VIEWS AND PROPOSALS
OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION (BIO) AND
THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA)
FOR THE EIGHTH MEETING OF THE AD-HOC OPEN-ENDED WORKING GROUP
ON ACCESS AND BENEFIT-SHARING

July 31, 2009

General Comments:

The Decisions of the Conference of the Parties (COP) of the Convention on Biological Diversity (CBD) define the work program for the Ad Hoc Open-ended Working Group on Access and Benefit-Sharing (ABS Working Group). Decision VII/19 requires the ABS Working Group to continue to "elaborate and negotiate an international regime on access to genetic resources and benefit-sharing" at its eighth meeting in Montreal, Canada in November. Decision VIII/4 instructs the ABS Working Group to complete its work by the earliest possible time before the tenth meeting of the COP in October 2010.

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 submit, for further elaboration and negotiation of the international regime on access and benefit-sharing, views and proposals including operational text, where relevant, in respect of the main components listed in Annex I to the present decision, preferably with supporting rationale."

In response to this invitation, the Biotechnology Industry Organization (BIO) and the Pharmaceutical Research and Manufacturers of America (PhRMA) are pleased to submit the following views and proposals of their members regarding the components listed in Annex I to Decision IX/12 that were not addressed at the seventh meeting of the ABS Working Group. These topics are: Traditional Knowledge Associated with Genetic Resources, Capacity Building, and Nature of the International Regime.

This submission also includes views and proposals related to the main components of the Regime taken up at the seventh meeting of the ABS Working Group (Fair and Equitable Benefit-sharing, Access to Genetic Resources and Compliance) that also will be taken up at the eighth meeting. This part of the submission builds on the Annex to the Report of the Seventh Meeting of the ABS Working Group (UNEP/CBD/WG-ABS/7/8), as requested in the notification from the Executive Secretary.

It should be emphasized that these views are limited to a group of priority issues for BIO and PhRMA and do not represent an exhaustive list of BIO's and PhRMA's views on the draft texts or the topics raised thereby. BIO and PhRMA intend to continue to engage actively on these and other matters in this process with the goal of establishing an International Regime that benefits all stakeholders by the 2010 deadline.

BIO and PhRMA are pleased to take this opportunity to submit such views and proposals on matters to be addressed by the ABS Working Group, and respectfully request that the ABS Working Group Members take these comments into consideration during their deliberations.

Specific Comments:

Proposal applicable to multiple sections of the Annex to document UNEP/CBD/WG-ABS/7/8 (the "Paris Annex"):

Comment:

BIO and PhRMA have indicated a strong view that the International Regime must be within the scope of the CBD and must be consistent with the mandate from the COP. The International Regime should only regulate "genetic resources" consistently with the scope of the relevant CBD provisions (e.g., Article 15). Derivatives, products, and other items should only be included if they fall within the definition of a "genetic resource" under the Convention.

Proposal for Amendment of text:

All bracketed references to "biological resources," "derivatives" and "products" should be deleted.

Specific suggestions for consolidation of repetitive text in the Paris Annex:

There are a number of similar or identical topics currently addressed in different sections of the text. As the text evolves, there is a substantial risk that these sections could become inconsistent. This could result in a number of unintended consequences, including inconsistent approaches to a particular desired result. Also, if there are differences in the final text, it would be presumed that the drafters intended different results, even though this may not be the case. In sum, each of the different sections addressing the items listed below should be consolidated, preferably in a single section.

- Awareness-raising activities: Section III.A.8 and Section III.C.1.a. of the Paris Annex
- International access standards to support compliance: Section III.A.11, Section III.B.5, and Section III.C.1.h. of the Paris Annex
- Development of model clauses for potential inclusion in material transfer agreements: Section III.A.15 and Section III.C.1.c of the Paris Annex and Section III.E.5 of COP Decision IX/12
- Link between access and equitable benefit-sharing: Section III.A.1 and Section III.B.2 of the Paris Annex
- Access to and transfer of technology: Section III.A.4 of the Paris Annex and Section III.E.3 of COP Decision IX/12

Specific comments and proposals on the topics to be considered by the Eighth Meeting of the ABS Working Group:

Note: As noted, these views are limited to a group of priority issues for BIO and PhRMA and do not represent an exhaustive list of BIO and PhRMA's views on the draft texts or the topics raised thereby.

