

ACCESS & BENEFIT SHARING AND BIODIVERSITY: AN OVERVIEW OF NATIONAL AND INTERNATIONAL LEGAL REGIME

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Abstract

Biodiversity, the natural biotic capital of the earth, is fundamental to the fulfilment of human needs and vital for the survival of this planet. Biodiversity is essential for maintaining the ecological functions, including stabilizing of the water cycle, maintenance and replenishment of soil fertility, pollination and cross-fertilization of crops and other vegetation, protection against soil erosion and stability of food producing and other ecosystems. Conservation of biological diversity leads to conservation of essential ecological diversity to preserve the continuity of food chains. However, biodiversity is being increasingly threatened globally on account of various factors. The Conservation of biological diversity and its sustainable development is essential for the maintenance of ecosystem and protection of environment of this earth.

One key issue that has dominated the Convention on Biological Diversity landscape globally and the implementation of the Biodiversity Act,2002 domestically is that of Access, and with it, Benefit sharing, together referred to in the Convention on Biological Diversity as Access and Benefit Sharing. The government's guidelines on access and Benefit sharing notified in 2014 have only marginally added to what the act and its rules lay down. Moreover, the issues relating to biodiversity conservation law and policy in India are very complex and are still evolving especially in the context of Access and Benefit Sharing and associated traditional knowledge. This Paper is an attempt analyse the available legal framework on Biodiversity and the author(s) also seeks to explore the interplay of access and benefit sharing with the legal framework of intellectual property right with an attempt to harmonize the two.

Keywords: Biodiversity, Sustainable Development, Access and Benefit Sharing and Traditional Knowledge.

Introduction

During the end of the Earth Summit in 1992, the Convention on Biological Diversity (hereinafter referred to as CBD) was born as a strategic step taken by the nations of the world to ensure conservation and to provide mutual respect for the sovereign rights of the contracting parties over their animals, plants and genetic resources, found within their borders. The initiative was welcomed not only as a step towards conservation and sustainable use of the genetic resources of the world but more importantly as a commitment to respect and protect the

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sovereign right of developing nations which are abundantly rich in genetic resources.

The CBD provided far reaching benefits to such developing nations with tremendous genetic resources since for the first-time nation states collectively came forward and recognized the sovereign rights of the developing nations over the biological and genetic resources within their territories and provided a multilateral framework for the formation of national laws on aspects of access and benefit benefits arising out of the commercial and non-commercial use of these resources.

Access and benefit sharing are to be understood as the way by which biological and genetic resources may be accessed and used and the manner in which the benefits arising from such utilization is to be shared between its users i.e. people or countries using the resources and the providers i.e. people or countries that provide them.¹ Access and benefit sharing has been regulated over a long period of time, much before the inception of the Convention on Biological Diversity. It initially started off with the advent of the phase of decolonization, an era of new emerging nation states concerned about their resources. The first step in this direction was the Antarctica Treaty of 1959, followed by the Outer Space Treaty of 1966 and the Law of the Sea Convention in 1982.

The rather striking feature at this point of time is the shift in the approach prior to the Convention on Biological Diversity and the stance of nation states on such resources after 1992. Prior to the CBD, under all these conventions and treaties, the perception of biological and genetic resources of the world was that they were to be seen as the common heritage of mankind however subsequently. However, after 1992, nation states recognized to have and exercise sovereign rights over such biological and genetic resources which lie within the borders of their territory.

The last three decades have seen a significant growth and advancements in the biotechnology industry, thereby creating peculiar issues pertaining to intellectual property vis-à-vis the product based or created out of such genetic or biological resources and the technology used thereof in achieving these products. Commercial interests in aspects of intellectual property rights created on account of advancements of technology to enable utilization of resources for commercial use led to the formalization of the Agreement on Trade Related Aspects of Intellectual Property Rights (hereinafter referred as TRIPs) in 1995, at the end of the Uruguay Round of GATT negotiations.

Intellectual Property (hereinafter referred as IP) signifies creations of the mind in the forms of inventions, literary and artistic works, designs, and symbols, names and images used in commerce.² The notion behind the idea of attributing such ownership and rights over intellectual property is in order to incentivize, promote and reward those who have achieved on

¹ WIPO, A Guide to Intellectual Property Issues in Access and Benefit-sharing Agreements, *available at* https://www.wipo.int/edocs/pubdocs/en/wipo_pub_1052.pdf (Visited on May 13, 2021).

² WIPO, What is Intellectual Property, *available at* [https://www.wipo.int/about-ip/en/#:~:text=Intellectual%20property%20\(IP\)%20refers%20to,and%20images%20used%20in%20commerce](https://www.wipo.int/about-ip/en/#:~:text=Intellectual%20property%20(IP)%20refers%20to,and%20images%20used%20in%20commerce) (Visited on May 13, 2021).

account of creative human endeavour. Like other property rights, one of the aims of IP rights is to allow its creator to obtain a copyright or trademark or a patent and thereby to own, utilize and earn through it while at the same time to preserve and protect it from encroachment and wrongful claimants.

Nevertheless, not all such creations signify that they can be protected as IP and therefore different thresholds and conditions are set for such a creation to qualify as protected. Often such IP related aspects become relevant at the stage of negotiations undertaken at the time of drawing up access and benefit sharing agreements wherein parties determine the specific intellectual properties relevant to the agreement and the IP rights involved therewith.

The Agreement on Trade-Related Aspects of Intellectual Property Rights is a multilateral agreement under the World Trade Organisation (hereinafter to be referred to as WTO), in order to set minimum standards in international rules and legal framework pertaining to intellectual property. Essentially, both TRIPS and CBD, compliment each other with respect to the fact that both are outcomes of multilateral systems and therefore in case of any inconsistency that may arise in the two Agreements would have to be addressed so that the signatory countries can meet the requirements for complying with both the Agreements.³

Moreover, the World Trade Organization, which monitors the TRIPS Agreement, has taken several steps to bring about a balance between the objectives of sustainable development and trade.⁴ It is this path of balancing trade with sustainable developments that the scope of development in general is broadened and made even more inclusive. Therefore, the aspects of access and benefit sharing is multidimensional and not merely limited to the issue of sovereignty over resources within territorial limits but also transgresses into aspects of trade and intellectual property ownership.

