United Nations Conference on Trade and Development

Elements of an International Regime for the Recognition of National Regulations on Access to Genetic Resources

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Foreword

The widespread poverty in many developing countries is in stark contrast to the wealth of biological diversity to be found in their forests, drylands and other ecosystems. Their remarkable range of flora and fauna constitutes a valuable stock of genetic resources that may yield important technological and commercial discoveries in the future. In addition, many traditional and indigenous communities in developing countries are expert in utilizing these resources for a variety of medicinal, nutritional and spiritual purposes.

There is thus great potential for developing countries to harness their genetic resources and associated traditional knowledge for sustainable development goals, for example through the commercialization of new products and technologies. The Convention on Biological Diversity (CBD) identifies a number of principles to ensure that such activities genuinely contribute to sustainable development. In particular, it stipulates that access to genetic resources and associated traditional knowledge should be allowed only after obtaining prior informed consent, and should involve the fair and equitable sharing of any resulting benefits. Yet many developing countries are concerned that their sovereign rights over such resources are being undermined through the inappropriate award of intellectual property rights (IPRs) in foreign jurisdictions, such as the granting of patent rights to individuals or companies that have violated principles enshrined in national regulations.

This paper aims to assist the international community in its efforts to curb the misappropriation of genetic resources and associated traditional knowledge through IPRs. It outlines how an international legal regime may assist the enforcement of decisions made under national access and benefit-sharing regulations by providing for the recognition of such decisions in foreign jurisdictions.

In addition to offering some useful background on the complex legal issues involved, the paper outlines some of the elements that could constitute such a legal regime, and examines the different options for implementing it at the international level. It provides a useful complement to research previously commissioned by UNCTAD on “disclosure of origin” in patent applications.

It is my hope that this paper will prove to be an important contribution to the current debate on this urgent issue, thus helping to ensure that the custodians of genetic resources and associated traditional knowledge gain greater control over the use of these assets and share in any resulting benefits. Such an outcome would be a significant step towards rewarding the conservation of biodiversity and traditional knowledge and achieving sustainable development.

Supachai Panitchpakdi
Secretary-General of UNCTAD

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Contents

Abbreviations

CBD	Convention on Biological Diversity
FAO	Food and Agriculture Organization of the United Nations
IPR	intellectual property right
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
PGRFA	plant genetic resources for food and agriculture
PIC	prior informed consent
TRIPS	trade-related aspects of international property rights (also WTO TRIPS Agreement)
UNCTAD	United Nations Conference on Trade and Development
WTO	World Trade Organization

Executive summary

The Convention on Biological Diversity (CBD) created a framework rooted in the sovereign rights of States over their genetic resources for regulating access to and the sharing of benefits arising from the exploitation of such resources. Many countries have implemented, or are in the process of establishing under different modalities, national access legislation in line with the Convention, that requires prior informed consent (PIC) as a condition for obtaining access to genetic resources and sharing of the benefits generated by their commercial exploitation.

Numerous cases have been reported of genetic resources and their associated traditional knowledge being acquired in breach of such national legislation and the principles of the CBD. Moreover, those resources and knowledge have subsequently been the subject of IPRs granted in foreign jurisdictions. Such misappropriation has become a problem of global dimension.

The establishment of an international obligation requiring disclosure of the source of genetic resources (and associated traditional knowledge) claimed in patent applications could help curb their misappropriation. It may also contribute to ensuring compliance with the PIC and benefit-sharing provisions. The adoption of such an obligation is under discussion in different forums, notably in the TRIPS Council of the World Trade Organization (WTO).

To be fully effective, the proposed obligation would need to be supplemented by other legal mechanisms. Patent laws are of a territorial nature. Although violation of a national access law or a breach of a benefit-sharing contract may justify the challenge of a patent granted in a foreign jurisdiction, or a claim to other remedies (such as a transfer of ownership interests in the application or granted patent), the admissibility of such a challenge will be decided by the competent authority of the country that grants the patent, in accordance with its national law. That authority is not obliged to take into account a violation of access laws that has occurred in another country.

Under the international law principle of comity and some international treaties, the enforcement of foreign judgments and arbitral awards is possible in certain circumstances. However, existing instruments do not seem to provide effective responses to the problem posed by a misappropriation of genetic resources and traditional knowledge.

In fully recognizing the space available to countries to determine their patent policies, subject to the applicable international treaties, this paper explores the possible development of an international regime for the recognition, in the country of grant of a patent, of determinations made under the national access legislation of the country where the genetic resources and associated traditional knowledge were obtained in breach of the applicable national law.

The purpose of such a regime would be to provide remedial measures in cases where misappropriation (with or without commercial intent) of genetic resources and associated traditional knowledge has been determined by the competent authority in the country where the resources or knowledge were accessed.

The main features of the proposed international regime would be as follows:

a) It would essentially be based on the broadly accepted notion of comity under international law, with no extraterritorial application of a foreign law.
b) It would be applicable to a signatory party when a patent involving claims over genetic materials and associated traditional knowledge accessed in another signatory party has been applied for or granted.
c) It would require a party to recognize a final determination made by a competent authority of the party where such resources and knowledge have been accessed in violation of the national law.
d) There would be no requirement of substantive harmonization of national access or patent laws; signatories would retain the latitude to design and implement their own legal approaches and regimes within the framework of existing international treaties on the matter.
e) The proposed regime could be based on an independent international convention or on a protocol to an existing one, such as the CBD.

In sum, this paper intends to make a contribution to finding a solution to an outstanding problem in the international arena: the misappropriation of genetic resources and their associated traditional knowledge. The proposed international regime would support, through a simple mechanism, the implementation of national measures adopted to curb such misappropriation, while respecting the sovereign rights of States over genetic resources and the territoriality of patents.

I. Introduction

The misappropriation of genetic resources and associated traditional knowledge has generated an intense debate, particularly since the adoption of the Convention on Biological Diversity (CBD) in 1992. The CBD introduced, for the first time in an international binding agreement, provisions on access to genetic resources and the sharing of benefits derived from their exploitation. One basic objective of the Convention is "the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources" (article 1). The CBD reaffirms the sovereign rights of States to exploit their genetic resources "pursuant to their own environmental policies" (article 3). Access to genetic resources, where granted, "shall be on mutually agreed terms" and "subject to the prior informed consent of the Contracting Party providing such resources" (article 15.4 and 15.5). In addition, each contracting party shall take legislative, administrative or policy measures with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the supplying contracting party. Such sharing shall be upon mutually agreed terms (article 15.7).

Despite the high expectations that the CBD created in developing countries, the possible benefits arising from the exploitation of their resources (and associated traditional knowledge) have not materialized.[1] There is little evidence, in effect, of benefits accruing to countries that have provided genetic materials for industrial purposes. With regard to access and benefit-sharing of plant genetic resources for food and agriculture (PGRFA), a special framework has been developed under the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). According to this Treaty, the benefits deriving from the use of PGRFA[2] are to be shared multilaterally in the case of 35 food crops and 29 forage genera important for food security, as listed in Annex I to the Treaty.[3]

Although there are probably many reasons for the failure to generate benefits under the CBD principles[4] (their analysis is beyond the scope of this paper), there is a growing perception

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1 See, for example, Garforth K and Cabrera JM, eds. *Sustainable Biodiversity Law: Global Access, Local Benefits – A Scoping Study on Future Research Priorities for Access to Genetic Resources and Benefit-Sharing*, Montreal, 13 August 2004; available at: http://www.cisdl.org/pdf/CISDL_ABS_Scoping_Study.pdf, p. 12; Correa C, Are access regimes promoting the use of genetic resources and benefit sharing? *International Journal of the Environment and Sustainable Development*, 2005, 4(4): 444-463.

2 Under the Multilateral System established by the Treaty, PGRFA can be accessed and exchanged free of charge if they are to be used solely for research, breeding or training purposes. Hence, PGRFA under the Multilateral System (Annex I of the ITPGRFA) are not subject to PIC and bilateral benefit-sharing. However, PGRFA in Annex I used for purposes other than breeding, research and training for food and agriculture and non-Annex I PGRFA are subject to PIC and bilateral benefit-sharing.

3 In addition, article 12.3(d), (d) of the ITPGRFA states: "[R]ecipients 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".

