



**LEGAL ASPECTS OF
SUSTAINABLE NATURAL
RESOURCES**

**LEGAL WORKING
PAPER SERIES**

**THE NAGOYA PROTOCOL: STATUS OF
INDIGENOUS AND LOCAL
COMMUNITIES**

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2011

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1.Introduction

Adopted on October 2010 in Nagoya, Japan¹ by the Parties to the *Convention on Biological Diversity* (CBD) of 1992, the *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization* (NP)² opened for signature on 2 February 2011 until 1 February 2012 and will, according to Article 33 of the NP, come into force after its 50th ratification.³ The Protocol was conceived to respond to the many criticisms voiced concerning the Access and Benefits-Sharing (ABS) provisions in the CBD. One of the most frequent of these criticisms concerns the protection afforded to Indigenous traditional knowledge, a great deal of which is based on Indigenous methods of natural resource management.

The basic reproach is that ABS have simply not been realized. There have been some success stories but overall Indigenous people are still waiting for legal protection of the genetic resources that underlie their traditional knowledge and to share in the benefits, decades later. Current estimates for herbal products run up to 60 billion dollars and are expected to climb to 5 trillion dollars by 2020.⁴ Alikhan notes that, “Eli Lilly’s extraction of the rosy-periwinkle plant based on traditional knowledge from Madagascar and commercialisation of the resultant drug totaling US\$ 100 million with no returns to the local people.”⁵ In short the Convention on Biological Diversity is concerned more with assuring access to, and sharing the benefits of, genetic resources than the protection of Indigenous traditional knowledge and the well being of indigenous and local communities. This is not to say that the *raison d’être* of the CBD is not important, just that it was not necessarily conceived with the protection of Indigenous traditional knowledge as a primary goal.

In its preamble the NP recalls Article 15 CBD (*Access to Genetic Resources*) and Article 8 (j) CBD (*In-situ Conservation* and the importance of related traditional knowledge) as well as the 3rd objective of the CBD:

*...the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.*⁶

In addition, the NP affirms the linkage of this objective of the CBD to the other two objectives by adding “thereby contributing to the conservation of biological diversity and the sustainable use of its components.”⁷ Many have perceived the adoption of a new Protocol under the CBD⁸ as a milestone,

1 Secretariat of the Convention on Biological Diversity (CBD), *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: Text and Annex*. (Montréal: Secretariat of the Convention on Biological Diversity, 2011); COP 10 Decision X/1 X/1. Access to genetic resources and the fair and equitable sharing of benefits arising from their utilization, online: CBD <<http://www.cbd.int/decision/cop/?id=12267>>.

2 UN Convention on Biological Diversity, 5 June 1992, 1760 UNTS 79; 31 ILM 818 (entered into force 29 December 1993), online: <<http://www.cbd.int/doc/legal/cbd-un-en.pdf>>

3 CBD, ABS, online: <<http://www.cbd.int/abs/>>.

4 Shahid Alikhan, *Socio-economic Benefits of Intellectual Property Protection in Developing Countries*, (Geneva: WIPO, 2000) at 83

⁵ *Ibid.* at 84

⁶ Article 1 *Objectives*, CBD

⁷ Article 1 NP also Compare Bonn Guidelines, E. Objectives 11 (a), paragraph 24 and 48

even though reactions in particular with regard to the interests of developing countries as well as indigenous and local communities (ILC) have been diverse.⁹

The adoption of the CBD in 1992 as one of the three “Rio Conventions” introduced a paradigm shift. For the first time an international agreement with conservation as the overall goal did not only address environmental issues, but also recognized the importance of other issues including social, economic, scientific, educational, cultural, recreational and aesthetic values for conservation.¹⁰ In the spirit of the Rio Earth Summit and the Brundtland Report¹¹ the different goals and interests were thereby not seen as contrary, but as mutually reinforcing or complementing. In this regard the Parties stated in the preamble of the CBD that Contracting Parties are:

...aware that conservation and sustainable use of biological diversity is of critical importance for meeting the food, health and other needs of the growing world population, for which purpose access to and sharing of both genetic resources and technology are essential.

Parties also recognized that, “economic and social development and poverty eradication are the first and overriding priorities of developing countries”. In addition the role of ILC in preserving and enhancing biodiversity was explicitly acknowledged. This preambular paragraph was complemented by Article 8 (j) which stipulates that:

“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;...”

8 The Cartagena Protocol on Biosafety to the Convention on Biological Diversity was adopted on 29 January 2000 and entered into force on 11 September 2003 and the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety was adopted together with the Nagoya Protocol in October 2010 in Nagoya.