Understanding of Access and Benefit Sharing

Access and benefit sharing legal regime has shaped up considering the distressing position of genetic resources and associated traditional knowledge being exploited at the hands of biopiracy, exploitation and misappropriation. The access and benefit sharing system responds to such dangers by putting in place an equitable and transparent trade system that mutually assist the provider and the user of genetic resources.⁵

The access and benefit sharing system includes an array of ways by which access can be gained to genetic resources and associated traditional knowledge (hereinafter referred as TK) at the same time provides for the essential prerequisites for benefit sharing from their use between the provider and user. This concept was formally envisaged in 1992 in the negotiation and terms of the Convention on Biological Diversity. In furtherance of these activities it is constantly required that all States practice fair and equitable access to genetic resources and

³ Biswajit Dhar and R.V. Anuradha, "Access, Benefit-Sharing and Intellectual Property Rights" 7 *JWIP* 597 (2004).

⁴ *Ibid.*

⁵ G. Emde, Graham and D. Rothman, *Access and Benefit Sharing: Protecting Rights to Genetic Resources and Traditional Knowledge* (2011) (Unpublished Thesis, Josef Korbel School of International Studies, University of Denver).

sharing of benefits arising from the use of genetic resources and associated TK.⁶ It also lays down the basis for providers and users of such genetic resources to negotiate and enter into agreements on mutually acceptable terms (hereinafter referred as MAT).

Often genetic resources are required by research organisations, pharmaceutical companies, product development and companies engaged in scientific research. Therefore, benefit sharing may be understood as distribution of benefits that accrue from the utilization of genetic resources and associated traditional knowledge, practices and innovations. Benefits can be categorized as monetary such as royalties, licensing fees, salaries and non-monetary such as taxonomy, conservation, technology transfer, exchange of information, etc.⁷

Genetic Resources

The term genetic resources connote living organisms such as plants, animals and microbes that carry genetic material that could be potentially useful to human beings. These resources can be derived from wild, domesticated or cultivated sources.⁸ Such genetic resources can occur *in situ* i.e. in their own ecosystem or natural habitat or it can occur *ex situ* i.e. from manmade efforts in the form of gene banks, seed banks, botanical gardens, microbial culture collections, etc.

The significance of such genetic resources stems from the fact that they are a reservoir of benefits and remedies. At the same time, they provide a great wealth of essential information for mankind to better understand the underlying hidden truths of the natural world and be utilized for the general welfare and benefit of the world. This may include product or service development, especially in the fields of medicines, agricultural practices and environment preservation and protection.

However, these resources are not distributed evenly across the globe. The assimilation of such genetic resources be it microorganisms, animals and plants, form complex balanced ecosystems which if misused may lead to endangering several such ecosystems or genetic resource forever. Therefore, the approach should be fair and equitable while accessing and utilizing genetic resources, keeping in mind their unsurmountable and unknown benefits which further incentivizes the provider and the user to conserve them to support the vision of sustainable development.

Traditional Knowledge

It is pertinent to understand that though we contribute various advancements to modern day science, however the starting point for the same lies in the knowledge gathered over

⁶ Thomas Greiber, *et. al.*, *An exploratory Guide to the Nagoya Protocol on Access and Benefit Sharing* 372 (IUCN, Gland, Switzerland, 2012).

⁷ National Environment Management Authority, Kenya's Access and Benefit-Sharing Toolkit for Genetic Resources and Associated Traditional Knowledge, *available at*: [https:// absch.cbd.int/api/v2013/documents /A5F8E9A7-C066-77CC-7446-D188F351F10A/attachments/ABS% 20TOOL%20KIT%20FINAL.pdf](https://absch.cbd.int/api/v2013/documents/A5F8E9A7-C066-77CC-7446-D188F351F10A/attachments/ABS%20TOOL%20KIT%20FINAL.pdf) (Visited on May 15, 2021).

⁸ Secretariat of the CBD, Convention on Biological Diversity: ABS, *available at* <https://www.cbd.int/abs/infokit/brochure-en.pdf> (Visited on May 15, 2021).

centuries. Knowledge associated with genetic resources have a long history and is usually not a mere offspring of modern-day science. For centuries now, local and indigenous communities across the world have strived to learn and study the benefits and uses of genetic resources surrounding them. This traditional knowledge is used, developed and passed on from generations to generations. Therefore, TK is an essential part of the life and living of such communities in their natural habitats.

These biological resources serve various everyday purposes for these indigenous communities and gradually they associate these practices with their identity and consider themselves as the guardians and protectors of their surrounding environment and habitat. Therefore, TK has served a dual purpose in this regard, it has served the environment by incorporating and following practices which have in turn preserved and protected the environment. At the same time, it has granted numerous benefits to the everyday life of such indigenous and local communities.

Today, TK plays a crucial role in identifying sources of information for both commercial and non-commercial use of genetic resources. TK is also extremely useful as a guide for prospective users in search of genetic resources for specific issues, since it indicates such users to already known useful aspects and benefits of such genetic resources, which may be still an unknown fact to the rest of the world. It is also extremely relevant for the Competent National Authorities, who would be aware of the worth and importance of such genetic resources in advance and would be in a better position for balancing the interests of users, providers and indigenous and local communities during negotiations.

Therefore, genetic resources can never be truly divorced from the associated traditional knowledge developed over centuries of use of such resources by local and indigenous communities. In the context of access and benefit-sharing, TK signifies such knowledge and traditional practices of indigenous and local communities primarily based on genetic resources. Therefore, TK is developed through the experiences and learning of the communities over centuries, which has been developed by adapting it to their specific requirements, needs, environment and culture and passed down from generation to generation.

