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Access and Benefit Sharing under the Convention on Biological Diversity and the Nagoya Protocol

*Justry Patrick Lumumba Nyaberi**

Abstract

The Convention on Biological Diversity and 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 are international instruments which were enacted to address access to genetic resources and the fair and equitable sharing of benefits arising from their utilization. These instruments arose due to concerns over the unregulated exploitation of genetic resources acquired from countries rich in biological diversity and resulting in great financial benefits; without any of those benefits going to the countries that provided the genetic resources.

Therefore, countries which provided genetic resources called for the setting up of a legal framework to regulate access to genetic resources and ensure fair and equitable benefit sharing from their exploitation. Consequently, the Convention on Biological Diversity and later on, the Nagoya Protocol came into force. This article seeks to analyse the legal framework for access and benefit sharing from the exploitation of genetic resources as established under these two international instruments in order to determine whether it is fit for its intended purpose and what can be done to ensure its efficacy.

1. Introduction

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[1] (Hereinafter referred to as "the Nagoya Protocol" or "the Protocol") came into force on 12th October 2014. The Protocol developed as a result of the need to expand on the third objective of the Convention on Biological Diversity (CBD)[2], which is "…the fair and equitable sharing of the benefits arising out of the utilization of genetic resources…"[3].[4]

Genetic resources are naturally occurring components containing functional hereditary units which when exploited have actual or potential value such as agricultural crops, medicinal plants and breeds of animals. Historically, genetic resources were considered the common heritage of mankind (CHM) and were therefore exchanged freely as no one had ownership over them. This in turn led to their unregulated ex-

* PhD (Law) Candidate, University of Copenhagen, Denmark. Special thanks go to my Supervisor Prof Peter Pagh of the Faculty of Law, University of Copenhagen, Denmark for his superb guidance in the writing of the thesis from which this article is extracted.

[1] Nagoya, 29 October 2010.

[2] Rio de Janeiro, 5 June 1992.

[3] Article 1 of the CBD.

[4] In September 2002, the heads of state at the World Summit on Sustainable Development in Johannesburg, South Africa stressed the need for an international regime to promote and safeguard a fair and equitable sharing of benefits and called for negotiations to be carried out within the framework of the Convention on Biological Diversity in order to come up with such an instrument. This led to the development of the Nagoya Protocol which came into effect in October 2014.

ploitation especially due to technological developments that have facilitated the exploitation of genetic resources resulting in enormous financial and scientific benefits to individuals and companies.

The unregulated exploitation and lack of benefit sharing from the use of genetic resources led countries, which formerly would provide these genetic resources for free, to call for the establishment of legal frameworks to regulate access to genetic resources and ensure fair and equitable benefit sharing from their exploitation. They no longer wanted genetic resources to be under the CHM but for states to have sovereign rights over the genetic resources in their countries and thus control access to these resources with the end that they would benefit from their exploitation.

This led to the development of the CBD which explicitly recognized the authority of states to determine access to genetic resources as part of their sovereign rights over natural resources under their jurisdiction.[5] The CBD also provided that the benefits derived from the use of genetic resources should be shared in a fair and equitable manner.[6] However, since the CBD did not clearly provide for access and benefit sharing (ABS) between providers and users of genetic resources, States saw a need to develop an international instrument that would make clear provisions. This led to the adoption of the Nagoya Protocol.

This article will examine the ABS legal framework under the Nagoya Protocol, highlight challenges of the Protocol and propose measures that can be taken to address these challenges in order to make the Protocol fit for its intended purpose. To this end, the article is divided into three main parts. First, the article will provide an extensive background on the circumstances that led to the enactment of the Nagoya Protocol. Second, the article will analyse the Nagoya Protocol and its provisions on ABS. This will include challenges facing the Protocol. Finally, the article will make recommendations on how the challenges in the Nagoya Protocol can be addressed in order to strengthen the ABS legal framework.

2. Background to the Nagoya Protocol

2.1 The Tragedy of Commons

> Ruin is the destination towards which all men rush, each pursuing his own best interest in a society that believes in the freedom of the commons. Freedom in a commons brings ruin to all.[7]

Where every individual tries to reap the greatest benefits from a given resource, the demand of the resource overwhelms the supply as every individual who consumes an additional unit directly harms others who can no longer enjoy the benefits, as the resource of interest is easily available to all individuals. Thus the individuals involved deflect the well-being of the society in the pursuit of personal gain leaving the resource depleted and unsustainable even for future generations. This was the state of genetic resources before 1993, when the CBD was adopted. Genetic resources were prospected without any consideration to conservation or their sustainable use. Countries had no jurisdiction to control the use of genetic resources as they were regarded as a common heritage. This led to what is now known as the tragedy of commons.

The tragedy of commons can therefore be described as a situation in which many individuals, acting independently and rationally, con-

[5] Article15(1) of the CBD.
[6] Article 1 of the CBD.
[7] Hardin, G. (1968). The Tragedy of Commons. *Science*, [online] 162(3859), pp.1243-1248. Available at: http://science.sciencemag.org/content/162/3859/1243 [Accessed 13 Aug. 2018].

sulting their own self-interest, ultimately deplete a shared limited resource even when it was clear that it was not in anyone's long-term interest if the resource is depleted. This concept was first described by Hardin[8] in 1968 and is usually applied to issues of environmental conservation and its sustainable use. This concept is clearly applicable to genetic resources before the Convention for Biological Diversity where individuals, states or companies would undertake bio prospecting through the open access system until most of these genetic resources almost faced extinction. Further, when these resources were exploited, no compensation was paid to the countries in which they were found as they were considered public goods. This led states to seek for sovereign rights over their resources and a share of the benefits derived from the exploitation of these resources.

However, the principle of 'tragedy of commons' has come under criticism especially considering technological advancements that have made it such that the amount of genetic material needed for research and development has drastically reduced to the point where there are limited concerns in terms of conservation and sustainable use.

Nevertheless, the 'tragedy of commons' is still applicable with regard to the sharing of benefits arising from the use of genetic resources. This is because before the CBD, *ex-situ* collections[9] acquired genetic resources through the open access system in countries throughout the world.[10] Expeditions would be undertaken both at the national and international level in order to acquire genetic resources. Other methods through which these resources were acquired include exchanges with other collections and buying from collectors. These collections were thereafter approached by entities such as cosmetic and pharmaceutical companies who wanted to exploit these genetic resources for commercial gain through product development. As a result, these companies made huge financial benefits from the exploitation of these resources without benefits flowing to the countries which provided the resources originally.

This led countries that were rich in biodiversity to reject the principle of the common heritage of mankind over resources found within their borders on the basis of the concept of tragedy of commons. This in turn created a need for a legal framework that would affirm the sovereign rights of states over GR found within its borders with the attendant right to control access to these genetic resources. Moreover, such a legal framework would need to provide for the fair and equitable sharing of benefits derived from their exploitation. These objectives led to the establishment of the CBD and the Nagoya Protocol which dealt with access and benefit sharing of genetic resources.

2.2 The Convention on Biological Diversity (CBD)

In November 1988, the United Nations Environment Programme (UNEP) convened a working group of experts on Biological Diversity to come up with an international convention on biological diversity.[11] In May 1989, an *ad hoc* working group of experts was convened to draft a legal document addressing the conservation, sustainable use of biological resources, and the need to share benefits between provider and user coun-

[8] Hardin, P. 1248.

[9] Article 2 of the CBD defines *ex-situ* collections as the conservation of components of biological diversity outside their natural habitats.

[10] Jackson, P.S.W., 1997. Botanic Gardens and the Convention on Biological Diversity. *Botanical Gardens Conservation (BGC)News*, 2(8). Available at: https://www.bgci.org/resources/article/0025/ [Accessed August 15, 2018].

