A Critical Comment on Access and Benefit Sharing in India under Biological Diversity Act, 2002: In the Light of Nagoya Protocol on Access & Benefit Sharing

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Abstract

In recent times the importance of biological/genetic resources has increased in manifold because of their use in technical and scientific research leading to various kinds of inventions which gets commercially exploited giving rise to revenue generation. This growing importance has posed a new threat to the biological/genetic resources in the form of unauthorised use of the same. This was realised when developing countries like India faced several cases of bio-piracy in the mid-90s. These bio-piracy cases surfaced when a peculiar phenomenon was observed in which developed countries like USA started misappropriating the bio-resources and the associated traditional knowledge of the developing countries in creating inventions and claiming exclusive rights over them through Patent system, thereby stopping the rest of the world from using those resources and/or associated knowledge. This led to a situation where the country which provided the bio-resource and/or the associated knowledge also known as the Provider country was at complete loss as even after contributing in the process of creation of the concerned invention by providing resources and knowledge, it could not secure a share of the benefit arising from commercial exploitation of the invention, in its account. And In order to address this new challenge an attempt was made at the international level to come up with a framework which will allow the countries to secure their right of sovereignty over their bio-resources which in turn will help them in preventing cases of bio-piracy. With this, came the Convention on Biological Diversity which brought the concept of state sovereignty over bio-resources, their conservation and sustainable use and fair and equitable benefit sharing which further was discussed in details in its Nagoya Protocol on Access and Benefit Sharing. Authors in this paper will look into this identified threat and would specially focus on the concept of ABS under Nagoya Protocol and under the Indian law i.e. Biological Diversity Act, 2002.

Keywords: Convention on Biological Diversity, Access and Benefit Sharing (ABS), Nagoya Protocol on ABS, Biological/Genetic Resources, Associated traditional knowledge, Biological Diversity Act, 2002.

1. Introduction

Biodiversity as a whole plays a very significant role in various sectors of development. A rich biodiversity always serves as a boon for a nation, bringing an all-round development for itself and its people, including

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the two major forms of development i.e. social and economic development. The role of biodiversity in accelerating a nation’s development even becomes more crucial and significant when it comes to various developing and underdeveloped countries which mostly have a rich biodiversity and a comparatively poor skill based research and developmental set-up including technological infrastructure, unlike developed nations whose strength is considered to be their technology and infrastructure. In such a scenario, it becomes essential for the biodiversity rich nations to acknowledge their strengths and make proper provisions for preservation, conservation and use of various components of their biodiversity. In this context, it is important to understand the evolution of the concept of ‘nations claiming their rights over biodiversity’. This concept was an outcome of the mutual consensus achieved among the debating nations through numerous deliberations at the ‘Convention on Biological Diversity’ (CBD) which introduced the idea of ‘State’s sovereignty over the biodiversity available within its territorial limits’, thereby rejecting the ‘idea of commons’ with respect to biodiversity i.e. biodiversity to be a part of public domain and no nation to have exclusive rights over it. This empowered the nations not only to regulate the access by other nations over the various biological resources that are available as a part of the biodiversity within their territories, but also to stop the unauthorised use of these biological resources by such nations, thereby significantly contributing in the attempt of curbing the menace of ‘Bio-piracy’, which is often termed as an unauthorised exploitation of the available biological resources of one country by another country. Biodiversity is commonly understood to be the diversity/variety found among the various life forms under two broad categories i.e. Flora and Fauna, which on a larger scale is observed as Ecosystem as a whole. Hence the concept of biological resources would also be broadly categorised in to plant bio resources and animal bio resources. Considering the growing importance of bio-resources, for example the use of medicinal properties exhibited by the medicinal plants and the associated traditional medicinal knowledge in modern healthcare systems worldwide, it is essential for the nations to have proper legislative frameworks in place to protect their bio resources and prohibit the unauthorised use and exploitation of such bio-resources and associated traditional/indigenous knowledge. And in an attempt at achieving the above mentioned goal of legislating a comprehensive legal framework which will not only ensure protection against the unauthorised use of biological resources available in India but also ensure the fair and equitable sharing of benefits arising out of the commercial exploitation of biological resources among the stakeholders involved in such commercial exploitation, majorly between the provider of the biological resources and/or associated knowledge and the receiver of the same who in turn use such resources and/or associated knowledge to generate revenue, India legislated The Biological Diversity Act in the year
2002 (hereinafter to be read as the Act). This Act came into force as a step towards compliance of the TRIPS mandate\(^3\) and CBD’s obligation\(^4\) on the member countries. One of the most highlighted features of this Act is the unique structural framework of Access Control mechanism involving the 3 tier statutory authorities regulating the access to biological resources available in India on one hand and the concept of determination of Benefit Sharing arising out of commercial use of such biological resources with respect to which, access has been granted under the Act to the party who has used such biological resource/s in commercially generating revenue/benefit on the other. (Both being discussed in the later segment of this paper). The other highlight of this paper would be the discussions of the concept of “Access and Benefit Sharing” under the Nagoya Protocol on Access and Benefit Sharing tracing the evolution of this protocol which was adopted as a protocol to the Convention on Biological Diversity. The authors, in this paper will also attempt at the discussions on the concept of ABS in India in the light of the Biological Diversity Act, 2002 and will examine to what extent these provisions under the Indian Act have been able to be in compliance with the obligations placed by CBD upon India as a member country to CBD and to what extent the provisions relating ABS under the Nagoya Protocol has been justified under the Biological Diversity Act, 2002 and will finally conclude by making an overall remarks on the whole concept of ABS from an global as well as Indian standpoint.