4 They may include, among others, the long periods that are necessary for developing and commercializing products based on obtained resources, the small number of countries that have implemented access legislation pursuant to the CBD, the cumbersome procedures established in some countries that have implemented it, and difficulties in negotiating and implementing cooperative research agreements. See, for example, Liebig K et al., in collaboration with the South East Asia Regional Initiatives for Community Empowerment. *Access to Genetic Resources and Approaches to Obtaining Benefits from their Use: the Case of the Philippines*, German Development Institute (GDI), Bonn, (2002); Cabrera Medaglia J. Bioprospecting: policy, regulatory and market incentives, paper presented at the Megadiverse Countries Meeting on Environmental Legislation on Access to Genetic Resources, Protection of Traditional Knowledge and Intellectual Property Rights, Cusco, November 27-29 2003; Caillaux Zazzali J and Ruiz Müller M. *Acceso a recursos genéticos. Propuestas e instrumentos jurídicos*, SPDA, Lima, 1999; Correa C. Traditional knowledge and intellectual property. A discussion paper, QUNO, Geneva, 2001, available at: http://www.quno.org; Febres ME *La Regulación del Acceso a los Recursos Genéticos en Venezuela*, CENDES, Caracas (2002); Barber CV, Glowka L and La Viña A. Developing and implementing national measures for genetic resources access regulation and benefit sharing, in: Laird SA, ed. *Equitable Partnerships in Practice: Research and Commercial Use of Biodiversity and Traditional Knowledge*, Earthscan, London, 2002; Rosenthal JP. Politics, Culture, and Governance in the Development of Prior Informed Consent, in: *Indigenous Communities, Cultural Anthropology*, Feb. 2006, 47(1): 119.

in developing countries that the absence of effective benefits is due, at least to some extent, to a mismatch between the CBD (and its implementing regulations, where they exist) and the protection of intellectual property rights (IPRs) as required by the WTO Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement) and provided for under national laws.[5]

WTO member States agreed to examine the relationship between the CBD and the TRIPS Agreement in the context of the "Millennium Round" of the WTO that was launched in November 2001. Subsequently, in paragraph 19 of the Doha Ministerial Declaration,[6] trade ministers instructed the TRIPS Council to examine, inter alia, the relationship between the TRIPS Agreement and the CBD. This process, however, has been slow and has not led to any concrete result so far.

Several proposals have been made to address the interface between the CBD and the TRIPS Agreement. An important one is the demand for recognition of an international obligation to disclose the origin of genetic resources (and associated traditional knowledge) claimed in patent applications. This proposal, discussed in the World Intellectual Property Organization (WIPO), WTO and CBD, aims at preventing misappropriation (biopiracy) of genetic resources and associated traditional knowledge, and at ensuring compliance with the prior informed consent and benefit-sharing provisions of the CBD.[7] In general, this international obligation would require patent applicants to disclose the source of genetic resources and associated traditional knowledge, along with relevant documentary information regarding compliance with access and benefit-sharing requirements.[8] The premise of the disclosure obligation is to make transparent the use of genetic resources and associated traditional knowledge leading to inventions for which patents are sought, and thereby to prevent violations of CBD access and benefit-sharing requirements and other inequitable conduct. Even without a new international obligation, existing national laws regarding CBD access and benefit-sharing requirements, as well as contracts providing for compliance with such requirements adopted under such national laws, already may require such disclosures in patent applications.[9]

The misappropriation of genetic resources and associated traditional knowledge by commercialization (including the acquisition of patents) is taking place on a global scale. Given the territoriality of patents, measures adopted at the national level are insufficient to prevent misappropriation in other jurisdictions, as the measures require recognition and enforcement by national governments of countries in which such misappropriation occurs. This is why other IPR holders have actively sought the adoption of international standards in WIPO and GATT/WTO. The establishment of an *international* obligation of disclosure of origin would provide a mechanism to monitor and eventually challenge the ownership or validity of patents that claim genetic resources and associated traditional knowledge obtained in breach of the respective access legislation. This includes cases where the patent

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5 Patent offices in many jurisdictions have extensively granted patent protection for genes, microorganisms and other life forms as well as for claimed inventions derived from traditional knowledge. In developing countries' view, these practices may conflict with the recognition of sovereign rights over the exploitation of genetic resources. This concern is particularly acute with regard to national patent systems that do not provide prior art status to undocumented traditional knowledge that was otherwise disclosed in foreign countries.

6 WTO document WT/MIN(01)/DEC/1, available at: http://www.wto.org.

7 See, for example, Declaration of Liked-minded Megadiverse Countries, Cancun, 18 February 2002, para. H, at: http://www.megadiverse.com/armado_ingles/PDF/three/three1.pdf.

8 See, for example, WIPO/GRTKF/IC/Q.3, Part I, Annex, available at: http://www.wipo.int/tk/en/consultations/questionnaires/ic-q3/responses.pdf; WIPO/IP/GR/05/03, available at: http://www.wipo.org; IP/C/W/368; IP/C/W/310 ; IP/C/W/198, IP/C/W/296, IP/C/W/341, available at: http://www.wto.org. See also Sarnoff J and Correa C. *Analysis of Options for Implementing Disclosure of Origin Requirements in Intellectual Property Applications*, UNCTAD/DITC/TED/2005/14, Geneva, 2006, available at: http://www.unctad.org/en/docs/ditcted200514_en.pdf.

9 See, for example, IP/C/W/368, available at http://www.wto.org.

would be considered *valid* under the applicable patent law.[10] Most importantly, it may permit realization of the benefit-sharing principles contained in the CBD and implemented in some national laws.

A patent ownership or validity challenge is decided according to the prescriptions of the law of the patent-granting country and would only take into account factors that are relevant under the applicable law. Such factors typically include whether the invention is new and whether the applicant is the true inventor, but in theory they may also take into account equitable restrictions on ownership interests. There are no limitations under the TRIPS Agreement with regard to the determination of inventorship or ownership.[11] However, in order to be effective, a disclosure obligation should aim at ensuring compliance with PIC and benefit-sharing requirements in the country where the genetic resources (and associated knowledge) were acquired, as elaborated by a number of developing countries in their submissions to the TRIPS Council.[12]

Purpose of this paper

The following illustrates the problem addressed in this paper:

> Company A obtained genetic resources and associated traditional knowledge from country X (hereinafter "providing country"), whose national law requires PIC and benefit-sharing in accordance with the CBD. Company A did not request or complete procedures to obtain PIC or, having obtained it, did not enter into or comply with an agreement for benefit-sharing. Based on the genetic resources and associated traditional knowledge obtained, company A applied for a patent in the country of grant (hereinafter "country of grant") where a patent was granted.

If a violation of a national access law or breach of a benefit-sharing contract occurred, to what extent could these events be used to challenge the award of patent rights in the country of grant, or to obtain remedial measures such as transfer of ownership interests in the application or granted patent, cancellation of the granted patent, or sharing of the commercial benefits acquired from the patent?

Such a challenge is currently extremely problematic, as the patent office/authority in the country of grant has no obligation to apply a foreign law when awarding patent rights. Similarly, if an authority in the providing country made a determination that national regulations or specific agreements had been violated, the patent authority in the country of grant would have no obligation to take account of that determination. An authority (such as

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[10] In some cases, individual countries or indigenous communities supported by non-governmental organizations (NGOs) have taken steps to challenge the validity of rights conferred in foreign countries over traditional knowledge or genetic resources, based on substantive patentability criteria. An example was a United States patent (No. 5.401.504), awarded to the University of Mississippi Medical Center in March 1995, over the use of turmeric in wound healing, which covered "a method of promoting healing of a wound by administering turmeric to a patient afflicted with the wound". The powder of the turmeric plant was a classic "grandmother´s remedy" in India. It had been applied to the scrapes and cuts of generations of children. In this case, upon request of India's Council for Scientific and Industrial Research (CSIR), the United States Patent and Trademark Office invalidated on 14 August 1997 the patent after ascertaining that there was no novelty. Lack of novelty was found on the basis of a 1953 article in the *Journal of the Indian Medical Association* and in Ayurvedic texts.

[11] See the Report of the WTO case, *United States-Section 211 Omnibus Appropriations Act of 1998* (WT/DS176/AB/R), where the appellate body (supporting the panel's view) held that neither the TRIPS Agreement nor the Paris Convention addresses the question of how the ownership of a trademark is determined, and that this is an issue to be determined by national law (paras. 188-189). The same doctrine is arguably valid for patents and other IPRs.

[12] See IP/C/W/ 420, IP/C/W/420 Add. 1 and IP/C/W/429.

a court) in the country of grant might, however, act on the basis of the principle of "comity", that is, the voluntary recognition of the legislative, executive, or judicial acts of another State (subject to principles of international law and the protection of domestic public interests). It might also apply, where pertinent, the mechanisms provided for under conventions for the recognition of arbitral awards and foreign judgments. The main problem, as examined below, is that if the country of grant does not provide such a voluntary recognition of a foreign determination, the ownership and validity of the patent would only be judged according to the domestic law of the country where protection is sought or recognized. This principle of "territoriality" is a basic tenet of intellectual property law.[13]

This paper outlines some possible elements of an international legal regime aimed at ensuring recognition by the country of grant of determinations made under the national regulations of the providing country relating to access to genetic resources and associated traditional knowledge, benefit-sharing and PIC.[14]

The paper first examines some examples of access-related legislation adopted pursuant to the CBD and, in particular, the modalities under which the PIC and benefit-sharing obligations have been implemented nationally. Second, it discusses issues pertaining to the acquisition of IPRs, and focuses on the implications of the principle of territoriality as applied to those rights. Third, it briefly refers to international conventions that may facilitate the enforcement in foreign jurisdictions of arbitral awards and judgments, and the limitations in their application to the problem presented above. Finally, the paper provides a preliminary discussion of some of the issues to be addressed in a possible international regime for the recognition of foreign determinations made on the basis of national access legislation.

It is important to emphasize that the eventual adoption of such an instrument, as proposed in this document, would be without prejudice to the introduction in the TRIPS Agreement and other relevant instruments of an international binding obligation on disclosure of origin. In fact, such an instrument and an international obligation would be mutually supportive and would contribute to a more effective implementation of the CBD principles and objectives, and to improvements in the granting of IPRs involving genetic resources and associated traditional knowledge.