[11] Shah, A. (2011). *Why is biodiversity important? Who cares?*. Available at: http://http://www.globalissues.org/article/170/why-is-biodiversity-important-who-cares [Accessed 20 Oct. 2015].

tries as well as to recognize the importance of traditional knowledge associated with genetic resources. By February 1991, this working group became an inter-governmental negotiating committee and concluded its work at the Nairobi Conference on 22nd May 1992 with the adoption of an agreed text of the Convention on Biological Diversity which was opened for signature on 5th June 1992 at the Rio Earth Summit, which was a United Nations' Conference on Environment and Development. It remained open until 4th June 1993 by which time it had received a total of 168 signatures. The convention came into force on 29th December 1993, 90 days after ratification by the 30th member. Presently the Convention has 196 parties including member states and regional bodies.

2.3 ABS Provisions in the CBD

The Preamble of the CBD reaffirms the sovereign rights of states over their biological resources. It further recognizes the dependence on biological resources by indigenous and local communities (ILCs) as part of their traditional lifestyle and the desirability that benefits that proceed from the utilization of traditional knowledge (TK), innovations and practices relevant to the conservation of biological diversity and the sustainable use of its components should be shared in a fair and equitable manner.[12] This desire is further outlined in Article 1 which states that one of the objectives of the convention is "the fair and equitable sharing of the benefits arising out of the utilization of genetic resources". To this end, the CBD makes a number of provisions.

2.3.1 State Sovereignty

Article 3 and Article 15 (1) of the convention provide for the sovereignty of states over the genetic resources found within its borders. This provision is important for provider countries because the recognition of their sovereign rights allowed them to enact national laws on access to such resources which in turn will ensure that they share the benefits arising out of the commercial and non-commercial use of these resources. Through this provision, the CBD has restricted the unregulated exploitation of genetic resources by giving states the right to regulate access to their biodiversity which in turn enables them to put conditions in place to allow for fair and equitable sharing of benefits derived from their exploitation. Nevertheless, the authority of any state to determine access is subject to Article 15(2) of the CBD which requires contracting parties to create conditions that facilitate access for environmentally sound uses and not impose restrictions that run counter to the CBD's objectives.

2.3.2 Jurisdiction

According to Article 4 of the CBD, ABS of genetic resources can only result from those genetic resources that are found in the provider country. This Convention therefore does not provide for access and benefit sharing for genetic resources that are found beyond the national jurisdiction of any of the contracting parties such as marine genetic resources found in the high seas.

2.3.3 Traditional Knowledge

Article 8(j) of the CBD requires contracting parties to respect and promote practice of indigenous and local communities (ILCs) in conservation, sustainable use and equitable sharing of benefits derived from the utilization of genetic resources. This is because traditional knowledge (TK) is often the lead in the initial screening for isolating particular properties of genetic resources thereby guiding a number of institutions in the

[12] Preamble of the CBD.

development of new products.[13] Nevertheless, article 8 (j) of the CBD does not define what TK is thus leaving it to individual perspectives and formulations. A number of attempts have been made to come up with a definition but there is none that is universally accepted. The United Nations Environmental Program (UNEP) has defined TK as what a distinct society holds or acquires "by means of inquiry peculiar to that culture, and concerning the culture itself or the local environment in which it exists."[14] Therefore, it encompasses knowledge and practices adhered to by a society that has developed over time through modification by additions and subtractions and is passed through generations.

Moreover, problems have arisen as to when the ownership of TK occurs and therefore it is not clear when ILCs can be involved in ABS. Also, there are times whereby the ILCs who are the rightful holders of TK cannot be determined with precision. Furthermore, there are instances where the TK was neither supported by Prior Informed Consent (PIC)[15] nor protected by intellectual property law.[16] This is despite the fact that Article 15(5) of the CBD makes PIC a condition upon which access to genetic resources is granted and where such access has been granted, it must be based on mutually agreed terms (MAT)[17] as per article 15(4) of the CBD. The CBD only requires PIC to be obtained from national governments thus leaving out PIC from ILCs. The procedure for PIC and MAT is not provided for in the CBD as it was intended to be governed by the national legislation.

2.3.4 Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT)

Under Article 15(5) of the CBD, prior informed consent (PIC) is made a condition upon which access to genetic resources is granted and where such access has been granted, it must be based on mutually agreed terms (MAT) as per article 15(4) of the CBD. This means that PIC and MAT are the conditions precedent to obtaining access and subsequent fair and equitable benefit sharing from the utilization of genetic resources. PIC simply connotes that the provider of the genetic resources has given his consent through affirmative action based on the information provided by the potential user of the genetic resources before access was allowed. The CBD only requires PIC to be obtained from national governments thus leaving out PIC from ILCs.

MAT, on the other hand, implies that negotiations have taken place between the provider and the user parties leading to an agreement containing provisions for BS. The procedure for PIC and MAT is not provided for in the CBD as it was intended to be governed by the national legislation. It falls on the parties to decide, in exercising their sovereign rights, whether or not they require PIC.

2.3.5 Access

The CBD provides for the authority of national governments to regulate physical access to ge-

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[13] Laird, S. & Wynberg, R., 2008. *Access and Benefit-Sharing in practice: Trends in Partnerships Across Sectors*, Secretariat of the Convention on Biological Diversity. Available at: https://www.cbd.int/doc/publications/cbd-ts-38-en.pdf.

[14] UNEP/CBD/COP/3/Inf. 33, Annex 2.

[15] This refers to a situation whereby the provider of genetic resources gives his consent through affirmative action based on the information provided by the potential user of the genetic resources before access to these resources is allowed.

[16] Medaglia, J.C., Perron-Welch, F. & Rukundo, O., 2012. *Overview of National and Regional Measures on Access to Genetic Resources and Benefit Sharing: Challenges and Opportunities in Implementing the Nagoya Protocol* 2nd ed., Montréal, Canada: Centre for International Sustainable Development Law (CISDL).P 16.

[17] This refers to legal terms on access and benefit sharing agreed upon after negotiations have taken place between the provider and the user of genetic resources.

netic resources within their jurisdiction under Article 15(1). The authority of any government to determine access is subject to Article 15(2) which requires contracting parties to try and create conditions that facilitate access for environmentally sound uses and not impose restrictions that run counter to the CBD objectives. However, what entails "environmentally sound" uses is left to the determination of the providing parties of the genetic resources.

Article 15(3) states that the genetic resources covered by the CBD are those provided by the country of origin or those acquired in accordance with the CBD. This means that access to genetic resources acquired before the CBD are not included.

2.3.6 Benefit Sharing

Article 15(7) of the CBD provides for benefit sharing. Each contracting party is mandated to take legislative measures in achieving a fair and equitable sharing of benefits thus leaving it to the discretion of states. Article 15(7)[18] the CBD does not define the benefits to be shared but they could be monetary as provided in Articles 20 and 21 of the CBD or no-monetary such as research and development results, transfer of technology[19] among others.[20] Benefit sharing is to be based on MAT and negotiations should be on each individual case.[21] Usually non-commercial research means non-profit making research leading to new scientific insights. This was obviously one of the critical reasons for the conservation and sustainable use of biodiversity. Countries which provided access to genetic resources for non-commercial research would attract non-monetary benefits such as exchange of technology.

Monetary benefits can take the form of access fees, licensing rights over patents or one off compensation payments.[22] Access fees refer to a situation whereby the provider sets a fee for access and the user pays. One off compensation refers to a situation whereby a person in possession of TK gives such knowledge in exchange for a onetime payment with no subsequent payments. Licensing rights refer to a situation whereby the patent derived from the use of the GR or TK is co-owned by both the provider and user and both share the benefits that are derived from its utilization.

The provisions of Article 15(7) creates a relationship between states whereas for the most part it is private entities that engage in the collection of genetic resources and the MAT are usually outlined in private law contracts. On the provider side, it is often private land owners and local communities that give these genetic resources. It is therefore important that when national legislation is being drafted, such considerations are put in place to ensure that the key stakeholders are involved for purposes of ensuring fair and equitable sharing of benefits.

