Chapter 1
The International Framework for Access and Benefit Sharing of Genetic Resources and Associated Traditional Knowledge

I. Introduction

The focus of this handbook is legislation at the international level (treaties) and how that affects national policymaking and legislation mainly from the perspective of the provider countries. In this regard, treaties are agreements that have been negotiated between States, stipulating the terms, conditions, rights and obligations which the signatories must abide by. They may be bilateral, meaning that the agreement binds two States, or multilateral, meaning that the agreement binds more than two States. Multilateral treaties may cover a region (the European Union (EU)) or a sub-region (the Mekong countries); they may be between regions (EU-African, Caribbean and Pacific (ACP) countries) or global in scope (the Patent Cooperation Treaty, the Agreement on Trade-related Aspects of Intellectual Property Rights (the TRIPS Agreement)). A number of formalities may be needed for a treaty to become effective, including, for example, ratification. In many cases, treaty provisions will need to be implemented through national legislation, which may call for either establishing new laws or changing existing ones to fully comply with a treaty. Finally, established treaties may be amended or be further elaborated by means of additional or supplementary treaties such as protocols. This chapter examines the multilateral treaty framework for access and benefit sharing (ABS) of genetic resources and associated traditional knowledge (TK).

II. The Global Framework for Access and Benefit Sharing

The starting point for understanding the existing international framework for ABS of genetic resources and associated TK is the Convention on Biological Diversity (CBD). The CBD is one of the multilateral treaties that opened for signature at the 1992 United Nations Conference on Environment and Development in Rio de Janeiro, Brazil (hereafter the Earth Summit or UNCED). To date, the CBD has been ratified by 193 parties, making it nearly universal. Of the major user countries, the United States of America remains a non-party (and consequently not bound by its provisions), despite having signed the treaty in 1993. The treaty entered into force on 29 December 1993, and has three objectives, namely:

1. the conservation of biological diversity;
2. the sustainable use of the components of biological diversity[7]; and
3. the fair and equitable sharing of the benefits arising out of the utilization of genetic resources.

Parties to the CBD have nominated national focal points, which act as the designated person representing a Party on all matters related to the Convention.

[7] Sustainable use – the use of components of biological diversity in a way and at a rate that does not lead to the long-term decline of biological diversity, thereby maintaining its potential to meet the needs and aspirations of present and future generations (Article 2, CBD).

The CBD contains a large number of obligations which its signatories must abide by, including requirements for general conservation measures, *in situ* and *ex situ* conservation, incentives, and a range of other topics.[8] The substantive provisions agreed to in the CBD with respect to the fair and equitable sharing of benefits arising out of the utilization of genetic resources[9] is found in Articles 15, 16 and 19 of the treaty, which are reproduced in Box 2 below.

Box 2
CBD Provisions on Access and Equitable Sharing of Benefits

Article 15. Access to Genetic Resources

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.

2. Each Contracting Party shall endeavour to create conditions to 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 this Convention.

3. For the purpose of this Convention, the genetic resources being provided by a Contracting Party, as referred to in this Article and Articles 16 and 19, are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.

4. Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.

5. Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.

6. Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties.

7. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 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

[8] *In Situ* – conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties (Article 2, CBD). *Ex-situ* – conditions where genetic resources exist outside their natural habitats, such as botanic gardens, zoological garden and gene banks (Article 2, CBD).

[9] The CBD and other international instruments utilize closely related descriptions of 'genetic material', 'genetic resources' and 'biological resources.' According to the CBD, genetic material means any material of plant, animal, microbial or other origin containing functional units of heredity (Article 2, CBD). With respect to plant genetic material, the term is defined to include any material of plant origin, including reproductive and vegetative propagating material, containing functional units of heredity (Article 2, The International Treaty on Plant Genetic Resources for Food and Agriculture). As a result, genetic material is a description of the subject matter without reference to human use. 'Biological resources' under Article 2 of the CBD are defined as genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems *with actual or potential use or value for humanity*. With this definition, the actual or potential use by humans defines the subject matter. Biological resources include genetic resources and microorganisms. Genetic resources are genetic materials of actual or potential value (Article 2, CBD). The scientific concept of micro-organism refers to a "member of one of the following classes: bacteria, fungi, algae, protozoa or viruses' (UNCTAD-ICTSD (2005), p. 392). Plant genetic resources refer to the economic, scientific or societal value of the heritable materials contained within and among species (FAO, p. 33). From a legal perspective, therefore, the 'actual or potential value' differentiates genetic resources, microorganisms and other biological resources from simple genetic material.

resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.

Article 16. Access to and Transfer of Technology

1. Each Contracting Party, recognizing that technology includes biotechnology, and that both access to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives of this Convention, undertakes subject to the provisions of this Article to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment.

2. Access to and transfer of technology referred to in paragraph 1 above to developing countries shall be provided and/or facilitated under fair and most favourable terms, including on concessional and preferential terms where mutually agreed, and, where necessary, in accordance with the financial mechanism established by Articles 20 and 21. In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights. The application of this paragraph shall be consistent with paragraphs 3, 4 and 5 below.

3. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that Contracting Parties, in particular those that are developing countries, which provide genetic resources are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights, where necessary, through the provisions of Articles 20 and 21 and in accordance with international law and consistent with paragraphs 4 and 5 below.

4. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that the private sector facilitates access to, joint development and transfer of technology referred to in paragraph 1 above for the benefit of both governmental institutions and the private sector of developing countries and in this regard shall abide by the obligations included in paragraphs 1, 2 and 3 above.

5. The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.

Article 19. Handling of Biotechnology and Distribution of its Benefits

1. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, to provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research, and where feasible in such Contracting Parties.

2. Each Contracting Party shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms.

3. The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.

4. Each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction providing the organisms referred to in paragraph 3 above, provide any available information about the use and safety regulations required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced.

Source: The Convention on Biological Diversity (1992).