[13] Although there are a number of ongoing projects and litigation that would develop a private international law on intellectual property, none are likely to change this basic principle.

[14] Hereinafter referred to in this paper as "access legislation".

II. Background

Flexibility in implementing the CBD

The CBD is grounded, as mentioned, in the recognition of the sovereign rights of States to exploit their genetic resources pursuant to their own environmental policies.[15] Each contracting party shall endeavor to create conditions that facilitate access to genetic resources for environmentally sound uses by other contracting parties and not to impose restrictions that run counter to the objectives of the Convention (article 15.2). However, access is not automatic, but shall be granted on mutually agreed terms and subject to the prior informed consent of the country providing the genetic resources.[16]

The CBD sets out a framework to regulate international action by contracting parties in the field of biodiversity. Many of the provisions define the objective to be achieved (e.g. equitable benefit-sharing) without specifying how it could be attained. Contracting parties have broad flexibility under the CBD to shape access legislation in order to implement the Convention's rights and obligations.[17] The capacity of countries to choose the method of implementing their international rights and obligations is a well-established principle under international law.[18]

Despite the general support that the CBD receives from developing countries, a relatively limited but growing number of them have implemented the CBD rules domestically through access legislation.[19] In 2002, the sixth Conference of the Parties (COP) of the CBD adopted voluntary guidelines (the Bonn Guidelines) to address access to genetic resources and fair and equitable benefit-sharing arising from use of those resources.[20] This, along with the possible adoption of an international regime to implement access and benefit-sharing requirements,[21] may encourage the enactment of national access legislation by a larger number of countries in the years to come.

Access legislation is sometimes contained in special laws (e.g. Provisional Measure No. 2.186-16, 2001, of Brazil; Biodiversity Law No. 7788, 1998, of Costa Rica), or regulations (e.g. Philippines' Executive Order (EO) No. 247 "Prescribing Guidelines and Establishing

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15 According to article 3 on "Principle", "States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction". Sovereign rights over genetic resources located within the territory of States is also reflected in the CBD Preamble ("*Reaffirming that States have sovereign rights over their own biological resources*") and Section 2 on Definitions ("'Country of origin of genetic resources' means the country which possesses those genetic resources in *in-situ* conditions"), as well as article 15.1 ("Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.").

16 See paragraphs 4 and 5, article 15, of the CBD.

17 Illustrative of this room for manoeuvre is the adoption of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) of the Food and Agriculture Organization of the United Nations (FAO), which establishes special rules for access to and benefit-sharing in relation to plant genetic resources for food and agriculture. Its objectives are the conservation and sustainable use of plant genetic resources and fair and equitable benefits arising out of their use, *in harmony with the CBD*, for sustainable agriculture and food security. It establishes a multilateral system of access to and benefit-sharing from plant genetic resources for a list of 35 food crops and 29 forage genera crops selected on the basis of interdependence and food security.

18 See, for example, article 1.1 of the TRIPS Agreement.

19 See http://www.grain.org/brl/?typeid=20.

20 UNEP/CBD/COP/6/20, § 3 and Annex, available at: http://www.biodiv.org/doc/decisions/COP-06-dec-en.pdf.

21 See COP Decision VII/19.

a Regulatory Framework for the Prospecting of Biological and Genetic Resources, their By-products and Derivatives, for Scientific and Commercial Purposes, and for Other Purposes"). In other countries prior informed consent and benefit-sharing obligations are not prescribed in a single legal instrument, but in several pieces of legislation. For example, in India, the Biological Diversity Bill (2000) applies to all activities affecting biodiversity, though some matters affecting biodiversity are also governed by the Protection of Plant Varieties and Farmers' Rights Act, 2001 (Plant Varieties Act). Both the Plant Varieties Act and the Bill include benefit-sharing rules, but each sets up its own distinct mechanisms. The procedures for granting benefit-sharing are set out in the Plant Varieties Act in greater detail than in the Biological Diversity Bill. In Costa Rica, an access regime was adopted under the Biodiversity Law No. 7788 of 1998, but most bioprospecting contracts have been issued under the Law of Wild Life Conservation No. 7317 of October 21, 1992, and its regulation No. 26435-MEE of December 3, 1997.

In some countries that have adopted access legislation, one single authority is competent to deal with access applications, often with the intervention of other entities or interdepartmental committees, such as the Inter-Agency Committee on Biological and Genetic Resources (IACBGR) of the Philippines. In other countries several authorities may intervene. This is the case in Peru, where the Instituto del Mar del Peru (IMARPE) is competent for marine resources, the Instituto Nacional de Recursos Naturales (INRENA) for any application involving wild species and wild relatives of domesticated species, and the Instituto Nacional de Investigación Agrícola (INIA) for domesticated plant species.

Unlike other areas of law, such as trade law,[22] there is no principle in this field that requires countries to publish or notify laws and regulations applicable to access to genetic resources, or to make public final judicial decisions and administrative rulings of general application pertaining to that area. National competent authorities have generally exercised considerable discretion in determining the conditions for any grant of access to genetic resources according to the circumstances of each particular case. In many countries, there are no documented guidelines or criteria for decisions by competent authorities, which results in casuistic application of the access regimes.[23]

As this analysis suggests, a possible regime for the international recognition of determinations on access to genetic resources will have to recognize and operate in a context of considerable legal and institutional diversity, since the CBD only provides a general framework for domestic regulations, and countries can shape their access regimes according to their diverse legal and administrative practices and circumstances. Further, national legislation that implements the CBD generally leaves considerable discretion to national competent authorities in the application of domestic regimes.

Scope of access legislation

The scope of access legislation enacted pursuant to the CBD will, in principle, determine the situations in which the application of a disclosure obligation may be triggered. Three aspects are relevant for the present discussion.

First, access legislation generally regulates access to genetic resources held both in *ex situ* and *in situ* conditions. Hence, a disclosure of origin obligation would apply whether the materials claimed in a patent have been collected in the field (for instance, directly obtained from farmers or indigenous communities) or acquired through institutions holding such

[22] See, for example, Article X of GATT; Article 63 of the TRIPS Agreement on "Transparency".

[23] See, for example, Correa C, Are access regimes promoting the use of genetic resources and benefit sharing? *International Journal of the Environment and Sustainable Development* (forthcoming).

materials (such as botanical gardens or gene banks), which may be located in countries other than those from where the materials were originally collected.

In some cases, access legislation is also applied to physical and information products *derived* from genetic resources.[24] The extent to which access to such products would trigger a disclosure of origin obligation raises complex issues,[25] notably as the concept of "derivation" is not univocal and, if broadly defined, it may extend the application of the obligation to a large number of cases. In situations involving derivation, it may be difficult to establish when that obligation will cease to apply. However, failing to include derivatives may drastically undermine the achievement of the main objectives of access legislation.

Second, access regulations apply not only to access to and transfer of genetic resources with commercial intent, but also to cases where the objectives are merely of a scientific or conservationist nature. In fact, most access applications in the Andean countries were made by researchers or academic institutions, some of which were working in partnership with private companies on bioprospecting projects.[26] In the Philippines, if research and collection of biological and genetic resources is intended directly or indirectly for commercial purposes, the agreement to be entered into is considered a commercial research agreement. If the prospecting of biological and genetic materials is intended primarily for academic purposes, the agreement constitutes an academic research agreement. The relevant executive order distinguishes the conditions applicable to each of these agreements.[27] One problem with this distinction is that in most cases an initially scientific activity may lead to commercial applications.

Third, access legislation generally applies to bioprospecting and other relevant activities in the national territory by natural and legal persons domiciled in the country and abroad. This means that such legislation ordinarily has both domestic and international dimensions. The latter is limited, however, to situations arising from the acquisition of materials within the national territory. Cases[28] in which materials have been obtained in foreign jurisdictions are not covered, including where IPRs were claimed in the country applying the access legislation.

Acquisition and validity of intellectual property rights

As examined elsewhere,[29] some countries have established in their domestic legislation an obligation to disclose the origin of the biological materials claimed in patent applications. In India, the Biological Diversity Bill has gone a step further. Consent by the National Biodiversity Authority is required to apply for IPRs in *or outside* India for any invention

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[24] See, for example, Decision 391 of the Andean Community, which defines "access" in article 1 as "the obtaining and use of genetic resources conserved *in situ* and *ex situ*, of their by-products and, if applicable, of their intangible components, for purposes of research, biological prospecting, conservation, industrial application and commercial use, among other things" (emphasis added). "By-product" is, in turn, defined as "a molecule, a combination or mixture of natural molecules, including crude extracts of live or dead organisms of biological origin that come from the metabolism of living beings".

[25] With regard to derivatives of plant genetic resources, see, for example, Fowler C, et al. The question of derivatives – Promoting use and ensuring availability of non-proprietary plant genetic resources, *Journal of World Intellectual Property*, 2004, 7(5): 641-663.

[26] See, for example, Correa C. The access regime and the implementation of the FAO International Treaty on Plant Genetic Resources for Food and Agriculture in the Andean Group countries, *The Journal of World Intellectual Property*, November 2003, 6(6): 795-806.

