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Genetic Resources and Biopiracy: A Critical Analysis of Access and Benefit Sharing Mechanisms Under the International and National Biodiversity Laws

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ABSTRACT

Access and benefit sharing (ABS) is one of the important objectives of the Convention on Biodiversity (CBD) and, with 195 countries and other governmental and NGO's being part of the Convention, the principle has gained international relevance. Articles 15, 16, and 19 of CBD deal with ABS, however, it was only in 2002, through Bonn Guidelines that a systematic ABS was institutionalized. Additionally, in 2010, CBD came up with another important protocol giving more importance to access and benefit sharing objectives at Nagoya, called Nagoya Protocol. The parties to the Convention modeled their ABS mechanisms based on these guidelines and protocols, each country has its own access and benefit sharing mechanism. The paper propose to analyse the ABS mechanism from six domestic jurisdictions, namely, Australia, Brazil, Costa Rica, South Africa, Kenya and India. In this paper, the authors will try to understand the core policies behind the ABS mechanisms of this selected countries.

Keywords: *Access and benefit sharing, genetic resources, benefit sharing, commercial utilization.*

I. INTRODUCTION

Earth is gifted with large varieties of biodiversity and trillions of genetic resources are present in this global biosphere. Even a tiny microbe has its importance and plays its own role in sustaining the global environment. Large parts of these genetic resources are concentrated in the tropical regions of the earth and most of this region is occupied by developing countries. The imperialistic and colonial exploitation of genetic resources for commercial purposes was common, especially in the absence of any strict legal mandate for protecting the biological

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diversity.³ Degradation of genetic resources and associated traditional knowledge alarmed for forming various international organizations in this era.⁴ One of the important international regulatory frameworks that mandate biodiversity conservation, sustainable use and benefit sharing in fair and equitable way from the genetic resource access is CBD. With a membership of 195, including countries and non-governmental organizations, the Convention has led to the implementation of domestic legislation in almost all countries that ratified CBD.⁵

In CBD, Articles 15, 16, 19 deal with access and benefit sharing. However, any guideline of how to share the benefits from the access of genetic resources is not given in these provisions. In 2002, CBD made a guideline at Bonn that described benefit sharing from the access of genetic resources. This deals with different guidelines for ABS, participation of stakeholders, steps in the access and benefit sharing process, types of benefit sharing which could be monetary or non-monetary, suggested elements of material transfer agreements and other provisions. Also, it explains about four types of access implementing tools; Prior Informed consent (PIC), Mutually Agreed Terms (MAT), permits and Material Transfer Agreement (MTA). These guidelines are not legally binding, the fact that these were adopted unanimously by 180 countries and it is comprehensive and unexceptionable.

Also, in 2010, Nagoya protocol came to give more importance to access and benefit sharing. Based on these guidelines and protocols, each country has their own access and benefit-sharing mechanism. From those countries, six countries such as Australia, Brazil, Costa Rica, South Africa, Kenya and India are selected to study their existing benefit-sharing mechanisms.

II. AUSTRALIA

The continent Australia and all member states follow a uniform general legal system.⁶ Across all states, Australia has one biodiversity law based on CBD, the Environment Protection and Biodiversity Conservation Act 1999 (EPBC Act). Besides this common law legal system, each state has its own local legislative body and individual laws.⁷ The EPBC Act provides provisions for the benefit sharing for the access of genetic resource in the Australian Commonwealth areas.

³ M.B RAO ET. AL, BIOTECHNOLOGY, IPRS AND BIODIVERSITY, (DORLING KINDERSLEY (INDIA) PVT. LTD, 2007).

⁴ CBD in a Nutshell, Global Youth Biodiversity Network, (2016).

⁵ Examples are India have Indian Biological diversity Act 2002, Australia have Environment Protection and Biodiversity Conservation Act 1999, Brazil have Biodiversity Law No. 13.123/ 2015, Costa Rica have Biodiversity Law No. 7788 of April 30 1998, South Africa have National Environmental Management : Biodiversity Act 2004 , Kenya have Environment Management and Co-ordination Act 1999 etc.

