of BIO's concerns. Please feel free to contact me at [tdilenge@bio.org](mailto:tdilenge@bio.org), or via telephone at 202-962-6671, if you desire additional information.

Sincerely,



Tom DiLenge  
Vice President and General Counsel

