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Access and Benefit Sharing in the Context of Genetic Resources in Digital Era

Anina Vincent*

Inter University Center for Intellectual Property Rights (IUCIPRS), Cochin University of Science and Technology (CUSAT), Ernakulam, Kerala, India,

* Correspondence: aninavincent2000@gmail.com

Abstract: Traditionally, the access of genetic resources from a country in their physical form requires the fulfillment of many legal procedures like accessing permit, mutually agreed terms (MAT) or prior informed consent (PIC) from the country of origin of genetic resources. These legal procedures are mandatory in the "Convention on Biological Diversity" (CBD) and "Nagoya Protocol", through its third objective of benefit sharing from the access. Further, these international obligations are implemented in India through the enactment of the "Biological Diversity Act" in 2002. According to this act, if a person or a company wants to access a genetic resource from a country, they must provide benefits to the concerned authority of biodiversity. However, increased use of genetic resources by multinational corporations has bypassed the third objective and invariably led to various misappropriation including biopiracy. There are several cases of biopiracy from all over the world as these companies are not complying with the international and national requirements and are also circumventing the obligations using technology. This research aims to analyze the working of the access and benefit sharing system in India and what are the challenges faced in the effective implementation of the relevant statutes.

Keywords: access; benefit sharing; India biological diversity Act; CBD; Nagoya protocol

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1. Introduction

Biodiversity, or biological diversity, is the umbrella covering the whole life system on the planet earth, encompassing tiny organisms, to large animals and trees. All forms of biological life depend on this biodiversity, also referred to as 'variety of life'. Both living and non-living things, associated with biodiversity, are connected by food-webs. Various life concepts are grouped into "genetic diversity", "organismal diversity" and "ecological diversity" (Kevin et al. 2004), which indicates that biodiversity contains a variety of living organisms, including animals, plants, fungi, and microorganisms.

Biodiversity is not only the reservoir of varieties of organisms, also the reservoir of various knowledge, such as traditional knowledge (TK). For example, Kani tribe's Arogyapacha (*Trichopus zeylanicus*) found in the Agasthyar hills of the State named Kerala, used as a food gives energy, strength and stamina for doing the work (Pushpandan et al. 1988). TK is the "knowledge, innovation, and practices of indigenous and local communities around the world". Different parts of the world contain various traditional knowledge (TK) about herbs like Arogyapacha. Broadly speaking, TK includes agricultural knowledge, scientific knowledge, technical knowledge, ecological knowledge, and biodiversity related knowledge.

Biodiversity and TK are closely interlinked, and an emotional attachment exists between these two. Tradition, belief, spirituality, custom, and moral values, all are associated with this. All TK arises from biodiversity, indicating that biodiversity is the essence of life. There is increasing concern that TK must be protected in the society.

2. Methods

Given the nature of the research, doctrinal methodology was followed by collecting the primary and secondary literature of the information and facts about the topic. Relevant legal texts and related articles were analyzed in a systematic manner. Further, the access and benefit sharing concept was critically analyzed in the context of changes in the technological world.

3. Results and Discussion

3.1 Genetic Resources and Developing Countries

Biodiversity is distributed not evenly on earth and is richer in the regions between the tropics and the equator. Less than 10% of the earth's surface is covered by the tropical forest ecosystems, which contains a large number of the world's species (Gaston and Spicer 2004). More than 70% of the earth's surface contains marine biodiversity, including marine organisms.

Generally, biodiversity tends to concentrate on hot spots. Atlantic forest in Brazil is considered as one of the largest treasures of biodiversity, having many plants, animals, microbes, and fungi (Galindo-Leal and Gusmão Câmara 2003). The Amazon forest in South America is the largest and considered as the lungs of the earth. The island of Madagascar and India are also known for their rich biodiversity.

