Nature, traditional knowledge and capacity building

Submission to the Secretariat of the Convention on Biological Diversity for the 8th Ad Hoc Open Ended Working Group on Access and Benefit-Sharing, Montreal, 9-15 November 2009

Highlights

- General principles
- Nature of International Regime
- Capacity building
- Traditional knowledge associated with genetic resources
Nature, traditional knowledge and capacity building

Submission to the Secretariat of the Convention on Biological Diversity for the 8th Ad Hoc Open Ended Working Group on Access and Benefit-Sharing, Montreal, 9-15 November 2009

Introduction

The business delegation – coordinated under the umbrella of ICC – remains committed to contributing constructively on substantive discussions in the CBD access and benefit sharing (ABS) negotiations. A diverse range of different business sectors played an active role in the 7th Ad Hoc Open Ended Working Group on Access and Benefit Sharing (ABS-7), and the business delegation has also contributed its expertise and experience to the Technical Expert Groups on Concepts, Terms, Working Definitions and Sectoral Approaches, on Compliance, and on Traditional Knowledge.

All businesses are engaged in a continuous evaluation of risk and return on investment. A high risk environment will discourage investment and reduce opportunities for creating benefits. Given the long time period and heavy investments required to commercialize inventions using genetic resources, businesses need national laws or guidelines which are transparent, practical, science-based, non-discriminatory, and provide legal certainty to justify their investments.

Business therefore supports the creation of a practical and workable IR which will facilitate the activities of the different sectors working with genetic resources today and take into account the future evolution of those activities.

The current paper reiterates some of the general principles set out in more detail in the ICC submission to ABS-7 and provides more specific input on the following items which the 8th Ad Hoc Open Ended Working Group on Access and Benefit Sharing is mandated to negotiate: nature; traditional knowledge associated with genetic resources; and capacity building. ICC has previously made submissions on the other items of the agenda already discussed during ABS-7 such as compliance, fair and equitable benefit sharing and access.

General Principles

It is of critical importance that the IR should be a precisely targeted, facilitative structure that promotes national ABS regimes that are transparent, non-discriminatory, predictable and coherent across borders; national ABS regimes that are difficult to reconcile with each other should be avoided. The IR should

5 See footnote 3.
6 See footnote 5.
not be a heavy regulatory framework that will stifle the creation of value from genetic resources, and their trade and sustainable uses. This approach will promote not only the efficient organization of access and benefit sharing, but also the other two pillars of the CBD: conservation and sustainable use of genetic resources. Lessons should be learnt from the experiences of national regimes which show that highly regulated and bureaucratic ABS systems have failed to generate social and economic benefits.

In order to ensure that the CBD’s objectives are attained, business submits that the IR should be based on the following principles:

- An IR should include clear definitions consistent with the terms and jurisdictional limitations of the CBD itself.
- Research, economic activity and freedom to innovate using genetic resources should be encouraged rather than constrained.
- The IR should not seek to restrict what can be mutually agreed and should encourage the systematic use of contracts, which remain the best means to manage ABS of genetic resources.
- The IR should leverage national law, enforcement, and regulatory structures rather than attempt to create new mechanisms and obligations that are yet to be proven effective in real world experience. The IR should therefore focus on the further development and harmonization of national regimes in the spirit of the Bonn Guidelines.
- Such national ABS regimes should identify a national focal point which is authorized to grant access and prior informed consent and to facilitate the negotiation of mutually agreed terms – this is essential to provide legal certainty and transparency for all stakeholders. Any measures to ensure the participation and involvement of indigenous and local communities in mutually agreed terms, and the sharing of benefits with traditional knowledge holders, must be part of a transparent ABS regime.
- The IR should take a sectoral approach to address the unique aspects of how genetic resources are accessed and managed in the many business and science sectors using genetic resources.
- The IR should draw a distinction according to the specialties of sectors rather than between commercial/non-commercial uses.
- The IR should not promote ABS regimes characterized by the stacking of multiple payments for a single product.
- When negotiating the IR, CBD Parties should consider the implementation costs of proposed elements for both countries providing genetic resources and users, as well as the bureaucratic challenges that could have significant negative impacts on SMEs and research, and on the generation of potential benefits.
- The IR should be a prospective system with no retroactive effect. Provisions of the IR should only take effect after the entry into force of the IR and its ratification in the provider country consistent with the provisions of Article 36 of the CBD.

**Nature**

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.

---

7 More detail on these principles can be found in ICC’s submission to ABS-7 “Objective, scope, fair and equitable benefit sharing, access and compliance” – 15 December 2008, http://www.iccwbo.org/uploadedFiles/ICC/policy/intellectual_property/statements/ICC%20Submission%20to%20AHOEWG%207%2015%2012%2008.pdf
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.”

**Traditional knowledge associated with genetic resources: additional views**

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 2009.8

**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.

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). 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.

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.

Capacity building
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.

---

10 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.
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.

Subsection III.E.1

1. Capacity-building measures at all relevant levels for:

(a) Development of national legislation

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 contractual negotiations; and (c) information and communication technology

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

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) Bio-prospecting, associated research and taxonomic studies

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.\(^{11}\)

**(f) Monitoring and enforcing compliance**

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**

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.\(^{12}\)

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 exportation\(^{13}\). 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 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.

---


\(^{12}\) [http://www.apfed.net/dialogue/pdf/200901_biodiv/7sumida.pdf](http://www.apfed.net/dialogue/pdf/200901_biodiv/7sumida.pdf)

3. Measures for technology transfer and cooperation

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 well-trained 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. Research may also be carried out in transnational collaborations between institutions from different countries (see case study in Tanzania – box 1).

---

“The Biotechnology Promise: Capacity-building for Participation of Developing Countries in the Bioeconomy” - UNCTAD, 2004
Nature, traditional knowledge and capacity building

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 Dar-es 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 AstraZeneca-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&dd1ID=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 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. 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 non-exclusive 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 GIM, 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 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.

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

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.
The International Chamber of Commerce (ICC)

ICC is the world business organization, a representative body that speaks with authority on behalf of enterprises from all sectors in every part of the world.

The fundamental mission of ICC is to promote trade and investment across frontiers and help business corporations meet the challenges and opportunities of globalization. Its conviction that trade is a powerful force for peace and prosperity dates from the organization’s origins early in the last century. The small group of far-sighted business leaders who founded ICC called themselves “the merchants of peace”.

ICC has three main activities: rules-setting, dispute resolution and policy. Because its member companies and associations are themselves engaged in international business, ICC has unrivalled authority in making rules that govern the conduct of business across borders. Although these rules are voluntary, they are observed in countless thousands of transactions every day and have become part of the fabric of international trade.

ICC also provides essential services, foremost among them the ICC International Court of Arbitration, the world’s leading arbitral institution. Another service is the World Chambers Federation, ICC’s worldwide network of chambers of commerce, fostering interaction and exchange of chamber best practice.

Business leaders and experts drawn from the ICC membership establish the business stance on broad issues of trade and investment policy as well as on vital technical and sectoral subjects. These include financial services, information technologies, telecommunications, marketing ethics, the environment, transportation, competition law and intellectual property, among others.

ICC enjoys a close working relationship with the United Nations and other intergovernmental organizations, including the World Trade Organization and the G8.

ICC was founded in 1919. Today it groups hundreds of thousands of member companies and associations from over 130 countries. National committees work with their members to address the concerns of business in their countries and convey to their governments the business views formulated by ICC.