COMMENTS OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION (BIO) AND THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA) ON ISSUES TO BE ADDRESSED BY THE TECHNICAL AND LEGAL EXPERTS GROUP ON COMPLIANCE

Introduction:

Decision IX/12 of the Ninth Session of the Conference of the Parties (COP-9) of the Convention on Biological Diversity (CBD) "*[i]nvites* Parties, Governments, international organizations, indigenous and local communities and relevant stakeholders to provide information and views related to the issues to be addressed by each expert group."

The Biotechnology Industry Organization (BIO) and the Pharmaceutical Researchers and Manufacturers of America (PhRMA) appreciate this opportunity to submit comments on matters to be addressed by the Technical and Legal Experts Group on Compliance ("Compliance TEG"). BIO and PhRMA respectfully request that the experts selected for the Compliance TEG take these comments into consideration during their deliberations.

General Comments:

BIO and PhRMA members firmly believe that the proposed international regime on access and benefit-sharing should be within the scope of the CBD. It is also our strong belief that a "one size fits all" approach is not workable for the International Regime. Suppliers and recipients of genetic resources will obtain optimum economic and social benefits through the negotiation of "mutually agreed terms" for access and benefit-sharing at the "point of access," rather than applying a fixed access scheme and a fixed "basket" of benefits mandated by a treaty. Negotiations at the point of access would allow suppliers and recipients to determine the appropriate balance between "up-front" and "back-end" benefits for the relevant transaction as well as to determine an appropriate level of benefits arising from the contemplated arrangement. Compliance measures envisioned under the International Regime should be consistent with this approach.

BIO and PhRMA members support providing for effective compliance measures under the International Regime to ensure that the objectives of the CBD can be implemented in a fair and equitable manner that facilitates access. In that light, the use of existing tools, including the use of private international law mechanisms, should be further considered. Some of these tools, including mediation, arbitration and other dispute settlement mechanisms, are currently used effectively in many international business transactions and provide a good foundation for facilitating transactions relating to genetic resources. The delegation of Canada has explained the utility of such measures in their submission to the sixth session of the ABS Working Group (UNEP/CBD/WG-ABS/6/INF/3/Add.2).

<u>*Note on compliance and intellectual property.*</u> Industry strongly opposes acceptance of proposals for new disclosure requirements in patent applications relating to genetic resources. Industry is of the view that such requirements will be (a) ineffective in promoting the objectives sought (e.g., compliance with CBD principles) and (b) will introduce uncertainties into the patent system that will inhibit innovation in relevant technologies and will thereby decrease potential benefit-sharing from such efforts. Detailed and lengthy discussions in the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO) have confirmed this view. These requirements should not be included in the International Regime. Instead, promoting access and benefit-sharing through "mutually agreed terms" is the best approach. To the extent further discussion is necessary on these proposals, it should be done at WIPO, which has an intergovernmental committee (IGC) with a specific mandate to discuss matters regarding the relationship of intellectual property and genetic resources, traditional knowledge and folklore.

Specific Comments:

The terms of reference of the Compliance TEG provide that the experts group will consider and address the following questions. The questions are reproduced below and are followed by the comments of BIO and PhRMA.

(a) What kind of measures are available, or could be developed, in public and private international law to:

(i) Facilitate, with particular consideration to fairness and equity, and taking into account cost and effectiveness:

a) Access to justice, including alternative dispute resolution;

b) Access to courts by foreign plaintiffs;

(ii) Support mutual recognition and enforcement of judgments across jurisdictions; and

(iii) Provide remedies and sanctions in civil, commercial and criminal matters;

in order to ensure compliance with national access and benefit-sharing legislation and requirements, including prior informed consent, and mutually agreed terms;

Comment:

Facilitating access to justice and access to courts by foreign plaintiffs

Any enforcement measures considered by the Compliance TEG should build on existing systems.

In the case of enforcing ABS systems and facilitating access to justice, private international law offers many alternative dispute mechanisms that are currently used to enforce contractual agreements relating to international business transactions around the world.[1] Existing measures such as negotiation, mediation, arbitration and consideration of enforcement of foreign judgments should be further elaborated and adapted for use in this context. The New York Convention on the Recognition and Enforcement of Foreign Arbitral Awards (New York Convention) could provide a good starting point for discussion. The New York Convention currently has 143 members. It is truly a multilateral agreement and is an effective mechanism for settling disputes involving cross-border parties.