[27] See Executive Order No. 247, 1995, Prescribing Guidelines and Establishing a Regulatory Framework for the Prospecting of Biological and Genetic Resources, their By-products and Derivatives, for Scientific and Commercial Purposes, and for Other Purposes.

[28] The CBD obligations for prior informed consent and benefit-sharing apply under Article 15.3, 15.5 and 15.7 to contracting parties that provide genetic resources and that are countries of origin or have acquired the resources "in accordance with this Convention."

[29] See, for example, IUCN, ICTSD, CIEL, IDDRI, QUNO. *Disclosure requirements: Ensuring mutual supportiveness between the WTO TRIPS Agreement and the CBD*, 2005. Available at http://www.iprsonline.org/resources/docs/Disclosure_req_book.pdf.

based on research or information on Indian biological resources (section 6).[30] Although the Authority certainly cannot prevent such rights from being granted in a foreign country, it may oppose the granting of such IPRs in any country (section 19(4)).[31]

Similarly, Decision 391 (1996) of the Andean Community establishes that any IPRs or other claims to genetic resources shall not be considered valid if they were obtained or used in violation of the terms of a permit for access to biological resources found in any of the Andean countries, as regulated under that Decision. The member countries "shall not acknowledge rights, including intellectual property rights, over genetic resources, by-products or synthesized products and associated intangible components that were obtained or developed through an access activity that does not comply with the provisions of this Decision" (second complementary provision). However, the reach of this provision is limited, by its own terms, to rights granted in any of the members of the Andean Community; that is, it has no extraterritorial effects (although other countries might choose to recognize and enforce the limitations established by the Decision).

Despite the process of harmonization that has taken place under the TRIPS Agreement and other conventions, and the international procedures available under the Patent Cooperation Treaty, the granting and validity of patents and other IPRs continue to be firmly based on the principle of territoriality.[32] According to this principle, issues relating to the acquisition, including eligibility for protection, and validity of IPRs are solely subject to the law of the country where protection is sought or obtained (*lex loci protectionis*).[33]

The relevant issue for the purpose of this analysis is the extent to which foreign administrative or judicial authorities would be bound to recognize rights claimed by different parties, including States, as the basis for the review or revocation of IPRs that may have been granted in conformity with the applicable national law in the country of grant, but involving conduct that violates access legislation of another country, such as the failure to obtain PIC.

In the absence of international rules on the matter, nothing prevents a country from granting and sustaining the ownership or validity of patents obtained in accordance with its own *domestic* legal requirements. Hence, whether or not the claimed genetic resources and associated traditional knowledge have been obtained in violation of a foreign access legislation would, in principle, be irrelevant for the purposes of the application of substantive

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30 However, if such consent were not requested and conferred, the validity of a foreign patent could not be contested on the grounds of non-compliance with Indian law, unless the authority in the country where protection is sought recognized the extraterritorial effects of such a law. This limitation is illustrative of the kinds of problems developing countries face in enforcing CBD principles.

31 In the Indian Patent (Second Amendment) Bill 1999, the grounds for rejection of the patent application, as well as revocation of the patent, include non-disclosure or wrongful disclosure of the source of origin of the biological resource or knowledge in the patent application, and anticipation of knowledge, oral or otherwise. It is also incumbent upon patent applicants to disclose in their patent applications the source of origin of the biological material used in the invention.

32 Moreover, in the case of patents, the principle of *independence* applies. In accordance with article 4bis of the Paris Convention for the Protection of Industrial Property, "(1) Patents applied for in the various countries of the Union by nationals of countries of the Union shall be independent of patents obtained for the same invention in other countries, whether members of the Union or not. (2) The foregoing provision is to be understood in an unrestricted sense, particularly in the sense that patents applied for during the period of priority are independent, both as regards the grounds for nullity and forfeiture, and as regards their normal duration."

33 In the United States, however, courts have made reference in some cases to the grant or denial of a foreign mark to help apply the doctrine of foreign equivalents; that is, the determination under foreign law has helped to apply the United States law. See Otokoyama Co. v. Wine of Japan Imp. Inc. 175 F.3d 266, 273 (2d Cir. 1999); see also Orto Conserviera Sameranese di Giacchetti Marino & C. v. Bioconserve S.R.L., 49 U.S.P.Q.2d 2013, 2015 (S.D.N.Y. 1999) (considering evidence of foreign usage relevant to a determination of a mark's genericness).

criteria of patentability. The patent laws of various countries are also unclear as to whether such violations could be considered as fraud or other misconduct, or whether they could lead to the refusal of a grant under inventorship rules.

Although the recognition of a foreign law, or of the determination made thereon, would conflict with the received understanding of the territoriality principle,[34] there are several situations in international intellectual property law where exceptions to that principle have been accepted,[35] such as article 6 *quinquies* (A)(1)[36] and article 6*bis* (1)[37] of the Paris Convention. In these cases, however, the countries where the protection is sought retain the right to apply exceptions (such as Article 6*quinquies*(1)(B) with regard to the recognition of trademarks "*telle quelle*"). Other examples of extraterritorial application are found in agreements[38] that recognize foreign geographical indications as protected in a foreign country, as established in some bilateral and multilateral conventions. Thus, the Lisbon Agreement for the Protection of Appellations of Origin and their International Registration (1958) provides that the countries party to it undertake to protect on their territories, in accordance with the terms of the Agreement, the appellation of origin of products of the other contracting parties, recognized and protected as such in the country of origin[39] and registered with the International Bureau of the World Intellectual Property Organization (WIPO). More recently, the European Communities and their member States have proposed[40] an international registration system for geographical indications for wines and spirits, under which registered indications would be automatically protected in the participating members, subject to a procedure for dealing with oppositions from each member that considers a geographical indication is not eligible for protection in its territory.[41]

The application of the principle of territoriality of patents was addressed in the WTO Decision of August 30, 2003, which was incorporated as a formal amendment to the TRIPS Agreement in December 2005. The new Article 31bis(3) of the Agreement allows,

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34 Prof. Dinwoodie has argued, however, that there is no single obvious meaning to "territoriality"; hence, if the patent in Y uses the resources taken from X, there is an argument that both the State X and State Y have interests in the granting of the patent, and that there are two "territories" implicated (personal communication of June 2006, on file with the author).

35 See, for example, Dinwoodie G. Towards an international framework for the protection of traditional knowledge, paper prepared for UNCTAD, 2004, available at: http://www.unctad.org/trade_env.

36 "Every trademark duly registered in the country of origin shall be accepted for filing and protected as is in the other countries of the Union, subject to the reservations indicated in this Article. Such countries may, before proceeding to final registration, require the production of a certificate of registration in the country of origin, issued by the competent authority. No authentication shall be required for this certificate".

37 "The countries of the Union undertake, ex officio if their legislation so permits, or at the request of an interested party, to refuse or to cancel the registration, and to prohibit the use, of a trademark which constitutes a reproduction, an imitation, or a translation, liable to create confusion, of a mark considered by the competent authority of the country of registration or use to be well known in that country as being already the mark of a person entitled to the benefits of this Convention and used for identical or similar goods. These provisions shall also apply when the essential part of the mark constitutes a reproduction of any such well-known mark or an imitation liable to create confusion therewith".

38 Some court decisions have loosened the requirements of the actions that must be completed in the country of recognition of an IPR for a finding of liability for exploitation of the protected subject matter abroad. See, for example, Halewood M. Common law aboriginal knowledge protection rights: Recognizing the rights of aboriginal peoples in Canada to prohibit the use and dissemination of elements of their knowledge, dissertation submitted to the faculty of Graduate Studies of York University, Toronto, Canada, 2005: 294.

39 Article 2(2) defines the country of origin as being "the country whose name, or the country in which is situated the region or locality whose name, constitutes the appellation of origin which has given the product its reputation."

40 See IP/C/W/107, 28 July 1998.

41 These derogations to the territoriality principle have found considerable resistance by some countries, as exemplified by the limited adherence to the Lisbon Agreement for the Protection of Appellations of Origin and their International Registration, and by the ongoing debate on geographical indications in WTO. See, for example, Bowers S. Location, location, location: the case against extending geographical indication protection under the TRIPS Agreement', *AIPLA Quarterly Journal*, 2003, 31(2): 129-164.

inter alia, re-exportation of a pharmaceutical product to a developing or least developed country (LDC) that is a party to a regional trade agreement, at least half of the current membership of which is made up of countries listed as LDCs. The provision clarifies that "[I]t is understood that this will not prejudice the territorial nature of the patent rights in question". However, Article 31bis contains aspects that limit the territoriality of patent rights. According to the new appendix to the Annex to the TRIPS Agreement, members are bound to recognize the determination by another eligible importing member of "insufficient or no manufacturing capacities" for certain pharmaceutical product(s),[42] for the purposes of granting a compulsory licence (in the exporting member).[43]

In sum, derogations to the territoriality principle are not unknown in the intellectual property field. The more difficult issue concerns the extent to which governments would be prepared to accept a new type of derogation to protect foreign interests, especially those that are not covered by the intellectual property regimes as such, as is the case with compliance with PIC requirements and benefit-sharing. This derogation would be more radical than that proposed for geographical indications, or eventually for exports of medicines, as it would threaten the very existence or enforceability of the patent rights. However, such a departure from the territoriality principle would be justified on equity grounds, because the grant of patent rights in cases of misappropriation of genetic resources and their associated knowledge would be contrary to international legal principles and the relevant national laws, and would therefore be unjust.

