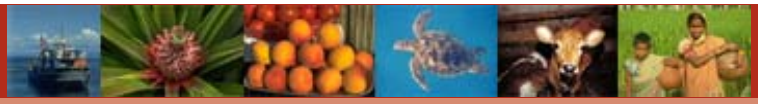
COP-8 BIODIVERSITY AND TRADE BRIEFINGS



By the International Centre for Trade and Sustainable Development (ICTSD) at COP-8 to the CBD

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Access, Benefit-sharing and Intellectual Property Rights

International trade in genetic resources today involves high economic stakes and has attracted strong interest from industry groups and traders. The issue therefore has a bearing not only on the providers of such resources, but also on modern industry, which relies on access to biological or, more specifically, genetic resources. Relevant industry sectors include pharmaceuticals, botanical medicines, horticulture and crop protection. Estimating the full value of trade in genetic resources in monetary terms is difficult if not impossible. Nevertheless, as a rough estimate, a 1999 study evaluated the global market at US$300 billion a year for the pharmaceutical sector using genetic resources, while the market for the horticultural industry was estimated at US$20 billion.[1]

Due to the considerable financial stakes involved, there have been substantial discussions and deliberations on the issue of access to genetic resources and associated traditional knowledge and the sharing of benefits derived from their use in different contexts and fora, including the Convention on Biological Diversity (CBD), the World Intellectual Property Organization (WIPO), the World Trade Organization (WTO) and the Food and Agriculture Organisation (FAO). Discussions have also taken place at regional and local levels. These debates have highlighted that effective access to resources and sharing of benefits can have an impact on numerous policy areas, including biological diversity, food security, environmental sustainability, agricultural productivity, business ethics, human rights, international trade, public health, scientific research, sustainable development and wealth distribution.

ABS Negotiations under the CBD

Fair and equitable sharing of benefits arising from the use of genetic resources is one of the three primary objectives of the CBD, in addition to the conservation of biological diversity and sustainable use of its components, each being linked to and deriving strength from the other. The principles underlying these goals are those of *equity* and *balance*. They link traditional conservation efforts to the economic goal of sustainable use of biological resources. The CBD recognises national sovereignty over all genetic resources. It is important to note that it is the first international treaty to link access to genetic resources to the equitable sharing of benefits related to those resources.[2]

Out of the three goals, developing countries place special emphasis on the objective of benefit-sharing, as they hold the lion's share of global biological resources.[3] The CBD proposes a mechanism for access to valuable biological resources on fair grounds, that is, on 'mutually agreed terms' and subject to the 'prior informed consent' of the country of origin. When a micro-organism, plant or animal is used for a commercial application, the providers of these resources have the right to benefit. The benefits may be monetary or non-monetary, such as the transfer of biotechnology equipment and know-how.

IP references in the CBD

The problem rests in the implementation of the CBD's objectives, which intersect with the intellectual property regime.[4] Parties to the CBD must endeavour to ensure that the protection of mostly private intellectual property rights (IPRs) does not run counter to and is supportive of the objectives of the CBD, which confers and protects public rights. IPR-related issues are covered in various provisions of the CBD:

- The only explicit reference is in Article 16 (dealing with transfer of technology), which recognises that patents and other IPRs may have an influence on the implementation of the Convention. Article 16(3) directly links access to genetic resources and IPRs by stipulating that developing country providers of genetic resources should have access to and transfer of IPR-protected technology that uses those resources.
- IPRs are also relevant in the context of knowledge, innovations and practices of indigenous and local communities. Some of the most critical controversies relate to the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) and IPRs in general have arisen from debates falling within this issue area.
- Article 11 calls on Parties to adopt economically and socially sound measures that act as incentives for conservation and sustainable use. This provision

constitutes the very core of the relationship between IPRs and genetic resources, raising the question whether IPRs act as a positive or negative incentive for the conservation of genetic resources.

