HANDBOOK ON BIODIVERSITY PROTECTION IN INDIA

Editor-in-Chief:
Prof. (Dr.) Kiran Dennis Gardner

ACIPR
ALLIANCE CENTRE FOR INTELLECTUAL PROPERTY RIGHTS
ALLIANCE SCHOOL OF LAW, ALLIANCE UNIVERSITY, BENGALURU

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FOREWORD

India is rich in biodiversity, owing to the existence of differing flora, fauna, climate and altitudes throughout the country. Biodiversity is essential for the development of several sectors of the economy such as the agricultural and pharmaceutical industries. Generally, products made from biological resources and traditional knowledge are offered protection under the patent system. However, this raises a number of additional issues within the global Intellectual Property framework. The legal complications surrounding the protection of traditional knowledge and biodiversity have yet to be addressed.

The role of traditional knowledge in the development of modern medicine and science has remained vital throughout generations. With corporations all over the world rushing to make use of this knowledge and profit from it, providing adequate protection to the stakeholders becomes vital. Traditional knowledge is a community right, intended to benefit society at large and it has been carefully passed on from generation to generation with the same intention. It, therefore, becomes incumbent that such knowledge is not controlled and monopolized by a selected-few, and that

the rights of the keepers of such knowledge are given due recognition. However, in recent times, the rising number of grants given over traditional knowledge has diluted the culture and essence of the indigenous communities.

Thus, the Handbook on Biodiversity Protection in India focuses on Intellectual Property laws and their role in the protection of traditional knowledge, genetic and biological resources. It also discusses the issue of biopiracy and bioprospecting of traditional knowledge, and biological resources. This handbook serves as a testament to the need of the world to transition to sustainable innovation and development while ensuring the protection of biological diversity, traditional knowledge, and the rights of aggrieved communities.

Dr. Sheetal Vohra (Ms.)
Advocate (PhD. Law)
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MESSAGE
FROM EDITOR-IN-CHIEF

It is our immense pleasure to release the *Handbook on Biodiversity Protection in India*, a book covering the developing arena of biodiversity and bioprospecting, presented by Alliance Centre of Intellectual Property Rights, Alliance University. The protection of traditional knowledge and biodiversity has several legal complexities that are yet to be dealt with. One of the main hurdles that arises repeatedly is the existence of biopiracy.

The book tries to highlight these problems through several case studies, judgments and regulations. The book also provides a detailed explanation of the international instruments on bioprospecting agreements, genetic resources and benefit sharing.

The Centre is extremely grateful to the patrons, editors, researchers and contributors for their dedication and relentless efforts towards the completion of this handbook. The handbook is an attempt to consolidate all information pertaining to the field of biodiversity and IPR in an accessible format for academic usage.

We hope that this book serves as a medium for discussions and deliberations on the sustainable use of intellectual property and holistic development of technology, the environment and the community at large.

Warm Wishes,
Prof. (Dr.) Kiran Dennis Gardner,
Editor-In-Chief, Dean, Alliance School of Law,
Alliance University, Bengaluru

PREFACE

This handbook comprises of chapters relating to Bioprospecting, Intellectual Property Rights and Protection of Biodiversity and Traditional Knowledge against Biopiracy. It highlights the existing problems in the IP regime in this regard. The handbook explains the role of Intellectual Property as a mechanism in fighting against biopiracy through several case studies. The book also discusses relevant international agreements and conventions like the Convention on Biological Diversity, TRIPS Agreement, Nagoya Protocol, etc.

Traditional Knowledge, biological and genetic resources play an important role in the development of biotechnology at large. Not only do they belong to a certain indigenous community that deserve to have some rights over it, but they also garner a lot of benefits if provided with sufficient protection. It is often argued that Intellectual Property protection isn't enough to address the full scope of protection required, that there is a need for a sui-generis law. This has resulted in the misuse of traditional knowledge and increasing cases of biopiracy, with instances of corporations

unfairly making profits in millions out of such knowledge while the keepers of such knowledge are left high and dry.

The book addresses the major hurdles in providing adequate protection to such knowledge and resources. The book also tries to shed light on the debate about bioprospecting being a more discreet way of pirating such biological resources and traditional knowledge.

Thus, the handbook will attempt to provide the readers with an understanding of the IP regime relating to biodiversity and the study of important cases in this regard. This will help the readers get a more detailed insight into this developing arena of law. The book also analyzes the existing laws and conventions on biodiversity and how it helps to tackle the issue of biopiracy, while allowing bioprospecting. It also provides certain suggestions and recommendations that can help overcome the existing problems.

Editorial Committee,
Handbook on Biodiversity Protection in India

INTRODUCTION

A community's heritage is passed on from generation to generation. WIPO defines traditional knowledge as "*a living body of knowledge that is developed, sustained and passed on from generation to generation within a community, often forming part of its cultural or spiritual identity*." Thus, traditional knowledge also forms a part of the heritage of a community and may include anything such as music, agriculture, craftsmanship, etc.

It can also be inherited from plants, animals and microorganisms in the surrounding nature. These resources and knowledge have great commercial values. Unfortunately, in most cases, the communities are unaware of this and do not avail the requisite protection for their knowledge and resources. This leads to biopiracy as many companies and corporations take advantage of the community's lack of awareness and exploit their Traditional Knowledge and genetic resources. This is where the Intellectual Property protection mechanism can prove to be beneficial.

Despite there being many international discussions on the IP regime regarding the protection of traditional knowledge, many feel that the term biopiracy is being

overused, especially in cases of bioprospecting. However, there is also a pertinent debate on whether bioprospecting is paving way for discreet instances of biopiracy. There is also the issue of companies and corporations patenting the traditional knowledge and biological resources which leads to long term legal disputes. Furthermore, there are constant discussions on the lacunae in the IP system that falls short for the protection required for such Traditional Knowledge especially with regards to community benefit sharing. It is often argued that Traditional Knowledge in general requires a sui-generis law in order to address the full range of protection it demands. There are many international and domestic legislations that try to overcome these lacunae.

The chapters of this handbook delve further into these topics and issues providing the readers an insight of the extent of existing legal mechanisms, the changes required and how to accommodate such changes. It provides the readers with a comprehensive idea of this arena and probes them to further research into this contemporary area.

Editorial Committee,
Handbook on Biodiversity Protection in India

Contents

PART I

CHAPTER 1

INTRODUCTION TO BIODIVERSITY

1.1 CIRCUMSTANTIAL FRAMEWORK

Species are dispersed unevenly across the earth's surface. We could see how the tropical and temperate systems change in magnitude with even little changes in location. If carefully observed, the Earth's biological and physical processes carry humans' unmistakable imprint throughout the ages. Ecologists have always been intrigued by patterns of species abundance and diversity. Some questions raised by these patterns, such as the diversity of island assemblages, have proved amenable to study. Others, including latitudinal gradients to diversity, or the distribution of commonness and rarity in ecological communities, continue to challenge investigators.[1] Since Darwin's time, biologists have undertaken the task of documenting discovered species, usually in easily accessible areas.[2] Subsequently, naturalists from Europe began travelling to faraway places to study new flora and fauna, consequently

1 ANNE MAGURRAN, MEASURING BIOLOGICAL DIVERSITY 4 (Blackwell Publishing 2004).

2 T.C.H. Sunderland, *Food Security: Why Is Biodiversity Important?*, 13 INT FORESTRY REV 265, 270-274 (2011).

writing monographs for each location. Thereafter, the recording of biodiversity began along a gradient.

Lovejoy used the term "biological diversity" in 1980 to describe the number of species found in a group. It alludes to the entirety of a district's qualities, species, and environments. Joined Nations Earth Summit characterized natural variety as: 'Biological variety implies the changeability among living organic entities from all sources including, entomb alia (in addition to other things), earthbound, marine, and other oceanic environments and the natural edifices of which they are a section; this incorporates variety inside species, among species and of ecosystems.'[3] As opposed to the more unambiguous term species variety, the term biodiversity was authored to stress the numerous intricate sorts of varieties that exist inside and among organic entities at various degrees of association. Norse and McManus (1980) stressed the importance of both genetic and ecological variety. Walter G. Rosen coined the term "biodiversity" from "biological diversity" in 1985, and it came into force after the United Nations Convention on Biological Diversity (UNCBD), which was drafted during the United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro in June 1992.[4] It is described as "the variability among living creatures from all sources, including, but not limited to, terrestrial, marine, and other aquatic ecosystems and the ecological complexes of

3 United Nations, *United Nations Conference on Environment and Development, Rio de Janeiro, Brazil, 3-14 June 1992*, https://www.un.org/en/conferences/environment/rio1992 (last visited Aug 12, 2021).

4 86 PRIYADARSAN SENSARMA, BIODIVERSITY IN GAUTAMA-SAMHITA 167–177 (Annals of the Bhandarkar Oriental Research Institute 2005).

which they are a part; that includes diversity within species, between species, and within ecosystems" [5]

Biodiversity shifts with changes in scope or height. As we move from the posts to the equal pinnacle, the biodiversity increments, as well as the other way around. The expansion in species extravagance or biodiversity that happens from the posts to the jungles frequently alluded to as the latitudinal slope in species variety, is one of the most broadly perceived designs in ecology. In general, species variety diminishes as we get away from the equator towards the shafts. With not many exemptions, jungles harbour a larger number of animal types than mild or polar regions. For instance, Colombia situated close to the equator has almost 1,400 types of birds while New York at 41° N has around 105 species and Greenland at 71° N something like 56 species. [6]

Even beyond the development of terminology and definitions, we should understand that the biological assets we have now, which include microorganisms, flora, and fauna, have been subjected to generations of wear and tear, which we label as evolution. Since the first single cells appeared over 3.5 billion years ago, and the intricate development of species that took off in the last 600 million years, we have lost a tremendous diversity of life to get to where we are.[7] Mother earth is home to various diversity of species that provide us with food, medicine, infrastructure, and various kinds of things that are needed for the existence of mankind. The forest ecosystem is diverse in

5 CONVENTION ON BIOLOGICAL DIVERSITY, https://www.cbd.int/ (last visited Sept. 9, 2021).

6 BIODIVERSITY AND CONSERVATION 261 (NCERT 2022).

7 Charles Q. Choi, *How Did Multicellular Life Evolve?,* ASTROBIOLOGY AT NASA (last visited Sept. 9, 2021, 11:58 PM) https://astrobiology.nasa.gov/news/how-did-multicellular-life-evolve/.

nature, consisting of bacteria and higher plants/animals, and at all levels of the organization, from gene to the ecosystem, encompassing structure, function, and ecological processes at all these levels. As a result, biodiversity has several dimensions, including compositional, structural, and functional variety, as well as diversity within species, between species, and within ecosystems. The current distribution and scale of biodiversity have developed over 4.5 billion years since the earth was formed, because of diversification, migration, extinction, and, more recently, human effects that may be characterized at several hierarchical levels. Furthermore, at three fundamental and hierarchical levels of biological structure, it may be extended to the variety of genes, species, and ecosystems. The negative consequences of human activities on biodiversity are becoming evident, jeopardizing the growth of sustainable development. Habitat fragmentation caused by human activity is one of the most serious concerns linked with biodiversity loss, followed by climate change, nitrogen loading, and biotic interactions. The forecasts imply that as the world's population grows, land-use patterns would alter dramatically, particularly in tropical regions. The loss of biodiversity resources puts our food supply chain, supplies of timber, medicine, and energy, among other things, in jeopardy. To maintain global biodiversity, systematic biodiversity conservation initiatives would be necessary, with a focus on tropical regions.[8] Different kinds of animals, plants, microbial organisms, and other related concepts come under the concept of biodiversity. It is estimated there are almost 10 million distinct kinds of species inhabiting the planet.

Food, medical research, and farming methods, all come under the purview of biodiversity. Humans use at least 40,000 species of plants and animals daily. Individuals and corporations

8 S Chatterjee, *"Biodiversity Conservation Issues of Northeast India."*, 10 INT'L FORESTRY REVIEW. 315, 315-324 (2008).

alike, across the world, still depend on wild species for some or all of their food, shelter and clothing, and other production needs. All our domesticated plants and animals came from wild-living ancestral species. In addition, almost 40 per cent of the pharmaceuticals used in the United States are either based on or are synthesized from natural compounds found in plants, animals, or microorganisms.

Evelyn Chrystalla Pielou, a well-known system ecologist, invented the phrase "Ecological Diversity" in 1975 to describe the richness and diversity of natural ecological communities. Since then, we have employed the term in a multitude of contexts, propelling it to the pedestal where it is now synonymous with biological diversity. The term ecology was introduced into the picture by the same strain. An ecosystem is a collection of living species existing in each habitat, as well as the physical and environmental conditions that influence them. Ecosystems are essential to existence because they manage many of the chemical and climatic processes that provide us with clean air, clean water, and enough oxygen. Forests, for example, manage rainfall and soil erosion by regulating the quantity of carbon dioxide in the air, producing oxygen because of photosynthesis. Ecosystems, in turn, rely on the health and vitality of the individual creatures that make up their composition. The removal of even a single species from an ecosystem might distort its efficient functioning at large.

This emphasizes the need for species conservation. Species with considerable conservation significance or those that contribute disproportionately to community function are not given further consideration. The only variable that impacts a species' significance in a diversity assessment is its relative abundance in an ensemble. Richness metrics do not distinguish between species at all, and they evaluate both extremely abundant and extremely uncommon species equally.

These initiatives will need rigorous quantitative monitoring and baseline data at every level of biodiversity organization at many sizes ranging from region to region in the world. Due to large fluctuations in temperature and precipitation, India has a wide range of climatic conditions (tropical, subtropical, temperate, alpine, and so on). The nation's flora and fauna are diverse due to climatic differences, making it a "mega biodiversity country" in the globe. The reports from the Ministry of Environment, Forest and Climate Change have reported that India consists of 10 major biographical zones and 27 biographical provinces based on their distinctive biota.[9]

The flora and faunal composition of one biotic province or biogeographical province differ from that of another. It accounts for only 2.4 per cent of the total land area of the planet, yet it accommodates more than 8% of the total number of species found worldwide. India, with a lot of its property region in the tropical scopes, has more than 1,200 types of birds. The tropical Amazon tropical jungle in South America has the best biodiversity on the Earth - it is home to more than 40,000 types of plants. Just like latitudinal variety, altitudinal variety additionally causes changes in biodiversity. A reduction in animal types of variety happens from lower to higher heights on a mountain. A 1000 m expansion in elevation brings about a temperature decrease of around 6.5 C.[10] The decrease in temperature and more noteworthy occasional fluctuation at higher elevations are the main considerations that lessen biodiversity.

9 J.S Singh, S.P.S Kushwaha, *Forest Biodiversity and Its Conservation in India.* THE INT'L FORESTRY REVIEW 292, 302-304 (2008).

10 ALISON NUGENT, DAVID DECOU, ATMOSPHERIC PROCESSES AND PHENOMENON, (Pressbooks 2019).

The bulk of the species is found in ecologically diverse tropical forest zones.[11] The rapid clearing of tropical forest areas and the resulting loss of plant diversity around the world has necessitated identifying biodiversity hotspots and in situ biodiversity conservation by mapping the distribution of vegetation diversity across different habitats and landscapes and tracking rates of change over time. For in situ biodiversity protection, hotspots are defined based on the number of endemic species and the degree of danger to the environment. Four of the 35 global hotspots discovered so far are located in India: The Western Ghats, Himalaya, Indo-Burma, and Sunderland. Because of the country's high biodiversity, ecologists and environmentalists must conduct a critical evaluation of the country's biodiversity and develop conservation plans. Following the adoption of the United Nations Convention on Biological Diversity (UNCBD) at the United Nations Conference on Environment and Development (UNCED)[12] in Rio de Janeiro in June 1992, the human population began to recognize the importance of biodiversity, support appropriate sharing of the advantages deriving from the use of genetic resources, and promote sustainable use of its components. The CBD requires signatory countries to conduct a biodiversity inventory to give basic information on its distribution and richness.

India was one of the first countries to sign the CBD Treaty. At the global, regional, and local levels, environmental services provided by species and ecosystems are critical. India is a mega-diverse country that is home to around 8% of the

11 J.S Singh, S.P.S Kushwaha, *supra* note 9 at 303.

12 David A. Wirth, *The Rio declaration on environment and development: two steps forward and one back, or vice versa*, 29 Ga. L. Rev. 599, 599-653 (1994).

world's species.[13] It also has a long and illustrious cultural history dating back thousands of years. Much of India's biodiversity is closely linked to the country's socio-cultural traditions. Several species are threatened with extinction because of population growth, climate change, and slack enforcement of environmental regulations.

1.2 SIGNIFICANCE OF BIODIVERSITY:

Biological diversity plays a very crucial role in the survival of human beings on earth. Humans directly or indirectly depend upon biological diversity for fulfilling almost every need in their life such as food, energy, medicine, housing, etc. Biological diversity helps to maintain the ecological balance. It provides various ecological services and is vital for maintaining, preserving, and restoration of various ecological processes. Biological diversity helps maintain biogeochemical cycles, maintain the flow of water bodies like rivers and streams all-round the year, soil formation, control floods, prevention from soil erosion, circulation of air globally and its cleansing, nutrient recycling, and life support of all the species. Following are the direct and indirect values of biological diversity.[14]

Biodiversity refers to the variety of living forms found in a given habitat. It encompasses a wide range of species, genetic differences among them, and natural habitats and ecosystems.[15] This diversity is a result of 3.5 billion years of

13 Ministry of Environment and Forests, Government of India, *India's Fifth National Report to The Convention on Biological Diversity 2014*, CBD INT, https://www.cbd.int/doc/world/in/in-nr-05-en.pdf (last visited Oct 9, 2021).

14 Sheetal Rani, Sonika Kumari, Pankaj Kumar, Vinod Kumar, *Biological diversity: Introduction, values, threats and conservation measures,* 1 BDCP 1, 11 (2021).

15 Dilys Roe, Nathalie Seddon, and Joanna Elliot, *Biodiversity Loss, Development Crisis?* INT'L INSTITUTE FOR ENVIRONMENT AND DEVELOPMENT (2019).

evolution caused by natural processes. It is used as a parameter to determine the health of the environment.[16] Biodiversity is important to humans because it offers a variety of ecological services, including:

• Provisioning services, such as food, wood, medicine, fibre, and water

• Climate regulation, water purification, erosion prevention, flood control, and so forth.

• Recreation and education are examples of cultural services.

• Auxiliary functions such as soil formation, nutrient cycling, and so on.[17]

Biodiversity is examined on three levels:

- Genetic diversity: This refers to the range of genetic information found in all individual plants, animals, and microbes found within a species' population. Simply put, it refers to gene variation within species and populations. The hereditary variety empowers the populace to adjust to its current circumstance and answer normal choices. How much hereditary variety is the premise of speciation? It plays a vital part in the support of variety at the species and local area levels. Hereditary variety inside an animal category frequently increments with ecological fluctuation.
- Species diversity: This refers to the number of different species or living beings. It is quantified in terms of the richness of a particular species, which is the

16 Ali Mehdi, *Climate Change and Biodiversity: India's Perspective and Legal Framework*, 52 JOURN. IND L. INST 343, 343-347 (2010).

17 J.S Singh, S.P.S Kushwaha, *supra* note 8 at 293.

approximate number of the said species in a defined area.

- Ecosystem Diversity- Ecosystem diversity deals with the study of different ecosystems in a certain location and their overall effects on humans and the environment as a whole. It focuses both on aquatic as well as terrestrial ecosystems.

However, when it comes to species, it can be classified according to their functions.

a) Functional kinds: Functional types are organisms that perform a variety of ecological activities.

b) Functional analogues: Functional analogues are taxa that perform the same or very comparable ecological roles as each other.

c) Ecosystem diversity: This refers to the biosphere's diversity of habitats, biotic populations, and ecological processes.

Developmental activities have posed a danger to biodiversity in recent years. Various international accords and state legislation have been developed to maintain the same. The current rate of species extinction is now approximately 1000 to 10,000 times higher than natural extinction rates and is reducing biodiversity. The increase in the human population is destroying the natural resources that are needed for these species. Pollution has reached its peak[18]. If future generations are to live in a safe, productive, and healthy environment, sound policies and effective conservation programs must be

18 David Pimentel, Christa Wilson, Christine McCullum, Rachel Huang, Paulette Dwen, Jessica Flack, Quynh Tran, Tamara Saltman and Barbara Cliff, *Economic and Environmental Benefits of Biodiversity, Bioscience*, 47 Oxford Journal 756, 757 (1997).

implemented to protect biodiversity before it is too late for meaningful action. [19]

While discussing the importance of Biological Diversity, Chris D. Thomas, a well-known professor, author, and scholar on Biodiversity and Entomology, also emphasized the change that has been caused to the environment and that the position for us to improve the situation is detrimental. However, the global efforts of every nation to sign the Convention on Biological Diversity have resulted in a considerable change in the international aspect via the aforementioned framework. The representatives of each nation go back home from their international congresses, charged with at least slowing the rate at which biodiversity is lost within their own country. This requires each country to establish what it already has. The convention has been immensely beneficial, but the setting of baselines for species and habitats, and the calculation of trends separately for each country, has had a very negative side-effect. It has formalized a no-change-is-best framework for conservation throughout the world when we know that dynamism is how species ultimately survive periods of environmental change. By saddling our assessment to fixed baselines within national boundaries, all changes, including gains of new species that arrive from other countries, represent deviations from the baseline that has been set.[20]

1.3 FLORA AND FAUNA OF INDIA

One of the main aspects of India's ancient philosophy has been a broad understanding of the environment. India's

19 Pimentel D, Stachow U, Takacs DA, Brubaker HW, Dumas AR, Meaney JJ, O'Neil J, Onsi DE, Corzilius DB, *Conserving biological diversity in agricultural/forestry systems*. 42 BioScience 354-362 (1992).

20 Chris D Thomas, Inheritors of the Earth 242 (Hatchet Book Group 2017).

civilization has developed near the natural world.[21] In the Indian intellect, there has always been sympathetic regard for all forms of existence. For physical and spiritual support, human groups have traditionally relied on biological resources. Biodiversity provides us with food, medicines, materials, and opportunity in the end. The biological resources of the planet are essential for mankind's economic and social growth. As a result, there is a growing understanding that biological diversity is a worldwide asset with enormous worth for current and future generations. Human actions have never been more brutal and insensitive to the environment than in the present era of scientific and technological discoveries, driven by excessive commercialization and unsustainable production and consumption practices. We are currently in the sixth extinction phase.[22] Only competent direction, awareness, education, transfer of advanced technologies, study, conservation, and sustainable use of biological diversity can solve this challenge. According to the Brundtland Report of 1987, sustainable development is a development that meets current demands without jeopardizing future generations' ability to satisfy their own needs[23]. Sustainable development, in the new globalized order, is the integration of economic, social, and environmental development as interdependent and mutually reinforcing pillars that work at the local, national, regional, and global levels.

The Zoological Survey of India, in their reports, has mentioned that there are about 1,399,189 species that belong

21 Arundhati Kulkarni, *Biodiversity and Sustainable Development: A Critical Analysis,* 3 International Journal of Scientific & Engineering Research, (2012).

22 UN Biodiversity Conference, *Biodiversity and the Sustainable Developments Goals,* COP-14 (2018).

23 *Id.*

to the kingdom Animalia in the world, and India over 92,873 species belong to this kingdom which constitutes 6.64%. India is considered one of the 12 mega diversity hubs in the world; India's record of agrobiodiversity is equally impressive.[24] There are 167 cultivated plant species, 320 wild plant cousins, and several domestic animal species. India ranks seventh in terms of contribution to world agriculture, with over 50,000 rice varieties, 1,000 cultivars of mango, 100 different kinds of pepper, 27 breeds of cattle, 22 breeds of goats, 40 breeds of sheep, 18 breeds of poultry, 8 breeds of buffalo (the world's entire biodiversity), and several other varieties of pigeon peas, turmeric, ginger, sugar cane, currants, and so on.[25]

India has a rich and diversified biological history, including an estimated 850 kinds of microorganisms. Similarly, there are around 6,850 bacteria species, 6,500 algae species, 14,500 fungal species, 2,000 lichen species, 2,850 moss species, 1,100 pteridophyte species, 64 gymnosperm species, and 17,500 angiosperm species.[26]

India is a biologically diverse country, according to the International Union for Conservation of Nature (IUCN), with 7-8 percent of all known species, including plant and animal species, while having only 2.4 percent of the world's geographical area.

1. Plants make up roughly 45,000 species or about 7% of all species on the planet. Only about a third of them are native to the area.

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24 Hengeveld, R. and Heywood, *Biodiversity Letters*, 3 VOL INFO. (1996).

25 Singh, K K; Kumar, S; Rai, L K and A P Krishna, *Rhododendrons conservation in the Sikkim Himalaya*, 84 CURRENT SCIENCE 602, 602-606 (2003).

26 University Grants Commission, *Biodiversity*, (Jan 15th 2022). https://www.ugc.ac.in/oldpdf/modelcurriculum/chapter4.pdf.

2. There are 15,000 flowering plants on the planet, which make up about 6% of the total. Around 1,500 plant species are in danger of becoming extinct.

3. The world's animal species number roughly 91,000, accounting for around 6.5 percent of the overall fauna. Among them are 60,000 insect species, 2,456 fish species, 1,230 bird species, 372 mammals, over 440 reptiles and amphibians (with the largest concentration in the Western Ghats), and 500 mollusks.[27]

4. Livestock comes in a wide range of species. There are 400 sheep breeds in India, 27 cattle types, and 22 goat breeds.

5. It is also home to some of Asia's most endangered animals, such as the Bengal Fox, Asiatic Cheetah, Marbled Cat, Asiatic Lion, Indian Elephant, Asiatic Wild Ass, Indian Rhinoceros, Markhor, Gaur, Wild Asiatic Water Buffalo, and others.[28]

1.4 TYPES OF BIODIVERSITY IN INDIA

Genetic diversity, species diversity, and community or ecosystem diversity are the three interconnected hierarchical layers of biodiversity:

1. Genetic diversity:

Every species on Earth is linked to another through genetic links. The more genetic information two species share and the more similar they appear, the closer they are genetically. Close relatives are members of an organism's species or organisms with whom it can mate and produce children. Genes, which are biological information bits that impact how animals seem, act, and survive, are shared among members of a species. Any

27 J.S Singh, S.P.S Kushwaha, *supra* note 8 at 298.

28 T.N Khoshoo, *India Needs a National Biodiversity Conservation Board*, 71 Current Science 506, 510-513 (1996).

variation seen within the nucleotides, genes, chromosomes, or complete genomes of animals is referred to as genetic range.[29]

Genetic variety refers to the genetic information stored in the DNA of individuals of plants, animals, and microbes that live on the planet. It is required for all species to retain reproductive vigour, disease resistance, and the ability to adapt to changing environments. Allows a population to respond to natural selection and adapt to its surroundings. Speciation is based on the amount of genetic variation. Environmental heterogeneity typically enhances genetic variety within a species. Such genetic diversity has enabled the development of novel crops, plants, and domestic animals, as well as the adaptation of species to changing environmental circumstances across the world.

There is a species that is equivalent and closely related to it in every habitat. Grey squirrels can be found west, not east, of the Rocky Mountains. Although western grey squirrels are more similar to their eastern counterparts than they are dissimilar, they do not have the same mating habits. Even when placed near together, eastern and western grey squirrels do not mate, demonstrating that they are two distinct species.

Each species also has other, more distantly related species with whom it has a broader range of traits. Grey squirrels, chipmunks, marmots, and prairie dogs are all members of the squirrel family because they have similar tooth numbers and shapes, as well as similar skull and muscular architecture. All these creatures are rodents, a broad group of distantly related mammals with chisel-like incisor teeth that continue to develop. All rodents are members of the mammalian family. Mammals have hair, milk-fed babies, and three bones

29 Ernst Mayr, Animal Species and Evolution 797 (Belknap Press of Harvard University Press 1963).

in their middle ear. Mammals, in turn, are more distantly related to other vertebrates, or creatures having backbones. These species are all animals, yet they all have the same cell structure as plants, fungi, and certain microorganisms. Finally, ribonucleic acid (RNA) is a chemical found in all living species, and most also have deoxyribonucleic acid (DNA). This is the "basic currency of diversity", and the foundation for all other types of organism diversity. [30] While all species descend from a single common ancestor, species diverge over time and acquire their unique characteristics, contributing to biodiversity.

Individuals and sexually reproducing creatures develop genetic variety through gene and chromosomal mutation, which is disseminated across the population by the recombination of genetic materials during cell division following sexual reproduction. Genetic diversity has the following importance:

i. It aids in the development of new species through speciation.

ii. It's beneficial for adjusting to changes in the environment.

iii. It is critical for agricultural development and production.

2. Species diversity:

It refers to the quantity and variety of spices accessible in a certain area. Species richness may be measured by the number of species per unit area. It can also be called genetic diversity. A species' diversity reflects the degree of biodiversity in an area and may be used to compare different sites. Species are

30 Heywood, V.H. and R.T. Watson, *Global biodiversity assessment*, CAMBRIDGE UNIVERSITY PRESS, 1140 (1995).

groupings of genetically related creatures that may be kept and reproduce viable progeny.

