International Chamber of Commerce
The world business organization

Access and Benefit Sharing: Priority Issues for the Compliance TEG

Submission to the Technical Experts Group on Compliance

Introduction

Business has consistently sought to support development of an Access and Benefit Sharing (ABS) International Regime (IR) that is practical, and provides transparent, predictable and non-discriminatory (i.e. between domestic and foreign actors) processes and outcomes. As reflected by record levels of attendance at the Ninth Conference of the Parties, the business community remains engaged and focused on substantive discussions in the ABS negotiations, including on the objectives, scope and main components of an ABS IR. The ABS IR should include compliance measures with proven effectiveness in the real world, that do not inhibit activities needed to generate benefits from commercial use of Genetic Resources (GR) with or without Traditional Knowledge (TK). This submission to the Technical Experts Group (TEG) on Compliance therefore seeks to identify effective compliance measures, consistent with the encouragement of sustainable, commercial use of GR and related TK in the ABS IR.

The business community has been an active participant in negotiations concerning access to and the sharing of benefits from genetic resources even before the entry into force of the Convention on Biological Diversity (CBD) in 1993. The business delegation, coordinated by the International Chamber of Commerce (ICC), today represents various business sectors with diverse interests in genetic resources and related traditional knowledge and their sustainable commercial uses. These include, in alphabetical order: agricultural biotechnology, animal breeding, cosmetics, farming, flavors and fragrances, forestry, herbal medicines and supplements, industrial biotechnology, pets, pharmaceutical and bio-pharmaceutical products, and plant breeding.

ICC Members remain committed to the voluntary Bonn Guidelines, which also represent the broad consensus of CBD Members, and include the principles of prior informed consent (PIC) and mutually agreed terms (MAT); in fact the vast majority of business players always try to adhere to laws and regulations. As the ABS IR will affect and regulate the behavior of legitimate players, emphasis overall should be put on creating an enabling environment that will help generate benefits from the sustainable use of GR with or without TK. Based on careful analysis and consideration of real-world experience, an ABS IR which enables and eases legal compliance would have a much greater likelihood of generating sustainable long-term benefits for all ABS

International Chamber of Commerce
38 cours Albert 1er, 75008 Paris, France
Telephone +33 1 49 53 28 28 Fax +33 1 49 53 28 59
Web site www.iccwbo.org E-mail icc@iccwbo.org

stakeholders. It will also be crucial to educate all ABS stakeholders and to provide them with the necessary information on ABS laws to further facilitate compliance.

If the IR is to be effective in promoting economic activity, it should maintain and foster the diversity of uses of GR as well as of the commercial arrangements through which they are acquired. ICC believes that it is of key importance that the IR should be a facilitative structure that promotes national ABS regimes that are transparent, non-discriminatory, and predictable. It should not, business believes, become a heavy regulatory framework that would stifle the creation of value from genetic resources, trade and sustainable uses. A highly-targeted and efficient ABS IR will promote the generation of social and economic benefits, and will also support the two other pillars of the CBD: conservation and sustainable use.

Some of the international instruments currently under discussion should be considered with caution to avoid overly bureaucratic approaches to ABS that preclude benefit generation. Burdensome measures introduce significant costs for governments, traditional and local communities, research institutions, and business alike. Heavy regulatory burdens may deter larger companies from generating benefits and may price innovative small and medium-sized enterprises out of the market entirely. Most significantly, many of these proposed measures have not been "reality-tested" or subject to a benefit-cost analysis, i.e. proven to create benefits in the real world.

With these thoughts in mind, ICC Members offer the following in response to the Terms of Reference for the Technical Experts Group on Compliance:

(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;

(i) An ABS IR should seek to ensure transparency, predictability, certainty, and non-discriminatory treatment with respect to compliance measures, including clear definitions consistent with the terms and jurisdictional limitations of the CBD itself. Business, like other stakeholders in the ABS process, seeks transparent, predictable, cost-effective and timely remedies in case of difficulties that may arise in the ABS process.

(ii) If the ABS IR meets these conditions, business is convinced that the great majority of participants in ABS activities will comply with the ABS IR. Nevertheless business does recognize that serious concerns remain relating to misuse and/or misappropriation of GR, with or without related TK. Therefore business supports a fact-based approach, with agreed parameters and definitions of misuse/misappropriation, to clearly identify the

magnitude of the problem within the agreed scope of the International Regime. This would greatly assist in identification, where applicable, of any appropriate and proportionate measures, and contribute to the likelihood of success of the ABS IR overall.