Article 16(3) provides for technology transfer which can be to governmental or private institutions. If IPRs are involved in the technology transfer, access will be on the conditions of the registered IPR.

Article 18 provides for technical and scientific collaboration between the relevant stakeholders involved in research on biodiversity.

[18] Medaglia *et al.*

[19] Nevertheless, Article 16 (2) of the CBD states that in cases where technology is protected by IPRs, access to such technologies is to be provided for on terms that are "consistent with the adequate and effective protection of IPRs". However, Article 16(5) of the CBD requires parties to cooperate in order to ensure that national and international laws creating IPRs are supportive of and do not run counter to the objectives of the convention.

[20] These are provided for in Articles 16-19.

[21] Article 19 (2), CBD.

[22] Kwa, E.L. *et al.*, 2006. *Access and Benefit Sharing: Policy and Legal Implications for Papua New Guinea*, Report for the Papua New Guinea Institute of Biodiversity.

Such collaboration in research is geared towards building human capacity and strengthening institutions on the basis of laws and policies at the national level.

Article 19 provides for benefit sharing as a result of the exploitation of biotechnology whereby contracting parties are to take measures whether legal, policy or administrative in order to ensure benefits arising from biotechnologies are shared in a fair and equitable manner.

Emerging trends in technology and science have greatly affected these issues of research and development, technology transfer and biotechnology. Scientific and technological advances have led to changes in the nature of genetic resource demands, how they are used, the business environment among others. For instance, in the 1990s, large samples of plants as well as other samples were collected for mass screening including TK on medicinal plants.[23] Currently, genetic resources required in order to conduct research had reduced dramatically thus reducing the need to go to provider countries to get huge amounts of genetic material for purposes of research. Further, a lot of genetic material needed for a certain compound can now be found in the country of the user. Moreover, the spread of means of communication especially the internet has made it such that genetic information is readily available online thus negating the need to travel to other countries to get the information required. All the above pose challenges for benefit sharing as the CBD did not make any provision for these emerging trends.

2.3.7 Intellectual Property Rights (IPRs)

Under the CBD, IPRs affect provisions relating to fair and equitable sharing of benefits arising from the utilization of genetic resources, preservation of and respect for the knowledge, innovations and practices of indigenous and local communities and technology transfers.[24]

Fair and Equitable Benefit Sharing

Article 15(7) of the CBD call on parties to take measures at a legislative, administrative and policy level that would ensure fair and equitable benefit sharing resulting from research and development and the commercial use of GR. IPRs systems can have negative effect on benefit sharing under the CBD. This is because IPRs can be granted in one country over genetic resources that have been acquired in another country. Often, these GR are acquired without PIC and MAT which result in benefits not accruing to provider states.

Developed countries have, through their patent offices, given patents that cover genetic resources without obtaining permission from the providers of these resources and without sharing the benefits with them.

The implementation of measures to ensure the sharing of benefits, whether monetary or non-monetary by patent holders may be undermined by the use of the TRIPS agreement. This can be done by challenging such benefit sharing measures on the basis that they "unreasonably prejudice" interests of patent holders.[25]

[23] Laird, S. and Wynberg, R. (2012). *Bioscience at a Crossroads: Implementing the Nagoya Protocol on Access and Benefit Sharing in a time of Scientific, Technological and Industry Change*. Secretariat of the Convention on Biological Diversity.

[24] Monagle, C., 2001. *Biodiversity & Intellectual Property Rights: Reviewing Intellectual Property Rights in Light of the Objectives of the Convention on Biological Diversity*, Gland, Switzerland: World Wide Fund For Nature (Formerly World Wildlife Fund), Gland, Switzerland and by CIEL, Geneva, Switzerland. Available at: https://www.ciel.org/Publications/tripsmay01.PDF.

[25] Monagle, P. 13.

Indigenous Local Communities (ILCs) and Traditional Knowledge (TK)

Traditional knowledge cannot be protected under TRIPs because its development occurs within a cultural context and it therefore does not meet the criteria set out in TRIPS. Further, because TK is collective in nature, determinations of who holds the IPRs are difficult to determine. Benefit sharing as envisaged under the CBD has therefore been affected by the IPRs system as provided for by the TRIPs agreement as IPRs have been granted to individuals or companies in one country over the genetic resources of a local community of another country without PIC and MAT that would guarantee fair and equitable sharing of benefits.[26] These challenges related to the protection of the rights of holders of TK led to proposals for the development of *sui generis* systems of IP protection that would cover traditional knowledge so that ILCs can share in the benefits derived from the exploitation of genetic resources that incorporates their knowledge.

Technology Transfer

Technologies that are developed from genetic resources and their subsequent transfer are affected by IPRs. The technologies referred to in the CBD are those 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"[27]. These technologies are to be transferred to developing countries on "fair and most favourable terms".[28]

Nevertheless, in cases where technology is protected by IPRs, access to such technologies is to be provided for on terms that are "consistent with the adequate and effective protection of IPRs"[29] However, Article 16(5) of the CBD requires parties to cooperate in order to ensure that national and international laws creating IPRs are supportive of and do not run counter to the objectives of the convention.

This provision on technology transfer can bring problems in situations where parties who own technology are obliged to be given licenses to such technologies based on considerations outside the TRIPS. However, if a conflict arose between the CBD and TRIPS, then the latter would prevail based on Article 30 of the Vienna Convention on the Law of Treaties.[30]

2.3.8 Relationship with other Conventions

Article 22 (1) outlines the relationship between the CBD and other conventions. It states that the rights and obligations of contracting parties "shall not affect the rights and obligations or any Contracting Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity". Nevertheless, the convention does not define the term "serious damage or threat" and it is therefore difficult to determine what falls under this classification.

[26] Among many examples: Neem patent is also a contentious one. The patent was granted by the European Patent Office to the USA department of agriculture and the W.R Grace Corporation over the process of extracting oil from the Neem tree, which had been used for generations in India. The patent was overturned in 2000. Although overturned in Europe, the Neem patent remains unchallenged in the USA. In Rural advancement foundation international (RAFI), Biopiracy annual update 1996. www.rafi.org.

[27] Article 16(1) of the CBD.

[28] Article 16(2) of the CBD.

[29] Article 16(2) of the CBD.

[30] The Article provides that when interpreting two treaties that are dealing with the same subject matter but having provisions that are different, the provisions of the treaty that is most recent will prevail unless otherwise expressly stated to the contrary.

2.3.9 Marine Genetic Resources

Article 22 (2) provides that parties are to implement the provisions of the CBD in a manner that is consistent with the rights and obligations of states under the United Nations Convention on the Law of the Sea (UNCLOS).[31]UNCLOS is the main treaty governing oceans and seas and sets out a legal framework within which all activities in the oceans and seas must be carried out by coming up with different maritime zones whereby countries have different degrees of ownership rights over the natural resources in their zones. These zones range from: Internal waters to international seabed areas. As per article 8 of UNCLOS, the internal waters are those waters that are lying landward off the baseline[32] including harbour waters, deltas and estuaries. The coastal state sovereignty extends to these waters.

Another maritime zone is the territorial sea.[33] The territorial sea is a belt of sea adjacent to a coastal state, the breadth of which may not exceed 12 nautical miles measured from the baseline. Other maritime zones include; the contiguous zone[34], the exclusive economic zone (EEZ)[35], and the continental shelf.[36] According to UNCLOS the coastal states have sovereign and exclusive rights over these zones on exploration, exploitation and conservation of natural resources. Hence resources in these zones are governed by UNCLOS and to some extent the CBD and Nagoya protocol where such resources are under the national sovereignty of a given country.