ELEMENTS ADDRESSED AT THE SEVENTH MEETING THAT ARE TO BE TAKEN UP AGAIN AT THE EIGHTH MEETING

Note: These elements are referenced by Section number contained in the Paris Annex.

III.A. FAIR AND EQUITABLE BENEFIT-SHARING

General Comment on Fair and Equitable Benefit-Sharing:

BIO and PhRMA support fair and equitable benefit-sharing as set out in the CBD. The CBD is clear, however, that the benefit-sharing "shall be on mutually agreed terms" (*see, e.g.*, Article 15.7). Thus, any provisions in the International Regime relating to fair and equitable benefit-sharing must permit providers and users to decide the terms freely. Such terms will normally be embodied in a contract or other agreement that represents a meeting of the minds of the provider and the user of the genetic resources at issue. Typical rules for contracts should be applied to those contracts and agreements involving benefit-sharing. Specific mandatory benefit-sharing terms would appear to be both inconsistent with CBD principles and unworkable.

1) Linkage of Access and Benefit-Sharing

Comment:

BIO and PhRMA support linking fair and equitable sharing of benefits to access to the genetic resources. Benefit-sharing should be handled at the point of access through mutually agreed terms embodied in an appropriate ABS agreement to reduce any uncertainties as to the status of genetic resources and benefits arising from their use. The current text contained in the Paris Annex does not clearly articulate the importance of mutually agreed terms.

Proposal for Operative Text:

"Parties may require that prior informed consent for access to genetic resources shall be obtained based on mutually agreed terms between the provider and the user in accordance with the Convention."

2) Benefits to be shared on mutually agreed terms

Comment:

Consistent with principles of legal clarity and transparency, once a user has reached mutually agreed terms with the appropriate provider in accordance with the national access and benefit-sharing regime, the user should not be subject to additional claims by third parties, e.g., other communities or entities, which claim some relation to the genetic resources at issue. For example, if there are competing claims to particular genetic resources grown in *in-situ* conditions within a particular jurisdiction, such claims should be properly directed to the national competent authority. The appropriate hierarchy between claims should be resolved in the national law.

Proposal for Operative Text*:*

"Parties should require that, where mutually agreed terms have been reached between provider and user in accordance with national law, the user shall not be subject to additional claims relating to those genetic resources from parties other than the provider."

3) Monetary and/or non-monetary benefits

Comment:

The International Regime should not seek to pre-determine or influence the content of mutually agreed terms on behalf of providers and users, which would be inconsistent with the Convention. Rather, providers and users should freely choose the benefits in light of the specific circumstances surrounding the transfer of genetic resources. These benefits can include, *inter alia*, those listed in Appendix II of the Bonn Guidelines.

Proposal for Operative Text:

"The benefits to be shared may include, but are not limited to the monetary and non-monetary benefits listed in Appendix II of the Bonn Guidelines."

4) Access to and transfer of technology

Comment:

BIO and PhRMA support measures that promote effective technology transfer and cooperation. However, it should be understood that effective technology transfer generally cannot be coerced. Rather, it is often a very complicated process that requires good will and commitment by the transferor and the transferee that can only be obtained in a voluntary, cooperative and mutually supportive arrangement. Technology transfer also requires an enabling environment provided by an effective legal and policy framework including, e.g., effective protection of intellectual property rights, a legal framework to support market-based licensing of those rights, regulations favoring investment and trade, funding incentives for research, and appropriate policies in other areas. Parties also can provide incentives, such as tax incentives or other benefits, to entities in their jurisdiction to engage in technology transfer arrangements.

Proposal for Operative Text:

"Parties may provide incentives for users and providers of genetic resources to consider, when negotiating mutually agreed terms for access to genetic resources, access to and transfer of technology which makes use of those genetic resources."

