



BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

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**Fourth Meeting of the Ad Hoc Open-Ended
Intersessional Working Group
On Access and Benefit Sharing:
Granada Spain
January 30-February 3, 2006**

BIO Side Event: January 31, 2006

BIO's Guidelines for Bioprospecting

Background

The Biotechnology Industry Organization (BIO) consists of more than 1000 enterprises in over 36 countries. BIO's members create a wide range of products from agricultural and environmental products to healthcare products. More than 90 percent of BIO members are small businesses that are years away from profitability. It can take decades and hundreds of millions of private dollars for a biotechnology company to commercialize a biotechnology product. This is because of the lengthy R&D timeframe and the rigorous regulatory review process generally associated with biotechnology products. In order to translate an innovative idea into a commercially viable product, companies turn to their patent portfolios to generate private investment funding. Consequently, changes that add uncertainty or complexity to the process of obtaining or maintaining patents decrease the value of the patent system to investors which, in turn, discourages research and development of new biotechnological products.

Most biotechnology companies rely on biotechnology platforms to develop new products. Very few biotechnology companies focus on natural product development through bioprospecting, but those that do engage in bioprospecting have a strong track record of creating pioneering arrangements and compliance with the *Bonn Guidelines* developed under the Convention on Biological Diversity (CBD). BIO's members insist on following the strictest of standards with respect to bioprospecting. In fact, our recent *Guidelines for Members Engaged in Bioprospecting*, developed at the request of our members as general principles, reflect standards of conduct articulated in international agreements and the best of national practices. Also, these *Guidelines* were intended to educate members who do not presently bio-prospect but who may wish to do so in the future.

1225 EYE STREET, N.W., SUITE 400
WASHINGTON, D.C. 20005-5958

202-962-9200
FAX 202-962-9201
<http://www.bio.org>

BIO's Guidelines

BIO's *Guidelines* (1) correspond closely to the conditions and requirements of the CBD and the *Bonn Guidelines* and (2) address certain matters that are likely to arise in connection with bioprospecting, but in respect of which the CBD provides incomplete or no guidance.

Our *Guidelines* (1) recognize the importance and value of biological diversity; (2) provide assistance to BIO members seeking guidance in this area; and (3) educate BIO members how to conduct bioprospecting in compliance with national and international regimes by (a) identifying certain "best practices" that can be followed when bioprospecting, and (b) providing a useful "roadmap" for BIO members to use when bioprospecting.

Our *Guidelines* apply to "Regulated Genetic Resources" (those subject to the CBD and the *Bonn Guidelines*) but do not apply to human materials, genetic resources placed in an *ex situ* collection in a Party before the date the CBD entered into force with respect to a Party, genetic resources made available to the public on an unrestricted basis, or publicly available information.

Before BIO members engage in bioprospecting, they are directed to: (1) identify the "Providing Party" and any established requirements for bioprospecting; and (2) negotiate a "Bioprospecting Agreement" which includes "Prior Informed Consent" and proper use and handling conditions. If a BIO Member cannot identify the requirements for bioprospecting, that member is still directed to provide at least the following information to the Providing Party: (1) the general nature of the planned activities to be conducted (screening, growth, *etc.*); (2) the anticipated ultimate use (pharmaceutical, agricultural, *etc.*); and (3) the identity of the lead researcher or a contact point for the research.

Our *Guidelines* also direct BIO members to give good faith consideration to benefit sharing, including: (1) monetary benefits upon signing the Bioprospecting Agreement; (2) later payments upon commercialization; (3) technical sharing and cooperation; (4) training opportunities; (5) joint research; and (6) research and origination credit and information sharing.

Importantly the *Guidelines* direct BIO members to: (1) respect the customs, traditions, and values of indigenous and local communities; (2) respond to their requests for relevant information; (3) take reasonable steps to handle confidential information as requested; and (4) avoid actions that impede the traditional use of Regulated Genetic Resources. BIO members are further directed to: (1) take reasonable steps to prevent harm or alteration to the local environment; (2) avoid taking actions that pose a threat to the conservation or sustainable use of biological diversity; and (3) take all reasonable steps and give good faith consideration to sharing data derived from research that may be useful to support conservation efforts.