2. Evolution of The Nagoya Protocol on Access and Benefit Sharing

The Convention on Biological Diversity (hereinafter to be read as CBD) which is considered as one of the leading international frameworks and one of its kind first attempt at focusing on the protection of biodiversity at large as a global concern and advocating for the protection of biological resources and interests of the communities safeguarding such resources and holding associated knowledge, was adopted on 22\(^{nd}\) May 1992 at the United Nations Conference on Environment and Development (UNCED) also

\(^3\) Article 27 (3) allows member countries to make appropriate domestic legal frameworks to ensure protection and regulation of plant and animals including the plant and animal based biological/genetic materials/resources which can act as an alternative protection framework to patents because as per the general consensus achieved at TRIPS that Plants and animals are to be excluded from the Patent protection yet to be protected in the light of these plants and animals generating inventions and innovations and hence this placing of the obligation on the member states to come up with alternate protection framework.

\(^4\) CBD places obligations on its member states to make such domestic legal frameworks which will ensure protection to biodiversity in general and biological/genetic resources in particular with basic objective of conservation and sustainable use of the biodiversity and its components respectively and ensuring fair and equitable sharing of benefits arising out of commercial utilization of the biological/genetic resources/materials.

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called as the Earth Summit at Rio de Janeiro. It was opened for signature on 5th June 1992 and finally came in force on 29th December 1993 with the following chief objectives under Article 1:

- Conservation of biological diversity
- Sustainable use of its components
- Fair and equitable sharing of the benefit arising out of the utilisation of the genetic resources.

As the first attempt by the global community to address the concern of biological diversity as a whole, CBD placed its foundations on the broad ecosystem approach unlike the sectoral approach focusing on single ecosystems, species, cites etc. and their concern, which had been adopted by many protection & conservation international and domestic frameworks prior to CBD. CBD defines biological diversity (biodiversity) as the variability among living organisms from all sources, occurring at three levels: diversity within species (genetic diversity), diversity between species, and diversity of ecosystems.

The CBD objectives are a result of the two opposing visions of two worlds of the globe, which is also better known as the difference in the vision and approaches of the developing and developed countries and even more popular in terms of the North-South divide. While the developing nations pushed more for the conservation, protection, access to biological resources and in turn benefit sharing arising out of the use of such resources, the developed ones were more concerned with the commercial use of the biological resources and the corresponding rights arising out of that which are more proprietary in nature. So in order to create a balance between these two set of differing ideas, certain concepts were introduced in CBD like, “State Sovereignty on biological resources available within the territorial jurisdiction of the nation”, “need for regulating the access to such biological resources”, “Commercial utilization of biological resources with authorization” “use of biological resources in scientific researches”, rights of the entities creating novel inventions using biological resources”, “rights of the indigenous communities and other knowledge holders holding traditional or otherwise knowledge over the biological resources”, “Benefit Sharing arising out of utilization of biological resources” etc. Out of all these concepts, the one which attracted substantial debate and discussion was that of the concept of “Access and Benefit Sharing” to such great extent that a separate legally binding and supplementary agreement to CBD had to be

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7 Genetic diversity refers to the frequency and variability of the gene pool within a single species. It includes the variation both within a population and between populations.
adopted in the year 2010 in the name of 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, also known as the Nagoya Protocol on Access and Benefit Sharing.