Climate conditions are the primary determinant of biological variety. The number of individuals of diverse species in each area is used to determine species evenness or equitability. The product of species richness and species evenness determines a region's species diversity. A species that is limited to a particular geographic region is known as endemism. "Species are groups of natural populations that actually or potentially interbreed and that are reproductively isolated from other similar groups"[31]. The quantity and kind of species, as well as the number of individuals per species, vary in nature, resulting in more diversity. Species variety alludes to the range of species inside a district. The least complex proportion of species variety is species extravagance, for example, the number of species present in per unit region. By and large, the more prominent the species' extravagance, the more noteworthy the species' variety. Several people among the species may likewise change, coming about into contrasts inequality, or fairness and thus diversity. Species wealth and uniformity Species lavishness is just a single part of the variety. Not all species exist in equivalent numbers: some are uncommon, some are normal yet not various, and others are exceptionally plentiful.

It is considered to be important because it interconnects the varied species in their respective ecosystems. Not only them but also humans are part of these food chains like chocolate, honey, and many more on which we rely.

31 R.H. Whittaker, *Evolution and measurement of species diversity*, 21 TAXON 213, 249-251 (1972).

3. Community level/ Ecological Biodiversity

It is defined using the species that live in a certain area and their interactions. It shows a species' collective response to a set of environmental circumstances. Deserts, grasslands, wetlands, and woodlands are biological categories that help to maintain the proper functioning of the environment by providing ecological services to people. There are three levels of diversity in terms of network and atmosphere.

• It might be variation inside a network (alpha variety), diversity between groups (beta variety), or a variety of habitats across a landscape or geographical region (gamma variety).

Diverse Alpha, Beta, and Gamma Whittaker (1972) used the terms alpha, beta, and gamma variety to describe how biodiversity is measured across geographical scales.[32] Alpha diversity refers to the variation within a certain territory or atmosphere and is commonly stated as the number of species (i.e., species richness) present in that environment. Beta variety refers to the contrast in variety across habitats, which is often assessed in terms of the number of species that migrate between ecosystems. Gamma variety is a measure of the overall variation within a large area. Species diversity at a regional scale is consistent with Hunter's findings.[33]

According to Whittaker [34], community diversities are of three types:

(I) (α) Diversity:

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32 77 Malcolm L Hunter, Fundamentals of Conservation Biology (Blackwell Science 2002).

33 Prabodh K. Maiti and Paulami Maiti, Biodiversity, Perception, Peril and Preservation 542 (PHI Learning Pvt. Ltd. New Delhi).

34 R. H Whittaker, "*Dominance and Diversity in Land Plant Communities.*", 147 Science 250, 260 (1965).

It describes the diversity of species in a specific community.

It is dependent on the diversity and evenness of species.

(II) (β) Diversity:

It refers to a variety of communities formed because of species replacement caused by the existence of various microhabitats, niches, and environmental circumstances.

(III) (γ) Diversity:

It refers to the variety of habitats across a large amount of land or a geographical location.

This emphasizes the gathering and interaction of spices living near one another, as well as the physical environment in a certain region. It links the diverse ecosystems, biotic populations, and ecological processes that make up the biosphere. It also offers information about the diversity of the environment. It is termed as Land escape diversity because it spans the location and magnitude of various ecosystems.[35]

Landscapes such as grasslands, deserts, and mountains, for example, demonstrate ecological variety. The diversity of niches, trophic levels, and ecological processes such as nutrient cycling, food webs, energy transfer, the function of dominant species, and other biotic interactions contribute to ecosystem diversity. Such diversity can result in more productive and stable ecosystems or communities that can withstand a variety of stressors, such as drought and flooding.

1.5 SIGNIFICANCE OF BIOLOGICAL DIVERSITY

Human-caused habitat degradation and climatic extremes are posing serious risks to global biodiversity, leading to the

35 Chandra Shekhar Jha C.B.S Dutt Kamaljit S Bawa, *Deforestation and Land Use Changes in Western Ghats, India*, 79 Current Science 231, 238 (2000).

extinction of many species. In wake of recent extinction, numerous forests are declared as protected areas wherein no greater human activities are allowed. However, the scope of these protected regions got broadened from mere conservation to poverty comfort and sustainable improvement within the course of the decades. Though those protected regions appear to be supportive of biodiversity conservation, numerous disputes and gaps have emerged that want to be addressed for powerful conservation and sustainable control in those protected areas.[36]

Biodiversity is an essential component of any ecosystem and is critical to its operation and services. Diverse forms of diversities aid in keeping the natural equilibrium. As a result, biodiversity and its correct conservation are critical to the continued existence of life on Earth. The most common technique of measuring the importance of biological variety is to consider it as a resource for the country and to do so, three aspects must be considered:

- Consumption of use value: Biological resources are directly eaten without ever reaching the market. Natural items such as firewood, fodder, game meat, and so on are evaluated.
- Productive use value: The resource is obtained through trade or the market. Determine the worth of economically obtained items such as timber, fish, market-sold game meat, ivory, and medicinal herbs.
- Non-consumable use value: Resources set aside for future uses of biodiversity (tourist, scientific study), as well as ecological equilibrium.

36 P. Sujithra, E. Sobhana, K. Elango, G. Vijayalakshmi and P. Arunkumar, *Protected areas in biodiversity conservation of India: An overview*, 67 (2021).

Some fundamental reasons that explain the importance of biodiversity are discussed below:

1. Ecological Stability

In an ecosystem, each species serves an important function. They usually collect and store the energy needed for biological functions. They also create and degrade organic molecules in the environment. Many services are provided by the ecosystem that people require to exist. By preserving the interaction dynamics of the world's ecosystems, biodiversity provides a buffer capacity and life stability on the planet. The ecosystem's services are also related to the services offered by different species. Ecological stability is therefore the outcome of a diversified, productive ecosystem, which aids ecosystems in coping with environmental shocks.

2. Economic Importance

Biodiversity is a storehouse of resources to manufacture food, cosmetic products, pharmacies, and more. Some rich resources of food include crops, livestock, fishery, and forests. Various Wild plants (i.e., Cinchona, Foxglove, etc.) are good sources of pharmacies and can be used for medicinal purposes. Additionally, most resources such as wood, fiber, lubricants, resins, resins, poisons, and others also derive from various plant species. Thus, the economic importance can be broadly categorized into:

a) Food value: Thousands of years of providing food for the human population on our planet. Man has evolved various types of plant and animal life during the course of human civilization that directly or indirectly assist him in solving his nutritional challenge. Many new high-yielding taxa have been found as a result of scientific advancements.

b) Commercial value - Wood, which is a key component of the material used to give human protection, has a commercial

value. Humans continue to wear garments made of natural fibers such as cotton and silk.

c) Medicinal value - medications, medicines, and pharmaceuticals. The extraction of fundamental medicinal compounds uses a lot of plant genetic resources. Actinomycetes and fungi, as well as huge trees, are among the plant resources.

3. Ethical Importance

Everyone has the right to life since all species play important roles in the environment. Humans should not cause them any difficulties and should instead assist them in surviving. Humans have no legal authority to contribute to the extinction of any species. Biodiversity also helps to sustain the equilibrium between distinct species and preserves the presence of diverse civilizations and spiritual traditions. Conservation of biodiversity is so critical. Considering it as a global issue and a resource, it should be preserved at all costs.

Biologists that specialize in conservation have made it their mission to protect biodiversity from the most severe forms of environmental damage that can be caused by humans. The majority of these attempts to halt, reverse, or even just delay the reduction in biodiversity are futile, and the declining trends in the majority of biotic groupings are not showing any indications of abating. The pressure that humans are putting on the remaining areas of natural habitat has not lessened, and it seems anticipated that this demand will increase as a result of climate change.

As per the Utilitarian theory, the significance can be perceived through how biodiversity provides us with a variety of productive resources, such as agricultural commodities or food, medicine, industrial raw materials, and so on. Over sixty wild species have been employed to improve the world's 13 primary crops by supplying insect resistance, increased yield,

and improved nutrition genes.[37] 7,000 plant species have been used for human consumption since agriculture began some 12,000 years ago.[38] While the majority of people rely on domesticated animals for their sustenance, some 200 million people rely on wild species for at least part of their nutrition. Populations in South and East Asia are reliant on complex rice-fish agro-ecosystems, in which fish and other aquatic creatures offer important services for rice productivity in flooded fields while also providing nourishment to local populations. Fisheries produce at least 15% of the animal protein consumed directly by humans. By giving inputs to the aquaculture and cattle industries, fisheries indirectly assist further food production.

1.6 INTER-RELATIONSHIP BETWEEN BIOTECHNOLOGY AND BIORESOURCES

Biotechnology refers to a varied group of conventional and modern technologies that utilize biological systems, live creatures, or derivatives to manufacture goods or processes for a specific application.[39] Intellectual property rights are granted to boost innovation and the overall development of human life. Through biotechnology, this innovation can be fostered by making use of the genetic resources of plants, animals, and microorganisms. Although the pursuit of ever-higher standards of living by an ever-growing human population is the cause of the biodiversity crisis, it can also be the source of its mitigation by harnessing the technological innovation that is driving economic development to stop the loss of biodiversity.

37 IUCN Annual Report, IUCN, 18-26 (2012).

38 Jonathan C.K. Wells, *Life History Transitions at the Origins of Agriculture: A Model for Understanding How Niche Construction Impacts Human Growth, Demography and Health,* 11 FRONT. ENDOCRINOL 1, 1 (2020).

39 Biotechnology law, HELLO COUNSEL (Sept. 12, 2022, 8:36 PM), https://www.hellocounsel.com/biotechnology-law/.

To achieve such a goal, even higher invasive mediation in biological processes would be required. This will result in an even larger blurring of the border between nature and people, which conservation biologists have worked hard to maintain for a long time. However, the moment may have come to enter into a connection that is more openly symbiotic with our environment and the biota that it harbours. Humans are distinct from other creatures because of their aspirational nature and their ability to exert influence over natural processes through the development of innovative technologies. To tackle the risks to biodiversity that technology itself has helped to produce, conservation biologists today require the innovativeness that they have hitherto lacked.[40] IPR protects inventions related to biological resources found in India through various forms of IP, such as Patents, Traditional Knowledge, Technology Transfer, Protection of plant varieties, etc.

If looked that an international perspective, the proposed construction of homes and businesses along the coast of north eastern Australia poses a danger to the Great Barrier Reef's status as a World Heritage Site designated by the United Nations Educational, Scientific, and Cultural Organization. In the future, attempts to provide habitat to safeguard species and biological processes will focus on preserving and managing protected areas rather than consolidating existing ones because competition for space will continue to be an almost insurmountable obstacle for biological conservation. If it is discovered that the boundaries of established terrestrial and marine parks do not anymore preserve intact habitats or trophic webs as a result of poor management or other threats such as climate change and pollution, or even if their location is seen to inhibit economic development, then the protected

40 John O'Brien, *Technologies for Conserving Biodiversity in the Anthropocene,* 32 Issues Science & Technology 17, 17-21 (2015).

status of these parks could be revoked globally. This could happen both on land and in the ocean. If we have real-time data on the health of the habitats, biota, and biological processes that our global complement of national parks and marine reserves harbor, we will be able to better mitigate the threats that they face and ensure that their value is maintained. This will be the best way to ensure that their value is maintained. In recent years, significant progress has been made in the areas of imaging techniques, data analysis, and modes of deployment, which enables hyperspectral imagery of landscapes to provide detailed information on a variety of chemical and geological parameters as well as biological processes in terrestrial and aquatic systems.

The use of aerial and aquatic drones to do routine monitoring of large swaths of habitat and even individual animals is becoming increasingly common. These sorts of remote sensing have the potential to offer the prospect of rapid alert systems for failed food webs or trophic systems or excessive human involvement, both of which can help to guarantee that habitats continue to be healthy and conserve the biota for whom they serve as refuges. The application of ecological restoration techniques has the potential to make a major contribution to the enhancement of the conservation value of degraded and marginal areas. Indeed, the expanding land bank of degraded ecosystems around the world as a result of excessive exploitation allows environmentalists and wildlife protectors. Because bioremediation techniques have improved to the point that we can now employ natural processes to assist "re-wild" damaged environments, for example, the use of plants and bacteria to absorb metal pollutants from the environment is an example of one such strategy. However, natural habitat restoration can also take place in the most unexpected places if people can be kept out of the equation. For instance, the region surrounding Chornobyl, Ukraine, has

made remarkable progress toward recovery since the nuclear disaster that occurred there in 1986. Local flora and fauna have taken advantage of the lack of human activities to re-wild the exclusion zone, which suggests that even the most damaged landscapes are not beyond the possibility of recovery if technology can be used to limit the number of human incursions.

The techniques that have been developed for captive populations in zoos, aquaria, and botanic gardens will increasingly be employed in the wild, where fragmented and isolated populations will mirror the scenario of ex situ conservation. This will be the case because wild populations are expected to become more fragmented and isolated in the future. Cloning technology can reverse the tragic extinction of the bucardo, also known as the Pyrenean ibex, which occurred in January of 2000 when the last known example of the species was taken out of existence when a tree fell on it. Indeed, the birth of a bucardo in 2009 represented the successful completion of a proof-of-concept experiment.[41] Despite the use of cryogenics, plant and animal germplasm can be conserved through the current biodiversity crisis; this provides a safety net for species by storing material for potential cloning operations in the future, should it become necessary. Once competence with this technology has been achieved, future efforts should focus on keystone species that went extinct relatively recently rather than species such as mammoths and other fauna and flora that have been extinct for a very long time. It is futile to try to bring back an extinct species if the habitat in which it existed has been destroyed and the circumstances that led to its extinction have not been resolved; otherwise, such efforts are nothing more than a conveyor belt for scientific oddities. It has already

41 Mohammed Kasso, *Ex Situ Conservation of Biodiversity with Particular Emphasis to Ethiopia,* Hindawi Publishing Corp., 11 (2013).

been attempted for the mouflon, which is a species of wild sheep, to use cloning to reintroduce genetic diversity back into genetically-depauperate populations using DNA taken from museums or other preserved specimens. Cloning could also be used to reintroduce genetic diversity back into genetically-depauperate populations using DNA taken from a museum or other preserved specimens. The technology used to propagate endangered plant species, such as the large-flowered fiddleneck, has advanced at a rapid pace in recent years, and it has been remarkably successful in thwarting the extinction of some of these species. Under certain climate change projections, assisted migration of endangered plant species is anticipated to become an increasingly common conservation strategy. In a similar vein, it is abundantly clear that the current level of gene flow between geographically distinct populations, such as those of the giant panda, is insufficient, and that the number of individuals present in certain habitat fragments is insufficient for the long-term survival of the species. Therefore, people can be required to mediate the required gene flow either by relocating individuals or, more logically, by transferring their gametes or embryos via various forms of artificial reproductive technology (ART). Although a great deal of progress has been made in ART for both humans and domestic animals, and although there has been some success with confined species, notably the panda, the applicability of ART to wildlife management has gotten less attention than it could have. Both the San Diego Zoo Institute for Conservation Research in the United States and the Kew Royal Botanic Gardens in the United Kingdom are leading the way in innovative efforts to make assisted reproductive technology (ART) a more workable option for the conservation of the most critically endangered species in their natural habitats.[42]

42 David Adamson, *Regulation of Assisted Reproductive Technologies in the United States,* 39 Family Law Quarterly 727-744 (2005).

Modern Biotechnological Sphere

The term "technologies" can refer to a wide variety of management strategies, such as participatory approaches and economic incentives. Additionally, technologies can refer to evaluations of the current sustainability of systems and predictive scenario modelling.[43] Other types of biodiversity technology, such as modern biotechnologies and access and benefit sharing, are included in the legally binding framework of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the CBD. This protocol was created in response to the Convention on Biological Diversity (CBD). This agreement strongly recommends that all parties "support and encourage access to technology by, and transfer of technology to, developing country parties". The CBD target framework has led to the identification of essential metrics of biodiversity, which will serve as the foundation for the establishment of a set of biodiversity indicators. These metrics were determined as a result of the CBD target framework. Given the newly established Aichi objectives, there is still a significant amount of work to be done. The lack of a clear definition of biodiversity technology, the large number and variety of activities that comprise biodiversity technology as it is currently defined by the CBD, and a general lack of technology needs assessments are all factors that inhibit consistent reporting on the transfer of biodiversity technology. On the other hand, examples of technology transfer as a result of access and benefit sharing (ABS) agreements are still extremely limited.

In its broadest definition, technology can be defined as information that is used to the completion of a particular

43 Monika Bohm and Ben Collen, *Toward equality of biodiversity knowledge through technology transfer,* 29 Conservation Bio 1290, 1299-1302 (2015).

activity. Technology is frequently equated with hardware. Soft technologies are also included in this definition. The CBD includes technologies that address all of its aims and goals; as a result, biodiversity technology—as defined by the CBD—is a complex construct, involving both hard and soft technologies that are relevant to the conservation and sustainable use of biodiversity or make use of genetic resources and do not cause significant damage to the environment. The CBD includes technologies that address all of its aims and goals. Therefore, the term refers to both hard technologies and soft technologies that are associated with the following five broad constituent parts: in situ and ex situ conservation; sustainable management of biodiversity resources; monitoring techniques; modern biotechnologies that use genetic resources; benefit sharing and access to research results. For instance, biodiversity technologies that relate to species monitoring could include both the hardware used for the monitoring work itself (such as camera traps, and acoustic monitoring equipment) as well as the knowledge to use the hardware and carry out meaningful species surveys. These technologies could be grouped under the umbrella term "acoustic monitoring equipment." This information may be found in publications that have been subjected to peer review or may be acquired through the use of web-based learning or workshops. The issue of defining biodiversity technology is further complicated by the fact that its five broad constituent parts are not mutually exclusive (for example, monitoring is an integral part of in situ conservation), and some of the subcomponents themselves have very broad definitions. This makes the matter more difficult to resolve. For example, sustainable resource use has a broad definition because we do not have adequate terminology to differentiate between the various concepts that fall under its remit and because it combines biological, social, cultural, and economic factors.

The Convention on Biological Diversity (CBD) has acknowledged the imbalance in biodiversity technology that arises as a result of economic disparities between countries. Our attention is directed in this direction of transfer since it is the flow direction that is most likely to contribute to the preservation of the world's biological diversity, which is the aspect of the CBD that is most frequently discussed. However, the conventional view of technology transfer from the north to the south (for example, from resource-rich countries to biodiversity-rich countries in the original context of the CBD) is increasingly being called into question due to the increasing significance of technology transfer from the south to the north. There is a good chance that in the not-too-distant future, south-to-south transfer will call for a higher amount of attention as more agreements are created to encourage these exchanges. The majority of the concerns and ideas that we go over here apply as well to either north-north or south-south transfer. Countries with high-income economies may be able to exchange technology as a result of collaboration in research and development, but other countries may choose to utilize their purchasing power to get technology rather than develop it themselves.

Indian Perspective

Bringing attention to India, The Indian Patents Act 1979, amended in 2002, complies with TRIPS provisions. Section 3(j) was amended to make living organisms patentable, which was a major issue, particularly in the cases of *Dimminaco A.G. v. Controller of Patents*[44] *and Designs*&*Diamond v. Chakraborty*.[45] In the former case, it was held that an invention that contains a living substance is patentable if it is novel, useful, and capable

44 Dimminaco A.G. v. Controller of Patents and Designs, (2002) I.P.L.R. 255 (Cal).

45 Diamond v. Chakraborty, 447 U.S. 303 (1980).

of industrial protection while in the latter case, it was held that microorganisms are patentable.

The Protection of Plant Varieties and Farmers Rights Act, 2001 grants farmers certain rights. This act seeks to protect breeders' and farmers' rights by giving a free hand to the farmers to, grow, cultivate, breed, and conserve the protected variety of seeds. The act is often criticized to be tilted in the favor of breeders as farmers cannot share the cultivated protected breed with anyone apart from the breeder itself. It also allows farmers to get rewarded by the National Gene bank. This act was enacted in obligation with WTO which mandates countries to either form Their own Sui generis system of protection for plants or to either follow the much-criticized International Union for Protection of New Plant Varieties (UPOV Convention). The PVFR act of 2001 puts farmers in the shoes of breeders giving them rights comparable to the breeders apart from cultivating and selling branded seeds, India was initially not very keen to join the International Union for Protection of New Plant Varieties (UPOV Convention) as it prohibited the farmers from re-using the cultivated seeds and restricted them from exchanging it with their neighbours.

Although there is no specific legislation for regulating technology transfer, the law of contracts can be used to prevent any breach of technology transfer agreements. Article 16 of the CBD provides for the transfer of technology related to genetic resources to facilitate access to technologies that conserve and promote sustainable use of biodiversity without causing significant damage to the environment.[46] Article 8 of the CBD states that the contracting parties must ensure that the contributions of indigenous and local communities which are relevant to the conservation and sustainable use of biodiversity

46 S.K. Verma, *Access to Biological and Genetic Resources and their Protection,* 43 Jour Of Ind'n Law Inst, 2-23 (2001).

must be protected and respected. Such provisions ensure that traditional knowledge of communities related to the use of genetic resources is not commercially exploited and ensure that their approval is taken before using such knowledge for equitable sharing.[47]

Although IPR seeks to protect biodiversity and encourage benefit-sharing, some argue that in agriculture, IPR may encourage monocultures that are based on genetically uniform varieties which might reduce the traditional agricultural systems which are biologically diverse.[48] Furthermore, due to the market incentives that IPR provides, the poorer communities may suffer. For example, certain technologies would result in complete dependency of the farmers on the corporate seed companies, these technologies are referred to as genetic use restriction technologies, terminator technologies, or traitor technologies, all of which pose a significant threat to the farmers' rights and biodiversity. IPR can also harm access and transfer of technology to developing countries based on fair and most favorable terms as per the mandate of CBD. IPR encourages the participation of private entities who are more interested in the commercial profits arising from IPR rather than the development of humanity. This results in increased prices, unreasonable restrictions on issuing licenses, restrictions on research, etc.

Non-regulation of IPR may fail to ensure and implement equitable benefit sharing on fair and favourable terms. Further, the protection provided by IPR can be misused and its purpose

47 S.K. Verma, *Biodiversity and Intellectual Property Rights,* 39 Journal Of Indian Law Institute, 204- 215(1997).

48 Vandana Shiva, *Farmers' Rights, Biodiversity, and International Treaties,* 28 Economic And Political Weekly, 555-560 (1993).

to preserve biodiversity may in turn, in turn, result in causing harm to the environment.[49]

A Way Forward:

Working towards the attainment of goals of Sustainability and bio-diversity, preservation and implementation of various international conventions and domestic laws have been drafted. IPR and Biodiversity are very much interrelated. IPR ensures that biodiversity is protected through various forms of IP such as patents, technology transfer, traditional knowledge, and the sui generis protection of plant varieties. IPR affords protection to innovations related to genetic resources thus promoting innovation to protect biodiversity, promote sustainable development, and mitigate the effects of climate change provided that the principle of equitable benefit sharing based on fair and favorable terms is implemented strictly. Through its associated targets, the Sustainable Development Goal recognizes not only socioeconomic but also environmental dimensions of poverty, encompassing the poor and vulnerable strata's rights to natural resources, land tenure, basic services, and resilience to socioeconomic and environmental shocks and disasters. Many of them rely on healthy ecosystems for survival. In terms of access to diverse ecosystem services, the existing set of global metrics may not completely capture the multifaceted component of poverty. Through additional monitoring and reporting of pro-poor policies and programs that contribute to safeguarding or enhancing access to ecosystem services, the implementation, follow-up, and review of SDG and its interrelationship with other relevant Sustainable Development Goals could be further encouraged to take into account the benefits of biodiversity and ecosystem services for the poor.

49 Catherine Monagle, *Biodiversity, and Intellectual Property Rights: Reviewing Intellectual Property Rights in Light of the Objectives of the Convention on Biological Diversity* CEIL 1-22 (2001).

As a result, existing biodiversity laws can be determined to bring them into compliance with the convention's provisions and to reflect current knowledge of biodiversity conservation. Comprehensive legislation on biodiversity conservation and usage, particularly fisheries policies, is required, which is currently lacking. From the perspective of biodiversity, the formulation of policies for the protection of wetlands, grasslands, sacred groves, coastal flora and fauna, and other regions is critical. Biodiversity documentation is important. Increase the amount of money set aside for biodiversity conservation and Integrate conservation with development.

Apart from its applications, modern biotechnologies such as Terminator technology and Genetically Modified Organisms (GMOs) developed through genetic engineering may cause "Genetic pollution" and "Genetic contamination," as well as social consequences that necessitate economic, ethical, and environmental considerations. Even though biotechnology offers numerous benefits and many technologies that can help with biodiversity conservation, the introduction, and spread of new biotechnologies, like other modern technologies, has social implications with winners and losers.

In the case of biotechnology, this has sparked heated public debate on a variety of issues, including ethical, economic, legal, and environmental issues. Terminator technology and GMOs are examples of modern biotechnologies that can hurt biodiversity. Environmental concerns such as "genetic pollution" and "genetic contamination" must be addressed or confirmed before innovative technologies are released that may pollute biodiversity and the natural/wild genetic pool, resulting in irreparable damage. Since many nations have outlawed the use of technologies such as GMOs and terminator technology, countries like Ethiopia must learn from others rather than jeopardize or risk genetic resources due to genetic pollution and contamination. On the other hand,

the employment of safe and well-known technology should be encouraged and employed to supplement the country's biodiversity conservation and development efforts.

Emerging from the landscape of the Forest Service's experience with biodiversity, the conscientious development of its regulations, the complexity, and difficulty of the Pacific old-growth and the Tongass Forest plans, the ongoing legal battle over diversity standards, the allure of regulations that are so ambiguous that service plans are exempt from judicial scrutiny, and the allure of a single bullet, unassailable in its target "ecosystem management" that would cut through the controversy and solve all of these problems in a stroke, it is hard not to sympathize with the Service as it proposed to run for cover from its planning regulations and their implementation in the next round of forest decisions. In so doing, the Service would make a major strategic mistake.

As onerous as rules and the prospect of judicial review may be, they are nothing to the contorting influence on agency life of economic interests and politics. Biodiversity is a relatively new descriptive and normative notion that first appeared in the 1980s to offer a more precise emphasis on a variety of environmental, resource management, and agricultural initiatives. This notion is important for lawyers to understand because it will influence how local governments utilize their delegated police power and how courts evaluate their efforts. Biodiversity conservation has been studied and supported by several scientific and ethical viewpoints.

Assuming that biodiversity conservation is a societal goal of varying importance that can be justified largely as a form of insurance against future disasters and that it entails the creation of new social institutions to protect the planet's biological riches. According to a typical formulation of this conservation goal, states must "keep maximal biological variety

by ensuring the survival and supporting the conservation of all species in their native environment.

Another aspect is the international patent system is based on the Western value system countries, which provide special human rights as an industrial stimulus new. Developed countries have designed their IPR regimes according to their own goals needs and circumstances and then set up their governments which have been made the standard of the international IPR. Western values represented by IPRs are often contradictory and those of developing countries. Separation of shares and assets also biodiversity, which in some countries extends to human beings' environment, is different in many countries and societies in developing countries. However, they are unable to get out of the TRIPS agreement as the WTO negotiated package agreement.

The fact that patents on genetic material do not respect the rights of local communities in their traditional knowledge has been enhanced by many developing countries and NGOs since the adoption of the TRIPS Agreement. Indigenous knowledge associated with biodiversity often contributes to determining the properties or uses of resources that form the basis for the acquisition or establishment of a patent. However, traditional knowledge systems, including community-based conservation, exchange, and biodiversity improvements, have also had an impact on the erosion of traditional knowledge itself.

Emphasized as a joke that many countries wrongly complain of traditional and genetic information resources are managed at a global level while very few take steps to stop similar exploitation in domestic markets. The view that IPR rules are generally inappropriate and inadequate to protect rights and resources for traditional practitioners and local communities is shared by several developing countries, NGOs, and academics.

Some writers put first the concept of Indigenous Rights, which respects "indescribable communication" between cultural and natural diversity and does not see a conflict between human rights.

Thus, although the importance of biodiversity has been acknowledged in the past couple of decades, affirmative action and active involvement in this field would help in the overall promotion of IPR and biodiversity.

PART II

CHAPTER 2

LEGAL FRAMEWORK OF BIODIVERSITY IN INDIA

2.1 LINK BETWEEN BIODIVERSITY AND INTELLECTUAL PROPERTY

Biodiversity is important in a variety of ways, including promoting the aesthetic value of the natural environment and contributing to our material well-being through utilitarian values such as food, fodder, fuel, timber, and medicine when compared to the range of habitats, biotic communities, and ecological processes in the biosphere. The life support system is biodiversity. The air we breathe, the food we eat, and the water we drink are all dependent on it. Wetlands filter pollutants from water, trees, and plants absorb carbon, and bacteria and fungus break down organic matter and nourish the soil, all of which help to minimize global warming. The abundance of native species, as well as the quality of life for people, has been scientifically related to ecosystem health. Biodiversity-ecosystem services are maintained through soil formation and

protection, water conservation and purification, hydrological cycle maintenance, biochemical cycle regulation, pollutant and waste material absorption and breakdown through decomposition, and natural world climate determination and regulation. Despite the benefits of biodiversity, today's threats to species and ecosystems are growing at an alarming rate, and nearly all of them are caused by human mismanagement of biological resources, which is often fueled by reckless economic policies, pollution, and faulty institutions, as well as climate change. It is critical to protect biodiversity to ensure intragenerational and intergenerational equity.

