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The International Regime on Access to Genetic Resources and Benefit-Sharing:

Progress, Elements and Recommendations

Policy, Biodiversity and International Agreements Unit - PBIA

Bundesministerium für
wirtschaftliche Zusammenarbeit
und Entwicklung

The International Regime on Access to Genetic Resources and Benefit-Sharing:

Progress, Elements and Recommendations

JORGE CABRERA MEDAGLIA

PREPARED FOR THE WORLD CONSERVATION UNION

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Av. De los Shyris 2680 y Gaspar de Villarroel
P.O. Box 17-17 626
Edificio Mita Cobadelsa, PH
Quito, Ecuador
Tel: +(593) 2 2261075
Fax: +(593) 2 263075
samerica@sur.iucn.org
www.sur.iucn.org

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I. Introduction

The World Summit on Sustainable Development (WSSD) affirmed the importance of biodiversity conservation and sustainable use of biological resources for achieving poverty alleviation, sustainable livelihoods and cultural integrity. A critical outcome in this regard was the mandate, in paragraph 44 (o), of the Johannesburg Plan of Implementation, to negotiate, within the framework of the Convention on Biological Diversity, an international regime "to promote and safeguard the fair and equitable sharing of benefits arising out of the utilisation of genetic resources." Indeed, Access and Benefit Sharing (ABS) and the linkages with intellectual property rights, traditional knowledge and gender equity are among the most relevant aspects of the global biodiversity and development agenda.

The present document attempts to analyse the progress of discussions regarding the development of an International Regime on Access to Genetic Resources and Benefit-sharing (IR) as well as options for its future development. The options proposed have been developed on the basis of the findings of the project “Supporting the Global Biodiversity Agenda“ funded by the German Federal Ministry for Economic Co-operation and Development (BMZ) and implemented by IUCN’s Policy, Biodiversity and International Agreements Unit (PBIA), based at IUCN Headquarters in Gland, Switzerland, in collaboration with its Regional Office for South America, based in Quito, Ecuador. The elements and proposals contained in this document emerged from the analysis, technical documents, workshop reports, consultations and dialogues of this project, which aimed at providing policy options for the implementation of paragraph 44 (o) of the WSSD Plan of Implementation. Key premises of this work were the need to ensure that such international regime had to be supportive of national and regional efforts in order to lead to effective outcomes, and that these efforts needed to be coherent with each other, as well as with related global regimes of the World Trade Organisation (WTO) (especially the Trade-Related Aspects of Property Rights - TRIPS), the World Intellectual Property Organisation (WIPO), and the Food and Agriculture Organisation (FAO) International Treaty on Plant Genetic Resources for Food and Agriculture (IT), as well as regional regimes.

The main issues presented here have been selected from a wide variety of options that have arisen during the negotiation process, the technical and policy contributions of the project and from other sources of information, bearing in mind the following important characteristics: their potential use and relevance for achieving the objectives of the Convention on Biological Resources (CBD); the technical and political feasibility of these elements effectively becoming part of the IR; and the central importance they have acquired in the current debate on the IR. This document does not aim to thoroughly address the different substantive issues that have been identified as priorities for the International Regime but only to describe them and briefly explain why they merit consideration as components of the International Regime.

The project “Supporting the Global Biodiversity Agenda” has been a key contribution in many ways to the progress of technical and conceptual issues regarding ABS negotiations at regional and global levels. In particular, the project contributed to developing legal and policy advice to governments, especially in the context of the CBD and WIPO negotiations; it provided platforms for multi-stakeholder dialogue, including key actors in the ABS negotiations process, such as private sector, governments, civil society, indigenous peoples and academia; and it offered the possibility to strengthen alliances with other organisations, as well to establish a network of

experts working on ABS and related issues at regional and global levels. Finally, the project identified areas where there is a need for further work as well as the key challenges for an effective implementation of ABS provisions at different scales.

Martha Chouchena-Rojas
Head
Policy, Biodiversity and International Agreements
IUCN - The World Conservation Union

II. Background on the Process of Elaborating and Negotiating the International Regime on Access to Genetic Resources and Benefit-Sharing

A. Preliminary considerations

During the process of elaborating the CBD, it was considered necessary to negotiate benefit-sharing provisions arising out of the utilisation of genetic resources as an essential counterpart to address traditional biodiversity-related issues[1] (conservation and sustainable use). However, it is generally recognised – particularly by developing countries – that it has not yet been possible to fully achieve the third objective of the CBD, or at least that its degree of achievement has been insufficient.[2] However, although the perception of limited benefit-sharing may explain the motivation behind the initiative to elaborate an International Regime, it is striking that there are no systematic studies describing the fundamental causes hindering the effective achievement of the third objective of the CBD. These causes should inevitably be addressed by the International Regime[3].

In this regard, the negotiation of an International Regime results mainly from the following factors:

1. Frustration due to the limited economic and non-economic benefits (monetary and non-monetary) obtained from the different bioprospecting projects and, in general, from the application of ABS frameworks.[4]

2. Cases of illegal access, misappropriation or "biopiracy" that have occurred in countries and communities, especially in Latin America, Asia, and Africa, and the difficulties in finding cost-effective legal solutions within the framework of national ABS legislation or in the context of industrial property law.[5] Emblematic cases such as "Maca" in Peru or the "Neem" in India, among many others, have frequently been mentioned as a rationale for undertaking modifications to the text or operation of intellectual property right systems, particularly patents, which so far have proven to be one of the main causes of complaints being filed for misappropriation or biopiracy.[6]

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1 Cfr. Gloyka, L., Burhenne-Guilmin, F., and Synge, H, A Guide to the Convention on Biological Diversity, IUCN, Gland, Switzerland and Cambridge, U.K., 1994.

2 See, among others, Young, Tomme, Gaps and Obstacles in Developing/Implementing National ABS Legislation, document presented at the Expert Workshop on Access to Genetic Resources and Benefit-sharing, Cape Town, September, 2005.

3 Studies or analyses can basically be found on specific aspects, such as the challenges of regulating the utilisation of GR in user countries once they have left the provider country, etc.

4 The implementation of ABS regulations, and even the existence of concrete initiatives on bioprospecting, have not generated the huge benefits some had expected for the provider countries and the communities or indigenous peoples. Cfr. Cabrera Medaglia, Jorge, A Comparative Analysis of the Legislation and Practices on Access to Genetic Resources and Benefit Sharing: Critical Aspects for Implementation and Interpretation, IUCN, ABS Project, Bonn, 2004 and Cabrera Medaglia, Jorge, Biodiversity Prospecting In Practice, IP Strategy Today, No 11, Biodevelopments, New York, 2004.

5 It is difficult to quantify the level of these activities due to the lack of legal certainty on the definition of biopiracy. For some, it consists of the acquisition of genetic resources and traditional knowledge without the consent of the country or holder of the resource or knowledge; when rules for fair and equitable benefit-sharing are not established; when IPR protects innovations that are copies or cosmetic modifications of the genetic resources; or when IPR protects biotechnological innovations based on the genetic resources, whether or not prior informed consent exists, etc. On the topic of biopiracy and the difficulties of judging whether certain activities constitute misappropriation, Cfr. Dutfield, Graham, What is Biopiracy?, document presented at the Expert Workshop on Access and Benefit-sharing, Cuernavaca, Mexico, October, 2004; and, Young, Tomme, Analysis of Claims of Unauthorized Access and Misappropriation of Genetic Resources and Associated Traditional Knowledge, a report prepared for IUCN-Canada and distributed at the Fourth Meeting of the Working Group on ABS, Granada, Document UNEP/CBD/WG-ABS/4/INF/6, January, 2006.

6 The idea of disclosure of origin, which will be explained further on, is partly in response to this.

3. Finally, although the CBD mandates the Parties to take measures to ensure fair and equitable benefit sharing (see particularly the provisions of article 15.7), it has mostly been developing countries that have issued regulations on ABS[7]. Thus, the nations where pharmaceutical, biotechnological and agricultural companies have their headquarters (mostly developed countries) have not put into force the corresponding regulations to ensure benefit sharing and comply with their legally binding international agreements. The absence or limited presence of so-called "user country measures"[8] (which will be explained further on) has been criticised as one of the causes of high transaction costs and the sometimes highly controlling nature of current access regulations. The need for "user country measures" has been stressed by those who have noted the transboundary nature of trade relations regarding ABS[9] and the inefficiency of local regulations after the samples or information on genetic resources leave the country of origin. In this context, ABS provisions in the countries of origin are particularly inadequate for creating an ABS system that is functional and consistent.

4. One of the common factor of ABS is the lack of trust among the different actors involved in these issues,[10] creating an inadequate ground for negotiations, at the global level, among countries, or local level through contracts between providers and users of genetic resources and associated traditional knowledge.

B. Negotiations of an International Regime on ABS.[11]

In general, these brief considerations are based on the following basic assumptions:

1. The International Regime on ABS is currently comprised of a variety of legal instruments, both binding and non-binding, of a national, regional, and multilateral nature. This International Regime, which might more accurately be called "ABS governance", has existed for several years. In terms of compliance with benefit sharing objectives, it clearly has not worked to the satisfaction of all of the actors involved.

2. The International Regime must mainly be negotiated and developed within the context of the CBD, as indicated in the WSSD Plan of Implementation (2002), thus, its scope of action will necessarily be limited by this specific circumstance. This means that since the existing International Regime is composed of instruments and mechanisms outside the CBD, the Convention has, legally speaking, a limited influence on them, since they are independent instruments. Therefore, it is necessary to explore how synergies among the different international processes and instruments can be strengthened.

7 Cfr. the study by Gatforth et al., describes current ABS measures and legislation. According to this study, approximately 25 countries have some kind of specific legislation on ABS. In many cases, they are laws of a general nature whose effective application requires additional regulations or laws to further develop the general precepts.
8 Cfr. Barber, Charles, et al, User Measures: Options for Developing Measures in User Countries to Implement the Access and Benefit Sharing Provisions of the Convention on Biological Diversity, UNU/IAS, Japan, 2003.
9 Young, Tomme, Gaps and Obstacles, op. cit. Cfr. Young, Tomme, Genetic Resources and Utilisation of Genetic Resources: a Legislative View, document presented to the International Expert Workshop on Access to Genetic Resources and Benefit Sharing, Cuernavaca, Mexico, October, 2004.
10 International Institute for Sustainable Development (ISSD), Stratos and Jorge Cabrera, A Guide to Using the Working Draft ABS Management Tool, State Secretariat For Economic Affairs (SECO), Switzerland, Berne, 2005.
11 A significant amount of literature is now being written about the IR. Particularly it is recommended Gatforth, Kathryn, and Cabrera Medaglia, Jorge, Sustainable Biodiversity Law: Global Access, Local Benefits, in the ICFAI Journal of Environmental Law, Vol. IV, No 4, October 2005, India; Ruiz Manuel, The International Regime on Access to Genetic Resources and Benefit Sharing: in Search of the Right Path, Policy and Environmental Law Series, No 17, SPDA, Lima, 2006; Dross, Miriam and Wolff, Francisca, New Elements of the International Regime on Access to Genetic Resources and Benefit sharing- the role of certificates of origin, BfN, Bonn, 2005; Dross, Miriam and Wolff, Francisca, Do we need a new access and benefit-sharing instrument? Yearbook of International Environmental Law, Vol. 15, 2004, Oxford University Press; Cabrera Medaglia, Jorge, Las negociaciones sobre el Régimen Internacional de acceso a recursos genéticos y distribución de beneficios: opciones para un país en desarrollo, in Puentes, Vol. V, No 3, May-June 2004; Hodges, Tim and Daniel, Anne, Promises and Pitfalls: a First Step on the Road to the ABS International Regime, RECIEL, 14. No. 2, 2005, UK; Young, Tomme, Opciones y Procesos de desarrollo de un Régimen Internacional sobre Acceso y Distribución de Beneficios: Manual de Resumen para las delegaciones de la CBD; The ABS Project, IUCN, Bonn, 2004 and Oxley, Alan and Bowen, Bill, Developing an Effective International Regime for Access and Benefit Sharing for Genetic Resources: Using Market-Based Instruments; Australian APEC Study Centre, Monash University, Australia, 2006.

3. Likewise, the substantive provisions of an agreement (e.g., the World Trade Organisation or the FAO International Treaty on Plant Genetic Resources for Food and Agriculture) can only be modified by the Parties of that agreement, in accordance with the procedures established in the respective Agreement or Treaty (number of votes needed or unanimity, time frame, forms and modalities for submission of reform proposals, etc.)

4. Nevertheless, in compliance with the Vienna Convention on the Law of Treaties - the universal standard accepted by international dispute settlement bodies, even by countries that have not ratified this Convention - if a flagrant conflict or contradiction arises between two international instruments, the instrument that entered in force on the later date shall prevail, based on the principle that the more recent law derogates the prior one in any aspects where they differ (article 30 of the Convention). However, this potential regulatory contradiction is unusual in international law since treaties are normally interpreted as a complementary instrument.

5. Therefore, in accordance with international law, a State is legally bound to comply with all the treaties to which it is a party, as long as their provisions are not contradictory (the principle of accumulation of international obligations). The case of contradictory provisions has been examined to a much lesser degree. In general, the following recommendations are based on the principle of integration included in the Rio Declaration on Environment and Development (Principle 4) and on the consideration that environmental treaties and trade objectives must be mutually supportive, as prescribed by the Johannesburg Plan of Implementation (Paragraph 92).

C. Background, progress and current content of the draft International Regime under negotiation.

During the negotiations that preceded the drafting of the CBD, the developing countries fought for, and succeeded in including as one of the objectives of this agreement, the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources. Thus, along with the objectives related to the conservation and sustainable use of biodiversity, benefit sharing became one of the goals that should guide the actions of the CBD. Although this international agreement observed the interests of its parties, little has been done to put theory into practice. Since the Fourth Conference of the Parties held in Bratislava in 1999, some concrete actions have been taken. For example, COP 4 decided to form a Panel of Experts on Access to Genetic Resources and Benefit Sharing, which has met twice (San Jose, 1999 and Montreal 2001). The results of the Panel's work at its first meeting were presented at the Fifth Conference of the Parties (Nairobi, 2000), which decided to create an Ad Hoc Open-Ended Working Group on Access and Benefit-sharing (WGABS) to prepare a draft of international ABS guidelines and norms. This group concluded its task in October 2000 in Bonn when it completed the Bonn Guidelines on Access to Genetic Resources and Benefit Sharing, which, with a number of changes and additions, were finally approved at the Sixth Conference of the Parties held in The Hague in 2002. The Conference also required the Working Group to meet for a second time to discuss certain pending issues, such as definitions, user country measures, etc.

