BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

February 5, 2004

Claudia McMurray
Deputy Assistant Secretary for Environment
Bureau of Oceans and International Environmental and Scientific Affairs
U.S. Department of State
2201 C Street NW
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Dear Ms. McMurray:

I write on behalf of the Biotechnology Industry Organization (BIO). BIO is a trade association representing the biotechnology industry, having more than 1000 members worldwide. We very much appreciate your efforts and those of your staff to keep the private sector aware of the issues that are likely to arise at the upcoming Conference of the Parties (COP) of the Convention on Biological Diversity.

We remain deeply concerned about the direction and potential outcome of the upcoming meeting of the COP. In particular, certain proposals related to the Convention's provisions for Access and Benefit Sharing would, if implemented, impose unwarranted constraints on our Members' business activities – even those having no relationship to the genetic resources the Convention ostensibly protects. We also believe that many of the proposals now advocated would unreasonably complicate the international intellectual property landscape. Because worldwide intellectual property protection is essential to the biotechnology industry, we view these proposals as particularly troublesome. Indeed, the practical effect of many of these proposals would be to undermine the primary purposes of the Convention to promote the conservation, preservation and sustainable use of genetic resources.

We offer the following comments for the consideration of the U.S. Delegation. Many of these points have been previously communicated to the State Department, the Patent and Trademark Office, and the Office of the United States Trade Representative. We appreciate that the United States is not a Party to the Convention and that the role of the U.S. Delegation is, therefore, somewhat limited. Nevertheless, we believe that the positions of the U.S. Delegation influence the Parties and encourage the Delegation to actively participate in the Conference.

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General approach

We do not believe that any changes to international law – particularly the Convention on Biological Diversity, or trade agreements or treaties – are needed to protect the rights and interests of countries from which genetic resources originate. Rather, we believe that additional experience with the Bonn Guidelines, capacity building particularly in the area of negotiation of material transfer agreements and other contracts, and appropriate national regimes are the keys to ensuring that providers in countries of origin share equitably in the benefits derived from use of their biological resources.

As a consequence, we prefer that the Conference adopt the "gap" approach embodied in the second alternative for the chapeau of paragraph 2 of Recommendation 2/4 on access and benefit-sharing (see UNEP/CBD/COP/7/6). This, in our view, would preclude negotiating redundant or possibly conflicting instruments. In view of the study and analysis this approach would require, we believe that the target of 2010 for completion is more appropriate than any shorter timeframe. Moreover, all of the tasks envisioned in the recommendations of the Ad Hoc Working Groups on Access and Benefit-sharing and on Article 8(j) represent an ambitious agenda. We do not think that sufficient resources – human or financial – exist to undertake those recommendations and a fast-track negotiation on an international regime for access and benefit-sharing.

Relationship to the Convention

We believe that any negotiation under the auspices of the Convention on Biological Diversity should be closely linked to the goals and jurisdiction of the Convention. Thus, we support limitations to this effect in Recommendation 2/4 and other recommendations. We believe that such limitations would:

(1) preclude difficult negotiations on access to human genetic resources, as those resources are expressly excluded by a Decision of the Parties interpreting the Convention;

(2) confine negotiations regarding traditional knowledge to such knowledge covered by Article 8(j) of the Convention – a much more manageable and more appropriate task than regulating the universe of traditional knowledge; and

(3) preclude negotiations on resources acquired before the entry into force of the Convention and, thus, avoid some thorny issues of retroactive application.

Special disclosure requirements in patent applications

We do not believe that special disclosure requirements would significantly improve the possibilities for sharing benefits equitably with providers of genetic resources. Furthermore, we believe that such requirements would impair the operation of existing intellectual property

systems, even with respect to inventions that do not use genetic materials found through bio-prospecting. We also believe that concepts and models suggested to date would not be workable, and indeed, would impose costs and risks on use of genetic resources that would make our Members even less likely to attempt to explore, study, use or develop such resources. Consequently, we believe a mandate to negotiate such a system, or to define special patent application requirements, is not desirable, and is strongly opposed by our Members.

Derivatives

We note Recommendation 2/4 would extend disclosure requirements to "derivatives" of genetic resources (i.e., a disclosure of an invention using a "derivative" of a genetic resource would be required to include the origin of the underlying genetic resource). A definition for this term is proposed in Recommendation 2/2. We do not believe that the term should be used in Recommendation 2/4 until it has been defined. More to the point, we seriously doubt that it would be appropriate to incorporate the term under any definition that we can envision.

Prior Informed Consent

Recommendation 2/5, involving prior informed consent, contains several bracketed provisions that concern technical information that could be supplied by the World Intellectual Property Organization. We believe that discussions under the auspices of the Convention would benefit significantly from such expert information. We therefore support removing the brackets and incorporating the text in the Recommendation.

Sui generis protection for traditional knowledge

Recommendation 3/7 contains provisions that would initiate discussions within the Convention on Biological Diversity on the protection of traditional knowledge. We note, however, that this Recommendation is not limited to the subset of traditional knowledge defined in Article 8(j). Instead, the discussions would include traditional knowledge involving human biological resources and traditional knowledge unrelated to biological resources or the conservation of biological diversity. Thus, the Recommendation goes well beyond any expertise or mandate of the Convention. It should be limited.

Traditional knowledge and the public domain

We find certain proposals regarding traditional knowledge to be particularly problematic. In particular, we note that several of the "whereas" clauses in Recommendation 3/7 reveal that its drafters wish to gain economic rights over traditional knowledge now considered to be in the public domain, and to give control of information acquired before the entry into force of the Convention. If adopted, this Recommendation would create many significant legal and practical problems.