Initiatives under the CBD for resolving the ABS and IP issues

In order to facilitate better implementation of the CBD obligations with respect to access and benefit-sharing (ABS), Parties have undertaken several activities. Decision IV/8 of the Conference of the Parties (COP) established a regionally-balanced panel of experts on ABS with representation from diverse interest groups. The first meeting was held in 1999. At COP-6, it was decided to establish an Ad Hoc Open-ended Working Group with the mandate to develop guidelines and other approaches for submission to the COP. One of the important outcomes of COP-6 was decision VI/24, which established the *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilisation*.

The Bonn Guidelines are a way to operationalise the CBD provisions with respect to ABS. These Guidelines are voluntary and indicate detailed procedures at the national level to facilitate access to genetic resources based on 'prior informed consent' (PIC) of the country of origin, as well as 'mutually agreed terms' (MAT). The Guidelines assist in establishing and developing national ABS regimes while promoting capacity-building, transfer of technology and the provision of financial resources. They also seek to promote sustainable use of genetic resources by promising to improve users' (commercial and non-commercial) access to valuable genetic resources in return for sharing the benefits with the countries of origin and with local and indigenous communities.

The COP has also taken a number of decisions on IP issues. Decision III/17 on intellectual property rights called for case studies to be developed on the impacts of IPRs on achieving the CBD's objectives, including the relationship between IPRs and traditional knowledge relevant for the conservation and sustainable use of biological diversity. The Decision called for further work to develop a common appreciation of the relationship between IPRs, the TRIPS Agreement and the CBD. This last point was reiterated in COP Decision IV/15.

The Bonn Guidelines also contain a section on the role of intellectual property rights in the implementation of ABS arrangements. The section suggests that Parties and other governments encourage the disclosure of the country of origin of genetic resources and traditional knowledge in intellectual property rights applications in order to help track compliance with requirements relating to PIC and MAT. It further calls for the origin of relevant traditional knowledge, innovations and practices to be disclosed in IPR applications.

In 2002, governments at the World Summit on Sustainable Development signed on to the objective to significantly reduce biodiversity loss by 2010. One of the methods identified to achieve this was to ensure that the benefits arising from the sustainable use of biodiversity reach local people in countries of origin of the material. To this end, the Johannesburg Plan of Implementation mandates countries to negotiate an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilisation of genetic resources under the auspices of the CBD. The scope of the regime was subequently expanded to also address issues related to the access to genetic resources.

The ABS Working Group met in Bangkok in early 2005 to start discussions regarding the international regime on access and benefit-sharing. In February 2006, the Working Group met again in Granada, Spain. The main outcomes forwarded to COP-8 included:[5]

a. *International Regime*: A heavily bracketed draft international regime on access and benefit sharing was put forward. Options for the kind of instrument, scope and objectives were listed, and discussions continued on the legal nature of the regime. Biodiversity rich countries argue that it should be legally binding, while most of the user countries consider that it should be a set of non-binding guidelines.

b. *Certificates for origin, source or legal provenance*: The Working Group called on stakeholders to prepare further studies on the design of such an international certificate, examining, *inter alia*, the rationale, objectives, desirabl e characteristics, practicality and feasibility, and has asked the COP to decide whether to establish an expert group on the issue.

c. *Measures to support PIC requirements and MTA, once access has been granted*: Such measures could require the disclosure of origin/source/legal provenance of the genetic resource and associated traditional knowledge. The Working Group invited the Parties to consider the introduction of such a requirement in their national IP legislations and to conduct studies in this area and to transmit the information to WIPO and other relevant fora.

d. *Indicators for access and in particular for fair and equitable sharing of benefits*: The Working Group urged all members and relevant stakeholders to further evaluate the need and possible options for such indicators.

All these measures directly or indirectly have an impact on the debates related to IP and ABS, including on the relationship between the CBD and the TRIPS Agreement.

ABS at the WTO

The relation between the objectives of and obligations under the CBD and the TRIPS Agreement has been the subject of contentious debate in the WTO. These discussions have been primarily focused on the possible need for amending the TRIPS Agreement so that it helps support the objectives of the CBD.

