



**Convention on
Biological Diversity**

Distr.
GENERAL

UNEP/CBD/WG-ABS/8/5/Add.1
26 October 2009

ORIGINAL: ENGLISH

AD HOC OPEN-ENDED WORKING GROUP ON
ACCESS AND BENEFIT-SHARING

Eighth meeting
Montreal, 9-15 November 2009

**COLLATION OF ANY OTHER VIEWS AND INFORMATION SUBMITTED BY PARTIES,
GOVERNMENTS, INTERNATIONAL ORGANIZATIONS, INDIGENOUS AND LOCAL
COMMUNITIES AND RELEVANT STAKEHOLDERS WITH RESPECT TO TRADITIONAL
KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES, CAPACITY-BUILDING AND
THE NATURE OF THE INTERNATIONAL REGIME**

Addendum

SUBMISSION BY THE INTERNATIONAL CHAMBER OF COMMERCE

Note by the Executive Secretary

1. The Executive Secretary is circulating herewith views and information submitted by the International Chamber of Commerce related to traditional knowledge associated with genetic resources, capacity-building and nature as an addendum to the collation of any other views and information made available as document UNEP/CBD/WG-ABS/8/5.
2. For ease of reference, the portions of the submission that correspond to elements of the text of annex I to decision IX/12 have been shaded. Otherwise, the text is being circulated in the form in which it was received by the Secretariat.

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**ANY OTHER VIEWS AND INFORMATION RELATED TO TRADITIONAL KNOWLEDGE
ASSOCIATED WITH GENETIC RESOURCES, CAPACITY-BUILDING AND NATURE
FOLLOWING THE STRUCTURE OF ANNEX I TO DECISION IX/12¹**

III. MAIN COMPONENTS

D. Traditional knowledge associated with genetic resources²

International Chamber of Commerce

Business shares a common interest with indigenous and local communities in greater transparency, predictability, and a balance of benefits against costs of proposed ABS regulations at both the national and international level. Business underscores its continuing commitment to commercialization of GR and associated traditional knowledge (TK) only with the prior informed consent (PIC) of relevant stakeholders and on mutually agreed terms (MAT), consistent with the Bonn Guidelines.

The following comments supplement ICC's submission to the CBD ABS Technical Expert Group on Traditional Knowledge associated with Genetic Resources dated 30 April 2009:³

▪ **Using the existing IP system**

There are several possibilities for the preservation, protection and promotion of traditional knowledge using the existing intellectual property system. None of them are perfectly adapted for the special circumstances of TK, but they can be useful in particular cases. Examples include:

- Patents (for TK that is not public knowledge, or which is a new development of public TK or the novel application of TK to a particular technical area), which are increasingly being filed on developments of traditional medicine;
- Trade marks (including certification trade marks), which may be used by appropriate authorities to guarantee the origin of goods, or other standards that they meet;
- Geographical indications (which are sometimes implemented through trade mark laws), which may also be used where traditional goods have a given quality, reputation or other characteristic essentially attributable to geographic origin;
- Registered designs and copyright; which may be particularly useful for protecting expressions of TK;
- Plant variety rights; and
- Confidential information or trade secrecy protection, which may be useful where TK is held in secret. Such information will typically be disclosed under the protection of confidentiality agreements.

¹ For ease of reference, the text of annex I to decision IX/12 reproduced in this document has been shaded. In accordance with the decision taken at the seventh meeting of the Working Group on Access and Benefit-sharing to no longer distinguish between bricks and bullets, the sub-headings under "Traditional knowledge associated with genetic resources" and "Capacity" are consecutively numbered.

² The title is without prejudice to the eventual scope of the international regime.

³ "Traditional knowledge associated with genetic resources" – 30 April 2009, http://www.iccwbo.org/uploadedFiles/ICC/policy/intellectual_property/Statements/ICC%20Submission%20to%20TEG%20on%20TK%2030%20April%202009.pdf

While some may feel that these mechanisms are neither easy nor inexpensive, it may be more practical in many cases to optimize use of existing tried and tested systems for TK rather than to wait for potential new and untested ones.