Enforcing foreign judgments and arbitral awards

States and other interested parties willing to challenge the granting of rights in a foreign jurisdiction due to misappropriation or to non-compliance with PIC requirements or benefit-sharing obligations may initiate administrative or legal actions in the country where such rights have been applied for or recognized. However, this is not simple for most developing countries, since litigation in foreign jurisdictions is costly, especially in cases involving patent validity or other complex technical matters (see below). Moreover, foreign courts may not easily accept evidence generated abroad. Alternatively, the States or other parties can first seek a court decision, such as a declaratory judgment, in their own country and subsequently pursue the enforcement thereof in the jurisdiction where the complaining party is domiciled or the rights are sought or obtained.[44]

National laws generally recognize foreign judgments on the basis of the principle of comity. Under common law, the decision to recognize a foreign judgement or not depends on an analysis of various factors, such as procedural fairness, impartial justice between

[42] This determination may be made in either of the following ways: "(i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector; or (ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply".

[43] The exporting country, however, is not *required* to grant a compulsory licence, thereby mitigating the possible derogation of the territoriality principle.

[44] A judgment may formally need recognition and enforcement in each country, but sometimes the issue may be resolved in a single legal action in one country (e.g. opposition to patents issued by the European Patent Office). Even if not decided for all countries in a single action, the initial decision regarding lack of compliance with access legislation might be given "collateral estoppel" effect, which bars relitigation of the same issue by the patentee in another jurisdiction.

aliens and citizens, and absence of fraud.[45] Under continental law, a reciprocal treatment between the foreign country and the country where the judgement originates is generally important, in addition to due process and public order considerations.[46] There exist bilateral and international treaties on reciprocal recognition and enforcement of judgments between States that may be applied. For example, the Hague Convention on the Recognition and Enforcement of Foreign Judgments in Civil and Commercial Matters (concluded 1 February 1971 and entered into force on 20 August 1979) applies to decisions rendered in civil or commercial matters by the courts of contracting States,[47] provided that they are no longer subject to ordinary forms of review in the State of origin. The recognition is not subject to review of the merits of the decision rendered by the court of origin (article 8), and the authority addressed shall be bound by the findings of fact on which that court based its jurisdiction, unless the decision was rendered by default (article 9). However, the jurisdiction of the court of the State of origin need not be recognized by the authority addressed, *inter alia*, if the law of the State addressed confers upon its courts exclusive jurisdiction, either by reason of the subject matter of the action or by virtue of an agreement between the parties as to the determination of the claim which gave rise to the foreign decision (article 12(1)).

The applicability of the Hague Convention to cases relating to access and benefit-sharing may be limited, as it applies only to civil or commercial matters (article 1). Whereas disputes relating to compliance, for instance with a benefit-sharing contract, may be deemed under some circumstances[48] as being subject to the Convention, non-compliance with prior informed consent may not. Moreover, decisions relating to the validity of granted patents, as discussed, are subject to the law of the recognizing country (*lex loci protectionis*) and to the exclusive jurisdiction of its courts.

An additional complication is that in most cases, the judgment obtained in the providing country (where a violation of the access regime has occurred) will not be a judgment regarding the patent in the country where it is granted. Rather, it will be a judgment regarding ownership interests or equity that may be used in litigation involving the patent in the country of grant, but which does not directly address its validity or enforceability. This is important, because the nature of the recognition and enforcement may need to be much broader:[49] it should involve issues subject to patent law in the country of grant, not specifically litigated in the providing country.

The Convention on Choice of Court Agreements (concluded on 30 June 2005, and not yet in force)[50] applies in international cases to exclusive choice of court agreements concluded in civil or commercial matters.[51] Article 2 stipulates that the Convention does not apply to

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45 In the United States, for instance, the holder of a foreign judgment, decree or order must file suit before a competent court in that country, which will determine whether to give effect to the foreign judgment relying on the Uniform Enforcement of Foreign Judgments Act, 13 U.L.A. 261 (1986) and the Uniform Foreign Money-Judgments Recognition Act, 13 U.L.A. 149 (1986). See also the Council Regulation (EC) No. 44/2001 of 22 December 2000 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters.

46 See United Nations University (UNU)-Institute of Advanced Studies (IAS), User Measures. Options for Developing Measures in User Countries to Implement the Access and Benefit–Sharing Provisions of the Convention on Biological Diversity, 2nd edition, 2003, available at: http://www.ias.unu.edu/news/details.cfm/articleID/458, p. 36.

47 Sixty five States are parties to this Convention, including France, Germany, Japan, Switzerland the United Kingdom and the United States.

48 Thus, material transfer agreements entered into between public gene banks and research institutions may be deemed non-commercial contracts.

49 Typically, the issues addressed by recognition and enforcement relate to restoring possession of tangible goods or to executing judgments against tangible property located in other countries.

50 Only Mexico has ratified the Convention so far.

51 The basic obligation established by the Convention is that the court or courts of a contracting State designated in an exclusive choice of court agreement shall have jurisdiction to decide a dispute to which the agreement applies, unless the agreement is null and void under the law of that State (article 5.1).

exclusive choice of court agreements relating, *inter alia*, to the validity of IPRs other than copyright and related rights (article 2(n)), and to "infringement of intellectual property rights other than copyright and related rights, except where infringement proceedings are brought for breach of a contract between the parties relating to such rights, or could have been brought for breach of that contract" (article 2 (o)). The Convention on Choice of Court Agreements may be of relevance, given its scope, to address issues relating to misappropriation of genetic resources and non-compliance with PIC and benefit-sharing obligations, but only in cases where contracts involve "civil or commercial matters" and the choice of courts has been agreed upon.[52] It should be borne in mind, however, that this Convention is useful only in terms of establishing jurisdiction; it does not have a recognition component like that of the Hague Convention.

National access laws and regulations do not generally refer to arbitration as a mechanism for the enforcement of the rights and obligations created thereunder. There may be situations, however, in which a private party and the State may agree, in access or benefit-sharing contracts, to submit a dispute to arbitration.[53] If claims relating to non-compliance with PIC or benefit-sharing were submitted to arbitration, the enforceability of a final award could be ensured through the application of the New York Convention on the Recognition and Enforcement of Foreign Arbitral Awards (1958). More than 130 countries are parties to this Convention. It obliges the courts of contracting States to recognize and enforce foreign arbitral awards, as well as to recognize arbitration agreements made in writing, and to refuse to allow a dispute to be litigated before them when it is subject to an arbitration agreement.

There could also be a situation where a private party may have recourse to arbitration against a State that applies access legislation. Rights emerging from an access contract may be deemed an "investment" under the standard definition of bilateral investment agreements (BITs), as such a definition generally covers licences, authorizations, permits and similar rights conferred pursuant to applicable domestic law. For example, the Canada-Argentina BIT (1993) defines investment as inclusive of "a right conferred by law or under contract to search for, cultivate, extract or exploit natural resources" (article I(a)(v)).[54] Hence, if an access contract were to be invalidated, the affected private party might consider that its "investment" had been jeopardized, provided that the authorization to get access created rights that are protected under domestic law.[55]

CBD mechanisms

Article 3 of the CBD requires members to ensure that "activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction", and Article 5 deals with the types of cooperation that are

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[52] In view of the foreseen limited scope of the Convention with regard to intellectual property, some scholars have proposed a Convention on jurisdiction and recognition of judgments in intellectual property matters. See Dreyfuss R and Ginsburg J. Draft convention on jurisdiction and recognition of judgments in intellectual property matters, *Chicago-Kent Law Review*, 2002, 7(3):1065–1153.

[53] For instance, under the terms of an agreement for the collection and use of traditional knowledge, negotiated within the framework of the International Collaborative Biodiversity Group Program (ICBG) in Peru, the parties agreed to submit disputes to arbitration in New York under the rules of the American Arbitration Association. See United Nations University (UNU)-Institute of Advanced Studies (IAS). op. cit.: 36.

[54] See also Canada-Lebanon BIT, 1997, (article I(d)(vi)); and Correa C. Bilateral investment agreements: Are they leading to new global standards for the protection of intellectual property rights? 2004, Available at: http://www.grain.org.

[55] See, for example, the definition of "investment" under article 1, footnote 2, of the United States Model BIT (2004).

expected to make the CBD work.[56] Moreover, a country that is party to the CBD recognizes third State sovereignty over genetic resources. If the CBD is deemed self-executing[57] (and this varies from State to State), government authorities representing third States could file a claim of misappropriation before the national courts of the country that improperly recognizes patent rights. If the treaty is not deemed self-executing, a claim may be submitted to the arbitration mechanism of the CBD – which provides for the adoption of awards that are binding on the contracting parties[58] – or before the International Court of Justice (ICJ).[59] The argument could be made in these cases that a State that is a contracting party[60] is obligated to provide a mechanism by which the sovereign rights over genetic resources can be upheld in order to give effect to the obligations under the CBD. Although such procedures could establish some precedents of use to claimants in local courts, they would admittedly be cumbersome and costly. Moreover, they could only be initiated by the contracting parties and not by traditional/indigenous communities directly affected by a case of misappropriation.