9 Compare Krystyna Swiderska, “What happened at Nagoya?”, International Institute for Environment and Development, November 2010 online: iied <<http://www.iied.org/natural-resources/key-issues/biodiversity-and-conservation/what-happened-nagoya>>; Priscilla Jebaraj, “Nagoya Protocol, a big victory for India”, The Hindu (31 October 2010), online: The Hindu <<http://www.thehindu.com/news/national/article859977.ece>>; a more critical standpoint is taken by Evanson Chege Kamau, Bevis Fedder & Gerd Winter, “The Nagoya Protocol on Access to Genetic Resources and Benefit Sharing: What is New and what are the Implications for Provider and User Countries and the Scientific Community?” (2010) 6:3 Law, Environment and Development Journal 246 at 262 [Kamau, Fedder & Winter]; Native Women of Quebec, “Joint Statement of North American Indigenous Organizations on the Nagoya ABS Protocol of the Convention on Biological Diversity”, Kahnawake, December 14, 2010; Union for Ethical BioTrade, Nagoya Protocol on Access and Benefit-Sharing - Technical Brief (Berne, Switzerland: Union for Ethical BioTrade, 2010).

10 G. Kristin Rosendal, “Balancing Access and Benefit Sharing and Legal Protection of Innovations From Bioprospecting” (2006) 15:4 The Journal of Environment & Development at 430, 431.

11 Report of the World Commission on Environment and Development: Our Common Future, transmitted to the General Assembly as an Annex to document A/42/427 - Development and International Co-operation: Environment, UN General Assembly 96th plenary meeting, 11 December 1987.

The legal tool to take into account all the different interests was the introduction of the so-called access and benefit-sharing instrument (ABS)¹². In response to concerns raised by developing countries, that industrialized countries exploit their natural wealth, provider countries of genetic resources (and thus mainly developing countries) were empowered to regulate access to their genetic resources with the aim of benefit sharing arising out of their utilization. At the same time Parties were encouraged to create conditions to facilitate access to genetic resources for environmental sound use (Article 15.2) as ABS was not seen as an instrument of exclusion of users, but as an instrument to generate and share benefits from genetic resources in order to incentivize conservation and sustainable use.¹³

It is argued however, that the tense nature of State/Indigenous Peoples relationships makes it unlikely that States would give Indigenous people access to an international arena such as the WTO in an unfettered manner. Sovereignty over natural resources is attributed to national governments and hence the CBD is unable to deal with the volatile nature of the relationship between Indigenous peoples and their respective national governments, both in the developed and developing world. Khor in assessing the CBD suggests that, “reflecting the uncomfortable political deal which was struck in bringing the CBD to conclusion, the language of the Convention is unfortunately vague. The positive affirmation of principles in a number of areas is qualified by vague transcendental values.”¹⁴

Giving all control over natural resources, including biological diversity, to the State severs the all-important connection between community and biodiversity. This situation results in a lack of control for Indigenous Peoples over the ecosystems that they developed and maintained since time immemorial. There is ample evidence to suggest that cultural diversity and the unique natural resource management techniques that ensue are elemental to a healthy ecosystem. As Parajuli explains, “the field of politics for ecological ethnicities is the community, and not necessarily the civil society or the nation-state as one would usually suppose...the seeds of regeneration need the firm soil of community and culture, vernacular technology and agriculture, collectivities and memories.”¹⁵

Furthermore, the implementation of the CBD proved slow due to the complexity of the issues addressed as well as hardly any guidance from the CBD as a framework convention¹⁶. After almost

12 See also the Multilateral System of Access and Benefit-sharing established under the International Treaty on Plant Genetic Resources for Food and Agriculture, ITPGRFA, which came into force in 2004: Claudio Chiarolla & Stefan Jungcort, *Outstanding Issues on Access and Benefit Sharing under the Multilateral System of the International Treaty on Plant Genetic Resources for Food and Agriculture* (Zurich & Oslo: The Berne Declaration & Development Fund, 2011).

13 Rosendal, at 433.

14 Martin Khor, *Intellectual Property, Biodiversity and Sustainable Development: Resolving the Difficult Issues*, (London: Third World Network, 2002) at 40.

15 Parajuli, P., "Learning from Ecological Ethnicities: Toward a Plural Political Ecology of Knowledge" in J. A. Grim, *Indigenous Traditions and Ecology. The Interbeing of Cosmology and Community*, (Cambridge: Harvard University Press, 2001) at 574.