India is the seventh largest country in the world based on geographical area. India is rich in biodiversity from north to south and from east to west. Out of 25 hotspots of biodiversity identified in the world, India has two hotspots namely the Eastern Himalayas and western Ghats. Great marine diversity is present due to its 7500 km long coastline and varieties of endemic species can be identified here. This indicates that India is a rich biodiverse country (Kumari 2019). Similarly, Colombia is characterized by a rich biodiversity content, with a high number of species per unit area with the largest number of endemic organisms. Colombia is included in one of the world's "mega-diverse" countries, hosting near 10% of the diversity of plants. Overall, this country is first in orchid species and bird diversity and second in freshwater fishes, plants, amphibians and butterflies.[1] Madagascar of African continent has many dry deciduous forests and lowland rain-forests, which shows a high number of endemic organisms. Since the Madagascar separation from the mainland Africa, many organisms evolved independently.[2] Indonesia is a combination of near 17,000 islands having large number of plants, animals and microbes (Normile 2010). This indicates Indonesia is also a rich country with a wide variety of diversity in the ecosystem.

Measuring the differences of biodiversity is a very difficult task. There is a chance of selection bias by researchers, which may contribute to biased empirical research in estimating the biodiversity. More than half of the world's bio diversity is concentrated in Brazil, India, Madagascar, Indonesia, and Africa like developing countries. Hence, biodiversity is mainly concentrated in developing countries.

3.2 Biodiversity Values in Human Life

Although biodiversity, is useful at all levels in food, medicine, biological control, and industrial materials, primarily its valuable is food, being the foundation of all food industries and related services. Nearly, 99% of produced energy from agriculture and 95% of all animal and plant proteins are consumed by humans" (Rao and Guru 2007). Main plant foods consumed by humans are rice, wheat, banana, sweet potatoes, maize, beans, millet, cassava, maize, sorghum, soya-bean, and sugar cane. Animal diversity exploited for food are commonly for getting meat, milk, and eggs. Besides the use in food cycle, biodiversity is also useful in providing shelter, raw materials and companionship. Natural products are extracted from many biological resources. A study indicates that nearly 25% of the drugs used in the USA are of plant origin (Rao and Guru 2007). A substantial part of the global human population relies almost entirely on plant medicine.3 Plants and animals are used to treat many diseases, for example as anti-blood clotting agents during wound healing. Tiny but powerful contributors of biodiversity, such as, protozoan, bacteria, virus, and fungi which are visible only under the microscope, have high commercial value in the global market.

Since biological resources have monitory values, so these are exploited heavily. Multinational corporations (MNCs) in the North exploit the biodiversity and its associated TK for commercial profit by patents. The actual holders of that traditional knowledge remain without benefits. During the colonial period, many biological resources were taken from the developing countries and commercially exploited by developed countries (Rao and Guru 2007). Most of this exploitation indirectly leads to biopiracy.

3.3 Biopiracy

The judgment in the "*Diamond Vs Chakrabarthy* case opened the door for everything made by man under the sun is patentable".[4] This judgment has a huge impact on genetic resource manipulation and its patenting. Many samples of the South are stored in a gene bank in the North, being genetically manipulated without any benefit sharing mechanism for the original owners of that treasure.

"There are more than fifty-three patents for the neem (*Azhadirechta indica*) tree, mostly held by multinational companies (MNC)".[5] "Basmati rice was patented in the USA by 'Ricetac' as Texmati rice in 1997" (Mukherjee 2016). "The University of Mississippi Medical Center got a patent on turmeric, which was revoked when challenged" (Jayaraman 1997). A mixture of traditionally available plants like *Kareela, Jamun and Brinjal* were patented by Cromak Research Inc as an edible Ayurvedic composition to decrease sugar levels in USA ".[6] "USPTO granted a patent for wild Pepper".[7] Patents were granted on *Aswagandha* formulation to Reliv international Inc for use as a supplement for healthy joints".[8] Natural products derived from *Amla, vasbr, saptrangi*, and *bel* also have been patented. A patent was granted on hessian (jute), which was revoked later when challenged.[9] The traditional method grinding of wheat, was patented by the Con Agra in the US. European Patent Office (EPO) granted patent on a staple food recipe named "vegetable pulao", used in many parts of the world from a long time ago.