Vinblastine and vincristine provide one example. These drugs were created from the Madagascar rosy periwinkle in the 1950s to treat Hodgkin's disease and leukemia. This was, of course, long before the conclusion of the Convention on Biological Diversity; knowledge resources were then considered "free access goods." The patents associated with these active ingredients have expired, and the technology disclosed in thee patents is in the public domain in the United States and, we expect, in most other countries. Indeed, there are three approved generic suppliers of vinblastine in the United States, and there are four approved generic suppliers of vincristine in addition to the drug's originator. The drafters of Recommendation 3/7 wish to remove this technology from the public domain and gain economic rights over it, presumably in perpetuity.

The Recommendation would lead to even more extreme consequences. Consider that an indigenous community in South America transferred knowledge to early European explorers that the bark of the *Chincona ledgeriana* tree could be used to treat malaria. This information was disseminated worldwide. Use of the information eventually led to the isolation of quinine, still one of the leading antimalarial drugs. Hundreds of patents were granted in the United States containing the world "quinine" in the claims (198 since 1976 alone), many of which have expired and are in the public domain. Yet, if Recommendation 3/7 were adopted, this information would permit recapture of economic rights over the technology – not only for the original knowledge, but for all improvements since the 17th Century!

We find proposals that would have these consequences wholly unrealistic, inherently unworkable and entirely objectionable. Moreover, should this become the true focus of efforts to protect traditional knowledge, we fear that it would legitimize a perspective on this issue that is deeply troubling; namely, that the mere existence of plants or possession of knowledge somehow outweighs the immense, value-adding contributions of innovators in converting undeveloped natural resources into valuable innovative products and services.

We also cannot see how such a development could contribute in any way to encouraging the United States to ratify the Biodiversity Convention. Indeed, it would cause BIO to reevaluate its recorded support for this Convention. As such, we believe it is imperative that protection for traditional knowledge be limited to knowledge acquired after the entry into force of an international agreement or relevant national laws, and be implemented in a manner that does not conflict with other forms of intellectual property protection.

Access to genetic resources and the public domain

Little has been said to date about imposing benefit-sharing provisions with respect to resources acquired before the entry into force of the Convention on Biological Diversity. It is the proverbial "elephant in the room" that everyone is ignoring. We believe that proponents of an international regime on access and benefit-sharing wish any negotiated regime to apply to those resources. As with proposals regarding traditional knowledge, retroactive requirements would not be feasible, given that most of these resources have entered the public domain in the

United States and most other countries. It would also conflict with the well-established principle in the Convention that its terms were to apply in a prospective-only manner.

Again, we believe that it is imperative that any negotiating mandate be limited to resources accessed after the entry into force of the Convention on Biological Diversity.

Certification systems

Several of the recommendations would authorize rather sweeping discussions of systems to certify the origin of genetic resources and prior informed consent. Apparently the drafters assume that certification systems may make it easy to police access to genetic resource in a relatively "simple" manner.

We find it very difficult to believe that certification systems would be a useful tool in any but the most limited circumstances. We are certain that they would not be inexpensive or simple to operate. Yet, the drafters predicate the feasibility of some patent disclosure requirements on the existence of working certification systems – systems that are years away from operation, if they will ever operate. To the extent possible, we believe that negotiating instructions should not rely on the assumption that effective certification systems will be available.

TRIPS Agreement and other agreements

Recommendations 2/4 and 3/7 are drafted broadly and give the negotiators plausible authority to suggest solutions that would be inconsistent with the TRIPS Agreement. We believe that this is inappropriate. Any suggested solutions should be within the scope of the Convention on Biological Diversity and consistent with the provisions of the TRIPS Agreement.

Communication from the Commission

In December the European Commission forwarded a Communication to the European Parliament and Council on the operation of the Bonn Guidelines within the European Union. Section 7.3 of the Communication states (emphasis in original):

> The Commission believes that the EC and its [Member States] should be ready to discuss, in the relevant international fora, the possibility of introducing under intellectual property law the same **disclosure requirement** presented above [i.e., a requirement for the disclosure of the geographical source of genetic resources] but **as a formal condition for patentability** and not only as a self-standing obligation. The consequences of the non-respect of such a formal requirement could lie both within and outside the patent law system. In relation to patent law, they could include the non-processing of the patent application until the patent applicant has provided the required declaration, and the invalidation or revocation of the patent if the incorrect declaration of the source is due to fraudulent

intention. Outside patent law, they could give rise to distinct sanctions to be determined at national level as in the case of a self-standing obligation.

This appears to be a change in the position of the Commission, which previously insisted that sanctions for failure to fulfill disclosure requirements should be outside the patent system. It had previously viewed such sanctions as inconsistent with the TRIPS Agreement. We are therefore concerned that the Commission is essentially stating that it would be willing to re-open the TRIPS Agreement to accommodate the results of negotiations on disclosure requirements. It would be useful to determine if this was the intent of the Commission, or if instead, this portion of the document was poorly drafted.

Conclusion

We hope these comments will be useful to the Delegation, and we stand ready to assist them. If there are any questions on our views or other assistance needed, please contact Lila Feisee (202-962-9502) of my staff, or our trade counsel, Jeff Kushan of Sidley Austin Brown and Wood (202-736-8914).

Sincerely,

L. Val Giddings, Ph.D.
Vice President for Food and Agriculture

cc: Christine Dawson, Bureau of Oceans and International Environmental and Scientific Affairs [DawsonCL@state.gov]
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