16 Bram de Jonge and Niels Louwaars, ““The Diversity of Principles Underlying the Concept of Benefit-Sharing” in: Kamau, Fedder & Winter, *supra* note 6 at XXV, 37; Miriam Dross & Franziska Wolff, *New Elements of the International Regime on Access and Benefit-Sharing of Genetic Resources - the Role of Certificates of Origin* (Bonn: German Federal Agency for Nature Conservation, 2005) at 12; Gurdial Singh Nijar, *The Nagoya Protocol on Access and Benefit Sharing of Genetic Resources: Analysis and Implementation Options for Developing Countries* (unknown: South Centre, 2011) at 7; Kathryn Garforth et al., *Overview of the National and Regional Implementation*

no or insufficient domestic implementation efforts were undertaken to accomplish “fair and equitable benefit sharing” Parties adopted the non-binding *Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising out of Their Utilization* (Bonn Guidelines) in 2002 in an attempt to guide and foster implementation of ABS in domestic legislation¹⁷.

The interaction of the ABS regime with other international regimes, especially the Agreement on Trade Related Aspects of International Property Rights (TRIPS) under the World Trade Organization (WTO), is also regarded as critical in achieving fair and equitable benefit-sharing and negotiations on harmonizing different legal regimes have been ongoing since the adoption of the CBD¹⁸. The most prominent call has thereby been to require the disclosure of origin of genetic resources or associated TK in patent applications as a compliance measure for ABS¹⁹. Also it is argued that TRIPS needs to specifically address TK, which at the present moment it does not.

This paper examines how the NP has changed the ABS landscape with special focus on the role of Indigenous and Local Communities.

2.ABS and the CBD

ABS as an international legal concept was for the first time introduced in 1992 in the CBD in its Article 15:

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.

of Measures on Access to Genetic Resources and Benefit-Sharing, 3 ed. (Montreal: Centre for International Sustainable Development Law (CISDL), 2005).

17 Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization, in Report of the Sixth Meeting of the Conference of the Parties to the Convention on Biological Diversity, UN Doc. UNEP/CBD/COP/6/20 (2002).

18 Jorge Cabrera Medaglia, *The Political Economy of the International ABS Regime Negotiations: Options and Synergies with Relevant IPR Instruments and Processes* (Geneva, Switzerland: International Centre for Trade and Sustainable Development, 2010); Jorge Cabrera Medaglia, "The Relationship Between The Access and Benefit Sharing International Regimen and Other International Instruments: The World Trade Organization And The International Union For the Protection of New Varieties of Plants" (2010) 10:3 Sustainable Development Law & Policy; J.C. Medaglia, "Trade, Particular Free Trade Agreements and Access to Genetic Resources and Benefit Sharing: Exploring Some the Linkages" (2008) 10:3 Asian Biotechnology and Development Review; Jess Nierenberg & Alejandro García Alvarez, eds., *Triggering the Synergies between Intellectual Property Rights and Biodiversity* (Eschborn, Germany: Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ) GmbH, 2010).

19 Megadiverse Countries Call for Legally Binding ABS Regime, *Bridges Trade BioRes*, vol. 5, no. 2, 4th February 2005, online: ICTSD <<http://ictsd.org/i/news/biores/63359/>>; Carlos M. Correa, *Geographical Indications and the Obligation to Disclose the Origin of Biological Materials: Is a Compromise Possible under TRIPS?* (Geneva: ICTSD Programme on IPRs and Sustainable Development, 2010); Charles R. McManis, *Biodiversity and the Law : Intellectual Property, Biotechnology and Traditional Knowledge* (London; Sterling, VA: Earthscan, 2007); Dross & Wolff, at 104; Nierenberg & Alvarez, eds.

2. Each Contracting Party shall endeavour to create renditions 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 resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.**

The main idea is thus that in recognition of the sovereign rights of states over their natural resources states can regulate access to genetic resources within their jurisdiction. Thereby the CBD defines genetic resources as genetic material of actual or potential value (Article 2 CBD).

Access to genetic resources shall be subject to the prior informed consent (PIC) of the Contracting Party providing such resources. Article 15 CBD also provides that access shall be based on mutually agreed terms (MAT) in order to ensure the fair and equitable sharing of benefits arising from the commercial or other utilization of these genetic resources with the Contracting Party providing such resources. In addition to regulating access to genetic resources as well as the sharing of the benefits arising out of the utilization of their use, Article 8(j) CBD addresses ABS with regard to traditional knowledge (TK). The provision promotes a wider application of TK associated with genetic resources with the approval and involvement of the holder and encourages the equitable sharing of the benefits arising from its utilization. However, Article 8(j) does not require the PIC of indigenous TK holders.

Article 8(j) CBD earned a lot of criticism for its soft language (“each Contracting Party shall, as far as possible and as appropriate, subject to its national legislation”, “promote”, “encourage”). Moreover parties and stakeholders debated whether the provision contained an obligation for users to require PIC of ILC to access TK as well as an obligation to share the benefits from the utilization of TK.²⁰

20 Kamau, Fedder & Winter, "The Nagoya Protocol on Access to Genetic Resources and Benefit Sharing: What is New and what are the Implications for Provider and User Countries and the Scientific Community?" at 1.