"Parties may provide incentives to enterprises and institutions in their territories for the purposes of promoting and encouraging voluntary transfer of technology that is relevant to the conservation and sustainable use of biological diversity or make use of genetic resources to least-developed country Parties."

12) Benefit Sharing for Every Use

Comment:

BIO and PhRMA support the concept of providing for mutually agreed terms for access and benefit-sharing for both commercial and non-commercial uses. However, the concept of benefit-sharing "for every use" may be interpreted to encompass mandatory benefit-sharing for uses that are not subject to mutually agreed terms (e.g., uses of a genetic resource made freely available or other uses exempted from such requirements in the national law, e.g., taxonomic uses). This is outside the scope of the CBD and should not be included in the International Regime. However, Parties may want to encourage providers and users to take any potential uses into account when negotiating access and benefit-sharing terms.

Proposal for Operative Text:

"Parties may encourage that providers and users consider, when negotiating mutually agreed terms, the potential uses for the genetic resources."

13) Multilateral benefit-sharing options when origin is not clear or in transboundary situations

Comment:

When multiple countries hold the same genetic resource, these countries may agree to share benefits received for transfer of a specimen of a genetic resource from one country or local or indigenous community with the other countries. Such agreements should be separate from the ABS agreement between the provider and the user and should not have any effect on the liabilities or obligations of a user of genetic resources that is not party to that agreement. Permitting claims of third countries not party to an ABS agreement would add great uncertainties to the process and discourage the transfer of genetic resources. As noted, if there are competing claims to particular genetic resources grown in *in-situ* conditions within a particular jurisdiction, the appropriate hierarchy between claims should be resolved in the national law.

Proposal for Operative Text:

"Where genetic resources are shared by different countries of origin, Parties that are countries of origin may enter into agreements with other countries of origin for that resource that include mutually agreed terms for the sharing of benefits between the Parties concerned when that resource is provided by one of the Parties concerned. Such agreements between Parties shall not impose additional restrictions on granting prior informed consent in any one Party and shall have no effect on the rights and obligations of providers and users established in the mutually agreed terms governing the access of the relevant genetic resources in particular access and benefit-sharing agreements."

15) Development of menus of model clauses for potential inclusion in material transfer agreements

Comment:

BIO and PhRMA comments on sectoral menus of model clauses for material transfer agreements are provided below in respect of Section III.C.1.c.

B. ACCESS TO GENETIC RESOURCES

General Comment on Access to Genetic Resources*:*

BIO and PhRMA support the concept of access to genetic resources being linked to fair and equitable sharing of benefits on the basis of mutually agreed terms, as envisioned in the CBD. However, national laws governing the terms of access, e.g., in national ABS regimes, should be non-discriminatory and should thereby treat domestic and foreign researchers on similar terms. In addition, access terms should be transparent and "facilitative" in nature and should not be burdensome or punitive in nature.

2) Linkage of access to fair and equitable sharing of benefits

Comment:

This topic should be consolidated with the section of the identical name in III.A.1.

C. COMPLIANCE

General Comment on Compliance:

BIO and PhRMA support the incorporation of effective compliance provisions in the International Regime to ensure that the objectives of the CBD can be implemented in a fair and equitable manner that facilitates access and benefit-sharing on mutually agreed terms. In that light, a contract-based approach

that includes tools currently used effectively in many international business transactions, such as private international law mechanisms including alternative dispute resolution mechanisms and civil law regarding enforcement of foreign judgments, can ensure effective compliance. In respect of foreign enforcement of judgments, however, it should be noted that CBD Parties have been generally reluctant to recognize judgments from other jurisdictions.

C(1) – Development of Tools to encourage compliance

(b) *International understanding of misappropriation/misuse*

Comment:

A further understanding of the concept of "misappropriation" or "misuse" may be helpful to the dialog among Members of the ABS Working Group.

However, it should be recalled that the terms "misappropriation" and "misuse" are not found in the CBD. A common understanding of these terms should include the notion of a link to compliance with national ABS laws. In other words, if there is no violation of the national ABS law (which should be consistent with the provisions of the CBD), there is no "misappropriation." This type of understanding would ensure that expectations of provider countries are clearly enshrined in national rules and are clearly available and communicated to prospective users. In addition, we believe that a further understanding of these terms will only be possible if there is clarity as to the context in which they are to be used.