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[56] Article 5 states: "Each Contracting Party shall, as far as possible and as appropriate, cooperate with other Contracting Parties, directly or, where appropriate, through competent international organizations, in respect of areas beyond national jurisdiction and on other matters of mutual interest, for the conservation and sustainable use of biological diversity".

[57] A treaty is considered self-executing when its obligations become enforceable within a jurisdiction merely with its ratification, without the need for adopting implementing legislation.

[58] See Annex II, Part 1, article 16 of the CBD.

[59] Article 27 of the CBD states: "1. In the event of a dispute between Contracting Parties concerning the interpretation or application of this Convention, the parties concerned shall seek solution by negotiation. 2. If the parties concerned cannot reach agreement by negotiation, they may jointly seek the good offices of, or request mediation by, a third party. 3. When ratifying, accepting, approving or acceding to this Convention, or at any time thereafter, a State or regional economic integration organization may declare in writing to the Depositary that for a dispute not resolved in accordance with paragraph 1 or paragraph 2 above, it accepts one or both of the following means of dispute settlement as compulsory: (a) Arbitration in accordance with the procedure laid down in Part 1 of Annex II; (b) Submission of the dispute to the International Court of Justice. 4. If the parties to the dispute have not, in accordance with paragraph 3 above, accepted the same or any procedure, the dispute shall be submitted to conciliation in accordance with Part 2 of Annex II unless the parties otherwise agree. 5. The provisions of this Article shall apply with respect to any protocol except as otherwise provided in the protocol concerned."

[60] None of this will bind the United States – where most cases of biopiracy have occurred due to the relatively low standard of novelty that is required there for a patent to be granted – because the United States has not ratified the CBD.

III. Possible elements of an international regime for the recognition of foreign determinations made on the basis of access legislation

Objectives

The fundamental objectives of an international regime for the recognition of foreign determinations made on the basis of access legislation would be:

a) To prevent the misappropriation, with or without commercial intent, of genetic resources and associated traditional knowledge, including their derivatives; and
b) To ensure compliance with access legislation, both with regard to PIC requirements and benefit-sharing.

The need to ensure compliance with access legislation may arise either where a party gains access to genetic resources without PIC and mutually agreed terms, or where a party gains access pursuant to an access agreement but subsequently uses those genetic resources in ways that are not allowed by the agreement or that otherwise fail to comply with the contractual benefit-sharing provisions.

Where the national access laws of countries that provide genetic resources are violated, there is a notable lack of remedies available to those countries. This constitutes a significant gap in the implementation of the CBD principles and obligations. In particular, countries lack an effective means to enforce remedial measures when alleged infringers are located outside the providing country. Misappropriation through patents or other titles is one of the situations where such a gap is the most evident, given the territoriality of both access laws and IPRs. The absence of mechanisms for the recognition and enforcement in foreign countries of court judgments made in the providing country, and the limited membership of international agreements for the enforcement of arbitral awards, seriously limit the scope for action in cases where misappropriation of genetic resources has taken place.

As mentioned, an obligation to disclose the source of biological resources and/or traditional knowledge used in inventions has been proposed to promote compliance with the CBD principles and obligations. Such an obligation may not only contribute to make such principles and obligations effective, particularly in relation to prior informed consent and benefit-sharing, but it may also assist patent offices.[61] A disclosure of origin obligation would help to ensure that all relevant prior art information is available to patent offices as they assess the patentability of a claimed invention or address disputes on inventorship or entitlement.[62] The same applies to other IPRs, notably breeders' rights with regard to plant variety protection through the Union for the Protection of New Varieties of Plants (UPOV).[63] The international instrument proposed in this paper would be without prejudice to the current efforts to amend the TRIPS Agreement and introduce such an obligation in a new paragraph under article 29 of that Agreement.[64]

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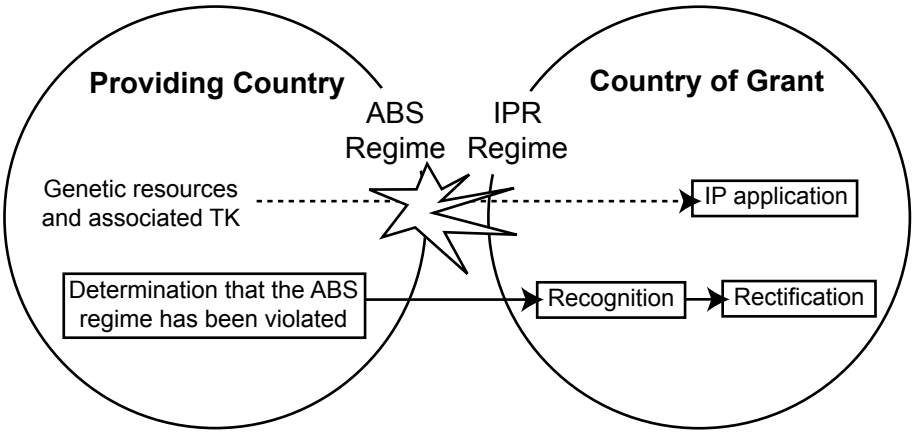
[61] See, for example, WTO. Elements of the obligation to disclose the source and country of origin of biological resources and/or traditional knowledge used in an invention – submission by the Bolivarian Republic of Venezuela, Brazil, India, Pakistan, Peru and Thailand IP/C/W/429 of 21 September 2004, para. 4-5.

[62] A disclosure obligation may also provide the courts with relevant information to address those issues as well as infringement cases, thereby contributing to a proper functioning of the patent system.

[63] Note, however, that the UPOV's Council addressed the obligation to disclose the origin of plant materials on the following terms: "UPOV encourages information on the origin of the plant material, used in the breeding of the variety, to be provided where this facilitates the examination [for distinctness], but could not accept this as an additional condition of protection ... Indeed, in certain cases, for technical reasons, applicants may find it difficult, or impossible, to identify the exact geographic origin of the material used for breeding purposes". Equally, "UPOV encourages the principles of transparency and ethical behaviour" (UPOV C/37/21, Annex III).

[64] See WTO documents IP/C/W/474 (2006) and IP/C/W/475 (2006).

Figure 1. Illustration of the basic concept behind the proposed regime



Note: ABS = Access and benefit-sharing

The above diagram illustrates the basic concept behind the proposed agreement.

Box 1. Preamble[1]

The Preamble of a possible international instrument may read as follows:

Reaffirming that States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources,

Noting the principles and obligations of the Convention on Biological Diversity (CBD),

Convinced that compliance with the benefit-sharing obligations provided for under the CBD, in accordance with national legislation, is essential for the global conservation and sustainable use of genetic resources,

Stressing that the acquisition and enforcement of intellectual property rights, consistently with the WTO Agreement on Trade-related Aspects of Intellectual Property Rights, should be compatible with the principles and obligations set forth by the CBD,

Noting that cases of misappropriation of genetic resources and their associated traditional knowledge have been reported in different jurisdictions,

Recognizing that the existing international conventions for the enforcement of foreign judgements and arbitral awards may play a role in providing remedies in cases of non-compliance with national access laws,

Convinced that an international agreement that facilitates the recognition of foreign determinations made on the basis of access legislation will help provide an effective solution to the problems of misappropriation of genetic resources and associated traditional knowledge, and

Emphasizing that the adoption of such an agreement should be without prejudice to the possible establishment of an international binding obligation on disclosure of origin in the TRIPS Agreement and other relevant instruments,

The Parties to this International Agreement [on the Recognition of Foreign Determinations on Compliance with Access Legislation] have agreed as follows:

[1] The wording presented in this and the following boxes is illustrative of the type of legal formulation that could be given to the elements discussed in the paper. It is not intended to provide definitive treaty wording. The proposed agreement may be rather simple and only contain a preamble and a few provisions.

The objectives of a possible international agreement for the recognition of foreign determinations made on the basis of access legislation may be spelt out in a preamble (box 1). The preamble to a treaty is an essential element that provides the context for the interpretation of the treaty's obligations.[65]

Scope

The proposed international agreement would be applicable to a party when an IPR has been granted involving claims over genetic materials and associated traditional knowledge supplied from another party (box 2).

Box 2. Application of the proposed Agreement

1. This Agreement shall apply when an intellectual property right has been applied for or has been granted in a Party. For the purposes of this Agreement, an "intellectual property right" is a patent application or grant involving claims over genetic resources and associated traditional knowledge accessed in another Party under the conditions laid down in 2(c) below. Parties may also apply this Agreement to plant breeders' rights granted in their jurisdictions.

The Agreement would apply when patents are applied for or granted. It could be optionally applied to plant breeders' rights. The scope of the Agreement, as defined, would not extend to eventual disputes exclusively based on contractual rights or other types of claims.

Covered determinations

Although, as noted above, there are some exceptions to the principle of territoriality as applied to IPRs, in general lawsuits over the alleged illegal granting of intellectual property in foreign countries have to be brought in countries where such rights are granted or otherwise recognized, pursuant to their national legislation.