3. The Nagoya Protocol on Access and Benefit Sharing: An Overview

Nagoya Protocol establishes a framework for regulating how users of genetic resources and/or traditional knowledge associated with genetic resources (for example, researchers and commercial companies) may obtain access to such resources and knowledge. It provides for general obligations on sharing the benefits arising from the utilization of such resources and knowledge. And it obliges Parties to ensure that users under their jurisdiction respect the domestic ABS legislation and regulatory requirements of the Parties where the resources or knowledge have been acquired.\(^8\)

As far as the objective of the Protocol is concerned it derives its force from the third objective of CBD which reads as “Fair and Equitable Sharing of Benefits arising out of utilization of genetic resources” and hence focuses on the various facets of Benefit Sharing which includes appropriate access to genetic resources, appropriate transfer of relevant technologies, and appropriate funding.\(^9\) Accordingly, benefit-sharing entails more than sharing a certain percentage of the profits when a product is developed on the basis of a genetic resource. Furthermore, it is re-stated that when sharing benefits, the rights over the accessed resources and to the transferred technologies have to be taken into account.\(^10\) While focusing on the main objective of Access and Benefit Sharing, Nagoya Protocol also doesn’t undermine the importance of the other two objectives of CBD i.e. Conservation of biodiversity and sustainable development of all its components as all the provisions drafted under Nagoya Protocol are in consonance with these two objectives of CBD.

As far as the scope of the Protocol is concerned there was a lot of debate and discussions among the member countries of the CBD during the negotiations of the Protocol and after much deliberations a general consensus was achieved that the scope of the protocol will be same as the scope of CBD i.e. the mechanism of access and benefit sharing has to be understood with respect to genetic resources as defined under the scope of CBD, because, as envisaged at the outset of the negotiations of the Nagoya Protocol, there could not been a general agreement among the deliberating countries with regard to any positive list as to what could be included or any

\(^8\) Supra note 3  
\(^9\) The Nagoya Protocol on Access and Benefit Sharing, art.1  
\(^10\) Supra note 6
negative list as to what is to be excluded in terms of certain biological resources which can be brought under the purview or put out of it to while deciding the scope of applicability of the Nagoya Protocol. In absence of any specific list defining the subject matter of protection under the Nagoya Protocol, a general provision was included defining its scope that refers to “genetic resources within the scope of Article 15 of the Convention” and to “traditional knowledge associated with genetic resources within the scope of the Convention”

Another important aspect of the Protocol which reflects on its applicability with regard to other international instruments and processes relating access and benefit sharing says that Protocol’s provisions shall not affect rights and obligations from existing international agreements; that Parties may develop and implement other specialized ABS agreements in the future; that such specialized ABS agreements prevail if they are in line with the objective of the Nagoya Protocol; and that due regard should be paid to ongoing international processes.13

3.1. Some important provisions relating to “Access” & “Benefit Sharing” under Nagoya Protocol

As the basic objective with which the Protocol was adopted as a part of the CBD was to have some general international consensus with regard to access and benefit sharing concerning biological resources available within the territorial limits of the member countries and also to put an obligation on the member countries to ensure the authorised access to their biological resources and fair and equitable sharing of benefits among the various stakeholders involved in the utilization of the resources through apt domestic legal frameworks, it is important for the authors here to look in to the relevant provisions of Nagoya Protocol concerning the access to biological resources & associated traditional knowledge and the provisions relating to fair and equitable sharing of benefits arising out of utilization of such biological/genetic resources.