However, under UNCLOS,[37] coastal states must share with the international community part of the revenue derived from exploiting resources from any part of the continental shelf beyond 200 nautical miles. Nevertheless, all states enjoy the freedom of the high seas on navigation, over flight, scientific research and fishing.[38] The high seas comprise of all the parts of the sea that are not included in the EEZ, territorial sea or in the internal waters of a state. In the international sea bed Area all solid, liquid or gaseous mineral resources, *in situ* are considered the common heritage of mankind.[39]

Therefore, even though UNCLOS defines the various maritime zones above, it does not expressly provide a legal framework for ABS of marine genetic resources in areas beyond the national jurisdiction.[40] Coastal states have jurisdiction over the genetic resources in all the maritime zones within their jurisdiction and the ABS system contemplated in the CBD and the Nagoya protocol 2010 is applicable since these zones are under the sovereignty of the respective coastal states as per UNCLOS.

2.3.10 Dispute Settlement

Article 27 of the CBD deals with dispute settlement. The provisions here state that dispute settlement shall be by way of negotiations.[41] Ar-

[31] The United Nations Convention on the Law of the Sea (UNCLOS) was adopted in 1982.

[32] Article 5 of UNCLOS. The normal baseline for measuring the breadth of territorial sea is the low water line along the coast. Article 7 where the coastline is heavily indented or where there is a fringe of islands in its immediate vicinity. Straight baselines may be drawn connecting points on land.

[33] Article 3 of UNCLOS.

[34] Article 33 UNCLOS, the contiguous zone may not extend beyond 24 nautical miles from the baseline.

[35] Article 55-57 UNCLOS, EEZ is zone immediately adjacent and beyond the territorial seas extending to a distance of 200 nautical miles from the baseline.

[36] Article 76 UNCLOS, the continental shelf covers the sea bed and subsoil of the submarine areas out to a distance of 200 nautical miles irrespective of whether the continental margin extends that much.

[37] Article 82 of UNCLOS.

[38] Article 86 of UNCLOS.

[39] Article 136 of UNCLOS.

[40] Greiber, T., 2011. *Access and Benefit Sharing in Relation to Marine Genetic Resources from Areas Beyond National Jurisdiction: A Possible Way Forward* , Federal Agency for Nature Conservation. P. 11. Available at: https://www.bfn.de/fileadmin/MDB/documents/service/Skript_301.pdf.

[41] Article 27(1).

ticle 27(2) allows parties to pursue mediation if it is jointly requested. If the above mechanisms do not work, Article 27(3) provides for parties to pursue arbitration or go to the International Court of Justice if they declare their willingness to do so in writing when ratifying, accepting, approving or acceding to the convention. However, no mandatory provision for settling disputes in the event that a state party is aggrieved is given if the other state party refuses to cooperate or has previously not made a declaration as per Article 27(3).

Further, no sanctions are provided for to compensate an aggrieved party in the event of non-compliance by another state party. Moreover, the convention does not provide a mechanism for settling disputes where the conflicting parties are not states but private entities within states.

2.4 Challenges Facing ABS under the CBD

First, technologies that are developed from genetic resources and their subsequent transfer are affected by Intellectual Property Rights (IPRs). In cases where technology is protected by IPRs, access to such technologies is to be provided for on terms that are "consistent with the adequate and effective protection of IPRs"[42] However, the implementation of measures to ensure the sharing of benefits, whether monetary or non-monetary may be hindered on the basis that they "unreasonably prejudice" interests of patent holders.[43]

Second, the CBD does not create an institutional framework to implement its provisions. This has been left to member states, leading to competition among existing environmental agencies within some countries regarding the authority to grant access. Furthermore, in other countries there is a multiplicity of institutions seeking consultation hence fostering incompetence, corruption and unclear and overlapping roles. There is also a lack of personnel who can comprehend the technical aspects of BS.[44]

Third, most genetic resources had been collected in *ex-situ* collections before or after the adoption of the CBD. *Ex-situ* collections take the form of gene banks for seeds, zoos, botanical gardens, in- vitro storage and DNA storage among others. Most of the collections that are *ex-situ* have genetic resources whose source is unknown hence making it hard to implement ABS, even though most of these genetic resources came from biodiversity rich countries. The CBD itself excludes them from its jurisdiction as it does not provide for retrospective application of its provisions.

Fourth, the CBD does not provide for instances where there are trans-boundary genetic resources. In most cases genetic resources as well as TK are not restricted to a specific country. Some genetic resources and TK may be found in different countries or in more than one geographic region. However, the CBD envisages only bilateral arrangements which can be problematic especially with regard to benefit sharing. This is because a bilateral agreement on benefit sharing can be unfair as it would give a single provider the rights to receive benefits to the exclusion of other owners of the same genetic resources or TK.

Fifth, there is a lack of proper cooperation between developing and developed countries. Under Article 15(3) of the CBD, the ABS concept was founded on a bilateral relationship between a provider of the genetic resources on one hand

[42] Article 16(2) of the CBD.
[43] Kwa, E.L. *et al.*, P. 13.
[44] Carrizosa, S. *et al.* eds., 2004. *Accessing Biodiversity and Sharing the Benefits: Lessons from Implementing the Convention on Biological Diversity*, IUCN, Gland, Switzerland and Cambridge, UK, in collaboration with BMZ, Germany and GRCP, University of California, Davis CA USA. P. 14.

and the user on the other.[45] For the most part provider states are from developing countries while user states are from developed countries. Many developing countries do not have the capacity to implement comprehensive legislations dealing with ABS, while developed countries have shown reluctance in adopting measures that would facilitate fair and equitable benefit sharing.

Finally, with regard to dispute settlement, no mandatory provisions are given in the event that a state party is aggrieved by another. Further, no sanctions are provided for to compensate an aggrieved party in the event of non-compliance by another state party. Moreover, the CBD does not provide a mechanism for settling disputes where the conflicting parties are not states but private entities within states.

2.5 From the Convention on Biological Diversity (CBD) to the Nagoya Protocol

From the above analysis, it is clear that the CBD had a number of regulatory gaps. This is partly due to the fact that, in order to secure the consensus necessary for adoption of the CBD, the text was severally altered resulting in many ambiguities and omissions. It had broad objectives of wide scope and having emerged through contentious negotiations among polarized groups, many grey areas.[46] There was no agreement on how benefits would be shared equitably and fairly amongst provider and user countries even though the objective is clearly provided for in the Convention.[47] In September 2002, the heads of state at the World Summit on Sustainable Development in Johannesburg, South Africa stressed the need for an international regime to promote and safeguard a fair and equitable sharing of benefits and called for negotiations to be carried out within the framework of the Convention on Biological Diversity in order to come up with such an instrument. An *ad hoc* open-ended working group on access and benefit sharing was set up to elaborate and negotiate an international regime on access to genetic resources and the fair and equitable sharing of benefits arising out of the utilization of genetic resources and implementation of Article 15 and 8(j) of the CBD on access to genetic resources and preservation of traditional knowledge respectively.[48] After six years of negotiations, on the 29th October 2010, at the tenth meeting of the Conference of Parties in Nagoya Japan, there was adopted a protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization to cover the third objective of the CBD above. The protocol came to be called the Nagoya protocol 2010.

3. The Nagoya Protocol

The Protocol is said to be the most significant and decisive step towards complying with the third objective of the CBD, namely, achieving easy access and a fair and equitable benefit sharing arrangement of benefits arising out of the utilization of genetic resources as it creates a legal framework to this end.

3.1 ABS Provisions in the Nagoya Protocol

3.1.1 Scope of Application

Article 3 of the Nagoya Protocol restates the provisions of the CBD by stating that the scope of the protocol shall be "to genetic resources within the scope of Article 15 of the convention and to the benefits arising from the utilization of such resources". The protocol defines "utilization of genetic resources" to mean "to conduct research

[45] Medaglia *et al*. 2011, P. 12.
[46] Goldstein, P. & Reese, R.A., 2013. *Selected Statutes and International Agreements on Unfair Competition, Trademark, Copyright and Patent, 2013*, Foundation Press. P. 617.
[47] Shah.
[48] Shah.

and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology".[49] This is a major improvement as many supporters of strong benefit sharing rules, mostly developing countries, wanted coverage to extend to research on naturally occurring biochemical compounds (that is derivatives), notwithstanding any lack of hereditary units.[50] This is an improvement from the CBD which was limited to materials containing functional units of heredity.