The valuable experience and insight of such genetic resources in the form of traditional knowledge creates a wealth itself over which the first right remains of such indigenous communities. Therefore, it is pertinent to value and preserve such TK in order to fairly and equitably utilize it and at the communities which rely on it do not suffer from any risk. Furthermore, in order to ensure that the users of such TK recognize and respect the rights of indigenous and local communities. Therefore, at the time of negotiations, aspects pertaining to access and benefit sharing of such genetic resources and the associated TK is also undertaken and crystallized in the form of mutually agreed terms.

Prior Informed Consent

Prior Informed Consent (hereinafter to be referred to as PIC) signifies that permission has been given to the user seeking access or benefit sharing, by the Competent National Authority (hereinafter referred as CNA) of the Contracting State which represents the provider, in view of the appropriate legal requirements. Such CNAs are government bodies which

represent the resource providers and at the same time undertake responsibility to grant access to users.

Mutually Agreed Terms

Mutually Agreed Terms are primarily agreements entered in between the provider and the user of the genetic resource with regards to its access, benefit sharing and usage. This is an in-built aspect of the CBD on account of the recognition of sovereignty of State over the biological and genetic resources within its territorial limits. Therefore, it is pertinent that States individually develop their legal frameworks which are most relevant to their requirements in terms of ensuring that their genetic resources and its associated TK are preserved and utilized in a fair and equitable manner.

The key stakeholders involved therein are:

- Providers of genetic resources
- Users of genetic resources
- National Focal Points
- Competent National Authorities

International Legal Framework for Access and Benefit Sharing Towards a Convention on Biological Diversity

The 1960s saw great initiative towards dialogue with regards to the conservation of ecosystems. Between 1968 and 1974, International Biological Programme, an effort to coordinate large scale ecological and environmental studies, greatly influenced the notions of conservation and resulted in the Inter-Governmental Conference of Experts on the Rational Use of Biosphere Reserves.⁹ As a result of this Conference, UNESCO established the Man and Biosphere (MAB) Programme in 1971.

Subsequently, in 1972, the UN Conference on the Human Environment in Stockholm was held as not only an environment centric conference but also to facilitate dialogue during the heightened tensions between the global North and South. The strategic focus now shifted from the hands of the developed to the hands of the developing nations.¹⁰ A significant impetus to discussions on strategies for management, conservation, governance and legal regimes pertaining to biodiversity found place in the 1980s with the World Conservation Strategy.¹¹

World Conservation Strategy also brought forth the notion of sustainable development before an international audience and became the precursor of the Brundtland Commission. However, the World Conservation Strategy had no teeth and therefore remained limited to a conceptual draft lacking legal force. Biodiversity was now recognized as a global concern and as a result of several negotiations and funding initiatives led to the development and adoption

⁹ C. Kwa, "Representations of Nature Mediating Between Ecology and Science Policy: The Case of the International Biological Programme" 17 *SSS* 413-442 (1987).

¹⁰ T.E.J. Campbell, "The Political Meaning of Stockholm: Third World Participation in the Environment Conference Process" 8 *SJIS* 138 (1973).

¹¹ A.E. Nilsson, *Framing and Reframing of Biodiversity: Scale Perspectives and their Implication for the Science-policy Dialogue in International Governance*, Colorado Conference on EArth System Governance, Stockholm Environment Institute, Sweden, 17-20 May 2011, available at: http://nbaindia.org/uploaded/docs/BD_and_Governance.pdf (Visited on May 17, 2021).

of international multilateral agreements such as Convention on International Trade in Endangered Species and Convention of Wetlands of International Importance.¹²

By the 1980s, several conflicts over preference of international organisations involved in various aspects of biodiversity advancement became apparent. The United Nations Environment Program (hereinafter referred as UNEP) however was perceived as the most acceptable forerunner in this regard in the eyes of both developed and developing nations. In 1988, the UNEP convened the Ad Hoc Working Group of Experts on Biological Diversity to assess the need for a Convention on Biodiversity. Thereafter, the Ad Hoc Working Group of Technical and Legal Experts was established in 1989 with the objective of preparing an international legal instrument to conserve and sustainably use biodiversity.

The negotiations initiated towards achieving the Convention on Biological Diversity resulted in changing the outlook of the world towards biological resources. To diffuse the tension between the North and South, the various countries had to ultimately recognize biodiversity and genetic resources as a national sovereign resource and not as a common resource of mankind. This turn in perception, for the first time placed the developing nations in a position to bargain and set out their own terms over the genetic resources found within their respective territories.¹³

However, the primary issue remained on account of the deficiency in trust of the South in the scientific community lead by the North. Therefore, to create inherent trust the negotiations had to determine greater responsibility on the developed nations to provide for benefit sharing and technology transfer, while the developing countries were to engage in greater conservation, preservation and sustainable development.

The Ad Hoc Working Group, later came to be known as the Intergovernmental Negotiating Committee, completed its work on 22nd May 1992 and was adopted at the Nairobi Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity. Thereafter, the Convention was kept open for signature from 5th June 1992 at the United Nations Conference on Environment and Development, also known as the Earth Summit. Finally, upon ratification of 30 States, the Convention on Biological Diversity finally came into force on 29th December 1993. As of date, the Convention on Biological Diversity has 196 states party to it.

➤ **Convention on Biological Diversity, 1992**

The Convention on Biological Diversity envisaged three primary objectives:

- a) conservation of biological diversity
- b) sustainable use of the components of biological diversity
- c) equitable and fair benefit sharing arising out of the utilization of genetic resources¹⁴

¹² L.E. Christoffersen, "IUCN: A Bridge-Builder for Nature Conservation", in *Green Globe Yearbook* 59-69 (Fridtjof Nansen Institute Oslo Norway, 1997).