▪ **TK databases**

There is no doubt that computerised TK databases can contribute usefully to defensive protection of TK. Where such databases exist, and are accessible to patent examiners, they can help prevent the improper patenting of inventions that are already known, or are obvious from what is already known. The status of the knowledge in such databases needs to be clear, however.

India has compiled such a database relating to traditional medical knowledge, known as the Traditional Knowledge Digital Library (TKDL).⁴ The TKDL has been made available to the European Patent Office (EPO). It is not however being made available to the general public and the database is accordingly not itself in the public domain, because of fears that this might encourage use by others without prior agreement or benefit-sharing. Nevertheless, in order for the TKDL to be effective, relevant prior art disclosures cited by the patent examiner will have to be made available to patent applicants. The TKDL has already been suggested as a model for countries seeking to protect their TK from misappropriation.⁵

TK databases also may be used directly to promote positive protection of TK. Access to the database may be offered to interested parties under confidentiality agreements, specifically providing for ABS (see paragraph 1 above). Further, such agreements relating to information in such a database may serve as prima facie evidence that it has been accessed legitimately.

▪ **Multiple claims to ownership of TK**

Any ABS system for TK must be practicable if it is to be effective. The objective of the CBD is to facilitate access to and promote sustainable uses of genetic resources, not inhibit these. The same applies to TK under Article 8j. ICC wishes to re-emphasise the importance of this. If the same TK can be subject to multiple claims of ownership or authority over TK, then the uncertainties involved in accessing and developing it will likely be too high to justify development in all but quite exceptional cases. This is particularly important where competing claims might call into question the validity of established ABS agreements between legitimate providers and users of TK.

Industry must be able to rely on rights received from appropriate TK holders under national ABS regimes. In cases of dispute, these should be settled between different parties claiming to be holders of the TK in question, without involving, or diminishing the rights of, licensees who have acted properly and in good faith. If business actors and others seeking appropriate access to TK cannot rely on properly negotiated ABS agreements, the incentive to seek them will be seriously undermined, and benefits will be lost to all.

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

⁴ See "About TKDL," available at <http://www.tkdil.res.in/tkdil/langdefault/common/Abouttkdl.asp?GL=Eng>.

⁵ The latter are free to argue that the original disclosure which was referred to in the database differs from their allegedly new inventions; and that the information in the database was not in fact available to the public.

- 2) Measures to ensure that access to traditional knowledge takes place in accordance with community level procedures**
- 3) Measures to address the use of traditional knowledge in the context of benefit-sharing arrangements**
- 4) Identification of best practices to ensure respect for traditional knowledge in ABS related research**
- 5) Incorporation of traditional knowledge in development of model clauses for material transfer agreements**
- 6) Identification of individual or authority to grant access in accordance with community level procedures**
- 7) Access with approval of traditional knowledge holders**
- 8) No engineered or coerced access to traditional knowledge**
- 9) Prior informed consent of, and mutually agreed terms with, holders of traditional knowledge, including indigenous and local communities, when traditional knowledge is accessed**
- 10) Internationally developed guidelines to assist Parties in the development of their domestic legislation and policies**
- 11) Declaration to be made on the internationally recognized certificate as to whether there is any associated traditional knowledge and who owners of traditional knowledge are**
- 12) Community-level distribution of benefits arising out of traditional knowledge**

E. Capacity

International Chamber of Commerce

ICC supports capacity building measures as a means to achieve fair and equitable access and benefit sharing. These efforts can improve the ability of Parties to implement CBD obligations and, eventually, mechanisms under the International Regime. Subsection III.E.1 of the Annex to Decision IX/12 lists a number of areas for capacity building efforts. Each of these areas offers opportunities for capacity building efforts that may assist Parties in building up abilities and resources to develop clear and transparent access and benefit-sharing systems, including national focal points and national competent authorities, consistent with the approach of having providers and users of genetic resources reach enforceable mutually agreed terms. Existing funding mechanisms, such as those provided by the World Bank, UNDP and other intergovernmental organizations, can be used to help finance such initiatives.