Moreover, the scope of the Protocol's application is Article 15(1) of the CBD which covers genetic resources found within the national jurisdiction of a party. This means that the ABS regime under this Protocol does not cover genetic resources found beyond its borders. Article 10 which provides for a multilateral benefit sharing system is primarily aimed at instances where parties cannot meet their obligations of prior informed consent (PIC)[51] such as in Article 11 on trans-boundary genetic resources and traditional knowledge (TK)[52] associated with genetic resources.

3.1.2 Access to Genetic Resources

Access to genetic resources is provided for in Article 5 and 6 of the Nagoya Protocol. Article 6(1) of the Protocol confirms and consolidates Articles 15(1) and 15(3) of the CBD by requiring PIC before access to genetic resources is given. This is in recognition of the sovereign rights of member states over the genetic resources that are within their national jurisdiction. Parties are required to take measures, whether, policy, legislative or administrative to govern access to genetic resources.[53]Users of genetic resources are in turn required to comply with the access requirements of the provider country.[54]

Parties to the Nagoya Protocol who require PIC to access genetic resources are obliged to take the necessary domestic measures to realize the international access standards as outlined under Article 6(3) (a) to (g). These standards seek to ensure that access to genetic resources is achieved with transparency and predictability in the application process, adherence to due process when applying for PIC and to support the effective implementation of user country measures on PIC and mutually agreed terms (MAT)[55]. The standards also obligate the provider country to issue permits at the time of access and lastly it indicates the contents of MAT as key components in spelling out contractual obligations.

Article 6(2) and 6(3)(f) of the Protocol obligates parties to ensure that indigenous and local communities are involved in giving PIC or approval when obtaining access where these communities have established the right to grant access. This provision goes beyond Article 8(j) of the CBD where the right was only recognized in

[49] Article 2(c) of the Nagoya Protocol.

[50] Oliva, M., 2011. Sharing the Benefits of Biodiversity: A New International Protocol and its Implications for Research and Development. *Planta Medica*, 77(11), pp. 1221–1227. Available at: https://www.thieme-connect.com/products/ejournals/pdf/10.1055/s-0031-1279978.pdf.

[51] Prior informed consent refers to a situation whereby the provider of genetic resources gives his consent through affirmative action based on the information provided by the potential user of the genetic resources before access to these resources is allowed.

[52] The United Nations Environmental Program (UNEP) has defined TK as what a distinct society holds or acquires "by means of inquiry peculiar to that culture, and concerning the culture itself or the local environment in which it exists." In UNEP/CBD/COP/3/Inf. 33, Annex 2. Therefore, it encompasses knowledge and practices adhered to by a society that has developed over time through modification by additions and subtractions and is passed through generations.

[53] Article 6(3) of the Nagoya Protocol.

[54] Article 6(1) of the Nagoya Protocol.

[55] Mutually agreed terms refer to legal terms on access and benefit sharing agreed upon after negotiations have taken place between the provider and the user of genetic resources.

relation to conservation and sustainable use of genetic materials. In the protocol, it indicates the increasing emphasis on the rights of ILC.

3.1.3 Multilateral Benefit Sharing Mechanism

Article 10 of the Protocol provides for the establishment of a multilateral benefit sharing mechanism which can be used in the event that "it is not possible to grant or obtain prior informed consent" or where genetic resources or traditional knowledge associated with genetic resources are found in more than one country. Situations where the granting or obtaining of PIC may be difficult include genetic resources whose country of origin is unknown, areas that are beyond the national jurisdiction of any one country or genetic resources obtained from *ex-situ* collections.

A number of *ex-situ* collections including botanical gardens consider the entirety of their collections, despite the time of their collection, as being under the obligations created by the CBD.[56] Networks of ex-situ collections have adopted ABS codes of conduct, guidelines and/or best practices including:[57]

- The International Plant Exchange Network (IPEN) Code of Conduct for botanical gardens governing the acquisition, maintenance and supply of living plant material, which was developed in 2001; and
- The Consortium of European and Taxonomic Facilities (CETAF) Code of Conduct and Best Practice for Access and Benefit-Sharing, which was developed in 2012.

These codes of conduct function to raise awareness among researchers on the international ABS regime, institutional recognition and support for the international ABS regime and facilitate exchange of genetic resources through a group where such exchanges are carried out within a code of conduct that is standardized and ABS compliant.[58] This is in line with the Nagoya Protocol which encourages parties to develop, update and use "voluntary codes of conduct, guidelines and best practices and/or standards in relation to access and benefit-sharing".[59]

Article 10 is therefore a good step forward as it can remove the ambiguity as to how benefits derived from genetic resources sourced through the aforementioned means can be shared. Benefits derived from this multilateral mechanism would be "used to support the conservation of biological diversity and the sustainable use of its components globally".[60]

Such a multilateral mechanism can be modelled after the Food and Agriculture Organization's (FAO) International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). The main objective of this treaty is the conservation and sustainable use of plant genetic resources for food and agriculture and fair and equitable sharing of benefits derived from their use. Both objectives of ITPGRFA are covered by the CBD in its third objective and are, by extension, similar to the objective of the Nagoya protocol. Under this treaty, member countries undertake to establish an efficient, effective and transparent multilateral system to facilitate access to plant genetic resources for food and agriculture and to share the benefits in a fair and equitable way.

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[56] Brogiato A., Dedeurwaerdere T., Batur F. and Coolsaet B. Access, Benefit Sharing and the Nagoya Protocol: The Confluence of Abiding Legal Doctrines. In Coolsaet, B., Batur, F., Broggiato, A., Pitseys, J. and Dedeurwaerdere, T. (2015). *Implementing the Nagoya Protocol: Comparing Access and Benefit-Sharing Regimes in Europe*. Leiden: Brill Nijhoff. pp. 10.

[57] Brogiato *et al*. Access, Benefit Sharing and the Nagoya Protocol: The Confluence of Abiding Legal Doctrines. In Coolsaet *et al*.

[58] Brogiato *et al*. Access, Benefit Sharing and the Nagoya Protocol: The Confluence of Abiding Legal Doctrines. In Coolsaet *et al*.

[59] Article 20(1) of the Nagoya Protocol.

[60] Article 10 of the Nagoya Protocol.

The implementation of the treaty is overseen by the governing body composed of the countries that have ratified the treaty with FAO serving as the Secretariat. This body is responsible for setting up the conditions for access and benefit sharing of plant genetic resources for food and agriculture under the treaty through material transfer agreements.[61]The conditions for access under this system are to the effect that resources are obtained for conservation and utilization in research, breeding and training from the multilateral system. When a commercial product is developed using these resources, the treaty provides for the payment of an equitable share of the resulting monetary benefits. If the product is used by others, then payment is voluntary. The ITPGRFA provides for sharing of benefits of varying plant genetic resources for food and agriculture through information exchange, access to and the transfer of technology and, capacity building. It also considers a funding strategy in mobilizing funds for activities, plants and programmes to help in information exchange, transfer of technology among others.

3.1.4 Fair and Equitable Benefit Sharing

Article 5(1) of the Nagoya Protocol provides for fair and equitable benefit sharing with the provider state thus reiterating the provisions of the CBD[62]. It requires parties to take "legislative, administrative and policy measures" to ensure that benefits arising from utilizing genetic resources and TK associated with genetic resources held by communities are shared in an equitable manner. These benefits can be either monetary or non-monetary as listed in Annex 1 of the Protocol. The list is not exhaustive. This also covers benefit sharing resulting from the use of derivatives as they are included in the definition of the term "utilization of genetic resources". Benefit sharing also includes technology transfer as stated in Article 1 of the Protocol though the formulation here is not as elaborated as in the CBD. Article 23 of the Protocol encourages the parties to promote access and transfer of technology to developing and least developed countries. During negotiations, developing countries wanted to add to this Article 23 provisions that were specifically targeting the private sector of developed countries as these are the ones who for the most part hold these technologies. Nevertheless, this was not included in the final draft and therefore concerns on enforcement of this obligation arise. National legislations will need to take this into account.