Although these instructions or guidelines were welcomed by the developed countries and companies that use these resources, some developing countries believed that this effort was fundamentally lacking for two reasons: 1) these guidelines are of a voluntary nature; 2) they pay

little attention to the measures to be taken by the countries where users are located (developed countries with companies that use genetic resources) in order to fulfil their obligations under the Convention, especially those related to taking administrative measures and establishing policies and laws on benefit sharing.

Parallel, in January 2002, the Group of Like-Minded Megadiverse Countries (GLMMC) was formed in Mexico (created by the Cancun Declaration)[12].

At the initiative of the government of Mexico, the Ministers and high-level representatives of the megadiverse countries of Brazil, China, Colombia, Costa Rica, Ecuador, India, Indonesia, Kenya, Mexico, South Africa and Venezuela, met in Cancun from 16-18th February 2002 and decided to establish the GLMMC. They subsequently signed the Cancun Declaration, and Bolivia, Malaysia, and the Philippines were formally accepted into the Action Group.[13]

All together, the GLMMC represents approximately 70 percent of the planet's biological diversity, around 45 percent of the world's population, and an extraordinary cultural diversity.

The group was formally incorporated through the Cancun Declaration, which decided "to establish the Group of Like-Minded Megadiverse Countries as a mechanism for consultation and cooperation to promote our interests and priorities related to the preservation and sustainable use of biological diversity".

Its objectives include the following:

- Present a common front at international fora dealing with biological diversity.
- Promote in-situ and ex-situ conservation of biodiversity and the development of joint research projects.
- Ensure that the goods, services, and benefits arising from the conservation and sustainable use of biological diversity are utilised for the development of our peoples.
- Jointly explore ways to exchange information and to harmonise our respective national laws and regulations on the protection of biological diversity, including associated knowledge, as well as access to biological and genetic resources and the sharing of benefits arising out of their utilisation.
- Promote the development of a *Sui Generis* Regime for the protection of traditional knowledge.
- Encourage international property systems to take traditional knowledge into account when evaluating requests for patents.
- Combat misappropriation of genetic resources.
- Promote the development of an International Regime to effectively promote and safeguard the sharing of benefits arising out of the use of biological diversity and its components. The Regime shall include, among other elements, the certificate of legal provenance, prior informed consent (PIC) and mutually agreed terms (MAT) for the transfer of genetic material, as requirements for the application for and granting of patents.

12 See www.megadiverse.com
13 Congo and Madagascar were accepted as members of the Group at its Ministerial meeting held during the VII Conference of the Parties in Malaysia.

The GLMMC made an important achievement at the World Summit on Sustainable Development in Johannesburg, in promoting the establishment of an International Regime, in accordance with the provisions of the Cancun Declaration, to effectively promote and safeguard fair and equitable benefit sharing. This determination was recorded in paragraph 42 (O) of the Johannesburg Plan of Implementation, in terms almost identical to those included in the Declaration. On 20th December 2002, Resolution 57-260 of the United Nations General Assembly invited the Conference of the Parties to take the necessary measures regarding the commitment established at the Summit to negotiate this regime[14].

The Beginning of Negotiations

At its second meeting (Montreal, December 2003) the Working Group gave the International Regime detailed consideration and developed a series of recommendations, mostly bracketed, to be analysed at the Seventh Conference of the Parties. These recommendations were taken into account at COP 7 in Kuala Lumpur, which agreed, through Decision VII/19, to begin negotiations.

Decision VII/19 of the COP 7 is probably one of the most comprehensive and detailed of all of the decisions regarding access to genetic resources. This decision calls for the Working Group on ABS to meet again "… with the collaboration of the Ad Hoc Open-ended Intersessional Working Group on Article 8 (j) and Related Provisions, ensuring the participation of indigenous and local communities, non-governmental organisations, industry and scientific and academic institutions, as well as intergovernmental organisations, to elaborate and negotiate an International Regime on Access to Genetic resources and Benefit Sharing with the aim of adopting an instrument/instruments to effectively implement the provisions in Article 15 and Article 8 (J) of the Convention and the three objectives of the Convention". This group has met twice (Thailand in February 2005, and Spain in January 2006) and its results were presented at the Eighth Conference of the Parties held in Curitiba, Brazil in March 2006. The group has operated in accordance with the terms of reference contained in the Annex to Decision VII/19.

Basically, the relevant sections of these terms of reference address the following aspects:

Process: The nature and scope of the International Regime on access to genetic resources and benefit-sharing, as well as the elements to be included, will be elaborated and negotiated within the framework of the Convention, drawing on, inter alia, an analysis of existing legal and other instruments at national, regional, and international levels, including contracts, implementation experiences, compliance mechanisms, and other options. As part of the process, the group will review the elements contained in the annex and determine how to address gaps. The study of the elements is not established as a condition for the negotiation of the regime.

Nature: The regime could be composed of one or more instruments within a set of principles, norms, rules and procedures of a legally binding and/or non-binding nature.

Scope: The scope includes three aspects: access to genetic resources; the promotion and safeguarding of fair and equitable sharing of the benefits arising out of the utilisation of genetic resources; and innovations, traditional knowledge and practices in accordance with article 8 (j).

14 Although the language of the Summit refers only to benefit sharing, the meeting of the Convention's Program of Work of the Convention (Montreal, March 2003) recommended that the Working Group on ABS consider, at its second meeting, the process, nature, scope, elements and modalities for an international regime on access to genetic resources and benefit sharing.

Elements: The elements of the regime comprise an exhaustive list. This includes a wide variety of options (23 total), ranging from measures to promote and encourage collaborative scientific research to research for commercial purposes and the commercialisation of genetic resources, the certificate internationally known as the certificate of origin/source/legal provenance, and the consideration of derivatives of genetic resources, among others.

Decision VII/19 also mentions other relevant topics, particularly the promotion of user country measures (subsection E) and an ambitious and comprehensive capacity building program (subsection F). In addition, it reaffirms the importance of the Bonn Guidelines (subsection A), indicates the need for further examination of other approaches that are complementary to the Guidelines (subsection C); and addresses the use of terms or definitions (subsection B).

The Third Meeting of the WGABS (Thailand, 2005) allowed the Parties to express general ideas on different aspects of the Regime, but showed that substantial work was still needed on the definition of national and regional positions and the understanding of what the content of the International Regime should be[15]. Although the developing countries' positions are not identical, they have recognised the critical need to identify gaps in existing instruments and, based on that information, to proceed to take the necessary measures to rectify them. Although the developing countries do not have a totally clear position regarding the content of the International Regime, they have stated that the Group's main goal is to negotiate. Likewise, some interesting ideas were presented regarding how the next negotiation process should be approached.

The Fourth Meeting (Granada, Spain, 2006) made it possible to progress a little further in identifying concrete mechanisms and instruments for potential inclusion in the International Regime; however, it demonstrated that there are still important differences among the Parties regarding how to achieve the CBD objective, the nature of the mechanisms, and, in general, the direction (and time frame) to follow. With no intention to minimise the progress made so far, there are still diverse views regarding the instruments required in order to make the International Regime operational, as well as concerning their scope and how these will contribute to achieving the third objective of the Convention, to mention the main controversial issues.

Current Status of Negotiations of the International Regime

The Eighth Conference of the Parties to the CBD was held in Curitiba, Brazil, and the analysis of the International Regime was one of the main topics of debate. While the discussion focused largely on non-substantive aspects of the process, agreement was reached on a number of topics of interest.

Decision VIII/4 established that the Annex (the results of the Granada meeting) would be delivered to the Working Group on ABS (WGABS) at its Fifth Meeting, so that, in accordance with Decision VII/19, it could continue to elaborate an International Regime, including the following additional inputs:

a) The outcomes of the Group of Technical Experts on the certificate of origin/source/legal provenance;
b) A progress report on the gap analysis, and the matrix, and;
c) Other inputs submitted by the Parties relating to access and benefit sharing.

15 If all of the documents produced at the Thailand meeting were analysed, it would be found that practically everything conceivably related to ABS was mentioned.

This Annex reflects the opinions expressed by the Parties at the meeting in Granada.

Governments, local communities and indigenous peoples, international organisations and other relevant actors were invited to provide information related to the analysis of legal and other instruments relating to ABS, at national, regional and international levels. This information should be submitted to the Secretariat four months prior to the WGABS meeting. The Secretariat was requested to prepare a compilation of the aforementioned information and to make it available to the Working Group.

Two permanent Co-Presidents were appointed: Fernando Casas from Colombia and Timothy Hodges from Canada. The WGABS was given the mandate to continue developing and negotiating the International Regime in accordance with Decision VII/19 and to complete its work as soon as possible before the Tenth Conference of the Parties (2010). This Working Group should meet at least twice before the Ninth Conference of the Parties (2008).

Likewise, the different interested parties were asked to provide input for the gap analysis, bearing in mind that this analysis must be carried out in parallel and should not delay the work on the development and negotiation of the International Regime.

Finally, the Parties were invited to submit information to the Secretariat on the legal status of genetic resources in their countries' legislation, including property rights, and the Secretary was asked to send a report to the Fifth Meeting of the WGABS.

On the Results of Granada: the Annex for the Work of the WGABS 5.

In general, the Annex addresses the following basic elements[16]:

- **Nature.** The International Regime may be composed of one or more instruments within a set of norms, principles, rules, and decision-making procedures that may be both binding and non-binding.

- **Objectives.** More than ten potential objectives of the International Regime have been listed, on which no consensus has been reached and which occasionally overlap. These include: creating conditions to [facilitate] [regulate] access to genetic resources for environmentally sound uses; ensuring the fair and equitable sharing of monetary and non-monetary benefits; preventing the misappropriation of genetic resources, their derivatives and associated traditional knowledge; ensuring compliance with the PIC and the MAT of the countries of origin and local communities and indigenous groups; contributing to the effective implementation of articles 15, 8 (j) [16 and 19] and of the three objectives of the CBD; ensuring that the relevant international instruments and processes are mutually supportive [offering support and do not contradict the Convention's objectives], etc.

- **Scope.** Regarding the scope of the International Regime, it has been proposed and is under discussion that it be applied to: access to genetic resources, their regulation or facilitation (including derivatives or products – a topic on which there are still significant disagreements); the sharing of the benefits arising out of the utilisation of genetic resources; the protection or preservation, respect and maintenance of traditional knowledge; the relationship between the FAO Treaty and the WIPO Intergovernmental Committee; and, in general, the need to ensure that the different processes are mutually supportive; the exclusion of human genetic resources, etc.

16 The main aspects included in the Decision are listed. It should be clarified that most of these aspects are still subject to negotiation and are therefore bracketed. Nonetheless, it seems appropriate to present the current status of the document at this time in order to better understand the direction that the Parties wish to take in elaborating the IR.

- **Elements.** The following have been proposed as potential elements of the International Regime:

  a. Access to Genetic Resources: access to genetic resources [and derivatives and products], recognising the sovereignty of the countries and their authority to establish access conditions; a description of access procedures that are clear, simple, transparent, and provide legal certainty; the Parties that are not countries of origin of genetic resources shall not allow access to the resources without the PIC of the countries of origin of genetic resources; if the countries of origin cannot be identified, the Parties shall allow access on behalf of the international community;

  b. Recognition and Protection of Traditional Knowledge associated with Genetic Resources [derivatives and products]: The proposals contained in the Annex include the following: the Parties shall consider developing, adapting or recognising national, local or international *sui generis* systems for the protection of traditional knowledge; subject to national laws, the Parties shall recognise and protect traditional knowledge and ensure or promote the fair and equitable sharing of benefits arising out of the utilisation of traditional knowledge associated with genetic resources [derivatives and products]; the Parties or users shall comply with the PIC of the traditional knowledge holders in accordance with article 8 (j) and subject to national legislation.

  c. Fair and Equitable Benefit Sharing: The possibility is left open for the International Regime to establish conditions or obligations for benefit sharing through a financial mechanism, applicable in cases where access agreements lack specific provisions. Should it be impossible to identify the country of origin, this arrangement would provide for monetary benefits to be channelled through a financial mechanism and for non-monetary benefits to be made available to the Party requiring them. The disclosure of origin or source, including evidence of compliance with the provider country's legislation on PIC and benefit-sharing, etc., is required on intellectual property rights applications that use or are composed of genetic resources and traditional knowledge.

- **Certificate of Origin/Source/Legal Provenance.** The International Regime may establish an international certificate of origin/source/legal provenance to be issued by the country of origin or provider country. These certificates can serve as evidence of the existence of PIC and MAT and intellectual property rights application and can be used to comply with disclosure of origin obligations.

- **Implementation, Monitoring and Reporting on the International Regime.** The Parties shall establish legislation to comply with the International Regime, as well as procedures for monitoring and reporting on its implementation.

- **Compliance and Observance.** Several proposals have been made that require each Party to comply with the access legislation of the countries of origin or provider countries. These proposals also include the establishment of procedures by the International Regime to ensure compliance with access conditions, including the PIC of indigenous peoples and local communities, the establishment of cooperative procedures and institutional mechanisms to promote or ensure compliance; mechanisms to prevent misappropriation of genetic resources and traditional knowledge; identification of activities or cases of misappropriation; the creation of mechanisms to facilitate collaboration among the institutions responsible for compliance among user and provider countries, etc.

- **Access to Justice and Reparations.** It has been recommended that measures be established to facilitate or ensure access to justice and reparation through administrative or judicial means.

- **Mechanisms for the Settlement of Disputes arising from the Application of the International Regime.** These may consist of a new dispute settlement mechanism or of the use of the existing CBD mechanism (article 27).

- **Financial Mechanism.** A financial mechanism has been proposed, including for ABS arrangements.

- **Capacity Building [and technology transfer].** The current draft associates capacity building with the implementation of the IR at national, regional and international levels. Also, measures are suggested for an effective technology transfer and cooperation to support the generation of social, economic, and environmental benefits.

- **Institutional Support.** The draft of the International Regime distinguishes between commercial and non-commercial uses (including taxonomic research).

- **Non-Parties**

Without minimising the importance of some of the progress made with the content and structure of the International Regime, it should be noted that some of the elements are basically repetitions or mere explanations or specifications of the current provisions of the CBD; clarifications of which actions countries may undertake on their own, independently from the International Regime. Some of the contents also describe actions whose relevance to achieving CBD objectives and addressing the underlying difficulties and existing motivations for the International Regime is unclear and even questionable.

Other Aspects of Decision VIII/4

Subsection B of the Decision, referring to the Bonn Guidelines, invites the Parties to present reports on their experiences and lessons learned from the implementation of the guidelines. The Parties are also required to submit reports on their experiences gained in the implementation of article 15, including obstacles and lessons learned, four months prior to the WGABS meeting.