This understanding could be reflected in a footnote to operative text.

Proposal for Operative Text:

"A Party should take measures aimed at ensuring that access to genetic resources is consistent with its national access and benefit-sharing rules.[1]

[1]*The term "misappropriation" of genetic resources is sometimes used to describe the provision and/or use of genetic resources that is not consistent with national access and benefit-sharing rules."*

(c) Sectoral menus of model clauses for material transfer agreement

Comment:

A sectoral approach to MTAs in the International Regime is appropriate as a general matter because a "one size fits all" approach likely would be unworkable given the vast differences in how genetic resources are utilized by different industries and different non-commercial entities. Thus, the model clauses can be tailored for particular uses of genetic resources and, therefore, be more useful.

Further, the development of model clauses may be helpful to guide ABS negotiations in certain cases. However, if established, any such clauses should not be binding or mandated as the International Regime should permit flexibility in achieving mutually agreed terms for material transfers on a case-by-case basis to better facilitate access. BIO and PhRMA also support providing guidance with respect to certain access principles consistent with the CBD requirement to "facilitate" access in Article 15.2. For example, guidelines that would help ensure transparency and clarity, including identification of specific authorities and points of contact.

In addition, alternatives, such as a database of sample clauses from successful agreements, modeled on the WIPO Database of searchable contract clauses for access and benefit-sharing agreements should be considered.[1]

Proposals for Operative Text:

[1]http://www.wipo.int/tk/en/databases/contracts/index.html

"Parties may, in consultation with users and providers, develop sectoral menus of model clauses for possible use in contracts and make them publicly available for consideration by users and providers when negotiating mutually agreed terms.

"The Secretariat shall establish a central database of model clauses for possible use in access and benefit-sharing agreements that is publicly available, and shall maintain and regularly update the database."

"Parties may submit the sectoral menus of model clauses for possible use in contracts to the Secretariat for inclusion in a central database of model clauses for possible use in access and benefit-sharing agreements. Parties and interested stakeholders may submit clauses used in publicly available access and benefit-agreements to the Secretariat for inclusion in the central database of clauses for access and benefit-sharing agreements."

"Parties may regularly review and, where appropriate, update the menus of model clauses, if any, based on factors including, but not limited to, experiences in successful access and benefit-sharing agreements."

(d) Codes of conduct for important groups of users and (e) Identification of best-practice codes of conduct

Comment:

Voluntary "Codes of Conduct" for industry or other users of genetic resources may be helpful. Any such code should be established on a voluntary basis by an industry association or group of non-commercial entities representing users of genetic resources with participation from industry and/or other relevant actors. The relevant group itself may monitor compliance. One current example in the biotechnology sector is the BIO Guidelines on Bioprospecting. Another example is the IFPMA Guidelines on Access to Genetic Resources and Equitable Sharing of Benefits Arising Out of their Utilization. As a point of contrast, mandatory "codes of conduct" would be counterproductive and would not be appropriate.

Proposal for Operative Text:

"The development, review and update, by relevant users of genetic resources, of voluntary codes of conduct related to access and benefit-sharing may be useful for users and providers of genetic resources."

2) Development of tools to monitor compliance

(a) Mechanisms for information exchange

Comment:

BIO and PhRMA support, in principle, mechanisms for information exchange between Parties relating to monitoring compliance with CBD requirements. Such mechanisms may assist collaboration between Parties and increase exchanges of experience with respect to national implementation of CBD provisions. However, any mechanism for information exchange must be understood to protect confidential information under national laws and international agreements.

Proposal for Operative Text:

The following sentence should be added as a new stand-alone sentence to Section III.C.2.a:

"In facilitating information exchange, Parties shall ensure that confidential information is fully protected according to national laws consistent with international agreements."