ICC encourages consideration of the following points from which capacity building efforts can benefit. The points below follow the points and numbering in the Annex to Decision IX/12.

- 1) Capacity-building measures at all relevant levels for:**

(a) Development of national legislation
International Chamber of Commerce

Legal certainty is one of the most important elements in building an innovative economy. The geographic, geopolitical and economic situation of each country is different and as such a “one size fits all approach” is not likely to present favourable results in all countries. National governments are best capable of determining the types of tools that can facilitate their research and development capacity. Predictable, facilitative, national legislation developed by national governments in consultation with appropriate stakeholders is critical toward enhancing the research and development capacity of a country. Such legislation, if implemented appropriately, will not only attract researchers but also private and public investment. Capacity building efforts may be targeted so that lesser developed countries have a greater ability to develop such systems consistent with their obligations under the CBD.

(b) Participation in negotiations, including contract negotiations and (c) Information and communication technology

International Chamber of Commerce

Once appropriate national legislation is in place, countries should take into consideration the complexity of access and benefit sharing negotiations. Training, (both legal and scientific) and appropriate tools (e.g., information technology) should be a part of any capacity building measure.

Increasing IT capacity and communications tools will increase transparency and awareness of ABS regimes, which will in turn help promote compliance. In this regard, countries may also want to consider developing or enhancing their capacities in technologies supporting taxonomic and associated research.

Capacity building efforts also may help develop the necessary background in principles of contract law and negotiations so that both government and non-government providers, including local and indigenous representatives can more actively take part in the system envisioned in the CBD and elaborated in the International Regime.

(d) Development and use of valuation methods

International Chamber of Commerce

The ability to derive benefits from available resources hinges on the appropriate view of the value of said resources. Countries need not recreate the wheel with regard to valuation of such resources. Rather, countries should consider existing best practices and look to various organizations already deeply involved in these activities, e.g. Asian Pacific Economic Cooperation (APEC), which have done significant research into this area. Capacity building measures can be designed to assist countries in building up their knowledge base on these matters.

(e) Bioprospecting, associated research and taxonomic studies

International Chamber of Commerce

In countries where genetic resources are abundant, capacity building activities can be enhanced by coherent and transparent rules for bioprospecting. Countries are likely to attract researchers and interested investors when they have sufficiently documented and catalogued their available resources. Such organization of genetic resources is usually accomplished through government initiatives.

The Sarawak Biodiversity Center in Malaysia is an example of a region taking stock of its resources by cataloguing and classifying its genetic resources and through material transfer agreements enhancing research and development capacity.⁶

(f) Monitoring and enforcing compliance

International Chamber of Commerce

Parties may need assistance in developing systems to help them with certain monitoring and enforcement or compliance issues in the context of mutually agreed terms established by providers and users of genetic resources. This should not be construed as a licence for the government to intervene in situations where it is not a party to an ABS agreement. Instead, capacity building efforts should focus on the ability of providers and users to enforce their mutually agreed terms, where appropriate, in various Parties. For example, efforts assisting the establishment of local courts with sufficient capacity and authority to determine breaches of contract, consistent with general principles of contract law, where appropriate, may be needed in certain less developed countries.

Capacity building efforts could also aim to educate contracting parties to ABS agreements in the use of contractual mechanisms to monitor compliance with the terms of such agreements. In addition, certain monitoring functions involving administrative mechanisms, through a national competent authority, for keeping records of access transactions pursuant to national law may be envisioned. Each of these items is also important to facilitate compliance of providers and users with national laws.