The article provides that benefit sharing will result from the use of genetic resources accessed "in accordance with the Convention". This raises the question of what happens when genetic resources are acquired through a means contrary to the CBD. Will benefits arising from their exploitation still be shared? This would create an awkward situation where a country has to negotiate a benefit sharing scheme with a country that has violated its sovereign rights. This issue ought to be provided for in national legislations.

Benefit sharing under the Protocol not only covers the whole process of research and development, but also subsequent application and commercialization. Issues arise when third parties are involved in the above named processes, who were not party to the agreement between the user and provider. National legislation should include such considerations in order to ensure benefits accrue to such original providers. This situation is provided for in the Protocol which states that rules and procedures for MAT may include "terms on subsequent third party use"[63].

[61] www.fao.org/ag/acgrfa/itpgr/htm. [Accessed on 15 January 2014].

[62] Article 15(7) and 15(3).

[63] Article 6(3)(g)(iii) of the Nagoya Protocol.

Article 5(2) of the Protocol states that parties shall take measures for benefit sharing 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". This provision seems to provide that only ILCs with rights that have been established by national law can share the benefits arising from the utilization of their genetic resources under their control. In creating national laws, governments need to provide extensive lists of genetic resources under the control of ILCs in order to ensure that they can share in the benefits of their exploitation.

3.1.5 Traditional Knowledge

Article 7 of the Protocol requires that PIC or approval and involvement be obtained from ILCs before the utilization of genetic resources or traditional knowledge associated with genetic resources. The difference between PIC and approval and involvement is not clear. COP 5 through Decision V/16 adopted General Principles that made clear that "access to TK, innovations and practices of ILCs should be subject to prior informed consent or prior informed approval from the holders of such knowledge, innovations and practices". Therefore, there would seem to be no significant difference between these two expressions. This enlarges the provisions in the CBD Article 8(j) which only promotes the wider application of TK with the involvement and approval of ILCs.

The provisions in Article 7 are subject to domestic law and are to be applied "as appropriate". These qualifications can be taken to mean that the consent of ILCs is only required in instances where they have rights that have been provided for by formal legislation. On the other hand, the flexibility provided to nations in this clause was thought to be a good thing during the negotiations for this Protocol as it was felt that the complex nature of TK can best be dealt with at a national level.[64]

The use of the term "as appropriate" may be interpreted to give discretion to a user on what they deem as appropriate as this has not been expressly provided for in the Protocol. These issues need to be clearly addressed in national laws in order to ensure the consent of ILCs is obtained and that they can subsequently share in any accrued benefits.

Further, Article 12 provides conditions for benefit sharing upon utilization of TK. Parties are required to take into consideration "customary laws, community protocols and procedures"[65] when implementing their obligations under the Protocol. Further, parties are required to "establish mechanisms to inform potential users of TK associated with genetic resources about their obligations".[66] This is a further measure that is geared towards ensuring that benefits obtained through the exploitation of TK relating to genetic resources are shared in a fair and equitable way with ILCs.

Parties are also obliged to help ILCs develop mechanisms to facilitate benefit sharing such as community protocols, minimum requirements for MAT and model contractual clauses.[67] The exchange of TK between ILCs is not to be restricted in the implementation of the Protocol.[68]

ILCs participated actively during negotiations of the Nagoya Protocol for benefit sharing. While these ILCs advocated for the recognition of their rights over genetic resources and TK, other parties had concerns about such recognition

[64] Nijar, G.S., 2011. *The Nagoya Protocol on Access and Benefit Sharing of Genetic Resources: Analysis and Implementation Options for Developing Countries*, South Centre. P. 26.
[65] Article 12(1) of the Nagoya Protocol.
[66] Article 12(2) of the Nagoya Protocol.
[67] Article 12(3) of the Nagoya Protocol.
[68] Article 12(4) of the Nagoya Protocol.

premised on issues such as the complex nature of TK especially when it traverses borders or is in the public domain. A proposal was made regarding the provisions for benefit sharing upon use of TK in the public domain, this was however not included in the final text of the Protocol.

This is contrary to the ITPGRFA which makes provision for the protection of traditional knowledge held by ILCs. The treaty recognizes the important contribution made by farmers and their communities in the conservation and development of plant genetic resources and protects the farmers' rights which include the protection of traditional knowledge and the rights to participate equitably in benefit sharing and the national decision making process on plant genetic resources. The treaty dealt with farmers' rights under article 9 pursuant to the resolutions of both the Nairobi Conference under Resolution 3 and the FAO Conference. The article in recognition of the contributions of ILCs and farmers in the conservation of plant genetic resources, places the responsibility of ensuring the protection of their rights on the national governments. In this regard, national governments are required to ensure the protection of Traditional Knowledge relevant to plant genetic resources for food and agriculture,[69] the rights of farmers to participate in benefit sharing arising from the utilization of those plant genetic resources and the right of farmers to participate in making decisions at national level on issues of conservation and sustainable use of plant genetic resources for food and agriculture.

3.1.6 Research and Development

Article 8(a) of the Protocol instructs parties to "create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including through simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research".

Biodiversity research encompasses a wide spectrum from bio-prospecting for commercial purposes to basic research carried out in a number of institutions such as universities. There are some research undertakings which present classification challenges on whether they are commercial or non-commercial. During negotiations of the Nagoya Protocol, it was stressed that the ABS regimes should not undermine academic or basic research, but also, such provisions for ease of access were acceptable only if measures were taken to ensure that these genetic resources were not redirected to commercial use. None the less, the ability to put this provision into practice will depend on the legal provisions at the national level and their subsequent implementation. National laws ought to provide for procedures to be followed if there is a change in usage of genetic resources or third-party sales of genetic resources. This is situation is provided for in the Protocol which states that rules and procedures for MAT may include "terms on changes of intent"[70].

With regard to benefit sharing from research and development, it has been argued that in order for developing countries to benefit from their genetic resources, expectations of fair and equitable benefit sharing and the demand by other countries to capitalize on their natural resources must be balanced.[71] Unprocessed biodiversity is rarely the source of wealth. This is because success in discovery of beneficial components is low

[69] Article 9 (2)(a) of the ITPGRFA.

[70] Article 6(3)(g)(iv) of the Nagoya Protocol.

[71] Kursar, T.A. *et al.*, 2006. Securing Economic Benefits and Promoting Conservation through Bioprospecting. *BioScience*, 56(12), pp.1005–1012. Available at: https://academic.oup.com/bioscience/article/56/12/1005/221596. P. 1006.

and therefore, financial benefits are highly unlikely.[72] Moreover, it may take over 10 years from the time of discovery to the reaping of benefits. It has therefore been proposed that the way to get benefits through bio-prospecting is by facilitating research in these provider countries. This will enable these biological resources to be the subject of research that can yield value to the provider state. Moreover, other benefits arising from having research conducted in provider states include development of infrastructure, job creation, capacity building and continued investment in research and development.[73]

3.1.7 Compliance

Article 15 and 16 of the Protocol provide for compliance with domestic legislations and regulations for benefit sharing from the use of genetic resources and TK associated with genetic resources respectively. Articles 15 and 16 provide that parties shall take "appropriate, effective and proportionate" measures, whether legislative, administrative or policy that provide that genetic resources or traditional knowledge associated with genetic resources used in its jurisdiction were accessed through PIC or approval and involvement of ILCs (in cases of TK) and MAT "as required by the domestic access and benefit-sharing legislation or regulatory requirements of the other party". Developing countries found this to be a key provision as it mandated user countries to put in place compliance measures in their own countries, including measures to address non-compliance.[74]

These provisions are aimed at ensuring that the genetic resources and TK used in a country have been acquired legally. Nevertheless, the term "appropriate, effective and proportionate" as used in these two articles are not defined thus leaving it to the discretion of individual states.