⁶ LEGAL SYSTEMS IN AUSTRALIA: OVERVIEW, PRACTICAL LAW, <http://uk.practicallaw.thomsonreuters.com/0-638-7137> (last visited Jul 01, 2023).

⁷ Example is, Queensland State have a biodiversity law called Biodiscovery Act, 2004 which complied with CBD.

Under the EPBC law, the EPBC Regulations, 2000 is also stand to governs the access to biological resources and its fair and equitable benefit sharing.

According to the EPBC law, for accessing a biological resource, there is a need to obtain PIC from the native indigenous owner on Indigenous people's land. This practise is generally accepted by Australian governments for access and benefit-sharing, which ensures the traditional knowledge (TK) use takes place with the coordination of TK holders on MAT.⁸

Under the regulation, there is a need for a permit from the 'Department of Sustainability, Environment, Water, Population and Communities' (SEWPAC) for accessing a genetic resource for the purpose of research and development.⁹ These permits are available either for commercial or non-commercial purposes and if it is needed for commercial purposes, permit will be allowed only after the access party made an agreement of benefit sharing with the biological resource providers. Also, if the resources are used only for non-commercial purposes, the applicant shall give a statutory declaration showing that, they are not used for commercial purposes without any agreement with providers of biological resources and will not allow others to perform their research using the biological research. After the research using the biological resources, the results showing reports and each sample's taxonomic information should be provided to a taxonomy related public institution of Australia.

The Australian permit system has been developed to a transparent system. The 'Genetic Resources Information Database' (GRID), which have the capacity to verify the applications of permits and other related reports. This mechanism provide a number of issued permits and the information of collected samples to the public for transparency.

Regarding benefit sharing, the Act provides the details in Schedules 3 and 4. Schedule 3 describes the threshold payment. This shows what percentage of money want to pay for the specific purpose of the product as benefit sharing. The payment must be done within the twenty-eight days after the acquiring correct tendered tax invoice receipt.¹⁰ The amount showed in total revenue received in one calendar year are in Australian Dollars and the threshold payment shows the percentage corresponding to total revenue.

| Product Purpose | Total revenue received in one calendar | Threshold Payment |
|-----------------|--|-------------------|
|-----------------|--|-------------------|

⁸ MODEL ACCESS AND BENEFIT SHARING AGREEMENT BETWEEN AUSTRALIAN GOVERNMENT AND ACCESS PARTY, WIPO, <https://www.wipo.int/tk/en/databases/contracts/texts/australiaprovider.html> (last visited Aug 08, 2023).

⁹ Australian Government Response to Notification 2011-2016 Access to Genetic Resources and Benefit-sharing, <https://www.cbd.int/abs/doc/protocol/icnp-1/australia-en.pdf> (last visited 08 Jul, 2023).

¹⁰ **Id.**

| | year | |
|---|------------------------|-----|
| Agriculture/ Pharmaceutics/ Nutraceutics s | < 500 000; | 0 |
| | 500 000 – 5 000000 and | 2.5 |
| | > 5 000000 | 5.0 |
| Research | > 200 000 or | 2.5 |
| | < 100 000; | 0 |
| | 100 000 – 3 000000 and | 1.0 |
| | > 3000000 | 3. |
| Industry/ Chemical/ Diagnostic/ Other purposes | > 200 000 or | 1.5 |
| | < 100 000; | 0 |
| | 100 000 – 3 000000 and | 1.0 |
| | > 3000000 | 2.0 |

Table 1 : A Table showing Threshold Payment Corresponding to Various Product Purpose

Schedule 4 of the EPBC Act describes additional benefits. A range of monetary and non-monetary benefits outlined in the CBD ‘Bonn Guidelines is also applicable here. Generally, in most cases, the benefits are as determined by the parties to the contract on MAT.