(g) Use of access and benefit-sharing for sustainable development

International Chamber of Commerce

Access and benefit sharing can be a valuable means of enhancing research and development capability, which is an important precursor to sustainable development efforts. ICC encourages Parties to dedicate benefits received to further capacity-building. Since the adoption and the ratification of the CBD by its Parties, several countries have either implemented or are in the midst of implementing ABS regulations. It is important that countries profit from each other's experiences. This can only be done through outreach programs and open exchange of experiences between governments about ways that their implementation of ABS has promoted investment in their country. An example of such outreach efforts is the Japan Bioindustry Association's symposium focusing on implementation of ABS in Japan.⁷

Many developing countries have breeding programmes for crops which are staple foods or key to their economies or have developed biotechnology programmes in the health sector to both promote public health objectives and develop products for exportation⁸. These agricultural and health research programmes will often depend on facilitated access to genetic resources from other countries. For example, the FAO International Treaty on Plant Genetic Resources for Food and Agriculture provides a model multilateral system of access and benefit sharing for food and agriculture. To ensure that ABS systems contribute to the sustainable development of countries which rely on such programmes for

⁶ <http://www.sbc.org.my/>

⁷ http://www.apfed.net/dialogue/pdf/200901_biodiv/7sumida.pdf

⁸ "Development of Cuban biotechnology" Ernesto Lopez, Boris E. Acevedo, Ricardo Silva, Blanca Tormo, Ricardo Montero and Luis Herrera, 27th September, 2002
<http://gndp.cigb.edu.cu/NEWS/PDF/Development%20Cuban%20Biotech.pdf> and "The Biotechnology Promise: Capacity-building for Participation of Developing Countries in the Bioeconomy" - UNCTAD, 2004.

economic development as well as to promote public policy goals such as health and food security, it is essential for governments to take into account the impact of ABS systems on such domestic programmes.

2) National capacity self-assessments to be used as a guideline for minimum capacity-building requirements

3) Measures for technology transfer and cooperation

International Chamber of Commerce

ICC supports the underlying aim of the CBD to promote the development and dissemination of genetic resource-related technologies. Effective policies for technology development and transfer have the potential to not only help translate raw genetic resources into useful products and technologies, but also to spur economic development and increase technological capacity in countries. ICC believes that it is in the interest of governments to build up innovative capacity within their countries and create technologies that will succeed in global markets, rather than be reliant in the long-term on technologies from other countries. It is therefore essential that any policies relating to technology development and dissemination should keep in mind the need to encourage both sustained local innovation as well as technology transfer.

Development and transfer of technologies relating to genetic resources do not take place in a vacuum and must be supported by appropriate policies in various areas. These include developing a welltrained and educated workforce, providing suitable tax incentives, ensuring effective protection of intellectual property rights, providing a legal framework to support market-based licensing of those rights, putting in place regulations favouring investment and trade, providing funding incentives to research, developing and cataloguing genetic resources, and implementing appropriate policies in other areas.

Technology transfer usually takes place in the context of commercial transactions, hence its role not only as a means to disseminate technology, but also as a means to create jobs and impact local economies. In making decisions on partners for technology collaboration, technology owners place importance on a positive policy stance on innovation based on genetic resources, respect for contracts, market-friendly policy frameworks and a suitably trained workforce. Effective technology transfer policies pertaining to genetic resources will likely attract technology owners for the purpose of developing these resources. Technology developers in both the private and public sector require incentives and regulatory frameworks that provide legal clarity and certainty to justify the significant investments required for R&D into genetic resources.