At the national level, the implementation of the ABS provisions, as called for under Articles 15, 16, and 19 of the CBD, have generally been slow since its entry into force in December 1993. The continuing lack of "user measures" that implement the benefit sharing obligations of CBD Parties, as well as support for user compliance with ABS legislation in provider countries and negotiated MAT conditions have been highlighted as persistent problems. Of those countries that have ABS legislation, few contain substantial provisions on "user measures" while practically all address access issues. While several biodiversity-rich countries developed access-oriented policies and legislation, the lack of corresponding benefit-sharing policies and legislation in industrialized countries since the coming into force of the CBD turned into a bone of contention and finally resulted in the call of the 2002 World Summit on Sustainable Development to negotiate an "international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources", providing the mandate to begin the long and arduous process that led to the adoption of the Nagoya Protocol in 2010.[10] There is still much work to be done even on the provider side as well. According to the multi-donor ABS Development Capacity Building Initiative, only 6 of the 54 African countries had developed ABS legislation as of 2011.[11]

Two protocols have been adopted under the CBD to date, further elaborating the obligations of its signatories on specific issues. As called for under Article 19(3), the *Cartagena Protocol on Biosafety to the Convention on Biological Diversity* (the Cartagena Protocol) regulates at the international level the safe handling, transport and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health. The Protocol was adopted on 29 January 2000 and entered into force on 11 September 2003.

The second protocol adopted under the CBD is the *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization to the Convention on Biological Diversity* (the Nagoya Protocol). The Nagoya Protocol sets out the rules and mechanisms for access to genetic resources and associated TK, and supports the fair and equitable sharing of benefits arising from their utilization, and, along with the basic provisions of the CBD on ABS, forms the central body of law that defines how the ABS system operates. Many of the provisions of the Nagoya Protocol borrow from the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization, a set of voluntary non-binding guidelines on access and benefit sharing endorsed by the CBD Conference of the Parties (COP) at its Sixth Session in 2002.[12]

[10] See para. 44(o) of the Plan of Implementation of the World Summit on Sustainable Development, A/Conf.199/20 of 4 September 2002.
[11] GIZ (2011). http://www.abs-initiative.info/struct_compedium0.html.
[12] Decision VI/24 of COP VI (2002).

The Nagoya Protocol was adopted by the 10th COP to the CBD in Nagoya, Japan on 29 October 2010, and opened for signature for one year from February 2011, finally receiving 92 signatures, amongst them 22 European Union (EU) Member States and the EU. When the period for signatures ended, the Nagoya Protocol had two ratifications.[13] The treaty has now been ratified by over 50 countries, and will come into effect as from 12 October 2014. For countries that have ratified the CBD and the Nagoya Protocol, domestic ABS legislation will be shaped by the relevant provisions of the CBD and the Nagoya Protocol, as treaty implementation relies to a large extent on national legislation to put the access and benefit sharing provisions into effect. The decision making bodies of the CBD and its Protocols are serviced by the CBD Secretariat, located in Montreal, Canada, which is administratively part of the United Nations Environment Programme (UNEP).

Over the years, the CBD Secretariat has commissioned a number of studies on the relationship between IP and the CBD, including, in particular, the compatibility of disclosure requirements with the TRIPS Agreement (see Chapter 3). Article 16 of the CBD recognizes the impact of intellectual property (IP) on access and benefit sharing. Specifically, it states that "[t]he Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives." In order to achieve agreement in 2010 among the governments negotiating the treaty text in Nagoya, however, IP ended up being largely absent in the Nagoya Protocol, with the exception of its mention as a means for possibly securing equitable benefit sharing (see the Annex to the Nagoya Protocol). Despite its importance for the ABS system, the relatively few references to IP in the Protocol means that it is not possible to derive an understanding of the interface between IP and ABS from the CBD and the Protocol alone, and that other sources of law will need to be consulted.

Key Points

⇒ The CBD enjoys nearly universal acceptance as the most comprehensive source of international law to date on issues of biological diversity. The CBD established the basic principle that States have sovereign rights over their own biological resources.

⇒ The Nagoya Protocol, the text of which was agreed in October 2010, sets out the system to implement those rights and obligations on ABS of genetic resources which on the basis of CBD Article 8(j) also cover traditional knowledge associated with genetic resources. The Nagoya Protocol received 92 signatures and awaits 50 ratifications to enter into force.

⇒ National implementation of ABS legislation, while required by the CBD, is slow and generally tends to focus more on access issues and much less on benefit sharing.

⇒ Despite its importance, intellectual property is largely absent in the Nagoya Protocol, with the exception of its mention as a means for possibly securing equitable benefit

[13] As of the 3 September 2014, 52 countries have either ratified or acceded to the Protocol. For an updated list, readers may consult http://www.cbd.int/abs/nagoya-protocol/signatories/default.shtml. COP12 of the CBD, scheduled for October 2014 in Korea, will also be the first meeting of the Parties to the Nagoya Protocol.

sharing. As a result, it becomes important to examine other legal instruments in order to determine how best to shape national IP legislation to further the goals of the CBD.

A. How Does the Global Access and Benefit Sharing System Work?

Underlying the ABS provisions of the Nagoya Protocol and the CBD is the notion, as stated in the Preamble to the CBD, that States have sovereign rights over their own biological resources. Access to genetic resources by users must therefore be based on *prior informed consent* and equitable benefit sharing must occur on *mutually agreed terms* (hereafter PIC and MAT, respectively; Nagoya Protocol, Articles 5 and 6 (see Box 3 below) and CBD, Articles 15, 16 and 19).

Box 3
Nagoya Protocol Provisions on Access and Equitable Sharing of Benefits

Article 5. Fair and Equitable Benefit Sharing

1. In accordance with Article 15, paragraphs 3 and 7 of the Convention, benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention. Such sharing shall be upon mutually agreed terms.

2. Each Party shall take legislative, administrative or policy measures, as appropriate, with the aim of ensuring that benefits arising from the utilization of genetic resources that are held by indigenous and local communities, in accordance with domestic legislation regarding the established rights of these indigenous and local communities over these genetic resources, are shared in a fair and equitable way with the communities concerned, based on mutually agreed terms.

3. To implement paragraph 1 above, each Party shall take legislative, administrative or policy measures, as appropriate.

4. Benefits may include monetary and non-monetary benefits, including but not limited to those listed in the Annex.

5. Each Party shall take legislative, administrative or policy measures, as appropriate, in order that the benefits arising from the utilization of traditional knowledge associated with genetic resources are shared in a fair and equitable way with indigenous and local communities holding such knowledge. Such sharing shall be upon mutually agreed terms.

Article 6. Access to Genetic Resources

1. In the exercise of sovereign rights over natural resources, and subject to domestic access and benefit-sharing legislation or regulatory requirements, access to genetic resources for their utilization shall be subject to the prior informed consent of the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention, unless otherwise determined by that Party.