CASE STUDY OF ABS AGREEMENT BETWEEN EXGENIX, CALM AND NCI

A benefit sharing agreement was entered between ExGenix,¹¹ Department of Conservation and Land Management (CALM) and the US National Cancer Institute (NCI).¹²

¹¹ ExGenix, old name is AMRAD Discovery Technologies.

¹² House Representatives, Standing Committee on Primary Industries and Regional Services, Bioprospecting: Discoveries changing the future, Parliament of the Commonwealth of Australia, (2001), https://www.aph.gov.au/parliamentary_business/committees/house_of_representatives_committees?url=priming/bionic/subs.htm (last visited 08 Jul, 2023).

A group of botanist from Agricultural Department of US gathered nearly 1200 specimens of Western Australian plants in 1981, which were handled by the Herbarium of Western Australia and given to NCI for the purpose of screening. A *Conospermum* species, commonly known as smokebush collected from there shows anti-cancer properties by the end 1980s and then a patent is taken on the active compound of *Conospermum* known as ‘Conocurovone’ by NCI. On that exact time, some Western Australian scientists identified the anti-HIV activity on that same compound.

CALM wanted to guarantee the maximum benefit from the use of its own biological resources for WA and they compelled to develop and produce drugs with the participation of Western Australia. Then CALM discussed with ExGenix about the ABS terms and conditions and granted the permission to develop commercial products. In return to allowing the access of *Conospermum*, ExGenix must pay the royalty to CALM US\$730,000, and first refusal right in research work to CALM with the ‘Conocurovone’ research. Also, for the collaborative research between the Western Australian scientists and NCI, ExGenix has given US\$320,000, for working with eight *Conospermum* patents lodged with CALM. The research would explore the in-depth characteristics of concunvone compound and their derivative product development. The ExGenix-CALM ABS agreement promoted both conservation and sharing of benefits from the access.¹³

There are other benefit sharing cases like AstraZeneca and Griffith University. This indicates that the Australian benefit-sharing system is some advanced and its more modifications will come in the coming years.

III. BRAZIL

Brazil is one of the richest biodiversity country in the world. Brazil is an important source of innovation and inspiration for natural ingredients used in cosmetics, foods and pharmaceuticals. Brazil’s new Biodiversity Law No. 13, 123/15 was signed, May 20, 2015, and the legislation explains conservation, sustainable use and access to the Brazilian genetic heritage and sharing of its benefits. The 2001 law was repealed by the making of 2015 law, which seems to be highly complex, ambiguous and bureaucratic.¹⁴

In the case of access to genetic heritage, the Federal Government will be named as the beneficiary of the benefit sharing. In the case of associated traditional knowledge, beneficiaries

¹³ Ten Kate, K. and Laird, S, *The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit-Sharing*, Earth scan, (1999).

¹⁴ Lisa L. Mueller Et.al, *Brazil’s New Biodiversity Law*, NAT L. R, (2015).

are indigenous peoples, traditional communities and traditional farmers.¹⁵

The exceptions from the obligations of benefit sharing include small enterprises, single entrepreneurs and business groups, traditionally cultivating farmers and related individuals or groups with yearly total revenue same or less than that explained in their legal framework. The intermediate product, which is used in the production chain, as an input, is also exempted from the obligation to share benefits.

According to this law, the important access and benefit sharing implementing tools are permits, MAT, MTA and PIC. Today all these can be done by registration in the SisGen database. For accessing a genetic heritage, registration in the SisGen database is compulsory which can be done online in every time before the depositions of samples which were collected, result publications, or the product commercialization. By finishing the registration process, an electronic declaration will be generated with the compliance in law. It has been stated that this model will reduce compliance to an authoritative action by the engaging parties such as scientists, MNCs or others.¹⁶

Regarding the research undertaken by foreigners, it has been stipulated that the foreign institutions can only access Brazilian biodiversity in partnership with a Brazilian institution. Registration is mandatory for accessing genetic resources and the , benefit sharing will be tracked through this publicly accessible online system.