Further, the term "research and development" as used in these articles is not defined and discretion is given to states to define it. Such a definition could possibly cover different stages of research, innovation, development, modification, pre-commercialization and commercialization involving the use of the genetic resource.[75]

Moreover, though countries are obliged to designate one or more checkpoints to monitor compliance and enhance transparency[76], no obligations are outlined as to the type of checkpoint to be created. Nevertheless, countries should establish clear rules and regulations on disclosure at such checkpoints.

3.1.8 Monitoring the Use of Genetic Resources

Article 17 of the Protocol provides for the monitoring of the utilization of genetic resources in order to support compliance measures. The article provides for the establishment of 'checkpoints' that will monitor compliance with benefit sharing regimes. These checkpoints would collect information to determine compliance with ABS requirements such as PIC and MAT. Parties are required to take "appropriate, effective and proportionate" measures in addressing instances of non-compliance. Such measures are however not defined and can only find expression at the national level.

During negotiations, countries differed on whether or not these measures should be compulsory or voluntary, the extent of their incorporation into administrative structures and where to strike a balance between transparency, confidentiality and practicability.[77]

Article 17 which establishes these check-

[72] Kursar T.A. *et al*.
[73] Kursar T.A. *et al*.
[74] Article 15(2) and 16(2) of the Nagoya Protocol.
[75] Nijar, G.S. P. 6.
[76] Article 17 of the Nagoya Protocol.
[77] Maria Julia Oliva, M.J.

points states that they ought to 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"[78]. This formulation of the provision was agreed to by developing countries in a bid to include key element for effective checkpoints encompassing situations whereby new genetic resources or traditional knowledge associated with genetic resources are marketed, patented or otherwise dealt with.[79]

The obligation to disclose information by the user on PIC and MAT has been couched in the term "as appropriate".[80] This can be interpreted to mean that discretion lies with the user as to whether or not to disclose any genetic resource they have acquired and the terms under which they have acquired it. Parties should include mandatory disclosure agreements in their national laws as a way to prevent non-disclosure.

The provisions of Article 17 are "without prejudice to confidential information".[81] Information that is deemed to be confidential is not defined in the protocol. None the less, parties can be guided in the development of national legislation by the Cartagena Protocol on Bio-safety which elaborates on what constitutes confidential information and how and when claims of confidential information can be made.[82]

Article 17 on monitoring compliance does not make reference to traditional knowledge associated with genetic resources, which has often been a victim of bio-piracy[83]. National laws should endeavour to capture TK monitoring in their laws.

Despite the challenges mentioned, the measures introduced by the Nagoya Protocol could prove to be effective in curbing bio-piracy and ensuring fair and equitable benefit sharing.

3.2 Challenges facing ABS under the Nagoya Protocol

The first and the most critical problem is that the Nagoya Protocol does not make reference to patents or other intellectual property rights[84] (IPRs) as part of the monitoring and enforcement

[78] Article 17(1)(a)(iv) of the Nagoya Protocol.
[79] Nijar, G.S. P. 9.
[80] Article 17(1)(a)(i) of the Nagoya Protocol.
[81] Article 17(1)(a)(iii) of the Nagoya Protocol.
[82] Article 21 of the Cartagena Protocol on Biosafety.
[83] Bio-piracy refers to a situation whereby Intellectual property systems are used to legitimize the exclusive ownership and control of biological resources and knowledge without recognition, compensation or protection of the contribution from indigenous and rural communities. In Gian Carlo Delgado. Biopiracy and intellectual property as the basis for biotechnological development: The case of Mexico. International journal of politics, culture and society. Vol 16, no 2 (winter 2002) 299.The Nagoya Protocol was intended to address bio-piracy. The question was whether the general provisions under Article 15 could enable parties to take measures to address bio-piracy by initiating concrete obligations on parties to monitor the use of genetic resources under their jurisdiction. Developing countries strongly argued that there was need to establish checkpoints at patent offices where users could be obliged to disclose information that could be assessed in a bid to demonstrate the legal status of the genetic resources. Developed countries opposed the obligations of disclosure and even issuance of an international certificate of compliance arguing that they were inflexible, costly and ineffective in identifying instances of bio-piracy. At the end of the day, the issues of disclosure, checkpoints and international certificates were done away with in the Nagoya protocol. Nevertheless, some countries have included measures on disclosure in their legal systems.
[84] Intellectual property rights are the rights protecting intellectual property and allow creators or owners of patents, trademarks among others to benefit from their own works or investments in the creation of those ideas. On the other hand, Intellectual property simply refers to any ideas skillfully expressed and comprises of creations of the mind in form of inventions, literary and artistic works and take the forms of symbols, names and images used in commercial aspects.

process[85] despite the evidences acknowledging the problem. In so doing, the Nagoya Protocol fails in utilizing the established intellectual property mechanisms to enhance fair and equitable benefits sharing of genetic resources. Intellectual property laws in form of patents, exclusive rights, moral rights, copyrights, design rights and even trademarks could be applied to achieve appropriate, effective and proportionate measures in the utilization of genetic resources.[86]

On the other hand, intellectual property regimes also have potential to serve as a barrier to equitable benefit sharing of genetic resources by limiting the enforceability of the later regime. The question then arises as to what extent intellectual property law will be applied to ensure equitable benefit sharing under the Nagoya Protocol. The Protocol also fails to address the issue of disclosure during registration of IPRs. This was supposed to be considered by the Nagoya protocol as it had achieved exemplary notoriety in the genetic resources legal regime.

The second critical issue affecting the Nagoya protocol is how to effectively implement the Nagoya Protocol at the national level. Countries are bound under the Protocol to come up with a legal framework to spell out the terms of the relationship between those countries that want to utilize genetic resources and those that possess the genetic resources. Further, the Protocol seems to presuppose that there should be a model law or a legal regime which should be adopted by all countries. The problem is that user countries may not adopt a uniform legal framework that will support a fair and equitable sharing of benefits of genetic resources. This is because most users of genetic resources are individuals or companies and not countries themselves. In essence, the Nagoya Protocol is supposed to be enforced by the states which have no direct interest in genetic resources, since most of them are used by research institutions and corporations. These legal instruments are vested in the state, including policing powers over individuals and companies who might use those genetic resources in their foreign branches, offices or industries. Countries cannot be expected to track down organizations and individuals with regard to the use of genetic resources especially across borders. The Protocol, therefore, foresees an ideal system of enforcing benefit sharing which is not always the case. The indigenous and local communities in developing countries may also lack information and resources to implement and facilitate benefit sharing frameworks to their detriment.[87]

The third legal aspect is that the Nagoya Protocol is a further expression of Article 15(7) of the CBD dealing with access and equitable benefit sharing of genetic resources. The question is what happens to those countries that have ratified the CBD and fail to ratify the Nagoya Protocol. The Nagoya Protocol is supposed to expand the CBD by introducing concepts such as prior informed consent and mutually agreed terms. In other words, the Nagoya Protocol dependent on the CBD. The question then is: will the countries that have not adopted the Nagoya Protocol be bound by these concepts?[88] Besides, there are new provisions that occur in the Nagoya Pro-

[85] UNCTAD & ICTSD, 2011. *What Comes After Nagoya? Addressing Developing Country Needs in Intellectual Property Rights and Biodiversity*, The United Nations Conference on Trade and Development (UNCTAD) and the International Centre for Trade and Sustainable Development (ICTSD). Available at: https://www.ictsd.org/sites/default/files/downloads/2011/05/ictsd-unctad-what-comes-after-nagoya-report.pdf [Accessed January 20, 2011].