2. In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that the prior informed consent or approval and involvement of indigenous and local communities is obtained for access to genetic resources where they have the established right to grant access to such resources.

3. Pursuant to paragraph 1 above, each Party requiring prior informed consent shall take the necessary legislative, administrative or policy measures, as appropriate, to:

(a) Provide for legal certainty, clarity and transparency of their domestic access and benefit-sharing legislation or regulatory requirements;

(b) Provide for fair and non-arbitrary rules and procedures on accessing genetic resources;

(c) Provide information on how to apply for prior informed consent;

(d) Provide for a clear and transparent written decision by a competent national authority, in a cost-effective manner and within a reasonable period of time;

(e) Provide for the issuance at the time of access of a permit or its equivalent as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms, and notify the Access and Benefit-sharing Clearing-House accordingly;

(f) Where applicable, and subject to domestic legislation, set out criteria and/or processes for obtaining prior informed consent or approval and involvement of indigenous and local communities for access to genetic resources; and

(g) Establish clear rules and procedures for requiring and establishing mutually agreed terms. Such terms shall be set out in writing and may include, *inter alia*:

(i) A dispute settlement clause;

(ii) Terms on benefit-sharing, including in relation to intellectual property rights;

(iii) Terms on subsequent third-party use, if any; and

(iv) Terms on changes of intent, where applicable.

Source: The Nagoya Protocol (2010).

National legislation must therefore provide a means of ensuring that those who seek to access genetic resources and associated TK for utilization have the PIC of the country or indigenous peoples and local community (hereafter ILC) concerned. Parties to the Protocol may specify the instances where PIC is required for access, which may include:

- genetic resources from areas under national jurisdiction

- in case they are countries of origin,

- including such genetic resources in *ex-situ* collections.

On the other hand, the Protocol specifies various procedural requirements, which must be complied with. These include the requirement to formulate fair and non-arbitrary rules and procedures for access, information on how to apply for PIC, the issuance of permits as evidence of PIC, the requirement to provide written decision by the competent national authority within a reasonable period of time and the like. National legislation must also provide a way to ensure that the results of research and development (hereafter R&D) and the benefits arising from the commercial and other utilization of genetic resources are shared in a fair and equitable manner, based on MAT. [14]

The Nagoya Protocol establishes a compliance system for ABS. As noted above, Parties need to ensure that genetic resources utilized from the area under national jurisdiction have been

[14] Frein and Meyer (2012).

accessed based on PIC and MAT as required by the provider country. A national competent authority must be established to implement the ABS system, where it will be possible to register ABS agreements and any other documentation that can potentially serve as evidence of PIC and MAT (Nagoya Protocol, Article 13). The competent authority grants a permit for access when it is satisfied that PIC and MAT requirements under national law have been met.

Supportive measures with regard to the utilization of genetic resources include the nomination of one or more effective checkpoints relevant to the entire product chain (Nagoya Protocol, Article 17(1)(a)), designed to provide information to the authority about permit applications and to investigate claims where ABS regulations have not been followed. The competent authority also facilitates the transformation of the national access permit – providing information on PIC, MAT, etc., into an internationally recognized certificate of compliance through publication by the ABS Clearing House (Nagoya Protocol, Article 17(2)), which is designed to facilitate the legitimate movement of resources across borders. This Clearing House has recently been established and is now in its pilot phase.[15] Furthermore, Parties need to support the fulfilment of MAT through the opportunity for legal recourse and access to justice (Nagoya Protocol, Article 18(2) and (3)).

Agreed upon ABS rules for PIC and MAT are thought, *inter alia*, to help combat 'biopiracy' or in more legal terminology, the misappropriation and misuse of genetic resources and associated TK. As mentioned above, IP rights, by granting the right to exclude others from the use of an intellectual creation, are one means by which misappropriation can occur. At the same time IP rights are also one means to generate income from the commercialization of a technology that contains a genetic resource and associated TK, from which benefits could potentially be shared.

Key Points

⇒ Articles 15, 16 and 19 of the CBD and Articles 5 and 6 of the Nagoya Protocol set out the basic rights and obligations of Parties on ABS of genetic resources. These provisions establish the requirement that access to genetic resources shall be based on prior informed consent (PIC) and mutually agreed terms (MAT). Benefits accruing from the utilization of genetic resources need to be shared on a fair and equitable basis.

⇒ While laying down procedural requirements for the grant of PIC, the Protocol leaves leeway to countries to determine the substantive conditions under which PIC is required.

⇒ Competent national authorities need to be established to administer the system, which checks whether PIC and MAT have been complied with, and issues access permits when applicable requirements have been met. The national competent authority will also be in charge of ensuring that national permits based on compliance with domestic legislation are converted into an internationally recognized certificate of compliance through the ABS Clearing House. The ABS Clearing House is currently in its pilot phase.

[15] See http://absch.cbd.int/.

B. What Does the Global Access and Benefit Sharing System Cover?

The Nagoya Protocol covers the utilization of genetic resources as defined in Article 2 of the CBD, meaning any material of biological origin containing functional hereditary material for use in R&D – i.e., when working on the genetic or biochemical composition of the material, including development of products and processes through biotechnology. The simple sale of a fruit or vegetable across borders for consumption would therefore not be covered under the Protocol. On the other hand, the transfer of sample plants and animals for research purposes, even if not immediately commercialized, would trigger the Protocol. If biological resources are brought across borders for trade or consumption purposes initially, but later used for research, the provisions of the Protocol would still apply. This sometimes creates difficult situations as documents for the mere purchase of commodities do not necessarily have clauses in them that address requirements to obtain PIC and MAT. According to a recent study by Laird and Wynberg published by the CBD Secretariat:

> *"According to the CBD and the Nagoya Protocol, ABS policies are intended to address research and development on genetic resources and associated traditional knowledge, and biodiscovery, rather than the commodity trade of raw materials that may result from research and development, or local trade and subsistence use. While it is important to ensure that regulatory frameworks address the differences between biotrade and biodiscovery, it also needs to be acknowledged that these distinctions are becoming less clear with increasing research and development focus of commodity-based industries such as food"*[16]

The following sections describe some of the key controversies surrounding the scope of coverage of the ABS system as established by the CBD and the Protocol.

Key Points

⇒ The Protocol requirements are triggered when genetic resources are 'utilized' for R&D purposes outside the provider country.

⇒ Contracts and other documents for the simple sale of seeds, plants or vegetables for consumption purposes would not trigger the Protocol, but if research is conducted using these commodities, then the requirements would be triggered. In practice, many sales contracts do not specify what needs to happen in the case the objective for which a genetic resource is provided changes.