(b) Internationally recognized certificate issued by a domestic competent authority

Comment:

There are still many outstanding issues regarding the feasibility of establishing such an international certificate system (*see, e.g.*, the Report of the Technical Experts Group in UNEP/CBD/WG-ABS/5/7 (Feb. 20, 2007)). In that light, it is premature to include specific provisions regarding such certificates in the International Regime until a much more thorough discussion has taken place as to the actual use of such certificates. Further, these certificates, if pursued, should not be tied to other laws, e.g., intellectual property laws or regulatory laws.

Proposal for Operational Text:

"Parties shall continue to examine proposals made for internationally recognized certificates issued by a domestic competent authority and the relation of such proposals to the International Regime in a manner to be determined by the Conference of the Parties."

(e) Disclosure requirements

Comment:

BIO and PhRMA reiterate their opposition to proposals made regarding new patent disclosure requirements (e.g., regarding source/origin of genetic resources). BIO and PhRMA are 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 WIPO and WTO have confirmed this view and, further, have not led to any consensus on such proposals. To the extent further discussion is necessary on these proposals, it should be done at WIPO, which has specialized expertise on matters of intellectual property.

These proposed requirements should not be included in the International Regime. Instead, promoting access and benefit-sharing through "mutually agreed terms," including terms that may address intellectual property issues that may arise in respect of a given transfer of genetic resources, is the best approach. This approach, and its relationship to intellectual property rights, is reflected in the draft operative text proposal that follows.

Proposal for Operative Text:

Current paragraphs III.C.2.e.1 – 3 should be deleted and replaced with the following alternative provision:

"Recognizing that patents and other intellectual property rights may have an influence on the implementation of the Convention in accordance with Article 16(5), Parties may encourage providers and users to include contract clauses relating to intellectual property, as appropriate, in mutually agreed terms."

3) **Development of tools to enforce compliance**

Any enforcement system should build on existing systems. In cases involving violations of national access laws, appropriate, effective and proportionate measures (including civil and/or criminal measures) should be considered. However, extraterritorial "enforcement" mechanisms created at the international level under the auspices of the CBD itself, e.g., international CBD tribunals, would be unworkable and should be avoided.

In the case of enforcing ABS agreements, private international law offers many dispute settlement mechanisms that are currently used to enforce contracts relating to international business transactions around the world; *see, e.g.*, paper by the delegation of Canada submitted to the sixth ABS WG meeting (UNEP/CBD/WG-ABS/6/INF/3/Add. 2 (Jan. 15, 2008)). Alternative dispute resolution mechanisms and consideration of enforcement of foreign judgments (e.g., based on principles of international comity or under existing agreements such as the New York Convention on the Recognition and Enforcement of Foreign Arbitral Awards) should be further considered.

The voluntary use of existing mechanisms in mutually agreed terms, could provide a good starting point for discussion.

Proposal for Operative Text:

"Parties may encourage providers and users of genetic resources under their jurisdiction to include provisions relating to dispute resolution and other enforcement matters, in mutually agreed terms relating to access and benefit-sharing of those resources in order to facilitate enforcement of the mutually agreed terms."

ELEMENTS NOT ADDRESSED AT SEVENTH MEETING THAT ARE TO BE TAKEN UP BY THE EIGHTH MEETING

Note: These elements are referenced by Section number contained in the Annex to COP Decision IX/12.

III.D. TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES

General Comment on Traditional Knowledge Associated with Genetic Resources:

BIO and PhRMA support the goals of Article 8(j) of the Convention, specifically "subject to … national legislation, to respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices…." We note that this Article is simultaneously narrower and broader than discussions in other organizations on the treatment of traditional knowledge. It is narrower in the sense that it addresses more limited subject matter, i.e., knowledge innovations and practices associated with genetic resources that are useful to conserve those resources or to promote their sustainable use. It is broader in the sense that it actively favors greater use of such knowledge, innovations and practices.

BIO and PhRMA strongly believe that the scope of the International Regime in this area should be limited to the narrower subject matter of Article 8(j) and should be formulated in a manner to encourage greater use of the subject matter of Article 8(j). For the purposes of these comments, references to "traditional knowledge," unless otherwise noted are meant to be synonymous with the language used in Article 8(j).