The principles or goals of CBD are very much relevant in understanding the linkage between biodiversity and IPR as countries are limited to its use of biological resources, conservation and sustainable use of resources, the benefits and commercial utilization of such resources which may be granted with some conditions to facilitate the use of it, wider application or implementation of knowledge and innovation relating to biodiversity and its protection.[50] Not just at the international level even at national levels, countries with their developing legislation and measures respond and abide by these treaties addressing the relation between biodiversity and IPR.[51] The discussion of the second and third conferences of parties to CBD recognized the need for sustainable development, use of biodiversity, and technological transfer. There have also been committees concerning trade and the environment to build a relationship between the two. For the best sustainable sustenance and development, a proper and good balance must be there between IPR and conservation of biological diversity

50 Convention on Biological Diversity, Art.3 and Art. 6.

51 Lyle Glowka, *A Guide to Designing Legal Frameworks to Determine Access to Genetic Resources*, IUCN Environmental Law Centre, (1998), https://portals.iucn.org/library/sites/library/files/documents/EPLP-034.pdf.

with other IP protection like patents and copyrights to protect plant varieties and biotechnology as well through the sui generis mechanism. The current and recent IPR regimes like the protection of plant varieties, monoculture, and genetically modified organisms are a few of the encouraging regimes or laws that are helping with the protection of biodiversity. The principles or objectives that are aimed at the emergence of CBD are somehow directly or indirectly connected to IPR to protect, enforce and have control over resources and usage of them through various pharmaceutical or biological products. The concept of exclusive rights in IPR helps with the distribution and sharing of benefits of resources and as a type of technology improvement for the use and conservation of biological diversity.[52] Sui generis system of protection and patent gives extensive protection to biodiversity and for implementation of CBD for benefit sharing, conservation, and use of biodiversity. Biological resources, bio utilization, commercial utilization such as drugs, cosmetics research, and access to such biological resources are a few of the points where patents and biodiversity are linked.

We have the potential to make significant strides forward in our utilization of bioindicators to signal environmental hazards and quantify harm caused by invasive species. Environmental DNA, often known as Edna, is the DNA that plants and animals leave behind in the environment after they die. It has the potential to be used to quickly identify invasive species. Automated sequencing stations might routinely sample environmental DNA from different mediums, such as air, soil, or water, to maintain continuous surveillance of crucial habitats for biological invaders. Remote sensing data collected by satellites and unmanned aerial vehicles (UAVs) can be used

52 Maria Julia et.al; *A Guide to Intellectual Property Issues in Access and Benefit -Sharing Agreements*, WIPO 22, 22-82 (2018).

to identify biological incursions and monitor the effectiveness of biological control agents. This can be done, for instance, by mapping the effects of these agents on the local flora and fauna.

Even though biological controls can sometimes do more harm than good (like when cane toads were brought into Australia to control beetle infestations), increasing our understanding of ecological interactions and demographics ought to enable us to design more effective eradication programs for invasive plants and animals. One example of this is the introduction of cane toads into Australia to control beetle infestations. Utilizing the unique volatile organic chemical signatures of invasive plant species to entice targeted biocontrol is one potentially innovative method that may be taken. But even while we may never be able to stop all of the biological invasions that are caused by humans, new technology approaches can help us manage the ones that do happen. By adopting technology that records animal movements and interactions, one can keep an eye on the possibility of zoonotic disease transmission from invasive species as well as the possibility of hybridization between invasive species and native flora and fauna. This study highlights the practical applicability of genetic profiling and the potential for technology to help reverse some of the damage caused by biological invasions. The genetic sequencing of a species of bee (Apis mellifera syriaca) has revealed genes that endow resistance to the mite Varroa sp. that causes colony collapse.

Reforestation, zoological gardens, botanical gardens, national parks, biosphere reserves, germplasm banks, and the adoption of breeding techniques, tissue culture techniques, and social forestry are only a few examples of present biodiversity protection efforts.

On Earth, biodiversity is not uniformly distributed. It is the most abundant in the tropics. The warm temperature and high primary production near the equator result in the highest levels of terrestrial biodiversity. Coastal areas have the greatest levels of marine life. The maximum sea surface temperature is found in the Western Pacific, as well as the mid-latitudinal band in all oceans. In terms of species diversity, there is a latitudinal gradient. Biodiversity tends to congregate in hotspots, and while it has been rising over time, it is expected to slow down in the future.

Usually, the two terms i.e. - Biodiversity and IPR (intellectual property rights) are interpreted as contradictory terms and are thought of as being difficult for them to sustain simultaneously. Many environmentalists have a pre-notion that IPR harms the ecological balance of the earth's ecosystem, but as an advocate of the IPR regime, it could be assured that IPR is not a barrier to attain sustainable development but rather it could prove as an instrument to facilitate and promote biodiversity.[53] Any developing country needs to ensure that both entities are smoothly functioning. The state must form legislations that create such a balance that commercial and economic development of the society takes place without compromising on nature.[54] There is nothing wrong when you take something from nature and return to it in a different form. It is rather difficult to strike a balance between biodiversity and intellectual property rights since there are numerous occasions when these two come in direct loggerheads with each other,

53 Graham Dutfield, *Literature Survey on Intellectual Property Rights and Sustainable Human Development*, United Nations Conference on Trade and Development (UNCTAD) 3, 3-109 (2003), https://www.files.ethz.ch/isn/124121/2002_02_Literature_Survey_on_.pdf.

54 John Merson**,** *Bioprospecting or Bio-Piracy: Intellectual Property Rights and Biodiversity in a Colonial and Postcolonial Context*, 15(1) The University of Chicago Press Journals 282 (2000), https://www.journals.uchicago.edu/doi/10.1086/649331.

creating a situation that one of them must be compromised to give a green signal to the other.

On the face of it - biodiversity and intellectual property rights seem to be in contravention of each other. IPR protects the work (that has originated from human intellect) against imitation, unauthorized use, and exploitation. IPR gives monopolistic rights to creators for a specific period, it seeks to protect individual rights, and biodiversity provisions on the other hand try to protect the rights of a community. The protection of biodiversity over IPR sounds good morally and ethically but is it possible to attain sustainable development of biodiversity without providing IPR protection to individuals? Though in the -short run IPR only rewards the individuals in a long run it seeks to encourage research, development, and overall growth of the community. If we investigate the various legislations throughout the world, we will find out that most countries give preference to biodiversity over IPR. In India, any patent application that goes against the biodiversity provisions of the 2002 act is either rejected or is open for Pre and Post opposition grants. The balance seems slightly shifted in favor of biodiversity with India prohibiting the gene patenting and patent engineering of related macro-organism, patent - grant related to multicellular organisms is also prohibited.

Biodiversity, biotechnology, and Property Management consist of a complex interdependence with each other when it comes to related functions between them. Property rights are by two international treaties, namely, the CBD (Convention on Biological Diversity) and TRIPS (Trade-Related Aspects of Intellectual Property Rights) are essentially the two authorities of sovereignty and property rights over bio-resources. The primary issues relating to property rights are the interrelatedness of the CBD and the TRIPS as the primary authorities and also suggests that the fundamental problem of controlling access to biological resources from sovereign rights

to private property rights is a problem leading to undermining of the state's rights over bio-resources in favor of corporate interest.[55]

In the biotechnology industry, there is no difference made between granting a patent for a living form and granting a patent for an industrial product. IPR policies and management are strengthened by an institutional capacity to protect biodiversity awareness by focusing on controlling available biodiversity resources and striking a balance between biodiversity, biotechnology, and IP rights.[56]

An IP policy should address three key objectives: revenue generation, success recognition, and technology transfer. e.g., this is especially important in biotechnology where most research methods and products are in the hands of the private sector. In the current global market, the economic success of a country depends on its ability to employ new knowledge and technologies. However, there is a growing concern that the protection of excessive intellectual property could interfere with the continuation of academic research. The issue here arises as to finding a balance between conservation and appropriate exploitation of national resources to not affect corporate advancement and protection of the environment and the bio-resources. Properly balanced economic development opportunities form the foundation for promoting human rights, leading to growth, sustainability,

55 Aykut Çoban, *Caught between State-Sovereign Rights and Property Rights: Regulating Biodiversity*, 11(4) Review Of International Political Economy 736, 736-762 (2004).

56 Suresh Pal, Robert Tripp, Niels P. Louwaars, *Intellectual Property Rights in Plant Breeding and Biotechnology: Assessing Impact on the Indian Seed Industry*, 42 (3) ECONOMIC AND POLITICAL WEEKLY 231, 235 (2007).

and human development.[57] To achieve this equality, economic and social rights must be integrated into efforts to define and recognize the reunification of human rights policy. In other words, the recognition and application of human rights in development promotes economic, social, and cultural rights to the same degree as political and social rights. The development of biotechnology however is in line with the dynamic state of Intellectual Property (IPRs).

2.2 LEGAL FRAMEWORK IN INDIA REGARDING THE PROTECTION OF BIODIVERSITY

The Biological Diversity Act 2002 and The Biological Diversity Rules 2004:

India enacted the Biological Diversity Act to fulfil its obligation of providing fair and equitable sharing of benefits under the Convention on Biological Diversity.[58] This Act establishes a National Biodiversity Authority to aid the implementation of the Act. The main objectives of the Act are the same as that of the CBD, i.e., conservation of resources, promoting sustainable use of such resources, and promoting fair and equitable sharing of benefits arising from the use of genetic resources. The Act also provides for the protection and rehabilitation of threatened species.

Helping Hand:

- Article 3 of the Act prevents individuals from conducting any research or any commercial activity related to the biological resources found in India without the prior approval of the National Biodiversity Authority (NBA).

57 Jorge A. et.al, *Agricultural IP and the Public Sector*, 302 George Town University 780, 781-782 (2003).

58 Parameswaran Prajeesh, *India Lays the Cornerstone of Biodiversity access and benefit sharing system*, 112 Current Science 24, 24-86 (2017).

- Article 4 further prevents individuals from sharing/ transferring the results of any research conducted concerning the biological resources found in India without the prior approval of the NBA.
- Article 6 states that no individual can apply for any Intellectual Property Right concerning any invention based on biological resources in India without the approval of the NBA.[59]

The Biological Diversity Rules provide for the members of the NBA, the term of their offices, removal, etc along with their general functions which include collecting, compiling, and publishing technical and statistical data related to the conservation of biodiversity.[60] The Rules further provide procedures for assessing biological resources which are related to traditional knowledge, transferring results of research, and the procedure for seeking approval of the board before applying for IP protection. Hence, the Biodiversity Act and the rules prove to be reliable sources for the development of biodiversity.

Other laws which are related to biodiversity in India are:

- Schemes like conservation of aquatic systems, conservation of vulture species, development of wildlife habitats, recovery of species that have been endangered, and conservation of community reserves.

Other laws that aim to protect biodiversity and the environment are the Indian forests act [61]; the water prevention

59 The Biological Diversity Act, 2002, sec. 4,5,6, No. 18, Acts of Parliament, 2003 (India).

60 The Biological Diversity Rules, 2004, Rule 12.

61 Indian Forest Act, 1927.

and pollution control act[62]; the mining and mineral development act [63], and the environment protection act.[64]

2.3 THE EXISTING LEGAL SITUATION RELATED TO BIODIVERSITY IN INDIA

Being an active member of the meeting on the convention of biodiversity (CBD) held in Rio de Janeiro Brazil 1992, and a signatory of Trade Related Intellectual Property Rights (TRIPS) and member of WTO. India was forced to bring a law on the conservation of biodiversity, and it rightly did so in 2002 bypassing the biological diversity act of 2002 which was implemented from the year 2003.[65] The fundamental goal behind the legislation was to ensure benefit-sharing and to give a right to local communities against exploitation. This act ensures that no exploitation of natural resources takes place without the permission of local communities. The act seeks to provide equal and beneficial sharing of the natural resources arising out of traditional knowledge. It empowers the communities which have preserved the local communities for a long time. it prescribes imprisonment of up to five years with a fine of Rs 10 lakhs. It mentions ways how the benefit-sharing could take place through technology transfer, payment of compensation, joint ownership of intellectual property regime, etc. The problem with India is that it neither invests in the public nor private sector of agriculture. The Intellectual property rights and convention of biodiversity also form a special relationship between a developed nation

62 Water (Prevention and Control of Pollution) Act, 1974.

63 The Mines and Minerals (Regulation and Development) Act (1957).

64 Environment Protection Act, 1986.

65 The Biological Diversity Act, 2002. *See.* The Biological Diversity Act, of 2002 is an Act enacted by the Parliament of India for the preservation of biological diversity in India and provides a mechanism for equitable sharing of benefits arising out of the use of traditional biological resources and knowledge.

and developing countries as the most efficient and effective technology for adapting IPR lies with the developed countries while the developing countries are rich in having natural resources. The flow of natural resources from developing countries to developed nations takes place to strengthen the development/invention.

2.4 THE CRITICISM OF IPR REGARDING BIODIVERSITY

There are numerous criticisms of the IPR by the advocates of biodiversity. The protection of the plant variety act requires the protection of the crops only after uniformity is proven, but in promoting uniformity the diversity dies. The other concern regarding IPR is that when genetic engineering is performed its results are not fully known, so there might be a possibility that the new species generated after gene interference might destroy the existing species of the ecosystem One of the main differences between patent protection and plant protection is that the criteria of plant protection are a bit lenient. Plants' protection requires the new variety to be novel and distinctive but lacks the requirement of non-obviousness, inventive steps, or industrial application, which gives a free hand to breeders who do not make any efforts in creating new varieties of crops. The use of fertilizer and other forms of pesticides that is essential for the new and hybrid varieties to grow and to protect them from various pests and insects are harmful to nature. These chemical fertilizers which are deadlier than the ones used for normal crops create - health-related problems for humans such as cancer, asthma, brain tumour, etc. These chemical pesticides when coming into contact with water also harm aquatic animals.

Apart from that, royalties given to the developed countries and MNCs working on seed development will highly increase the debt burden in the countries which in turn increases

the environmental, social, and ecological disruption. This is because the money usually goes away from environmental and development funds. Though there are problems in implementing IPR and biodiversity provisions simultaneously, nobody could deny the positive impact of intellectual property rights on the protection of biodiversity.

2.5 POSITIVE IMPACT OF INTELLECTUAL PROPERTY RIGHTS ON THE PROTECTION OF BIODIVERSITY

Apart from preserving information (both contemporary and traditional) that aids in the long-term conservation of biodiversity, the IPR also allows for green patenting. Green patenting is a patent innovation that aids in the preservation of the earth's inherent green character. These green technologies also aim to lessen the environmental impact by replacing existing alternatives. Green patents include a wide range of ideas, including those that reduce pollution and identify new methods to develop without harming the environment. As a result, green patenting is a gift to biodiversity from IPR. Intellectual Property Rights have aided in the prediction of factors such as climate and natural catastrophes, as well as assisting the appropriate authorities in minimizing human and animal collateral damage. Intellectual property rights are also used to search for innovative pharmacy-related inventions that not only help people live longer but also help them live healthier lifestyles. Though granting monopoly rights to individuals may have a short-term negative impact on society, the Intellectual Property Regime has put in place several internal management systems to address these issues, such as granting monopolistic rights for a limited time, rejecting applications that violate public morality or could endanger human life, and not granting patents for human clones. As a result, it is possible to conclude that IPR is not necessarily harmful to biodiversity, but that it may also be beneficial.

CHAPTER 3

INTER-RELATIONSHIP BETWEEN BIODIVERSITY, BIOTECHNOLOGY AND INTELLECTUAL PROPERTY RIGHTS

3.1 BIODIVERSITY, BIOTECHNOLOGY, AND IP RIGHTS

The Uruguay negotiations for the GATT talks which included TRIPS were a major step towards establishing a state legally binding international IP protection system. The scope of patent extensions to livelihoods was a major area of discussion. Since the early 1990s, a coherent process has been in place, where international law and policy have shifted from viewing genetic resources as the common heritage of humanity thus being free for all. This process has changed giving the State power and sovereignty over these resources that is, giving private ownership over genetic resources.

In addition, the rising promotion of private ownership and the use of IPRs over plants and plant species aggravated the problem. It's also worth mentioning that many developing nations lacked IPR rules before joining the World Trade Organization (WTO) in 1995, and hence are subject to the WTO Convention on Commercial Proprietary Properties'

implementation (TRIPS). Other important authorities, such as the Conference on Biological Diversity (CBD) and the FAO International Treaty on Plant Genetic Resources for Food and Agriculture, are still being used by these nations. With the continuous focus on genetic resources and the use of biotechnology to generate new species and goods, there is a rising international interest in the knowledge and awareness that indigenous peoples and rural communities have cultivated and utilized for millennia.

Over the years, Concerns and discussions have arisen about how traditional knowledge, innovation, and practices are accessed and used by non-indigenous people and public and private investigators in both developed and developing countries. In this context, positions change as countries continue to understand the possible procedures and regulatory mechanisms to protect the rights of traditional owners at the national and international levels, as well as the effects of these options on other policy areas, such as research, trade, or agriculture.[66]

3.2 POSITIONS IN THE RELATIONSHIP BETWEEN TRIPS AND CBD

The inhabitants of Southern Africa called the 'San People' have formed an allied African group called the Working Group of Indigenous Minorities in Southern Africa (WIMSA) continue to oppose the patent for plant species specific to the indigenous Hoodia plant to be used for commercial use as it is an essential part of their way of life and the patent of it by Pharmaceutical companies are denying the group access to the same. Thus, they are proposing certain articles in the TRIPS Agreement to be reviewed to prevent copyright in systems,

66 Carolina Lasén Díaz, Intellectual Property Rights And Biological Resources (Wuppertal Papers 2005).

animals, and micro-organisms; primarily biological processes for the production of plants or animals, as well as non-biological and micro-organic processes for the production of plants or animals. The review seeks clarity regarding Members' rights to change differently, which is different because of social or moral order. In the field of genetics and traditional knowledge, the African Group proposes that the TRIPS Agreement needs to be amended to require all patent applicants to disclose the country and place of origin of any biological and indigenous resources used or involved in establishing and to provide compliance with all domestic entry laws. It is also important to note that, the impact of the public on IPR standard-setting activities should be highlighted. After government and business, NGOs are considered third parties to IPR politics, serving as a source of analysis and partners of developing countries.

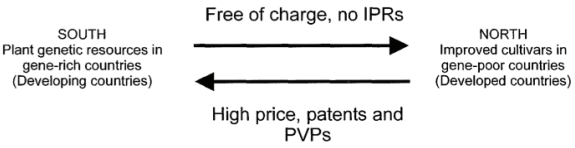

Figure 167

The figure above shows the simplified description of the terms of exchange for plant genetic resources between developing and developed nations. Here, the developed nations are gene-poor, and developing nations are gene-rich.

The first issue is about the type of patent, especially the patent given to living things. Copyright is granted for

67 Paul Gepts, *Who Owns Biodiversity, and How Should the Owners Be Compensated?*, 134 American Society Of Plant Biologists 1295, 1300-1307 (2004).

innovation, intellectual property, and use. Copyright for biodiversity, be it genetic or physiological, challenges these three main mechanisms, yet they are increasingly common. The second issue associated with the Canadian "Onco-mouse" decision [68] is that it differs from the imitation pattern. IPRs are generally believed to promote innovation, despite opposing views.[69]

With the advancement of technology, genetic material and data are being digitally integrated into GenBank. This is called DSI. Although there is no single definition, DSI contains data from data analysis contained in a digital file containing a specific order of nucleotides, amino acids, or cell molecular structure. DSI is also able to reveal more details about genetics, such as the evolutionary process that leads to the adaptation of living organisms through DNA barcodes. Currently, DSI, which is available as open-access data, is not legally regulated or adopted by the CBD and Nagoya Protocol.

The main reason for this has to do with the definition of genetic resources under CBD as genes of real or potential value, which is translated as in this case, it follows that the intractable DSI is unable to generate genetic resources as defined by the CBD. At the time of CBD development, ABS intended to demonstrate the application of modern biotechnology by testing the usefulness of genetic and biological chemicals, rather than by obtaining genetic resources. As technology advances, it is possible that biotechnological R&D could add even greater value to genetic resources. This small explanation has also led to the secrecy of the ABS reality: information, whether visible or intangible. This means that the countries

68 Harvard College v. Canada, 2002 SCC 76, 219 D.L.R. 577, 21 C.P.R.2004.

69 *Id.*

that use it do not have to pay foreign suppliers because the data contains the details of the genetic sequence.[70]

The problems mentioned above are only expected to get significantly greater owing to the TRIPs Agreement. Its attempt to standardize IPR regimes, in particular, interferes with a nation's or community's freedom to decide how to handle the use and preservation of knowledge. Additionally significant is the absence of any protections for indigenous and regional community knowledge. Due to its nature, such knowledge might not be shielded by the current IPR laws. Finally, it makes no mention of the requirement for an equitable distribution of the advantages of biodiversity-related knowledge. It legitimizes the traditional injustices that have characterized the relationships between the industrial and commercial use of information connected to biodiversity and the use of such knowledge by the community and citizens. In certain nations, the effects of TRIPs on the three CBD objectives are already starting to be felt. To fight these risks, identify existing regimes' provisions that can be used, and investigate alternative regimes that promote conservation, sustainable usage, and equitable benefit-sharing are all urgently needed.[71]

3.4 HISTORICAL VIEWS IN IPR, BIODIVERSITY, AND BIOTECHNOLOGY

IPRs are the rights to ideas and information used in new products or processes, as the term implies. The owner of these rights may prevent the actors from marketing those new

70 Bhaya Ganashree, *Who Owns Ocean Biodiversity?: The Legal Status and Role of Patents as a Means to Achieve Equitable Distribution of Benefits*, 53 CASE W. RES. J. INT'l L.197 (2021).

71 Ashish Kothari and R.V. Anuradha, *Biodiversity and Intellectual Property Rights: Can the Two Co-exist?*, 2(2) Journal Of International Wildlife Law & Policy 204, 204-223 (1999).

processes or processes for a specified period to the formula or concept behind the product/process. IPRs have the effect of providing governance over the exploitation of intellectual or information trade for a limited period. IPRs are designed to encourage innovation by providing higher financial returns than the market could otherwise offer. While IPRs such as patents and trademarks have been around for centuries, the use of IPRs for living people and their knowledge/technology is relatively new. The United States ratified the Patent Act in 1930, granting IPR species varieties of plants that have been reproduced. Several other countries followed suit, offering the same or different plant species protection until 1961 when the International Convention for the Protection of Plant Biodiversity was signed. Most of the signatories were developed countries that have already joined the Union for the Protection of New Plant Variety (UPOV). The agreement came into effect in 1968.[72]

Plant varieties or farmers' rights (PVRs / PBRs) give limited control over the sale of 'their' varieties to the right holder. Most governments have exempted farmers and other farmers from the provision of these rights until recently, provided that they do not engage in brand-name transactions. However, after the 1991 review, UPOV tightened the status of PVRs / PBRs, and several nations significantly reduced the emancipation of farmers and ranchers. In addition, patents that are now fully restricted are now available through genetic plants, microorganisms, and genetically modified animals in many countries. The United States Supreme Court ruled in 1972 that Ananda Chakrabarty's patent for the genetically modified virus was effective. This supports the idea that

72 Monica Armillotta, Technology Pooling Licensing Agreements: Promoting Patent Access Through Collaborative Ip Mechanisms 219 (Nomos Verlagsgesellschaft mbH 2010).

everything made by humans and that is not found in nature can be patented. Genetically modified animals, such as Harvard University's onco mouse (famous for cancer research), were soon patented. Finally, certain patent claims have been made on human genetics, and some have been approved, including claims on things that have not been altered. Until recently, these practices were limited to a few countries that they could not enforce on others.[73]

However, this has changed since the signing of the TRIP agreement. TRIPS require all member states to use the following: Microorganisms and "microbiological processes" are patented; and IPRs on plant species by some "active" species, such as patents or sui generis (new). TRIPs enable governments to release animals and plants from plunder. The above laws, on the other hand, have far-reaching consequences, as countries can no longer completely deny patents for species (microorganisms must be open to patents). The term "efficiency" can be taken by industrialized countries to show a UPOV-like approach, so it is unlikely that there will be much flexibility in building sui generis plant protection regimes. Indeed, a series of events in 1999, such as meetings organized by the UPOV, WTO, or other organizations in Africa (February 1999) and Asia (March 1999), have shown that this definition is already being pushed into 'poor' countries. The African Intellectual Property Organization (OAPI) has agreed to join UPOV 1991, which represents 15 French countries.

73 Anthony E. Chavez, *Exclusive Rights to Saving the Planet: The Patenting of Geoengineering Inventions*, Northwestern Journal Of Technology And Intellectual Property, (2015).

3.4 GENERAL CORRELATION BETWEEN BIODIVERSITY, BIOTECHNOLOGY, AND IP RIGHTS

Farmers who establish seeds by re-use, exchanges with other farmers, and other methods can be prevented from doing so if the strong governments that were favoured by UPOV 1991 were established in their countries; these regimes will also increase the financial burden on farmers, preventing new inventions. The effects of IPR behaviour are huge and are one of the strongest reasons for many communities and individuals to oppose current IPR regimes.[74]

Trying sui generis bold techniques to protect plant species, promote the use of prudent policy in all trades and other activities, etc. Pushing to use the maximum space allowed in existing IPR regimes, including extending the definitions of "public interest" to their reasonable limits, experimenting with bold ways to protect plant species, etc. Challenging governments and organizations known to violate Article 8(j) and other CBD laws applicable to international forums, and promoting the implementation of Articles 16 (5) and 22 of the CBD; Developing an international agreement (or CBD protocol) for the protection of traditional and local public information, as well as access mechanisms associated with profit-sharing mechanisms; directing FAO reviews of Plant Genetic Resources, WIPO's efforts for "new beneficiaries," and other programs (including the proposed Database Treaty) in directing conservation, sustainable use, and benefit-sharing flexibility are included in the forthcoming TRIPs Article 27.3 (b), allowing countries to completely exclude species from the copyright and to create sui generis protection schemes for various "operational" species from a national or public perspective; Develop and implement local laws that protect the protection of the environment and the protection of the

74 *Id.* at 94.

health of local communities. Some of these measures were also requested at an international workshop on Biodiversity Conservation and Intellectual Property Rights held in February 1999, co-hosted by the Research and Information System on Non-Aligned and Developing Countries (RIS) and Kalpavriksh - Environmental Action Group and sponsored by IUCN - World Conservation Union. While the recommendations of the workshop are highly dependent on the experience of South Asian countries, they have a much broader application. As a result, recommendations regarding international procedures are withdrawn.

The link between biodiversity, rural livelihoods, advances in biotechnology, and intellectual property has been extensively explored and analyzed in recent years. The use of IPRs to plant species and the role of biotechnology are very important impacts given to the relationship between genetic resources, agricultural systems, food security, and the increasing level of poverty around the world. There is a growing interest in the potential commercial use of biodiversity, viz driving most of the policy and legal developments in the area, such as partnerships for profit, the role of traditional knowledge owners, and the role and responsibilities of countries providing and using these services and information. Central to these problems lies the complexity of the international system that regulates biodiversity, the availability of genetic resources, the protection of indigenous knowledge systems, and the use of intellectual property rights.

The extent to which developing countries can affect global outcomes the IPR controversy has been analyzed by many academics and activists, for everything to conclude that they are relatively weak. The main reason for this shortage of influence over the years, which can be tested in the results of international debates in IPR cases, they are asleep in the ongoing use of webs imposed by the US and the EU, both

remain united in the need for strict international standards for intellectual property. The same author reviewed TRIPS conversations based on the notion of democratic property rights, which argues that higher property rights are superior may occur if three conditions are met: (i) all relevant interests must be represented in the negotiation process (representation status); (ii) all stakeholders in discussions there should be a thorough knowledge of the consequences of the various possible outcomes (state of complete details); and (iii) one party must not force others (state of non-dominance).