1) Temporal Scope of the Treaties

In the Nagoya Protocol negotiations, there was an extensive debate over whether the final instrument is meant to cover genetic resources acquired prior to its entry into force. Like many other issues, the debate at Nagoya took place over largely North-South lines and the text of the Protocol avoids providing a clear answer to this question. The extent to which the Protocol dealt with this question was to simply suggest that the Parties consider the establishment of a global multilateral benefit-sharing mechanism to address the sharing of

[16] Laird and Wynberg (2012), p. 12.

benefits derived from the utilization of genetic resources and related TK for which it is not possible to grant or obtain PIC (Nagoya Protocol, Article 10).

On one hand, many genetic resources were acquired by user countries before the Protocol, as well as before the CBD. Up until 12 October 2014 when the Protocol comes into force, genetic resource transfers to outside the provider country in fact continue to be pre-Nagoya (in the absence of Nagoya-compliant ABS legislation). It could be argued that the exclusion of pre-Nagoya/pre-CBD resources condones misappropriation and merely encourages countries to delay ratification, with a view to avoiding otherwise applicable PIC and MAT requirements.[17]

The problem with an approach applying the Protocol to pre-Nagoya/pre-CBD acquisitions is that such acquisitions include not only those resources that had been accessed without PIC and MAT, but also those that had been the subject of agreed transfers. Plants that are part of *ex situ* collections or animals that reside in zoos are examples of such genetic resources. Such resources are also in gene banks around the world. To declare that Nagoya Protocol requirements apply to genetic resources already acquired also means that the Protocol would be applied retroactively, which is generally frowned upon as a matter of law. The economic consequences could be significant if the Protocol were used to invalidate earlier agreements, pre-Nagoya or pre-CBD. As pointed out by the United Nations University Institute for Advanced Studies (UNU-IAS):

> *"Requiring pre-CBD collections to produce evidence of a legal right to use resources, based on the existence of a sound legal title obtained from a country of origin, would have significant impact on their commercial value. The wide distribution of genetic resources over centuries – many of which are mainstays of global food security – is frequently posited as a reason to avoid extending control over pre-CBD collections."*[18]

As a matter of national law, it is unlikely that courts in most jurisdictions (as well as government officials administering ABS laws) would seek to apply laws retroactively to genetic resources acquired before a Protocol compliant domestic ABS regime had been put in place, absent a clear intent in the ABS law to do so.

In order to address the problem of pre-Nagoya/pre-CBD acquisitions, some authors have suggested that national ABS laws make the Protocol requirements applicable to new uses of genetic resources acquired prior to that law, making the timing of the acquisition irrelevant.[19] This would at least help to ensure that some benefit sharing occurs with respect to new applications of genetic resources acquired prior to a Nagoya Protocol-compliant ABS law. There is nothing in the Protocol that would prevent Parties from including such a requirement in their respective laws.[20]

[17] Nijar (2011a), p. 19.
[18] Tobin, Burton and Fernandez-Ugalde (2008).
[19] See, for example, Nijar (2011a), p. 20.
[20] Benefit sharing under Article 5 of the Nagoya Protocol is not linked to access conditions under Article 6, so the benefit sharing obligation could also extend to GR and TK accessed pre-Nagoya, whether the resource was accessed with or without PIC.

Key Points

⇒ The Nagoya Protocol never clearly stipulates whether it is intended to cover the utilization of genetic resources that had been acquired prior to Nagoya-compliant ABS legislation. Nonetheless, judges (and government officials) will often be unwilling to retroactively apply ABS legislation unless there is a clear intent in the law to do so.

⇒ National ABS legislation can stipulate that it should apply to new applications utilizing genetic resources acquired before Nagoya-compliant ABS legislation took effect (i.e., pre-Nagoya/pre-CBD).

2) Traditional Knowledge (TK)

Aside from the genetic resources themselves, the CBD and the Nagoya Protocol also address the treatment of TK associated with genetic resources and genetic resources held by ILCs. As regards genetic resources held by ILCs as a matter of law, the same PIC and MAT requirements would apply as genetic resources that fall under the jurisdiction of national authorities. The only major difference would be that the ILC has the standing under domestic law to grant PIC and negotiate MAT, rather than the national competent authority. The former, i.e., associated TK, are governed by different provisions of the Nagoya Protocol, and are discussed below in historical context.

During the preparations for the 1992 Earth Summit, the efforts of a number of indigenous organisations resulted in greater visibility of TK and biodiversity-related innovations on the global agenda. In February 1992, the Charter of the Indigenous and Tribal Peoples of the Tropical Forests was adopted in Penang, Malaysia.[21] Article 45 on "Intellectual Property" states:

> *"Since we highly value our technologies** and believe that our biotechnologies can make important contributions to humanity, including 'developed' countries, we demand guaranteed rights to our collective intellectual property in both national and international law, and control over the development and manipulation of this knowledge."*

At the Earth Summit, the indigenous organisations adopted the Kari-Oca Declaration and the Indigenous Peoples' Earth Charter.[22] Selected articles of the Charter with specific relevance to TK, genetic resources and IPR in the context of this chapter are:

> *"25. Indigenous peoples should have the right to their own knowledge, language, and culturally appropriate education, including bicultural and bilingual education. Through recognizing both formal and informal ways, the participation of family and community is guaranteed.*

[21] International Alliance of Indigenous and Tribal Peoples of the Tropical Forests, (as revised in 2002) http://www.international-alliance.org/charter_eng.htm, accessed in Jan 2012 (**author's comment: the first version of this Charter dealt with IP in Article 44 and spoke of "traditional technologies", see Posey (1999), pp. 556 ff).

[22] Text and more information available at: http://dialoguebetweennations.com/IR/english/KariOcaKimberley/KOCharter.html, accessed in Jan 2012 (*** authors' comment: this last, and in the light of the recent developments, crucial sentence is deleted from paragraph 102 presented at the mentioned webpage, but contained in the original Charter, see Posey (1999), pp. 560 ff).