National access laws could require specific language regarding dispute resolution to be included in access and benefit-sharing contracts. The agreement's provisions might stipulate, for instance, that the parties consent to take a dispute regarding IPRs relating to accessed resources to the courts of the country of grant, and that they recognize the determinations made by an authority in the providing country with regard to non-compliance of a contract. This would be within the contractual freedom normally enjoyed by contracting parties. However, in the absence of an access agreement, or of such specific provisions in the agreement, there would be no legal grounds for a court in the country of grant to give legal effect to determinations made in the providing country. In addition, contractual provisions on the matter might also be challenged in court and be subject to a judicial evaluation on the grounds of local public interest.[66]

An international regime, as proposed here, for the recognition of foreign determinations made on the basis of access legislation would aim at incorporating extraterritorial considerations for the granting or review of IPRs. This could occur if the country of grant agreed to take into consideration, for instance, non-compliance with the PIC requirement of the providing

[65] Article 31(2) of the Vienna Convention on the Law of the Treaties states: "[t]he context for the purpose of the interpretation of a treaty shall comprise, in addition to the text, including its *preamble* and annexes…" (emphasis added).

[66] These are some of the main limitations of the purely contractual approach for addressing the disclosure of origin issue suggested by some developed countries.

country when assessing a patent application or the adoption of other measures (such as revocation or administrative sanctions).

The recognition of rights relating to genetic resources and associated traditional knowledge by the country of grant (that is, where a patent has been granted) could take place in two possible ways:

(1) Based on a determination of rights made by the competent authority in the country of grant; or
(2) Based on a determination of rights made by the competent authority in the providing country.

The first option would represent a significant departure from the territoriality principle, as the authority in the country of grant would be required to assess a legal situation and take a decision on the basis of a foreign law. This would be particularly complex in the case of access legislation since, as mentioned above, such laws are frequently framed in general terms and leave significant discretion to local authorities for their application. Moreover, the authority in the country of grant would not only be required to apply a substantive foreign law, but also to review evidence supporting the claims of the concerned parties (e.g. absence of equitable benefit-sharing). Because of these considerations, this option is unlikely to be practicable, and would make it difficult to garner significant support for any proposal for an international regime for the extraterritorial recognition of rights and obligations emerging from access legislation.

The second option would entail deference by the national authority (court or administration) in the country of grant to a foreign determination of rights. This may be deemed less intrusive than the first option, but it requires the enforcement of a foreign law as interpreted and applied by a foreign authority. A distinction could also be made between the following two situations:

2(i) The authority in the country of grant relies on a determination of rights made in the providing country. The authority in the country of grant takes account of this determination when deciding on the integrity of rights conferred according to its country's law (for example, a patent authority in the country of grant orders the revocation of a patent due to non-compliance with the PIC principle in the providing country, as determined by the authority of that country); and
2(ii) The authority in the country of grant limits itself to enforcing a determination made by an authority in and under the law of the providing country in a manner that does not affect the integrity of rights conferred according to the law of the country of grant (for example, the award of patent rights are unchallenged but benefit-sharing provisions are enforced).

In any of the two options mentioned above, three alternatives may arise depending on whether the determination in the providing country was made by:

a. A judicial authority,
b. Arbitration, or
c. An administrative authority (e.g. an authority competent to grant PIC or sign or approve access contracts).

In the hypothesis 2(i), in principle, the authority in the country of grant would not interpret the scope and content of the foreign right (though, as mentioned below, such interpretation might be required in some cases); rather, it would give effect to claims based on such a right. In the case of 2(ii), the authority would limit itself to giving some legal effects to a foreign decision.

Of course, the degree to which an international regime would allow for any of these options will depend on the ambition of the contracting parties and their willingness to defer, on a reciprocal basis, to foreign national laws or foreign determinations based thereon.

It would be important to clearly identify the authorities whose determination could be accepted as a basis for action in a foreign jurisdiction. A logical approach would be to rely on final judicial determinations. As discussed above, there are international conventions that would permit the enforcement, under certain circumstances, of judicial and arbitral decisions (that is, cases falling under 2(ii)a and 2(ii)b). However, the downside of this solution would be that obtaining a final decision by a judicial court may take several years in many countries.[67] An arbitral decision may be much faster, but the scope for arbitration is also far more limited than potential judicial intervention. The possibility of accepting administrative determinations should not be ruled out, but it may be less acceptable to countries that are potentially interested in an international regime.

Another issue for consideration is that in many cases there may not be a prior judgment in the providing country regarding the lack of compliance with its access legislation, as the issue may have needed to be raised in the first instance in the country where the patent is acquired.

In addition, when the authority in the country of grant relies on a determination of rights made in the providing country, that determination may not only relate to rights in the providing country, but also to whether the providing country's laws regarding rights are intended to have extraterritorial effect. If so, the outcome of such a case may rest on the degree to which the country of grant recognizes and accepts the extraterritorial intent of the providing country's law.

Given the objectives of a possible international regime for the recognition of foreign determinations made on the basis of access legislation, the application of the proposed regime would be triggered, as noted, when IPRs have been sought or acquired in a foreign jurisdiction, and any of the following circumstances exists:

a) The relevant genetic resources and associated traditional knowledge were accessed without complying with PIC requirements;
b) The IPRs were sought or acquired without authorization from the national competent authority in the providing country, when so required;
c) The relevant genetic resources and associated traditional knowledge were accessed without entering into a contract on mutually agreed terms for benefit-sharing (access contract);
d) There was a breach of the access contract by the party that accessed the genetic resources; and
e) IPRs were applied for or acquired with regard to such genetic resources and associated traditional knowledge.

These circumstances involve non-compliance with the access law itself, except in the case d) where a breach of contract may be alleged instead of, or in addition to, non-compliance with the access law. This distinction is important, as in the latter case international conventions for the recognition of foreign arbitral awards or judgments may eventually be applied.

The international agreement may provide for a *juris tantum* presumption of fraud if an IPR has been applied for without disclosing the source of the claimed materials, when so required by the applicable law.

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[67] Referral to domestic administrative authorities might be necessary to resolve judicial actions regarding compliance with access and benefit-sharing (ABS) requirements.

It is also to be noted that, for the purposes of a possible international system for the recognition of decisions relating to PIC and benefit-sharing, relevant situations may arise independently from the nationality or domicile of the party that has applied for or obtained intellectual property protection in relation to materials accessed in violation of the access regime. Thus, States' agencies, nationals or those domiciled in the country whose access legislation has been violated may request recognition of their rights in countries where such protection has been sought or obtained, even in cases where applicants or title-holders are not nationals or domiciles of the latter country.

Although there are many legal complexities to define the kinds of obligations that the parties may assume, the Agreement may contain a straightforward formulation of parties' commitments (box 3).

Box 3. Legal effects of foreign determinations

2. The Parties agree to recognize, in accordance with their national laws and the provisions of this Agreement, a determination made in another Party when:
   (a) Such determination has been made by a competent administrative or judicial authority of the Party where genetic resources have been accessed;
   (b) The determination is final;
   (c) The authority of such Party has established, in accordance with its legislation, that:
      (i) no prior informed consent has been requested by or granted to that Party, and that no access agreement has validly been signed or is in force, or
      (ii) the Party acceding to the genetic resources and associated traditional knowledge has not complied with the benefit-sharing obligations under an access agreement in force;
   (d) The Party where the resources were accessed is the country of origin of such resources or has acquired them in accordance with the Convention on Biological Diversity.[1]
3. It shall be presumed, unless proven to the contrary, that an intellectual property right has been applied for fraudulently when an applicant who was required by the applicable law to disclose information about the country providing the genetic resources and associated knowledge failed to provide such information.
4. Subject to national law and 2(a), (b) and (d) above, a Party shall, upon request, refuse the application for or revoke a granted intellectual property right when the competent authority of the Party providing the genetic resources and associated traditional knowledge has determined that any of the circumstances indicated in paragraph 2(c) have occurred. The Party may also transfer the application or rights to the Party that was actually entitled thereto. This Agreement shall apply when an intellectual property right has been applied for or has been granted in a Party. For the purposes of this Agreement, an "intellectual property right" is a patent application or grant involving claims over genetic resources and associated traditional knowledge accessed in another Party under the conditions laid down in 2(c) below. Parties may also apply this Agreement to plant breeders' rights granted in their jurisdictions.

[1] This text is in line with the requirement of article 15.3 of the CBD.

Harmonization of access legislation is not required

The CBD provides, as indicated, a general framework that leaves considerable room for contracting parties to implement its obligations. National laws differ significantly, as they must be adapted to different legal systems and institutional settings and to the characteristics

of the biodiversity and associated traditional knowledge of each jurisdiction. In furtherance of COP Decision VII/19, an international regime on access to genetic resources and benefit-sharing will be negotiated. If adopted as a binding instrument, it may create the conditions for greater harmonization of access legislation in the years to come, and for better assuring that conditions for PIC and benefit-sharing are complied with worldwide.

However, a possible international regime for the recognition of foreign determinations made on the basis of access legislation, as discussed in this paper, is not premised on a substantive harmonization of such legislation; rather, it envisages a system that would allow parties to preserve the latitude to design and implement their own legal approaches and regimes on the matter.