The TRIPS agreement does not meet the conditions for democratic negotiations. The middle question is whether international acceptance and expansion of normality standards of copyright protection by international agreements, established to meet the conditions and requirements of developed countries, can result in undermining biodiversity, indigenous knowledge systems, and food security communities in developing countries. Global trade has emphasized the link between international trade rules, domestic priorities, IPR protection standards, and resource requirements, leading to a rapid growth gap between industries and developing countries, as well as growing diversity and inequality within their countries. Current controversies regarding species and interactions between IPRs and biodiversity, to shed light on the impact of policy development and world positions are a take on the future life of the planet. In the case of genetic sources, it should be made clear where the plants were subject to technical or technological intervention in the production of new plant species, they are under a different state and therefore are not covered by copyright different. Plant species are considered new, different from wild plants as found in nature, and need patent protection or sui generis kingdoms. This is a different treatment for plant species in TRIPS. The agreement described the lack of consensus among the negotiating

countries, especially between the US and Europe, although since then their levels are approaching. While in 1973 the European Patent Convention declared that plants and animals were not patented, there was a different translation of this provision which led to the adoption of the 1998 EU Directive to measure copyright in EU countries. The directory is not fully functional and excludes plant species from copyright, such as organisms isolated from their environment or the production of technology "may be an invention if ever before in nature", a condition criticized by the NGO again by other EU countries itself. The major impact of the increase in the use of biotechnology in seed and plant production, their effects under patents or patents such as plant breeders' rights, has to promote private sector management of crops and agricultural practices, making farmers responsible for paying royalties and changing their traditional practices by restricting their use and seed exchange. The results of IPR policies on research priorities and funding points focus on developing a profitable commercial sound product, not for the needs of individuals and communities living in poverty. The private sector is a major player in biotechnology research worldwide.[75]

75 Chandra Nath Saha and Sanjib Bhattacharya, *Intellectual property rights: An overview and implications in pharmaceutical industry*, 2 J Adv Pharm Technol Res 88, 90 (2011).

CHAPTER 4

INTERNATIONAL CONVENTIONS RELATING TO BIODIVERSITY

4.1 CONVENTION ON BIOLOGICAL DIVERSITY (CBD)

The convention on biological diversity (CBD) is an agreement that emerged from Rio Earth Summit to protect biological resources for future generations. The convention primarily aims at the conservation and sustainability of resources. The convention also provides a link between two conservations which are *in situ* and *ex-situ* for the development of biological standards nationally.[76] It extends to species, ecosystems, and even genetic resources. It has three main objectives i.e., to conserve biological diversity, to promote sustainable use of its components, and to achieve fair and equitable sharing of benefits that are a result of the utilization of genetic resources.[77] The preamble of the Convention acknowledges that conservation and sustainable

76 S.K. Verma, *Biodiversity and Intellectual Property Rights*, 39 Journal Of Indian Law Institute, 203, 203-205(1997).

77 Catherine Monagle, *Biodiversity, and Intellectual Property Rights: Reviewing Intellectual Property Rights in Light of the Objectives of the Convention on Biological Diversity*, CEIL 3 (2001).

use of biodiversity is important for meeting human needs such as food, health, and other such needs. It further acknowledges that States have sovereign authority over biological resources, and they are responsible for conserving them. Article 8 of the Convention mandates the Contracting parties to take appropriate action to stop the destruction of species, ecosystems, and habitats. Article 7 states that the parties must identify the processes that affect biodiversity conservation. Clause 2 of Article 15 mandates that the States must facilitate sharing and access to genetic resources to the other contracting parties. Therefore, the convention creates an obligation on the owners of genetic resources to protect them as well as allow the contracting parties to access them on mutually beneficial terms. The Nagoya protocol under this convention particularly aims at sharing the benefits which arise from the utilization of genetic resources fairly. Some of the other conventions include the Convention on International Trade in Endangered Species of Wild Fauna and Flora which aims at protecting endangered species by prohibiting their trade; the Convention on the Conservation of Migratory Species of Wild Animals (Bonn Convention) aims at protecting migratory species by preventing, reducing and controlling factors which can endanger them; The International Treaty on Plant Genetic Resources for Food and Agriculture aims at conservation and sustainable use of plant genetic resources agriculture; Convention on Wetlands (Ramsar Convention) 1971, recognizes the wetlands as the most productive ecosystems and prevents their loss and promotes their conservation; The UNESCO Convention 1972, covers the protection of certain species of plants and animals which are threatened, etc.[78]

78 Ali Mehdi, *Climate Change and Biodiversity: India's Perspective and Legal Framework*, 52 JOURN IND LAW INST 343, 343-347 (2010).

The Convention on Biological Diversity was signed in 1992 at the United Nations Conference on Environment and Development. The main objectives of the Convention include the conservation of biological diversity, sustainable use of the components of biological diversity, and equitable sharing of benefits derived from the use of the components of biological diversity. The Convention on Biological Diversity contains provisions on scientific and technical cooperation, transfer of technology, access to genetic resources, and appropriate funding mechanisms. CBD is different from other international conventions in setting goals and there is no list of priorities as to species or habitats. It is the Contracting nation that decides on the ways of implementation of the provisions entailed in the CBD.[79]

4.2 NEXUS BETWEEN CBD AND IPR

Two extremely important provisions in the Convention on Biological Diversity dealing with Intellectual Property Rights are Articles 16.5[80] and 22[81]. As per Article 16.5, the Contracting Parties must work together to ensure that the intellectual property rights comply with CBD's objectives subject to national legislation and international law. According to Article 22, if the Contracting Parties are part of an existing international agreement, the provisions of CBD shall not interfere with their rights and obligations. However, it can interfere, if the said rights and obligations would cause serious damage or threat to biological diversity.

Intellectual Property Rights are likely to significantly accelerate the trend of homogenization in agricultural

79 *The Convention on Biological Diversity*, 3(2) Botanic Garden Conservation International (BGCI) 29, 29-33 (1999).

80 The Convention on Biological Diversity, Article 16(5).

81 The Convention on Biological Diversity, Article 22.

production and medicinal plant use systems. Current IPR regimes have made it possible for industrial and commercial interests to appropriate the resources and knowledge of resource-rich but economically underdeveloped countries and communities, further impoverishing them and denying them the benefits of technological innovation. Any corporation in the agricultural industry, for instance, that has invested a substantial sum of money in getting an IPR, would want to promote its variations as much as possible. As a result, the local crop diversity may be severely displaced.

Inevitably, species-wide IPRs (like those for transgenic cotton and soybeans) could hinder the creation of new crop varieties even in the public and small-scale private sectors. The amount of debt that many nations would have to carry if they were to pay significant royalties to industrial nations and corporations, could exacerbate the already widespread environmental and social disturbance brought on by debt repayment strategies like exporting natural products. If stricter regimes like the UPOV 1991 sanctions are imposed on their countries, it would also increase the financial burden on farmers, further discouraging innovation. Farmers who innovate on seeds through reuse, exchange with other farmers, and other means would be increasingly discouraged from doing so.

4.3 FLEXIBILITY WITHIN CBD

Countries possess some amount of flexibility pertaining to intellectual property rights owing to Articles 16(5) and 22 of the Convention on Biological Diversity. A Contracting nation can refuse to grant IPRs if it can prove that doing so will harm conservation, sustainable usage, and/or equitable benefit-sharing goals. Since TRIPs also comprise international law, the proviso in Article 16(5), "subject to national legislation and international law" may make this challenging. Under

international law, it may be argued that TRIPs, the convention that was signed later, would take precedence over the CBD in cases where there are conflicting provisions. However, it may be claimed that the CBD's provisions should take precedence over TRIPS given that it deals much more specifically with the protection of public interest and morality, which TRIPs recognize as legitimate justifications for protective measures. There is currently no active case in the international sphere where the interface of the relevant agreements has been challenged. Article 8(j), which requires nations to respect and protect indigenous and local community knowledge, ensure that such communities are consulted before using their knowledge for wider societal benefits, and promote equitable sharing of benefits resulting from such use. This provision contains the beginnings of a completely new concept for preserving information and producing and dispersing rewards. This potential has been discussed in the CBD forums, including at previous Conferences of Parties, especially because a variety of indigenous and local community groups have used the forums to make their claims. The issue of whether a country can challenge another country's IPR regime because it does not adequately protect the informal innovations of indigenous or local groups and, as a result, breaches, Article 8j of the CBD is an intriguing one. This inquiry was made by the Indian delegation to the WTO's Committee on Trade and Environment in a meeting in June 1995, but reportedly no response was given.[82]

4.4 BONN GUIDELINES

Bonn Guidelines were adopted by the Convention on Biological Diversity (CBD) during the conference of 2002.

82 Ashish Kothari and R.V. Anuradha, *Biodiversity and Intellectual Property Rights: Can the Two Co-exist?*, 2(2) Journal Of International Wildlife Law & Policy 204, 204-223 (1999).

These guidelines intend to assist the development of nations to ensure transparency in the framework that allows access to the genetic process and its benefits, fairly and equitably. This is supported by the access and benefit sharing (ABS) procedures, as per Article 15[83] of the Convention[84]. However, these guidelines are voluntary and not mandatory. These guidelines were prepared with the view of ensuring their ease of use, acceptability, flexibility, practicality, and evolutionary approach[85].

Bonn guidelines have two major aims, such as being a guide to countries to set up their own national legislative, administrative, and policies for access and benefit sharing, and assisting the parties in the negotiation of mutually agreed terms (MAT). These guidelines are for users and providers of resources related to genetics on two levels. Firstly, as governments, develop their national access and benefit-sharing measures, the second level is institutions and individuals, who negotiate access and benefit-sharing agreements such as prior informed consent (PIC)[86] and MAT.

Bonn guidelines have 12 objectives, which are:-

"(a) To contribute to the conservation and sustainable use of biological diversity; Bonn Gu*idelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of Their Utilization*

83 Convention on Biological Diversity, Article 15.

84 Convention on Biological Diversity, https://www.cbd.int/abs/infokit/revised/web/factsheet-bonn-en.pdf (last visited Aug 18, 2022).

85 Convention on Biological Diversity, https://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf (last visited Aug 18, 2022).

86 *Id*. at 26.

(b) To provide Parties and stakeholders with a transparent framework to facilitate access to genetic resources and ensure fair and equitable sharing of benefits;

(c) To provide guidance to Parties in the development of access and benefit-sharing regimes;

(d) To inform the practices and approaches of stakeholders (users and providers) in access and benefit-sharing arrangements;

(e) To provide capacity-building to guarantee the effective negotiation and implementation of access and benefit-sharing arrangements, especially to developing countries, in particular, least developed countries and small island developing States among them;

(f) To promote awareness of the implementation of relevant provisions of the Convention on Biological Diversity;

(g) To promote the adequate and effective transfer of appropriate technology to providing Parties, especially developing countries, in particular, least developed countries and small island developing States among them, stakeholders and indigenous and local communities;

(h) To promote the provision of necessary financial resources to providing countries that are developing countries, in particular, least developed countries and small island developing States among them, or countries with economies in transition to contribute to the achievement of the objectives mentioned above;

(i) To strengthen the clearing-house mechanism as a mechanism for cooperation among Parties in access and benefit-sharing;

(j) To contribute to the development by Parties of mechanisms and access and benefit-sharing regimes that recognize the protection of traditional knowledge, innovations, and practices of indigenous and local communities, in accordance with domestic laws and relevant international instruments;

(k) To contribute to poverty alleviation and be supportive of the realization of human food security, health, and cultural integrity, especially in developing countries, in particular, least developed countries and Small Island developing States among them;

(l) Taxonomic research, as specified in the Global Taxonomy Initiative, should not be prevented, and providers should facilitate the acquisition of material for systematic use and users should make available all information associated with the specimens thus obtained"[87].

These guidelines lay down various responsibilities and obligations to the parties and stakeholders, who could be either users or providers or both, such as, "ensure that all stakeholders take into consideration the environmental consequences of the access activities"[88] while users must "respond to requests for information from indigenous and local communities" and providers[89] should "strive to avoid the imposition of arbitrary restrictions on access to genetic resources", etc. Various such responsibilities are laid down which must be adhered to by the parties. In the case of PIC, there are no fixed deadlines set, however, it is mentioned that the granting of access, and all related decisions must happen "within a reasonable period[90]" and should be based on specific use, for which the consent is granted.

The process and procedure for obtaining prior informed consent are also mentioned within the guidelines. The procedure for obtaining PIC, states that an application for access should be given, with required information such as:-

87 *Id*. at 26.

88 *Id*. at 26.

89 *Id*. at 26.

90 *Id*. at 26.

"(a) Legal entity and affil*iation of the applicant and/or collector and contact person when the applicant is an institution;*

(b) Type and quantity of genetic resources to which access is sought;

(c) Starting date and duration of the activity;

(d) Geographical prospecting area;

(e) Evaluation of how the access activity may impact on conservation and sustainable use of biodiversity, to determine the relative costs and benefits of granting access;

(f) Accurate information regarding intended use (e.g.: taxonomy, collection, research, and commercialization);

(g) Identification of where the research and development will take place;

(h) Information on how the research and development is to be carried out;

(i) Identification of local bodies for collaboration in research and development;

(j) Possible third-party involvement;

(k) Purpose of the collection, research, and expected results;

(l) Kinds/types of benefits that could come from obtaining access to the resource, including benefits from derivatives and products arising from the commercial and other utilization of the genetic resource;

(m) Indication of benefit-sharing arrangements;

*(n) Budge*t;

(o) Treatment of confidential information"[91].

91 *Id*. at 26.

Similarly, the guidelines elaborate on mutually agreed terms (MAT), wherein, it even discusses the type, timing, and distribution of benefits. Which could be near-term, medium-term, and long-term benefits. There are various other requirements and parameters to be followed to meet initiate MAT. The basic requirements for MAT are as follows:-

(a) Legal certainty and clarity;

(b) Minimization of transaction costs, by, for example:

(i) Establishing and promoting awareness of the Government's and relevant stakeholders' requirements for prior informed consent and contractual arrangements;

(ii) Ensuring awareness of existing mechanisms for applying for access, entering into arrangements, and ensuring the sharing of benefits;

(iii) Developing framework agreements, under which repeat access under expedited arrangements can be made;

(iv) Developing standardized material transfer agreements and benefit-sharing arrangements for similar resources and similar uses (see appendix I for suggested elements of such an agreement);

Towards the end of the guidelines, it talks about other provisions, such as Incentives, Accountability in implementing access and benefit-sharing arrangements, national monitoring and reporting, means of verification, settlement of disputes, and remedies.[92]

92 Dr. Konstantia Koutouki and Katharina Rogalla von Bieberstein, *The Nagoya Protocol: Sustainable Access and Benefits-Sharing for Indigenous and Local Communities*, 13(3) VERMONT JOURNAL OF ENVIRONMENTAL LAW 513, 513-535 (2012).

4.5 ACCESS AND BENEFIT SHARING

The Sustainable Development Goals include targets SDG-2 pertaining to zero hunger and SDG-15 about life on land. The use of genetic resources and associated traditional knowledge results in the promotion of access to fair and equitable sharing of benefits and is a step toward achieving those targets.

The agreed-upon indicator for SDG goal 15.6 records the number of nations that have developed administrative policy, and legal frameworks to promote just and equitable benefit distribution. However, both policymakers and stakeholders are aware that creating legal or policy frameworks for access and benefit-sharing (ABS) is one thing; putting those frameworks into practice is entirely different. Many nations now have laws or policy measures governing Access and Benefit Sharing. However, as the data from the ABS Clearinghouse indicates, many more may still be creating or making adjustments to them. The data indicate that implementation, and specifically the actual issue of permits, may present much greater difficulties. Only six countries had registered less than 100 ABS licenses or their equivalents with the ABS Clearinghouse as of 1 October 2017. The UN Food and Agriculture Organization (FAO) approved the Plant Treaty in 2001, which addresses ABS for the majority of plant genetic resources. The Plant Treaty, which came into effect more than ten years before the Nagoya Protocol, makes it easier to access the genetic materials of the 64 crops included in the Multilateral System for research, breeding, and agricultural training. The Treaty does not, however, address ABS for other genetic resources for food and agriculture (GRFA), such as genetic resources from livestock, forests, or aquatic life.

It is commonly accepted that Genetic Resources for Food and Agriculture (GRFA) differ from "wild" biodiversity in

several ways. The Nagoya Protocol explicitly acknowledges the special nature of agricultural biodiversity, its distinctive features, and problems requiring different solutions. The Protocol also mandates that the Contracting Parties take into account the importance of genetic resources for food and agriculture and their special role for food security in the development and implementation of its access and benefit-sharing legislation or regulatory requirements. It is indeed a complex challenge that few may have fully appreciated in 2010 when the Protocol was adopted. Elements to Facilitate Domestic Implementation of Access and Benefit-Sharing for Different Subsector of Genetic Resources for Food and Agriculture were created in 2013 after the FAO's Commission on Genetic Resources for Food and Agriculture (Commission) decided to take on this task. After consulting with the Commission's intergovernmental technical working groups on an animal, forest, and plant genetic resources, the Commission established an expert group on ABS for GRFA, which presented a preliminary draft. The outcome of this process, the ABS Elements, was welcomed by the Commission and the FAO Conference in 2015. These elements aim to help governments considering developing, adapting, or implementing ABS measures take into account the significance of GRFA, their unique role in ensuring food security, and the unique characteristics of the various GRFA subsectors, while complying, as appropriate, with international ABS instruments. In 2018, the Commission will focus more on ABS. To increase the understanding of Commission Members, their various authorities participating in ABS, and other stakeholders, the Commission decided to keep working on ABS for GRFA. To contribute to the achievement of SDG targets 2.5 and 15.6, the work should help Members reflect in their ABS measures on the significance and unique role of GRFA for food security as well as the unique characteristics of the various subsectors. It should also make it possible

for the subsectors to participate meaningfully and foster communication in pertinent processes at local, national, regional, and international levels.[93]

4.6 NAGOYA PROTOCOL ON ACCESS TO GENETIC RESOURCES AND BENEFIT-SHARING

At its 10th conference, held on October 29, 2010, in Nagoya, Japan, the Conference of the Parties to the Convention on Biological Diversity endorsed the Nagoya Protocol. It became effective on October 12, 2014. The European Union was one among the 123 Parties as of April 2020, although numerous States and territories with sizable indigenous populations and frequently abundant biodiversity were left out (Australia, Brazil, Canada, Colombia, Greenland, New Zealand, the Russian Federation, USA, inter alia). Except for the USA and the Holy See, all non-Parties to the NP are nevertheless subject to the CBD's more general rules for ABS for the sustainable use of biodiversity, including articles 1, 8, and 15. Along with several national and regional initiatives, the CBD Secretariat has established an ABS clearing house that helps users and suppliers put ABS provisions into practice. Aspects of NP implementation that were not resolved during initial negotiation are currently the topic of ongoing discussion and definition among Parties due to its recent entrance into force. A process for assessment and review is established in Article 31[94] to determine the efficacy of the NP. An indicator framework and benchmarks were devised by the initial review, which was accepted in Decision NP-3/1 in November 2018, to gauge progress in subsequent assessments. By July 2018, 57 Parties

93 *Why Biodiversity Matters: Mapping the Linkages between Biodiversity and the SDG's*, INTERNATIONAL INSTITUTE FOR SUSTAINABLE DEVELOPMENT (September 4, 2022, 5:20 PM), https://sdg.iisd.org/commentary/policy-briefs/why-biodiversity-matters-mapping-the-linkages-between-biodiversity-and-the-sdgs/.

94 The Nagoya Protocol, Article 31.

had established one or more competent national authorities, 44 were revising or developing new procedures to implement the NP, and 75 Parties had legislative, administrative, or policy measures on ABS in place (including many that were in place before the adoption of the NP). To execute fair and equitable benefit-sharing on the genetic resources owned by indigenous people and local communities (IPLCs), forty-one Parties had legal, administrative, or policy measures in place, and forty-two had measures on related traditional knowledge. 23 parties, or 47% of the Parties where IPLCs have the right to offer access to genetic resources, adopted steps to ensure prior informed consent and IPLC engagement. 21 parties, or 43% of Parties with IPLCs in their nation, have taken action to ensure that traditional knowledge related to genetic resources is accessed with prior informed consent and IPLC participation under mutually agreed-upon circumstances.

In order to deal with situations involving genetic resources and traditional knowledge connected to genetic resources that occur in transboundary settings or for which it is not possible to grant or obtain prior informed consent, Article 10 of the NP[95] envisions a global multilateral benefit-sharing mechanism. In accordance with Decision NP-3/13, which was adopted at the third meeting of the Parties, a study is to be commissioned to (a) identify specific cases, if any, that cannot be resolved through a bilateral approach; (b) if such cases are found, options for resolving them, including a potential global multilateral benefit-sharing mechanism.[96] While from a scientific standpoint these difficulties appear to be significant, Parties view these as being "special cases" and not significant in the grand scheme of things. Some nations stated that further

95 The Nagoya Protocol, Article 10.

96 The Convention on Biological Diversity, Decision Adopted by the Parties to the Nagoya protocol on access and benefit sharing (Nov. 30, 2018), https://www.cbd.int/doc/decisions/np-mop-03/np-mop-03-dec-13-en.pdf.

understanding on this topic was necessary because no instances of access to genetic resources or related traditional knowledge that was present on the soil of more than one nation had yet been discovered.[97] Implementing the IPLC-related provisions is one of the major issues mentioned in decision NP-3/1. Building the ability of Parties connected to IPLCs and of IPLCs concerning ABS is one of the recommendations. This may involve building institutions within and among IPLCs (e.g., through community protocols), supporting IPLCs in developing minimum standards for mutually acceptable terms, and supporting IPLCs in developing model contractual clauses, among other things. National mechanisms for IPLC participation in the NP may also be included.[98]

4.7 PROTECTION OF TRADITIONAL KNOWLEDGE UNDER CBD

Indigenous peoples, local communities, and their traditional knowledge play a critical role in the protection of biodiversity around the world, as stipulated in the CBD and its Protocols. Indigenous peoples and local communities are major stakeholders in the preservation and restoration of the majority of the world's critical ecosystems and genetic resources since they reside in those regions. Significantly, their traditional sustainable management techniques aid in the preservation and defense of biodiversity. Traditional knowledge is defined as the wisdom, discoveries, and customs of indigenous and local groups that have been passed down from centuries for useful purposes such as the preservation and sustainable exploitation of biodiversity. These in-depth and distinctive insights into local environments are an essential part of the lives of indigenous

97 Convention on Biological Diversity, Assessment And Review of the Effectiveness of Nagoya Protocol (May 28, 2018), https://www.cbd.int/doc/c/15ec/ada6/2e4895fca3076383e4b74164/sbi-02-03-en.pdf.

98 *Id*. at 38.

peoples and local communities, but they can also help in the creation of effective biodiversity policies and initiatives that will significantly advance local, national, and international conservation efforts. Article 8(j) of CBD and accompanying provisions recognize the value of traditional knowledge. The provision requires Contracting parties to protect, preserve, and maintain traditional knowledge that is important for the conservation and sustainable use of the biological variety, subject to applicable national laws. Parties are also urged to support the widespread application of traditional knowledge while guaranteeing the equal distribution of its benefits. Traditional knowledge and customary sustainable use of biodiversity are also emphasized in Aichi Biodiversity Target 18 as integral components of sustainable development and conservation. The preservation of traditional knowledge and biodiversity often go hand in hand and including indigenous people and local communities in decision-making and policy planning is crucial for everyone's benefit.[99]

Article 8(j) states "each contracting Party shall, as far as possible and as appropriate: Subject to national legislation, respect, preserve, and maintain knowledge, innovations, and practices of indigenous and local communities embodying traditional lifestyles relevant to the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations, and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge innovations and practices"[100].

99 Target 18: Traditional Knowledge and customary sustainable use, LOCAL BIODIVERSITY OUTLOOKS 2 (Sept. 7, 2022, 7:53 PM), https://lbo2.localbiodiversityoutlooks.net/target-18-traditional-knowledge-and-customary-sustainable-use/.

100 Convention of Biological Diversity, Article 8(j).

Local Biodiversity Outlooks 2 (LBO-2) was introduced in September 2020. Over 50 indigenous and local authors, as well as local communities, contributed to LBO-2, a significant work of joint study and analysis. It covers indigenous and local perspectives on the transformative changes necessary to realize the vision of a world living in harmony with nature and underscores the crucial roles IPLCs play in maintaining and increasing biological and cultural diversity.[101]

Biodiversity's richness was mirrored in taxonomy, culture, and literature, as well as historical and traditional knowledge. Flora, fauna, ecosystems, agriculture, culture, and topology are the five disciplines in which cultural elements of biodiversity have been studied. For decades, indigenous peoples around the world have coexisted with their traditional territories, surviving off the land and its resources while protecting the ecosystem's integrity. Sustainability is a must for indigenous communities, as their livelihoods would be jeopardized without it. Traditional ecological knowledge and practices have proven to be so successful that, while accounting for less than 22% of the world's land area, indigenous lands are home to nearly 80% of the world's biodiversity[102]. As a result, the usefulness of Traditional Ecological Knowledge (TEK) in supporting sustainable land management and scientific discovery, as well as providing environmental data to help climate adaptation measures, is becoming more widely recognized. The management and maintenance of their lands have been committed to indigenous peoples. The Indigenous Protected Areas program has provided major economic and cultural advantages to indigenous people in addition to functioning

101 CONVENTION ON BIOLOGICAL DIVERSITY, https://www.cbd.int/gbo5/local-biodiversity-outlooks-2 (last visited Aug. 22, 2022).

102 SCIENTIFIC AMERICAN, https://blogs.scientificamerican.com/observations/indigenous-knowledge-can-help-solve-the-biodiversity-crisis/ (last visited Aug. 22, 2022).

as a crucial component of Australia's biodiversity preservation strategy[103]. The development of effective techniques for managing and protecting natural ecosystems is becoming increasingly critical in light of the developing biodiversity issue. Environmental conservation initiatives and climate change action on a national and global scale have mainly failed. Indigenous peoples' participation in environmental management provides an essential opportunity to learn from years of meticulous observation while also confirming indigenous peoples' entitlement to use, access, and act as stewards of their native lands. A rising number of collaborative efforts aimed at incorporating viewpoints and knowledge of indigenous people to better environmental conservation and management are strengthening environmental governance. Traditional knowledge is essential for the long-term sustainability of natural resources such as forests, water, and agroecosystems in landscapes ranging from households to farms, villages, commons, and wilderness.[104]

Due to a slew of risks posed by unprecedented growth and consumerism, humanity faces an unprecedented problem of depleting natural resources and deteriorating ecosystem services. The biodiversity and long-term viability of vital ecological processes and life support systems in human-dominated ecosystems are also in jeopardy at all scales. Global change, biodiversity extinctions, and disturbance of ecological processes are all signs of human dominance of the globe. Environmental issues and unequal access to resources result in human suffering and risks to the livelihood security of the

103 Gadgil Madhav, *Indigenous Knowledge for Biodiversity Conservation*, 22 SPRINGER 151, 151-156 (1993).

104 Deep Narayan Pandey, Traditional Knowledge Systems for Biodiversity Conservation, INFINITY FOUNDATION (Sept. 6, 2022, 10:58 am), https://www.infinityfoundation.com/mandala/t_es/t_es_pande_conserve.htm.

people. Several underlying causes affect biodiversity, including population growth, demographics, trade pressures, political instability, perverse incentives, economic performance, poverty, corruption, lack of law enforcement, poor protection standards, lack of awareness, lack of information, and a clear articulation of the rights and obligations of the people and the government respectively.

Traditional Knowledge (TK) is a fundamental piece of the personality of most networks. It is a central part of the social and actual environment of the public. Endeavors to control TK for mechanical or business gain can add to the misappropriation of TK and can hurt the privileges of its real overseers. The safeguarding, security, and advancement of TK-based developments and practices of neighborhood networks are of specific significance to non-industrial nations. Their rich information on TK and biodiversity assumes a basic part in medical care, food insurance, local area, religion, character, environment, exchange, and improvement. However, this significant resource is in danger. Safeguarding of classified customary information; Protection of regular data is significant in different regards; the shortfall of clear administrative approach structures for the preservation of TK in agricultural nations makes a hole for created and industrialized countries to misuse the TK. Since the TK consolidates data and expertise on a wide scope of issues, including customary medications, and creative and social plans, their legitimate security is critical to the support of the conventional practices of Indigenous people groups. A right of social legacy should be ensured and shared even-handedly considering a legitimate concern for every individual. The need to get TK is more significant today. Neither public enactment nor worldwide programmes recognize the interests of native people groups, they are in any case subject to native standard law.

The issuance of licenses on non-patentable innovation, considering current clinical information in the created world or on a little distinction of that information is proving to be worrisome. A portion of the models show the bio-theft of customary information, and, in large numbers of these cases, the nation has to battle for the repudiation of the fake licenses, the disavowal of which may not be a reasonable choice for all licenses dependent on conventional information, since it includes gigantic expenses and time. The latest release of the Draft Treaty was shipped off to the Committee at its 39th Session on 22 March 2019 and was revised between 17th to 21st June 2019. The Preamble perceives the right of native and nearby networks to "keep up with, control, ensure and foster their licensed innovation over their social legacy, including their customary information; The autonomy, social character, and good standards of ordinary information holders; recognizes the requirement for new laws and capabilities on the arrangement of sufficient and worthy means for the insurance of existing data advantages, considering variations in public law frameworks.

- Misappropriated customary information.
- Uncompensated customary information use; and
- Error giving of protected innovation rights over custom.