Point C mentions other approaches, including consideration of a certificate of origin/source/legal provenance. It establishes an Ad Hoc Technical Expert Group (AHTEG) to explore and elaborate possible options, without prejudging their convenience, form, intent and functioning of such a certificate. This group shall analyse their practicality, feasibility, costs and benefits, with a view to achieving the objectives of articles 15 and 8 (j). The group of experts shall provide technical input to the WGABS 5 and operate in accordance with the following Terms of Reference:

a) Consider the possible rationale, objectives and need for an internationally recognised certificate of source/origin/legal provenance.

b) Define the potential characteristics and features of different options of such an internationally recognised certificate.

c) Analyse the distinctions between the options for the certificate of origin, source and legal provenance and the implications for achieving the objectives of articles 15 and 8 (j).

d) Identify associated implementation challenges, including the practicality, feasibility, costs and benefits of the different options, including the need for mutual supportiveness and compatibility with the Convention and other international agreements.

The Group shall be composed of 25 experts appointed by the Parties (regionally balanced) and 7 observers from, among other sectors, indigenous peoples and local communities, industry, research and academic institutions, botanical gardens, other holders of ex-situ resources, and representatives of relevant organisations and agreements.

The Experts shall be recommended by the Chair for Bureau approval. This Group shall meet at least six months prior to the Fifth Meeting of the WGABS.

Interested parties are also invited to submit to the AHTEG, research and views on the certificate, including certificate models.

Subsection D – Measures to support compliance with prior informed consent of the contracting Party providing genetic resources and mutually agreed terms on which access was granted in contracting Parties with users of such resources under their jurisdiction - reaffirms the fact that disclosure of origin in Intellectual Property Rights (IPR) applications is part of the terms of reference of the Annex to Decision VII/19 D for the development of the International Regime. It recognises that this issue has been discussed in the WIPO and the WTO, and invites the relevant fora to begin (or continue) discussing the topic of disclosure of origin in IPR applications, bearing in mind the need to ensure that their work does not run counter to and is supportive of the objectives of the CBD. The Parties, governments, and other interested parties are urged to continue taking appropriate measures in cases of utilisation of genetic resources and traditional knowledge in order to support compliance with the PIC and MAT on which access was granted in accordance with Article 15 and national legislation. Likewise, the WGABS is requested to consider such measures at its Fifth and Sixth Meetings. The Executive Secretary is required to renew his application for accreditation as an observer before the TRIPs Council.

Finally, subsection E refers to the CBD Strategic Plan and to possible ABS indicators.

III. Recommended Elements to be Included in the Elaboration and Negotiation of the International Regime

Considering the nature and scope of the work and research undertaken to date and the most relevant options, from a practical, political, and technical point of view, for achieving the third objective of the CBD, the following elements are suggested as being of interest for prioritisation within the framework of the International Regime. Based on the criteria stated at the beginning of this document, these are some of the main components that might be established in the framework of the International Regime.

A. User Country Measures to Support Prior Informed Consent (PIC) and the Mutually Agreed Terms (MAT) on which Access was Granted in the Country Providing the Resource

One of the aspects that may have had the greatest influence on the decision to negotiate an International Regime is the lack of measures by user countries, or their inadequacy to support the PIC and MAT of the countries / communities that provide genetic resources or their associated traditional knowledge. Even the Bonn Guidelines, as they were first adopted in draft form at the First WGABS Meeting, contained no reference to user country measures; the paragraph that addresses them (16.d) was subsequently negotiated during the formal adoption of the Guidelines at COP 6 in The Hague.

In this regard, it has been said that: "Any International Regime will require a cooperative effort from the providers and users of genetic resources and traditional knowledge and will require that both take actions to mutually support the common objectives of the CBD relating to fair and equitable benefit sharing".[17]

The existing problems with current ABS systems justify the establishment of user country measures. Some of the aspects presenting the greatest difficulties for the operation of an ABS system have to do with monitoring and compliance with the provider country's legal provisions (on which access was granted), as well as with the observance of those provisions.

The problem with monitoring and compliance is considered to exist at two levels[18]. First, although most ABS systems have established mechanisms for monitoring, inspection and verification, experience has generally shown that governments have limited resources to monitor bioprospecting activities. Secondly, problems arise after the genetic resources have left the country (for example, once they are in the facilities of companies located in other countries). Most laws are based on periodic reporting to evaluate compliance with access conditions, but this instrument has proven insufficient.[19] The idea of a certificate of origin/source/legal provenance is of interest in this context, improving transparency and traceability and providing guarantees that the provider country's legal requirements have been complied with.

17 Barber, Charles, et al., User Measures: Options for Developing Measures in User Countries to Implement the Access and Benefit Sharing Provisions of the Convention on Biological Diversity, UNU/IAS, Japan, 2003.
18 Cfr. Ogolla, Dan, Legislative Regimes on Access and Benefit Sharing: issues in national implementation, document presented to the Expert Meeting on ABS, Cape Town, September 2005.
19 Cfr. Cabrera, A Comparative, op. cit. This is the main mechanism used to verify compliance, but its effectiveness is limited. Other schemes such as the use of identification codes for samples, access to research logs, etc., have been used, for example, by the National Biodiversity Institute in Costa Rica, Cfr. Cabrera Medaglia, Jorge, Access and Benefit Sharing in Costa Rica: Lessons Learned from the Monitoring and Tracking of Genetic Resources in Access Contracts, research document prepared for the Centre for International Sustainable Development Law, Montreal, 2004.

The main problems with observance of ABS regulations are posed by the possibility of non-compliance with the provider countries' legislative provisions or with provisions in access contracts. The ability of the provider countries to enforce their legal requirements will largely depend on mechanisms for access to justice and the existence of administrative or judicial solutions in foreign jurisdictions. Thus, user country measures would be very useful to support compliance with access conditions, considering the transnational nature of most ABS agreements or undertakings.

Regarding the inadequacy of the measures taken by the countries providing genetic resources, it has been observed that a possible cooperative response may be to adopt a set of user country measures that allow regulation of the other "spectrum" of ABS. While provider country measures allow controlling the access stage, user country measures permit controlling use, research and development, patenting of products and processes, etc. That is, it will help to close the gap that exists between the resource acquisition stage (access permits or contracts) and the development stage, also reducing the burden and problems that occur in developing countries as a result of monitoring and compliance procedures in their national ABS regulations.[20]

In general, certificates of origin/source/legal provenance and disclosure of origin in IPR applications have been mentioned as mechanisms to facilitate the enforcement of ABS regulations, but the International Regime may also want to consider other kinds of mechanisms.[21]

For these reasons, a critical issue for the International Regime is the extent to which mechanisms, measures, and instruments are negotiated and developed with an emphasis on monitoring of genetic resources, compliance and observance of ABS agreements.[22] These elements would help to build trust in the development of ABS relations, in that they would resolve – at least to a certain degree – the costs and problems associated with access to justice in foreign countries in cases of non-compliance. Although the draft text of the International Regime includes components on access to justice and collaborative relationships among authorities in cases of non-compliance, it is still necessary to examine in greater depth the best way to develop this aspect in practice, considering the differences between the legal systems and existing international instruments on access to justice.

Another interesting development is the promotion of voluntary measures[23], such as Codes of Conduct, principles, and guidelines that may be of value, at least in a relative sense[24], especially given the previously mentioned problems related to access to justice, monitoring, and observance.

A study carried out by the Institute for Advanced Studies of the United Nations University[25] (IAS-UNU) mentions the following user country measures:

1. Codes of Conduct (and in general, voluntary self-regulatory mechanisms), information and certification.
2. Import and transport regulations.
3. Disclosure of origin in IPR applications.
4. Mechanisms to improve access to justice, especially in the case of non-compliance with the conditions on which access to the genetic resources or traditional knowledge was granted.
5. The certificate of origin/source/legal provenance.

20 Fernandez, Jose Carlos, The Feasibility, Practicality and Cost of a Certificate of Origin System for Genetic Resources: Economic Considerations, Yokohama Round Table: Towards Fair and Equitable Benefit Sharing. Instruments for the Effective Implementation of the Bonn Guidelines under the Convention on Biological Diversity, UNU-IAS and JBA, March 2005.
21 Cfr. Walloe, Morten, Elements for Legislation in User Countries to Meet the Fair and Equitable Benefit Sharing Commitment, in Journal of World Intellectual Property, 2006, Vol. 9 No 2.
22 Ruiz, Manuel, The International Regime, op. cit.
23 The need for guidance and orientation is evidenced by the guidelines and principles, in either final or draft form, developed by biotechnological organizations in the United States, Europe, and Japan (in the latter case, in conjunction with the Japanese Trade Ministry).
24 Their value is relative in that some actors wishing to carry out illegal activities will do so irrespective of codes of conduct that may exist in their specific sectors.
25 Barber et al., op cit.

B. Disclosure of Origin in Intellectual Property Right Applications. The Impact of the International Regime on Intellectual Property Systems.

The Work of the CBD[26].

One of the first measures suggested in order to achieve a synergistic relationship between the CBD and intellectual property systems (in particular, the WTO TRIPs) was the disclosure of the origin of genetic resources or associated traditional knowledge in intellectual property right applications, particularly in patents. For several years the CBD, the WTO, the WIPO, and numerous activities and reports have insisted on the need to promote disclosure of origin in IPR applications.[27]

The Conferences of the Parties to the Convention have also addressed the relationship between IPR and biodiversity. For example, at the Third Conference of the Parties, Decision III-15 (access to genetic resources) requested the Executive Secretary to cooperate with the WTO through its Committee on Trade and Environment in order to explore the extent to which there may be links between Article 15 of the Convention and the TRIPs. Decision III-17 also recognised, among other things, that further research is required in order to understand the relationship between the provisions of the TRIPs and the CBD, particularly those points relating to technology transfer and the conservation and sustainable use of biodiversity, fair and equitable benefit sharing, protection of traditional knowledge, etc. The Fourth Conference of the Parties (1999 Bratislava), in addition to reiterating a number of previous calls from past COPs, emphasised the need to ensure consistency in the implementation of the Convention and the TRIPs, in order to increase mutual supportiveness between both regimes and ensure that biodiversity-related concerns receive IPR protection (IV-15). The Fifth Conference (2000, Kenya), in Decision V-26, requested the WIPO and UPOV to properly take into account the relevant provisions of the Convention in their work, including the impact IPR might have on the conservation and sustainable use of biological diversity and particularly on the value of traditional knowledge. Subsequently, it invited the WTO to bear in mind that the TRIPs and the CBD are mutually related and called for a more in-depth exploration of that mutually supportive relationship. Resolution VI/24/C 1, "The Role of IPR in the Implementation of Benefit-Sharing Agreements", exhorted the governments and Parties to promote disclosure of the origin of genetic resources in intellectual property right applications when the protected material consists of or makes use of genetic resources in its development. The aim of this disclosure is to help track compliance with prior informed consent and the mutually agreed conditions on which access to those resources was granted. Numeral 2 contains the same invitation regarding associated traditional knowledge. At the Seventh Conference of the Parties, Decision VII/ 19 requested the WGABS to identify aspects related to disclosure of the origin of genetic resources and associated traditional knowledge in IPR applications, including aspects related to the certificate of origin/source/legal provenance. It also asked the WIPO and UNCTAD to prepare studies on disclosure of origin in IPR applications, based on a list of topics that need addressing.[28]

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26 Discussions of these issues in the WTO and the WIPO will be analysed in subsection H of this section.

27 Concerning technical and legal aspects of disclosure of origin, readers are referred to the following studies which, in addition to being comprehensive, present some differing conclusions on various aspects: WIPO, Technical Study on Patent Disclosure Requirements Related to Genetic Resources and Traditional Knowledge, Study No 3, 2005; Sarnoff, Joshua and Correa, Carlos, Analysis of Options for Implementing the Disclosure of Origin Requirements in Intellectual Property Applications; UNCTAD, February 2006; Rojas, Martha et al., Disclosure Requirements, op. cit.; Sarnoff, Joshua, Compatibility with Existing International Property Agreements of Requirements for Patent Applications to Disclose the Origins of Genetic Resources and Traditional Knowledge and Evidence of Legal Access and Benefit Sharing, available at www.piipa.org; Ho, Cynthia, Disclosure of Origin and Prior Informed Consent for Applications of Intellectual Property Rights based on Genetic Resources. A Technical Study of Implementation Issues. Final Report, July, 2003; and, Hoare, Alison, Background Paper for the Chatham House Workshop: "Disclosure Requirements in Patent Applications - Options and Perspectives of Users and Providers of Genetic Resources." 9-10th February 2006, Energy, Environment and Development Program, Chatham House.

28 Point H, regarding synergies, describes the content of this request by the COP 7 in greater detail.

As stated, various decisions of the Conferences of the Parties to the CBD have mentioned disclosure of origin, at least since COP 4. The Bonn Guidelines also refer to this topic when they indicate that user country measures should take into account measures to promote disclosure of the origin of genetic resources and the origin of knowledge, innovations, and practices in intellectual property right applications (16.d.ii).

The Main Elements of the Proposal

It is not surprising that the requirement for disclosure of origin / proof of legality of access in intellectual property applications should be the object of intense political and legal debate. Although different legislations contain references to this requirement, they differ in terms of their consequences.[29] Some of the biodiversity or intellectual property laws of several countries contain the obligation to disclose the origin of genetic material utilised in inventions or plant varieties, or even to present proof of the existence of PIC or a certificate of origin that establishes the legality of access to the genetic material or associated traditional knowledge. This stipulation would help to support compliance with the CBD provisions on access to genetic resources and benefit sharing.

In most cases, the European laws that have introduced this requirement refer only to the obligation to disclose the origin or, in the case of Norway, to prove the existence of PIC (only for genetic materials, not for traditional knowledge). However, these laws do not affect the existence of intellectual property rights as such, but rather fall within the penal or civil domains. Likewise, few laws on plant breeder rights, especially in India, consider this situation.

As Correa states, “Although the purpose of this obligation and its rationale seem clear enough, and there is substantial – though not unanimous - support for it to be established, the conditions and circumstances of this obligation and how it will be applied need to be more precisely defined..." The scope and conditions of application of the obligation should be consistent with its purpose, and care should be taken not to impose a disproportionate burden on the applicants and the institutions in charge of their applications”.[30]

From a technical point of view, progress needs to be made in defining a series of elements that will determine the way disclosure would work, particularly if this instrument is to become a practical tool.[31] These elements include:

- What information should be disseminated? Would genetic or biological resources (or both) and their associated traditional knowledge be the object of disclosure?

- The meaning of origin. Whether this refers to the country of origin of the resource or to its source, i.e., the country from which the resource was received; to the country that contributes or provides the resource; to its geographic origin; or to a combination of different options, for example, the disclosure of the source together with, if known, the country of origin of the resource.

29 For example, Brazil, the Andean Community, Costa Rica, India and Egypt, among others. Cfr. Hoare, op cit.
30 Correa, Carlos, Alcances jurídicos de las exigencias de divulgación del origen en el sistema de patentes y derechos de obtentor, Research Documents, Initiative to Prevent Biopiracy, Year 1, No 2, August 2005.
31 Correa, op cit.