In response to this debate COP 5 (2000) established a general principle (but did not modify the existing text) that access to TK of ILC should be subject to the PIC of its holders.²¹

3. The Bonn Guidelines

Although the CBD was adopted in 1992 and entered into force at the end of 1993, the operationalization and thus the implementation of provisions related to ABS was slow²². Starting with the Philippines in 1995 selected provider countries started enacting ABS legislation. But as their approaches to access were mainly restrictive and thus contrary to the CBD objective of facilitating ABS, the Conference of the Party to the CBD (COP) 5 (2000) established the Ad Hoc Open-ended Working Group on ABS with the mandate to develop guidelines.²³ The result is the Bonn Guidelines, adopted unanimously by some 180 countries²⁴.

The Bonn Guidelines are of voluntary nature and according to I.A.1. “*may serve as inputs when developing and drafting legislative, administrative or policy measures under Articles 8(j), 10(c), 15, 16 and 19 CBD; and contracts and other arrangements under MAT for ABS*”. The Guidelines identify the steps in the ABS process, with an emphasis on the obligation for users to seek PIC of providers. They also identify the basic requirements for MAT and define the main roles and responsibilities of users and providers.²⁵ With regard to PIC, the Bonn Guidelines distinguish between ILC associated with the genetic resources being accessed and TK associated with the genetic resources being accessed. In both cases PIC of ILC and in the latter also the approval and involvement of the holders of TK should be obtained in respect of established legal rights (paragraph 31).

Furthermore the Guidelines introduce a proposed list of elements that could be considered as guiding parameters in contractual agreements as well as basic requirements for MAT particularly with regard to ILC and TK (paragraph 43):

(a) Regulating the use of resources in order to take into account ethical concerns of the particular Parties and stakeholders, in particular ILC concerned;

(b) Making provision to ensure the continued customary use of genetic resources and related knowledge;

(c) Provision for the use of intellectual property rights include joint research, obligation to implement rights on inventions obtained and to provide licences by common consent;

(d) The possibility of joint ownership of intellectual property rights according to the degree of contribution.

21 Gurdial Singh Nijar, "Incorporating Traditional Knowledge in an International Regime on Access to Genetic Resources and Benefit Sharing: Problems and Prospects" (2010) 21:2 European Journal of International Law at 459, 460.

22 Bram de Jonge and Niels Louwaars in: Kamau, Fedder & Winter, supra note 6 at XXV, 37; Dross & Wolff, at 12; Nijar, The Nagoya Protocol on Access and Benefit Sharing of Genetic Resources: Analysis and Implementation Options for Developing Countries at 7; Garforth et al; Country reports, in: Kamau, Fedder & Winter, supra note 6.

23 Kamau, Fedder & Winter, "The Nagoya Protocol on Access to Genetic Resources and Benefit Sharing: What is New and what are the Implications for Provider and User Countries and the Scientific Community?" at 248.

24 Bonn Guidelines, Introduction.

25 *ibid.*

Finally the Bonn Guidelines state that, “*benefits should be shared fairly and equitably with all those who have been identified as having contributed to the resource management, scientific and/or commercial process. The latter may include governmental, non-governmental or academic institutions and ILC...*”²⁶ Besides the voluntary nature of the Guidelines representatives of indigenous peoples have especially criticized that they do not distinguish between their role and any other stakeholder who might be involved in resource management. As a result their participation in ABS is not a question of rights enforcement but rather a question of national recognition of ILC rights.²⁷

In addition it has been criticized that the Guidelines focus too much on the access side and thus on provider country measures as opposed to user country measures.²⁸ Whereas access and the agreement to share benefits take place in the country providing the genetic resources, the actual utilization of the genetic resources and thus the benefits triggering moment usually happens in another jurisdiction – the one of the user country. The need for user-country measures has therefore been stressed in order to ensure compliance with domestic ABS legislation of the provider country and to monitor the utilization of genetic resources and associated TK to enforce benefit-sharing agreements.²⁹

Different groups of developing countries including the Group of 77 and China as well as the Group of Like-minded Megadiverse Countries (LMMC)³⁰ thus pushed for a protocol on ABS.³¹ At COP 7 (2004) the Working Group-ABS was given the mandate to elaborate and negotiate an international regime on ABS in cooperation with the Working Group on Article 8(j)³².

4. The Nagoya Protocol

According to different observers the final adoption of the Protocol at the meeting in Nagoya was not certain until the last minute³³. The main critical points were the scope of the NP, the design of compliance or user-country measures as well as the involvement of ILC when access to TK associated with the genetic resources is not requested.³⁴ The NP is structured into 27 preambular paragraphs, 36 articles, and one annex. In the following the core provisions will be summarized and analyzed.