(iii) Business proposes that the ABS IR encourage the systematic use of MTAs, contracts, or other mutual agreements to the greatest extent possible. These written agreements may include, in addition to the terms and conditions for access and benefit sharing, clauses addressing agreed dispute settlement mechanisms, choice of law, and/or future termination of the agreement, as appropriate.

(iv) Established forms of alternative dispute resolution, including mediation and arbitration, based on previously agreed written agreements, may provide a cost-effective alternative to cross-border civil litigation given the international scope of arbitral decisions. An example of such an arbitration clause, which cites the Rules of Arbitration of ICC, can be found in Article 8(4)(C) of the sMTA established under the Food and Agriculture Organization (FAO) International Treaty for Plant and Genetic Resources for Food and Agriculture (ITPGRFA). In addition, the New York Convention on the Recognition and Enforcement of Foreign Arbitral Awards ("New York Convention") is an internationally recognized mechanism for foreign enforcement of arbitral decisions - to which most CBD countries adhere - that can provide effective enforcement in cross-border disputes.

(v) Business also supports voluntary capacity building for resource poor stakeholders in respect of compliance related matters and is active in these efforts. In particular, ABS stakeholders may find more information and background relating to ICC arbitration services, through educational resources either provided by the ICC International Secretariat or at a national level through local ICC committees, or by other trade associations in collaboration with NGOs and CBD Members.

(vi) Business understands the priority that a number of CBD Members place on mutual recognition of and enforcement of judgments across borders to enforce domestic national ABS regimes in cases involving allegations of misuse or misappropriation of GR with or without related TK. At the same time, business notes the historic reluctance of states to enter into multilateral obligations requiring mutual recognition. Business looks forward to a deliberative discussion of this difficult issue so that it can learn more about possible approaches to address legitimate concerns while providing access to justice and due process for all ABS stakeholders.

(vii) Finally, all compliance measures should also be "reality-tested" and subject to a benefit-cost analysis, i.e. shown in real-world circumstances not to have, on balance, negative implications for the generation and sharing of benefits from sustainable utilization of GR with or without TK.

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

(i) Best practices: Business believes that discussion of existing voluntary guidelines and "best practices" may help to address a broad range of circumstances that arise in the course of ABS agreements between users and providers, including obligations of the parties, mechanisms for sharing results, causes for termination and ways of dispute settlement.

ICC Members look forward to providing additional information about such existing guidelines and best practices.

(ii) Guidelines and Codes of Conduct already in place include: the Biotechology Industry Organization (BIO) Guidelines for BIO Members Engaging in Bioprospecting, EuropaBio Principles for Accessing Genetic Resources, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Guidelines for IFPMA Members on ABS, the BIO Model Material Transfer Agreement (MMTA), and the International Standard for Wild Collection of Medicinal and Aromatic Plants.

(iii) Business also looks forward to discussion of best practices for prior informed consent (PIC), including guidelines for identification of relevant stakeholders in the negotiation process. Without greater clarity on predictable standards for PIC, business is unable to invest the considerable financial and other resources needed for sustainable commercialization of GR with or without TK. Best practices for PIC, based on a number of existing models and statutes, may provide greater certainty for business while at the same time representing a practical approach to provide guidance for all ABS Stakeholders. (*See "Prior Informed Consent and Access and Benefit Sharing: Recognition and Implementation," DRAFT PAPER, Anne Perrault, Center for International Environmental Law (March 2006) (pp. 16 – 24 providing PIC-related Procedures, Legislation, Guidelines and Agreements*).

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

ICC members' views on an appropriate definition of "misappropriation" will be influenced in large part by the decisions taken by CBD member states on the nature and scope of the ABS IR, decisions which will be taken only after the discussions of the upcoming Compliance TEG. Accordingly, the following is offered as a possible working definition, for discussion purposes, to further greater understanding among delegations in the Working Group process, based to the greatest extent possible on terms, definitions and standards of the CBD:

"Misappropriation of Genetic Resources with or without associated Traditional Knowledge:

Acquiring non-human "Genetic Resources" found in "in situ conditions" - each as defined in Art. 2 of the CBD - in contravention of ABS provisions of a national law pursuant to the International Regime and in force at the time of this acquisition."

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

(i) Business has sympathy with the view that the issue of customary law of indigenous and local communities should be addressed by technical and legal experts with expertise in TK issues, ie the TEG on TK. This would minimize the risk that two expert groups would reach different recommendations on the same or similar issues. As noted above, this is

an important area where greater clarity from the TK TEG is needed in order for business to give a fuller opinion on possible definitions of "misappropriation" within the ABS IR.