- What kind of information or documentation should be submitted? Whether the mere disclosure of information would be sufficient to comply with the requirement, or the application should be accompanied by a declaration from the applicant, or by some form of documented evidence to prove compliance with access laws, such as a copy of the access contract or other authorisation document.

- How should the information be presented? Should standardised terminology and certain specific content, etc. be established?

- How should the relationship between biological / genetic resources and associated traditional knowledge and the invention be determined? For example, if they form part of the material for which intellectual property rights are requested; if they have been used in the process of developing the invention; if they have been used to facilitate the development of the material to be protected; if they constitute the necessary antecedent for that material, etc.

- When should access to resources or knowledge be considered to have been duly authorised?

- When will the information be examined and by whom?

- What should the consequences be for non-compliance, including civil or penal liabilities? The application of provisions on unfair competition; administrative sanctions; suspension of the processing of the application; revocation or annulment of rights when the information submitted is insufficient or false; the requirement that patent rights be transferred either partially or completely if they were granted for the purpose of ensuring fair benefit sharing; the requirement that any benefits received be repaid, etc.?

Other aspects that should be taken into account when considering the inclusion of disclosure in the International Regime:[32]

a- The instrument has a limited impact on the prevention of misappropriation or biopiracy, and should therefore be accompanied by other complementary mechanisms. For example, in a number of documented cases of misappropriation through patents, the geographical origin of the resource was mentioned. In order to improve the quality of the granting of patents and other intellectual property rights, complementary mechanisms are required, such as improvements in search systems in order to determine if the inventions are novel. The WIPO Intergovernmental Committee on Genetic Resources and Intellectual Property, Traditional Knowledge and Folklore has explored these complementary mechanisms.

b- Consideration should also be given to whether the countries have the ability to effectively monitor patent applications and patents granted in order to determine if there has been misappropriation of materials. Even if misappropriation is detected, it is doubtful that the countries have the economic and financial capacity to invalidate patents in foreign jurisdictions, considering the long and costly process involved. This situation point once again to the need to study other user country measures, for example, those that facilitate access to justice, as required to achieve the objectives of the CBD.

32 Cfr. Correa, op cit.

c- One way to prevent misappropriation is to improve access to information existing in the public domain, and make it available to the technical staff in charge of reviewing patents to aid them in determining if they are novel and if prior art exists. This is one of the aspects the WIPO has been working on through the Intergovernmental Committee, as will be indicated further on.

d- Finally, although these provisions have been included in some countries' patent laws or in their biodiversity or related laws, it is also advisable, strictly at a national level, for the countries to begin introducing a new statutory obligation into their access or related laws: namely, the requirement for an access applicant to disclose the origin or source of the resource at the time access is granted if the access applicant presents a patent application. Although it is not possible to categorically state whether or how the patent offices will take these legal or contractual provisions into account, or whether they will take action against an applicant that does not comply with them, this measure merits consideration. Incorporating this provision will require that actions be taken at a national level, which should not wait for the conclusion of international negotiations on the Regime or the WTO discussions.

Disclosure of origin is one of the elements that should be included in the International Regime, and consideration should be given to the efforts and progress made on the subject to date, particularly in the WTO, the WIPO and within the CBD itself. Disclosure of origin would make it possible, among other things, to prevent misappropriation of genetic resources and associated traditional knowledge. Thus, it would not only be a transparency measure for the granting of IPR, but also a defensive measure aimed at protecting traditional knowledge against misappropriation or irregular appropriation.

Chart 1: Disclosure of Origin in Intellectual Property Rights.

Although the idea of disclosure of origin / evidence of prior informed consent / evidence of benefit-sharing has mainly been discussed within the context of patent systems, it is applicable - taking technical differences into account - to plant variety systems and to approval processes in general.

The objectives of the proposal are:[33]

1. Transparency: To allow national authorities that grant access to genetic resources to track the use of these resources in patent applications and deeds.

2. Compliance with access conditions: To make it possible to track compliance with prior informed consent and the mutually agreed conditions on which access was granted.

3. Determination of prior art: The disclosure would allow Patent Offices to better analyse novelty and the level of inventiveness.

4. Relationship between the TRIPs Agreement and the CBD: Disclosure of origin would help prevent conflicts between the TRIPs Agreement and the CBD and would support their mutual implementation.

33 Girsberger, Martin, Transparency Measures under Patent Law Regarding Genetic Resources and Traditional Knowledge, The Journal of World Intellectual Property, July 2004, Vol. 7, No 4, Geneva.

5. Biopiracy: Disclosure would stop biopiracy or misappropriation of genetic resources or traditional knowledge as a result of the granting of “bad patents”.

Concerning plant varieties, the UPOV Convention (1991) specifically establishes that the requirements to grant or cancel a plant breeder right shall not differ from those stipulated by the UPOV. It expressly states that plant breeder rights shall not be subject to further conditions (article 5), provided that national formalities have been complied with and the required fees have been paid. It also stipulates that the rights shall not be cancelled or annulled for reasons other than those indicated in articles 21 and 22. It should be noted that the UPOV has mentioned that it is not opposed to disclosure that facilitates the examination of the material, but that it will not consider such disclosure a requirement or an additional condition for protection.

It is therefore important, first, to emphasise that article 5 expressly stipulates that plant breeder rights shall be subject to each country's formalities. Consequently, it is legally possible to establish disclosure of origin as a formal but non-substantive requirement. If this requirement is not met, the application will not be processed. Secondly, the case of false disclosures of origin should be considered. In countries where the disclosure requirement has been applied, two possible solutions have been adopted: the annulment or cancellation of the patent (India, Brazil, the Andean Community, etc.) or penal, administrative or civil sanctions outside patent law (European countries such as Norway, Denmark, Belgium, and Sweden, and the European Union in general). Thirdly, it is important to consider the details concerning the origin of plant varieties and the extent to which disclosure of origin would safeguard the legality of access to the material, whether its origin is national or foreign – the latter being more likely in the case of imported materials.

On this matter, the Report of the **Commission on Intellectual Property Rights** stated that “countries should enact laws requiring the mandatory disclosure in patent applications of the geographical origin of the genetic resources from which the invention is derived."

In the case of plant varieties, there may be technical and practical obstacles to this provision unless it is carefully structured.

A variety of objections have been raised regarding the applicability of disclosure to plant varieties, such as: problems that occur when plant varieties originate from different countries and from crosses and back-crosses; obstacles to determining the origin of the germplasm of a variety, which can originate from a combination of genes from different countries; the impracticality of stipulating benefits because the origins of plant varieties can be traced to different countries and communities, etc., as opposed to pharmaceutical products that can be derived or moulded from a single natural component.

Chart 2: Position of the UPOV Council on Access to Genetic Resources and Benefit Sharing Related to Plant Breeders Rights (Adopted by the UPOV Council in its 37th Session, on 23rd October 2003).

Access to genetic resources: Access to genetic resources is a key element to enable progress to be made in the area of plant breeding. The plant breeder exemption reflects the position that the global community of plant breeders requires access to all kinds of materials to make the best possible progress in the area of plant breeding and thus maximise the use of genetic resources for the benefit of society.

Disclosure of Origin: Plant breeders must usually provide information on the genetic origin of the variety on the technical questionnaire accompanying the application for protection. When UPOV examines the variety, it encourages the provision of information on the origin of the genetic material used in creating it, but it does not accept disclosure of origin as an additional condition for protection. The Convention requires protection for varieties that are novel, homogeneous, stable and distinct and designated by a denomination, and does not admit additional requirements. In some cases, it can be impractical or difficult to identify the exact origin of the genetic material used. Disclosure of origin should not be introduced as a condition for the protection of varieties, although it may be included in separate laws.

Prior Informed Consent: UPOV promotes the principle of transparency and ethical behaviour regarding the legality of access to genetic resources, including proof of prior informed consent. Consequently, access to genetic material must be carried out in accordance with the legal framework of the country of origin. However, the Convention requires that plant breeder rights not be subject to any additional condition other than those required for protection (article 5 of the UPOV, 1991). In addition, it considers that the competent authorities are not in the best position to verify if access to the genetic resource has taken place in accordance with the applicable legislation of the country of origin of the resource.

Benefit Sharing: UPOV would be concerned if mechanisms were established to ensure the sharing of benefits arising out of access to the plant genetic resources used in a new variety. This obligation would even be incompatible with the plant breeder exemption, which does not require acts of improvement carried out on other varieties to be subject to restrictions. Also, in such cases, the holders of the initial varieties are not entitled to any compensation, except in the case of varieties that are essentially derived. This requirement might lead plant breeders to stop trying to protect or develop their varieties.

Subsistence Farmers: The UPOV contains an exemption that allows for non-commercial and private actions to be carried out, since they are excluded from the scope of breeder rights.

Re-use of Seeds: The re-use of seeds is an optional mechanism for benefit sharing stipulated by the Convention. However, this provision is subject to reasonable limits and requires the safeguarding of the breeder's legitimate interests. For example, some countries only apply the exemption to certain species or limit its application according to the size of the property or production level.

Access and PBR: The laws on access to genetic resources and plant breeder rights have different objectives and scopes of application, and require different structures to administer and monitor them. Therefore, it is considered appropriate to include them in different legislation, although the regulations must be compatible and mutually supportive.

Disclosure of Origin and Free-Trade Agreements (FTAs)[34]

We should also mention the potential implications of the FTAs that numerous countries have signed and ratified with the United States and the European Union and their corresponding provisions on IPR. For example, the Free-Trade Agreement between Central America, the Dominican Republic and the United States (CAFTA) has established a restriction related to disclosure of origin. The language used in the CAFTA is taken directly from the legislation of the United States in stating that "Each party shall provide that a disclosure of a claimed invention shall be considered to be sufficiently clear and complete if it provides information that allows the invention to be made and used by a person skilled in the art, without undue experimentation, as of the filing" (article 15.9.9). Doubts have been raised about whether this text implies a restriction on additional information being requested when the patent is disclosed. The need to state the best way to make the invention is not mentioned, as required by numerous national laws.

C. Certificate of Origin/Source/ Legal Provenance.[35]

One element that would make it possible to respond to the call for user country measures and also contribute to solving problems related to the monitoring and traceability of genetic resources is what is known as the certificate of origin/source/legal provenance. In addition, it should be recognised that this is one of the main proposals put forward by developing countries, such as the Group of Like-Minded Megadiverse Countries. It appears to have some degree of support, at least regarding an analysis of this proposal to determine whether it should be included in the International Regime and, if so, how this should be accomplished. The study of the different modalities of this instrument appears to have generated some consensus regarding the need to analyse its cost, feasibility, practicality and implementation challenges, as well as the differences between possible certificates of origin, source, or legal provenance.

Although it is difficult to accurately describe the initiative while there continue to be differing views on the different design options for the certificate and its features and utility for the purposes of the International Regime,[36] in general it can be defined as a document that accompanies the different transfers of genetic resources, or some of them. This certificate makes it possible to learn (during selected verification stages) about their subsequent use, and thus to facilitate monitoring of compliance with the original access and benefit sharing conditions.

The idea of the certificate is to prevent or minimise problems generated by the existence of two different jurisdictions for ABS arrangements – that of the place where the material is collected and that of the place where research and development activities are carried out. The existence of an internationally recognised document would make it possible to check the legality of access at the place where the activity (patent, product approval, etc.) generates value, and to discover the subsequent use of the resources and the origin of the corresponding benefit sharing. At the same time, this supposedly[37] would favour the creation of simpler access systems in provider countries, in that existing control mechanisms would be applied, via the certificate, in the later stages of

34 However, there is no single interpretation regarding the consequences of this language for the possibilities of requiring disclosure of origin. Also, according to some analysts, the situation in the Andean region is different and the obligations related to disclosure and proof of the legality of access included in the Andean Decisions prevail over the FTA, for example, regarding the agreement negotiated between Peru and the United States, see Ruiz, Manuel, The Protection of Knowledge, op. cit. Since different interpretations are possible, there is no reason why these countries should not include disclosure in their patent laws.35 It is not our intent to develop the idea of the certificate in depth. For further detail, see the following documents: Dross, Miriam and Wolff, Franziska, New Elements of the International Regime on Access and Benefit Sharing of Genetic Resources: the Role of Certificates of Origin, BFN. Bonn, 2005; Fernandez, Jose Carlos, The Feasibility, Practicality and Cost of a Certificate of Origin System for Genetic Resources: Economic Considerations; in Yokohama Round Table: Toward Fair and Equitable Benefit Sharing: Instruments for the Effective Implementation of the Bonn Guidelines under the Convention On Biological Diversity; Yokohama, Japan, 11 March 2005; Tobin, Brendan, Cunningham, David and Watanabe, Kazuo: the Feasibility, Practicality and Cost of a Certificate of Origin System for Genetic Resources, working paper submitted to the Secretariat of the Convention on Biological Diversity, February, 2005.
36 It is precisely these proposals that should be considered by the Group of Experts created by Decision VIII/4 of the recent COP held in Brazil.
37 An analysis of the causes behind processes to reform the implementation of ABS laws can be found in Gatforth, Kathryn and Cabrera Medaglia, Jorge, Factors Contributing to Legal Reform for the Development and Implementation of Measures on Access to Genetic Resources and Benefit-Sharing, publication pending.

research and development, thus helping to make the regulations on access to genetic resources more flexible. In this way, monitoring and regulation would be less strict during the access stage and stricter during the research and development stages, where control or verification stages would be established. This implies that the documentation would need to pass through the various buyers, but the monitoring stages would be reserved only for certain milestones in the research and development process, such as those related to product approval, IPR applications, publications, the presentation of funding proposals, etc.

Many aspects still need to be clarified before this system can become operational, including:[38]

1. The designation of national authorities to issue certificates that are mutually recognised.
2. The identification of conditions for verification and compliance of certificates, that is, the determination of which materials they would apply to, for what purposes, and at what moment or stage they would be verified.
3. Exemptions.
4. Provisions for cases in which it is not possible to identify the origin of the genetic resources, including benefit sharing.
5. Differential treatment of different sectors.
6. Dispute settlement mechanisms
7. The creation of an international certificate register.
8. How countries that are not parties to the International Regime will be handled.
9. Provisions related to the resources contained in *ex-situ* collections prior to the Convention.

Other aspects of interest could include:

1. What the certificate corresponds to: species, genes, specific biological samples, etc.
2. Transaction costs of the certificate.
3. Different types of certificates: origin, legal provenance, source.
4. Characteristics of the system: simplicity, flexibility, and avoidance of complex procedures.
5. Considerations regarding the product supply chain, etc.
6. Ability to comply with the objectives of the CBD, especially conservation.
7. Economic impacts and implications of the certificate for different actors (botanical gardens, etc.)
8. Content of the certificate.
9. Sanctions for non-compliance.
10. Lack of legislation on access.
11. Procedures for control and use of the ClearingHouse.
12. How to ensure that additional barrier is not created for the non-commercial exchange of resources.
13. Compatibility with international trade regimes,[39] etc.