3.1.1 Access

Nagoya Protocol reaffirms the concept of state sovereignty12 over the bio resources available within the territorial jurisdiction of such state thereby making these bio resources a subject matter of State regulation and hence giving powers to the individual states to make domestic frameworks which will regulate the access13 to these bio resources with the help of the involvement of the regulatory authorities to be established under such domestic framework. As per Nagoya Protocol, before granting access to any

11 Ibid.
12 The Nagoya Protocol on Access and Benefit Sharing, art. 6(1)
13 The Nagoya Protocol on Access and Benefit Sharing, art. 6(2)
biological/genetic resources available within the territorial limits of the member states, states are required to take the prior informed consent (PIC) (as also envisaged under Article 15 of CBD) from the community/communities who have been identified as the benefit claimers because of the fact that they safeguard the biological resource in question and/or possess the associated traditional knowledge over such biological resource in question. In addition to the PIC states through their relevant regulatory authorities also will have to ensure that the parties involved in the access and utilisation if any biological/genetic resources i.e. the provider at one hand and the receiver at the other must enter in to mutually agreed terms (MAT) (as also envisaged under Article 15 of CBD) with regard to the manner and methods of the determination of the quantum of benefit sharing between the stakeholder. Below mentioned are few points which can be taken in to consideration by the provider country while making provisions with regard to seeking a PIC certificate in connection with granting of access over certain biological/genetic resources:

- Provision for fair and non-arbitrary access rules and procedures;
- Provision of information on PIC applications;
- Provision for written and cost-effective PIC decisions within a reasonable period of time;
- Issuance of a permit or equivalent as evidence of PIC and MAT and notification of the ABS Clearing-House;
- Establishment of criteria and/or processes for obtaining PIC or approval
- Establishment of clear rules and procedures for establishing MAT

3.1.2. Fair and Equitable Benefit Sharing

Nagoya Protocol on Access and Benefit Sharing provides for a detailed analysis of the concept of “Fair and Equitable sharing of benefits” through the following provisions:

- Benefits to be shared shall include those arising from the utilization of genetic resources but also those arising from subsequent applications and commercialization;
- Benefits shall be shared only with the Party providing such resources, which is “defined” as the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the CBD; and

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14 Supra note 6.
15 The Nagoya Protocol on Access and Benefit Sharing, art. 14
16 The Nagoya Protocol on Access and Benefit Sharing, art. 5(1)
Specific benefit-sharing arrangements will be established through MAT between the provider and the user of genetic resources, thus on a contract basis.

The Protocol puts obligation\textsuperscript{17} on the member states to take appropriate measures within their domestic frameworks to implement the above mentioned provisions relating to determination of the quantum of the benefits and thereby its fair and equitable sharing between the stakeholders.

The Protocol also provides for the provision whereby the benefits once quantified and modes of sharing evaluated, should be directed towards the conservation and sustainable use of the biodiversity as a whole thereby creating a linkage with the other two basic objectives of CBD.\textsuperscript{18}

It also provides the legal basis for consideration of a potential global multilateral benefit-sharing mechanism that could be established in the future in order to address the fair and equitable benefit-sharing in specific cases where bilateral ABS on the basis of PIC and MAT is problematic\textsuperscript{19}. The Protocol further provides for specific provisions relating to the modes of sharing of benefits and clearly identifies two modes, one being the monetary sharing and the other being the non-monetary sharing. While the former includes upfront payments, royalties and continuous sharing of benefits the later includes measures like capacity building, taking steps for the development of the local/indigenous communities, sharing of the skill and knowledge, transfer of relevant technology, promoting technical and scientific research through collaborative projects between the provider country and the receiver country.\textsuperscript{20}

4. Access and Benefit Sharing in India under the Biodiversity Act: An Analysis

India is renowned globally to be rich in biodiversity due to its unique bio-geographic locations, diversified climatic conditions and vast eco-diversity and geo-diversity thereby being one of the world’s largest store-houses of biological resources.\textsuperscript{21} The other side of this development

\begin{itemize}
  \item \textsuperscript{17} The Nagoya Protocol on Access and Benefit Sharing, art. 5 (3)
  \item \textsuperscript{18} The Nagoya Protocol on Access and Benefit Sharing, art. (9)
  \item \textsuperscript{19} The Nagoya Protocol on Access and Benefit Sharing, art.(10)
  \item \textsuperscript{20} The Nagoya Protocol on Access and Benefit Sharing, art. (23)
  \item \textsuperscript{21} United Nations Development Programme India, \textit{India Biodiversity Awards, 2018} available at: http://www.in.undp.org/content/india/en/home/climate-and-disaster-resilience/successstories/IBA2018.html (last visited at Oct. 15, 2019, 12 PM). India is one of the 17 mega-bio diverse countries in the world having just 2.4 percent of the earth’s land area and accounting for 7 to 8 percent of world’s species. It is home to 96,000 species of animals and 47,000 species of plants and near about half of the world’s aquatic plants.
\end{itemize}
poses an important challenge of biodiversity maintenance for the sustainable development of these biological resources.