> *26. Our health rights must include the recognition and respect of TK held by indigenous healers. This knowledge, including our traditional medicines and their preventive and spiritual healing power, must be recognized and protected against exploitation.*
>
> *96. The TK of herbs and plants must be protected and passed onto future generations.*
>
> *97. Traditions cannot be separated from land, territory, or science.*
>
> *98. TK has enabled indigenous peoples to survive.*
>
> *99. The usurping of traditional medicines and knowledge from indigenous peoples should be considered a crime against peoples.*
>
> *100. Material culture is being used by the non-Indigenous to gain access to our lands and resources, thus destroying our cultures.*
>
> *102. As creators and carriers of civilizations which have given and continue to share knowledge, experience, and values with humanity, we require that our right to intellectual and cultural properties be guaranteed and that the mechanism for each implementation be in favour of our peoples and studied in depth and implemented. [This respect must include the right over genetic resources, gene banks, biotechnology, and knowledge of biodiversity programs.]****
>
> *103. We should list the suspect museums and institutions that have misused our cultural and intellectual properties."*

The 1992 Kari-Oca Declaration was reaffirmed by the Indigenous Peoples Global Conference at the Rio+20 and Mother Earth conference in 2012. The Rio+20 meeting in addition adopted a Kari-Oca 2 Declaration that states: "[w]e reject the assertion of intellectual property rights over the genetic resources and traditional knowledge of Indigenous peoples which results in the alienation and commodification of Sacred essential to our lives and cultures."[23]

Agenda 21[24] in its Chapter 26 "*Recognizing & Strengthening the Role of Indigenous People & Their Communities*" laid down an informal action plan for national governments on how to establish processes to empower indigenous people and their communities to strengthen the active participation of indigenous people and their communities in the national formulation of policies, laws and programmes relating to resource management. Agenda 21 also touches the controversial issues of self-determination and land rights when it suggests that governments could:

> *"(a) Consider the ratification and application of existing international conventions relevant to indigenous people and their communities (where not yet done) and provide support for the adoption by the General Assembly of a declaration on indigenous rights;*
>
> *(b) Adopt or strengthen appropriate policies and/or legal instruments that will protect indigenous intellectual and cultural property and the right to preserve customary and administrative systems and practices."*

[23] Text available at: http://indigenous4motherearthrioplus20.org/kari-oca-2-declaration/, accessed in June 2010.

[24] Text and more information available at: http://www.un.org/esa/dsd/agenda21/res_agenda21_00.shtml, accessed in Jan 2012.

The 1992 Rio and the Rio+20 documents treat TK as one of the many aspects of sustainable development and environmental protection, which should be dealt with in policy and legal activities at the national level. The Rio Summit did not, however, adopt any language to formally recognise customary rights of indigenous peoples at the international level. Instead, Principle 22 of the Rio Declaration on Environment and Development[25] states:

> *"Indigenous people and their communities and other local communities have a vital role in environmental management and development because of their knowledge and traditional practices. States should recognize and duly support their identity, culture and interests and enable their effective participation in the achievement of sustainable development."*

The documents are, nonetheless, important in so far as they affirm the collective position of ILCs that they ought to maintain some control over their TK and practices.
Of the three legally binding conventions adopted in Rio, the CBD[26] recognises in its Preamble:

> *"the close and traditional dependence of many indigenous and local communities embodying traditional lifestyles on biological resources, and the desirability of sharing equitably benefits arising from the use of TK, innovations and practices relevant to the conservation of biological diversity and the sustainable use of its components."*

Article 8(j) of the CBD promotes the sharing of benefits arising out of the utilization of such traditional knowledge but leaves any measures to achieve this objective to the domestic policies of the CBD members. It states, in relevant part, that:

> *"Article 8. In-situ Conservation*
>
> *Each Contracting Party shall, as far as possible and as appropriate: [...]*
>
> *(j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices;"*

The second article of relevance to indigenous and local communities is CBD Article 10(c), which states:

> *"Article 10. Sustainable Use of Components of Biological Diversity*
> *Each Contracting Party shall, as far as possible and as appropriate:*
> *(c) Protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements;"*

[25] Text available at: http://www.un.org/documents/ga/conf151/aconf15126-1annex1.htm, accessed in January 2012.
[26] Text and more information available at: http://treaties.un.org/Pages/ViewDetails.aspx?src=UNTSONLINE&tabid=2&mtdsg_no=XXVII-8&chapter=27&lang=en and http://www.cbd.int./convention/text/, accessed in Jan 2012

It has been suggested that "Article 10(c) requires Contracting Parties to protect and encourage customary uses of biological resources derived from traditional cultural practices which are compatible with the requirements of biological diversity conservation or the sustainable use of its components. The TK, innovations and practices of ILCs directly derive from the customary use of biological resources."[27] Therefore, Article 8(j) and Article 10(c) are closely interrelated and need to be implemented synergistically. As with Article 8(j), Article 10(c) drew criticism because the language neither explicitly mentions customary rights nor promotes their recognition at the international level.

While Articles 15, 16, and 19 of the CBD deal strictly with genetic resources and do not deal with TK, the 7th Conference of the Parties to the CBD (COP) in 2004 decided to mandate the Ad Hoc Open-ended Working Group on Access and Benefit-Sharing, with the collaboration of the Ad Hoc Open Ended Inter-Sessional Working Group on Article 8(j) and Related Provisions, to ensure "the participation of indigenous and local communities, non-Governmental organizations, industry and scientific and academic institutions, as well as intergovernmental organizations, to elaborate and negotiate an international regime on access to genetic resources and benefit-sharing with the aim of adopting an instrument/instruments to effectively implement the provisions in Article 15 and Article 8(j) of the Convention and the three objectives of the Convention".

The work of these bodies was eventually incorporated into Article 7 of the Nagoya Protocol, which stipulates that Parties to the Protocol need to ensure that access to TK associated with genetic resources is based on prior informed consent (PIC) and that benefit sharing will take place (without defining traditional knowledge and its utilization). These obligations cover only benefits from research and development (R&D), however, and not commercialization, on the condition that these groups have been granted the right to determine access to their genetic resources.

Also, it should be emphasized that the Protocol governs only that TK which is associated with genetic resources, rather than all TK. The Protocol does not define what kind of TK would be associated with genetic resources, leaving it up to national laws to determine what TK would be covered. Chapter 5 of this handbook examines the question of TK in more detail.

Key Points

⇒ During the preparations of the Earth Summit, indigenous organisations placed the issue of TK and biodiversity-related innovations successfully on the international agenda. In February 1992, the Charter of the Indigenous and Tribal Peoples of the Tropical Forests was adopted, and at the Earth Summit, the indigenous organisations adopted the Kari-Oca Declaration and the Indigenous Peoples' Earth Charter that laid down the basic policy and legal issues dominating the debate to this day.