On the issue of compliance, our *Guidelines* direct BIO members to: (1) comply with all Bioprospecting Agreement terms; (2) maintain records relating to handling, storage and physical movement of Regulated Genetic Resources; (3) avoid accepting samples of genetic resources from a third party without evidence of Prior Informed Consent; and (4) include provisions in Bioprospecting Agreements to resolve disputes.

BIO Members respect biodiversity and want to follow BIO's *Guidelines*. To do so, they need help with identifying the entities they should contact and negotiate with in each country and with obtaining certainty through clear legal requirements for bioprospecting - requirements that are practical and workable for all.

Search for Possible Cases of Biopiracy

In an effort to further the dialogue on alleged cases of biopiracy, the Government of Peru submitted a document to the WTO Council on TRIPS (IP/C/W/441/Rev.1) in which it identified 144 patent families that it suggested might be evidence of bio-piracy. Both BIO and PhRMA (Pharmaceutical Manufacturers of America) took concerns of Peru seriously and analyzed the document in some detail.

Cited patent families were not owned by members of BIO or PhRMA Members, with only a few exceptions. Furthermore, only a few patent families out of 144 cited claimed a "pharmaceutical" or "biotechnological" invention. The most prevalent uses of the inventions claimed in the cited patent families were herbal remedies or "nutraceuticals", food for animal or human consumption (not bioengineered), or cosmetics.

All of these materials alleged to have been expropriated through biopiracy are available from commercial suppliers on an unrestricted basis. More importantly, for nearly every species identified in the document there is at least one Peru-based supplier of samples. Again, to our knowledge, none of these suppliers imposed any conditions or restrictions on use of the samples of materials it provided.

Interestingly, most patent families disclosed the crushing, mashing, and then treating of plant materials with a solvent, which yielded an extract from the plant. It was this extract that was described as the invention, not the plant *per se* or isolated or characterized constituents of the extract. It should be noted that BIO or PhRMA members do not pursue these types of uncharacterized products. Moreover, in a few instances, the genetic resource cited by the Peru in the patent applications was not the resource utilized in the invention.

While, BIO and its members take these allegations of biopiracy seriously, they do not believe that the document submitted by the Government of Peru demonstrates the existence of widespread biopiracy, especially a type of biopiracy that could be most effectively regulated through the patent system.

An Academic's Perspective

Jorge Cabrera, INBio's legal adviser and international consultant on access and benefit-sharing (ABS), also commented on the difficulties facing the user of genetic resources due to the lack of clear frameworks for ABS in a huge number of countries. Only 25 countries have some ABS provisions in place. The BIO Guidelines are a good effort to present good practices and to prevent biopiracy claims. Any guidelines or codes of conduct should build trust between users and providers of genetic resources. For achieving the goal of equitable access and benefit sharing, some acceptance-recognition from the providers as a good practice would be useful. He highlighted the importance of integrating and promoting synergies among this initiative and other initiatives such as the ABS Management Tool.

A Company's Perspective

Du Pont, a BIO member company who participates in both agricultural and industrial biotechnology, was represented by Jeff Fritz who described his company's procedures for compliance with the CBD and other "best practices" with respect to access and benefit sharing. DuPont has for several years operated under a set of Bioethics Guiding Principles, developed by DuPont, and consistent with the CBD, the Bonn Guidelines and the new BIO Guidelines on Bioprospecting. Encompassed in those Principles are long-standing commitments to conserving biodiversity, providing net gains for the environment, identifying the legitimate right-holders of a genetic resource or technology, contributing to developing economies and alleviating hunger. As a result, DuPont has engaged in contract-based benefit sharing from many years. Since 2000, DuPont has utilized an independent panel of international experts to guide, review advise the Company on its compliance with these Guiding Principles, as well as its use biotechnology and sustainable resources.

Mr. Fritz also expressed the hope that the CBD will facilitate the development of national regimes for access and benefit sharing. He described several situations in which the lack of a coordinated national regime and authorized focal point, either threatened or eliminated the possibility of DuPont acquiring genetic resources and providing appropriate benefit-sharing there from.. For example, Du Pont refuses to acquire genetic resources from providers that cannot demonstrate that the resources were obtained with prior informed consent after implementation of the CBD. If no national authority exists to provide that consent, the opportunity for use of those resources, and the resulting benefit-sharing, is lost.