The negotiations undertaken by different nations of an international regime on Access and Benefit sharing through the Convention on Biodiversity (CBD) and the Nagoya Protocol were precisely in that direction of which India was a party to. The need for comprehensive legislative framework in India was imminently felt due to rising number cases of biopiracy like the Neem case\textsuperscript{22}, the Turmeric Case\textsuperscript{23} and the Basmati case\textsuperscript{24}, wherein India’s biological resources and traditional knowledge was sought to be misappropriated in foreign jurisdictions, thus denying the traditional local stakeholders or governmental authorities.

In this backdrop, India secured its access and benefit sharing obligations mechanism under the Biological Diversity Act, 2002 and the Protection of Plant Varieties and Farmer’s Rights Act, 2001. The Biological Diversity Act and the Biological Diversity rules were enacted by the government to act precisely as a tool to combat biopiracy on one hand and the rights of those local knowledge holders on the other hand by providing them their due share of benefits.

The Convention on Biodiversity (CBD) which entered into force on the 29th of December in 1993, is the lone international instrument which comprehensively addresses the sustainable use of biological diversity and mandates the parties to create an Access and Benefit Sharing (ABS) Mechanism. To fructify the objective of CBD on access and benefit sharing, several years later in 2014 the Nagoya Protocol on Access to genetic resources and fair and equitable sharing of benefits arising from utilization of genetic resources was adopted. India is a party to both of these international instruments and consequently the objectives enshrined in its domestic enactment, Biological Diversity Act of 2002 reflects the ideals of both these conventions.\textsuperscript{25}

Since, access and benefit sharing (ABS) is the core issue within this paper, it is imperative to discuss the ABS mechanism under the Act. The establishment of the ABS provisions and their effective implementation,
more specifically the access to biological resources and traditional knowledge to foreign citizens, companies and NRIs based on prior approval of the National Biodiversity Authority (NBA) under the Act is provided under Sections 3, 4 and 6 of the Act and in the corresponding rules under rules 14-20 of the Biological Diversity rules. Similarly, the access permits to Indian citizens, companies, associations and other organizations registered in India on the basis of prior intimation to the State Biodiversity Authority (SBA) along with providing exemption of prior approval for certain communities, local people including growers and cultivators of biodiversity under Section 7 of the Act.

The overall implementation of the Act is governed by three functional bodies, the National Biodiversity Authority (NBA) at the apex level, the State Biodiversity Boards (SBBs) in respective states and the Biodiversity Management Committees (BMCs). The NBA is the national body to discharge all decisions pertaining to ABS, including prior informed consent process, approval for access and transfer of biological resources and scientific research results and technologies to foreign citizens, companies and non-resident Indians (NRIs), prior approval for applying for Intellectual Property rights based on biological resources or traditional knowledge obtained from India, thus fixing criteria for benefit sharing, approval of third-party transfer of accessed biological resources and traditional knowledge, and several other matters pertaining to ABS.

It is pertinent to note that there is no overlap in the functions of NBA and SBBs on the issues of access and benefit sharing (ABS). Foreign individuals, companies or institutions, and non-resident Indians (NRIs) are required to seek prior approval from the NBA to obtain any biological resource occurring in India. Further, prior authorisation of the NBA is required to transfer the results of any research relating to any biological resource occurring in, or obtained from, India to any foreign individual, company or institution, and also for applying for Intellectual Property Rights (IPRs) for any invention based on any research or information on a biological resource obtained from India. 26

Indian citizens or firms registered in India can obtain any biological resource for commercial utilization or bio survey and bio utilization for commercial utilization after giving prior intimation to the State SBB only. As of October 2013, 28 states of India have established SBBs, and 32,221 BMCs have been set up at the local level. There is significant unevenness in the number of BMCs across states. Almost three-fourths of these BMCs have been set up in Madhya Pradesh (23743). The number of BMCs in

Karnataka and Kerala are 4374 and 1043 respectively. Uttarakhand, Maharashtra Andhra Pradesh and Mizoram have 598, 340, 222 and 221 BMCs in that order. All other states, barring Haryana, Orissa and Sikkim, where BMCs are yet to be established, have less than 100 BMCs.