The degree of insurance insists the accompanying standards: Member States will cling to the standard laws and practices of TK holders; the Member States shall make a public move to guarantee that TK holders have total and aggregate right to safeguard, manage, use, make, permit or deny admittance to and use/utilization of their conventional information; and get a reasonable and fair portion of the advantages got from its utilization and these states shall take measures to guarantee

the trustworthiness of customary information or to secure the interests (monetary and moral)of TK holders.

The Convention on Biological Diversity (CBD) and The Nagoya Protocol on admittance to hereditary assets and the reasonable and fair sharing of advantages emerging from their usage to the CBD (Nagoya Protocol) Article 8(j) spreads out an overall obligation on expecting States to "esteem, secure, preserve and empower mindfulness" of native networks and to "support their more extensive use with the consent and cooperation of the holders of that mindfulness. The Convention on Biological Diversity likewise expects States to "advance an equivalent appropriation of advantages coming about because of the utilization of TK". The Nagoya Protocol tends to the conventional information on hereditary qualities assets with access, advantage sharing, and consistency arrangements. It likewise manages hereditary freedoms where native and neighborhood populaces have the chance to give admittance to them. Contracting Parties will take measures to guarantee earlier educated assent and reasonable and fair sharing of advantages for these networks, remembering the laws and methodology of the Community just as the standard use and trade. There are fears that this information is misused and held by outsiders without the express assent of TK holders and that none, assuming any, of the benefits acquired are spoken with the social orders where the information creates and exists. Such issues have driven TK to the focal point of the global plan, inciting energetic conversation on the best way to monitor, shield, further develop and economically use TK. Reporting and digitizing TK-related subtleties as a TKDL (Traditional Knowledge Digital Library) keeps on being a significant method of securing TK and staying away from its misappropriation by outsiders. Biodiversity is the wide range of types of life on earth, including the various plants, creatures, miniature organic entities, the qualities they contain, and the

environment they structure. It alludes to hereditary variety, biological system variety, and species variety (number of species) inside a space, biome, or planet. Comparative with the scope of living spaces, biotic networks, and biological cycles in the biosphere, biodiversity is fundamental in various ways including advancing the tasteful worth of the common habitat, commitment to our material prosperity through utilitarian qualities by giving food, grain, fuel, lumber, and medication. Biodiversity is the existence emotionally supportive network. Organic entities rely upon it for the air to inhale, the food to eat, and the water to drink. Wetlands channel poisons from water, trees, and plants to lessen a worldwide temperature alteration by retaining carbon, and microbes and growths separate natural material and prepare the dirt. It has been experimentally shown that local species' extravagance is connected to the soundness of environments, just like the personal satisfaction of people. The environment administrations of biodiversity are kept up with through the development and security of soil, preservation,- and cleansing of water, keeping up with hydrological cycles, the guideline of biochemical cycles, retention and breakdown of contaminations and waste materials through decay, assurance, and guideline of the normal world environment. Despite the advantages of biodiversity, the present dangers to species and environments are expanding step by step at a disturbing rate and, every one of them is brought about by human botch of natural assets frequently invigorated by rash financial approaches, contamination, and flawed establishments notwithstanding environmental change. Biodiversity additionally incorporates hereditary contrasts inside every species - for instance, between assortments of harvests and types of domesticated animals. Chromosomes, qualities, and DNA-the structure squares of life decide the uniqueness of every person and every species. One more element of biodiversity is the assortment of biological systems, for example, those that happen in deserts,

woods, wetlands, mountains, lakes, streams, and farming scenes.

4.8 INTERNATIONAL REGULATION ON TRADITIONAL KNOWLEDGE

According to the Draft Agenda of the 30th World Intellectual Property Organization prepared by the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (WIPO Committee)[105], the definition of 'traditional knowledge has been expanded over the prior meaning of traditional knowledge, Indigenous peoples' or local communities' national and social identities are included in the proposed definition's discussion of the development, promotion, and preservation of traditional knowledge.[106] It is defined as follows: "*Traditional knowledge is the knowledge that is created, maintained, and developed by indigenous [peoples], local communities, [other beneficiaries], and that is linked with, or is an integral part of, the national or social identity and/or cultural heritage of indigenous [peoples], local communities; that is transmitted between or from generation to generation, whether consecutively or not; which subsists in codified, oral, or other forms; and which may be dynamic and evolving, and may take the form of know-how, skills, innovations, practices, teachings or learnings*".[107]

According to the 'Glossary of Key Terms Related to Intellectual Property and Genetic Resources, Traditional

105 Secretariat, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, (2018), https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_38/wipo_grtkf_ic_38_4.pdf.

106 Secretariat, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, (2014), https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_28/wipo_grtkf_ic_28_5.pdf.

107 The Protection of Traditional Knowledge: Draft Articles, Art.1.

Knowledge and Traditional Cultural Expressions[108], it is important to think about traditional knowledge both broadly and specifically. Traditional knowledge refers to knowledge systems, customs, and intellectual and intangible cultural heritage of traditional societies, including indigenous and local communities. When used in its strictest definition, the term "traditional knowledge" refers to knowledge as such, specifically information that is the result of intellectual effort in a traditional environment, and it includes "know-how, practices, skills, and innovations.[109] Despite the suggested definitions in the aforementioned publications, the experts in the analytical report for the 38th session of the WIPO Committee acknowledge that "there is no universally recognized definition of traditional knowledge" as such. The Convention on Biological Diversity's Article 8(j), the Nagoya Protocol's Article 7[110] on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Resulting from Their Utilization (Nagoya Protocol), the International Treaty on Plant Genetic Resources for Food and Agriculture's Article 9.2(a)[111], and other international agreements all refer to related concepts. Indigenous people and local communities suffer from knowledge misappropriation and encounter challenges for its protection, while nations and international organizations debate terminology suitable to traditional knowledge. Today,

108 Secretariat, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, (2018), https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_38/wipo_grtkf_ic_38_7.pdf.

109 World Intellectual Property Organization, *Intellectual Property Needs and Expectations of Traditional Knowledge Holders*, WIPO Report on Fact-Finding Missions on Intellectual Property and Traditional Knowledge, 2001, https://www.wipo.int/edocs/pubdocs/en/tk/768/wipo_pub_768.pdf.

110 The Nagoya Protocol, Article 7.

111 International Treaty on Plant Genetic Resources for Food and Agriculture, Article 9.2(a).

a sufficient number of international agreements—including the Convention on Biological Diversity, the Nagoya Protocol, the UNESCO Conventions, the UN Convention to Combat Desertification, the World Health Organization Primary Health Care Declaration of Alma Ata, the International Treaty on Plant Genetic Resources for Food and Agriculture, etc.—deal with various aspects of conservation, preservation, and safeguarding traditional knowledge within their particular policy contexts. The development of a single international instrument to protect traditional knowledge is still a challenging process because not all States are signatories to the aforementioned agreements, and some States do not have their conceptual policy on traditional knowledge issues. Cooperation at the regional level is essential to advancing international solutions for traditional knowledge protection, as was done in the African States with the approval of the Swakopmund Protocol.[112]

4.9 TRIPS ARTICLE 27

The TRIPS Agreement is regarded as a comprehensive new framework defining norms of intellectual property protection and addresses the protection of intellectual property in trade-related industries to a major extent. Additionally, the TRIPS Agreement is notable for being the first global agreement addressing all forms of intellectual property with numerous substantive provisions.

World Trade Organization (WTO) states that there are three main features of the agreement, namely, standards,

112 Zhyldyz Tegizbekova, *Challenges of traditional knowledge protection in the central asian states: perspective and experience of the kyrgyz republic*, WIP0-WTO Colloquium Papers 103, 103-117 (2018), https://www.wto.org/english/tratop_e/trips_e/colloquium_papers_e/2018/chapter_8_2018_e.pdf.

enforcement, and dispute settlement[113]. In each area of intellectual property covered by TRIPS, the agreement sets standards by making it obligatory to the main conventions related to IP, like WIPO, the Paris convention for the protection of industrial property, and the Berne Convention for the protection of literary and Artistic Works. Enforcement deals with the domestic procedures and remedies related to intellectual property rights, thus TRIPS lays down certain general provisions and rules.

The TRIPS Agreement must be administered and operated under the supervision of the TRIPS Council. The TRIPS Council provides a venue for member discussion on significant issues during its regular meetings. The TRIPS Council acts as a venue for discussions regarding a multilateral system of notification and registration of geographical indications (GIs) for wines and spirits during its special sessions. The TRIPS Council uses transparency tools to oversee the TRIPS Agreement's functioning and to foster an awareness of the member countries' intellectual property laws and policies. These procedures include notifications from WTO members, answers to questionnaires, assessments of implementing laws, summaries of reports on technical support and technology transfer, and contact points.

The TRIPS Agreement's Article 27 is still considered to be its most contested clause. It outlines patentable subject matter in this provision.

Article 27 of the TRIPS agreement states that:-

"1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are

113 WORLD TRADE ORGANIZATION, https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (last visited on Aug 25, 2022).

new, involve an inventive step, and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70, and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology, and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect public order or morality, including to protect human, animal, or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

(a) Diagnostic, therapeutic, and surgical methods for the treatment of humans or animals;

(b) Plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system, or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the WTO Agreement came into force"[114].

One of the seven intellectual property rights covered by the TRIPS Agreement is the patent. It mandates that all innovations, regardless of whether they are products or processes, in all branches of technology be eligible for patent protection, subject to the usual standards of originality, creativity, and industrial usefulness. Additionally, it calls for

114 WORLD TRADE ORGANIZATION, https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm (last visited on Aug 25, 2022).

the enjoyment of patent rights without regard to the location of the invention or whether the goods are made locally or elsewhere. Patents and patent rights have a geographical scope, meaning that only the territory of the country in which they were awarded may be used to enforce them. The fundamental principle of patentability stated in Article 27 has a few common exceptions. One is for innovations that go against morals or the public order. This also includes innovations that are harmful to the health or well-being of people, animals, plants, or the environment[115]. The utilization of this exemption is contingent on the need that the invention's economic exploitation be stopped as well. Second, Members may exclude diagnostic, medicinal, and surgical procedures for the treatment of people or animals from patentability.

The year 1999 was the deadline for a review of clause (b) of paragraph 3 of Article 27 of the TRIPS Agreement. The following is what the provision says: "*Member may also exclude the following from patentability: (b) Plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. Members must, however, make provisions for the preservation of plant varieties, whether via the use of patents, a strong sui generis system, or any combination of the two*"[116]. Four years following the WTO Agreement came into effect, the terms of this subparagraph must be reviewed. The examination could include three separate but related aspects of Article 27.3.

115 DEPARTMENT OF COMMERCE, https://commerce.gov.in/international-trade/india-and-world-trade-organization-wto/indian-submissions-in-wto/trade-related-aspects-of-intellectual-property-rightstrips/review-of-the-provisions-of-article-27-3-b-communication-from-india/ (last visited on Aug. 25, 2022)

116 *Id.* at 55.

By asking Members to contribute information on how the issues covered by this Article were currently handled in their national legislation, the TRIPS Council started an information-gathering process. Members from developed nations were required to disclose this information since they are already required to apply this clause, while others could do so using their best efforts. Since the majority of Members had not yet assumed their duties under this clause, the information obtained was insufficient. The material provided was also lacking because it mostly focused on how industrialized nations were implementing Article 27.3 (b) in their legal systems.[117]

The TRIPS Agreement mandates that Member nations make patents accessible for all inventions, including goods and processes, across all technological sectors, without discrimination, when put to the standard novelty tests, creativity, and commercial viability. In addition, a requirement that patent rights and availability exist delightful without regard to where it is located if a product is made locally or imported[118].

Any nation that exempts plant kinds from patent protection, nevertheless, must have a strong "sui generic" mechanism of defense. In addition, the entire clause is up for review four years after the Agreement enters into force. A product patent must grant the exclusive right to make, use, offer for sale, sell, and import the product for these purposes. Patent protection for processes must grant rights to both the things produced directly via the method as well as their usage. According to Article 27.3(b), plant varieties may be protected by patents, an effective sui generis system,

117 World Trade Organization, Module XI Current TRIPS Issues, (Sept. 8, 8:44 PM) https://www.wto.org/english/tratop_e/trips_e/ta_docs_e/modules11_e.pdf.

118 *Id.* at 55.

or any combination of the two. Therefore, it is evident from a simple reading of the text that governments have a variety of choices for protecting plant species, patents being only one of them. Governments have been allowed enough leeway to create a system that effectively protects plant species. It goes without saying that when creating such a system, a nation may be expected to consider its own public policy goals, such as those related to development and technology (which are expressly acknowledged in the TRIPS Agreement), as well as the commitments it has made in the context of the TRIPS Agreement and other international agreements. Given this, it is appropriate for the TRIPS Agreement to let the Member in question determine the mechanism for ensuring the protection of plant varieties in line with its particular legal framework and customs[119].

It is believed that the UPOV Convention offers a single set of models. The UPOV Convention was created to safeguard the rights of plant breeders in developed nations; it is unrelated to the demands of consumers in underdeveloped nations. The UPOV Act of 1978 does, however, recognize farmers' rights to resow farm-saved seeds. The 1983 International Undertaking on Genetic Resources for Food and Agriculture is now being revised by the FAO Commission on Genetic Resources for Food and Agriculture. That could offer an additional set of models. Some national or regional legislation that combines the preservation of biological diversity and plant variety protection might potentially serve as good models. Thus, there are several approaches to creating a successful sui generis system of plant variety preservation. There is no reason why nations cannot

119 Alagappa University, *Intellectual Property Rights And The Impact Of Trips Agreement With Reference To Indian Patent Law*, (2007), https://niti.gov.in/planningcommission.gov.in/docs/reports/sereport/ser/ser_alla.pdf.

create their models, which the TRIPS Agreement recognizes as functional sui generis systems[120].

During the study, there may be some general recommendations for developing a sui generis system that complies with the TRIPS Agreement while also taking environmental considerations into account[121]. One recommendation would be to make sure that carrying out duties under the Convention on Biological Diversity regarding preservation and benefit sharing is not viewed as eroding the system's efficacy. Another is to fully take into account the ethical and environmental issues raised by the above-discussed intellectual property rights on living things. Another is to make sure that any system that is seen to be efficient also fosters the security of both food and health. It would be crucial to make sure that maintaining farmers' rights wouldn't be seen as eroding the system's efficacy. Finally, it may be better to let each Member's legal system and practice develop as to what constitutes a successful sui generis system.

Furthermore, Lifeform patenting may have at least two aspects. The first ethical concern is the potential extension of private ownership to lifeforms. The second component is how IPRs are used in the industrialized world and whether they are suitable given the greater dimension of knowledge rights, including ownership, use, transfer, and dissemination. Only formal knowledge systems are recognized by international IPR regimes. Unofficial systems, such as the shrutis and smritis in Indian tradition and traditional remedies everywhere in the globe, receive little attention. Systems that fail to handle this

120 *Id.* at 59.

121 *Id. at 59.*

problem might have serious negative effects on humanity, some even claiming that they could cause our extinction.[122]

There is a need to reconsider the necessity of granting patents on lifeforms wherever in the world. Until such systems are in place, it may be advisable to:-

- Exclude all biological forms from patents; if this is not achievable, then
- Substantially derived items and methods from traditional/indigenous knowledge from the scope of patents, or at least
- To guarantee a fair distribution of benefits, insist on disclosing the place of origin of the biological resource and any related knowledge and obtaining the country's permission.

As lifeforms are of various forms and sizes, regarding microorganisms, the conversation would center on the range of microorganisms' patentability as well as non-biological and microbiological processes. The international definition of the range of patentable microorganisms and microbiological processes has numerous undefined regions.[123] In these negotiations, the WTO may consider different aspects of this. The first is the distinction between innovation and discovery; only the latter should be subject to patent protection. According to Article 27.1, all innovations are eligible for patent protection as long as they are original, creative, and have the potential for industrial use. Thus, before a patent may

122 Tamana Sharifi, Critical Analysis of Patent in Life Forms, LEGAL SERVICE INDIA (Sept. 9, 2022, 10:40 AM), https://www.legalserviceindia.com/legal/article-3052-critical-analysis-of-patent-on-the-life-forms.html.

123 Dr Mike Adcock and Dr Margaret Llewelyn, Micro-organisms, Definitions and Options under TRIPS, INSTITUTE OF AGRICULTURE AND TRADE POLICY (Sept. 9, 2022, 11:48 AM) https://www.iatp.org/sites/default/files/Micro-organisms_Definitions_and_Options_under_.htm.

be granted, the requirements of invention, non-obviousness, and usefulness must be met. The final aspect is how the Article addresses microorganisms. According to the Article, both non-biological and microbiological procedures are patentable. This suggests that a microorganism that is a synthetic, genetically modified bacteria may pass the patentability test.[124] The topic of whether biological substances including genes, plasmids, cosmids, enzymes, and cell lines can be patented is another.

It seems that these won't count as innovations unless there is human involvement or unless they are classified as microorganisms[125]. If the biological substance is also a chemical, as is the case with synthetic enzymes, then it could be possible to patent them as chemicals. It is assumed that since plants and animals are not included, other biological substances would similarly be omitted. So, unless a gene also qualifies as a microorganism that is patentable under national law, it cannot be protected by a patent. On this topic, there are many different national laws. Therefore, the determination of whether microorganisms are patentable should be left to national legislation. The article expressly disallows the creation of plants and animals by fundamentally biological processes. It may be important to remember that some ideas may not be patentable for other reasons listed in the TRIPS Agreement, whether or not they involve microorganisms. These justifications, which include public order, morality, human, animal, or plant life, health, and the environment, are listed in Article 27.2 of the Agreement. As a result, many of the worries about the potential negative effects of patenting

124 Ramkumar Balchandra Nair and Pratap Chandran Ramchandranna, *Patenting of microorganisms: Systems and Concerns*, 16 JOURNAL OF COMMERCIAL BIOTECHNOLOGY 337, 337-347 (2010).

125 Vartika Prasad, Microorganisms And The Indian Patents Scenario, MONDAQ (Sept 9, 2022, 5:28 PM) https://www.mondaq.com/india/patent/900702/microorganisms-and-the-indian-patents-scenario-.

microorganisms can be assuaged by appropriate national legislation that makes use of these exclusions as well as through efficient review of patent applications in this field. This makes it even more important that national policies determine the extent of microorganism patentability.

4.10 UPOV

The Geneva, Switzerland-based International Union for the Protection of New Varieties of Plants (UPOV) is an international organization that was founded in 1961. In order to encourage the creation of novel plant varieties for the benefit of society, UPOV's mission is to offer and advance an efficient system of plant variety protection. Countries and intergovernmental organizations can abide by the UPOV Convention, which offers a unified and uniform intellectual property framework on a global scale[126].

A nation or intergovernmental organization must have a domestic Plant Breeders' Rights (PBR) or Plant Variety Protection (PVP) statute that satisfies the UPOV Convention's minimal standards in order to join. Because plant development requires a lot of time, money, and resources, it is crucial to have a system in place for safeguarding plant types. However, it is simple and quick to replicate plants, often without the breeder's consent or without paying them fairly for their work and investment. A high level of expertise, specific tools, and knowledge are necessary for successful breeding (for example, greenhouses, growth chambers, and laboratories).

A good plant variety can often take several years to breed (7 to 15 years, depending on the species), however not all new variations will find a market. Therefore, by creating a new variety, a breeder is taking a chance, but if it succeeds, farmers

126 APBREBES, https://www.apbrebes.org/content/upov-convention (last visited on Aug 2022).

and society might gain greatly. A UPOV-based PBR/PVP regulation allows breeders to safeguard their varieties in the market, get a return on their investment, and promote further investment in plant development.

The term "right" of the breeder refers to the necessity of the breeder's consent in order to spread the variety for commercial use. The UPOV Convention outlines the actions that call for the breeder's consent when using seeds or other propagating material of a protected variety and, under certain circumstances, when using harvested material (e.g. grain or fruit). Under specific circumstances, UPOV members may also choose to extend protection to goods created directly from collected material[127].

Objective of UPOV

The European plant breeders who founded UPOV saw the necessity for breeders to have access to protected genetic resources in order to generate new variations and sought a way to boost the economic worth of the varieties they had developed. In order to safeguard breeders' inventions while granting open access to such kinds, plant breeders' rights were established. The organization's objective is to "create and advance an efficient system of plant variety preservation with the goal of fostering the production of novel plant varieties, for the benefit of society."

In order to execute plant variety protection (PVP), member nations establish "variety offices" that collect fees for variety testing, as well as additional payments, such as an annual cost for plant variety protection. The UPOV Convention is governed by four Acts, the original 1961 Act,

127 Burghard IIge and Sander Hehanussa, UPOV 91 And Trade Agreements, BOTH ENDS DISCUSSION PAPER (2018) https://www.bothends.org/uploaded_files/document/1LR_UPOV91_brochure_A4.pdf.

and three modifications in 1972, 1978, and 1991, each of which strengthened the protection of breeders' rights.[128]

Members

There are 76 Parties to the different Acts of the Convention as of July 2020: Members of UPOV78 include 17 nations, the majority of which are from the South; UPOV91 includes 57 nations, the European Union, and the African Intellectual Property Organization (OAPI) (current list of UPOV member States). The 1991 Act prohibits entry to the earlier Acts starting in 1996, whereas the 1978 Act permitted new members to the former Acts. Parties have the right to terminate their membership in UPOV at any time; the termination becomes effective at the end of the calendar year following the year in which the Secretary-General receives the notice (Art. 39 of UPOV Convention 1991 Act).

Main Features

A variety is regarded as new under UPOV if it hasn't been sold or otherwise disposed of within a certain amount of time. In other words, rather than defining originality by the fact that the variety did not previously exist, UPOV defines novelty in connection to commercialization.

All four iterations of the UPOV Convention stipulate that a plant variety must meet the "DUS criteria" (new, distinct, uniform, and stable) to qualify for protection.[129]

Newness or novelty: A variety must not have been propagated or harvested from that variety for more than a

128 KATZAROV's MANUAL ON INDUSTRIAL PROPERTY, https://www.katzarov-manual.com/conventions/international-conventions/international-convention-for-the-protection-of-new-varieties-of-plants-upov/summary-of-the-role-and-functions-of-the-union (last visited Aug. 23, 2022).

129 Ju-Kyung Yu and Yong-Suk Chung, Plant Variety Protection: Current Practices and Insights, 12(8) GENES(BASEL) 1, 1-12 (2021).

year to be designated "new" in the nation of filing. For trees and vines, it must have been sold in another UPOV member nation for over 6 years; for all other plant species, it must have been marketed in another UPOV member country for at least 4 years. To prevent breeders from extending the period during which they can profit from protection beyond what is appropriate, a specific time restriction is established for requesting protection in different UPOV member nations. All plant species have a defined time limit of four years, except for trees and vines, which have a six-year time limit. This acknowledges the slower development and reproduction of these kinds of plants.

Distinct: means that it must be easily recognizable from all other varieties that were generally known at the time the application was filed. It is typically essential to conduct many tests where the candidate variety seeking protection is cultivated alongside other comparable reference varieties for comparison reasons in order to prove the "distinctness" of a plant variety. The candidate variety must differ from the other varieties in at least one "clearly discernible" attribute in order to prove that it is in fact "different." Either qualitative (observable) or quantitative (measurable) characteristics can be employed to demonstrate distinctness. It is crucial to stress that in order for a prospective variation to be considered "different," it must be demonstrated that it varies from other varieties in at least one obvious way. The UPOV Office offers instructions on how "distinctiveness" for various plant species and crop types can be evaluated based on phenotypic/morphological characteristics.

Uniformity: In order for a plant variety to qualify for protection, it must also be regarded to be "uniform" (or sufficiently uniform in its pertinent features). This implies that the variety's propagating material must be uniform in appearance, and any variation in the expression of traits or off-types must fall within the allowed tolerances/standards for

that specific species or crop kind. Based on the particular plant species or crop variety being evaluated, the UPOV Office offers information on the allowed limits for differences in the expression of traits or the existence of off-types.

Stability: The plant variety must maintain its important features across several cycles of propagation in order to remain unaltered.

In addition to offering a framework for safeguarding plant breeding-derived variations, the UPOV Convention outlines special concerns for three distinct kinds, including:-

1) Varieties that are "essentially derived" from a protected variety

2) Varieties that are not distinguishable from a protected variety

3) Varieties whose production requires the repeated use of a protected variety

A plant variety that is mostly descended from another variety is referred to as an "essentially derived variety" (EDV), and it preserves the expression of the key traits that originate from the genotype or genotype combination of the original variety from which it was developed. The EDV must also be easily distinguished from the original variety from which it was developed in the expression of its few altered traits. EDVs often originate from selecting natural or induced mutants, a somaclonal variation, or picking specific variant plants via backcross breeding or genetic transformation since they only differ from the original variety in a few important features. To guarantee that the creators of popular and ground-breaking plant varieties are recognised and appropriately paid when another breeder just makes little modifications to that variety, the UPOV has an EDV clause. Any breeder may create an EDV by breeding it with a protected beginning variety

(Variety A) (Variety B). Without the consent of the breeder of the original variety, the breeder of an EDV variety may file for protection of that variety. A breeder of an EDV must, however, come to terms with the breeder of the original variety if they want to market and sell that variety.

According to the "Varieties that are not easily distinguishable" clause, if a breeder safeguards a variety (Variation A) and another variety (Variety B), protected or not, is discovered that is almost identical to Variety A, the breeder's right extends to cover both varieties. The goal is to reduce invention that has been stolen or plagiarised[130].

Those cultivars whose production necessitates the recurrent use of a variety that is protected Hybrids are one type of commercially accessible variety that comes from crossing two or more parental types. According to the UPOV Convention, if a protected variety is routinely utilized to generate another variation, protection must be given to that other variety as well (e.g. the hybrid)[131].

If a breeder meets all the requirements for protection for their new plant variety under the UPOV 1991 Convention, they are given exclusive rights to perform the following activities concerning the propagating material of that protected variety:

(i) Production or reproduction (multiplication),

(ii) Conditioning for propagation,

(iii) Offering for sale,

130 PLANT AND SOIL SCIENCES E-LIBRARY, https://passel2.unl.edu/view/lesson/f798630b33e5/9 (last visited on Aug 23, 2022).

131 Office of the Union-UPOV, Distinctness, Uniformity And Stability (Dus) And Test Guidelines, INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS, (Aug. 23, 2022, 7:35 PM) https://www.upov.int/edocs/mdocs/upov/en/twa_46_prep/twa_46_prep_2.pdf.

(iv) Selling or other marketing,

(v) Exporting,

(vi) Importing,

(vii) Stocking for any of the purposes mentioned in (i) to (vi), above.

The UPOV 1991 Convention contains key exemptions to the "breeder's right" intended to balance interests and ensure benefit sharing. The mandatory exemptions to the breeder's right include:

(i) Acts done privately and for non-commercial purposes,

(ii) Acts done for experimental purposes

(iii) Acts done to breed other varieties

4.11 BENEFITS OF THE UPOV SYSTEM

A report titled "UPOV Report on the Impact of Plant Variety Protection" was issued by the International Union for the Protection of New Varieties of Plants (UPOV) in 2005 and looked at the advantages for various nations that have domestic legislation based on the UPOV framework[132].

The study discovered advancements in four crucial areas:

1. Increase in the number of new varieties: A general pattern showed that the number of new varieties being issued rose with the establishment of a plant protection law based on UPOV. This was true not only for decorative plant species and horticultural crops, but also for common crops including barley, maize, rice, soybeans, and wheat. The overall advantage is that farmers have more options for acquiring new and improved plant types, and consumers have access to a wider variety of food items.

132 *Id*. at 75.

2. Improvement of varieties: Types' performance has improved as compared to earlier varieties, according to a tendency that has been noticed in several nations. In other circumstances, farmers adopted enhanced new kinds at a significantly higher rate. For instance, between 1994 and 2003, in Argentina, the usage of certified seeds climbed from 18% to 82% for wheat varieties and from 35% to 94% for soybean types.

3. Foreign variety introduction: The survey revealed an almost uniform tendency of non-resident foreign breeders requesting protection for their varieties in nations that have recently joined UPOV. The idea of "national treatment and reciprocity" is one of the fundamental components of UPOV membership. As a result, a breeder who resides in one UPOV member nation may request protection in any additional UPOV member country. As a result, farmers have more variety and choices in the plant kinds they may utilize. This encourages the introduction of new plant varieties into several markets and jurisdictions. This helps domestic breeding programs as anybody can conduct research studies and create new kinds using protected types according to the obligatory "experimentation and breeder exemptions."

4. Improvement in domestic breeding: Domestic breeding has generally improved, according to this study, which found that there are more breeding entities and variations available, as well as a wider variety of breeders. In several of the nations where the passage of a UPOV-based regulation resulted in a rise in the number of breeding organizations in both the public and private sectors, certain intriguing phenomena arose. Additionally, it looked like those breeding operations were becoming more diverse, resulting in the release of more novel types. The study also showed that a UPOV-based rule boosted plant breeding operations' variety.