Coherence between TRIPS and CBD obligations?

WTO Members have taken three different approaches to the relationship between the TRIPS Agreement and the CBD.[6] The position of countries such as Zambia, Bangladesh and even the African Group is that that the two treaties are incompatible due to a conflict between the private rights granted under the TRIPS Agreement and nations' sovereign rights over their genetic resources under the CBD. A somewhat more neutral approach is that of countries such as Brazil and India who believe that the two are not inherently incompatible, but could conflict in the way they are implemented. These countries advocate that the TRIPS Agreement – and in particular Article 27.3(b) dealing with the patentability of life forms – should be amended to reflect CBD obligations and avoid potential conflict. The third position, held by countries such as the US, Australia and Canada, considers that there is no incompatibility between the two legal instruments as they seek to achieve different objectives and address different subject matters. Therefore, they argue, countries can implement the two in mutually supportive ways with national measures.

The Doha negotiations

At the 2001 WTO Ministerial Conference in Doha, WTO Members agreed to examine – as part of the ongoing round of trade talks – the relationship between the CBD and the TRIPS Agreement under Paragraph 19 of the Doha Declaration. These discussions, which are also mandated to address the protection of traditional knowledge and folklore, have taken place in the TRIPS Council Special Session. The mandate if further strengthened by Paragraph 12 of the Doha Declaration which mandates WTO Members to resolve a number of so-called 'implementation issues' outstanding from the previous round of negotiations, which includes clarifying the CBD-TRIPS relationship in Article 27.3b of the TRIPS Agreement. Negotiations under this mandate, which have been held informally – on the sidelines of the TRIPS Council – under the leadership of WTO Deputy Director General Rufus Yerxa, have tended to be more political in nature.

A group of developing countries, led by Brazil and India, has proposed to amend the TRIPS Agreement to require a patent application relating to genetic resources or traditional knowledge to declare the origin of the resource and the traditional knowledge used in the invention, and to provide evidence of PIC from relevant authorities and of fair and equitable benefit-sharing. They believe that such a 'disclosure requirement' would help countries comply with the objectives of the CBD by preventing the misappropriation of genetic resources and associated traditional knowledge; increase transparency and credibility of the patent system; enhance the quality of patent applications; and ensure the sustainable and fair flow of genetic resources.

Most developed countries, notably the US and Japan, remain strongly opposed to any such amendment. As an alternative, the US has proposed a contract-based approach which would encourage national authorities to enact legislation requiring companies to set up private contracts with the holders of genetic resources The EU has signalled its willingness to discuss the disclosure aspect of the proposal (but not PIC and benefit-sharing). Switzerland would prefer these discussions to be taken up by WIPO.

At the WTO Ministerial Conference in Hong Kong in December 2005, India pushed strongly for an official launch of negotations on disclosure requirements which was met with stiff opposition by the US and others, including Canada and Australia.

Related discussions at WIPO

WIPO has been looking in depth at the intellectual property aspects of ABS under the aegis of the Intergovernmental Committee (IGC) on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, whose first session was held in 2001. The IGC aims to provide a venue for debating key issues, enabling information gathering, and commissioning further analytical work. Its mandate contains, *inter alia*, the following elements:

- evaluating the relevance of existing IP tools for TK protection (defensive as well as positive) and examining the best possible mechanisms for the protection of TK;
- discussing appropriate national and international patent measures, including disclosure of origin and evidence of prior informed consent, that will facilitate access to genetic resources and benefit-sharing; and
- identifying elements of the agreed subject matter that requires additional protection.[7]

So far, the IGC has been unable to forge consensus on the issues and some developing countries have resisted a discussions on disclosure requirements in this context given that – in contrast to the TRIPS Council – the IGC is not a negotiating forum.