The Biodiversity Act, 2002 mandates punishment under section 55 for the implementation of the provisions under section 3, 4 and 6 which states that for failure to implement the provisions imprisonment may be extended for an imprisonment for a term which may extend to five years or with a fine which may extend to ten lakh rupees.27

The relevant provisions of the Biodiversity Act, 2002 in access and benefit sharing are provided under Section 21 of the Act which stipulates that National Biodiversity Authority while granting approvals under section 19 or section 20 has to ensure that the terms and conditions subject to which approval is granted and secures equitable sharing of benefits arising out of the use of accessed biological resources, theirby products, innovations and practices associated with their use and applications and knowledge relating thereto has to be in accordance with mutually agreed terms and conditions between the person applying for such approval, local bodies concerned and the benefit claimers. Rule 14 of the Biodiversity Rules,2002 lay down the procedure for access to biological resources and associated traditional knowledge that any person seeking approval of the Authority for access to biological resources and associated knowledge for research or for commercial utilization shall make an application in Form I and this form shall include the following, namely: general objectives and purpose of the application for seeking approval; description of the biological resources and traditional knowledge including accompanying information; intended uses of the biological resources (research, breeding, commercial utilization, etc.) conditions under which the applicant may seek intellectual property rights; quantum of monetary and other incidental benefits. If need be, a commitment to enter into a fresh agreement particularly in case if the biological material is taken for research purposes and later on sought to be used for commercial purposes, and also in case of any other change in use thereof subsequently restriction to transfer the accessed biological resources and the traditional knowledge to any third party without prior approval of Authority; submitting to the Authority a regular status report of research and other developments; independent enforceability of individual clauses, provision to the extent that obligations in benefit sharing clauses survive the termination of the agreement, events limiting liability (natural calamities), arbitration and any confidentiality clause.28

27 The Biological Diversity act, 2002
28 The Biodiversity rules 2002
5. Conclusion

The Access and Benefit sharing mechanism put in place through the Biodiversity Act, 2002 in India has in recent times emerged as a tool in the hands of the developing nations to bargain with their developed nation counterparts, which these nations provide for the later.

The access and benefit sharing mechanism has developed as a tool for combating bio piracy, which was amply highlighted in the paper be it in the Turmeric case, Basmati case or the Neem case, wherein India’s valuable biological resources were tried to be misappropriated.

The Nagoya Protocol on Access to genetic resources and fair and equitable sharing of benefits arising from utilization of genetic resources was adopted in the year 2014 to fructify the objectives of the CBD and India realizing the importance of it adopted this protocol in the same year.

India, on the other hand has had a fair share of ups and downs in its domestic biodiversity protection regime. The Biodiversity Act of 2002 despite its shortcomings, on a number of occasions was able to push through for a fair and equitable sharing of biological resources for the numerous stakeholders, who constitute an important part of biodiversity regime. The examples are in the case of the Kani tribes from the state of Kerala in India, where the herb ‘Arogyapacha’ became the first case of successful access and benefit sharing. Similarly, the Pepsico case wherein benefits from the seaweed procured by Pepsico was shared with local fishermen off the coast of Tamil Nadu in India.

The Nagoya Protocol has tried to be implemented in India wherein certain provisions from the protocol have been put in the existing Biodiversity regime in India. However, a complete justice to the Protocol and its provisions remain far from the reality and there are many aspects of Access and Benefit Sharing like Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) which remain out of the picture thus making it actually difficult to call that principles enshrined in the Nagoya protocol have been implemented in true letter and spirit. It is in this sense, that there lies a tremendous scope for full implementation of the Nagoya Protocol thereby improving the access and benefit sharing mechanism in India.