38 Cfr. Fernández, José Carlos, Elements for the Design of a Certificate of Legal Provenance, document presented at the Expert Meeting on Access to Genetic Resources, Cuernavaca, Mexico, October, 2004.
39 On this last aspect, cfr. Louafi Salim, Morin, Jean Frederic, Certificates of Origen for Genetic Resources and International Trade Law, IDRRI, 2004, first draft.

Following are some of the advantages of using this instrument:[40]

a. It will serve as evidence of the legality of access to genetic resources in accordance with the provider country's requirements.
b. User country measures can be applied, thus reducing implementation costs.
c. The existence of verification and control points will discourage misappropriation.
d. Information exchange mechanisms will facilitate monitoring by providers and third parties.
e. It will bring about greater transparency and trust in transactions.

Nevertheless, some intrinsic limitations to the certificate should be pointed out, including:[41]

a. It does not ensure compliance with mutually agreed terms.
b. It does not solve problems related to the different capacities for negotiation among actors in ABS relations.
c. By itself, it does not ensure fair and equitable benefit sharing.
d. It does not lessen the need to develop national legislation.
e. In order for the certificate to become an effective instrument, the problems related to ex-situ collections prior to the Convention must be solved.
f. It offers a solution for those who are able to negotiate, and excludes those who are unable to negotiate contracts.
g. It is not equally adaptable to the needs of all sectors.

Although due to the lack of detail regarding its structure and operation, the implementation of the certificate of origin is uncertain - like the rest of the elements of the IR- this is at least one topic that could be central to the International Regime and which, by the end of the negotiations, may become one of the mechanisms to be used.

D. Derivatives.

Since the negotiations surrounding the Bonn Guidelines, and particularly in COP 6 in The Hague, one of the most controversial topics has been that of derivatives and products and their relationship to access (PIC) and MAT. This discussion was at least temporarily resolved by including derivatives and products in the context of benefit sharing. Thus, paragraph 44 of the Bonn Guidelines presents a list indicating the mutually agreed conditions included under point i: "provisions regarding the sharing of benefits arising from the commercial and other utilisation of genetic resources and their derivatives and products". Likewise, with regard to the procedures for obtaining prior informed consent, the Guidelines indicate in paragraph 36 (l) (in mentioning the information to be presented) the "kinds/types of benefits that could result from obtaining access to the resource, including benefits from derivatives and products arising from the commercial or other utilisation of the genetic resource."

For reasons that will later be explained, another element the International Regime should consider is to clarify the scope of the topic of derivatives.

In the discussions and negotiations, both within the ABS Working Group and in the Seventh and Eighth Conferences of the Parties, there have been recurring disagreements regarding the inclusion or not of derivatives and products.[42] This discussion promises to be one of the most difficult due to the strong interest developing countries have shown in including derivatives and products in the International Regime[43].

40 Fernandez, Jose Carlos, Elements, op cit.
41 Fernandez, Jose Carlos, Elements, op cit.
42 One need only observe the final Granada document (now Annex to Decision VIII/4 from the recently concluded COP 8), for example, to note how the references to derivatives and products are bracketed in the paragraphs where they are mentioned.
43 From the commercial point of view, it must be accepted that derivatives or biochemicals – if they are accepted as equivalent – are very valuable for the pharmaceutical industry, cfr. Battig in this respect, cited by Wolff, New Elements....op cit.

In order to fully understand the issue, it is necessary to explain a few premises that may in some way contribute to advancing international negotiations on this subject:

1. Genetic resources are defined by the CDB as genetic material of real or potential interest (art.2). However, a number of national laws contain much broader definitions, not necessarily more precise in scope, applying access procedures equally to derivatives.[44] Another approach taken by some national regulations has been to extend the coverage of their access regimes by considering biochemicals in this category.[45] Also, if it is accepted that the object of ABS regulations is "genetic information" more than the material in a physical sense, derivatives may be considered to be included in the CDB definition, although not expressly.

2. Based on the previous premise, one might wonder if it is necessary to regulate access to derivatives per se or if, to the contrary, it is more appropriate to establish regulations on access to the genetic resources from which they are derived. If this option eases the concerns of developing countries, it is undoubtedly preferable as long as it allows the derivatives to be subject to PIC and mutually agreed terms, including those related to benefit sharing (through access to genetic resources). Benefits arising from the genetic resources can be identified and monitored through mechanisms that should be incorporated in the International Regime, such as the certificate of origin/source/legal provenance, the disclosure of origin in IPR applications, and contractual arrangements on which access is based, as well as their monitoring clauses.[46]

3. It is equally important to recognise that there are differences in terminology, possibly resulting from problems of political will or disagreements, as well as regarding the practical consequences of including derivatives. Gloyka already indicated these differences in 1998 in mentioning that "There are two contexts in which the term derivative applies. In the first, derivatives may be described as non-modified chemical components other than DNA or RNA, but formed by the organisms' metabolic processes. As in the case of DNA or RNA, these components exist in samples of biological materials obtained under ex-situ or in-situ conditions. Derivatives in this context, for example, may constitute active biological components found in the collected plant material, but that have yet to be modified and used in technological applications. In the second context, derivatives can consist of chemical components that are modified and created or synthesised from materials originally obtained from in-situ or ex-situ sources. The resulting end products may be a hybrid seed, a traditional medicine or the synthetic version of a biochemical extract. Thus, they are products that are derived or synthesised from genetic or biochemical resources through human intervention. Access legislation may be extended to derivatives in the first context. However, it would be very difficult to extend it in the second context in that this would be a matter of regulating access to technologies ".[47]

44 Cfr. Cabrera Medaglia, A comparative, op cit.,
45 Cfr. for example, the Law of Biodiversity of Costa Rica, cfr. principally articles 4, 6 y 7.
46 Cfr. in a similar sense, Walloe, Morten, op cit.
47 Gloyka, A Guide to Designing Legal Frameworks to Determine Access to Genetic Resources, IUCN, Environmental Law Centre, Environmental Policy and Law Paper, No. 34, Gland, Cambridge and Bonn, 1998. Likewise, according to Burton, Geoff, the problem of derivatives is due to there being two interpretations or uses of the term derivatives. On the one hand, there are those who refer to derivatives as products or innovations that originating from biological materials; their underlying concern is to control the commercialisation or utilisation of genetic resources in order to obtain a share of the benefits. Conversely, others address the topic from the perspective of the inadequacy of the CBD definition of genetic resources in not including the organisms' components, the interaction of genes and the biochemical compounds they express, cfr. Burton, Geoff, Discussion Paper, Derivatives. Document presented at the International Expert Workshop on Access to Genetic Resources and Benefit Sharing, Cuernavaca, Mexico, October 2004. other

Casas coincides with this view when he states that "The international regime should not only cover genetic resources, but also their derivatives, understood as natural molecules that do not contain genetic information, but have resulted from a genetic resource. That is to say, they are compounds, extracts or secretions that occur as a natural expression of the genetic material and are the result of a metabolic process."[48]

4. Another possibility, although due to the direction the international regime discussions are taking, this seems less likely, is to combine regulation on access to genetic resources in the provider countries with regulation related to the "utilisation of genetic resources" in the user countries. In this way, if the user countries' laws define specific uses that are considered use of genetic resources or of the genetic information covered by the CDB, this would make it possible both to conduct monitoring and eventually to demand the respective benefits arising out of their utilisation, potentially involving derivatives of genetic resources. The countries of origin or focal points would be notified of this use by the user countries where the use is verified.

E. The conceptualisation of genetic resources: toward a better understanding of their national and international repercussions. Mechanisms based on utilisation.

Little attention has been paid to the need to precisely define a number of terms, whose inclusion in the International Regime[49] would improve the effective application of national ABS systems.

There are two concepts, which the International Regime could help to clarify in order to create consistent and functional legal frameworks[50]. There have been important incidences of legal difficulties arising due to a lack of understanding regarding the difference between biological resources and genetic resources.[51]

Related to this point, and in general to the definition of genetic resources, the different laws and practices of administrative authorities may be summarised as follows:

1. Countries that essentially have repeated the CBD definition of genetic resources without any additional modification, but at the same time have conceptualised "access to genetic resources" in a way that makes the rather vague original definition, more precise.

2. Countries that have introduced some variations, such as biochemical resources, derivatives, etc.

3. Countries whose national laws include the broadest reference to biological resources, together with definitions of access. However, at least in theory, this position could mean including the usual biological resource transactions in the scope of application of access regulations, which would create significant operational difficulties for the functioning of any regulation.

48 Casas, Fernando, Derechos de propiedad sobre los recursos genéticos. El asunto de los derivados. Derechos de propiedad tangible e intangible. Notas preliminares. Document presented at the International Expert Workshop on Access to Genetic Resources and Benefit Sharing, Cuernavaca, Mexico, October 2004.

49 Decision VII/19 had already mentioned the need to continue working on certain definitions. However, from the point of view of the IR, more than being a matter of simple conceptual clarifications, this has to do with essential aspects that are needed to give the ABS systems legal consistency and functionality.

50 The lawyer Tomme Young has been insisting for some time on the need to rethink certain basic premises of the ABS legal systems in order to make them consistent and functional, including clarifying the scope of the "utilisation" and of the terms "genetic resource" and "biological resource", among others.

51 Cfr., for example, the difficulties in analysing cases of misappropriation or biopiracy of genetic resources and traditional knowledge, given the lack of clarity about which activities constitute access to genetic resources (and which would consequently be required to follow the respective rules) and which, on the other hand, constitute the use of biological resources. Cfr. Young, Tomme, An Analysis of Claims of Unauthorised Access and Misappropriation of Genetic Resources and Associated Traditional Knowledge, report prepared for IUCN-Canada and distributed at the Fourth Meeting of the ABS Working Group, Granada, document UNEP/CBD/WG-ABS/4/INF/6. Likewise, a report on 36 cases of biopiracy in Africa, recently distributed during the Meeting of the Working Group in Granada, presents some examples in which there are at least well-founded doubts about whether a genetic or biological resource was involved, cfr. Edmond Institute and the African Centre for Biosafety, Out of Africa: mysteries of access and benefit sharing, available at www.edmonds-institute.org .

4. Countries that exclude certain activities that are not considered access to genetic resources, such as conventional uses of plants, etc., from access laws.

In general, however, there continues to be confusion regarding which activities involve access, and this generates ambiguity regarding the scope of the regulations and what constitute legal and illegal activities. The boundary between activities involving access to genetic resources and those that, to the contrary, make use of biological resources is not always clear.[52] In effect, it has been noted that the CBD definitions of biological and genetic resources are, strictly speaking, functionally identical so it is not possible to clearly distinguish between the two.[53]

According to a recent research study,[54] in most cases the differentiating criterion between access to genetic resources and biological ones is the "intended use", that is, the declared purpose for which the applicant indicates that he desires access to a sample of a material. If this purpose were the search for new compounds for the creation of medicines or similar uses, the activity would involve access to genetic resources. If the purpose were to collect specimens only for taxonomic identification, this activity would not be considered access.[55]

As a possible solution, it has been suggested that the term "actual or potential value" associated with genetic resources should be understood in the context of the CBD. In this way, the obligation of benefit sharing has its origin in "the benefits arising out of the utilisation of genetic resources" and "the results of research and development and the benefits arising out of the commercial or other use of genetic resources" (art. 15.7). From this perspective, the term 'genetic resource' should be understood to be all activities that result in capturing the real or potential value of genetic resources. Thus, it is suggested that instead of focusing on the intention of the party requiring access, the concept of genetic resources should be linked to specific uses. This would also lay the groundwork for user countries to issue measures in their territories, based on certain categories of utilisation.[56]

Other proposals have been developed[57] that present different options countries can consider in establishing limits between the two concepts. These include:

1. Determining the difference between biological and genetic resources, not to mention the intrinsic difficulties involved in controlling conventional uses of biological resources within the framework of ABS systems.

2. Genetic resources are more specialised than biological resources; for example, a genetic resource might be a particular type of material taken in a specific way, such as prepared dry materials.

3. The distinction lies in the intended use on the part of the applicant at the time of access, for example, whether access to the materials is sought for conventional purposes or with the intention of utilising them for their genetic or biochemical characteristics.

52 Cfr. Dross and Wolff, New Elements, op cit.
53 Cfr. Young, Tomme, Genetic Resources and Utilisation of Genetic Resources: a legislative view, document presented at the International Expert Workshop on Access to Genetic Resources and Benefit Sharing, Cuernavaca, Mexico, October 2004.
54 Cfr. Cabrera Medaglia, A Comparative, op cit.
55 For some, this is the most appropriate solution, cfr. Dross and Wolff, New Elements, op cit. Others believe that this would involve considerable legal difficulties in determining the legality of access. The difficulties mentioned include problems in objectively determining the applicant's intention; the possibility of his later being granted a different use of the collected materials by a third party – and possibly some time after the original collection was made, etc. Cfr. Walloe, Morten, op cit and Young Tomme, Genetic Resources, op cit.
56 Cfr. Morten, op cit., who calls this the ¨catalog approach".
57 Young, Tomme, An Implementation Perspective on International Law of Genetic Resources: Incentive, Consistency and Effective Operation, Yearbook of International Environmental Law, Oxford Press, Volume 15, 2004.

4. The term ‘genetic resource’ refers to genetic information, independent of physical access to it.

5. Genetic resources should be understood as the “right to use genetic information”.[58]

No solution is simple or free of problems. Considering the international and transboundary nature of ABS relations and the need for consistency and legal certainty[59], the International Regime should at least provide the countries with some guidance on this matter.

Attention should also be drawn to the need to reformulate benefit sharing options based on the idea of the use or utilisation of the genetic resources and traditional knowledge, which may not necessarily be based on access to genetic resources[60]. Both the CBD (article 1) and the Johannesburg Plan of Action refer to the need to share the benefits arising out of their utilisation. This may lead to the consideration of other ways of obtaining this sharing, through multilateral means, such as Funds or even taxes or fees[61].

F. Knowledge, innovations and traditional practices associated with genetic resources:[62]

Although the Johannesburg Plan of Action does not mention forms of traditional knowledge, they were included in Decision VII/19/D. For ethical reasons and in view of the negotiations, this should be another aspect considered in the elaboration and negotiation of the International Regime. The question, therefore, is not whether they should be incorporated in the IR, but rather what exactly should be included, and what part of the substantive work should concern the WGABS, given its main focus on access to genetic resources and benefit sharing.

The relationship between the WGABS and traditional knowledge should be realistically defined from this perspective. Both, protection of traditional knowledge issues (broadly speaking) and in general issues addressed by the Working Group on Article 8(j) and Related Provisions address more comprehensive – and undoubtedly more complex – aspects than those who only address access and benefit sharing issues.