¹³ D.M. McGraw, "The Biodiversity Convention - From Negotiation to Implementation", in P. Le Prestre (ed.), *Governing Global Biodiversity: The Evolution and Implementation of the Convention on Biological Diversity*, (Ashgate, London, 2002).

¹⁴ Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH Eschborn Germany, The ABS Agreement: Key Elements and Commentary, available at: <http://www.abs-initiative.info/fileadmin/media/>

The CBD gives due recognition to the sovereign rights of the State over the natural resources within its territorial limits of the state and thereby allows the state to exercise authority over it in order to determine the conditions necessary for gaining access to such genetic resources. Therefore, the CBD lays down the legal framework in establishing such regulatory mechanism to effectively protect and determine access to genetic resources within the jurisdiction of such States. The key principles laid down by the CBD are as follows:

- State sovereignty over the biological and genetic resources within its territory.¹⁵
- Establish regulatory legal framework to determine access to such resources.¹⁶
- Mutually agreed terms to be set out in order to determine how and the basis on which access to such resources is to be sought.
- It incorporates the principle of ‘prior informed consent’ available with the resource provider.
- Recognizes ‘fair and equitable’ principle for sharing benefits arising from such access and use of the resources.¹⁷
- It further requires Contracting States to strive to preserve and maintain the traditional knowledge and practices of the local and indigenous communities. Therefore, it lays down the provision requiring approval and participation of the indigenous and local communities who are the holders of such knowledge. It cements the ideals of fair and the equitable sharing of such benefits accruing from such traditional knowledge, innovations and practices.

Therefore, it provides Contracting States:

- (i) To 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
 - (ii) To promote their wider application with the approval and involvement of the holders of such knowledge, innovation and practices
 - (iii) To encourage the equitable sharing of benefits arising from the utilization of such knowledge, innovations and practices.¹⁸
- It sets the obligation upon the Contracting Parties of the CBD to strive and put in the effort to carry out scientific research based on genetic resources. Such effort is to be inclusive of opportunities of full participation by all Contracting Parties and to the greatest extent possible thereof.¹⁹

[Events/2014/5-8 August 2014 Nadi Fiji/The ABS Agreement Key Elements and Commentary.pdf](#) (Visited on May 18, 2021).

¹⁵ Convention on Biological Diversity, 1992, Art. 15.

¹⁶ *Ibid.*

¹⁷ *Ibid.*

¹⁸ *Id.*, Art. 8(j).

¹⁹ *Id.*, Art. 15.

- Furthermore, it provides for Contracting Parties to lay down legislative, policy and administrative measures in order to ensure other States, particularly developing nations, are provided the opportunity to access and participate in biotechnological research activities and to the extent feasible.²⁰
- It also provides for access and transfer of technology which makes use of such resources through legislative, administrative or policy measures set out by Contracting Parties, particularly for developing countries, which are also resource providers, on mutually agreed terms, including patented technology or technology protected by other intellectual property rights.²¹
- Contracting Party shall also undertake legislative, administrative or policy measures so that wherever feasible and to whatever extent possible, the private sector also provides for access to, joint development and transfer of technology in furtherance of the benefit of the governmental and private sector of developing countries.²²
- Ensure that the intellectual property rights regime which has an impact on access and benefit sharing, does not run contrary to the CBD principles and remains supportive of it.²³

Therefore, under the CBD regime, Article 15 lays down the outline for the principle of access and benefit sharing. It provides for the framework for resource access and sharing based on the principle of prior consent and approval of the resource providing nation. At the same time, it furthers the conditions for access to or use of genetic resources, including sharing of its benefits on mutually agreed terms which are negotiated between such countries while maintaining the broader principle of fair and equitable sharing.

The CBD reinforces parties' right to utilize their resources in furtherance of their own environmental policies²⁴ and establishes their sovereign right to regulate access to genetic resources.²⁵ However, these rights are limited for instance, parties need to endeavour to create conditions to facilitate access to genetic resources²⁶ and not to put in place unreasonable restrictions which affects the objectives of the Convention.²⁷

The approach of the Convention is based on the premise of mutual relevance, where it is pertinent for developing countries in terms of protecting and benefiting from its *in-situ* and *ex-situ* genetic resources within its territorial limits. On the other hand, it creates well founded obligations on developed countries such as fair and equitable benefit sharing, transfer of technology and biotechnology, technical and scientific cooperation.

However, the CBD remains limited as it does not provide for a proper mechanism to enforce these obligations nor does it provide for monitoring and ensuring compliance of the

²⁰ *Id.*, Art. 19.

²¹ *Id.*, Art. 16.

²² *Ibid.*

²³ *Ibid.*

²⁴ *Id.*, Art. 3.

²⁵ *Id.*, Art. 15(1).

²⁶ *Id.*, Art. 15(2).

²⁷ V. Koester, "International Beskyttelse af Biodiversitet", in E.M. Basse *et. al.* (eds.) *Naturbeskyttelsesloven med kommentarer* (Og Økonomiforbundets Forlag, 2006).

same. Therefore, the rights of the developing countries are not completely protected under the CBD. Moreover, the CBD lacks in it enough structure to make the benefit sharing obligation operational, thereby creating even more uncertainties with regards to the practicality and efficacy for developing nations.²⁸ Therefore, practical implementations of the CBD remained a big question.

BONN Guidelines

The Convention on Biological Diversity came into force by 1993, however it was only by 1999 work towards achieving the objectives under the CBD was undertaken. The steps taken then moved towards a more certain and definite shape, which is now formally known as the Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising Out of Their Utilization. In 2001, an intergovernmental meeting prepared the first draft of the Bonn Guidelines. In 2002, the Bonn guidelines were formally adopted by the Conference of the Parties to the Convention on Biological Diversity, held in Hague.