⇒ The Earth Summit documents treat TK as one of the many aspects of sustainable development and environmental protection. The Rio Summit did not adopt any language to formally recognise customary rights of indigenous peoples at the international level, however.

[27] Glowka et al. (1994), p. 60.

⇒ Article 8(j) of the CBD links the principle of benefit sharing not only to the utilisation of genetic resources but also to the utilisation of "*TK, innovations and practices*", and subjects any such measures to national legislation. Article 8(j) served as the point of departure for the inclusion of TK issues in the 2010 Nagoya Protocol on ABS.

⇒ Article 7 of the Nagoya Protocol requires countries to ensure that access to associated TK is based on PIC and that benefit sharing will take place. Such benefits are required to cover benefits from R&D, but not commercialization.

⇒ The Protocol governs only TK associated with genetic resources, and not all TK.

3) Plant Genetic Resources for Food and Agriculture

The International Treaty on Plant Genetic Resources for Food and Agriculture (the ITPGRFA) entered into force on 29 June 2004. The Treaty is overseen by a Governing Body composed of the 152 countries that have so far ratified it as of October 2014. The Governing Body is supported by a secretariat, located in Rome, Italy, which is part of a UN specialized agency, the United Nations Food and Agriculture Organization (FAO). This secretariat is also the body which administers the common fund for benefit sharing under this treaty.

The ITPGRFA establishes, *inter alia*, a multilateral system to facilitate access to plant genetic resources for food and agriculture and to share the benefits arising out of their use in a fair and equitable manner. Under the ITPGRFA's multilateral system, parties to the Treaty agree to make freely available genetic diversity and related information stored in gene banks concerning, at present, 81 forage species from 29 genera and an undefined number of crop species from 51 genera (covering the vast majority of plant crops consumed by humans but with important exceptions such as cocoa, coffee, cotton, soya or tomato). Breeders and scientists who wish to utilize the plant genetic resources and improve on these varieties are required to seek access in accordance with a standardized material transfer agreement (MTA) (Article 12.4, ITPGRFA). Those who access genetic materials through the system are required not to claim any 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" (Article 12.3(d)), ITPGRFA. If plant genetic resources accessed from the multilateral system are commercialized, the recipient "shall pay ... an equitable share of the benefits arising from the commercialization of that product, except whenever such a product is available without restriction to others for further research and breeding, in which case the recipient who commercializes shall be encouraged to make such payment" (Article 13.2(d)(ii), ITPGRFA). A pre-fixed percentage of the benefits from commercialization flow into a common fund that is used to support future research, breeding and training projects. The system is operationalized through the standard MTA (see Annex III).[28]

[28] An MTA, which can be a type of Access and Benefit Sharing (ABS) Agreement, is an agreement between provider and receiver of genetic resources governing terms of access, including, PIC, conditions of use, benefit sharing. In genetic resources, the MTA primarily consists of the transfer of specific genetic resources by the competent authority of the providing country, or other entity to recipients, such as research centers, pharmaceutical, biotechnology and other R&D based companies, or to other countries, under MAT. The term 'MTA' is also used in the context of an agreement for the transfer of tangible research materials between two entities, for example, between a university that undertook basic research on a genetic resource or a molecule and a private company that will develop the products for commercialisation.

The ITPGRFA also requires parties to implement in their national legislation measures to protect farmers' rights. The relevant provisions on farmers' rights are set out in Box 4 below. In the context of ABS and TK, it is important to note that the farmers' rights as codified in the ITPGRFA deal with benefit sharing but not with access aspects. During the ITPGRFA negotiations it was argued by some parties that farmers' rights should also cover free access to and exchange of IP-protected plant material as acknowledgement of farmers' contribution to the creation of the existing diversity of plant genetic material without which modern plant breeding could not exist. Such interference with the IP system was not accepted by countries with strong commercial plant breeder interests. The ITPGRFA finally was equipped with a provision in Article 9.3 that the national implementation of farmers' rights shall not "limit any rights that farmers have to save, use, exchange and sell farm-saved seed/propagating material, subject to national law and as appropriate." The only international treaty that currently provides for such rights, though only on a voluntary basis, is the International Treaty for the Protection of New Varieties of Plants (hereafter the UPOV Convention).

Box 4
Article 9. Farmers' Rights

9.1 The Contracting Parties recognize the enormous contribution that the local and indigenous communities and farmers of all regions of the world, particularly those in the centres of origin and crop diversity, have made and will continue to make for the conservation and development of plant genetic resources which constitute the basis of food and agriculture production throughout the world.

9.2 The Contracting Parties agree that the responsibility for realizing Farmers' Rights, as they relate to plant genetic resources for food and agriculture, rests with national governments. In accordance with their needs and priorities, each Contracting Party should, as appropriate, and subject to its national legislation, take measures to protect and promote Farmers' Rights, including:

a) protection of traditional knowledge relevant to plant genetic resources for food and agriculture;
b) the right to equitably participate in sharing benefits arising from the utilization of plant genetic resources for food and agriculture; and
c) the right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture.

9.3 Nothing in this Article shall be interpreted to limit any rights that farmers have to save, use, exchange and sell farm-saved seed/propagating material, subject to national law and as appropriate.

Source: ITPGRFA (2001).

Negotiated post-Earth Summit, a conscious effort was made to ensure that the ITPGRFA is fully consistent with the provisions of the CBD. A provision that is of relevance in the ABS context can be found in Article 12.3(h) which says that "[w]ithout prejudice to the other provisions under this Article, the Contracting Parties agree that access to plant genetic resources for food and agriculture found in *in situ* conditions will be provided according to national legislation or, in the absence of such legislation, in accordance with such standards as may be set by the Governing Body." According to the definition of "*in situ*" given by the ITPGRFA as well as by the CBD, this case would cover those plant genetic resources in natural surroundings as well as on farmers' fields if they have "developed their distinctive properties" in these locations. In 2010, the ad hoc Advisory Technical Committee on the

Standard Material Transfer Agreement and the Multilateral System of the ITPGRFA started its work on compiling information and views on such standards.

The Nagoya Protocol, having been negotiated after the ITPGRFA, has a provision that ensures that the latter treaty (and not the Nagoya Protocol/CBD) governs plant genetic resources for food and agriculture covered by the ITPGRFA for those countries that have ratified it. Under Article 4(4) of the Protocol, "[w]here a specialized international access and benefit-sharing instrument applies that is consistent with, and does not run counter to the objectives of the Convention and this Protocol, this Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument", except, as stipulated in Article 4(1) of the Protocol, "where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity."