Mediation and arbitration offer many advantages as a model for compliance methods under the CBD. First, there are existing models for these programs. The International Chamber of Commerce (ICC) has highly developed programs in amicable dispute resolution processes, such as mediation, and has a well-recognized court of arbitration. The WIPO Arbitration and Mediation Center also provides for the resolution of international commercial disputes between private parties with highly developed procedures that are widely recognized as particularly appropriate for disputes involving intellectual property.[2]

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[1] *See, e.g.*, *Compilation of Submissions Provided by Parties, Governments, Indigenous and Local Communities, and Stakeholders on Concrete Options on Substantive Items on the Agenda of the Fifth and Sixth Meetings of the Ad Hock Open-ended Working Group on Access and Benefit-Sharing: Submission from Canada*, UNEP/CBD/WG-ABS/6/INF/3/Add. 2 (Jan. 15, 2008).

[2] *See* description of WIPO Arbitration and Mediation Center, *available at* http://www.wipo.int/amc/en/.

It is also instructive that the text of the CBD itself provides for rules of dispute settlement between the Contracting Parties that follow a multi-step negotiation-mediation-arbitration model.[3] A similar approach is also included in the standard material transfer agreement (SMTA) concluded under the Food and Agriculture Organization (FAO) International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).

Supporting mutual recognition and enforcement of judgments across jurisdictions:

The potential to improve foreign enforcement of judgments should be studied further. However, CBD Members in the past have been reluctant to recognize judgments from other jurisdictions. Indeed, the relative failure of the 1971 Hague Convention on Recognition and Enforcement of Foreign Judgments in Civil and Commercial Matters stands in stark contrast to the wide membership of the New York Convention and is instructive as to the political difficulties of this issue.

Nonetheless, there are mechanisms in national laws that provide for the enforcement of foreign judgments in a number of CBD Parties when certain conditions are met. For example, according to the submission of Canada to the ABS Working Group,[4] the clear trend in Canadian courts is to recognize and enforce foreign judgments. In addition, the recent 2005 Hague Convention on Choice of Court Agreements may also provide a tool to be considered in this context.

Providing remedies and sanctions in civil, commercial and criminal matters:

This topic should be understood in the sense of exploring remedies and sanctions available through the dispute settlement mechanisms mentioned previously. The International Regime should not attempt to impose direct civil or criminal regulation with respect to bioprospecting or related activities at the international level. Any such specific regulation should be the domain of national laws.

Civil remedies for violation of contractual terms can include provision of damages, injunctions, or other mechanisms to address breaches of contractual terms.[5] In addition, the parties to agreement can include clauses in the mutually agreed terms providing for particular remedies if a breach occurs. The International Regime should not attempt to regulate long-held principles of contract law regarding available remedies in the various jurisdictions.

In respect of compliance with national laws on access to genetic resources, BIO and PhRMA members understand that there are significant concerns about perceived illicit bioprospecting activities and other acts that may raise concerns of "misappropriation" or "bio-piracy." In order to address these concerns, CBD Parties may provide fines or other sanctions for violation of ABS laws. Civil remedies also may be available in jurisdictions providing a cause of action for torts, such as conversion, that can address wrongful acts in respect of genetic resources.

In addition, more work should be done in respect of studying the scope of these perceived activities. Industry supports a fact-based consideration of this issue in order to identify the magnitude of any such perceived acts and any evident gaps in national ABS regimes that may result in particular problems. However, it appears that most perceived instances of misappropriation result either from the lack of appropriate national ABS regimes or lack of information to researchers working in-region. Punitive measures, therefore, will likely not address the perceived problems but may instead exert a significant chilling effect on legitimate researchers seeking to engage in activities in those countries. In that light,

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[3] CBD Article 27 provides that parties seek to resolve disputes first by negotiation, then mediation by a third party and, if those efforts fail, it provides for arbitration. CBD Article 27.3(b) also provides an option for submission of the dispute to the International Court of Justice. However, we do not view this as a workable model for disputes relating to ABS agreements concluded pursuant to the International Regime that may involve private parties.

[4] UNEP/CBD/WG-ABS/6/INF/3/Add.2, *supra* note 1.

[5] *See, e.g.,* E. ALLAN FARNSWORTH, FARNSWORTH ON CONTRACTS, Vol. III, §12.2, pp. 153-154 (1998).

overly punitive measures would be contrary to the requirements of the CBD to facilitate access and should be avoided.

The International Regime should focus instead on measures for increasing awareness of national ABS requirements by those engaging in bioprospecting activities, as well as capacity building efforts for countries developing effective ABS regimes.

(b) What kind of voluntary measures are available to enhance compliance of users of foreign genetic resources;

Comment:

Awareness-raising measures aimed at those engaging in bioprospecting activities, as well as capacity building efforts for countries developing effective ABS regimes are voluntary measures that would enhance compliance of users of foreign genetic resources. It is our belief that the vast majority of researchers and others seeking access to genetic resources are good-faith actors that intend to fully comply with local ABS laws. These methods would be highly effective at enhancing compliance of these actors.