The Bonn Guidelines were established to help various stakeholders, contracting states and parties to develop efficient, fair and equitable access and benefit-sharing strategies. The guidelines further assist in forming and establishing legislative, administrative or policy measures on access and benefit sharing and relevant for negotiating contracts on mutually agreed terms.²⁹

It also undertakes a capacity-building program keeping in sight the requirements of developing countries, in order to assist them to implement the CBD and Bonn Guidelines effectively. The Guidelines assist in identifying and simplifying the essential steps to be taken in order to clarify access and benefit sharing process, focusing especially on the requirements of the of the users. It further helps identify basic requirements and conditions for mutually agreed terms.

It elaborates on the role and responsibilities of users and providers and makes the entire process inclusive of all the stakeholders. Furthermore, the guidelines suggest aspects that need to be considered at the time of determining material transfer agreements. It provides a list which indicates monetary and non-monetary benefits.

BONN Guidelines

The basic elements required to be followed by potential users applying for access to a genetic resource as provided by the Bonn Guidelines is:³⁰

- Utmost transparency in legal grounds upon which restrictions be imposed on access to genetic resources.

²⁸ C. Chiarolla, "Making Sense of the Draft Protocol on Access and Benefit Sharing for COP 10" 7 *IDDRI* 4 (2010).

²⁹ UNEP, Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of their Utilization, Secretariat of the Convention on Biological Diversity 2002, *available at*: <https://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf> (Visited on May 21, 2021).

³⁰ Secretariat of the CBD, Convention on Biological Diversity: ABS, *available at* <https://www.cbd.int/abs/infokit/brochure-en.pdf> (Visited on May 21, 2021).

- Restrictions on access to genetic resources should not be contrary to the underlying principles and objectives of the CBD.
- Cost minimization for access to genetic resources.
- Legal transparency, certainty and clarity with regards to PIC and MATs.
- For the grant of PIC, Competent National Authorities should be established.
- Transparent and certain procedure to be set out for CNAs when potential users may apply for obtaining PIC.
- Defined and determined specifications of the use of PIC.
- Clear and specific timelines and deadlines to be determined and followed for grant of PIC
- Accessible and feasible consultation facilities and mechanisms to be put in place to facilitate consultation of various stakeholders.
- Facilitating the transaction essential to MATs through fixed channels providing clear information and specific formal procedures.
- MAT negotiations to be conducted in reasonable timelines.
- Terms when determined are to be specified in a written agreement.
- MAT to include specifications in terms of the type, quantity and geographical region of the genetic resource. It should provide recognition to the sovereign right of the provider country in whose jurisdiction the genetic resource originates. It should also specify limitations, if any, on the usage of such resource.
- MAT should specify clearly if the genetic resource can be transferred to a third party and if so, then under what terms and conditions.
- MAT should promote and facilitate capacity-building amongst various areas as are predetermined under the terms of the agreement.

➤ **Cartagena Protocol**

The first Protocol under the CBD was the Cartagena Protocol on Biosafety of the Convention (hereinafter referred as the Biosafety Protocol), adopted in the year 2000 and entered into force on 11th September 2003. The primary objective of the Biosafety Protocol is to protect biological diversity in the form of living modified organisms and genetically modified organisms developed as a result of modern biotechnology. The Biosafety Protocol envisaged the precautionary principle in dealing with products developed with technological advancements, thereby striving to strike a balance to be achieved between public health and economic benefits.

Nagoya Protocol

To truly realize the effect of the third objective of CBD, which provides for fair and equitable sharing of benefits of biological diversity, fresh debates were initiated in 1998 which continued for sixteen long years. After intensive debating and deliberations, the access and benefit sharing protocol pertaining to genetic resources and associated traditional knowledge was finally fleshed out. In 2010, during the Conference of the Parties to the Convention on Biological Diversity in Nagoya, Japan, the CBD formally adopted the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their

Utilization (hereinafter referred as the Nagoya Protocol).³¹ The Protocol, according to its Article 33, came into force after its 53rd ratification on the 12th of October 2014.

Nagoya Protocol aims to advance the third objective under the CBD by creating a strong legal regime for greater legal certainty and transparency. It provides for several obligations on the provider states to establish efficient compliance and regulatory regimes through domestic and lays down contractual obligations in the form of mutually agreed terms. These provision in turn create greater international uniformity and certainty for access to genetic resources and the consequent benefits which are to be monitored to ensure that they are in fact being shared in a fair and equitable manner. Furthermore, it prioritizes the interest of indigenous and local communities by putting in place an effective legal framework to strengthen their ability to access the benefits arising out the use of their practices and knowledge.

The Nagoya Protocol goes a step further than this and adds to the existing third objective of the CBD obligation that access and benefit sharing shall in turn facilitate conservation and sustainable use of its components.³² Therefore, the Nagoya Protocol in effect is linked to the entire objectives of the CBD. It has put in place incentives to promote and facilitate the sustainable use of genetic and biological resources and at the same time to ensure the conservation of biological diversity.

Nagoya Protocol on aspects of Benefit Sharing and Capacity Building

Benefit sharing is also another important aspect given due consideration under the Nagoya Protocol. Contracting parties are mandated to put in place legislative, administrative, or policy measures in order to make sure that the benefits accruing from the utilization of genetic resources and its subsequent commercialization and application is shared in a fair and equitable manner as envisaged under the Nagoya Protocol and the CBD principles.³³

The Nagoya Protocol addresses both monetary and non-monetary benefits in a manner similar to the Bonn Guidelines but at the same time, it further provides for greater collaboration and cooperation in the area research and development, specifically with the participation of the provider party.³⁴ Therefore, it emphasis on the requirements of technology transfer, technology sharing, especially keeping in mind the participation and benefits accruing for developing countries. The basic notion remains to encourage the discovery of valuable genetic resources and at the same time to stimulate sustainable use, the process for its conservation and to further encourage and support the flow of benefits in furtherance of these two objectives.³⁵

The Nagoya Protocol also lays down measures to enhance capacity, especially by calling upon State parties to further the endeavours of capacity-building and development, particularly, human resource and institutional capacities.³⁶ It further emphasizes on self-

³¹ Stellina Jolly, "Access and Benefit Sharing under Nagoya Protocol and Sustainable Development-A Critical Analysis" 9 *AIJJS* 38-45 (2015).