²⁶ Paragraph 48

²⁷ Dross & Wolff, at 19.

²⁸ *ibid.*

²⁹ Cabrera Medaglia, *The Political Economy of the International ABS Regime Negotiations: Options and Synergies with Relevant IPR Instruments and Processes*.

³⁰ The LMMCs include Bolivia, Brazil, China, Colombia, Costa Rica, Democratic Republic of Congo, Ecuador, India, Indonesia, Kenya, Madagascar, Malaysia, Mexico, Peru, the Philippines, South Africa and Venezuela (Megadiverse Countries Call for Legally Binding ABS Regime, *Bridges Trade BioRes*, vol. 5, no. 2, 4th February 2005, online: ICTSD <<http://ictsd.org/i/news/biores/63359/>>.

³¹ Krystyna Swiderska, *supra* note 6; Megadiverse Countries, ICTSD, *supra* note 24.

³² CBD, Working Group on Article 8(j), online: CBD <<http://www.cbd.int/convention/wg8j.shtml>>.

³³ *ibid.*, at 250; Union for Ethical BioTrade.

³⁴ Nijar, *The Nagoya Protocol on Access and Benefit Sharing of Genetic Resources: Analysis and Implementation Options for Developing Countries* at 11; for a table overview on controversial issues, the standpoint of user and provider countries as well as the outcome of the negotiations view Kamau, Fedder & Winter, "The Nagoya Protocol on Access to Genetic Resources and Benefit Sharing: What is New and what are the Implications for Provider and User Countries and the Scientific Community?" at 254, 255.

4.1. Preamble

The preamble first repeats some of the preambular paragraphs of the CBD and clarifies the importance of ABS for conservation further when stating that, “*economic value of ecosystems and biodiversity and the fair and equitable sharing of this economic value with the custodians of biodiversity are key incentives for the conservation of biological diversity and the sustainable use of its components.*”

Furthermore the preamble refers to some of the difficulties in implementation of the CBD so far, thereby namely recognizing the importance of promoting equity and fairness in negotiations of MAT between providers and users of genetic resources. The last seven points are concerned with TK highlighting amongst others Article 8(j) CBD, the importance of TK for the conservation of biological diversity, the diversity of circumstances in which TK associated with genetic resources is held or owned by ILC and their right to identify the rightful holder of their TK. In addition and for the first time in an international treaty, the preamble refers to the UN Declaration on the Rights of Indigenous People (UNDRIP) adopted in 2007.³⁵

4.2. Access and Benefit sharing

Starting with the provisions on benefit sharing before moving on to the regulation of access the Protocol clearly separates the two. Furthermore, Article 5 NP (*Fair and Equitable Benefit-Sharing*) also clearly distinguishes between benefits arising from the utilization of genetic resources, benefits that are arising from genetic resources that are held by ILC and benefits arising from the utilization of TK associated with genetic resources:

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 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

Benefits arising from the utilization of genetic resources that are held by [ILC], in accordance with domestic legislation regarding the established rights of these [ILC] over these genetic resources, are shared in a fair and equitable way with the communities concerned.

...Benefits arising from the utilization of traditional knowledge associated with genetic resources are shared in a fair and equitable way with [ILC] holding such knowledge.

In accordance with the CBD all such sharing shall be upon MAT and benefits may include monetary and non-monetary benefits, including but not limited to those listed in the Annex of the Protocol, which mainly reiterates the list of the Bonn Guidelines. In the following the Protocol also deals separately with access to genetic resources in Article 6 and access to TK associated with genetic resources in Article 7.

Article 6 reiterates that, under reaffirmation of sovereign rights over natural resources, access to genetic resources for their utilization is subject to PIC of the providing party. With regard to previous implementation efforts the Protocol is very elaborate on the procedural facilitation of

³⁵ After the Canadian government initially blocked reference to the UNDRIP, Canada only accepted to include in the preamble: “Noting the United Nations Declaration on the Rights of Indigenous Peoples” after widespread international criticism. (Native Women of Quebec)

access (Article 6.3 NP)³⁶. At this point it should be highlighted that Article 6.3(e) requires each Party to provide for the issuance at the time of access of a permit or its equivalent as evidence of the decision to grant PIC and of the establishment of MAT, and to notify the ABS Clearing-House (established by Article 14 NP) accordingly.