Negotiators should keep in mind the following points when determining policies to develop and transfer technologies relating to genetic resources:

- Technologies relating to genetic resources are very diverse, in keeping with the diversity of sectors working with genetic resources and the different techniques used by these sectors to add value to them.
- The development of these technologies is taking place in different regions of the world, including in developing and emerging economies. Important lessons may be learned from these economies. Most countries with developing and emerging economies have plant breeding programmes in national agricultural institutes. As an example, numerous products, methods and technologies utilizing palm oil have been the subject of patent applications by filers from emerging economies such as Malaysia, which leads the world in palm oil breeding. As another example, Brazil is the world leader in breeding technologies for sugar cane which is used for biofuels. There are also advanced biotechnology industries in several developing economies such as Cuba, China, Brazil

and India and emerging biotechnology programmes in many other countries such as Pakistan and Iran.⁹ Research may also be carried out in transnational collaborations between institutions from different countries (see case study in Tanzania – box 1).

Box 1

The United Republic of Tanzania is part of the Bioearn Project (www.bio-earn.org; an East African Regional Network in collaboration with Sweden that is providing training in molecular genetic tools and other biotechnology related fields). Through this project, the Mikocheni Agricultural Research Institute and the University of Dares Salaam are collaborating with the Swedish University of Agricultural Sciences, the Royal Institute of Technology and Lund University on agricultural, industrial and environmental biotechnology as well as biosafety. Most of these collaborations are providing technical and training at post-graduate level. Sokoine University of Agriculture collaborates with the International Livestock Research Institute (ILRI), a member of the Consultative Group of International Agricultural Research (CGIAR), to develop genetic markers for various livestock conditions. These include disease diagnostic tools, parasite identification methods and disease-resistant markers. (extract from “The Biotechnology Promise: Capacity-building for Participation of Developing Countries in the Bioeconomy” - UNCTAD, 2004) - <http://stdev.unctad.org/docs/biotech.pdf>

- While business plays a primary role in innovation, public sector institutions also carry out innovative activities, often in partnerships with the private sector. The success of several public-private partnership highlight the importance of building on successful models already in practice (see Astra Zeneca-Griffiths University case study – box 2).

Box 2

Queensland’s Biodiscovery collaboration between the Griffith University and AstraZeneca is a successful model. This partnership is instructive in terms of providing an example of a wide range of benefits in the short, medium and long term, undertaking high levels of research within provider countries, building scientific and technological capacity, and significant benefits for biodiversity conservation. Details of this collaboration can be found in the UNU-IAS report entitled, “Queensland Biodiscovery Collaboration the Griffith University, AstraZeneca Partnership for Natural Product Discovery: An Access and Benefit Sharing Case Study”- www.ias.unu.edu/sub_page.aspx?catID=111&ddIID=169

Governments can also support incentives for encouraging collaboration between public and private entities (see box 3)

Box 3

India and South Africa are examples of countries looking for ways to leverage government funded research through transfer of IP in order to build biotechnology capacity. India ranks among the world’s top ten largest industrial nations with an increasing number of patent filings. It has a technologically-prepared labor force ready to take advantage of authorized

⁹ “The Biotechnology Promise: Capacity-building for Participation of Developing Countries in the Bioeconomy” - UNCTAD, 2004

technology transfer and it has the third largest pool of scientifically and technically trained people. The Indian government is currently considering an intellectual property-related (IP) Bill that seeks to empower government-funded institutions to commercialise their research, besides ensuring some of that revenue flows back to the scientist. South Africa has gone one step further; it has recently enacted the Intellectual Property Rights from Publicly Financed Research and Development Act. The Act intends to enable and encourage recipients of government-funding to protect, using intellectual property, and license the results of their research in order to provide incentives for those recipients to work with industry players to commercialize research. Both of these countries have recognized the importance of IP in innovation and capacity building.