Legal standing

Access regulations are grounded in the concept that genetic resources are subject to the sovereign rights of the country where such resources reside (as stated in article 3 of the CBD). In the Andean States, for instance, genetic resources are deemed "goods or patrimony of the Nation or of the State", and corresponding rights are considered "inalienable and not subject to prescription or to seizure or similar measures; they are recognized without prejudice to property regimes of the biological resources that contain them, the land on which they are found, or the associated intangible component" (article 6, Decision 391). As a result, States can legally take action against acts of misappropriation.

It was on the basis of this concept, for example, that the Council for Scientific and Industrial Research of the Government of India successfully challenged a United States patent relating to the use of turmeric, as mentioned earlier.[68] the revocation of the patent, however, was not decided on the basis of Indian law, but strictly on the basis of evidence of lack of novelty under United States law. As mentioned, the Indian Government is empowered, under that country's Biological Diversity Bill, to oppose the granting of IPRs relating to inventions based on research or information on Indian biological resources in any country (section 19(4)). Decision 391 of the Andean Community expressly authorizes its member States to "request nullification and bring such actions as are appropriate in countries that have conferred rights or granted protective title documents" (second complementary provision).

In addition to States' sovereign rights, access laws confer rights to other persons, and, in some cases, to communities. For instance, in the Philippines, the rights of indigenous and local communities must be protected. According to Executive Order No. 247, concerning local communities, prospecting of biological and genetic resources shall be allowed if PIC is given. With regard to indigenous communities, the Order specifies that prospecting shall be allowed "within the ancestral lands and domains of indigenous cultural communities only with the prior informed consent of such communities; obtained in accordance with the customary laws of the concerned community." In Costa Rica, parties interested in obtaining access must file a request before the Technical Office (TO) and negotiate with the conservation area, indigenous territory, landowner or holder of *ex situ* collections, as appropriate. Agreements so developed must include conditions for a fair and equitable distribution of benefits, and be endorsed by the TO. In Peru, Law No. 27811 (2002) on the protection of the indigenous collective knowledge related to biological resources (*Ley que establece el régimen de protección de los conocimientos colectivos de los pueblos indígenas vinculados a los recursos biológicos*)[69] empowers indigenous communities to act against infringement of their rights, but it also authorizes the Peruvian State to initiate actions *ex officio* through the Instituto Nacional de Defensa de la Competencia y de Protección de la Propiedad Intelectual (INDECOPI).

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[68] See, for example, SUNS No. 4050, 8 August 1997.

[69] Diario Oficial, El Peruano, 10 August 2002.

As these examples suggest, access legislation may create rights for different parties (which may include individuals, such as landowners, and local or indigenous communities) to provide prior informed consent and to participate in the benefits arising from the commercial exploitation of biodiversity. Therefore, at a minimum, both States that claim sovereign rights over genetic resources and associated traditional knowledge, and indigenous communities that have been recognized by the relevant States as possessing such rights, should be recognized separately or jointly as having the authority to contest IPRs in a foreign jurisdiction where PIC violations and benefit-sharing requirements are alleged. Further analysis would be required to identify the conditions under which individuals or communities have such standing.

One complex issue is determining the attribution of rights to traditional/indigenous communities, especially when specific knowledge is held by more than one community. Communities are not generally recognized as having the legal *status* of natural and legal persons. In addition, it is difficult to identify not only the communities to which the relevant knowledge should be attributed, but also who legitimately represents them.[70] In some countries, the Western concepts of association, corporation, council and cooperative have been used in order to address communities' representation problem. Some legislation has sought to provide for the recognition of indigenous groups and communities in general (e.g. Australia's Aboriginal Councils and Associations Act), and of land-owning groups in particular (e.g. Papua New Guinea's Land Groups Incorporation Act). An attempt has also been made to tailor the legislation to the particular nature, functions and powers of the indigenous body concerned, as in the case of Anangu Pitjantjatjara, the corporate body established in South Australia to hold and manage the ancestral lands of the Pitjantjatjara people.[71]

The proposed international agreement could contain a general provision on legal standing, stating that any party and any physical or legal person domiciled in a party has the authority to make use of its provisions. Given that national laws may significantly differ with regard to the possible legal standing of traditional/indigenous communities, an optional provision may be included in this regard (box 4).

Box 4. Legal standing

5. Any Party and any physical or legal person domiciled therein may request the recognition of a determination made by an authority of such Party in another Party, as provided for in this Agreement. Any Party may recognize the legal standing of traditional/indigenous communities in accordance with its national law.

Stand-alone instrument, or protocol to an existing agreement?

A possible new international regime for the recognition of foreign determinations made on the basis of access legislation may be developed as an independent convention or as a

[70] See, for example, Greene S. Indigenous people incorporated: *A case study approach to the fight over pharmaceutical bioprospection, traditional knowledge and intellectual properties*, Mimeo, Chicago, 2001: 32.

[71] However, a review of the Australian Aboriginal Councils and Associations Act in 1996 found that the Act allowed little room for local cultural variation in corporate structures and decision-making processes, and in fact caused groups to lose control over their affairs. See Fingleton JS. Legal recognition of indigenous groups, 1998, *FAO Legal Papers Online*, available at: http://www.fao.org/Legal/prs-ol/lpo1.pdf, pp. 33, 34. This author notes that "the more the legislative regime allows groups to incorporate their own cultural concepts and processes into their formal legal structures, the more likely those structures are to be effective in meeting their members' needs and wishes. The recognizing law must, in other words, be culturally appropriate if it is to serve a useful purpose."

protocol to an existing one, such as the CBD. The latter approach would enable the use of the services of the existing secretariat for the negotiation of the instrument as well as for its implementation.

Whatever the form of the instrument and the chosen forum may be, governments wishing to protect their biodiversity may have a significant incentive to participate in the development of a new international regime and to eventually join it, since this may improve compliance with their own access regimes while cooperating in the enforcement of the laws applicable in other contracting parties.

Practical considerations

The practical operation of a new international regime for the recognition of determinations based on foreign laws on access legislation will depend on the capacity of the relevant stakeholders to monitor the application for and granting of IPRs that lead to a misappropriation of genetic resources and associated traditional knowledge. This is not a simple task, given the large number of patent applications annually filed worldwide in the various fields where such a situation might arise and the multiple forms in which claims relating to such resources and knowledge may be made. Searching for and analysing patents that may eventually be challenged require skills and considerable time. Of course, this task would be enormously facilitated if an international obligation to disclose the source of genetic resources and associated traditional knowledge were established internationally, and effectively enforced.

In addition, if a case of misappropriation were to be found and the recognition of a decision made in the providing country were to be sought in a foreign jurisdiction, it would be necessary to bear the respective litigation costs. These may be very high, especially when complex matters, such as patent validity, need to be elucidated.[72]

As a result, the effectiveness of an international regime may critically depend on the support for relevant stakeholders from governments and other organizations to both monitor and litigate.

Finally, it is worth mentioning that the proposed international regime will neither affect the territoriality of patents nor imply the extraterritorial application of foreign laws.

[72] For instance, the average cost of a patent infringement suit has been estimated in the United States at around $1.5 million. See, for example, Dawson G. Matchmaking in the realm of patents: a call for the marriage of patent theory and claim construction procedure, *Texas Law Review*, 2001, 79: 1257-1286.

IV. Conclusions

The expectations created by the adoption of the CBD and of national legislation to implement it, particularly with regard to benefit-sharing, have not been realized so far. One of the basic problems is the global nature of the misappropriation of genetic resources and associated traditional knowledge, and the limits imposed on any preventive or corrective action by the national reach of access legislation and the territoriality of IPRs.

Currently, even in the absence of any new international agreement regarding the recognition of determinations made under foreign laws on access to genetic resources and associated traditional knowledge, legal claims to address cases of misappropriation may be brought under existing principles of comity and international treaties. Without ignoring the possible application of international conventions for the recognition of foreign judgments and arbitral awards, this paper has sought to offer some preliminary ideas for discussions about a new possible international agreement for the recognition of foreign determinations based on access legislation. Such an agreement could provide a more effective mechanism than existing instruments have done so far.

The establishment of such an international agreement would have to deal with complex legal and practical issues, such as the barrier posed by the costs of litigating in a foreign country, which could be particularly significant for traditional/indigenous communities. Concerns may also be raised over situations where it is not clear from which country the genetic material or knowledge originates, or when the conditions imposed by the access regime go beyond what is required under the PIC and benefit-sharing principles of the CBD.

There is the risk that efforts to develop an international agreement with the objectives described in this paper would be perceived as undermining developing countries‘ other efforts to establish internationally binding provisions to prevent the misappropriation of genetic resources and associated traditional knowledge. Such an agreement should be viewed, however, as supplementing and not replacing other possible instruments and, in particular, as a means of giving tangible effects to the proposed international obligation to disclose the source of such resources and knowledge in patent applications. There is also the risk that developed countries would resist the idea of entering into an international agreement that would oblige them to enforce determinations made in foreign jurisdictions. Were only developing countries to sign up to such an agreement, protection against misappropriation could be enhanced in developing countries but the problem would persist in developed countries.

All these and other delicate issues need to be further considered. A clear and robust global mechanism to deal with the misappropriation of genetic resources and associated knowledge would be an important step towards the sustainable use of biodiversity for the benefit of present and future generations. The international community should pursue all possible alternatives under existing or new international conventions for a long-term and equitable solution to this problem.