Article 6.2 requires each Party to take measures that the PIC or approval and involvement of ILC is obtained for access to genetic resources where they have established right to grant access to such resources. Article 7 NP only consists of one paragraph and states that, “*in accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that [TK] associated with genetic resources that is held by [ILC] is accessed with the prior and informed consent or approval and involvement of these [ILC], and that [MAT] have been established.*”

4.3. Scope of application

4.3.1. The Utilization of Genetic Resources

Utilization of genetic resources is defined as “*research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2(c) of the Convention*”. Whereas the CBD defined genetic resources as genetic material of actual or potential value (Article 2 CBD) the term utilization of genetic resources has not been defined before and experts and national legislations offered different interpretations on the types of activities covered by the term.³⁷ The new definition thus aims at creating more legal certainty by including biochemical compositions under the scope of ABS. According to *Kamau, Fedder & Winter* this is of high importance since for example drugs based on the extraction of chemicals from biological resources are now subject to benefit sharing.³⁸ The NP also contains a definition of “derivative” which was also a central concern of developing countries, but the implications of this incorporation are not clear.³⁹

4.3.2. Temporal Scope

According to Article 3 the NP shall apply to genetic resources within the scope of Article 15 CBD, to the benefits arising out of the utilization of such resources, to TK associated with genetic resources within the scope of the CBD and to the benefits arising from the utilization of such knowledge. The provision was one of the most critical points in the negotiations. Developing countries wanted the NP to apply to existing collections of genetic resources and thus to genetic material accessed prior the adoption of the NP and prior to the adoption of the CBD. But industrialized countries (mainly the European Union) argued that this would go against legal clarity and certainty and eventually they succeeded with the reference to the scope of the CBD.⁴⁰

However, it is being argued that the provision does not imply that benefit sharing only relates to benefits from genetic resources and TK accessed post-CBD or even post-NP. Drawing on general

36 Kamau, Fedder & Winter, "The Nagoya Protocol on Access to Genetic Resources and Benefit Sharing: What is New and what are the Implications for Provider and User Countries and the Scientific Community?" at 250.

37 Union for Ethical BioTrade.

38 Kamau, Fedder & Winter, "The Nagoya Protocol on Access to Genetic Resources and Benefit Sharing: What is New and what are the Implications for Provider and User Countries and the Scientific Community?" at 251, 252.

39 Union for Ethical BioTrade.

40 Kamau, Fedder & Winter, "The Nagoya Protocol on Access to Genetic Resources and Benefit Sharing: What is New and what are the Implications for Provider and User Countries and the Scientific Community?"; Krystyna Swiderska, *supra* note 6; Nijar, *The Nagoya Protocol on Access and Benefit Sharing of Genetic Resources: Analysis and Implementation Options for Developing Countries*.

principles of international law the position is that new benefits arising from prior or ongoing uses may be considered as new situations for benefit-sharing requirements and thus that the NP would be applicable.⁴¹ In addition, the NP, as a way to bridge the different positions on temporal scope, refers to a Global Multilateral Benefit Sharing Mechanism which shall deal with situations where PIC from provider countries cannot be obtained (Article 10 NP). This mechanism could potentially cover collections made before the protocol is implemented.⁴²

4.3.3. Multilateral Benefit-Sharing Mechanism and Transboundary Cooperation

According to Article 10 NP (*Global Multilateral Benefit-Sharing Mechanism*), “Parties shall consider the need for and modalities of a global multilateral benefit-sharing mechanism to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and [TK] associated with genetic resources that occur in transboundary situations or of which it is not possible to grant or obtain [PIC]. The benefits... through this mechanism shall be used to support the conservation of biological diversity and the sustainable use of its components globally.” The establishment of a multilateral benefit-sharing fund has already been proposed by the Africa Group. The wording “not possible to grant or obtain [PIC]” is broad and could thus cover genetic resources or associated TK which origin is not clear or that were obtained prior to the entering into force of the NP and the CBD, for instance for ex situ collections. The fund thus provides a potential means of addressing developing country concerns over the temporal scope.⁴³

Next to a global benefit-sharing mechanism the NP also encourages regional cooperation. Article 11 NP (*Transboundary Cooperation*) foresees cooperation between Parties and involvement of ILC concerned if the same genetic resources are found in-situ within the territory of more than one Party or where the same TK is shared by one or more ILC in several Parties. In their assessment *Kamau, Fedder and Winter* come to the conclusion that Article 10 and 11 NP constitute “a kind of, though weak, derogation of absolute state sovereignty” and draw the comparison with the multilateral ABS of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).⁴⁴

And the Union for Ethical BioTrade observes that “in the [NP], the need to share the benefits derived from the use of genetic resources appears to have been detached from access to these resources. Fair and equitable sharing of benefits must still take place on the basis of [MAT], but it is not clear that benefit sharing requires, or only takes place ensuing, access procedures”.⁴⁵

4.3.4. User-Country Measures: Ensuring Compliance and Monitoring

According to Article 15 NP (*Compliance with Domestic Legislation or Regulatory Requirements on Access and Benefit-Sharing*) each Party shall take measures to provide that genetic resources, utilized within its jurisdiction have been accessed in accordance with PIC and that MAT have been established, “as required by the domestic [ABS] legislation or regulatory requirements of the other Party”. In addition Parties shall

41 Kamau, Fedder & Winter, "The Nagoya Protocol on Access to Genetic Resources and Benefit Sharing: What is New and what are the Implications for Provider and User Countries and the Scientific Community?" at 255; Union for Ethical BioTrade.