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1 Available online: http://www.cbd.int/countries/profile/?country.html (accessed on 11 July 2024)

2 Available online: http://www.pbs.org/edens /madagascar/eden.html (accessed on 11 July 2024)

3 Available online: http://www.who.int/news-room/fact-sheets/detail/biodiversity-and-health (accessed on 11 July 2024)

4 Diamond v. Chakrabarthy (1980) 447 U.S. 303.

5 Available online: https://twn.my/title/pir-ch.html (accessed on 11 July 2024

6 Available online: http://www.downtoearth.org.in/news/new-jerseybased-company-get-patent-rights-on-karela-brinjal-20239 (accessed on 11 July 2024)

7 Available online: http://www.no-patents-on-seeds.org/en/patent-cases/pepper (accessed on 11 July 2024)

8 Available online: http://www.patents.google.com/patent/US6224871B1/en (accessed on 11 July 2024)

9 Available online: http://www.patents.google.com/patent/US20130138408A1/en (accessed on 11 July 2024)

Many microbes are patented by MNCs without the consent of their country of origin of the microbe. Actually, for accessing the samples of the microbes, there is a need to access permission from the country of origin of the microbe under the Budapest Treaty.[10]

During the Green Revolution of Swaminadhan in the 1960s, many endemic germplasm and seeds of various food crops of India were shared as free to many gene banks of the developed countries. According to the United Nations Food and Agricultural Organization (UNFAO), about "46 % of the gene banks of ex-situ collections are housed in North America and Europe". A huge amount of genetic plagiarism is taking place all over the world. TK and its biodiversity, all are misappropriated. TK is the reflection of the intangible component of biodiversity. The TK values can save money, time and investment of the modern biotech industry. Hence, benefits must be share with indigenous people and the creators and holders of TK.

In this era, information about the genetic material of various genetic resources is abundantly available and are being for commercial and non-commercial purposes. Many branches of science, like synthetic biology, are being used to study the applications of genetic resources changing the traditional biopiracy concept to a modern digital biopiracy concept.

3.4 Convention on Biodiversity (CBD)

To avoid the biopiracy and ensuring effective access and benefit sharing, a convention in 1992 with the participation of many countries, non-governmental organizations (NGO's) and stakeholders was signed called "Convention on Biodiversity" (CBD). CBD has forty-two articles. Broadly, there are two parts. The first part of the articles contains important provisions about the main objectives and the second part of the articles contains provisions for the correct working. This convention gives a broader canvass than the traditionally associated common objective, namely conservation of biodiversity.

This convention is really a milestone from various angles. For the first time, the issues of biodiversity were addressed, and the term "genetic diversity" was specially mentioned. First objective of the CBD is to address the common concern of mankind. By including the access and benefit sharing issue of genetic resources, technology transfer and bio-safety issues, the CBD demonstrates a will to cover all views and ranges of biodiversity. The convention established a process to distribute funds to developing countries to help them to implement the CBD objectives, the need for additional and new resources to flow from developed to developing is also mentioned (Glowka et al. 1994). This convention is primarily focused on conservation, sustainable use of biodiversity and fair and equitable benefit sharing for the access of genetic resources.

3.5 TK on CBD

In the preamble, CBD specifically mentions the emotional attachment of many communities to their traditional access to biological resources and specially focuses on Article 8(j) of the provision saying that "respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities", and Article 10(c) gave importance to "encourage customary use of biological resources with respect to " traditional cultural practices" compatible with the first two objectives of CBD.[11] This Convention also addresses the value of TK arises from the biological resources and the evolved techniques from these are very useful to other common people. For sharing the benefits equitably, the paragraph shows that, when TK from the indigenous and local communities' practices becomes more widely used, then such people should receive benefits. Also, there is a need to access the approval of the TK holders or the community for getting the genetic resources. The types of benefits want to be determined, which gives flexibility. The phrase in the preamble, "embodying traditional lifestyles" seems to exclude the recent people descended from these communities no longer live in this way.