Key Points

⇒ The ITPGRFA establishes, *inter alia*, a multilateral system to facilitate access to plant genetic resources for food and agriculture, which is regarded as a major component of sharing the benefits arising out of the use of these genetic resources in a fair and equitable manner.

⇒ Under the ITPGRFA's multilateral system, parties to the Treaty agree to make freely available genetic diversity and related information stored in *ex-situ* collections concerning, at present, 81 forage species from 29 genera and an undefined number of crop species from 51 genera (covering the majority of major plant crops that are important for human food security). The system is operationalized through a standard material transfer agreement (MTA).

⇒ Those who access genetic materials through the system are required not to claim any 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. If plant genetic resources accessed from the multilateral system are commercialized, the recipient is required to pay an equitable share of the benefits arising from the commercialization of that product, except whenever such a product is available without restriction to others for further research and breeding, in which case the recipient who commercializes shall be encouraged to make such payment.

⇒ A pre-fixed percentage of the profits from commercialization flow into a common fund that is used to support future research, breeding and training projects. This system is established as a means of benefit sharing under the ITPGRFA.

⇒ The Nagoya Protocol, having been negotiated after the ITPGRFA, has a provision that ensures that the latter treaty (and not the Nagoya Protocol/CBD) governs plant genetic resources for food and agriculture covered by the ITPGRFA for those countries that have ratified it.

4) Viruses and other Pathogens

A pathogen is typically defined as an infectious organism, and includes viruses, bacteria and fungi, among others.[29] Some definitions also include biological substances such as prions.[30] The characteristic of pathogens is that they cause diseases. In humans, examples of such viruses include human immunodeficiency virus (HIV), Ebola, smallpox and influenza, while examples of bacteria include *Mycobacterium tuberculosis* (tuberculosis), *Escherichia coli* (gastro-intestinal disorders) and *Salmonella typhi* (typhoid). Examples of pathogenic fungi include *Candida* species (yeast infections) and *Trichophyton* species (athlete's foot). Abnormal prions can be pathogenic such as those that cause bovine spongiform encephalopathy (i.e., "mad cow disease"). Pathogens need not, of course, be limited to those that affect humans and could include those affecting other animals or plants as well.

Pathogens are important because they are used in research on the diseases which they cause and in the development of treatments for those diseases, as in the case of vaccines or monoclonal antibodies. According to the World Health Organization (WHO), IP is often not a barrier to the production of vaccines in developing countries. In many cases, modern vaccines embody multiple levels of technology licensed from multiple partners, implying that a would-be vaccine manufacturer in a developing country should be able to 'work around' any refusal by one IP holder to license any specific technology. Additionally, there is also vaccine production technology in the public domain, particularly for developing countries where patent owners have not opted to file a patent application in respect of the technology. [31] The same may not be true for some of the newer vaccines, however, and WHO and others caution that Patent Cooperation Treaty (PCT) applications on vaccine technology have been steadily rising over time. For example, an April 2011 report from the non-governmental organization (NGO) Third World Network catalogues a number of increasingly broad PCT patent applications in recent years for medicines, vaccines, microbes, peptides, nucleic acids and immunoassays with the term "H5N1" and/or "H1N1" in the claims.[32]

Various interpretations exist with respect to the status of pathogens under the CBD and the accompanying Nagoya Protocol. One interpretation is that pathogens such as viruses, which are innately harmful, are not linked to the first objective of the CBD, which is the conservation of biological diversity, and are therefore outside the scope of the Convention (and the NP).[33] Another view acknowledges that pathogens are covered within the scope of the CBD and NP, but that work done by the WHO on virus sharing takes precedence over the NP.[34] Yet another view supports the argument that pathogens are genetic material covered under the CBD and not specifically excluded by the NP or elsewhere.[35] The arguments in favour of the last view are summarized in Box 5 below.

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[29] http://www.medterms.com/script/main/art.asp?articlekey=6383.
[30] http://en.wikipedia.org/wiki/Pathogen.
[31] See Friede (2011). Note, however, that it cannot be assumed that any given developing country would be able to immediately make use of vaccine production technology in the public domain.
[32] Ibid. and Hammond (2011).
[33] See Abbott (2010) and Nijar (2011a).
[34] Nijar (2011a).
[35] Nijar (2011a) argues that a proposal to exclude human pathogens was considered and failed in the negotiations leading up to the Conference of the Parties that adopted the NP. Biotechnology industry groups have countered that at different points, draft texts have both included and excluded pathogens, indicating that no agreement on the inclusion of pathogens in the NP. See http://patentlybiotech.wordpress.com/2010/12/07/pathogens-and-the-nagoya-protocol-of-the-convention-on-biological-diversity/.

Box 5
Main Arguments Why Pathogens Are Covered by the CBD/Nagoya Protocol

The CBD was designed to preserve biological diversity that, among other things, would permit future research and development on biological resources that might yield treatments for disease.[36]

The CBD and NP were designed to allow developing countries to share in benefits from the exploitation of biodiversity resources. Pathogen materials, including virus materials, have a value in so far as they may be used to develop drugs or vaccines for human or animal use, and they have potential monetary value.[37]

A plain reading of the definition of 'genetic material' covered by the CBD leads to the conclusion that pathogens, such as certain bacteria or viruses, contain functional units of heredity and are replicable; nothing in the CBD, NP or other international agreement otherwise excludes pathogens from the scope of coverage.[38]

The work done by WHO on developing standard material transfer agreements (SMTAs) for the sharing of viruses (see Annex 2) is not a binding treaty that guarantees a fair access and benefit sharing regime for pathogens.

Source: authors.

The CBD does not refer to the term "pathogen" as such, but defines genetic resources as material of plant, animal, microbial or other origin containing functional units of heredity (Article 2, CBD). Paragraph 16 of the preamble to the Nagoya Protocol contains the only explicit reference in this document to pathogens, and stipulates that the Protocol is being adopted bearing in mind "the International Health Regulations (2005) of the WHO and the importance of ensuring access to human *pathogens* for public health preparedness and response purposes" (emphasis added). Further, Article 8(b) of the Protocol obligates each Party to the CBD, when formulating their access and benefit-sharing legislation and regulations, to "[p]ay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally." This clause goes on that state that Parties may "take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need, especially in developing countries."