Brazil has implemented Bonn Guidelines and both are monetary and non-monetary benefit sharing are permitted in Brazil. Additionally, in the case of monetary benefit sharing, a “National Sharing Fund” with the goal of promoting the sustainable use of resources. is established to support the communities that provide their traditional knowledge and to manage any compensation received.

The accessing person or the industry must pay a percentage of 0.1 -1.0 of the total money received from economic exploitation of the products which are created from: Matter obtained from Brazilian biodiversity; Resulting from the access to an ingredient or component of Brazilian genetic heritage. From the final product marketing, a maximum of 1% of the total money, open negotiations for the TK, 0.5% of profit to the fund of national benefit sharing during the product marketing period are the other important types of benefits. If the TK source is unknown, a 1% must be shared with fund of national benefit sharing and if it is known, it

¹⁵ Brazil: Law No. 13.123, May 20, 2015.

¹⁶ James R. Welch, *Brazil's New Biodiversity Law*, SOC. ETH BIO, 216, (2015).

must shared to traditional holders from the national benefit sharing fund.¹⁷

It has been criticized that the Biodiversity law in 2015 have been enacted without the consent of Brazilian indigenous peoples, as written in the “International Labor Organization Convention No. 169 on Indigenous and Tribal Peoples”. They provide a letter showing their interest are not adequately addressed in the current law of 2015. The main theme of this law is to promote the research activities and increase the commercial exploitation of the genetic heritage from Brazil. Through this, many domestic and foreign industries can isolate the active compounds for making several items in the agricultural, pharmaceutical and other industrial areas. This law will provide assurance to the industries for making products “without making conflict, troubles or disputes” in the utilization of Brazilian genetic heritage and its associated TK. However, this law clearly shows that it will not sufficiently protect the rights of indigenous peoples and local communities.

CASE STUDY ON ABS AGREEMENT BETWEEN BIOAMAZONIA AND NOVARTIS

“Brazil's Association for the Sustainable Use of the Biodiversity of Amazonia” (BIOAMAZONIA) come into a bioprospecting agreement with Novartis Pharmaceuticals for a period of three years. Novartis agreed to pay \$4 million from worldwide sales to BIOAMAZONIA as per the contract and Novartis sought the power to produce new extracts of Brazilian genetic heritage and ten year sole power to use the extracts after the invention of product. Novartis gave “1.6 million Brazilian reais for every clinically tested products”, “R\$ 750,000 for every patents”, “R\$ 500,000 on the first day a product is placed on the market” and “1% of all royalties for a ten year period” to BIOAMAZONIA as a return.¹⁸

The agreement was heavily criticized on the ground that, it would cause serious harm to the environment. This was usurpation of TK because the agreement does not provide any monetary and non-monetary values for the biodiversity conservation and its sustainable use and it allegedly violates many articles of the Constitution. One of the major problem Brazil faces is the widespread depletion and exploitation of the Amazon and in this context, the criticism is that this agreement increases the rate of biopiracies through the utilization of wide varieties of samples from the Brazilian genetic heritage. Additionally, as per the critics, this contract did not contribute anything to the progress of the Brazilian scientific community and became the hurdle for the development of Brazilian research by collecting all the relevant materials for the

¹⁷ Manuela da Silva, *Biodiversity Law*, 2015, <https://portal.fiocruz.br/en/biodiversity-law>, (last visited 28 Jul, 2023).

¹⁸ Vanessa Danley, *Biopiracy in the Brazilian Amazon: Learning from International and Comparative Law Successes and Shortcomings to Help Promote Biodiversity Conservation in Brazil*, Fla. A&M U. L. Rev, 318, (2015).

scientific works, did not allow the Brazilian scientists in the work of new techniques, and not provide any job opportunities for them. After strong public opposition to the BIOAMAZONIA - Novartis agreement, the Brazilian government cancelled the contract.