In addition, there are currently voluntary industry guidelines that seek to formalize "best practices." BIO has published guidelines to educate and assist its members on access and benefit-sharing practices.[6] BIO has also published a model material transfer agreement (MMTA).[7] In addition, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) has also published guidelines for its members in this area.[8] While not intended to be standard agreements or mandatory codes of conduct, these guidelines help identify "best practices" in the industry and also are intended to be updated as practices change.

(c) Consider how internationally agreed definitions of misappropriation and misuse of genetic resources and associated traditional knowledge could support compliance where genetic resources have been accessed or used in circumvention of national legislation or without setting up of mutually agreed terms;

Comment:

BIO and PhRMA members are strongly of the view that the International Regime must be within the scope of the CBD. In that light, providing a definition of "misappropriation" or "misuse" in the International Regime itself may not be appropriate as these terms are not found in the CBD.

However, a further understanding of the concept of "misappropriation" or "misuse" or other terms might be helpful for discussion purposes in the ABS Working Group. In that light, greater convergence by CBD members regarding the meaning of these terms for purposes of discussion could be helpful. It is noted that, in certain jurisdictions, "misappropriation" and "misuse" have particular meanings within the context of unfair competition and anti-competition laws, respectively, which further adds to confusion and, perhaps, may indicate that different terminology should be used to capture notions of illicit acts undertaken in respect of genetic resources.

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[6]Guidelines for BIO Members Engaging in Bioprospecting, *available at* http://www.bio.org/ip/international/200507guide.asp

[7] BIO Model Material Transfer Agreement, *available at* http://www.bio.org/ip/international/BIO_Model_MTA.pdf

[8]Guidelines for IFPMA Members on Access to Genetic Resources and Equitable Sharing of Benefits Arising Out of Their Utilization, *available at* http://www.ifpma.org/Issues/fileadmin/templates/ifpmaissues/pdfs/2008_05_22_Guidelines_Genetic_Resources_EN.pdf

Any definition should be linked to compliance with national ABS laws. In other words, if there is no violation of national law, there can be no "misappropriation." This is a concept that has not reached a level of common understanding in the Working Group. As noted in the submission of ICC for the Concepts TEG,[9] the International Regime cannot remedy gaps in national legislation; failure of countries to fulfill CBD obligations in developing ABS regimes will directly lead to non-fulfillment of ABS objectives.

(d) How could compliance measures take account of the customary law of indigenous and local communities?

Comment:

Compliance measures that take into account the customary law of indigenous and local communities should be developed at the national level. The vast differences in customary law approaches within and among States make it impossible to design a "one size fits all" approach that would be functional at the international level. The International Regime should include provisions that articulate guidance for national ABS regimes, such as the identification of clear points-of-contact to ensure that legal certainty, clarity and transparency are maintained. In this manner, recipients of genetic resources will know what requirements apply to obtaining genetic resources, whether these requirements are derived from customary law or not.

If the national ABS regime does not fully comply with customary law principles, it is the State that should be held accountable and the laws changed. As noted, the International Regime cannot remedy gaps in national legislation, whether these gaps relate to customary law or other matters.

(e) Analyse whether particular compliance measures are needed for research with non-commercial intent, and if so, how these measures could address challenges arising from changes in intent and/or users, particularly considering the challenge arising from a lack of compliance with relevant access and benefit-sharing legislation and/or mutually agreed terms.

Comment:

It is not clear whether particular compliance measures under the International Regime would be needed for research with non-commercial intent. Generally speaking, the type of research envisioned will likely drive the terms that are to be mutually agreed between the relevant parties. For such cases, a specific set of rules under the International Regime would not be necessary. The agreements themselves would limit the research to non-commercial uses, commercial uses or a combination of the two, and would address benefit-sharing terms accordingly. BIO and PhRMA members view this as the optimal approach.

Nonetheless, there may be some CBD Parties that envision a split system with different rules of access for non-commercial research. It will be very difficult to specifically define this activity. If such an approach is considered by the Working Group, any such work should full address the ability to "convert" from non-commercial to commercial research. This is likely highly fact-specific and would be workable if, and only if, a clear definition for what is intended by "non-commercial" research is developed and how this may transition to "commercial" applications.

It should be noted that even where a country may pursue a bifurcated system, the compliance measures previously described would be applicable to all cases of unauthorized access. Countries may choose to apply only a particular subset of such measures to behavior that can objectively be determined to have

[9] *Good Business Practices and Case-Studies on Biodiversity: Report Submitted by the International Chamber of Commerce*, UNEP/CBD/ABS/GTLE/1/INF/1 (Oct. 31, 2008).

been in pursuit of "non-commercial" research objectives. In any case efforts should be made to ensure that the compliance measures in question are effective to enforce ABS requirements while facilitating access consistent with CBD and do not become barriers to access themselves.