4.12 RELEVANCE OF TECHNOLOGY TRANSFER

The Convention on Biological Diversity (CBD) 2010 target assessment clearly showed that biodiversity continues to decline and the pressures driving this loss are increasing in magnitude and scope.[133] One of the most significant strategies for addressing environmental issues is the international transfer of technology and knowledge. Direct evaluations of the influence of knowledge exchange and its advantages for biodiversity, however, have trailed behind these recommendations.

4.13 NEXUS BETWEEN BIODIVERSITY AND TECHNOLOGY TRANSFER

The CBD target framework has led to the identification of important biodiversity measures that will serve as the foundation for the creation of several biodiversity indicators. Particularly in light of the new Aichi targets, there is still much work to be done. The lack of a precise definition of biodiversity technology, the large number and diversity of activities that make up biodiversity technology as currently defined by the CBD, and a general dearth of technology are all barriers to consistent reporting on biodiversity technology transfer. According to the CBD, biodiversity technology is a complicated concept that includes both hard and soft technologies that are relevant to the conservation and sustainable use of biodiversity or utilize genetic resources without adversely harming the environment. Thus, the term encompasses both hard and soft technologies that are related to 5 main constituents: in situ and ex-situ conservation; sustainable management of biodiversity resources; monitoring techniques; modern biotechnologies that use genetic resources; benefit sharing;

133 Butchart S. H. M., et al., *Improvements To The Red List Index*. 2(1) *PLoS ONE* , e140 (2007).

and access to research findings.[134] The definition of biodiversity technology is further complicated by the fact that some of its five major constituent pieces have very broad definitions and do not necessarily conflict with one another (for example, monitoring is a crucial component of in situ conservation). Sustainable resource use is broadly defined because we lack proper terminology to distinguish between the various ideas lying within its purview (for example, use, sustainability, and incentives) as well as because it incorporates biological, social, cultural, and economic variables.

The legally obligatory Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the CBD covers further forms of biodiversity technology relating to contemporary biotechnologies, access, and benefit sharing. In this Protocol, parties are urged to support and facilitate developing nation parties' access to and transfer of technology.[135] Through a variety of activities, technology is transferred between one or more people or organizations. Examples include correspondence, workshops, conferences, training, databases, publications, project funding, and sourcing of technology. Therefore, some technologies may be shared directly between particular people or groups, whilst others may be transferred indirectly to a wide population.[136]

As per Article 23, Parties are required to collaborate and work together in technical and scientific research, as well as development initiatives, and activities for biotechnology

134 Convention on Biological Diversity, Article 10(C).

135 Secretariat of the Convention on Biological Diversity Montreal, Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising From their Utilization, (Sept. 6, 2022, 12:08 PM).

136 Monika Böhm and Ben Collen, *Towards Equality Of Biodiversity Knowledge Through Technology Transfer*, 29(5) WILEY FOR SOCIETY FOR CONSERVATION BIOLOGY 1290, 1290-1302 (2015).

research. The requirement is unambiguous yet extremely flexible. States are required to engage in negotiations without mentioning the potential paths to take in order to address them: bilateral, regional, or multilateral level. The responsibility does not go so far as to require States to agree, so if this does not happen, they are still free to decide on technical and scientific research on their own.

But in doing so, Parties must take into account the interests of other Parties. It can be expected that the Protocol's governing body will offer a forum for facilitating such cooperation and will keep this issue under review given the significance of technological cooperation for the successful implementation of the Protocol and the maintenance of mutual trust among its Parties. The requirement to collaborate must be applied and understood in accordance with several CBD guidelines.[137] First, the CBD describes the content as the duty to cooperate in technical and scientific matters, which entails fostering international technical and scientific cooperation through the creation and implementation of supportive national policies, with special attention paid to the development of human resources and the establishment of institutional frameworks. The obligation also entails coming up with ways to cooperate for the development and use of indigenous and traditional technologies, including through staff training and the exchange of experts, which is extremely important for the Protocol's provisions pertaining to indigenous and local communities. Additionally, the responsibility indicates that cooperative

137 It should be noted that the CBD provisions mentioned in this Article of the Protocol do not include CBD Article 17 on the exchange of information from all publicly available sources, including the outcomes of scientific research and traditional knowledge combined with technologies using genetic resources. Arguments could be made that this results from the drafters' wish to avoid mentioning the repatriation of traditional knowledge (CBD Article 17(2)).

ventures and research projects for technology development should be encouraged.

In general, the provision of Article 23 is based on CBD Article 16's provision of access to and transfer of technology. Although it may initially seem as though the Protocol utilizes weaker language than the CBD, it should be kept in mind that Article 23 specifically references CBD Article 16 and other pertinent sections in this context.[138] When interpreted in accordance with the CBD's pertinent provisions, Article 23 requires Parties to implement domestic policies that either give access to genetic resource-using technologies, such as biotechnologies or at the very least promote access to such technologies, as well as policies that are pertinent to their preservation and sustainable use.[139] When developing countries are involved, this must be negotiated on the fairest and most advantageous terms possible, including concessional and preferential terms if both parties agree to them.[140] It is the responsibility of both the sending and receiving nations to make sure that the transferred technology does not seriously harm the environment.[141]

It is noteworthy that the Protocol "buries" just one mention of intellectual property in its Annex with relation to technology transfer, among the potential financial and non-monetary advantages There is a reference to the transfer of technologies on the most beneficial conditions possible,

138 This interpretation appears to offer the only justification for the crammed drafting of Article 23, as three different obligations are clustered in the same paragraph instead of being divided into three separate paragraphs. It can therefore be argued that the opening proviso 'in accordance with Articles 15, 16, 18 and 19 of the Convention applies to the entirety of Article 23.

139 Convention on Biological Diversity, Article 16(1).

140 Convention on Biological Diversity, Article 16(2).

141 Convention on Biological Diversity, Article 16(1).

including when agreed-upon preferential and concessional terms.[142] This reference uses language that is typical of multinational environmental agreements. The CBD specifically recognizes that technology is frequently in private hands, in contrast to the Protocol. As a result, it requires Parties to take domestic actions aimed at the private sector in order to make it easier for governmental organizations of developing nations and private sectors of those countries to access technology and collaborate on its development. By demanding that domestic legislation grant access to technologies even when they are covered by IPRs, on the basis of MAT, it also directly tackles the relevance of IPRs.[143] It places restrictions on access to such technologies while balancing the necessity for transfer with effective intellectual property protection.

The CBD may provide Parties with specific guidance for implementing Article 23. Therefore, Parties should create a supportive environment for technology transfer by offering and providing an institutional, administrative, and regulatory policy framework for both the public and private sectors, not only for the transfer but for the transmission of technology and for the application of that technology. Parties are also required to abolish any local regulations that obstruct the transfer of technology and violate international law.[144]

4.14 TECHNOLOGY TRANSFER FOR MARINE BIODIVERSITY

It has long been acknowledged that marine science and technology are crucial to enabling governments to execute

142 Nagoya Protocol Annex, paragraph 2(f).

143 Convention on Biological Diversity, Article 16(3).

144 2 ELISA MORGERA, ELSA TSIOUMANI, MATTHIAS BUCK, UNRAVELING THE NAGOYA PROTOCOL 314-321 (Brill 2014).

the 1982 United Nations Convention on the Law of the Sea (UNCLOS). In order to conserve and sustainably use marine biological diversity in areas outside of national jurisdiction under UNCLOS, a new international legally binding instrument (ILBI) must be developed. Cross-cutting issues in this process include the development of scientific capacity and technology transfer. In the creation of the ILBI, the acquisition, exchange, and use of scientific information is a crucial issue.

All ILBI components, including establishing a baseline for environmental impact assessments, choosing and overseeing area-based management strategies, and accessing, utilizing, and sharing the advantages of marine genetic resources, require scientific knowledge. Improved ocean observations will be essential to filling in scientific knowledge gaps on biodiversity outside of national borders. Few states, however, have the scientific and technological tools necessary to conduct biodiversity studies in regions outside of their borders. The ability of many states to engage may be hampered by capacity issues. Therefore, how to better apply the UNCLOS framework rules for maritime scientific research and the development and transfer of marine technology is one of the questions facing the establishment of the ILBI. As per the UNCLOS framework for marine technology transfer and marine scientific research, scientific capacity development and technology transfer are intertwined. For instance, among the fundamental goals of technology transfer outlined in UNCLOS Article 268, are the development of technological infrastructure and the development of human resources through training and education. One of the modes of technology development and transfer mentioned in UNCLOS Article 277 is the collecting, evaluation, and dissemination of marine scientific and technical knowledge, information, and data. UNCLOS Articles 269, 274, and 277 also include national and regional maritime scientific and technological centers as a modality

of technology transfer, along with international scientific collaboration (including scientist exchanges and conferences) and regional scientific capacity development. The UNCLOS framework's shortcomings and ambiguities, however, limit implementation.

Activities to build scientific capabilities may be bilateral or multilateral in structure. Scientific, educational, and technical support; training; research collaboration; exchange programs and joint research; access to equipment and data; and developing regional and national maritime science and technology centers are some examples of capacity development methods. Identification of gaps is necessary before capacity development and technology transfer can address national and regional needs. In accordance with UNCLOS Articles 266 and 275, technology transfer shall be made available to nations that "need and desire" it, including supporting the growth of marine scientific and technological capabilities and building national marine scientific and technical institutions. It might be helpful to provide governments with assistance in determining their needs for technological transfer and the development of scientific competence. For the long-term sustainability of capacity development projects, funding and implementation methods are essential. There are still many unanswered topics, such as whether technology transfer should be optional or compulsory, and possible solutions for intellectual property problems. According to UNCLOS Articles 266(1) and 269(b), the development and transfer of marine technology should take place under fair and reasonable terms and circumstances. There is unlikely to be a "one-size-fits-all" strategy given the diversity of technological forms and the range of technology transfer possibilities.[145]

145 Harriet Harden-Davies, *Capacity Building and Technology Transfer for Marine Biodiversity in Areas Beyond National Jurisdiction*, 111 CAM-

In 2019, Speakers presented a variety of perspectives on how — and on what basis — those types of support should be given to States as delegates working to draught a new treaty on biodiversity in areas of the ocean beyond national jurisdiction considered issues related to capacity building and transferring marine technology. Representatives specifically debated whether the new treaty's provisions regarding capacity-building and the transfer of marine technology should be voluntary or obligatory. Additionally, they discussed whether and how to address the relationship between the capacity-building and marine technology transfer processes provided for in the new instrument and those already occurring under other auspices. They also discussed proposed language on the special needs and requirements of small island developing States and developing countries. Some of these issues were reiterated by the American envoy, who also emphasized that the capacity-building and the transfer of marine technology outlined in the new treaty should not duplicate activities already taking place under other programmes. It was argued that for the inclusion of such phrases and the preservation of language, nation-driven capacity-building and the transfer of marine technology should be influenced by lessons learned.[146]

Technology advancements and enabling technologies may result in new paradigms of scientific capacity development being driven by scientific collaborations and "virtual" involvement, shifting the emphasis from technology transfer as a type of bilateral hardware giving to global information exchange.

BRIDGE UNIVERSITY PRESS ON BEHALF OF THE AMERICAN SOCIETY OF INTERNATIONAL LAW 243, 243-245 (2017).

146 Delegates Consider Role of Capacity-Building, Technology Transfer, as Deliberations Continue on Treaty Governing Marine Biodiversity Beyond National Jusrisdictions, United Nations Meeting Coverage and Press Releases (Aug. 20, 2019), https://press.un.org/en/2019/sea2110.doc.htm.

Avoiding duplication and ensuring long-term capacity building and technology transfer that matches national needs and benefits both the suppliers and the beneficiaries is essential. But in the end, the effectiveness of institutional structures and budget levels will determine how well capacity development and technology transfer are implemented.

PART III

CHAPTER 5

INTRODUCTION TO BIOPROSPECTING AND BIOPIRACY

The collection and usage of biological resources and traditional knowledge of a community for the purpose of research or commercial exploitation by individuals outside the community is a growing area of concern. The process, including the search, collection and exploration of such traditional knowledge belonging to communities, solely for the purpose of commercialization or the development of marketable products has been termed as "bioprospecting".[147]

The analysis of the collected traditional knowledge or information gathered through bioprospecting activities is termed as "bio-discovery". The underlying aim of the procedures is to identify natural products which can be put

147 Graham Dutfield, *A critical analysis of the debate on traditional knowledge, drug discovery and patent based biopiracy.*, 33(4): EURIP. REV. 238–244 (2011).

to beneficial use in fields like medicine and agriculture.[148] The problem with such commercial exploitation is that the knowledge of these indigenous communities is monopolized, taking away the rights from the keepers of such knowledge and then depriving them of the profits that are attained.

1.1 BIOPROSPECTING

Bioprospecting can be understood as the process of locating, collecting, and extracting genetic components from biodiversity samples for use in marketed medicinal, agricultural, industrial, or chemical processing end products. Bio prospecting was first defined by Walter V. Reid et al. as "the exploration of biodiversity for commercially valuable genetic resources and biochemical".[149]

Bioprospecting is a term that was created in response to the problematic relationship between global commercial interests, biological resources and indigenous knowledge of local communities and to the epidemic of biopiracy i.e., the patenting of indigenous knowledge related to biodiversity.

Biodiversity forms the basis of life. It is the foundation of the economies of two-thirds of humanity, who depend on biodiversity for their livelihoods and needs. Bioprospecting is viewed commercially as the exploration of potentially profitable biodiversity and biodiversity-related knowledge. However, biodiversity and indigenous knowledge are the basis of living economies and living cultures. Biodiversity and cultural diversity mutually conserve and shape each other.

148 Alexandra George, *Bioprospecting and Biopiracy,* ENCYCLOPEDIA OF G.JUS. (2011).

149 Another version of this essay appeared in Beth Burrows, ed., The Catch: Perspectives in Benefit Sharing, published in 2005 by The Edmonds Institute, a non-profit, public interest organization dedicated to education about environment, technology, and intellectual property rights. See http://www.edmonds-institute.org.

Viewed by indigenous communities, bio prospecting is seen as an expropriation of their collective and cumulative innovation, which they have utilized, protected, and conserved since time immemorial.

The very concept of bio prospecting is legally flawed since it is based on patenting traditional knowledge. A patent is granted for inventions, which must be novel. Existing knowledge—the product of thousands of years of collective innovation by indigenous cultures—is not an invention. Although traditional knowledge could not be patented previously but, the increased commercialization and globalization has now paved the way for granting of such patents, fulfilling the criteria of novelty, a fundamental prerequisite to obtain a patent registration

With the advent of modern biotechnology, the development of new techniques and procedures and the application of these scientific techniques to extract traditional knowledge resources has helped fulfill the test for novelty, allowing private firms and governments to obtain a monopolistic right over the extracted information, making it eligible for commercial exploitation.

This activity was viewed by some as a necessary step towards innovation and a future with significant biological developments. The rationale behind this collection was that by allowing the world to benefit from the traditional knowledge, and not only individuals who had access to the same simply because they lived in a certain area or belonged to a certain community, there would be increased human health benefits and potential treatments or cures to ailments previously left untreated. The catch was simple; the traditional knowledge of biodiversity was with the poorest people in the world, who could easily be commercially exploited.

1.2 BIOPIRACY

Biopiracy is when indigenous knowledge of nature, which originated with indigenous people, is exploited for profit by others without the permission of the indigenous people and with little or no compensation or recognition.

Indigenous peoples' lifestyles, knowledge, cultures, histories, and worldviews have attracted scientific interest throughout history. For their medical needs, majority of the world's population, especially in the "underdeveloped" countries, still rely on indigenous medicinal knowledge of local flora.

According to the ASI, India has 4635 ethnic communities. Each of these groups might theoretically have their own oral medical traditions that have evolved across time and space. Traditional knowledge includes not only the written understanding of medicinal plants, but also the oral information that has been passed down through the years. There have been numerous instances in India where indigenous knowledge has been attempted to be taken away. As stated by the UNDP Human Development Report, 1999 "The South is the source of 90% of the world's biological wealth," this has made India's biological resources and traditional knowledge a common target of biopiracy.

Bioprospectors, for example, draw on indigenous knowledge of medicinal plants. It is then patented by medical corporations without acknowledging that the knowledge is not new or generated by the patentee, denying the indigenous population of the right to commercialize the technology they developed.[150] These actions aggravate the disparity between

150 Shiva, Vandana. "Bioprospecting as Sophisticated Biopiracy." Signs, vol. 32, no. 2, pp. 307–313 (2007).

developing countries with vast biodiversity and developed countries that host corporations that engage in "bio piracy."

When selecting on a plant, animal, or other biological source to investigate, a multinational firm or an individual frequently draws on the traditional knowledge of local people. After successfully producing commercially valuable items from those organisms, the corporation files a patent application for those products in its own name. In most cases, the inventor does not even declare in his patent application that his product was generated from local community information.

As a result, biopiracy can be defined as the unjustified extraction of natural heritage and traditional knowledge from diverse parts of the globe in order to profit from economic exploitation and industrial monopolisation.

Biopiracy can be divided into three groups[151]:

i. Patent-based Biopiracy: The patenting of any biological resource derived from traditional knowledge recovered without requisite authorization, or without lawful compensation to the indigenous communities.

ii. Non-patent Biopiracy: The control over any biological resource derived from traditional knowledge through other forms of intellectual property, not including patenting, without adequate benefit-sharing or permissions.

151 Robinson, D.F., 2012. Biopiracy and the innovations of indigenous peoples and local communities. *Indigenous People's Innovation: Intellectual Property Pathways to Development*, pp.77-78.

iii. Misappropriation: can be defined as the illicit and unauthorized extraction of biological resources and/or traditional knowledge from other countries and indigenous or local groups, without proper benefit-sharing arrangements.

CHAPTER 6

INTERNATIONAL FRAMEWORK ON BIOPROSPECTING AGREEMENTS

The ethical aspect of commercialization is the sole distinction in between bioprospecting and biopiracy. The international community took cognizance of the fact that indigenous communities were indeed suffering from the growing power of private institutions, putting them at a severe economic disadvantage. In order to regulate the uncontrollable financial power of such corporations and governments, several efforts were made to create a blueprint or framework guiding bioprospecting in order to end biopiracy.

6.1 UNITED NATIONS CONVENTION ON BIOLOGICAL DIVERSITY (UNCBD A.K.A CBD)

The Convention on Biodiversity (CBD) is a multilateral treaty which was introduced for signing at the Earth Summit in Rio De Janeiro on the 5th of June, 1992. It was one of the first internationally recognized agreement in between nations which dealt with three fundamental goals; the conservation of biodiversity, the sustainable usage of biodiversity and benefit-sharing of genetic resources.

For the first time, the global community recognized the need to conserve biological diversity. Since a total restriction on the exploitation of traditional knowledge would be detrimental, the convention also recognized that biodiversity was an important part of global development, allowing nations and local indigenous communities to make sustainable use of genetic resource with fair and equitable benefit-sharing mechanisms.

There are several provisions related to bioprospecting and benefit-sharing enshrined within the CBD. Article 6 of the convention required that all signatories prepare a National Biodiversity Strategies and Action Plan (NBSAP), making them instruments of application of the convention.

Article 6 reads –

> *"Each Contracting Party shall, in accordance with its particular conditions and capabilities: (a) Develop national strategies, plans or programmes for the conservation and sustainable use of biological diversity or adapt for this purpose existing strategies, plans or programmes which shall reflect, inter alia, the measures set out in this Convention relevant to the Contracting Party concerned; and (b) Integrate, as far as possible and as appropriate, the conservation and sustainable use of biological diversity into relevant sectoral or cross-sectoral plans, programmes and policies."*

Article 8 (j) of the CBD places a duty on the signatory nation to ensure that –

> *"Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge,*

innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices."

The CBD recognized the need to balance the exploitation of traditional knowledge and genetic resource originating from indigenous and local communities and the rights of the affected communities, and placed a duty upon every nation to ensure that there existed only sustainable usage of such resource, furthering the goals of bioprospecting. Article 15 of the CBD provided for access to genetic resources, stating that such access was to be granted pursuant to mutually agreed terms.

In 2002, the release of the voluntary Bonn Guidelines was seen as a mechanism of assistance to members involved in the process of benefit-sharing. These guidelines were expected to help nations create a legislative framework which would regulate the negotiation of bioprospecting agreements or contracts. However, due to a lack of resources or underdeveloped technology, several developing nations found it extremely difficult to draft a framework, leaving much of the negotiation unregulated.

6.2 THE NAGOYA PROTOCOL

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 ABS (Access and Benefit Sharing), was added as a supplementary agreement to the Convention on Biological Diversity on 29th October 2010. With a sole focus on the third aim of the CBD, i.e the fair and equitable sharing of any benefits arising out of genetic resources, it set out several obligations for all signatories / contracting parties for regulating the benefit-sharing of genetic resources.

It is used as a means to govern the issues of the CBD framework, the main objective access and benefit sharing related to genetic resources[152]. Thus, essentially, this supplementary agreement to CBD focuses on benefit sharing and access of genetic resources which are to be used in a fair and equal manner. This agreement acts a supplementary to CBD by expanding the objectives of CBD framework in the concept of benefit sharing[153]. It is said that, the benefits arising from the use of genetic resources shall be shared among the living equally for the purposes of environmental sustainability and development[154].

6.3 AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY (TRIPS AGREEMENT)

The TRIPS Agreement is an international agreement between all the members of the World Trade Organization. The TRIPS is a global standard for legislations governing intellectual property, such as patents, trademarks, copyrights etc. The TRIPS helps in establishing a global enforcement system for intellectual property, providing a multilateral system for trading, and establishing minimum standards for all member countries for their territorial legislations.

Article 27 of the TRIPS reads –

"Article 27 – Patentable Subject Matter

152 The term 'Genetic resource' is defined as any non-human genetic resource.

153 This concept has indeed been subject to evolving interpretation by the CBD Parties as a tool for inter-State cooperation as well as for partnership between States, indigenous and local communities, and the private sector.

154 Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity (Nagoya, 29 October 2010, not yet in force), in CBD Decision 10/1, "Access to genetic resources and the fair and equitable sharing of benefits arising from their utilization" (20 January 2011) UN Doc UNEP/CBD/COP/10/27 (hereinafter, Nagoya Protocol or the Protocol).

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. (5) Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and *paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.*

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement."

Article 27 allows member countries to allow patents for any inventions in the fields of technology without any discrimination. This also includes upcoming technology such as bio-technology. However, Article 27.2 allows countries to exclude such inventions which are against *public order* or *morality*. Countries who decide that bio-piracy is against the

public order and morality can decide to exclude patentability of such inventions.

6.4. BIODIVERSITY ACCESS AGREEMENTS

A Biodiversity Access Agreement can be termed as an agreement or understanding between two parties, generally a country or a private establishment and another country, for allowing access to bio-genetic resource for the purpose of bio-prospecting. In a way, it legitimizes the process of collecting bio-genetic resources and natural products from indigenous people by ensuring equitable distribution of relief and benefits.

The CBD and TRIPS provide a basic framework for parties entering into a bio-diversity access agreement ("BAA"). The Bonn Guidelines of 2001 also provide a mechanism in which the rights of both parties entering into a BAA are balanced equitably. Although none of these principles are binding, they are followed by mutual agreement internationally. The final say in deciding the terms of the agreement lies with the parties.

Companies involved in biotechnology such as Diversa (a U.S based bio-tech firm) are party to several BAAs with countries such as Iceland, Hawaii, Indonesia, Mexico etc. Based on experiences with BAAs, three fundamental guiding principles can be narrowed down –

- Efficient and reasonable negotiations
- Efficient and reasonable permit systems
- Capacity building

CHAPTER 7

TRADITIONAL KNOWLEDGE AND IPR

7.1 INTRODUCTION

The Indian subcontinent is flourished with great flora and fauna, as well as diverse habitats due to the differing climates and altitudes all over the country. But there has been a worrying decrease in the biodiversity in the recent past. The biodiversity is at the threat of extinction due to several causes like climate change, deforestation, soil erosion, etc. Thus, there is a dire need to take the necessary measures for the conservation of biodiversity using both *in-situ* and *ex-situ* methods.

Biodiversity poses a crucial and valuable biological resource for industries and livelihood as well which result in sustainable economic development. For instance, industries like pharmaceutical, cosmetic, agricultural, horticulture and even waste treatment is dependent on biodiversity. It is also important for developing countries as 70-80% of their population depends up on plants as a source for medicine.[155]

155 S. Kannaiyan, *Biological Diversity and Traditional Knowledge,* NBA India, http://nbaindia.org/uploaded/docs/traditionalknowledge_190707.pdf.

Communities have their own distinct heritage that they inherit from their ancestors and the nature. It is included in everything ranging from economic, social, political systems to beliefs, norms and morals. Traditional Knowledge refers to the knowledge that has been discovered, maintained and passed down from generation to generation within a community or group, which forms an essential and integral part of their cultural or spiritual identity. Traditional knowledge also is a part of heritage which may be endorsed in music, literature, symbols, craftsmanship, agriculture, etc.

Heritage also includes inheritance from nature, like plants, animals and microorganisms in diverse ecosystems and biodiversity. These heritages including traditional knowledge and biological resources hold great commercial values. Business corporations are often seen trying to acquire all related IP rights of those traditional knowledge and biological resources in order to gain income by utilizing them commercially. Traditional communities, like farming or fishing communities, heavily depend upon such resources for their livelihood.

Traditional knowledge is very important as it plays a vital role in biodiversity conservation and traditional use of biological resources. It is used in the Indian treatments and medicines, like Ayurveda and Siddha. Farmers and agriculturalists use biological resources and traditional knowledge to cultivate and nurture diverse varieties of crops and livestock. The indigenous and local communities help protect and conserve the nature if it is sacred to them. From this, the value of traditional knowledge can be somewhat determined. This is why corporations and industries use such traditional knowledges either with or without the permission or consent of the original holders of the traditional knowledge. It is a known fact that several patents have been invalidly granted across the world for inventions based on the Indian

traditional medicinal system. This is where the IPRs comes into play.

7.2 TKDL AND THE PROTECTION OF TRADITIONAL KNOWLEDGE:

The protection and preservation of such traditional knowledge and biological resources of indigenous communities are very important, especially for developing countries, as they play a crucial part in the development of health, medicine, identity, trade etc. however, they are still under threat of biopiracy, often by developed nations. There have been several cases of misappropriation and commercial exploitation of such knowledge and practices around the world without obtaining the consent of the community or original holders of the traditional knowledge. Such prominent issues have led to the international discussions and intervention regarding the preservation, protection and utilization of traditional knowledge.

The developed nations usually get the traditional knowledge patented or protect it through any other IP regime in order to gain commercial control over it, which is a great concern for developing nations. The obvious way to tackle such biopiracy cases is to file for the revocation of the issued patent. But this becomes a tedious process and can lead to very lengthy proceedings It is therefore necessary to look into other alternatives to protect traditional knowledge as well.

The recent editions of the Draft Provisions/ Articles for the Protection of Traditional knowledge and Traditional Cultural Expressions, and IP & Genetic Resources was submitted to the Committee and amended in June 2019. It acknowledges and recognises the rights of local and indigenous communities to maintain, control, develop and protect their traditional knowledge. The objective of this Draft Treaty is to ensure adequate protection of IP against misappropriated

and uncompensated use of traditional knowledge. It also states that the contracting parties have to provide protection to the traditional knowledge of their local communities. They should allow access to such knowledge in exchange for equitable share to the community in the benefit accruing from its use.

Article 8(j) of the Convention on Biological Diversity states that members have to take measures to conserve, value, protect and encourage awareness of local and indigenous communities and ensure use of their knowledge and practices by obtaining informed consent and involvement of the original holders. The States should also ensure equitable benefit sharing from the utilization of the traditional knowledge. The same is also required under the Nagoya Protocol.

The Traditional Knowledge Digital Library (hereinafter TKDL) was developed by CSIR along with the Department of AYUSHI in order to provide more recognition to traditional knowledge in India. A task force was also formed in this regard which came up with a system for the classification of traditional knowledge called the "Traditional Knowledge Resource Classification". This method was used in the TKDL to convert and structure ancient scripts and texts into approximately 34 million pages. There are also various translations available like English, Spanish and German to name a few. Earlier, the International Patent Classification System provided only one sub-group for medicinal plants. But the introduction of the TKDL reformed it and following the 'Traditional Knowledge Classification task Force' by the WIPO, the number of sub-groups for medicinal plants was increase to 207.

The patent examiners can search through the TKDL database to examine the novelty and prior art regarding the invention. In most cases, the opposition filed against an issued patent can go on for about 5 to 7 years which also has its own expenses. For example, the neem patent opposition case went

on for around 10 years to be decided. The TKDL database can help prevent patenting of Indian traditional knowledge at an earlier stage. This way this database helps keep a check for biopiracy as well. Thus, the creation of TKDL was a positive step taken in relation to the recognition, protection and classification of traditional knowledge.