This benefit sharing agreement took place before the entry of the new biodiversity law of 2015. Compared to previous years, presently there are few improvements in the system, for instance the registration through online databases, which creates transparency. However, this system is also faced with issues like bypassing consent from traditional communities and the criticism that it is not enough to prevent biopiracy.

IV. COSTA RICA

Costa Rica is one of the prominent countries holding a large variety of species. It has undertaken several initiatives to conserve and use its biodiversity in a sustainable manner.¹⁹ Costa Rica has a longstanding and comprehensive environmental legal framework and it implemented CBD in 1994 through the Biodiversity Law No. 7788 of April 30, 1998. Conservation, its sustainable use and benefit sharing in a fair and equitable way from the access to Costa Rican biodiversity resources are the main three goals of this law.²⁰

According to the law, the Costa Rican genetic resources and its biochemical compounds are placed in the public domain, not in private ownership. Therefore, the state is considered as the owner and it has the whole power to regulate access to resources.²¹ If any research or related bioprospecting activities are taking place using the Costa Rican biological or biochemical resources, it must be within the territory of Costa Rica and also must acquire the access permit for those purposes,²² except it fall into one of the exceptions provided by the law. Notably, the only country in the world having fully documented records of bioprospecting projects is Costa Rica.

“Competent National Authority in Costa Rica” created the “National Commission for the Management of Biodiversity” (CONAGEBIO) according to the law for maintaining the ABS activities, creating biodiversity policies and ensuring proper technology transfer. This will provide reports to the “Ministry of the Environment and Energy” and also act as the “National Focal Point” on ABS under the CBD. CONAGEBIO acts through a “Technical Office” (TO)

¹⁹ Jorge Cabrera Medaglia, *Access and Benefit Sharing from the Use of Genetic Information: Costa Rica Case Study*, University Of Costa Rica, (2020).

²⁰ Biodiversity Law No. 7788 of April 30, 1998.

²¹ Carrizosa et al, *Accessing Biodiversity and Sharing the Benefits: Lessons from Implementation of the Convention on Biological Diversity*, IUCN, 13, (2004).

²² *Id.* at 18.

which processes, approves or rejects and monitors access-related activities.

In 1989, a non-governmental and non-profit intermediate organization, “National Biodiversity Institute” (INBio) was established to provide technical and scientific capacity and assist partners in bioprospecting activities. INBio will increase the awareness of biodiversity values for the purpose of biodiversity conservation and improving the caliber of life. Also, it will make several associations with various parties, example INBio-MINAE, for carry out activities related to the biodiversity, especially in identifying biopiracy and claiming benefits from the biological resource utilization in government’s protected areas.

The Costa Rican law regulates the equitable distribution of benefits and the protection of traditional knowledge and has incorporated Bonn guidelines to their system. The TO will determine the amount to be paid on a case-by-case basis In case of benefit sharing. 10% of the budget in research and 50% of royalties from the bio prospectors must be given to the “National System of Protected Areas”, “indigenous representatives”, or the “holder of the land that give biological resources”.²³ Most of the money reached through benefits is used for the conservation of biodiversity.

CASE STUDIES ON ABS AGREEMENTS BETWEEN INBIO AND OTHER PARTIES

Costa Rica allowed more than 650 permits and ABS agreements with several industries, universities and domestic and foreign research groups. Most of these agreements are made with INBio. The first example is the INBio-Merck Agreement.

This is the first agreement made with a commercial company, ‘Merck’, a pharmaceutical company based in the US, for the use of Costa Rican biological resources in veterinary sciences and pharmaceuticals in 1991. Later, this agreement was renewed in 1994, 1996 and 1998 on specific terms and conditions, finally expired in 1999.