(ii) Taking the foregoing into account, as a general principle business considers that such matters should be addressed at the national level in light of the vast differences in customary law approaches of different communities in CBD Parties. In this context, the ABS IR should include related provisions only to the extent needed to ensure that legal certainty, clarity and transparency of national ABS systems, including any provisions relating to customary law, are maintained. The ABS IR also should ensure that compliance-related provisions or principles of local customary law - as they relate to any individual ABS Agreement - are reduced to written form in a language understood by all parties to the contract. This would be necessary in order to determine whether these provisions need to be incorporated by reference into the MTA or whether additional clauses are needed, on a case-by-case basis.

(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.

(i) At the outset, it is important to recognize that very few collaborative bio-prospecting agreements result in successful products, even in the case of multinational corporations. Successive Merck/INBIO Agreements did not lead to successful commercialization of any of the discoveries found during a complex, multi-year relationship. Nevertheless, the Merck/INBIO agreement, and those that followed, contributed to Costa Rica's science-base through up-front payments, training and laboratory equipment, and collaborative research, providing substantial and continuing social and economic benefits.

(ii) Business as much as non-commercial research institutes may be deterred by increases in expenses or bureaucratic "red tape." Complicated requirements for access and benefit-sharing may have the unintended effect of causing a significant decline in academic and commercial research alike, or, as one commentator noted, may drive scientists underground, resulting in worse documentation of research activities. Declining research may also cause a decline in successful commercialization needed to create social and economic ABS benefits, particularly where outcomes are uncertain and potential commercial benefits lie far in the future.

(iii) This may be especially also true for small and medium enterprises (SMEs), start-up biotechnology or natural products companies, and certain industry sub-sectors like breeders of ornamental and fruit varieties. For SMEs in particular, it would be essential to find simple rules facilitating access and thus the possibilities to generate sharable benefits. At the same time, business in developing countries may have even a greater share of SMEs – these indigenous entrepreneurs would be particularly disadvantaged by a heavily bureaucratic approach in the ABS IR.

(iv) In reality, it may prove extremely difficult if not impossible to differentiate between ABS conditions needed to provide incentives for non-commercial and commercial research.

Scientific research that starts out as non-commercial may ultimately contribute to the commercial development of a product, either by the same party or by others. Similarly, commercial research may be licensed for public research purposes, as in the case of the development of Golden Rice, which relied heavily on commercially funded research. If a country nonetheless chooses to implement a bifurcated commercial/non-commercial use system, then, it is preferable to spell out the steps needed to convert MAT for non-commercial research into terms for commercial development that protects the interests of all parties, whether applying commercial or non-commercial research, in case of eventual successful commercialization. So it might be another consideration to not draw the distinction between commercial/non-commercial uses but rather distinguish according to the specialties of sectors.

(v) CBD Members clearly have the right to structure their domestic ABS regimes to provide incentives and approval only for non-commercial ABS activities. CBD Members choosing this option, however, need to be transparent about limiting access to non-commercial ABS activities and, by extension, explicitly recognize that they also are excluding themselves and their right-holders from potential future commercial benefits available to other CBD Members under the ABS IR.

(vi) Commercial and non-commercial ABS stakeholders have varied concerns and interests as regards publications relating to GR and associated TK. This is an important issue for consideration, particularly given assertions that prohibitions on academic publication rights would have no impact on taxonomic or other non-commercial research. Generally, universities seek open research, with unrestricted publication rights, while business sponsors of research may prefer limited publication rights, at least for an agreed term, in order to protect their proprietary research. This is an area where mutually agreed terms can bridge the gap, meeting individual needs on a case-by-case basis.

Document n° 450/1042

28 November 2008

ANNEX

Background material relating to arbitration

- "Arbitration explained" - Explanatory brief on what arbitration is

- "The Institute for Transnational Arbitration Scoreboard of Adherence to Transnational Arbitration Treaties" - Table of countries adhering to transnational arbitration treaties

- The FAO International Treaty on Plant Genetic Resources for Food and Agriculture Standard Material Transfer Agreement – see Article 8 on Dispute Settlement (http://www.planttreaty.org/smta_en.htm)

Industry sector guidelines

- The Biotechology Industry Organization (BIO) Guidelines for BIO Members Engaging in Bioprospecting (http://www.bio.org/ip/international/200507guide.asp)

- The BIO Model Material Transfer Agreement (MMTA) (http://www.bio.org/ip/international/BIO_Model_MTA.pdf)

- EuropaBio Principles for Accessing Genetic Resources – (http://www.europabio.org/positions/Bioprospecting%20Principles_Final.pdf)

- The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Guidelines for IFPMA Members on ABS (http://www.ifpma.org/Issues/CBD)

- The International Standard for Wild Collection of Medicinal and Aromatic Plants (http://www.floraweb.de/proxy/floraweb/MAP-pro/Standard_Version1_0pdf)