This Working Group has analysed a wide variety of issues that are relatively disconnected from the work of the WGABS, including Evaluation of the Environmental Impact on Sacred Sites, among others. In this sense, the following elements relating to traditional knowledge are suggested for consideration within the context of the IR, together with observations on how this might be accomplished[63].

58 This definition makes it possible, at least theoretically, to deal with the issue of access to information that is available electronically, such as that deposited in data bases. The same information generated by Genomic and Proteonomic projects, for example, may gradually substitute physical access to samples, conceived as part of the normal or traditional collection process of ABS projects. Curiously, the IR negotiators have not paid much attention to the impact of these technologies and the means of generating information on ABS proposals and systems, perhaps due to their technical complexity and the lack of analysis of their legal implications. Cfr. on the topic, Oldam, Paul, Global Status and Trends in Intellectual Property Claims. Genomics, Proteonomics and Biotechnology, CESAGEN, United Kingdom, 2005.

59 Cfr. Young Tomme, Genetic Resources... op cit.

60 The Annex to Decision VIII/4 contains some references to the use of the financial mechanism in cases in which the countries of origin of the genetic resources and derivatives cannot be identified.

61 It should be noted that the approach involving multilateral benefits through royalties from commercial uses and their channelling into a Fund or Trust Fund, is essentially, simply stated, the approach of the International FAO Treaty. Although the possibility of using fees or taxes has been mentioned, this has not been proposed in the negotiations, and therefore the details of how it would work have not been explained.

62 This document does not pretend to make even a superficial analysis of the issue of the protection of TK. It will only mention which elements should be considered within the context of the IR negotiations and how this might be accomplished.

63 Based on a holistic conception of TK and on the need to develop an integral protection system, it is evident that other actions are necessary or convenient, such as the use of existing mechanisms or tools, including those related to IPR. Cfr. Ruiz Manuel, La protección... op cit.

- Establishment of *sui generis* systems[64] for protection of traditional knowledge. The Working Group on Article 8(j) and Related Provisions has developed guidelines for the establishment of *sui generis* protection systems[65]. The WIPO, through its Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, has also proposed policy objectives and basic principles for the protection of traditional knowledge that may guide the countries in establishing these kinds of systems.[66] However, it is suggested that the WGABS should be limited to mentioning this kind of protection as part of the IR negotiations, while the substantive development of this integral part of the IR would be left to the Working Group on Article 8(j) and Related Provisions and to the WIPO[67].

- There is an important trend towards considering the role of customary law[68] in the protection of traditional knowledge. This is an aspect that had been little developed until now, especially in the Roman Germanic law systems, but that is beginning to draw growing attention.[69] For example, activities have been carried out in Latin America, sponsored by IUCN[70], among others, aimed at clarifying the role of customary law in the protection of traditional knowledge.

- A key aspect regarding ABS and traditional knowledge refers to the prior informed consent of indigenous peoples and local communities. This should be addressed from two perspectives: first, it should be guaranteed that PIC will be required from the interested parties, as established by the CBD and stipulated in article 8 (j); and secondly, ways should be considered to establish expedited procedures for obtaining PIC so that the rights of indigenous and local communities are protected at the same time as legal certainty is provided to the interested parties. Thus, the International Regime could contribute to establishing certain basic premises about PIC, the substantive development of which would be left in the hands of the Working Group on Article 8(j) and Related Provisions. In this sense, the measures the International Regime could develop to support the PIC and MAT of the provider countries and indigenous peoples and local communities constitute another element for the protection of traditional knowledge that the IR should consider. Specifically, the Regime could consider the acquisition of traditional knowledge without having obtained PIC an act of misappropriation in strict compliance with customary law (and establish the resulting access to justice measures). Likewise, disclosure of origin, which the WTO could be responsible to negotiate, as will later be explained, would contribute to the defensive protection of traditional knowledge.

- Finally, it should be noted that although COP 7 mandate clearly mentions the need for collaboration between the WGABS and the Working Group on Article 8(j) and Related Provisions, contact between them has been limited to holding a follow-up meeting (the meeting in Granada between the WGABS and the Working Group on Article 8(j)) and to the usual information exchange and presentation of reports[71].

64 Cfr. on this point, Ruiz Manuel, La protección, op cit and Dutfield, Graham, Protecting Traditional Knowledge. Pathways for the Future, ICTSD-UNCTAD, April 2006. Geneva.
65 Decision VII/16 of the COP 7, section H, presents a number of potential elements for consideration in the development of *sui generis* systems.
66 This point will be addressed later in section H on synergies.
67 The possibility of international instruments being developed by the WIPO may also be considered. However, so far, despite the reference to the international dimension of the WIPO Committee's mandate, it has mainly concentrated on providing guidance for application at national and regional levels. Regarding how to incorporate the international dimension, cfr. the WIPO document, Practical Means of Giving Effect to the International Dimension of the Committee's work, WIPO/GRTKF/IC/9/6 January 2006, distributed at the Ninth Meeting of the Committee, April 2006.
68 On the role of customary law in the protection of traditional knowledge, see De la Cruz, Rodrigo, op cit.
69 The United Nations University – IAS and the WIPO are also carrying out joint research on customary law.
70 Workshop on the Role of Customary Law in the Regulation of Access to Genetic Resources, Distribution of Benefits and Protection of Traditional Knowledge, held in Quito, Ecuador, January 09 - 10, 2006.
71 The related Decision VIII/5 C refers to the IR and the collaboration of the Working Group on Article 8(j) and the participation of local communities and indigenous peoples. The collaboration and contribution of the Working Group on 8(j) was requested to fulfil the mandate of the Working Group on ABS by providing views on the elaboration of the IR for ABS relevant to associated traditional knowledge. The Executive Secretary will need to compile these points of view and deliver them to the WGABS. Secondly, and most importantly, the Decision basically refers to mechanisms to facilitate or improve the participation of indigenous peoples in the WG meetings, preparatory meetings and in the Parties' delegations; and it urges the Presidents, as appropriate, to facilitate their effective participation and consultation on issues related to TK; all according to the rules of procedure of the Convention.

G. National ABS provisions: strengthening effective implementation.

The different studies carried out on the implementation of national ABS regulations[72] confirm the difficulties involved in adequately complying with the current legislation of the provider countries. In practice, the level of enforcement of these laws is relatively low[73]. There are many possible causes for this: limited negotiating capacities to deal with applications, particularly those involving transnational companies; opposition from sectors of civil society that consider the different bioprospecting initiatives to be biopiracy; the absence of detailed regulations on procedures to facilitate decision-making by government officials, etc. At the same time, it has been observed that ABS procedures are highly bureaucratic and based more on the premise of control[74] than on promotion. This situation is probably caused, at least in part, by the need to control the flow of resources, due to the inadequacy of national regulations for monitoring the use of genetic resources, as well as to the lack of user country measures. This has generated a situation of little legal uncertainty concerning access to genetic resources[75]. However, despite the opposition of some countries to the International Regime including any reference to access to genetic resources – beyond recognising the countries' sovereignty in the matter – other nations have insisted that the appropriate regulation of access (occasionally referred to as "facilitation") represents the other "side of the coin" if benefits are expected to be obtained.

In any case, in order to achieve the CBD objectives and particularly the third one, the importance of national frameworks and their application should not be neglected. This topic is closely related to capacity building.

Although it is reasonable to affirm that the countries providing genetic resources cannot effectively control access to the resources and benefit sharing and put functional ABS operating systems into effect by themselves, the opposite is also true. It is not possible to fulfil the objectives of the International Regime without having clear and precise legal regulations and the capacity to enforce them, at least not as long as the CBD approach remains fundamentally bilateral-contractual. From this perspective, the IR should contribute decisively to ensure the best possible application of existing legal frameworks on ABS, the strengthening of legal certainty and the creation of national capacities for that purpose.

Concerning legal certainty, one of the most pertinent aspects regards the definition of physical property rights to genetic resources, as recognised by the COP 8 when it requested the Parties to provide information to the Secretariat (Decision VIII/4 A).

The issue of property rights is one of the most complex. The concept of sovereignty is different from those of heritage and property; the latter is not addressed by the Convention, leaving each State free to decide if genetic resources are private or public property and under what circumstances.

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72 Cfr. in particular, Cabrera Medaglia, An Analysis, op cit and Gatforth et al op cit, Carrizosa, Santiago et al (eds.), Accessing Biodiversity and Sharing the Benefits: lessons from implementing the Convention on Biological Diversity, (eds), IUCN Environmental Policy and Law Paper No. 54, Gland, Cambridge and Bonn, 2004.

73 Nevertheless, some improvements are starting to be seen in the application of the legal ABS frameworks, such as in Brazil, for example, where the number of permits has grown steadily in the last few years, mostly having to do with non-commercial applications. For example, in 2005 there were almost 100 access applications for basic research and 20 for bioprospecting and technological development. Cfr. www.mma/port/cgen.

74 Cfr. Barber, Charles, Glowka, Lyle and La Vina, Antonio, Developing and Implementing National Measures for Genetic Resources, Access Regulation and Benefit Sharing, in Laird, Sara (ed.) Biodiversity and Traditional Knowledge: Equitable Partnerships in Practice, Earthscan, London, 2002. They suggest that two main approaches be taken into account in building and applying the ABS regulatory frameworks: that of those who aim to controlling access through extremely restrictive legal provisions; and that of those who seeking, on the contrary, to facilitate or promote access through more flexible regulations that are more coherent with the reality of bioprospecting.

75 On the topic of legal certainty, we suggest reviewing the document Legal Certainty for Users of Genetic Resources under Existing Access and Benefit Sharing (ABS) Legislation and Policy, UICN-Canada, presented to the WGABS at its Third Meeting, UNEP/CBD/WG-ABS/3/INF/10, February 2005.

For example, in the case of Colombia, the Council of State determined in Decision C-977 that *"the legal regime applicable to genetic resources of real or potential utility, is that which is established in general terms in the Political Constitution for public domain goods…."*, that is, genetic resources are inalienable, unattachable and imprescriptible, and the Nation's heritage. This is generally how the concept of the public domain is characterised. Most countries' legislations define other resources possessing such attributes, such as water, minerals, wildlife, hydrocarbons, and the maritime land zone, in the same way[76].

The consequences of this legal nature (public domain) for the content (rights and obligations) of ABS agreements still need to be analysed.

H. Synergies and modalities of the process.

Although the International Regime is being negotiated in the CBD, it is important to indicate that the substantive issues or elements to be addressed are also the object of analysis, discussion and negotiation in other international fora. Thus, coordination and synergies are indispensable in order to maximise opportunities for success and the use of human and financial resources.

Although there are many of these fora, given the complexity and wide range of aspects potentially addressed by the International Regime, it is considered pertinent to establish appropriate synergies with at least three of them, given the centralised nature of their operations in "ABS governance at a multilateral level."[77]

The Treaty on Plant Genetic Resources for Food and Agriculture[78]

The Commission of the Food and Agriculture Organisation of the United Nations adopted in 1983 the International Treaty on Plant Genetic Resources for Food and Agriculture. The main objective of this non-legally binding instrument is to *"ensure that plant genetic resources of economic and/or social interest, particularly for agriculture, will be explored, preserved, evaluated and made available for plant breeding and scientific purposes"*. The International Treaty declares plant genetic resources to be of free access and a common World Heritage. However, this instrument considers elite lines and improved varieties in the same category, the latter being protected by intellectual property rights. Given the potential conflicts in some legislation, fundamentally those of developed countries, a total of eight nations registered their uncertainties about this instrument. At the same time, a number of developing countries began to question the paradigm of free access and the absence of benefit sharing arising out of the use of their plant genetic resources. This led to the FAO negotiating and approving clarifications regarding the scope of the Treaty. Decision 4-89 (called "the Agreed Interpretation") established that the plant breeder rights established by the UPOV were not incompatible with the Treaty, and it also stipulated that the States should impose only minimal restrictions on the free exchange of materials in order to comply with their national and international obligations. This Decision recognised the enormous contribution farmers from all regions have made to the conservation and development of genetic resources. Finally, the Agreed Interpretation clarified that the term "free

76 Related to this, the rights granted to those involved in prospecting the materials raise a critical issue. What rights are granted when allowing access? Custody of the material for research purposes. What rights will the recipient-user of the material then have? Regarding the importance of clarity on this topic, cfr. Cabrera Medaglia, Jorge, Un análisis crítico de las regulaciones de acceso a recursos genéticos de la Ley de Biodiversidad y de las normas de acceso de la Comisión Nacional para la Gestión de la Biodiversidad, in Revista Acta Académica, UACA, San José. May 2003.
77 For an analysis of the different fora and processes, cfr. Lasen, Carolina, Intellectual property rights and biological resources. An overview of key issues and current debates. Wuppertal Institute for Climate, Environment and Energy. Germany, February 2005.
78 On the evolution of, and the activities carried out by, the Commission on Genetic Resources, cfr. www.fao/ag/cgrfa. See also Mohamed Ali Mekour, A Global Instrument on Agrobiodiversity: the International Treaty on Plant Genetic Resources for Food and Agriculture, Environmental Law and Policy, FAO, 2002 and Cooper, David, The International Treaty on Plant Genetic Resources for Food and Agriculture, RECIEL, London, 11(1), 2002.

access" does not mean free of cost and that the benefits under the Treaty are part of a mutually supportive system. Decision 5-89 (on Farmers' Rights) was adopted that same year as a counterpart to the recognition of plant breeder rights. It states that *"in the history of mankind, unnumbered generations of farmers have conserved, improved and made available plant genetic resources, without the contribution of these farmers being sufficiently recognised."* The concept of farmer rights was affirmed and they were defined as *"rights arising from the past, present and future contributions of farmers in conserving, improving and making available plant genetic resources"*. Such rights were said to be vested in the international community as trustee for present and future generations of farmers, for the purpose of ensuring full benefits to them.

However, despite the new approaches, the concept of a common World Heritage remained in effect. In 1991, based on this concept, Decision 3-91 of the FAO Conference recognised that the concept of a common World Heritage is subject to the sovereign rights of the States to their plant genetic resources. The Decision stipulated that the conditions of access to the resources would require further clarification, that the improved lines and the farmers' plant breeding materials would be available at the discretion of their creators during the period of development, and lastly, that the farmers' rights would be implemented through an International Fund. This has not worked in practice.

Finally, it is worth mentioning Decision 7-93, issued in reaction to the signing of the CBD, especially to Decision No. 3 of the Nairobi Proceedings, which established the need to resolve access to ex-situ collections not covered by the Convention, as well as the matter of farmers' rights, within the framework of the FAO. Decision 7-93 requested the Director General of the FAO to provide a Forum for Negotiations among the governments to adapt the Commitments to the CBD[79] and to consider issues of access to plant genetic resources on mutually agreed terms, including the case of ex-situ collections and the means of establishing farmers' rights.