This agreement provides that Merck can access to “chemical extracts from wild plants, insects, and micro-organisms” in return for the royalty of \$1 million to INBio. Merck should train the Costa Rican scientists and give funds for their education. For building the facilities for them, \$135,000 was given by Merck. Another characteristic of this agreement is that, 3% of the world wide sales, are given to INBio as a royalty. This also conditions “10% of the upfront fee” and “50 % of any future royalty” will be given to the funds of the National Parks for their biodiversity conservation and sustainable use. Therefore, this Merck-INBio agreement, is a great example of ABS, giving importance to biodiversity conservation.

²³ *Supra* note 19.

There are many other agreements such as, “INBio-MINAE Roura Agreement”, “INBio-British Technology Group (BTG)-Ecos La Pacifica Agreement”, “INBio-Phytera Inc. Agreement”, “INBio-Eli Lilly Agreement”, “INBio-Akkadix Corporation Agreement” etc. From these agreements, it is evident that Costa Rica has a relatively successful ABS mechanism and seems to be better than other countries’ ABS strategies.

V. SOUTH AFRICA

South Africa is a one of the biodiverse countries, having a large variety of plants, animals and other microbes. To conserve this richness of biodiversity, there are a number of conserved areas, including wild life sanctuaries, national parks and marine regions. These are maintained by the South African government. The important statutory act for protecting these, with compliance in CBD is called the “National Environmental Management: Biodiversity Act, 2004”. Important objectives of this Act are conservation of biodiversity, sustainable use and access and benefit sharing.²⁴

According to this Act, the main access implementing tools are MAT, PIC, permit and MTA. The meaning of “Benefit” in the Act, in relation to bio-prospecting involving indigenous biological resources, is “any benefit, whether commercial or not, arising from bio-prospecting involving such resources, and includes both monetary and non-monetary returns”. The types of benefits will change from case to case.

In South Africa, a benefit-sharing agreement is approved only when one or more of the following benefits are satisfied. They are the “conservation of the indigenous genetic and biological resources”; “support for further research on indigenous genetic and biological resources and TK”; “enhancement of the scientific knowledge and technical capacity to conserve, use and develop indigenous genetic and biological resources”; “any other activity that promotes the conservation, sustainable use and development of indigenous biological resources for the benefit of South Africa”; or “improve livelihoods of the communities and enhancement of the technical capacity of the communities or individuals involved”.

All types of benefits in Bonn guidelines are applicable to South Africa. To collect monetary benefit sharing, a Bioprospecting Trust Fund was established. In terms of the ABS agreement, every money shall be given into the “Bio-prospecting Trust Fund”, as written in “section 85(1)” of the South African biodiversity law. The responsibility of safekeeping and proper use of those money is given to the Director-General.

²⁴National Environmental Management: Biodiversity Act, [No. 10 of 2004].

CASE STUDY ON THE ABS AGREEMENT BETWEEN SAN COMMUNITY AND CSIR

Hoodia, the succulent plant seen in the arid regions of southern Africa, used for a long time as an appetite suppressor by the San community, a traditional tribal group. The TK of this plant was publicized by some plant researchers and utilized by the “South African-based Council for Scientific and Industrial Research” (CSIR) to find how the plant suppress the appetite. Later, this group received a patent on the use of active component of Hoodia which suppressing appetite in 1997. Subsequently, an agreement was entered between CSIR and a UK company “Phytopharm” in 1998. After this, a licence and benefit sharing agreement was done between this UK company and Pfizer pharmaceutical company of US. Filing of several patents in Hoodia were continued till 2001 by these companies.²⁵

In the beginning, about these agreements and the commercial exploitation of Hoodia, San community did not have any information and later in 2001, this news reached this community and they understood that companies used their TK without the PIC. By the law and media pressures, CSIR made an agreement with San community to implement the ABS requirements written in the “National Environmental Management: Biodiversity Act, 2004” and CBD.²⁶

Through this, San community received a 6% royalty for the exploitation of products using Hoodia. Along with these, this community also gets 8% of the “milestone income” of CSIR, which gets from Phytopharm for attaining particular targets during the period of their product development. When the product is successfully commercialized, these would be paid into the trust, made by the CSIR and the “South African San Council” to increase the standard of livelihood of San community. Overall, therefore, San community received nearly 0.03% of the total marketing of products is made from Hoodia and if this percentage is translated into money, it will be millions of dollars. To distribute the money, strict rules were created. This Hoodia case is the most discussed biopiracy case in South Africa, which shows the how to resolve the biopiracy and ABS issues.