- To be useful, technologies have to be appropriate to the needs and capacities of the recipient country or community. Technology transfer is of no use if the human resources and infrastructure necessary to make it work are not available.
- It should not be assumed that all technology transfer will necessarily take place from the more developed to lesser developed economies, or originate from the private sector. Genetic resource related technology transfer can take place among developing countries as well as from developing to developed countries. For example, the Biox process owned and developed in South Africa is now used in many other countries, and the success of the largest experimental solvent extraction electro-wining (SXEW) in Zambia has been used in 40 other mines in developed countries.¹⁰ Other examples are Cuban technologies relating to the meningococcal B and hepatitis B vaccines and recombinant streptokinase (see box 4). Such flows will increase to the extent that governments in such countries implement appropriate innovation policies.

Box 4

The Cuban meningococcal B vaccine is a good example about this kind of technology transfer. Transfer technologies from Cuba to southern countries include the technology to produce the hepatitis B vaccine and recombinant streptokinase, for instance. These products are transferred from Cuban institutions under special agreements to satisfy the local demand with some local manufacturing producers. In fact, more than 38 business operations are in progress or under negotiation from Cuba to 14 countries at the present (Algeria, Brazil, Canada, China, Egypt, India, Iran, Mexico, Malaysia, Russia, South Africa, Tunisia, the UK and Venezuela).

Patent licence is the other business model applied by Cuban institutions. A nonexclusive out-licence agreement to transfer technology know-how for the production of the Dextranase enzyme was carried out between the CIGB and an Indian company. Also, a patent for a humanising antibodies method was granted to the CIM, and under a non- exclusive licence, two European companies were given the rights for exploiting the principles of the method. (extract from "Development of Cuban biotechnology" Ernesto Lopez, Boris E. Acevedo, Ricardo Silva, Blanca Tormo, Ricardo Montero and Luis Herrera, 27th September, 2002 -

<http://gndp.cigb.edu.cu/NEWS/PDF/Development%20Cuban%20Biotech.pdf>

- Successful technology transfer often requires collaboration between the parties to the transaction over a period of time so that any know-how and experience necessary to use the technology can

¹⁰ "The Biotechnology Promise: Capacity-building for Participation of Developing Countries in the Bioeconomy" - UNCTAD, 2004 - <http://stdev.unctad.org/docs/biotech.pdf>

be shared. In these situations, companies are encouraged to make a long-term commitment and to integrate with local culture and values. Consensual transactions based on mutual understanding and respect of the needs, culture, and values of the respective parties are therefore the best means of ensuring that technology is transferred effectively with the requisite knowledge required for the recipient to work it.

- Government and academic contributions to innovation are frequently in the area of basic research and require large investments of private capital to make the fruits of this research available to the marketplace. The transfer or the licensing of intellectual property and related know-how to the private sector creates an incentive for the private partner to invest the necessary capital in the joint enterprise, and is the most efficient means of rapidly moving government and academic research to market. A supportive framework for market-based licensing is therefore essential for public sector research institutions to enter into collaborations with the private sector, which will help bring the benefits of the technology to the public.

For the above reasons, regulatory frameworks that support technology transfer transactions based on discussion of mutual needs and on mutually agreed terms between consenting parties are the most efficient means to ensure that technology is transferred effectively, and that such technology is translated into tangible benefits for the public.

4) Special capacity-building measures for indigenous and local communities

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

International Chamber of Commerce

ICC notes that material transfer agreements (MTAs) are a critical element of a viable ABS regime. However, the development of model clauses for MTAs is included in a number of other sections within the negotiating text. For the sake of simplicity and to eliminate duplication and inconsistencies, ICC recommends that these sections be consolidated.

6) Establishment of a financial mechanism

IV. NATURE

International Chamber of Commerce

Further development of an International Regime (IR) must occur before its nature can be determined. It is premature to determine if, or to what extent, an International Regime might be binding. As ongoing negotiations resolve the details of International Regime mechanisms, the question of the IR's binding or non-binding nature will then best be addressed.

As a result, the Ad Hoc Open Ended Working Group on Access and Benefit Sharing should not preclude any outcome at this point and retain Option 2 regarding nature in the Annex to Decision IX/12:

“2. A combination of legally binding and/or non-binding instruments.”