BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

March 31, 2006

By electronic mail and courier

Sybia Harrison, Special Assistant to the Section 301 Committee
Office of the United States Trade Representative
Washington, D.C.
FR0606@ustr.eop.gov

Re: "Identification of Countries Under Section 182 of the Trade Act of 1974: Request for Public Comment," 71 Fed. Reg. 2611 (January 17, 2006)

Dear Ms. Harrison:

I write on behalf the Biotechnology Industry Organization (BIO), a trade association representing more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations in all 50 U.S. states and 36 other countries. BIO members are involved in the research and development of health care, agricultural, industrial, and environmental biotechnology products and services. Our members depend heavily on predictable, enforceable intellectual property protection throughout the world.

BIO elected not to file a formal "Special 301" submission in response to your January 17 request. However, this letter is to inform you of our continuing concerns.

In its earlier submissions to the USTR, BIO identified a number of countries where serious deficiencies in the intellectual property systems deny adequate and effective protections for the activities of biotechnology innovators. These deficiencies are described in our previous 301 reports, including BIO's 2005 Special 301 Submission, attached for your convenience.

BIO appreciates the work that USTR has done to address our concerns. Indeed, BIO is gratified by tangible progress in several countries. For example, Israel has clarified its policies on patent term extensions and has made some progress regarding its data protection regime; and India has adopted TRIP-compliant standards for many products, including conventional pharmaceutical products, and has initiated consultations directed toward implementing a data protection regime.

However BIO is still concerned with a number of activities in these two countries. For example, both Israel and India still have problematic pre-grant opposition systems, used against innovators in the pharmaceutical sector by domestic competitors to delay the grant of enforceable patents. Further India defines the concept of "invention" narrowly, appearing to exclude the vast majority of biotechnology products from patent-eligible subject matter and has enacted a "source disclosure" requirement that imposes unreasonable burdens on patent applicants to trace the history of biological materials mentioned in patent applications. This disclosure requirement exists whether or not such information is relevant to making or using the inventions claimed.

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In spite of progress in some countries, activities this past year in others have raised particular concerns. In Brazil, the already dismal protections for the products of biotechnology innovators have deteriorated significantly in the last year. Brazil maintains its technology-discriminatory system for dual review of the patentability of medicinal agents. Patents for such agents are reviewed first by the Brazilian Patent Office and then by ANVISA, the pharmaceuticals regulatory agency. Contrary to Brazil's own patent statute and its obligations under the TRIPS Agreement, ANVISA has recently propagated guidelines that declare "second medical use" inventions (i.e., new uses for old products) are not patentable. In several well-publicized instances, the government of Brazil has also threatened to revoke legitimately granted patent rights to compel the owners of certain patents to conduct business on favorable commercial terms. BIO Members are deeply concerned about developments in Brazil that systematically deprive biotechnology innovators of adequate and effective protection for their products, and we urge USTR to act aggressively to promote needed reforms in that country.

Further, in Europe, BIO is dismayed that the European Commission has apparently discontinued any efforts to compel Member States of the European Union to adopt reforms necessary to comply with the European Biotechnology Directive (98/44/EC). In the absence of a uniform intellectual property regime in Europe, biotechnology innovators are burdened with the transactional costs of conducting business in a single market with inconsistent levels of intellectual property protection for their activities. We urge USTR to maintain its focus on this important issue.

In sum, BIO appreciates the efforts USTR has taken on behalf of our industry and applauds the USTR's 2005 accomplishments. However BIO continues to view all of the countries identified in our 2005 Special 301 submission with serious concern. Thus, for the reasons we identified in past years, we encourage USTR to continue its efforts to motivate appropriate reforms in the countries we have previously identified and to particularly scrutinize activities in Brazil, Argentina, China, Egypt, Canada, and Europe.

Please let us know if we can answer any questions regarding the above or provide additional information and/or resource materials to support USTR's efforts.

Sincerely,

Lila Feisee

Director for Intellectual Property