VI. KENYA

Kenya has rich biodiversities, ecological zones and has many protected and unprotected areas.²⁷

²⁵ Rachel Wynberg, *HOT AIR OVER HOODIA*, (2010), <https://grain.org/article/entries/4047-hot-air-over-hoodia> (last visited on Aug 08, 2023).

²⁶ The Commercial Development of Hoodia”, Case Study 7, https://www.cbd.int/doc/meetings/abs/abswg_06/other/abswg-06-cs-07-en.pdf (last visited 18 Aug, 2023).

²⁷ Kenya- main details, Biodiversity Facts, Status and trends of biodiversity, including benefits from biodiversity and ecosystem services, Convention of biodiversity, <https://www.cbd.int/countries/profile/?country=ke> (last visited 08 Aug, 2023).

Kenya also joined in CBD and for complying with its objectives, made the “Environment Management and Co-ordination Act, 1999” and the “Environmental Management and Coordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations, 2006”.

According to the Act, “benefit sharing” means the “sharing of benefits that accrue from the utilization of genetic resources”. The Kenyan government retained ownership over their biological resources, by representing all the citizens of Kenya. The Government also ensures specific steps to transfer the benefits to the biological resource providers, including to the local communities. Part 4 of the Regulations, describes the monetary and non-monetary benefit sharing. All types of benefit sharing obligations of the Bonn Guidelines are applicable. A guideline of percentage of sharing monetary benefit is not identified. Benefit sharing in Kenya is done on a case by case basis.^{28 29}

Many reports show that there are so much biopiracy cases, however in none of the cases, benefit sharing is not reported.

An instance of biopiracy reported in media is regarding the preparation of a drug for diabetics, “Glucobay” (acarbose) by Bayer, a pharmaceutical giant in Germany, based on a bacteria “Actinoplanes SE 50”, collected from the “Lake Ruiru” regions of Central Kenya. Till now, no compensation or benefit have been shared with any community in Kenya for this commercial exploitation. Although there are other instances of biopiracy in Kenya, no legal proceedings reported. This represents the issue of neglecting the rights of indigenous peoples and local communities.³⁰

VII. INDIA

India is the world's 8th most biodiverse region,³¹ encompassing wild variety of plants, animals, microbes and have different ecological zones such as forest, lakes, rivers, mountains, deserts, grasslands, plains, marine regions etc, which peaks the richness in biodiversity in all over the works. The presence of the great Himalayas, western and eastern ghats contribute to raising the

²⁸Kenya's Access and Benefit sharing Toolkit for Genetic Resources and associated Traditional Knowledge, National Environment Management Authority, 2013, https://absch.cbd.int/api/v2013/documents/A5F8_E9A7-C066-77CC-7446D188F351F10A/attachme%202875/ABS%20TOOL%20KIT%20FINAL.pdf (last visited 08 Aug, 2023).

²⁹The Environmental Management and Coordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations, 2006.

³⁰Nyamongo Rhodah, Noreen Kwamboka, *Biopiracy and the Case for Traditional Medicine in Kenya*, Strathmore University, 2017.

³¹India adds 557 new species to fauna, Zoological Survey of India, The Hindu, 2021, <https://www.thehindu.com/sci-tech/energy-and-environment/india-adds-557-new-species-to-its-fauna-zoologicalsurvey-ofindia/article36141615.ece> (last visited 08 Aug, 2023).

number of several endemic species. India is a party to CBD and complies with Bonn guidelines of access and benefit sharing. To comply with CBD objectives, India has the Indian Biological Diversity Act, 2002 released the “Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations” in 2014. Separate guidelines for TK related and biotechnology inventions are available.