The International Regime should not attempt to protect traditional knowledge generally. We note the work of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) over the last decade on developing guidelines for traditional knowledge including a definition for traditional knowledge, an identification of the potential beneficiaries of protection, and a delineation of unacceptable practices.[2] We also note that the IGC has not been able to reach consensus on these matters despite considerable efforts over a considerable length of time.

Therefore, we believe that it would be premature for the ABS Working Group to attempt to negotiate definitive provisions for protection of traditional knowledge, and that it would be more appropriate for the ABS Working Group to build on the outcome of the IGC when the results of that process are achieved. That is not to say that the International Regime should not contain some provisions to effectuate Article 8(j). Some suggestions for useful provisions follow.

1) **Measures to ensure the fair and equitable sharing with traditional-knowledge holders of benefits arising out of the utilization of traditional knowledge in accordance with Article 8(j) of the Convention on Biological Diversity**

[2] Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, *Revised Draft Report: Document Prepared by the Secretariat*, WIPO/GRTKF/IC/10/7 Prov. 2 (April 25, 2007) at Annex I.

Comments:

BIO and PhRMA support further consideration of measures to ensure the fair and equitable sharing of benefits with traditional knowledge holders. However, any such measures should be clear and transparent to ensure legal certainty regarding the access of traditional knowledge and benefit-sharing arising therefrom.

The CBD and the Bonn Guidelines are based on the fundamental principle that access and equitable benefit-sharing will be based on mutually agreed terms. This principle appears to be adaptable to associated traditional knowledge.

In addition, any provision relating to traditional knowledge should not attempt to regulate or repatriate information that has entered, or may enter, the public domain (i.e., where the information is now available for use or known or used by others outside the relevant indigenous or local community without restriction). This could have significant ramifications beyond the CBD context and would provide great uncertainty.

Proposal for Operative Text:

"Parties may require that prior informed consent for access to knowledge, innovations, and practices referred to in Article 8(j) shall be obtained based on mutually agreed terms between the provider and the user in accordance with the Convention."

"The International Regime shall not apply to knowledge, innovations, and practices referred to in Article 8(j) which, for the Party concerned, have fallen into the public domain."

2) **Measures to ensure that access to traditional knowledge takes place in accordance with community level procedures**

Comment:

A national focal point that can grant access to potential users consistently with the law is an essential part of the national regime. The national ABS regime should provide for procedures that a Party determines are necessary to ensure that access is only granted under terms and conditions that are consistent with those community level procedures deemed appropriate by the Party. A Party may deem it appropriate to put in place procedures requiring the national focal point to consult with those individuals or authorities at the community level that may appropriately grant access to the relevant traditional knowledge.

In this manner, the national ABS system should provide for meaningful compliance with community-level procedures while maintaining legal certainty for users.

5) **Incorporation of traditional knowledge in development of model clauses for material transfer agreements**

Comment:

BIO and PhRMA comments on sectoral menus of model clauses for material transfer agreements are provided in respect of Section III.C.1.c. Although material transfer agreements generally pertain to genetic resources, it appears that such agreements could be adapted for addressing specific instances of use of associated traditional knowledge and can represent the mutually agreed terms regarding the access and use of such knowledge. As noted, this Section should be consolidated with those comments to address model clauses for material transfer agreements dealing with both genetic resources and associated traditional knowledge.

6) **Identification of individual or authority to grant access in accordance with community level procedures**

Comment:

National governments may identify an individual or authority (e.g., a national focal point or other national competent authority) that will grant access only when access is in accordance with relevant community level procedures. This will ensure that the focal point, or other national authority that interacts with potential users of traditional knowledge, has created mechanisms for obtaining the informed consent of the indigenous and local communities located within its jurisdiction into the national ABS regime.