The effect of the development of TKDL could be felt on the European Patent Office (hereinafter EPO). Since July 2009, 215 patent applications relating to Indian medicinal systems were identified based on the TKDL evidences. In two cases, the EPO reversed their earlier decision to grant patents based on the evidences from TKDL.[156] So now, the applicants either alter their claims or withdraw their applications upon submission of TKDL evidence. A study conducted by the TKDL expert team in the EPO showed that there has been a decline rate of 44% in the no. of patent applications filed regarding Indian medicinal systems, especially related to medicinal plants. This show that TKDL has been effectively decreasing biopiracy cases.

Few of the successful examples of TKDL are listed below:

- The Netherland Company, Unilever withdrew their application no. EP1607006 for "Functional berry composition" after data from the TKDL was produces to show existence of prior art.
- Jumpsun Bio-Medicine Co. Ltd, a Chinese company, also withdrew its application no. EP 1889638 for "Medicaments and food for treatment or prevention of obesity and/or diabetes containing cicer arietinum extract".

156 Protecting India's Traditional Knowledge, WIPO Magazine (June 2001), https://www.wipo.int/wipo_magazine/en/2011/03/article_0002.html.

Industrial Research Limited and Otago Innovation Ltd., from New Zealand have withdrawn their application no. EP 1750809 for "Citrus Fruit Skin extract for Angiogenesis promotion" based on the data from TKDL submitted as evidences.

CHAPTER 8

BIOPROSPECTING V/S BIOPIRACY

The main international convention that recognises the importance of traditional knowledge in conservation of biodiversity is the Convention on Biological Diversity (hereinafter CBD). However, the scope of the traditional knowledge under this international instrument is limited to genetic materials. This convention lays down the basic principles that have to be followed by the contracting parties in their long-term work.

Article 8(j) mandates that the contracting parties, subject to their domestic legislation, have to respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities, tangible or visible lifestyles, that are necessary for the conservation and sustainable use of biological resources. They should also take measures to promote and apply such traditional knowledge, innovations and practices, with the consent and involvement of the original holders and also encourage equitable sharing of benefits arising from the use of such knowledge, innovations and practices.[157]

157 *Id.*

There are two important terms that have to be discussed in relation to IPR in traditional knowledge, i.e., biopiracy and bioprospecting. When others use the biological resources and related traditional knowledge of a traditional community by violating their rights over it, it is known as biopiracy. Biopiracy leads to both ethical as well as economic consequences. Unfortunately, in most cases the IPR protection of such traditional knowledge relating to biological resources or the commercial products made from these resources, usually patents or plant breeders rights, are wrongfully obtained by industries to get monopolistic control over its usage without the consent or knowledge of the original holders.

This way, the original holders are prohibited from commercializing their knowledge or related resources. The IPR holder will gain the control over the traditional knowledge, while the communities lose their rights over it. Thus, the original holders do not get any recognition for developing the knowledge or resources and also don't get any share in the benefits and profits gained from the commercial utilization of the products developed based on their knowledge and related resources.

Bioprospecting refers to the search and exploration for commercially valuable genetic and biochemical information from plants, animals or microorganisms for the development of a product for scientific and commercial use. Basically, it refers to the search for new biological resources in the biodiversity which may have been of some value. Such research and exploration are often carried out by industries like the pharmaceuticals, cosmetics, agriculture etc., where biodiversity plays a vital role. Bioprospecting recognises the value of natural products in the development process of new crop varieties and medicines, which are often obtained from traditional knowledge and practices. For a long time, legislations have tried to prohibit unrestricted bioprospecting, i.e., biopiracy. The role of

biodiversity in today's world is often severely underestimated. Leaving aside the obvious (but still ignored) importance it plays in regulating climate change, biodiversity forms the basis on which modern medicine, chemicals and drugs of great health and economic value are developed. The economic and commercial value of biodiversity has led to the development of the field of bioprospecting. Bioprospecting can simply be understood as the identification and use of biodiversity, biological resources or traditional knowledge for commercial exploitation; "*in essence, it means an activity involving survey, exploration, documentation and evaluation of biological resources and their derivatives, leading to identification and/or isolation of commercially valuable products (genes, biochemicals) compounds, derivatives and/or any other tangible and intangible components including IPR-covered processes, technologies and services derived from wild or domesticated biodiversity.*"[158]

An obvious drawback of bioprospecting is the risk of overexploitation of natural resources. Further, is the question of whether biological resources acquired from source countries, or from the native indigenous people who act as custodians of such resources are being adequately compensated for and whether they actually benefit from the profits that corporations make out of the use of their resources.

Both concepts may seem similar on the face of it, but they are different. Bioprospecting refers to search and collection of commercially valuable biochemical samples that can help in scientific research and development of useful medicines. Whereas, biopiracy refers to the illegal collection

158 P. Pushpangadan, V. George, V. M. Dan, *Biodiversity, Bioprospecting, IPR and Benefit Sharing with Stakeholders in the 21st Century India*, RESEARCH GATE (Jul. 22, 2021, 5:15 PM), https://www.researchgate.net/publication/262575819_Research_Trends_in_Medicinal_Botany_21st_Century_India.

or misappropriation of the traditional knowledge or biological resources that violate the rights of the indigenous communities and not provide equitable share in the benefits accrued. Biopiracy can be understood as when indigenous knowledge, resources are used and exploited without the prior permission of the indigenous communities with little to no compensation. This is often done by unfairly patenting such resources and processes and gaining a monopoly over them. Mostly big corporations and industries, usually from developed countries, prefer biopiracy over bioprospecting as they gain monopolistic control over the traditional knowledge through patenting and they don't have to invest time or effort to collect the samples legally.

Commercial use of new biological resources is vital for economic and social development. The main conflict with this is when such bioprospecting results in biopiracy or unsustainable use of the resources. This is one reason why bioprospecting has acquired a negative image, meaning that it is widely believed that bioprospecting often results in biopiracy. It is also considered to be violative and offensive to several traditional communities as it leads to the commercial exploitation of their resources and knowledge which is deemed to be sacred and part of their heritage, and often rely upon them for their livelihoods. This makes the traditional communities vulnerable to biopiracy. Such biological resources and traditional knowledge are not a private property, but it is deemed to be a communal property that is bestowed upon them through generations. Some examples of biopiracy includes:

a. Eli Lilly

A famous example of Biopiracy is that of the Rosy Periwinkle flower in Madagascar. Eli Lilly, a pharmaceutical company used this special flower to develop two important life-saving anti-cancer drugs – Vincristine and Vinblastine.

While Eli Lilly made millions by utilising of such traditional knowledge of the special properties of the flowers, the indigenous people of Madagascar who possessed such knowledge completely lost out and have not received any royalties.

b. Turmeric

An Indian example of this is the patenting of the medicinal properties of Turmeric in the United States. India objected to the patent stating that these properties were long known within India and provided ancient texts explaining these properties of Turmeric which led towards the subsequent revocation of the patent. Similarly, the patent on Neem in the United States was also revoked.

For such communities, private ownership of such resources or knowledge, like a seed variety for instance, is not a well-known concept which is why there are some difficulties in the appreciation of the IPR regime in this regard. Such local and indigenous communities are not able to utilize the IPR regime to their advantage due to lack of awareness about it and their social hierarchies. Even if they are aware of it, they are still unable to prevent biopiracy or gain a reasonable share in the benefit accrued by its commercialization due to reasons like illiteracy, low social and financial status, etc. The principles of the international IPR regime in relation to this have also developed in a way that makes the traditional communities more vulnerable to biopiracy and unsustainable use of their traditional knowledge and biological resources.

8.2 Biopiracy Cases

"*It is quite by accident and only from savage nations that we owe our knowledge of specifics [medicines]; we owe not one to the science of the physicians.*[159]"

p.-l. moreau de maupertuis, 1752

Biopiracy in its broadest sense means commercial exploitation of traditional knowledge. Biopiracy can be both patent related and non-patent related. Patent related biopiracy connotes to the practice of patenting traditional or indigenous knowledge without prior permission or any provision of benefit sharing[160]. Developed countries can mainly be seen appropriating from traditional and/or indigenous knowledge of developing countries by patenting the knowledge and commercially exploiting it by the exclusion of others. Some examples of patent related biopiracy cases would include the basmati case,[161] the neem case,[162] etc. Biopiracy can also be non-patent related. This means protecting the knowledge by some form of IP other than patent, it can be trademark or any plant variety protection accorded to the traditional knowledge[163]. In this chapter, the various patent and non-patent related

159 L. SCHIEBINGER, 2021. BIOPROSPECTING. PLANTS AND EMPIRE: COLONIAL BIOPROSPECTING IN THE ATLANTIC WORLD, 73 (Harvard University Press, 2021) https://doi.org/10.4159/9780674043275-004.

160 PETER DRAHOS(ED) AND SUSY FRANKEL (ED), INDIGENOUS PEOPLES' INNOVATION INTELLECTUAL PROPERTY PATHWAYS TO DEVELOPMENT, 88 (ANU E Press, 2012) https://press-files.anu.edu.au/downloads/press/p154251/pdf/book.pdf.

161 M.Z.M Nomani, F. Rahman, *Biopiracy of Traditional Knowledge Related Geographical Indications: A Select Study of Indian Case,* Manupatra, 135 (2016) https://www.researchgate.net/publication/321492837_Bio_Piracy_of_Traditional_Knowledge_Related_Geographical_Indications_A_Select_Study_of_Indian_Case.

162 *Id.*

163 *Supra* note 168.

biopiracy cases will be analyzed to give the readers an insight into the legal battle against biopiracy.

8.2 Patent related biopiracy cases

1. The Basmati Case

The Basmati rice controversy started in the late 1990s with the United States Patent and Trademark Office (USPTO) granting patent to the company RiceTec for Basmati rice. The company based out of Texas claimed to have invented a superior form of basmati rice compared to the already existing once. The USPTO allowed the company to use the name "Basmati" for their exports as well as for sale across the continent.[164] The patent related to "novel rice lines, plants and grains of these lines" was granted in 1997.[165] Basmati has been produced in India and other South-Asian countries including Pakistan for many decades, the aromatic flavor of basmati and its texture and shape has allowed India to hold a huge market of export of Basmati to different countries including the USA.[166] This granting of patent technically allowed the USA to use the name Basmati, produce the rice and appropriate from it. This served as a huge blow for India's export market by misappropriation of its traditional knowledge. The company claimed in its patent application that the Basmati that is to be patented is of a superior quality and has been cross-bred with a locally grown crop of the USA. But the question that arose from the side of the Indian Government was that the original crop which with the locally grown in the USA crop

164 Sergio Peña Neira, *Interpretation and Application of International Legal Obligation in a National Legal System: Taking Seriously Benefit Sharing from the Utlization of Genetic Resources in India*, 17 ANU. MEX. LAW INT. 651, 657 (2017) 1870-4654-amdi-17-00651.pdf (scielo.org.mx).

165 Lok Sabha Debates, 2nd series, Vol. 20(25), pg. 20 https://eparlib.nic.in/bitstream/123456789/759039/1/lsd_12_02_29-05-1998.pdf.

166 *Id.*

was cross-bred with a variety of a South-Asian origin Basmati as Basmati was particularly grown in northern region of India and Pakistan. The Indian Government claimed that patenting the basmati by cross-breeding was misappropriation of its traditional knowledge[167]. Growing basmati required fulfilment of certain climate conditions that were found traditionally in India and Pakistan and some other South-Asian countries, the cross-bred variety, RiceTec claimed could be grown in the North parts of America, they called it the American Basmati. The cross-breeding was done by crossing a Basmati germplasm of Pakistani origin with that of a long-grained rice grown in the USA. Originally the Patent was granted for 20 claims which were later contested by the Government of India. Of the 20 specific claims, claims 1-14 were pertaining to general characteristics of rice that grown natively in America, subsequently, claims 15-17 included rice grains that did not have any specific limitations of Geographical Indications and claims 18-20 pertained to the methods that RiceTec had applied in developing the allegedly superior quality basmati. The claims 15-17 had ramifications for India in the sense that the germplasms that were mentioned in these claims were specific to the Indian origin and RiceTec's claim of patentable subject-matter was in fact India's traditional knowledge of Basmati[168]. The Agricultural and Processed Food Products Export Development Authority (APEDA) filed a complaint for examination on the behalf of the Indian Government.[169]

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167 *Grain Drain,* DOWN TO EARTH (Oct. 31, 2000) https://www.downtoearth.org.in/news/grain-drain-18858.

168 M.Z.M Nomani, F. Rahman, *Biopiracy of Traditional Knowledge Related Geographical Indications: A Select Study of Indian Case,* Manupatra, 135 (2016) https://www.researchgate.net/publication/321492837_Bio_Piracy_of_Traditional_Knowledge_Related_Geographical_Indications_A_Select_Study_of_Indian_Case.

169 *Grain Drain,* DOWN TO EARTH (Oct. 31, 2000) https://www.downtoearth.org.in/news/grain-drain-18858.

The grounds for filing related to novelty, non-obviousness and utility. Various non-governmental organizations (NGOs) like the Center for Food Safety, the Center for Scientific and Industrial Research and the Research Foundation for Science, Technology and Ecology filed petitions in the USA.

There were a number of protests and issues raised with regards to the patenting of basmati rice by RiceTec, these issues can be summed as:

1. Whether "basmati" was a generic term?
2. Whether the criteria of novelty was fulfilled by RiceTec in acquiring the patent?
3. Whether the granting of the patent by the USPTO was a violation of the Trade Related Aspects of Intellectual Property Rights Agreements (TRIPS)?
4. Whether the patenting of basmati rice was bioprospecting?

It was argued by the Indian Government that basmati was not a generic term, it being secondarily associated with the long-grained rice that is grown specifically in India and Pakistan. Furthermore, the issue was that a patent was claimed for the rice, i.e., the biotechnologically improvement done to the Pakistani rice germplasms, however, the term "basmati" was not protected by any IP. RiceTec generally marketed the product as Texamati, however, in its packaging for sale in the USA, basmati was also mentioned in the packages. The only way that basmati of Indian origin could be protected was by Geographical indications but there was no legislature with respect to GIs at that point. This raised a very typical situation for India. In the claim for novelty, the government stated that basmati had already been in use since a long time in India, various documents and records were produced to prove the

same[170] this, the government stated, resulted in nullifying the novelty claimed in the product. But the counter was that the rice-grain claimed was a cross-bred variety and not the original basmati grain that is grown in India or other South-Asian countries. After some years of battle, only three claims succeeded among the 20 originally claimed. The three claims showed that the basmati that RiceTec was claiming was in fact different from the original basmati rice.

During this case, the Geographical Indications Act, 1999 was enacted. In this case, India partially won, however, three claims succeeded and the strain is still protected as superior quality Basmati. The movement for the reconsideration of this patent was in the end submitted on 28 April 2000. Soon after finishing the proposition for reconsideration, Rice Tec chose to eliminate claims 15-17 alongside guarantee. Biopiracy of conventional information is not limited to India alone.

1. The Wheat Patent Case:

In 2004, in *Research Foundation for Science Technology and Ecology & Anr. v. Union of India*171, an NGO, RFSTE, filed a writ case in the European Court of Justice, asking for directives to the Centre to dispute Monsanto's patenting of wheat. The petition was dismissed. The court ruled that there was no requisite for a mandate to the government to establish a permanent agency to monitor biodiversity preservation or to file patent claims in an international forum. In his order, he also stated that in any case, it is the responsibility of the petitioners to make a suitable representation to the Government, suggesting appropriate procedures, in case any further steps would be required to protect the biodiversity and ensuring prevention of biopiracy, as the petitioners allege. We

170 *Id.*

171 *Research Foundation for Science Technology and Ecology & Anr. v. Union of India,* Writ Petition (civil) 657 of 1995.

hope and believe that any such ideas will draw the attention of the government, which will then take whatever action it deems suitable in its judgement.172

2. Tomato Wild Relative Case

An examination of patent cases involving tomatoes reveals how hereditary rearing practises influence yield, detected with marker-assisted selection (MAS), a technique that is (surprisingly) widely used. When placed in the context of industry and NGOs, however, it can have a shadier aspect. The context of biopiracy It is through these procedures, which are used on wild tomato relatives, that the licenced tomato attributes investigated in this research were found to be valid. With the combination of It's become conceivable at times, thanks to these inherited ways and gifted patent lawyering. for patent candidates to pass the most stringent public access rules and, effectively, guarantee their success that has a lot of biodiversity. An examination of patent cases involving tomatoes reveals how hereditary rearing practises influence yield detected with marker-assisted selection (MAS), a technique that is (surprisingly) widely used. [173]When placed in the context of industry and NGOs, however, it can have a shadier aspect. The context of biopiracy It is through these procedures, which are used on wild tomato relatives, that. The licenced tomato attributes investigated in this research were found to be valid. With the combination of It's become conceivable at times, thanks to these inherited ways and gifted patent lawyering. for patent candidates to pass the most

172 Shan Kohli, *Biopiracy in the context of Plunder of Wheat in India*, SpicyIp, (Jan 10, 2022, 9:35 PM), https://spicyip.com/2016/03/spicy-ip-fellowship-2016-17-biopiracy-in-the-context-of-plunder-of-wheat-in-india.html.

173 TWN Info Service on Biodiversity and Traditional Knowledge. https://www.twn.my/title2/biotk/2015/btk150501.htm.

stringent public access rules and, effectively, guarantee their success that has a lot of biodiversity.

3. Turmeric Battle case

It is an unfortunate reality that the world regards innovation to be binary, where the innovations out of a laboratory or research centre is held at a higher pedestal as compared to innovations from informal settings like traditional knowledge from an indigenous community, which are most often undermined and overlooked. Developing countries especially have large quantities of diverse pool of traditional knowledge which are bestowed upon and passed down from generations.

As mentioned above, biopiracy refers to the appropriation of the biological resources and related traditional knowledge of a traditional community by businesses or industries in order to gain monopolistic and commercial control over its IP, usually patents or plant breeders rights. Such instances are usually common where the big corporations and individuals from Western nations commercially exploit the traditional knowledge and biological resources of developing Asian and South American nations.

One of the landmark cases on such monopolistic exploitation of traditional knowledge in India was related to the grant of patent for the medicinal use of turmeric by the US Patents Office (hereinafter USPTO). This war between the USPTO and India if commonly referred to as '*Haldighati ki Ladai*' or *'Turmeric Battle'* in English. This case highlighted the dire requirement for providing appropriate protection of traditional knowledge in India though the IPR regime. This case was undertaken by Dr. Mashelkar, the then Director General of the Council for Scientific and Industrial Research (hereinafter CSIR), who also has time and again reiterated the importance of innovation, and the responsibility to protect

what rightfully belongs to India. He also fought against the USPTO over the patents granted for neem and basmati rice.

USPTO granted patent for patent application no. 5401540 to two researchers with the University of Mississippi, Medical Centre for the "*use of turmeric in wound healing*" i.e., they were granted patent for the medicinal use of turmeric in treating wounds. They had claimed in their application that administering a certain amount of turmeric, either orally or directly applying, would catalyse the healing process of a wound.

In October 1996, the CSIR filed the re-examination claim with the USPTO to invalidate this patent application. The main argument put forward by the CSIR in this regard was that the invention for which the patent was granted was devoid of novelty, which is the most important criteria for patentability. This invention could be considered as a 'prior art' as the idea of using turmeric to heal wounds has been used in India since time immemorial. It is a traditional medicine that is used in various traditional medicinal treatments. This can be inferred from ancient Sanskrit, Hindi and Urdu references and a publication made by the Indian Medical Association in 1953. All these references and publication was submitted in furtherance of this contention by the CSIR.

The patentees countered stating that the turmeric paste and powder don't have the same qualities. They stated that the idea of using the powder in the same way as the paste would not be obvious to a 'person having ordinary skill in the art' (hereinafter PHOSITA) with any reasonable level of certainty. They further argued that the powder had to be used along with honey, which has its own healing properties. After looking into all the contention and evidences provided, the USPTO held that the use of turmeric powder is similar to its use as

a paste and thus the patent was invalidated on the basis of anticipation in 'prior art'.

Under the patent laws, there are three main criteria's that have to be fulfilled in order for the invention to be patentable, i.e., novelty, non-obviousness or inventive step, and capability of industrial application. Prior art refers to any knowledge that exists in relation to the invention and includes any patent or non-patent related information in patents, articles, publications, documents, etc that is available anywhere in the world.

It is not necessary that the prior art like publication for instance, have to be read by the public, it is sufficient if the prior art is accessible to the public without much trouble. In such cases, the novelty aspect of the patentability of the invention is killed and it becomes non-patentable. In the turmeric case as well, the references and publication submitted by the CSIR was evident to prove that there was sufficient prior art and thus the patent was invalided on this ground. The turmeric powder and paste, in both forms, showed similar healing properties which was apparent to the PHOSITA and thus the patent also lacked the second patentability criteria i.e., non-obviousness or inventive step. Therefore, in 1997 the USPTO revoked this patent.

The turmeric battle was the first significant case of its kind in India where a patent was granted on a traditional knowledge from a developing country. This was challenged and was successfully invalidated, thus protecting the traditional knowledge. This case also highlighted the inadequate laws in India for the protection of such knowledge and the need to develop a more reliable and stronger mechanism for the recognition, registration, digitalization and protection of traditional knowledge.

4. Neem Patent Case

The neem tree, *azadimchta indica,* is also known as "*sarva roga nivarini*" in Sanskrit meaning "curer of all ailments".[174] Neem has been used for centuries in various parts of the country and it is also a part of the Indian tradition and culture. Some of its uses are listed below:

- The bark of the neem tree is used to brush the teeth.
- The tree is considered to be sacred and is worshipped in few regions.
- The neem juice or extract is used to treat skin disorders.
- It is used to control parasitic infections and can be used as an antidote for malaria.
- It is used as a cure for ailing soil, plants and livestock. The neem cake i.e., the residue from the seeds after extracting the neem oil, is fed to livestock.
- The neem oil is considered to be a potent spermicide and is being tested as a female contraceptive.

The Western nations were ignorant of the properties of neem for centuries until 1959, when a German entomologist discovered the use of it as a potent insecticide when only the neem trees survived a locust swarm. Since then, researchers from all over the world have discovered this particular property of neem which is not harmful to humans, as one of the seed's active substances. But it is important to remember that this practice of using neem as insecticide was being used in India long before this global discovery. The neem seeds were taken

174 Emily Marden, *The Neem Tree Patent: International Conflict over the Commodification of Life*, 22 B.C. INT'L & COMP. L. REV. 279, 283-286 (1999), http://nationalaglawcenter.org/wp-content/uploads/assets/bibarticles/marden_neem.pdf.

out and soaked in wither water or alcohol after which it was used on crops.

In the 1990s, a group of US researchers looked into this practice and came up with a method to change the active ingredient in the neem extract to a more stable and storage able form of the extract. Finally in June 1992, the EPO granted patent no. 5124349 to an agricultural chemical company in Boca Raton, Florida called W.R. Grace & Co and the Us Department of Agriculture for a method for controlling fungi on plants using the hydrophobic extracted Neem oil. This patent covered the process of making the stable azadirchtin in solution form as well as the stable solution itself, both of which are significant for the pesticide industry and for farmers as well. In March 1994, 'Neemix', the first product from neem tree was approved for use in the US. This derivative product, i.e., the stable azadirachtin solution by W.R. Grace, was registered by the Environmental Protection Agency for use on food crops.

On the first look this patent seemed to be a significant innovation. Under the US law, patents can be granted for the claims of a purified matter that is obtained by modification or purification of a naturally occurring matter or compound. This patent granted to W.R. Grace also seemed to have fulfilled all the requirements under the 35 U.S.C. sections 101, 102, and 103.[175] One of those criteria's is regarding prior art and non-obviousness to a PHOSITA. In this case, the US laws state that in fact that this derivative or improvement was a prior art used in India and that it was obvious to Indian farmers, are not sufficient to invalidate its patentability in the US.

175 These 3 section of the 35 US Code lay down the requirements of an invention to become patentable: (1) it should have some practical usefulness, (2) novelty, (3) non-obviousness from the prior art to a PHOSITA at the time the invention was made, (4) provide sufficient description in order to enable a knowledgeable person to practice the invention in the best mode.

According to Sections 102(a) and 102(b), in order to invalidate a patent on the basis of novelty and prior art, it is necessary that the foreign knowledge in that regard has been published before the application for its patent was made.

It was further contented that there was a possibility that this patent in the US may not have any significant economic or social implications in India and its farmers. The Indian farmers can continue to produce and use their own neem extractions through any process, as initially the Indian patent regime did not allow the private ownership of agricultural and medicinal products. The company also argued that they had no intentions of seeking an analogous patent in India in the future, even after the incorporation of TRIPs provisions into the India patent regime. The reason they gave for this is that the Indian patent process was too lengthy and time consuming to be made useful.

It was also pointed out that the W.R. Grace's patent could highly benefit India and become its new cash crop. Since the company processes its neem seeds in India, the Indian farmers could harvest and sell neem to the processors a part from personal use. It is also not sure whether India would provide 'pipeline' protection i.e., the patent protection that extents its scope to include products whose subject matter was first found in India but are already patented elsewhere. This kind of protection is not mandatory to be provided under the TRIPs Agreement for applications preceding the entry-into-force, though it is required for subsequent applications.[176]

But to other activists around the world, this patent seemed problematic as it showcased the Western nations appropriating the traditional knowledge and biological resources from other developing nations. The activists gave this as an example to

176 *Supra* note 175.

prove how the imperial nations with more power can get whatever they want, even at the expense of violating the rights of developing countries. They also opined that the Grace patent should be invalidated and revoked as it ignores and fails to recognise the use of neem rooted in India for centuries, making the patent obvious and not novel. It was further stated that this patent is not only technically invalid, but it is also wrong on moral grounds as it commercializes it by violating the Indian cultural identity, as neem is considered to be sacred in India.

Finally in September 1995, a legal petition was filed in the US Patent and Trademark Office by a coalition group consisting of 225 agricultural, trade and scientific groups and around 100,000 Indian farmers as well. This coalition group was led by an US based organisation called Foundation on Economic Trends. They stated that the patent granted to W.R. Grace & Co should be revoked as it lacked novelty, was obvious and also immoral. The coalition tried to prove that the company was guilty of IP piracy. They provided evidence to prove that the knowledge and practice of using the neem seed extracts for fungicidal effect had been used by Indian farmers for centuries to protect crops, and so the patent should be revoked. On this very ground, they filed a petition for re-examination of the patent. However, this request was rejected due to the geographical limitation in U.S. patent regime regarding prior use.

Later in the same year, Magda Aelvoet, a member of the European parliament and representative of the Greens in the European Parliament, filed an opposition for this patent with the EPO along with two other Civil Society Organizations. They filed for revocation of the patent on the ground of lack of novelty under Article 54(1) and (2) of the European Patent Convention (hereinafter EPC) and lack of inventive step under Article 56 of EPC. They also claimed that the patent

was against public morality under Article 53(a) and lack of sufficient disclosure under Article 100 (b).

After reviewing the claims, the opposition division held that the requirement of sufficient disclosure was satisfied and that Article 53(a) of EPC was not applicable in this case. They also observed that the issue of appropriating traditional knowledge was related to novelty criteria and not morality as the applicant had not restricted India from acting on their knowledge. On the claim of lack of novelty, the opposition division decided in the opponents favour and held that the prior use had existed in various parts of Western India well before the application for its patent was made. In May 2000, the EPO ultimately decided to revoke the patent granted to W.R. Grace on the basis of disclosure to public prior to the filling of patent application and lack of inventive step.

The patentee appealed against the EPO's decision. In March 2005, the Boards of Appeal of the EPO gave its final decision. During the appeal proceedings, W.R. Grace company transferred their ownership of the patent to another US company called Thermo Trilogy Corporation and the US government remained co-proprietor of the patent. Here the appellate board also reconfirmed and stated that the patent should be revoked on the ground of lack of inventive step. Thus, the patent was finally revoked.

5. Artemisia Judaiaca

Misappropriation of traditional knowledge and commercial exploitation thereof is the subject-matter of biopiracy. However, to what extent traditional knowledge is protected and whether if an entity while using traditional knowledge gives due recognition to the source country, can the activity of monopolizing be called biopiracy is questionable. Furthermore, if a process patent is granted whether that amounts to biopiracy is also an issue to be mooted. The present

case deals with *Artemisia Judaiaca* a plant whose extract is used to treat diabetes traditionally in Libya. The patent was obtained in the USA by an UK company Phytotec Ltd. a subsidiary company of PhytoPharma PLC. The process which was patented was the "Artemisia Judiaca Fractionation Method", bearing patent no. 6350478[177].

Artemisia Judaiaca is a plant that is commonly found in Libya, the plant has many anti-diabetic, anti-bacterial and anti-inflammatory characteristics[178]. The extracts of the plant have also been used traditionally to treat diabetes[179]. In the patent claim for the Fractionation Method, McGrow reported that the company mentioned that "Artemisia judaica is used in Libyan traditional medicine as an infusion for the treatment of "wasting disease", almost certain diabetes mellitus.[180]" Confusion and debates with respect to whether this patenting of the process constitutes biopiracy or not started after this report published by Edmond Institute in cooperation with the African Centre for Biosafety.