From Articles fifteen, sixteen and nineteen, talk about how to access a genetic resource, conditions of technology transfer for the utilization of genetic resources, handling of biotechnology and distribution of its benefits etc. Tools for accessing genetic resources such as mutual agreement terms (MAT), Prior Informed Consent (PIC), permits are mentioned in this. Types of benefits like monetary and non-monetary benefits are just mentioned and described in the Bonn guidelines[12] and Nagoya protocol[13] of CBD. The Nagoya protocol gives importance to the access and benefit sharing objective of CBD. Most of the countries that ratified CBD have their own complementary biodiversity laws. For example, India has the Indian Biological Diversity Act, 2002.

3.6 TK on Indian Biological Diversity Act

India is a biodiversity rich country in the world having many practices of TK. According to CBD, TK is the "knowledge, innovation, and practices of indigenous and local communities around the world". This knowledge is transferred by these communities from the first generation and passed to the subsequent generations.[14] To protect these, India made the biodiversity Act in 2002 by obeying the objectives of CBD and also made an amendment to this Act in 2023.

3.6.1 TK on Indian Biodiversity Act 2002

The Indian Biological Diversity Act, 2002 was enacted by the Parliament of India for the protection of biodiversity and providing a mechanism for sharing of benefits equitably from the use of TK. The Act was enacted to meet the obligations under the CBD, because India is a party of the convention. The objectives of this Act are the same as the three objectives of the CBD.

Section three of the Act restricts certain persons from doing activities related to biodiversity without consent of the NBA. The Act specifies who that person is. The common view is that people who have no citizenship in India or other foreign institutions can't

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[10] Available online: https://www.wipo.int/treaties/en/registration/budapest/summary_budapest.html (accessed on 11 July 2024)

[11] Available online: https://www.cbd.int/ (accessed on 11 July 2024)

[12] Available online: https://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf (accessed on 11 July 2024)

[13] Available online: https://www.cbd.int/ABS (accessed on 11 July 2024)

[14] Available online: https://www.legalserviceindia.com/legal/article-5006-biodiversity-and-traditional-knowledge-under-biological-diversity-act-2002.html#google_vignette (accessed on 11 July 2024)

access genetic resources. The full list of such people is written in the Act.[15] Section four of the Act relates to the "research results relating to any biological resources occurring in or obtained from India for monetary consideration or otherwise should not be shared without the approval of the NBA to certain persons who have not a citizenship of India or a citizen of India etc. A complete list of people is written in the Act. Section five is about the "transfer or exchange of biological resources or information involved in certain collaborative research projects relating thereto between institutions, including government sponsored institutions of India, and such institutions in other countries, if such collaborative research projects satisfy the conditions, such as conforming to the policy guidelines issued by the Central Government in this behalf and be approved by the Central Government, shall not apply to section three and four. All other collaborative research needed the approval of the biodiversity board".

Section six of the Act is an important measure to prevent intellectual property rights using the biological resources present in India. This Act says applications for intellectual property rights should not be made without approval of the NBA. In addition to this section, TK related inventions, which will not qualify the standards of novelty and originality, are excluded from the purview of the subject matter of patent under section 3(p) of the "Indian Patent Act, 1970". Also, the Section 3(d) prevent patent for "mere improvement of already known substance, new form of a known substance" etc. These sections help to prevent patents on TK related inventions. Section seven of the Act talks about prior intimation for accessing the biological resources for certain purposes from the State Biodiversity Board (SBB). A list of persons written in this Act does not have the right to access any biological resource for commercial utilization, or bio-survey and bio-utilization for commercial utilization without the consent of the concerned SBB. There is exception to these sections to "the local people and communities of the area, including growers and cultivators of biodiversity, and *vaids* and *hakims*, who have been practicing indigenous medicine".

The authorities that monitor the three objectives of this biological diversity Act are NBA at the national level, SBB at the State level and the Biodiversity Management Committees (BMC) at local level. To give more importance to the benefit sharing objective, India released a guideline in 2014 named "Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations". All types of monetary and non-monetary benefit sharing as written in the Bonn guidelines are applicable to Indian guidelines, 2014. India specified percentage for certain activities like "benefit sharing for commercial utilization, transfer of research results, IPR and sharing of biological resources itself and its related knowledge accessed from India to a third party for commercial utilization or research".[16] Based on these guidelines, India is currently receiving the benefits from the monetary utilization of genetic resources. However, most of the access and benefit sharing data is not available to the public and also does not show how those received benefits are given to actual traditional knowledge holders. This was one of the drawbacks of the Indian Biodiversity's legal system. In the absence of data, it is not possible to say India has strict enforcement of the law.