Users should not be drawn into potential disputes between provider countries and holders of traditional knowledge within the relevant jurisdiction. Once a user has complied with the national law, the user should only be subject to claims arising from the mutually agreed terms necessary to obtain access. It should be the responsibility of the provider country concerned to ensure that the national law and procedures provide that the relevant indigenous groups and/or local communities give their consent in an appropriate fashion. Concerns over other issues, e.g., whether the appropriate community has been consulted, should be resolved by the national system and should not lead to any action against the user. Because access and benefit-sharing of traditional knowledge associated with genetic resources must be subject to national legislation, prior informed consent should only be required from the Party granting access, even if similar traditional knowledge is held by communities in other jurisdictions. Good-faith actors should not be subject to later claims by third parties that could interrupt a legitimate benefit-sharing arrangement.

7) **Access with approval of traditional-knowledge holders**

Comment:

The CBD and the Bonn Guidelines start with the fundamental principle that access and equitable benefit-sharing, where it is subject to national regulation, will be based on mutually agreed terms. These terms, reached at the point of access, also embody prior informed consent. Consequently, BIO and PhRMA members have consistently supported contract-based approaches to ensuring appropriate access and equitable benefit-sharing from the use of genetic resources and associated traditional knowledge.

When domestic procedures are implemented, the approval of holders of traditional knowledge may be made part of any "prior informed consent" requirements established at the national level.

8) **No engineered or coerced access to traditional knowledge**

Comment:

Engineered or coerced access to traditional knowledge without consent of the relevant holders of traditional knowledge would not be consistent with notions of prior informed consent based on mutually agreed terms. Appropriate legal authority to address this concern should be established at the national level. For example, many countries provide that contracts may be voided if entered into under duress. However, where the user has acted in good faith, a grievance that the national regime permits access in violation of community-level procedures should be considered a domestic matter regarding the ABS regime and should not affect the user and the terms agreed by that user.

III.E. CAPACITY BUILDING

General Comment on Capacity Building:

BIO and PhRMA generally support capacity building measures to improve the ability of Parties to implement CBD obligations and the eventual International Regime. This includes capacity building for the various acts listed in Subsection III.E.1 of the Annex to Decision IX/12, including: (a) development of national legislation; (b) participation in negotiations, including contract negotiations; (c) information and

communication technology; (d) development and use of valuation methods; (e) bioprospecting, associated research and taxonomic studies; and monitoring and enforcing compliance; and (f) use of access and benefit-sharing for sustainable development.

These capacity building efforts must be consistent with implementing access and benefit-sharing systems based on establishing mutually agreed terms between providers and users in accordance with the Convention. These efforts also should be implemented through activities coordinated through appropriate intergovernmental organizations and other forms of voluntary assistance. Stakeholders should not bear any mandatory obligation to provide resources for such activities. Instead, any participation should be done on a voluntary, case-by-case basis.

3) **Measures for technology transfer and cooperation**

Comment:

The comments and proposals of BIO and PhRMA are set forth in the discussion of access to and transfer of technology in respect of Section III.A.4.

5) **Development of menus of model clauses for potential inclusion in material transfer agreements**

The comments and proposals of BIO and PhRMA for operative text on development of menus of model clauses for material transfer agreements are provided in respect of Section III.C.1.c.

IV. NATURE

General Comment on Nature:

BIO and PhRMA support the view that it is premature to agree to a "binding" International Regime at this time. This is based on a number of factors, including: (i) many countries have only recently implemented or have not yet implemented national ABS systems; (ii) until further experience is gained, maximum flexibility should be afforded under the CBD while still documenting best-practices and norms to enhance operability of the agreement; and (iii) further consideration of utility of existing mechanisms, i.e., ABS agreements, alternative dispute resolution mechanisms, etc., should be pursued prior to entering into a binding regime.

However, we recognize that, after further development of the substance of the International Regime, the nature of the International Regime may need to be further considered. In that light, at the present time, the ABS Working Group should not preclude any outcome. Therefore, we suggest retaining Option 2 from the list of Options in the Annex to Decision IX/12 at this time, that is the International Regime shall be comprised of:

1. One legally binding instrument

2. A combination of legally binding and/***or*** non-binding instruments, or

3. A non-binding instrument

This Option would maintain all scenarios without prejudice to the outcome of the negotiations. Once the substantive provisions are more fully developed, then a more informed discussion may take place regarding the nature of the International Regime.

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