Article 8(b) of the Nagoya Protocol may have to a limited extent eliminated the need to continue the debate on the status of pathogens. While the Protocol does not specify what "due regard" means, it is quite possible that courts could interpret this clause to mean that in the formulation of national ABS legislation, Parties are obliged to grant user access to pathogens in certain emergency cases. Moreover, the Protocol does not provide guidance as to what constitutes an "emergency", but it could be assumed, for instance, that a declaration of a pandemic by the WHO could potentially provide the necessary trigger. National declarations of emergency by health authorities could also potentially suffice as a trigger. This means, for example, that an Ebola outbreak declared in a developed country Member could potentially be grounds for that country to demand access to a virus sample from an African country such as

[36] Abbott (2010), p. 13.
[37] Ibid.
[38] Nijar (2011a), p. 3.

Uganda. For provider countries, the second clause of the Article is designed to provide some assurance of benefit sharing for developing countries in the event a pathogen is shared with a user country in those emergency situations. Notably, the Nagoya Protocol does not specify how a Party could take into consideration the need for expeditious fair and equitable sharing of benefits arising out of the sharing of the pathogen, leaving it up to each Party to negotiate an appropriate response.

Key Points

⇒ There has been a longstanding debate among delegates on whether the CBD and Nagoya Protocol cover pathogens.

⇒ Article 8(b) of the Nagoya Protocol, however, arguably requires Member States to take into consideration the need for expeditious access to pathogens in emergency situations and expeditious benefit-sharing arising out of the use of such genetic resources. This could happen when a national health authority or the WHO declares an outbreak, for instance.

5) Derivatives

Prior to the conclusion of the Protocol, there was an intensive debate over whether the final text ought to cover access to derivatives of genetic resources. The debate on whether derivatives should be covered by the benefit sharing provisions of the Nagoya Protocol was not as controversial because the CBD Parties had already decided that the sharing of benefits arising from the use of derivates can be covered by contractual MAT clauses when they adopted the Bonn Guidelines.[39]

'Derivative' is a defined term under the Nagoya Protocol. According to Article 2(e) of the Protocol, 'derivative' means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources. The term 'derivative' is defined to clarify another defined term, i.e., 'biotechnology'. Biotechnology is defined in Article 2(d) of the Protocol as "any technological application that uses biological systems, living organisms, or *derivatives* thereof, to make or modify products or processes for specific use" (emphasis added). The term 'biotechnology' is, in turn, used in another definition, i.e., the 'utilization of genetic resources', which means to conduct research and development (R&D) on the genetic and/or biochemical composition of genetic resources, including through the application of *biotechnology* as defined under the CBD (Article 2(c) of the Protocol, emphasis added). Interestingly, apart from clarifying another definition, the term 'derivative' does not otherwise appear in the substantive provisions of the Nagoya Protocol.[40]

The debate over whether the Nagoya Protocol should cover derivatives exists at least partly because of different interpretations of the CBD definition of genetic material, i.e., those materials that contain functional units of heredity. Negotiators disagreed whether this means

[39] The Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising Out of their Utilization (2002).

[40] Interestingly, derivatives as defined in this way will never contain functional units of heredity, they are a result of the activity of these functional units, and if biological material contains functional units, it is a genetic resource according to the CBD.

that the material contains functional units of heredity only or can also contain other biological compounds apart from the functional units. If the second interpretation holds true, developed and developing countries differed in their positions as to whether the Protocol obligations should extend to these non-genetic compounds, i.e., derivatives, as for example proteins or medicinal active substances. The debate over the issue was heated, and the solution that negotiators came up with was not to interpret or rewrite the fundamental CBD definitions but to clarify the types of utilization of genetic resources that would trigger the provisions of the Protocol.

With respect to benefit sharing obligations, Article 5(1) of the Protocol states that "benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention. Such sharing shall be upon mutually agreed terms." Thus, the text of the Nagoya Protocol makes clear that benefit sharing obligations of the Protocol extend to genetic resources and subsequent applications and commercialization. This text formulation potentially covers a wide range of items, and, based on the definitions of utilization of genetic resources, derivatives and specifically biotechnology, would also include the utilization of items that are not naturally occurring but have been manufactured through its use. Nijar indicates that this broad interpretation is both supported by the negotiation history of the Nagoya Protocol, and makes sense since it is mostly through the development of products that are based on genetic resources that one could reap commercial benefits from such resources.[41]

Beyond benefit sharing, the status of products that are based on genetic resources remains subject to some interpretation. It seems reasonable, however, that PIC would be required for users who seek access to undertake R&D with a view to developing products based on genetic resources (this is because Article 6 of the Nagoya Protocol requires PIC as a prerequisite for access to genetic resources for their utilization, which by definition encompasses biotechnology R&D, i.e., any technological application that uses biological systems, living organisms, or derivatives thereof (Article 2(d), Nagoya Protocol)). PIC does not appear to be required under the Protocol for access to a derivative in the provider country, but only for the resource itself. National ABS laws could still provide, however, that access to derivatives be conditioned upon PIC, as is required for genetic resources.

Key Points

⇒ The Nagoya Protocol stipulates that the utilization of genetic resources as well as subsequent applications and commercialization are subject to benefit sharing obligations. The Protocol leaves it open to interpretation which substances or even which types of information generated from genetic resources through the application of biotechnology are subject to benefit sharing obligations.

⇒ While the Nagoya Protocol is less clear as to whether derivatives of genetic resources are subject to PIC requirements for access, there is nothing in the Protocol that prevents countries from adopting ABS legislation that introduces such a requirement.

[41] Nijar (2011a), p. 13.

III. Conclusion

The global ABS system for genetic resources and associated TK is set up by the CBD and the Nagoya Protocol. These multilateral treaties require that access to genetic resources be based on PIC and MAT. Parties also need to ensure that genetic resources and associated TK utilized in the area under national jurisdiction have been accessed based on PIC and MAT as required by the provider country. These treaty requirements need to be embedded in national law. The CBD is nearly universal, and the Protocol recently received the 50 ratifications required to come into force.

There has been some debate as to what is covered by the Protocol in terms of genetic resources. These debates have been with respect to genetic resources and TK accessed prior to the CBD and the Protocol, the status of pathogens and derivatives, and the scope of TK that is covered by these treaties. Certain plant genetic resources are excluded from the scope of the Protocol and are instead covered by the ITPGRFA.