India specified types of access and benefit sharing tools like MAT, PIC, MTA and permit in their guidelines. The “percentage of benefit sharing for commercial utilization”, “transfer of results of research”, “IPR and transfer of accessed biological resources and/ or associated knowledge to the third party for research/ commercial utilization” is also specified.³² Also, there is a debate on the use of the term local community instead of indigenous community, due to the vagueness in the word “indigenous”.

The money is deposited in the National benefit sharing fund and is used for conservation and sustainable use of biodiversity or it is distributed to the traditional knowledge holders.

CASE STUDY ON THE ABS AGREEMENT BETWEEN KANI TRIBES AND TBGRI

In 1987, there was a field trip by “Tropical Botanic Garden and Research Institute” (TBGRI) to the forest regions of *Agastyamala* Hills, home place of the Kani tribes in south India. This Kani have several knowledge about different medicinal plants, including the knowledge of *Arogyapacha* (*Trichopus zeylanicus*), used for getting energy. In between the field trips, TBGRI gained knowledge about this plant, and identified its scientific properties.³³ “Plathis”, the tribal healer of the Kani community, only has the right to transmit and practice traditional medicinal knowledge. This knowledge was transmitted by three Kani members to researchers by forgetting about their customary tradition, on the field trip of TBGRI. Later, these researchers isolated the active ingredients of *Arogyapacha*, and made a drug named “Jeevani”, and patents were filed on this medicine. Jeevani is marketed as a tonic form to increase energy and the immune system. Later, TBGRI transferred the license for preparing this medicine to the Aryavaidya Pharmacy Coimbatore, Ltd with a fee of U.S. \$25,000 for its commercial exploitation. When this news reached the Kani community, asked for benefit sharing and then an agreement was made between TBGRI and the Kani Community.

TGBRI provided the royalty of 2% on profits and 50% on the license fee from Aryavaidya

³²Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014.

³³ Moran Katy, *Lessons from Bioprospecting in India and Nigeria*, Cultural Survival Quarterly Magazine, 2000, <https://www.culturalsurvival.org/publications/cultural-survival-quarterly/lessons-bioprospecting-india-and-nigeria> (last visited 08 Aug, 2023).

Pharmacy to the Kani community. Also, a trust was established and registered among Kani tribes for benefit sharing. However, there is a skepticism about trust in the context of lack of transparency and the purposes for which the shared benefit is used. A report in the Science journal showed that \$21,000 were deposited as the first payment to the Kani trust in March of 1999. Also, give employment by telling them to cultivate *Arogyapacha* in the forest. Each family of the Kani community cultivates *Arogyapacha* on one or two acres and earns Rs. 30,000 per acre in the beginner year. Later in the subsequent years, the amount of money was raised..

This Kani tribe case has several criticisms. One important criticism is that tribes cultivate the *Arogyapacha* in the forest. It leads to several environmental impacts and another important criticism is the there is no conformity about the money shared through the trust is not reached in the every hands of the kani tribal community.

VIII. CONCLUSION

Most of the countries that ratified CBD have their own biodiversity acts and regulations. However, all country laws are not enough for preventing biopiracy. In many countries biopiracy is still continuing. In the biodiversity acts and regulations/guidelines, most countries show percentages of shared monetary benefits, but the reports are not available to the public. By law, benefit sharing to the TK holders is necessary, however, that benefits reached in the hands of people are not identified. In most of the cases, authorities show this as confidential/sensitive information. This is one of the information collection issues. By the comparison of six countries, identified that there are some differences in the implementation and working of laws. Some country legislations are more advanced than other, because of the working of law, vigilance in taking action against biopiracy etc. In the current scenario, the platform of biopiracy is changing from physical to digital areas and there is a need for more mechanisms to prevent these misappropriation. In the near future, each country's authorities must consider new developments in society and implement precautions to resist the harmful effects.