³² 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, Nagoya, 2010, Art. 1.

³³ *Id.*, Art. 5(1), 5(5).

³⁴ *Id.*, Art. 23.

³⁵ *Ibid.*

³⁶ *Id.*, Art. 22.

assessments as a viable tool for developing countries, especially where they wish to find out the present day needs and requirements.³⁷ These potential areas requiring work include, mechanism for enforcing these aspects, negotiations of MAT, research and development capabilities, transfer of technology and any other relevant aspect pertaining to the implementation of the Protocol.³⁸

The idea behind utilization of genetic resources belonging to another State is primarily to gain benefit out of it and subsequently share the benefit and therefore this utilization of the genetic resources is to be understood as the research and development on the genetic and biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention.³⁹

Nagoya Protocol on aspects of Traditional Knowledge associated with genetic resources

The Nagoya Protocol is particularly relevant for communities which possess great TK associated to genetic resources, especially in terms of participation in PIC and benefit sharing. Communities which are recognized under the domestic law to have rights over genetic resources and associated traditional knowledge are required to be given equal participation under the domestic laws in PIC arrangements for access to such genetic resources and the associated TK.⁴⁰ Moreover, such benefits derived from the utilization of genetic resources and associated TK is to be shared in a fair and equitable manner especially with the relevant indigenous and local community.⁴¹

To truly put in force an effective mechanism it is pertinent that information is provided in detail, transparent and accessible manner with regards to the TK associated with genetic resources and the obligations thereof.⁴² Active participation of such communities can be sought in terms of seeking suggestions to make the process more inclusive for PIC and MAT, and to flesh out sample contractual clauses as guides for future which represent the best interest of such communities.⁴³

Furthermore, to effectively increase awareness pertaining to genetic resources and the associated traditional knowledge, parties are obligated to hold meetings involving the particular indigenous and local community and to further involve them actively in decision making exercises. The relevant states can also establish help desk and help centres for such indigenous and local community to seek information and clarify and community directly about issues relevant to genetic resources and associated TK.⁴⁴

The Nagoya Protocol also emphasizes on improving the capacities of such indigenous

³⁷ *Id.*, Art. 22(3).

³⁸ *Id.*, Art. 22(4), 22(5).

³⁹ E.C. Kamau, B. Fedder, *et. al.*, "The Nagoya Protocol on Access and Benefit Sharing: What is New and What are the Implications for Provider and User Countries and the Scientific Community?" 6 *LEAD* 248 (2010).

⁴⁰ 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, Nagoya, 2010, Art. 6(2), 6(3)(f), 7.

⁴¹ *Id.*, Art. 5(2), 5(5).

⁴² *Id.*, Art. 12(2).

⁴³ *Id.*, Art. 12(1), 12(3).

⁴⁴ *Id.*, Art. 21(b), (c), (h).

and local communities so that the Protocol and the domestic legislations made in effect thereof, can be implemented effectively. Special focus is given to improve the capacity of women of such communities considering their pivotal role with regards to such access and benefit sharing processes within their communities.⁴⁵

Nagoya Protocol on aspects of Monitoring and Compliance

The Protocol has also put in place various mechanisms to effectively monitor the application and compliance of the Protocol especially in terms of the effective utilization of genetic resources. For instance, checkpoints have been put in place for potential users to submit relevant information pertaining to PIC, MAT as well as subsequent information with regards to the utilization of the genetic resource.⁴⁶ Thereafter, it is forwarded to various authorities and agencies, relevant stakeholders and provider parties within the State and to the access and benefit sharing clearing house mechanism.⁴⁷

The access and benefit sharing clearing house is established under Article 14 of the Nagoya Protocol as an element of the clearing house mechanism established under Article 18 of the CBD. The access and benefit sharing clearing house mechanism provides for a platform which facilitates the exchange of information pertaining to access and benefit sharing of genetic resources and thereby creates greater certainty and transparency on procedural aspects. It also creates an excellent monitoring system to assess the utilization and compliances including international certificate compliance pertaining to genetic resources.⁴⁸

It is mandatory for each party to report to the Conference of the Parties, CBD, in terms of the observations and progress in the implementation of the Protocol. and report regularly to the COP.⁴⁹ However the monitoring mechanism lacks specific procedure and strategies to keep a check on the utilization of TK under the Protocol, especially considering the fact that the Protocol creates a division between the utilization of genetic resources from the utilization of TK.

In terms compliance, the Nagoya Protocol leaves the option open to the respective parties to decide the most appropriate measures that suits their individual needs and conditions in determining the compliance, particularly in terms of checking the PIC and MAT with regards to the relevant genetic resource and the traditional knowledge.⁵⁰ Unfortunately, the Protocol does not provide for a strong obligation on parties to address and resolve situations of non-compliance.⁵¹ Though the Protocol draws upon the principle of sovereign rights of provider parties, it falls short in terms of culling out specific provisions on transboundary cooperation. It loosely states that for the objectives of the Protocol to be achieved, the parties shall 'endeavour to cooperate'.⁵²

⁴⁵ *Id.*, Art. 22(3), 22.5(j).

⁴⁶ *Id.*, Art. 17(1)(a).

⁴⁷ *Id.*, Art. 17(a)(iii).

⁴⁸ *Id.*, Art. 17(1)(b), 17(1)(c), 17(2).

⁴⁹ *Id.*, Art. 29.

⁵⁰ *Id.*, Art. 15(1), 16(1).

⁵¹ *Id.*, Art. 15(2), 15(3), 16(2), 16(3).

⁵² *Id.*, Art. 11.