The FAO Commission on Genetic Resources has reviewed the Commitments and has finally achieved a Treaty on Plant Genetic Resources for Food and Agriculture.[80]

Basically, the most important issues have been access to genetic resources, farmers' rights, the possibility of granting intellectual property rights to materials in the Multilateral System, the relationships among this instrument and other international agreements, especially the WTO TRIPs Agreement, and the list of species to be covered.

Regarding the concept of farmers' rights, the debates centred on their nature: whether they should be a mere abstract concept (proposed by some developed countries) or an actual right to be implemented. Although there are discrepancies concerning the scope and nature of these rights, it has been possible to reach agreement. The Parties have agreed that the responsibility for implementing farmers' rights rests with national governments. Each Party, according to its national legislation, shall adopt the following measures: protection of traditional knowledge associated with plant genetic resources; the right to participate equitably in benefit sharing; the right to participate in decision-making. None of this shall be interpreted in the sense of restricting the rights of farmers to conserve, use, exchange and sell planting or propagating material held on their farms, in accordance with national laws and as appropriate (article 9).[81]

79 In 1995, Decision II-7 of the Second Conference of the Parties had already recognised the differential characteristics of Agricultural Genetic Resources.
80 The Treaty took effect on the 29th July 2003 on receiving ratification No. 50.
81 The Preamble stipulates that the rights recognised in the current Treaty – to save, use, exchange and sell farm-saved seeds and other propagating material held on farms – are fundamental to the realisation of farmers' rights.

Concerning access to genetic resources and benefit sharing, a Multilateral System was created for the species covered by this system (about 35 crops and 29 forage species contained in Annex I), to be *"efficient, effective and transparent, both to facilitate access to plant genetic resources for food and agriculture, and to share, in a fair and equitable way, the benefits arising from the utilisation of these resources"* (article 10). The Multilateral System will include all resources in Annex I that are under the management and control of the Contracting Parties and in the public domain (article 11). Access shall be granted under the conditions indicated in article 12, and benefit sharing under the Multilateral System shall include the exchange of information, access and technology transfer, capacity building and the sharing of monetary benefits arising from commercialisation (article 13). In this regard, when the product incorporates material accessed from the Multilateral System, the user must pay an "equitable" share of the benefits to the Fund or Trust that is created, except whenever such a product is available without restriction to others for further research and breeding, in which case the recipient who commercialises shall be encouraged to make such payment. In other words, if patents protect the product, this payment is mandatory and, in principle, if it is protected by breeder rights or lacking any kind of right, the payment is voluntary[82]. The Treaty's Governing Body in line with commercial practice (article 13) shall later determine the level, form and means of payment.

Concerning intellectual property rights, a variety of proposals were presented during the negotiations. On the one hand, it has been suggested that IPR only be prohibited for genetic resources as they were received from the Multilateral System. This proposal does not mention their components (genes, cells, etc.) or derivatives. On the other hand, it has been proposed that the exemption should include materials received, their parts and components, limiting the protection to those rights and thus affirming the possibility of freely using plant genetic resources for a number of important crops.

The final text establishes that the recipients shall not 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 or components, in the form received from the Multilateral System (article 12).

In general, the Treaty's main provisions that may be relevant to the International Regime are as follows:

1. Restrictions on granting intellectual property rights on the material as it were received from the Multilateral System. However, this restriction shall be incorporated in the clauses of the Material Transfer Agreement that authorises the access and consequently its terms do not come under intellectual property regulations.[83]

2. Realisation of farmers' rights. The following rights are of interest: a) the extension and scope of the farmer's rights to reuse, exchange or sell protected seeds; b) the farmer's right to protect traditional varieties by means of a system of exclusive rights similar to the IPR system.

3. Support for conservation, the sustainable use and fair and equitable sharing of the benefits arising out of the access, in accordance with the objectives of the FAO Treaty (article 1).

82 Broad exceptions could still be made for research, despite the product being patented. And even if it isn't patented, access to the material could still be restricted by means of contracts.
83 A draft of the Materials Transfer Agreement now exists and will be presented at the first meeting of the Governing Body, cfr. www.fao/ag/cgrfa

The Commission on Genetic Resources, acting as the Interim Governing Body of the International Treaty, has made progress to date in drafting the Materials Transfer Agreement. A draft of this agreement was produced at the second meeting of the Contact Group on the Materials Transfer Agreement, held in Sweden. This agreement contains the standard terms that will govern the transfer of genetic resources carried out through the Multilateral System of Access. This topic was debated at the first meeting of the Governing Body carried out in Madrid, Spain from 12-16th June of 2006.

Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC).[84]

WIPO General Assembly established the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) in October 2000, as a forum for debate and dialogue on the relationship between intellectual property, traditional knowledge, genetic resources and traditional cultural expressions. It was considered that these issues did not fall within the scope of other WIPO bodies.[85] The IGC's mandate consists of analysing aspects of intellectual property related to genetic resources, traditional knowledge and the protection of expressions of folklore. At a session of the WIPO General Assembly in 2005, it was decided to extend the IGC mandate for another two years, including the possible drafting of legally binding instruments. One of the issues the Committee had considered – and continues to do so under its new mandate – is precisely the disclosure of origin in patent applications and the protection of traditional knowledge. The Committee has met on nine occasions.[86]

To date, the main work of the WIPO on the International Regime can be summarised as follows:

Access to genetic resources

1. Regarding access to genetic resources, WIPO has prepared several analyses of the clauses on IPR in the agreements on access to genetic resources and benefit sharing, including materials transfer agreements and model clauses. A database with public examples has also been created, with an emphasis on IPR clauses. Draft guidelines have also been prepared on IPR clauses in access and benefit sharing agreements.

2. In addition, following through Decision VI/24 of COP 6, WIPO was invited to prepare an article on disclosure of origin in patent applications, to include the following aspects, among others: a) genetic resources utilised in inventions; b) the country of origin of the genetic utilised in the inventions; c) the associated traditional knowledge, innovations and practices; d) the source of the associated traditional knowledge; e) evidence of prior informed consent. This study called the Technical Study on Disclosure of Origin Requirements in Patent Applications, was presented at the COP 7 in Malaysia and was well received by the COP (Decision VII/19/E). In addition, COP 7 requested WIPO to elaborate a new technical study including the examination and discussion, as appropriate, of aspects related to the relationship between access to genetic resources and disclosure of origin in patent applications, including the following aspects, among others:

84 Other aspects related to the topic of disclosure of origin are also being discussed by other WIPO Committees, such as the Standing Committee on Patent Law, in its work on the elaboration of a Substantive Patent Law Treaty, and the Working Group on Reform of the Patent Cooperation Treaty (PCT).
85 See further details at www.wipo.int/tk/en/igc/.
86 At its last session, the Committee limited itself to taking note of the documents and proposed resolutions it reviewed, without making any substantive decision regarding the issues of genetic resources and intellectual property, traditional knowledge and folklore.

a) Options for provisions on proposed disclosure requirements
b) Practical options for IPR application procedures with regard to disclosure requirements
c) Options for incentive measures for applicants
d) Identification of the implications of disclosure requirements in various WIPO treaties
e) Intellectual property-related issues raised by a proposed international certificate of origin/source/legal provenance.

WIPO has responded[87] to COP invitation by preparing a new technical document (WO/GA/32/8) entitled "Examination of Issues Relating to the Interrelation of Access to Genetic Resources and Disclosure Requirements in Intellectual Property Right Applications".

3. WIPO has also jointly prepared a study with UNCTAD and the CBD Secretariat on the role of IPR in technology transfer in the context of the CBD (in February 2006).

4. Despite the abundant information generated by WIPO, to a certain degree in response to requests from the CBD, and the exchange of opinions and positions that has taken place in the Committee's sessions, these debates have not resulted in initiatives to include disclosure of origin in IPR applications into national and international legal systems.[88] For this reason, fearing that the discussions will not generate actual regulatory progress, some countries have questioned why WIPO instead of the WTO is the entity charged with discussing issues of disclosure of origin.

5. The issue of disclosure of origin has also been discussed in the framework of revisions to the Substantive Treaty on Patent Law. In accordance with the mandate of the 2005 General Assembly, a process of two sessions of the Permanent Committee on Patent Law, one formal and another informal, was established to analyse this proposed instrument[89]. Likewise, due to Swiss proposals, the Patent Cooperation Treaty is discussing this issue. In conclusion, in order to harmonise patents, developing countries have presented proposals in the WIPO that include disclosure of origin, proof of PIC and of benefit sharing, as well as effective mechanisms for questioning the validity of patents.[90]

Traditional knowledge

6. WIPO has prepared an extensive number of documents on positive and defensive measures for the protection of traditional knowledge[91]. In addition, a range of activities of interest have been carried out on this subject, such as:

87 A procedure for consultation and information exchange was specially established in order to prepare the document.
88 However, note should be taken of the proposal prepared by the European Union and presented to the Committee (16th November 2004) on the subject of disclosure of the origin or source of genetic resources and associated traditional knowledge in patent applications. In synthesis, it proposes the following: a mandatory requirement should be introduced to disclose the country of origin or source in patent applications; the requirement would apply to national, regional and international applications; the applicant shall declare the country of origin or, if it is unknown, the specific source to which the inventor had physical access; the invention shall be based directly on genetic resources; the requirement would apply in the case of traditional knowledge – a concept requiring further study; if the patent applicant does not present the information, despite having been granted the possibility of rectifying the omission, the application will not be processed; if the information is incorrect or incomplete, effective, proportional and dissuasive sanctions shall be taken outside patent law; a notification procedure must be introduced, such as the Clearing-House Mechanism (CHM) of the Convention on Biological Diversity, to be implemented by the Patent Office for the purpose of bringing the respective application to the attention of the country of origin.
89 Even India has proposed that the Committee of Genetic Resources hold joint meetings with the Patent Law Committee.
90 In addition, the implications of the Provisional Committee on Proposals related to a WIPO Development Agenda, which was established at the WIPO General Assembly in 2005, must at least be considered due to requests by several countries that the development dimension be integrated into the WIPO system.
91 Cfr. WIPO, Intellectual Property and Traditional Knowledge, Booklet No 2.

- Systematic study and clarification of legal options for the protection of traditional knowledge
- Analysis of cases studies on the use of IPR for the protection of traditional knowledge, as well as of the establishment of *sui generis* protection systems
- Case studies and analyses of practical experiences
- Draft of a Tool Kit to document traditional knowledge associated with genetic resources
- Progressive recognition of traditional knowledge in patent systems, through the development of guidelines for patent examiners; mechanisms involving links to databases to ensure a better understanding of traditional knowledge as prior art; the incorporation of traditional knowledge in minimum standards for searches for novel forms by the Patent Cooperation Treaty (PCT).
- Development of a draft of policy objectives and basic principles on traditional knowledge. These provisions are considered compatible with the CBD although their scope is broader than traditional knowledge related to biodiversity, and they have taken into account the contributions and progress of the Working Group on Article 8 (j). These guidelines are more relevant for establishing national norms than international ones.[92]

The World Trade Organisation. Main WTO positions to date.

The Doha Declaration, which launched the current Round of Trade Negotiations (paragraph 19), specifically mandates the TRIPs Council to examine the relationship between the TRIPs Agreement and the CDB, the protection of traditional knowledge and folklore, and other new and relevant developments pointed out by the Parties. In particular, it shall take this into account in conducting the examination provided in paragraph 3 (b) of article 27; the examination of the application of the TRIPs Agreement provided in paragraph 1 of article 71; and in its work in compliance with paragraph 12 of the Declaration. In carrying out this work, the TRIPs Council shall be governed by the objectives and principles stated in articles 7 and 8 of the TRIPs Agreement and shall fully consider the dimension of development.

The issue of disclosure of origin in IPR applications has been discussed in the WTO based on the mandate established in Doha. The main positions of the different groups or countries can be summarised as follows:[93]

- The African Group has proposed the elimination of patents on life forms within the context of TRIPs. They have also stated that disclosure of origin should be included in IPR applications.

- The United States, with some level of support from Japan, has opposed this modification and the inclusion of disclosure of origin because it considers that this would not resolve the problems derived from the misappropriation of genetic resources and traditional knowledge and would cause uncertainty and practical problems in the operation of IPR systems. On the contrary, they are in favour of improving the quality of the patent granting process, of establishing search databases and other mechanisms that contribute to eliminating the problems associated with

92 The Committee has also elaborated a draft document on the fundamental objectives and principles of traditional cultural expressions or folklore, which may become one of the mechanisms for the protection of traditional knowledge in a broad sense. The Committee has already been distinguishing between protection in a strict sense (TK) and a broad sense (traditional cultural expressions).
93 For an analysis of the different proposals presented through February 2006, cfr. the relationship between the TRIPs Agreement and the Convention on Biological Diversity. Summary of issues raised and points made. Note by the Secretariat. Document IP/C/W/368/Rev.1, February 2006. This reading may be complemented by IP Quarterly Update, South Centre and CIEL, First Quarter, 2006.

"bad patents", and of using systems of annulment and revocation of existing patents, etc. They do not consider that a conflict exists between TRIPs and the CBD but rather believe that the solution lies in strengthening access laws and the use of contracts as means of avoiding misappropriation.

- Switzerland (due to the fact that considers disclosure of origin requirements to be of a formal and non-substantive nature) has proposed to modify the PCT and its regulations to allow – but not obligate – countries to include disclosure of the source of genetic resources in IPR applications based directly on those resources.

- The so-called "Group of Friends of Development", a group of 14 developing countries including Brazil, China, Cuba, Dominican Republic, Ecuador, India, Kenya, Pakistan, Peru, Thailand, Venezuela, Zambia and Zimbabwe, and occasionally supported by other countries, has expressed that the TRIPs and the CBD should be mutually supportive[94] and therefore suggests modifying the TRIPs. They argue that acts of biopiracy or misappropriation may occur through the patenting of biological resources, in violation of the recognition of national sovereignty established by the CBD. They have also noted that TRIPs does not contain elements to ensure the PIC of the holders of biological material used in patented inventions or to allow the countries of origin to claim benefit sharing. Therefore, this Agreement must be modified to include the obligation of: a) disclosure in patent applications of the source and country of origin of the biological resources and the traditional knowledge utilised; b) evidence of prior informed consent obtained in compliance with the national systems; c) proof of fair and equitable benefit sharing obtained in compliance with the national regimes.