At its sixth session – on an invitation from the COP to the CBD to examine issues regarding the interrelation of access to genetic resources and disclosure requirements

in intellectual property rights applications – the WIPO General Assembly established a specific process (distinct from the IGC) to develop a response to the CBD COP invitation, based on inputs by WIPO member states and observers. This resulted in the preparation of a study report, which as been transmitted to the consideration of the COP in Curitiba.[8]

Currently, negotiations are also underway at WIPO for a Substantive Patent Law Treaty (SPLT). While the TRIPS Agreement establishes the minimum level of IPR protection in national legislation, the SPLT will spell out the full substance of these rights in an effort to harmonise them. In its present form, the draft treaty does not allow parties to make any further demands on patent applicants other than those found in the treaty. This might preclude countries from implementing disclosure requirements as part of the patent application process, as these are not included in the current criteria.

There have also been discussions on this topic under the Patent Co-operation Treaty (PCT). Switzerland has proposed an amendment to the PCT to enable countries to require patent applicants to declare the source of the genetic resources and TK in patent applications, although such a provision would be merely voluntary, not mandatory as developing countries have demanded.

ABS under the International Treaty

The International Treaty for Plant Genetic Resources for Food and Agriculture (ITPGRFA), adopted in 2001, entered into force in 2004 and aims at the conservation and sustainable use of plant genetic resources for food and agriculture, the fair and equitable sharing of benefits arising out of their use, and sustainable agriculture and food security. At the heart of the Treaty is a 'multilateral system' (MLS) that seeks to facilitate access to a negotiated list of plant genetic resources, annexed to the treaty, as well as fair and equitable benefit-sharing. Genetic resources included in the MLS are to be circulated freely and that no one can claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts and components. Such access is to be provided through a standard material transfer agreement which is still under development.

Another issue that is relevant to IPR discussions relates to the treaty's benefit-sharing arrangement which provides for monetary contributions derived from the commercialisation of products developed from PGRFA accessed under the MLS. The payment is mandatory when the commercialisation of the product restricts the product's availability for use in further research and breeding, and voluntary when the product is freely available for such purposes. While the treaty does not explicitly discriminate between IPR holders – who are by definition conferred exclusive rights under the TRIPS Agreement – and others, it does so in practice due to the different rules for products available for further research and breeding and those that are not. Depending on how governments incorporate the provisions of this treaty into their IPR regulations, the possibility might arise that they could be challenged on the basis that in doing so, they contravene their TRIPS obligations under Articles 27.1 and 29 by imposing additional conditions for IPR protection.

From these discussions, it is obvious that some of the problems that are likely to arise with the implementation of this Treaty coincide with those under other agreements, such as the CBD and the TRIPS Agreement. Therefore, adequate discussion and resolution are not only crucial to ensure effective access and benefit-sharing, but also increasingly relevant to the intellectual property and development agenda being pursued by developing countries and institutions in diverse international fora, and WIPO in particular.

Endnotes

[1] K.K. Ten and S.Laird, "Commerical Use of Biodiversity", London: Earthscan, 1999

[2] C.L. Diaz, "Intellectual Property Rights and Biological Resources: An overview of key Issues and Current Debates", Wuppertal Institute for Climate, Environment and Energy, No: 151, 2005

[3] Some of these so-called mega-diverse countries include Bolivia, Brazil, China, Colombia, Costa Rica, Democratic Republic of Congo, Ecuador, India, Indonesia, Kenya, Madagascar, Malaysia, Mexico, Peru, Philippines, South Africa and Venezuela.

[4] As in the example of innovations utilising genetic resources that has been specified earlier

[5] UNEP/CBD/COP/8/5, www.biodiv.org/doc/meetings/cop/cop-08/official/cop-08-05-en.doc.

[6] For a summary of the discussions, see www.biodiv.org/doc/meetings/cop/cop-08/information/cop-08-inf-37-en.doc

[7] WIPO/grtkf/ic/1/3, www.wipo.int/documents/en/meetings/2001/igc/doc/grtkfic1_3.doc

[8] Intergovernmental Committee on Intellectual Property and Genetic Resources, Tradetional Knowledge and Folklore; Ninth Session, www.wipo.int/ edocs/mdocs/tk/en/wipo_grtkf_ic_9_9.doc

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