To bring about greater certainty in the resolution of disputes, it is pertinent that parties pre-determine the jurisdiction to resolve the dispute in terms of the applicable law and the mode and method, including possible alternative dispute resolution of their preference.⁵³ Moreover, parties should ensure mechanism to be put in place for mutual recognition, enforcement of foreign judgments and awards and access to justice.⁵⁴

The Nagoya Protocol sets out to keep the negotiations open by putting in place an enabling clause to provide a framework that would address issues not currently suited under the bilateral approach.⁵⁵ The global multilateral benefit-sharing mechanism under the Nagoya Protocol was conceived as an option to later on identify, discuss and resolve further issues on which the parties could not agree during the negotiations of the Protocol.⁵⁶ These global multilateral mechanisms in effect target three primary conditions where a multilateral mechanism would be necessary to resolve the access and benefit sharing requirements:

- a) For genetic resources and associated traditional knowledge that occur in transboundary situations
- b) Where it is not possible to grant PIC
- c) Where it is not possible to obtain a PIC

The implicit benefits of such a mechanism is that it opens the lines of communication and negotiation to resolve difficult issues and problems associated with access and benefit sharing and address questions which have not been included in the bilateral solutions such innovative options for conservation, effective cost and timelines, sustainable development and use of biodiversity, etc.

An interesting example of multilateral access and benefit sharing mechanism can be seen in the International Treaty on Plant and Genetic Resources for Food and Agriculture (hereinafter to be referred as ITPGRFA) which furthers the principles of fair and equitable sharing of the benefits accruing from creating a global pool of plant based genetic resources, for food and agriculture.⁵⁷ These benefits arising out of the ITPGRFA system are monetary as well as non-monetary.

Therefore, though this multilateral system is an example for the potential global multilateral mechanism that can be established under the Nagoya Protocol but the scope of the ITPGRFA

⁵³ *Id.*, Art. 18(1).

⁵⁴ *Id.*, Art. 18(3).

⁵⁵ T. Dedeurwaerdere, A. Brogiato, *et. al.*, “Governing Global Scientific Research Commons under the Nagoya Protocol”, in Buck, Morgera, *et. al.* (eds.), *The 2010 Nagoya Protocol on Access and Benefit-sharing in Perspective, Legal Studies on Access and Benefit-Sharing* 381-421 (Martinus Nijhoff Publishers, 2012); Maria Julia Oliva, “The Implications of the Nagoya Protocol for the Ethical Sourcing of Biodiversity”, in Morgera, Buck, *et. al.* (eds.), *The 2010 Nagoya Protocol on Access and Benefit-Sharing in Perspective* 369-387 (Martinus Nijhoff Publishers, 2012).

⁵⁶ 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, Nagoya, 2010, Art. 10.

⁵⁷ Food and Agriculture Organization, International Treaty on Plant Genetic Resources for Food and Agriculture, available at <http://www.fao.org/plant-treaty/en/> (Visited on May 25, 2021); E. Tsioumani, “International Treaty on Plant Genetic Resources for Food and Agriculture: Legal and Policy Questions from Adoption to Implementation” 15 *Yearbook of International Environmental Law* 119-144 (2004).

is only limited to one aspect alone. Therefore, it seems to be a daunting task to construct a global mechanism to fit the needs of all party states considering the fact that different nations have had different experiences with the implementation of the Nagoya Protocol.⁵⁸

Indian Law and Policy on Access and Benefit Sharing

India has taken upon this commitment before the world by signing the Convention on Biological Diversity on 5th June 1992. Subsequently, India ratified the CBD on 18th February 1994 and it came into force on the 19th of May, 1994. The CBD provided for the skeleton to flesh out laws and policy in furtherance of conservation, protection and sustainable use of India's rich biodiversity, genetic resources and associated Traditional Knowledge.

The Constitution of India itself lays the inherent foundation for the protection and preservation of the environment both as a duty on the State and the people of India. The Constitution provides for the obligation upon the State to maintain social order by saving the social and economic interest of the citizens of the country.⁵⁹ Indian Constitution also provides that state has to maintain equitable balance to protect common good.⁶⁰

Therefore, it is obligatory on the State to safeguard and protect the interest of the community by shielding ownership and control of material resources.⁶¹ It further provides for the State to endeavour to protect and improve the environment and to safeguard the forests and wild life of the country.⁶² At the same time, it casts a duty upon its citizens to protect and improve the natural environment including forests, lakes, rivers and wild life, and to have compassion for living creatures.⁶³

The Biological Diversity Act 2002

The Biological Diversity Act, 2002 (hereinafter referred as the BD Act 2002) is a legislation to further the objective of conservation of biological diversity while ensuring access and equitable and fair benefit sharing of biological resources and the associated traditional knowledge in India. It was a result of great cooperation and concerted efforts between government and non-governmental agencies in India. In 1994, a drafting group was constituted including members and representatives of the relevant government ministries, scientific community, research institutes and environment non-governmental organisations.

Biological Diversity Act 2002: Access and Benefit Sharing

The legislation strives to incorporate provisions for access to biological resources and subsequent fair and equitable sharing of benefits. It creates a legal framework for sustainable use and conservation of biological resources. It mandates the recognition, respect and protection of traditional knowledge of indigenous and local communities associated with biological

⁵⁸ Daniela Rat, The Global Multilateral Benefit-Sharing Mechanism under the Nagoya Protocol, *available at*: <https://politheor.net/the-global-multilateral-benefit-sharing-mechanism-under-the-nagoya-protocol/> (Visite on May 26, 2021).

⁵⁹ The Constitution of India, art. 38.

⁶⁰ *Id.*, art. 39(b).

⁶¹ Zubair Ahmed Khand, "Protection of Biodiversity in India and Bangladesh: A Legal Perspective" *ILI Law Review* 223 (2016).

⁶² The Constitution of India, art. 48-A.