- The European Union has indicated its willingness to discuss the issue within the WTO, although it considers that WIPO is the more appropriate forum. However, it is worth mentioning the proposal prepared by the European Union on the subject of disclosure of origin or source of genetic resources and associated traditional knowledge in patent applications, which was presented to the WIPO Committee on 16th November 2004. In summary, it proposes the following: a binding requirement should be introduced to disclose the country of origin or source in patent applications; the requirement would apply to national, regional and international applications; the applicant must declare the country of origin, and if it is unknown, the specific source to which the inventor had physical access; the invention must be based directly on genetic resources; the requirement would apply to traditional knowledge - a concept requiring further study; if the patent applicant does not present this information, despite having been granted the possibility of rectifying this omission, the application will not be processed; if the information is incorrect or incomplete, then effective, proportionate and dissuasive sanctions outside patent law should be provided; a notification procedure should be introduced, for example, through the Clearing-House Mechanism (CHM) of the CBD, to be implemented by the Patent Office for the purpose of bringing the respective application to the attention of the country of origin. In summary, the European Union appears willing to discuss disclosure of origin as a

94 The principal promoters of these proposals are the Group of African Countries, through the document entitled "Taking Forward the Review of Article 27.3.b of the TRIPs Agreement", and a group of developing countries, some of them megadiverse, headed by Brazil and India (as well as Bolivia, Cuba, Ecuador, Dominican Republic, Peru, Thailand and Venezuela). See http://docsonline.wto.org/DDFDocuments. Although the proposals differ with regard to language and certain legal considerations, in general they seek to introduce the requirement of disclosure of origin and proof of legality of access into patent systems. For a summary of different countries' responses to the granting of patents for plants and animals, or information on the characteristics of the protection system for existing plant varieties, see IP/C/W/273/Rev., February 2003. At the beginning of 2004, several developing countries presented a "check list" of the elements requiring discussion, which has served to guide the discussions.

mandatory requirement in patent applications; if the information is not presented, the application will not be processed. There should be a direct relationship between the invention and the genetic resource. The consequences of not complying with this would lie outside the patent system.

- Although Norway does not consider that there is a contradiction between TRIPs and the CBD, and has indicated its preference for national actions, it has stated that it is agreeable to discussing disclosure within WTO, although possibly in more limited terms and consistent with its national regulations (which require evidence of PIC, but not of benefit sharing).

Regarding discussion of the topic at the Hong Kong Ministerial Conference (December 2005) despite the insistence of India, Brazil and Peru, it was not possible to present a proposal to initiate negotiations based on a text.

Nevertheless, the Ministerial Declaration adopted in this Asian country provides (in paragraph 44) that note be taken of the work carried out by the TRIPs Council, in accordance with paragraph 19 of the Doha Declaration, and agrees that work will continue based on this paragraph and on the progress made to date. In addition, in accordance with paragraph 39 concerning implementation, it was decided to address the relationship between the TRIPs Agreement and the CBD through a consultation process on different aspects of implementation (paragraph 12 of the Doha Declaration). This consultation is being carried out with the intervention of the Deputy Director General of the WTO[95].

Finally, at the end of May 2006, six countries, including India, Brazil and Peru, submitted a proposal to the TRIPs Council suggesting concrete modifications to the TRIPs (a new article 29 Bis) in order to support disclosure of origin.

The Communication[96] aims to incorporate a new article 29 bis, of which the principal provisions are:

1. The purpose consists of establishing a mutually supportive relationship between the CBD and the TRIPs.

2. It includes biological resources and associated traditional knowledge.

3. When the subject matter of a patent application concerns, is derived from or developed with biological resources and/or associated traditional knowledge, Parties shall require disclosure.

4. Applicants shall be required to disclose the country providing the resources and/or associated knowledge; from whom in that country they were obtained; and after reasonable research, the country of origin. Evidence must be provided to show compliance with the applicable legal requirements in the providing country for prior informed consent and fair and equitable benefit sharing arising from the utilisation of such resources and/or associated traditional knowledge.

95 The Deputy Director General initiated this process by presenting a document containing 11 different questions on the topic, to be responded by the Parties as part of the consultation process.
96 WT/GC/W/564, 31st May 2006.

5. Parties shall require applicants to supplement and to correct previously provided information in light of new information of which they become aware.

6. Parties shall publish the information disclosed jointly with the patent application or grant. If additional information is provided to complement or correct the initial disclosure, it shall also be published.

7. Parties shall also prevent the patent from being processed or granted, or revoke or render unenforceable a patent when the applicant has failed to comply with the aforementioned disclosure obligations or provided false or fraudulent information.

Based on this information, the following chart shows the specific scopes of action and potential synergies suggested among these different fora, processes and instruments.

Chart 4: Main synergies suggested among the WGABS and other fora, processes and instruments.

FAO-IT	WIPO	WTO	CBD-WGABS	CBD WG ARTICLE 8 (j) AND RELATED PROVISIONS
The IR must respect the differentiated scope of the IT, especially relating to the access multilateral system, by making the necessary references in the IR. The experience gained in developing instruments such as the Materials Transfer Agreement or multilateral approaches may eventually be utilised if these kinds of instruments are included in the IR. The development of farmers' rights under the IT also constitutes a contribution to the IR (understood as a governance process, not as the CBD negotiation process), although it was developed in the IT.	The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore shall: - Continue with substantive discussion of TK: development of basic principles and policy objectives for their protection, and eventually with the development of international instruments. - Continue with work on modifications to the patent system to avoid misappropriation through the use of improved search systems and public databases with information on TK to facilitate evaluating the state of the art and novelty in IPR applications, etc. These issues should be addressed by the Committee on Patent Law (negotiation of the Substantive Treaty on Patent Law); the Provisional Committee for Proposals related to the Development Agenda; and the Cooperation Treaty on Patents.	Substantive negotiations to modify the TRIPs and demand disclosure of origin must be considered in the WTO. The IR would be limited to clarifying issues of PIC, benefit sharing, certificate or origin, etc.[97]	Develop umbrella or general provisions to promote the establishment of *sui generis* mechanisms for the protection of TK and the role of customary law in the protection of TK. Compliance with the PIC and MAT of indigenous peoples and local communities is required under penalty of the access being considered an act of misappropriation. However, substantive progress should be left to the Working Group on Article 8 (j) or the WIPO. Develop provisions on certificates of origin that will eventually be related to the WTO negotiations on the issue of disclosure of origin. Substantive development of issues such as: user country measures, access to justice, compliance and monitoring mechanisms, clarification of the issue of derivatives; definitions of utilisation, biological resources and their relationship to genetic resources, etc. Developments of measures to support compliance with PIC and MAT if indigenous peoples or local communities are the providers.	The Working Group on 8 (j) has a broader mandate than WIPO (although it is s not limited to TK associated with biodiversity). The IR only considers one aspect of the tasks of the Working Group on 8 (j) (that of access and benefit sharing). This group should be responsible to carrying out substantive work on the issues such as *sui generis* systems, customary law, etc.

97 For reasons related to the negotiation strategy, it should be advisable to maintain the discussion of disclosure in the CBD. However, the WTO is considered to be the most adequate forum due to the participation of countries such as the United States (non-ratifiers of the CBD); due to a greater probability that a larger number of ratifications could be obtained if the commercial agreement is modified; and the existence of effective dispute settlement mechanisms.

IV. Recommendations

1. The International Regime still appears to be particularly complex and it is uncertain how it will evolve in the future, including which elements will be considered binding and which not, how synergies will be developed and what kind of legal structure it will have. While the results of the WGABS meeting in Granada and the Decisions of COP 8 highlight a number of elements to be incorporated, it is possible that new measures and instruments may be added in the next few years.

2. It is striking that there are no comprehensive analyses of the causes that led to the limited fulfilment of the third objective of the CBD, to which the International Regime should respond appropriately. Only if the causes are clearly identified will it be possible to choose between the different policy and legal instruments to deal with them.

3. The current situation of negotiations and the progress made so far seem to demonstrate that better practical and tangible elements still need to be incorporated in the International Regime to respond to the identified obstacles to compliance with the CBD. Some of the proposals that have been presented have been limited to repeating or specifying what was established in the CBD or consist of measures that individual countries can take independently of the International Regime. In any case, it should be recognised that the negotiations have raised the issue of ABS to the highest policy level.

4. Given the transboundary nature of ABS relations and the difficulties inherent in monitoring, compliance and observance of the contracts or permits issued on the basis of the provider countries' access laws, it is essential that user country measures be implemented to facilitate compliance with the terms of PIC and MAT and promote trust among the different actors. To date, disclosure of origin in IPR applications and the certificate of origin/source/legal provenance are the most visible user measures in international debate, but aspects related to access to justice and cooperation in cases of contract in compliance, facilitation of monitoring, etc. must still be explored. Putting these measures into practice could help the provider countries to create access regimes or make their existing regimes more flexible, which promote rather than control the flow of genetic resources,

5. The certificate of origin/source/legal provenance, whose practical and operational details still need to be determined (in their different options), could become one of the central components of the International Regime. There is important consensus concerning the need to value it and study design alternatives, including consideration of potential implementation difficulties. The Group of Technical Experts responsible for studying the issue has the challenge of presenting design options that are clearer about the way the certificate or certificates would operate and what their true role would be in achieving the three CBD objectives.

6. There are also legitimate reasons and rationales for insisting on disclosure of origin in IPR applications, although it should be recognised that they may be more of a moral nature (to avoid misappropriation) rather than a strictly economic one (benefit sharing, restitution of rights, avoiding restrictions on exportations, etc.) Although in the WTO, its inclusion might imply a trade off, the developing countries should continue their efforts

to modify the TRIPs Agreement and include disclosure as an appropriate defensive measure to prevent or minimise the misappropriation of genetic resources and traditional knowledge as well as increase the transparency of the operation of the IPR system. The WTO is believed to be the most appropriate forum for considering these issues, while the CBD is responsible for defining other aspects related to PIC, national authority, etc. In addition, without waiting for the result of the international negotiations, the countries could establish in their national ABS laws that applicants must declare the country providing the material and from whom it was obtained. Lastly, disclosure should be included in a technically appropriate form in breeder right systems, and the legal implications for cases when the countries are members of the UPOV Convention should be specified.

7. In the case of traditional knowledge, it is suggested that the International Regime include umbrella agreements or general provisions, to be substantively developed in the appropriate fora such as the Working Group on Article 8 (j) and Related Provisions or the WIPO itself (at a national or international level). Among the elements to be considered for inclusion in the IR, emphasis could be placed on the following: the role of customary law in the protection of traditional knowledge; the establishment of *sui generis* systems; the development of operational guidelines or procedures for obtaining PIC from local communities and indigenous peoples. When the WGABS addresses user country measures, it should consider incorporating mechanisms to support the PIC and MAT of indigenous peoples and local communities, including access to justice in cases of misappropriation.

8. While the direction taken by the International Regime aims to promote actions in user countries, we should not lose sight of the need to strengthen access regimes and the capacity to enforce them as a requirement for the operation of the ABS systems and a means of achieving the CBD objectives. In theory, these laws would offer more certainty and flexibility if user country measures existed and would allow promoting greater trust among the actors and reducing the high costs of ABS transactions. The IR should not fail to incorporate national and regional activities in order to improve the application of existing ABS-related instruments.

9. In addition, the International Regime could offer guidance on key topics, such as the scope of the terms ‘genetic resource’, ‘biological resource’ and ‘utilisation’, as well as clarify the implications of property rights for ABS transactions and permits, etc. These definitions are also indispensable in order to grant legal certainty in cases of misappropriation or biopiracy. Multilateral mechanisms based on utilisation, rather than on access to genetic resources, could also be explored, such as funds, among others schemes

10. It is relevant, in order to further the negotiations, to establish the scope and consequences of including derivatives and products, clearly articulating the concepts, scope and practical consequences of their incorporation in the International Regime.

11. From a legal perspective, it is necessary to clarify how the International Regime will finally be structured (a CBD Protocol, COP Decisions, an Annex to the Convention, etc.) and the impacts and synergies it will have with other processes and instruments. The most advisable structure might consist of a combination of binding and non-binding

elements to be elaborated by the CBD, together with the development of processes to establish synergies with fora such as the WIPO, WTO and FAO, respecting each institution's scope of action. However, any decision, whether of a binding or non-binding nature, should be linked to the actual content to be incorporated.

12. It will still take several years to finish elaborating and negotiating the International Regime. Thus, the countries should consider establishing voluntary measures and means of generating incentives to promote compliance with national laws.

13. The relationship between ABS regimes and conservation, and in a broader fashion, the impact of ABS on conservation, have not been sufficiently studied and documented. The degree to which the International Regime will contribute to reaching the Millennium Development Goals (particularly Goal No. 7 referring to environmental feasibility) must still be explored. However, beyond strictly economic considerations[98] concerning the sharing of the benefits arising from ABS related to conservation, the IR can make a valuable contribution to the fulfilment of the Millennium Goals. The IR can help achieve the Millennium Goals to the extent that it allows for a better flow and transfer of genetic resources, guarantees the countries and communities greater participation in the benefits, ensures respect for and control over the knowledge, innovations and practices of indigenous peoples by channelling monetary and non-monetary benefits toward the custodians and guardians of biodiversity, and promotes more ethical behaviour in ABS relations.

14. The International Regime should also consider the new processes of generating genetic information (genomic, proteonomic) and the ways in which these will affect the regulation of ABS.

15. Access to genetic resources and benefit sharing, rather than being conceived as a "Green Gold Mine" awaiting some lucky collector, should be seen as an opportunity for sustainable development that requires investment in conservation, science and technology, along with an understanding of the market for products derived from biological resources, etc.

16. Finally, we can continue in a lack of legal certainty state, absence of trust among users and providers (individuals and countries), inadequate measures in user countries and few benefits to share; or establish an International Regime that makes it possible to generate enough trust on the part of the providers (clear and simple laws that encourage compliance and sanction incompliance) for them to establish partnerships with the users (whose guarantee of respect for national legislation, monitoring and incompliance measures will make it possible to facilitate access and generate benefits) and consequently promote benefit sharing and biodiversity conservation.

98 Since 1995, some authors have questioned the degree to which directing profits from bio-prospecting activities into conservation projects would be an appropriate conservation strategy and whether they would produce sufficient revenues. Cfr. Simpson, David, Sedjo Roger and Reid, John, The Commercialization of Indigenous Genetic Resources as Conservation and Development Policy, 1995.

V. Acronyms

ABS:	ACCESS TO GENETIC RESOURCES AND BENEFIT SHARING
TRIPS:	WTO AGREEMENT ON TRADE-RELATED ASPECTS OF INTERNATIONAL PROPERTY RIGHTS
CBD:	CONVENTION ON BIOLOGICAL DIVERSITY
COP:	CONFERENCE OF THE PARTIES TO THE CBD
GR:	GENETIC RESOURCES
IPR:	INTELLECTUAL PROPERTY RIGHTS
IR:	INTERNATIONAL REGIME
IT:	INTERNATIONAL TREATY ON PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE OF THE FAO
MAT:	MUTUALLY AGREED TERMS
PBR:	PLANT BREEDERS RIGHTS
PIC:	PRIOR INFORMED CONSENT
TK:	TRADITIONAL KNOWLEDGE
UPOV:	THE INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS
WGABS:	WORKING GROUP ON ACCESS TO GENETIC RESOURCES AND BENEFIT SHARING
WIPO:	WORLD INTELLECTUAL PROPERTY ORGANISATION
WTO:	WORLD TRADE ORGANISATION