[86] UNCTAD & ICTSD, 2011. Report.

[87] UNCTAD's Bio-Trade Initiative, "Implications for Bio-Trade of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization", http://www.biotrade.org/ResourcesPublications/UNCTAD_DITC_TED_2011_9.pdf (accessed on 20/01/2011).

[88] Nijar, G.S.

tocol which have no direct linkage to the CBD. For instance, the Nagoya Protocol refers to the utilization of genetic resources that are held by indigenous and local communities. In the CBD, the role of the indigenous and local communities is only recognized in relation to the traditional knowledge and not genetic resources.

Fourthly, the Nagoya Protocol provides for the concept of access. The question then arises as to when access occurs? This problem may arise in two circumstances, one, where the genetic material occurs on trans-boundary areas and secondly, where the genetic resources of the provider country are used to develop derivatives. The Question is: at what stage does access occurs: is it at the acquisition stage or after they have been value added? This problem was also noted when considering the various national legal frameworks.

Fifthly, the benefit sharing framework under the CBD and the Nagoya Protocol presupposes that the conditions imposed by the provider country such as prior informed consent and mutually agreed terms (MAT) shall be applied in the user country. However, given that the user country is a sovereign state, there may be no effective sanctions to compel it to implement these terms. This also raises the question of the extent to which the Nagoya Protocol interferes with the concept of state sovereignty.

The other aspect on benefit-sharing relates to prior informed consent (PIC). Under the Nagoya Protocol, for genetic resources to be used, there must be a PIC by the provider state. It is the terms of the PIC that are applicable even in the user state. This, then, means that user countries will be implementing terms which they may not be aware of and whose legal framework may be different from theirs. In any case, the legislation on equitable benefit sharing might not be uniform in all countries. This could prove to be worse where those conditions will be applied in a third country which is neither the user nor the provider state.

Sixth, there is the issue of integration of public participation in giving consent to use of genetic resources and the administrative infrastructure in the provider countries. For instance, should the community take responsibility in regulating access and benefit sharing agreement or should the same be left to the administrative authority or state? As things stand, it is not clear what role then should be played by the community as well as the administrative authority or state in the enforcement of the protocol.

Seventh, in order for the provider country or any other person to sue in a foreign country, he should have capacity. Most jurisdictions do not provide explicitly whether foreign entities have capacity to institute proceedings in their local court. This is especially necessary in the case of an unregistered local community organization or an amorphous body. There is the question of whether international contracts can be ventilated in national courts unless there is a specific law in that country empowering such courts to consider those contracts.

There is also the issue of how to address ”benefit-sharing” in relation to traditional knowledge associated with genetic resources that would accommodate the diversity of national circumstances.

Lastly, there is the legal challenge as to whether the Nagoya Protocol will apply retrospectively, that is, whether the benefit sharing will apply solely to those genetic materials accessed after the entry into force of the protocol on 12th October 2014 or whether it extends to the use of genetic resources that took place after CBD or even before the CBD was adopted. The Protocol does not elaborate on the scope of the genetic resources that are covered under it.

4. Recommendations

The CBD and the Nagoya protocol need to be re-assessed and amended as necessary to achieve an effective ABS system. The necessary amendments include:

4.1 For the CBD:

First, the inclusion of provisions for access and benefit sharing from the exploitation of genetic resources in areas beyond the national jurisdiction of any state.

Second, with regard to traditional knowledge, the CBD needs to include a clear definition of constitutes traditional knowledge; when ownership of traditional knowledge occurs, what constitutes an ILC and specific provisions for the protection of traditional knowledge.

Third, a provision needs to be included which requires the acquisition of PIC from ILCs before using genetic resources or associated traditional knowledge found in their territories.

Fourth, the provision for the need to enact legislative, administrative and policy measures for benefit sharing at the national level needs to be couched in mandatory terms in order to compel state action in this regard. Further, minimum requirements for the above measures should be included in order to promote uniformity in state implementation.

Fifth, the CBD needs to include a mandatory dispute resolution mechanism for all state parties as well as appropriate sanctions in cases of non-compliance. Sixth, the CBD need to create an international body that will oversee the implementation of the law on benefit sharing worldwide. Seventh, the CBD should make provisions for benefit sharing from the use of genetic resources acquired from *ex-situ* collections. Eighth, the CBD needs to make provision for benefit sharing in circumstances of trans-boundary genetic resources and associated traditional knowledge. Finally, the CBD needs to provide for how benefits will be shared in instances of third party users.

4.2 For the Nagoya Protocol:

First, it needs to include provisions on IPRs derived from the use of genetic resources and associated TK so as to curb bio-piracy and outline sanctions for those found culpable. This also includes making patent offices in state parties mandatory checkpoints where inventions that have used genetic resources can be examined to determine whether those resources were acquired in accordance with PIC and MAT. Further, an amendment of the Nagoya Protocol can also follow the pattern provided in the ITPGRFA. This Treaty has ensured that the rights of both users and providers of plant genetic resources for food and agriculture are secured in the interest of realizing sustainable agriculture and food security. To this end, Article 12(3) of the treaty, states that recipients of genetic resources under the treaty shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetics resources for food and agriculture or genetics components thereof in the form received from the multilateral system. This provision provides open access to genetic resources for food and agriculture while ensuring the researchers do not acquire IPRs on TK to the detriment of ILCs and against farmers' and breeders rights.

Second, the Nagoya Protocol should include provisions on ABS of genetic resources in areas beyond the national jurisdiction of any country. Such a provision can follow the model provided in the ITPGRFA by setting up a fund where benefits arising from the exploitation of genetic resources can be deposited into and shared equitably. Further, the Protocol can establish a body at the international level or grant power to an already existing body to govern genetic resources that are beyond the territorial borders of any

state. Such governance would include setting rules on access and how benefits acquired from the exploitation of such resources can be shared with third party states.

Third, provisions regarding technology transfer, as a form of non-monetary benefit sharing, should include clauses directed at the private sectors in states which should be included in national laws.

Fourth, the Nagoya Protocol needs to make mandatory provisions for the protection of traditional knowledge which are to be implemented nationally. Minimum standards of protection for traditional knowledge should be outlined in the Protocol.

Fifth, compliance measures provided in the Protocol need to be clarified such as what constitutes "appropriate, effective and proportionate" measures that a state needs to implement.

Sixth, the Protocol needs to clarify on the exact measures to be taken in instances of non-compliance with ABS processes.

Seventh, disclosure requirements at designated checkpoints in member states as provided in the Protocol should be made mandatory.

Eighth, the Protocol should be amended to provide for monitoring the use of traditional knowledge. Ninth, the Protocol should set out minimum standards to be included in national laws in order to change the current situation whereby national laws on benefit sharing vary from one country to the next. Finally, the Protocol should be amended to provide for a mandatory dispute resolution mechanism. This may also involve the setting up of an international ombudsman to deal with as was proposed by developing countries during negotiations for the Protocol.

5. Conclusion

The CBD and the Nagoya Protocol were landmark achievements in the quest to realize fair and equitable sharing of benefits from the exploitation of genetic resources and associated traditional knowledge. For the CBD, it demonstrated a global political will to tackle the loss of biodiversity by recognizing the need for taking coordinated efforts within an international forum and at a global scale. Thereafter, the adoption of the Nagoya Protocol focused the world's attention on the third objective of the CBD namely, access to genetic resources and the fair and equitable sharing of benefits arising from their utilization. Though the Nagoya Protocol was meant to provide certainty with regard to the CBD's third objective, there are clear inadequacies in its provisions which have affected its implementation at the international, regional and national level. Its wide and general provisions have led to divergent regional and national laws and regulations with provider countries focusing more on terms for benefit sharing while user countries fail to institute sufficient measures to monitor compliance with ABS requirements. There is therefore a need to re-evaluate the international regime governing ABS in order to forge the way forward in realizing the third objective of the CBD.