42 Union for Ethical BioTrade.

43 Kamau, Fedder & Winter, "The Nagoya Protocol on Access to Genetic Resources and Benefit Sharing: What is New and what are the Implications for Provider and User Countries and the Scientific Community?"; Krystyna Swiderska, supra note 6; Union for Ethical BioTrade.

44 Kamau, Fedder & Winter, "The Nagoya Protocol on Access to Genetic Resources and Benefit Sharing: What is New and what are the Implications for Provider and User Countries and the Scientific Community?".

45 Union for Ethical BioTrade.

take measures to address situations of non-compliance and cooperate in cases of alleged violation of domestic ABS legislation or regulatory requirements.

Article 16 NP (*Compliance with Domestic Legislation or Regulatory Requirements on Access and Benefit-Sharing for Traditional Knowledge Associated with Genetic Resources*) restates the three paragraphs summarized above for the use of TK associated with genetic resources. Although Article 15.7 CBD requires each contracting Party to ensure fair and equitable benefit-sharing and thus also addresses user countries, it is for the first time that compliance measures to be implemented by user-countries are explicitly addressed and specified.⁴⁶ Against the background that little progress has so far been made on such compliance or user-country measures and that this is widely perceived as one of the biggest obstacles for fair and equitable benefit-sharing, the issue was one of the most critical point of the negotiations⁴⁷.

Whereas Article 15 and Article 16 NP leave it primarily to Parties to decide on “*appropriate, effective, and proportionate legislative, administrative or policy measures*” for compliance, Article 17 NP (*Monitoring the Utilization of Genetic Resources*) requires Parties to support compliance by monitoring and enhancing transparency about the **utilization** of genetic resources.⁴⁸ A correspondent provision on TK is missing which could have far reaching consequences taking into account the clear distinction the NP draws between the utilization of genetic resources and the utilization of TK.⁴⁹

The most important requirement for Parties listed in Article 17.1(a) NP is the designation of one or more checkpoints. Checkpoints shall receive or collect information related to PIC, the source and utilization of the genetic resource and the establishment of MAT and submit it to relevant authorities, the provider party, and the ABS Clearing-House Mechanism.

To facilitate monitoring the Protocol introduces internationally recognized certificates of compliance which “*shall serve as evidence that the genetic resource which it covers has been accessed in accordance with [PIC] and that [MAT] have been established*” (Article 17.3 NP). Thereby the already mentioned permit issued in accordance with Article 6.3(e) NP shall constitute such a certificate (Article 17.2 NP).

The demand mainly from developing countries to include a list of mandatory checkpoints was not successful⁵⁰. Nevertheless Article 17.1(a)(iv) specifies that check points “*must be effective and should have functions relevant to implementation of this subparagraph (a). They should be relevant to the utilization of genetic resources, or to the collection of relevant information, at, inter alia, any stage of research, development, innovation, pre-commercialization or commercialization.*”

Possible checkpoints could for example include the patent application process (in response to the already mentioned critical relationship with IP protection), application processes for government

46 Nijar, *The Nagoya Protocol on Access and Benefit Sharing of Genetic Resources: Analysis and Implementation Options for Developing Countries* at 12.

47 Christine Godt, *Enforcement of Benefit-Sharing Duties in User Countries*, in: Kamau, Fedder & Winter, *supra* note 6; Nijar, *The Nagoya Protocol on Access and Benefit Sharing of Genetic Resources: Analysis and Implementation Options for Developing Countries* at 11; Union for Ethical BioTrade.

48 Kamau, Fedder & Winter, “*The Nagoya Protocol on Access to Genetic Resources and Benefit Sharing: What is New and what are the Implications for Provider and User Countries and the Scientific Community?*” at 252.

49 *ibid.*, at 252, 253.

50 *ibid.*, at 256, 257; Union for Ethical BioTrade.

funding for biodiversity-based research and development or market approval processes.⁵¹ Whereas Article 17 NP only monitors the establishment of MAT, Article 18 (*Compliance with [MAT]*) aims at achieving compliance with MAT by requiring Parties to encourage providers and users to include provisions in MAT to cover dispute resolution. In the following examples are listed specifying what those provisions should encompass. Article 18 NP thus makes clear that the enforcement of MAT and thus benefit-sharing is an issue of contract enforcement.⁵²

This leads Kamau, Fedderer & Winter to the conclusion that the main problem is the material issue that shall be checked: “*There is no specified obligation of user states to ensure benefit sharing. As before, the enforcement of benefit-sharing duties is left to contractual means, with all the difficulties of forum, litigation costs, and prosecution of titles. The fact that the Protocol does not go further in that direction constitutes a major disappointment for the provider side.*”⁵³ Nevertheless Parties shall take measures regarding access to justice and the utilization of mechanisms regarding mutual recognition and enforcement of foreign judgments and arbitral awards (Article 18.3) and paragraph 4 specifically requires the review of the effectiveness of this article.