Major disadvantages of this Act are, does not provide much importance to the conservation of biodiversity. Even though this Act mentions about BMC, there is only a limited decision-making power is given to the local communities and there is no much clarity in this area. An awareness providing mechanism regarding their rights over the genetic resources is not provided to the local communities. Further, the Act not well described about actually what constitutes benefit sharing. Other than this, there are other loopholes on this Act, which may lead to other issues. For example, there is no differentiating mechanism for finding the actual beneficiaries. The concept of indigenous people and local community are not well explored in India. A critical analysis of what will included under this term is not well explored. Regarding the issues of digitized information uses of genetic resources and its access and benefit sharing issues are also not well studied in this Act. There is no strict authority to monitor every use of genetic resources. Further, a strict implementation and enforcement mechanism is also absent for the access and benefit sharing.

3.6.2 TK in Indian Biodiversity (Amendment) Act 2023

In 2023, an amendment to the Indian biological diversity Act was passed, with the notification in the Gazette on 3rd October 2023 with additions and subtractions of many provisions.

This Act complies with Nagoya protocol and introduces significant changes. The important amendments are;

i. The definitions such as, "access", "codified traditional knowledge", "folk variety", "India", "land race" and "member secretary" were added. Likewise, many definitions are substituted, such as "benefit claimers", "biological resources", and "derivatives". From the title of Chapter II, word 'resources' is added in the place of the word 'diversity'. Also, the sections from three to seven show many notable changes.17
ii. In section three, NBA superintends the dissemination of research conclusions from the access of biological resources. For accessing the biological resources and applying for IPR, some people or organizations such as "non-citizens", "non-resident citizens", "organizations not registered in India" and "organizations registered in India with any non-Indian shareholding or management" need a clearance from NBA. This amendment elaborated the final one to admit the "foreign-controlled companies that are registered in India under the Companies Act, 2013".
iii. Previously, citizens of India and Indian registered organizations needed to inform the respective SBB and also had to obtain the clearance of NBA, before accessing any biological resources from India for monetary purposes. This provision is changed in the current biodiversity amendment, by strictly saying that any individual who has to use the biological resources must inform the respective SBB and there is no need to obtain the NBA consent. Also, it included that SBB must have the authorized individuals to find "benefit sharing" for accepting and objecting to applications for approvals.
iv. The earlier Act only just specified the individuals and organizations which need to obtain NBA approval for the commercial uses of Indian biological resources. However, the current amendment strictly commands these specified entities to show the PIC for the commercial uses of Indian biological resources and associated TK. The amendment altered the approval requirements for access of the biological resources and reduced the burden of obtaining consent before the IPR grant such as patent

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15 Available online: http://nbaindia.org/uploaded/docs/biological-diversityact-ii.pdf (accessed on 11 July 2024)

16 Available online: http://nbaindia.org/blog/676/3//GuidelinesonAccess.html (accessed on 11 July 2024)

17 Available online: https://egazette.gov.in/WriteReadData/2023/247815.pdf (accessed on 11 July 2024)

rather than the application itself. However, foreign companies still need to obtain the NBA's consent and domestic companies do not. These domestic companies only need to register with the NBA.

v. According to BMC in 2002 Act, the authorities of state government need to form BMCs for promoting the protection of habitat and conservation and sustainable use of specific plant, animal and microbial species. The current amendment emphasis that each BMCs must contain seven to eleven members and each state government must made BMCs in the areas of village and cities for the conservation of "landraces", "folk varieties", "domesticated stocks" etc.