⁶³ *Id.*, art. 51-A(g).

resources. It creates obligations on foreign nationals and foreign organizations to take prior informed consent and necessary approvals for access to the biological resource and associated TK. The mandate of approvals is also set out for Indian researchers, scientists, institutes and organisations for transferring outcomes of research on bioresource or associated TK before exporting the same to abroad.⁶⁴

The Act has introduced a new realm of conservation through development and preservation of biological diversity heritage sites and protection of endangered species. Extensive involvement is required of the authorities at the National, State and local levels. This would include involvement of the State Government to constitute Biodiversity Management Committees (hereinafter referred as BMC) and to notify heritage sites after consulting local bodies.

It also creates the framework to protect India's bioresources and associated traditional knowledge against biopiracy and unlawful misappropriation, especially at the hands of foreign individuals and organizations.⁶⁵ Furthermore, Section 8 of the Act establishes the National Biodiversity Authority (hereinafter referred as NBA), a statutory autonomous body for implementing and enforcing the provisions of the Act and was constituted in 2003. The NBA performs a myriad of regulatory and advisory functions pertaining to conservation, sustainable use and access of bioresources and fair and equitable sharing of the accruing on account of use of these resources.

It lays down detailed procedures and guidelines to regulate these activities particularly access and benefit sharing and Intellectual Property Rights with regards to biological resources and associated Traditional Knowledge. It provides for the necessary approval to access and utilize biological resources by signing an access and benefit sharing agreement with the NBA.⁶⁶ The NBA can restrict certain persons i.e. foreign nationals, NRIs, body corporates, associations or organisations not incorporated or registered in India or incorporated or registered in India which has any non-Indian participation in share capital or management from undertaking biodiversity related activities without its prior approval.⁶⁷

It can also restrict the transfer of research results where its prior approval has not been given.⁶⁸ Therefore for any transfer of results of any research relating to any biological resource occurring in, or obtained from India, be it by an Indian or foreign citizen or NRI or body corporates, associations or organisations incorporated or registered in India with or without any non-Indian participation in share capital or management and body corporates, associations or organisations not incorporated or registered in India.⁶⁹

It is also mandatory for any person before applying for intellectual property rights,

⁶⁴ Prof S. Kannaiyan, Chairman National Biodiversity Authority, An Overview on Biological Diversity Act, 2002, available at: <http://nbaindia.org/uploaded/docs/biological-diversityact-ii.pdf> (Visited on June 2, 2020).

⁶⁵ Krishna Prasad Oli and Tara Devi Dhakal, *Access and Benefit Sharing from Genetic Resources and Associated Traditional Knowledge* (Training of Trainees and Resource Manual, ICIMOD, 2009).

⁶⁶ Biological Diversity Act, 2002 (Act No. 18 of 2004), s. 3.

⁶⁷ *Ibid.*

⁶⁸ *Id.*, s. 4.

⁶⁹ *Ibid.*

within or outside India, pertaining to research or information on a biological resource obtained from India, to seek approval of the National Biodiversity Authority.⁷⁰ This includes Indian or foreign citizens or NRIs, body corporates, associations or organisations incorporated or registered in India with or without any non-Indian participation in share capital or management and body corporates, associations or organisations not incorporated or registered in India.⁷¹

The Act also mandates that in case where an Indian citizen, body corporate, association or organization registered in India, seeks to obtain any biological resource for commercial utilization, bio-survey and bio-utilization, without providing prior intimation to the SBB cannot access and utilize the said resource.⁷² However, people belonging to indigenous and local communities of that area including growers and cultivators of biodiversity, vaidas and hakims, who have been practicing indigenous medicine are exempted from the requirement of such prior approval.⁷³

Suggestions for Harmonizing Intellectual Property Rights under the Access and Benefit Sharing Framework

Developing nations have been the forerunners in suggesting initiatives to improve and harmonize the needs and requirements of the North and the South in terms of the access and benefit sharing regime with the purview of intellectual property rights in this regard. One such initiative can be with regards to putting in place effective obligations on the IP applicant in terms of disclosures. Disclosures can be specific to creating obligations for revealing place of origin of the resource and the associated traditional knowledge utilized in the product or process along with substantive proof of prior informed consent and benefit sharing. Such disclosures will effectively put the onus on the applicant to approach with clean hands and in effect it will create safeguards against misappropriation and biopiracy.⁷⁴

These disclosures will help create greater compliance and monitoring in the best interest of the IP rights and the access and benefit sharing legal regimes. It will assure compliance with the national laws on access and benefit sharing and would additionally enable patent offices to ascertain the level of inventiveness claimed and also improve their database while keeping them even more vigilant over aspects affecting bioresources. It will safeguard the interest of developing and least developed countries with immense biological resources and associated TK and in keeping a track on IP rights over bioresources and to assist them in establishing their claim in case of wrongful intellectual property rights.

Conclusion

It is a commendable feat for India to be one of the very few countries which has put in place an operational legal framework to give life to the principles enshrined in the CBD and the framework for access and benefit sharing of biological resources and associated TK. However, it is important that India ensures that these objectives are in fact realized and implemented

⁷⁰ *Id.*, s. 6.

⁷¹ *Ibid.*

⁷² *Id.*, s. 7.

⁷³ *Id.*, s. 7.

⁷⁴ WTO, *Council for Trade-Related Aspects of Intellectual Property Rights, Minutes of Meeting: Statement Made by Brazil in the TRIPS Council Meeting, IP/C/M/39* (March, 2003).

properly under the BD Act 2002 in an effective manner.

Therefore, India must strive to collaborate as much as possible with relevant ministries, stakeholder, environment, and scientific organisations to successfully achieve the scope of access and benefit sharing in India to further conserve the biodiversity, to ensure sustainable use and ultimately improve the lives of indigenous and local communities.⁷⁵

⁷⁵ Balakrishna Pisupati, "Access and Benefit Sharing: Issues and Experiences from India" 6 *JGLR* 31-38 (2015).