5. Other provisions

The NP introduces simplified conditions on PIC for basic research without a further definition of the latter and an emergency clause (Article 8 NP: *Special Considerations*). It also encompasses comprehensive measures on improving capacities with a special focus on ILC (Article 22 NP: *Capacity*) as well as complementing funding provisions (Article 25 NP: *Financial Mechanisms and Resources*).

In regard to ILC also Article 12 NP (*TK Associated with Genetic Resources*) should be mentioned. The Article requires Parties to; Take into consideration ILC’ customary laws, community laws and procedures with respect to TK associated with genetic resources; Establish mechanisms to inform potential users of TK associated with genetic resources about their obligations; Support the development by ILC of (a) Community protocols in relation to ABS in TK, (b) Minimum requirements for MAT and (c) Model contractual clauses for benefit-sharing; and To not restrict the customary use and exchange of genetic resources and associated TK within and amongst ILC in their implementation of the Protocol.

In addition and in the footsteps of the Bonn Guidelines the NP requires each Party to designate a national focal point on ABS as well as to designate one or more competent national authorities on ABS which is amongst others responsible for granting access (Article 13 NP). Last but not least the NP establishes an ABS Clearing-House as part of the clearing house mechanism under Article 19, paragraph 3 CBD (Article 14 NP) which shall serve as a means for sharing of information related to ABS.

51 Union for Ethical BioTrade.

52 Kamau, Fedder & Winter, "The Nagoya Protocol on Access to Genetic Resources and Benefit Sharing: What is New and what are the Implications for Provider and User Countries and the Scientific Community?" at 252.

53 *ibid.*, at 257.

6. Conclusion and Outlook

With the adoption of the NP as an international binding treaty, which implements the ABS provisions of the CBD, the Parties of the CBD accomplished to address many of the perceived obstacles to implementation so far – ranking from transparency of the ABS process, over lack of user-country measures to the role of ILC.

Nevertheless the Protocol is the outcome of compromise between all the different Parties of the CBD and thus national governments and that is the entry point for most of the criticism expressed by indigenous people or on their behalf. From the critics point of view state sovereignty clearly overrules the rights of indigenous peoples throughout the whole Protocol⁵⁴. The main arguments brought forward are the following:

First of all the language creates a double standard between ILC rights and those of state parties by using the terms “in accordance with domestic law”, “established rights”, “as appropriate”, “as applicable” and “with the aim of ensuring” whenever it is dealt with ILC rights throughout the whole NP.⁵⁵ (Compare Article 6.2, 7, 11, 12, 16.1 NP)

And second, and in particular with regard to Article 12.1 NP, references to customary laws are undermined when Parties shall only take them into account in accordance with domestic law.⁵⁶ Another point of criticism is of course still that the Protocol does not address the issue of intellectual property rights of Indigenous peoples’ TK. Instead the majority of states deferred the issue to WIPO despite the fact that the organizations mandate does not cover the protection of TK.⁵⁷ The main concern thereby is that the CBD and now the complementing NP only increase the pressure they already face in protection of TK through the commodification of their knowledge and by making it subject to domestic law if no sui generis system of protection is acknowledged.⁵⁸

The next COP as well as the established Interim Committee will primarily deal with cooperation procedures and institutional mechanisms to promote compliance with the NP as well as a Multilateral Benefit-Sharing Fund as proposed by the Africa Group.⁵⁹ Next to the development and outcome of these meetings a lot will depend on the implementation of provider and user countries – since the CBD despite all criticism is foremost an international treaty between sovereign states.

54 Native Women of Quebec.

55 Kamau, Fedder & Winter, "The Nagoya Protocol on Access to Genetic Resources and Benefit Sharing: What is New and what are the Implications for Provider and User Countries and the Scientific Community?" at 262; Native Women of Quebec.

56 Brendan Tobin, in: Kamau, Fedder & Winter, supra note 6 at 111.

57 Native Women of Quebec.

58 Brendan Tobin, in Kamau, Fedder & Winter, supra note 6 at 102; *ibid*.

59 Kamau, Fedder & Winter, "The Nagoya Protocol on Access to Genetic Resources and Benefit Sharing: What is New and what are the Implications for Provider and User Countries and the Scientific Community?" at 252; Krystyna Swiderska, supra note 6.

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