vi. Another important change is decriminalization. That is, imprisonment provisions were substituted with a penalty payment. Earlier, the offence was both "cognizable" and "non-bailable" under the 2002 Act. "Up to five years imprisonment and fine or both" was the punishment there. However, the current amendment decriminalizes these punishments only with a penalty payment between one lakh to five hundred lakhs. Due to the omission of decriminalization provisions, there is an appointment of an adjudication officer to conduct an enquiry for imposing penalty under Section 55(A) of the Act. If there is a dispute regarding the order made by the adjudication officer, there is a chance of giving an appeal to the "National Green Tribunal" constituted under "Section 3 of the National Green Tribunal Act, 2010". This decriminalization encourages different entities to use many Indian biological resources without any fear of imprisonment and may become a threat to the first and second objectives of the Act. That is, it will affect the conservation objectives as well as the sustainable use objectives negatively. Much awareness is absent there for introducing this decriminalization provision. This is the largest drawback of this amendment.

The main objectives of this amendment are to make an Indian system of cultivation of wildly available medicinal plants for producing medicines, speed up the procedures of tracking different research, patent applications, and transfer of the research results and support the foreign investments in the sector. Also, this amendment specially integrates the objectives of the Nagoya Protocol. The important reason for this amendment is to simplify for domestic companies. Users of codified TK, cultivated medicinal plants/products and Ayurveda, Unani, Siddha, Homeopathy (AYUSH) practitioners are excluded from the purview of sharing of benefits with the local communities. This amendment also removes bio-survey and research activities from the benefit sharing objectives of the current 2002 Act. The access and benefit sharing objective will be based on the terms agreed between the local management committee represented by the NBA and the user. A vague and broad interpretation of the amendment may exempt all locally available TK from the requirements of benefit sharing. The direct role of local communities in determining benefit sharing is removed from the provision.[18] Moreover, strict measures for preventing the misappropriations of genetic resources in the digital context is not well explored in this amendment. This amendment seems to be more ambiguous than the previous. The interests of various commercial entities and multinational companies are clearly dominated in this amendment. Moreover, the voice of traditional and local communities is absent here.

3.7 Current Technological Changes using Biological Resources

Today, every traditional field is modernized because of changing technologies. There is a competition among people to find new things in the world increasing the wide spread investigation of available resources in the biosphere. According to the U. N. Biology 2015, "synthetic biology is the further development and new dimension of modern biotechnology that combines science, technology and engineering to facilitate and accelerate the understanding, design, redesign, manufacture and/or modification of genetic materials, living organisms and biological systems".[19] Products and processes that utilize synthetic biology include new ways of producing pharmaceuticals, bio-fuels, treatment of diseases like making of transplants, micro-biome manipulation, and cosmetics production .[20] Most of the uses can bypass the traditional access and benefit sharing requirements like PIC, MAT and permit. Therefore, the biodiversity authority should identify the modern biopiracy and must include the concentrating of other fields as well to prevent the biopiracy rather like traditional fields.

4. Conclusions

Biodiversity is an important aspect of the environment and life itself. This knowledge is transferred by indigenous communities from the first generation to the subsequent generations. Innovations using biodiversity and its associated TK are the easiest way to acquire wealth, with the emergence of new techniques and tools. Especially by biotechnology, naturally available biological resources can be converted into commercially and industrially valuable products and processes, having increased productivity and application in many crucial areas such as pharmaceuticals, diagnostics, agriculture, genetics, synthetic biology, environment and climate protection. In all these areas, there are reports of issuing IPRs on biological resources which impact TK both positively and negatively. To reduce the negative impacts, there is a legal convention named CBD and its Nagoya protocol, having three main objectives of conservation, sustainability and benefit-sharing equally for the access. Based on these instruments, there are many domestic laws in various countries, including India. The enforcement of the proper benefit sharing objective of CBD is not practically working in many countries. All countries have written laws, however the benefits to deserved communities are not known. Besides lack of an enforcement and monitoring mechanism and, due to the technological advancements, the traditional biopiracy concept has changed. Because the technologies are developing at an unprecedented level, concerned authorities should be vigilant to reduce biopiracy. TK must be protected being the symbol of tradition, emotion, spirituality, custom and culture.

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