Authored by Jay McGrow, this report raised questions that are yet to be understood in its clearest sense. Some of the issues that McGrow raised in this report titled "Out of Africa: Mysteries of Access and Benefit Sharing[181]" were:

a. Whether the novelty criteria for the patent was fulfilled considering the company itself mentioned in

177 *Su*pra note 168.

178 Moharram, et al., *Pharmacological activity and flavonoids constituents of Artemisia judaica L aerial parts*, 270 J. Ethnopharmacol (2021).

179 DANIEL ROBINSON, CONFRONTING BIOPIRACY: CHALLENGES, CASES AND INTERNATIONAL DEBATES (Routledge, 2010).

180 Jay McGrow, *Out of Africa: Mysteries of Access and Benefit Sharing* (Edmond Institue, 2006).

181 *Id.*

the claims that Artemisia Judaica is used for treating diabetes traditionally in Libya?

b. Whether access and benefit sharing agreement has been concluded with Libya with regards to this patent?

Further, post the publication of this report, researchers[182] have raised various issues with regards to the patent, the main among these were:

a. Whether granting patent for a process that involves traditional knowledge is an example of biopiracy?

To answer McGrow's first issue, although the company mentioned in its claim that *Artemisia Judaiaca* has been traditionally used to treat diabetes in Libya and other Africa countries, the process that the company patented was found to have 'non-mutagenic properties' as compared to the traditional use of *Artemisia Judaiaca* that is said to have 'deleterious mutagen' in the extracts of the plant which rendered the extract non-usable for humans and animals. The mutagen was removed by chromatographic analysis in this case. This fulfilled the novelty criteria for obtaining the patent. The second issue with respect to access and benefit sharing is questionable. Although the process was developed using scientific method of chromatographic analysis, nevertheless, the traditional knowledge that existed priorly with regards to treatment of diabetes by using the extracts of this plant was the actual reason why scientists were drawn to this[183]. Therefore, both the traditional knowledge and modern medicine played a part in achieving the process patent. The question still remains as to whether access and benefit sharing was accorded to Libya.

182 *Supra* note 178.

183 *Supra* note 180.

Further, traditionally, process patents are not considered as a proponent for biopiracy. Nevertheless, in its strictest sense, the traditional knowledge was employed and fine-tuned to get a medicine for treating diabetes. This although amounts to misappropriation of traditional knowledge, whether the same is biopiracy is questionable. Further, no evidence could be found which suggested that the biological material to conduct such a research and come to a conclusive result was obtained by any unfair or unethical means.

This case is a clear example of restrictions of traditional knowledge and what amounts to biopiracy. It is still unclear whether the process patent obtained by the UK Company was in fact biopiracy and misappropriation of traditional knowledge. If so be it, an argument can be made that the traditionally used process of using the extracts of *Artemisia Judaiaca* had 'deleterious mutagens' and the traditional users used the same extracts not being aware of the side-effects of the same. A counter-argument of the same is that the scientists were drawn to the biological material due to the existing traditional knowledge that stated that the extracts of the plant can be used for treating diabetes. The convenient solution would be allowing access and benefit sharing as per the Nagoya Protocol to Libya for partially contributing towards obtaining the process patent.[184]

6. The instance of Quassia amara

Precisely[185] what can be protected, for how long, and by whom, varies between legitimate structures, which creates a lot of turmoil for analysts, governments, and customary nearby

184 *Supra* note 178.

185 Bourdy Genevieve, et al., *Quassia 'biopiracy' case and the Nagoya Protocol: A researcher's perspective,* J. Ethnopharmacol (2017) https://www.researchgate.net/publication/317270083_Quassia_biopiracy_case_and_the_Nagoya_Protocol_A_researcher's_perspective.

people groups. As of late, a Biopiracy case surfaced between the French Institute for Development Research (IRD) and nearby authorities in French Guiana, an abroad division and previous state of France. This debate embodies a few normal errors in Biopiracy. French scientists directed meetings in French Guiana to get some answers concerning neighborhood ant malarial cures. That fundamental exploration was distributed in 2005, and after ten years, a patent was allowed for another compound from the plant Quassia amara which had ant malarial properties. Analysts tracked down the compound not from customary arrangements of the plant in a tea, however from liquor-based extraction techniques. Consequently, in the European logical practice, the compound did not come from customary Guianese techniques yet was found by the researchers. Regardless, it was the neighborhood Guianans and their plant information that drove the researchers to inspect Q. amara and not huge number of others plants. As indicated by the recently carried out laws, arrangements ought to have been made before the exploration even started. Presently, French Guiana and the IRD are going into conversations to shape a retroactive arrangement. Biopiracy is not probably going to vanish any time soon. As environmental change compromises, numerous enormous agribusinesses and scientists are licensing dry season safe, heat-safe, and salt-safe qualities from plants for later use in crop species. To counter this, numerous analysts are endeavoring to gather qualities and distribute them in logical areas, (for example, the NIH's online Gen Bank or different seed banks). By sharing hereditary arrangements, researchers can keep large firms from asserting uniqueness and oddity, two models for licenses. While licenses were first used to secure creations and animate advancement, numerous enemies of Biopiracy activists and some scholastic and logical circles are pushing for changes in the framework, as it is presently

suspected to ruin research in numerous significant regions. For the time being, the issue of Biopiracy stays at an impasse.

7. Rooibos (Aspalathus linearis)

The Rooibos case of South Africa shows how negotiated agreements with regards to access and benefit sharing can put an end to biopiracy other than just mentioning the source of the traditional knowledge. Rooibos is native to South Africa; it is considered one of the oldest indigenous plant products grown on a commercial basis. Rooibos contain low tannin, is free from harmful stimulants and caffeine and is identified for its long-term medicinal use. Rooibos has been long known to have high flavanol content that helps the cardiovascular system due to its anti-inflammatory and antioxidant properties. The San and Khoi people of South Africa have demanded that they hold the traditional knowledge related to rooibos[186]. Along with it the small-scale coloured rooibos producers, also remains marginalized. Rooibos requires specific climatic conditions for its growth and regions of South Africa are the have the best climatic conditions for the growth of this plant. Rooibos has a history linked with the genocide of the San and Khoi communities and the apartheid in Africa. Nevertheless, this plant has been traditionally related to the communities of South Africa since a long time. Rooibos other than being used for medicinal purposes is also used as an herbal tea. It holds 10% of the herbal tea market internationally due to its qualities which includes it being non-caffeinated and having properties of anti-oxidants[187].

186 Prof Kaplan(Contr), The Economics Of Intellectual Property In South Africa 42 (Wipo, 2009) https://www.wipo.int/export/sites/www/ip-development/en/economics/pdf/wo_1013_e_ch_2.pdf.

187 *Id.*

Nestlé in 2009, filed five patents[188] with respect to Rooibos and Honeybush extracts claiming that the extracts can be used to treat inflammation or for better quality skin and hair. One of the claims with regards to Rooibos is produced below:

> *"Aspalathus linearis (Rooibos) or an extract thereof for the preparation of a product to treat and/or prevent inflammatory disorders – especially inflammatory disorders of the gut, osteoarthritis and rheumatoid arthritis. The patent also seeks to cover the use of the composition for food products, drinks, food supplements, nutraceuticals, cosmetic products, pet food products or medicaments[189]"*

The patent and applications linked to rooibos are largely exploitive in nature of the properties of Rooibos and its extracts. A small number among these applications are for new processes relating to Rooibos. There are the many investigators who demonstrated the health-giving properties of rooibos and have initiated different processing techniques[190].

The biopiracy concerns that rose with Rooibos is that Nestlé had not acquired any permit from the 'provider' country and/or community to use and commercially exploit Rooibos. Furthermore, no agreement of access and benefit sharing was concluded between Nestlé and its sister company L'Oréal and the San and Khoi communities. Nestlé on the other hand claimed that negotiated agreements have been entered between the companies and the communities. The claims for biopiracy were strengthened following a research report by the

188 Berne Declaration and Natural Justice, Dirty Business for Clear Skin: Nestlé's Rooibos Robbery in South Africa (2010) https://www.cbd.int/abs/side-events/resumed-abs-9/id2114-berne-policy-brief.pdf.

189 *Id.*

190 R Wynberg, Making Sense of access and benefit sharing in the rooibos industry: Towards a holistic, just and sustainable framing, 110 S. Afr. J. Bot., 40 https://www.sciencedirect.com/science/article/pii/S0254629916305300.

Berne Declaration and Natural Justice wherein it was stated that Nestlé in fact had no permit for commercially exploit Rooibos. The report titled 'Dirty Business for Clear Skin: Nestlé's Rooibos Robbery in South Africa' stated the violation of Nestlé as per both international and national legislations. According to the Convention on Biodiversity coupled with the Nagoya Protocol for benefit sharing a negotiated agreement has to be entered with the provider country or community for access and benefit sharing, but the report revealed that "*The South African Government confirmed to Natural Justice and the Berne Declaration that neither Nestec S.A. nor Nestlé has ever received consent to access Rooibos or Honeybush and has not negotiated a benefit-sharing agreement*[191]."

Nationally, The South African Biodiversity Act (which implements the CBD in South Africa) prerequisites a permit from the Government to do research with commercial intent on, or patent the use of, genetic resources that are found in South Africa. The permit can only be obtained if a benefit-sharing agreement has been negotiated. The Department of Environmental Affairs of the South African Government confirmed to Natural Justice and the Berne Declaration that Nestlé has never received the permits to use these South African genetic resources[192].

Subsequently, with the joint effort of the Berne Declaration and Natural Justice and the San and Khoi communities, Nestlé was in fact bought to the negotiating table wherein an agreement for access and benefit sharing was concluded[193], whereby Nestlé's was bound to provide benefit

191 *Supra* note 189.

192 *Id*.

193 *Rooibos Robbery- A Story of Bioprospecting in South Africa,* HEINRICH BÖLL FOUNDATION https://za.boell.org/en/2016/05/19/watch-rooibos-robbery-story-bioprospecting-south-africa.

sharing as per the Convention on Biodiversity coupled with the Nagoya Protocol for commercially utilizing the traditional knowledge of the San and Khoi community. This put an end to the outcry of biopiracy and misappropriation of the traditional knowledge held by the community.

8. White Kwao Krua (Pueraria mirifica)

The White Kwao Krua is a traditionally grown vine in Thailand which became a prime example of biopiracy both locally and internationally. The White Kwao Krua has its usage as early as 1931 in the scripts[194]. This herb has been used in cosmetics and for revitalizing in Thailand since a long time by Thai healers and traditionally in households. Recently it has been identified scientifically that the cosmetic effect that this herb produces is due to the presence of Phyto-oestrogen and Phyto-androgen, i.e., plant produced female hormones and plant produced male hormones respectively. It has been claimed that the extracts of this herb can aid in breast firmness and enlargement and also aid in addressing erectile issue of men.

The first patent was granted in the year 1999 by the Thailand Patent Authority bearing the Patent Number 8912. The patent was obtained for 'Medicinal herbal composition from kwao krua[195].' Plant patents and extracts thereof are not patentable in Thailand as per Section 9(1) of the Thailand Patent Act. Nevertheless, the patent for kwao krua was granted on the basis that it was a 'chemical derivative of the plant[196].' Post grant, the proprietor company who had applied for the patent released a public notice and advertisements in

194 *Supra* note 178.

195 *Id.*

196 DANIEL ROBINSON, CONFRONTING BIOPIRACY: CHALLENGES, CASES AND INTERNATIONAL DEBATES, 57 (Routledge, 2010).

newspapers barring any company or individual to use the kwao krua extract that had been patented. This resulted in a huge out-cry wherein companies and individuals stated that this would have a detrimental effect on the business considering that almost 35 companies used the patented kwao krua extract and it was used in up to 50 formulas of these companies' products[197].

Subsequently, issues were raised for allowing a patent of the extract of the plant, also, a question regarding fulfilment of the novelty criteria also came up. Kwao krua extract has been used by Thai households and by Thai healers for more than 100 years, appropriate documentation of the usage can be found in scripts in Thailand even from the year 1931, the argument was that the applicant had not fulfilled the novelty criteria which is an essential for granting patent and the Patent office had either ignored or was unaware of the existing traditional knowledge surrounding the herb kwao krua[198].

Subsequently, another proprietor Dr. Wichai from a University in Bangkok acquired three patents bearing numbers 046779, 048605 and 052443 in relation to extracts from kwao krua. The three claims related to white kwao krua, red kwao krua and black kwao krua respectively[199]. These patents were also challenged and spent quite a considerable amount of time under scrutiny. Nevertheless, the fear among the local producers and the household users of the kwao krua continued as the patents were for monopolizing the use of these extracts. Even in these patents the question of novelty was brought up

197 Daniel Robinson, *Biodiversity-Related Traditional Knowledge In Thailand: Intellectual Property Relations And Geographies Of Knowledge Regulation*, The University of Sydney 170 (2007) https://ses.library.usyd.edu.au/bitstream/handle/2123/8567/Robinson_Final_PhD.pdf;jsessionid=69305C20C2662168AF8F7842340565CD?sequence=4.

198 *Id.*

199 *Id.*

and mooted. This was one among the cases that dealt with local biopiracy and commercialization of indigenous knowledge even in the local community by excluding other users of the extracts of kuwa krua[200].

The issue with regards to kuwa krua, however, did not end with the local biopiracy, it continued internationally with two patents being granted in the USA for the use of the extract of kuwa krua. The first patent was held by a proprietor of Tokyo, Japan bearing patent number 6,332,685. The claims of the first patent were analysed by Dr. Jade Donavanik, an IP attorney. One of such claims is produced as:

> *"an external composition for skin comprising, as an essential ingredient, a liquid extract of a dried root lump of Pueraria mirifica; wherein said liquid extract comprises an extraction solvent which is at least one selected from the group consisting of water, lower alcohol, liquid polyhydric alcohol; and wherein said external composition for skin contains 0.00001 to 5 wt % of said liquid extract of said dried root lump of Pueraria mirifica as dried solid in the composition.[201]"*

On reading the claim it is quite clear that the end product is a gel like substance that is to be applied on the skin. The issue with this claim was that the extraction process that is rather very well-drafted, in generally terms, is very similar to the extraction process that was traditionally used in Thailand for years. The second patent was held by a proprietor in Seoul, Korea bearing patent number 6,673,377, one of the main claims is produced as:

> *"an extract derived from Pueraria mirifica having an effect on improving breast firmness, breast enlargement and wrinkle removal from the breast, wherein said extract*

200 *Id.*

201 *Id.*

is prepared by the steps of: drying tubers, roots, stems, leaves and/or tissue-cultured calluses of Pueraria mirifica, optionally by spray-drying, freeze-drying and/or vacuum-drying; pulverising the dried tubers, roots, stems, leaves, and/or tissue cultured calluses into pieces or powders and then immersing the plant pieces or powders in a mixture of methanol and water; extracting the mixture; and filtering the resulting extract and then concentrating it in a vacuum to remove the solvent[202]*"*

Again, the issue with this claim remained the same, the extraction method and the expected use mentioned in the claim is very similar to the traditional use by the indigenous community[203].

Patent number 052443 granted in Thailand become another source of controversy as it served as a main basis for the Korean patent number bearing 6,673,377.

In all these controversies the issue of novelty has been raised several times. The point of contention being that the Department of Intellectual Property (DIP) in Thailand and also the USPTO did not take into consideration the prior art that is one of the main grounds of rejection of patent application. It has been urged by researchers that patent official should be educated about traditional and indigenous knowledges prevalent in communities. Furthermore, prior art should be duly considered while granting patents to reduce the evils of biopiracy[204].

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202 *Id.*

203 Ryan D. Levy and Spencer Green, Pharmaceuticals and Biopiracy: How the AIA May Inadvertently Reduce the Misappropriation of Traditional Medicine, 23 U. Miami Bus. L. Rev. 401 (2014) https://repository.law.miami.edu/cgi/viewcontent.cgi?referer=&httpsredir=1&article=1251&context=umblr.

204 Robinson, *Governance and Micropolitics of Traditional Knowledge, Biodiversity and Intellectual Property in Thailand: Research Report*, National Human Rights Commission of Thailand, Bangkok, UNSW and University

9. Hoodia Case

The San people settled in South Africa around 150,000 years ago. Presently, there are about 100,000 San people living in the Kalahari region of South Africa, Namibia, and Botswana. The Khomani Sans did not own land and worked as farm labourers and domestic help. Their cultures, traditions and language started to disappear in the early 1990s. In 1994, the apartheid collapsed and the new government returned the ancestral lands to the Khomani San people. They settled their land disputes with the new government and established national and regional councils.

The CSIR is involved in mandatory research and development of technology in South Africa. One of its branches called the Foodtek Chemical and Microbial Products, undertakes several bioprospecting activities there and is working on producing natural products with chemical capacity. The council had been under severe pressure to get commercial investments as its funding from the government had declined. Thus, the council had to obtain many commercial contracts for developing products based on chemical compounds discovered through their research on natural products, since it was not equipped to do clinical or toxicological studies due to lack of funding.

The Hoodia cactus has been used as an appetite supressing agent by the San for centuries, especially during hunting seasons when they had little to no food available. They chopped the cactus stem off up to the size of a cucumber and ate that to avoid starvation and thirst. In 1963, CSIR became aware of this plants, traditional use though a paper published by a Dutch ethnobiologist in 1937 and from the San trackers who worked for the military. Finally in the early 1990s, the council

of Sydney (2006) https://www.iprsonline.org/resources/docs/Final%20HRC%20Micropolitics%20Report%20Mar%202005.pdf.

regained interest in this plant and researched upon it further. They separated the active ingredient from it, which was a compound called P57 and got its patent in 1995. In 1997, the CSIR licensed this patent to a British biotech company called Phytopharm for conducting double blind clinical trials on it to confirm its appetite suppressing properties.

In the first phase of the clinical trial, the compound or its placebo was given to obese people and it resulted in significant decrease of their daily foot intake by approximately 1000 calories, thus it was being developed as a possible remedy for obesity. This product was further sub-licensed by Phytopharm to Pfizer for $32 million. They got the right to produce and sell the product as a possible slimming medication and for the treatment of obesity.

A lawyer who was representing the Sans in their land disputes with the government found out about the license of CSIR's patent on P57 compound given to Phytopharm. He also learned that the CEO of this British biotech company believed that the Khomani San community had perished. The surviving San were residing in a tent camp 1500 miles away from their tribal land after being removed from there at the time. When the CEO was made aware of this erroneous information, he was willing to properly compensate the San community for the use of their traditional knowledge on hoodia plant. The head of the P57 compound research project at CSIR stated that he had full intention of notifying the company about this fact after the product had become successful. The lawyer representing San informed the then newly formed Sans political organisation about the patent of P57 by CSIR, which they decided to challenge as they had not been compensated for the use of their traditional knowledge.

In June 2001, an urgent meeting was convened between the Working Group of Indigenous Minorities in Southern Africa

(hereinafter WIMSA), an organisation that represented San community in the region, and the representatives of CSIR. A few months after this meeting, in November, the South African San Council was formed by the support of WIMSA, which represented the San community and their claims on the traditional knowledge and benefit sharing of the use of the hoodia patent in their negotiations with CSIR. They did not challenge the validity of the patent itself as it would mean that they will not receive a share in the profit gained from its commercialization, instead they demanded a share in the benefit earned from the commercial development of the product. They alleged that the company had bio-pirated their traditional knowledge and that CSIR had not acquired the consent of the tribe to use this knowledge which is a mandatory prerequisite under the Convention on Biological Diversity. CSIR accepted this contention to provide appropriate compensation and negotiated with the representatives on this regard.

In February 2002, the San political council and CSIR entered into a memorandum of understanding, which acknowledged the contribution of the traditional knowledge from the community in the commercial development process. They agreed to share the benefits with the South African San community as well as San communities in other countries around that region like Namibia, Angola and Zimbabwe.

The terms of the agreement mentioned that CSIR will pay a certain share of the amount it receives form Phytopharm, along with a fixed share of the royalties gained from the products that were developed based on the P57 compound, to a trust fund created for the San community called the San Hoodia Benefit-Sharing Trust. This fund was to be used to support local development projects and for purposes of provided employment, education and preservation of their language. Thus, this agreement became an epitome for

equitable benefit sharing from use of traditional knowledge of an indigenous community.

Unfortunately, in August 2003, Pfizer returned its sub-license to Phytopharm and discontinued their activities on P57 compound. Later this compound reached the grey market and the share in the benefits given to the tribe needs to be looked at again.

10. Ayahuasca Case

The "*banisteriopsis caapi*", is indigenous to the north-western regions of the Amazon rainforest in South America. Its bark has hallucinogen properties and its used in shamanistic rituals by the indigenous tribes in both Peru and Ecuador. The plant is used to make a ritual wine or cocktail called ayahuasca, which means "wine of the soul". It is believed to help see spirits, which is a sacred part of their culture and tradition. It also has healing qualities wherein the "mother spirit of the vine" is believed to enter into the visions of the sick person and gives them commands through special Ayahuasca songs.[205]

In 1974, an American citizen named Loren Miller received a sample of this plant from the Ecuador tribe in return for her promise to build a school in that region for the tribe. After returning to the US, she cultivated the plant in Hawaii and conducted further research. She developed a stable variety of the Ayahuasca plant that could be patented. Later she established a company called International Plant Medicine, to research and find out if the plant had any useful purpose. Finally in 1986 she was granted patent for a variety of the plant which was named "Da Vine." In the patent application,

205 Henrik Ardhede, *Traditional Knowledge and the Patent System – Irreconcilable differences or a simple case of mistaken identity?,* 30-34 (2006), https://lup.lub.lu.se/luur/download?func=downloadFile&recordOId=1555871&fileOId=1563800.

she mentioned that she got the plant sample from a domestic garden in the Amazon rain-forest. It was claimed that this variety of the plant is new and unique as it had different coloured flower petals from the original ayahuasca plant.

In 1994, the Coordinating Body of Indigenous Organizations of the Amazon Basin (hereinafter COICA) found out about the patent that was granted to Miller for a variety of the plant. This organisation includes more than 400 indigenous groups in the Amazon region. The reaction of the tribe was bad as they were not keen about the fact that an outsider used the ayahuasca plant that they has been using for centuries within the tribe. It went such an extent that a coalition actually threatened to physically harm Miller if she ever returned to the region. As a retaliation to this threat, the US government stopped all the aids that they were previously providing to the tribe.

The COICA was also aware of the fact that Miller had intentions to establish a pharmaceutical laboratory in Ecuador to process ayahuasca. This caused fear among the COICA members that a bilateral IP reciprocity agreement would be entered into between the US and Ecuador, which would force the tribe to acknowledge and recognize Miller's rights over the ayahuasca plant, which is a sacred and integral part of their cultural identity. To prevent this, the COICA and the Amazon Coalition decided to challenge Miller's patent in order to protect the tribe's rights to their traditional knowledge and their biological resource. They were being represented by the attorneys at the Centre for International Environmental Law (hereinafter CIEL).

In March 1999, they made a request for the re-examination of the patent to the USPTO. In this request, they contended that there was sufficient prior art to evidently show that the Da Vine variety was not novel or new, which is the first

requirement of patentability of an invention. The description of the ayahuasca plant made by Miller in her patent application was similar to those already stated in the literature and was known by the tribal community in Amazon. The CIEL attorneys further argued that the patent violated the Plant Patent Act because the variety is found in an uncultivated state. Their last argument was that the patent also violated the Patent Act's utility requirement, since any patent granted for a sacred plant of an indigenous community is against the notions of public policy and morality.

In May 1999, the patent office allowed the request for re-examination on the ground that the Da Vine variety was identical to other varieties of ayahuasca plant that were found in the V.S. herbarium collections. In November 1999, after the re-examination was completed, the patent office decided to revoke the patent that was granted to Miller on the basis that the same plant described in her patent application was found described in herbarium sheets in Chicago's Field Museum, a whole year before the application was filed. However, in April 2001, the inventor was able to convince the USPTO, which reconfirmed the original claims and restored the patent rights to the innovator for the remaining term, i.e., 2 years.

But the patent office did not attend to other pressing issues like whether the issue of a patent can be precluded in cases where there is a sacred plant of an indigenous community involved or in case of traditional knowledge.

Since there was a lack of response to these issues by the Congress or the patent office, many developing countries enacted laws that made it harder for researchers from developed nations to research and study the indigenous plants and animals for possible medicinal value. As mentioned above, since the Da Vine controversy occurred, there was no bilateral IPRs agreement proposed between US and Ecuador, which

might have probably signed this agreement if the controversy had not happened. From this case it can be seen that the US patent policy and policies of other developed countries result in international conflict and protectionist response from developing nations. Consequently, the useful traditional knowledge and biological resources from developing countries are often not exposed to the world, which has negative implications for both sides.

8.3 Non-Patent Related Biopiracy Cases

1. Jasmati Trademark

Jasmati trademark case rose in the 1990s when some parts of United States of America trademarked 'Jasmati' for their trade affairs. It was believed that Jasmati is a traditional rice grain grown in some parts of Thailand where was called as 'The Thai Rice'. Several farmers of Thailand started their protest against a U.S trademark for a strain of rice obtained under the company of Texas. Roughly 500-1000 farmers started this protest against the company of Texas RiceTec who trademark the rice grain 'Jasmati' in the year 1990. The fear of being denied to sell their traditional rice grain 'Jasmati' was creeping inside the farmers of Thailand.[206]

A letter had been posted by the farmers of Thailand to the United States Trade representative Charlene Barshefsky. They feared of being suppressed by a first world country. They stated that the trademark authorities of United States had illegally trademarked the name Jasmati for the benefits of the rich industrialists.

The Jasmati trademark case has been widely reputed in the early 2000s but, it came to the limelight few years ago in

206 Montira Narkvichien, *Thai Farmers Protest Trademark by US Company of Rice Strain,* Wall Street Journal (Jul. 23, 1998, 12:10 PM) https://www.wsj.com/articles/SB901135675864095500.

the United States of America. One can say that, the popularity of this case has shrunk in past few years but the issues have not been resolved, yet. [207]

The first trademark application was filed in the 1990s by Dogeut-Dishman Rice Company of a variant "Jasmine 85", which was named after the rice line Khao Kao Dok Mali 105 (KDML 105) which was basically a rice strain named Jasmine. In the coming years between 1990-2000, there were several companies such as Dogeut-Dishman Rice Company, some company originated in Arkansas who had subsequently filed a trademark application for Jasmine but, later withdrew it.

The Jasmati trademark was initially incorporated in their packaging by a company named Rice tec situated in Texas in the month of May 1990, which was later abandoned for defective statement of use. [208] Later, the same company registered with the Jasmine trademark and it was accepted in the year 1993.

The embassy of United States of America tried to calm these protests by the farmers of Thailand by giving a statement where they were assuring that the rights of people of Thailand are not been violated. The right for the shipment of Thai rice named Jasmati from Thailand will not be challenged. They further stated that these misunderstandings are results of false news reports and media botheration.

This is the first biopiracy case experienced by Thailand in the year 1997 due to the hybridisation of the Jasmine rice of Thailand and the Basmati rice of Indian subcontinent

207 Muriel Lightbourne, *The JASMATI Trademark affair,* GRAIN (Mar. 26, 1999) https://grain.org/fr/article/entries/2060-the-jasmati-trademark-affair.

208 *Id.*

originated in the state named Kashmir.[209] The fear of the people of Thailand rose as this could have mislead the consumers around the globe as Thailand was the sole producer of Jasmine rice, the hybridisation could also have uprooted the Thai cultured rice which started in the early 1950s. For this concern, a survey was conducted among the consumers around the globe, especially the consumers of United States of America where they have been asked if they were using the traditional Jasmine or the hybrid version of Jasmine and basmati named as 'Jasmati'.

The Rice Tec corporation later published a report where they clearly mentioned about the origins of this rice grain and its history. According to them, this grain has been derived from a hybridized variety called as Delta which was incorporated from the rice brand of Italy named as Italian Bertone rice.

Kasertsart University in the year 1998, a DNA fingerprinting report was submitted where it was proved that the alleged hybridization of the Thai Jasmine named as KDML 105 and Indian-origin Basmati is false. This report was not convincing enough and had been refused to be accept as proof by the USPTO legal advisor over a video conference which was held at Thailand U.S embassy in the year 1998. The advisor of USPTO was to conduct a survey among the USA consumers about the use of Jasmati and the traditional Jasmine rice grain.[210]

On June 24 1998, the department of foreign trade of Thailand filed an application for the trademark which was established as a complex certification mark named as "Thai Hom Mali" which was originated in Thailand. The literal

209 Chuthaporn Ngokkuen and Ulrike Grote, Challenges and Opportunities for protecting geographical indications in Thailand, 19(2) APDJ 93 https://www.unescap.org/sites/default/files/chap-5-Ngokkuen.pdf.

210 *Supra* note 208.

meaning of the trademark name is "jasmine fragrant rice". The application of this trademark was filed to reserve the rights of the Thailand people to trade the jasmine rice globally and to retain the long-lived heritage of Thailand. Later, to obtain the reputation, it gave a six-month priority period for any abroad associations to file another trademark.

Thus, the overall case was not against the quality or the hybridization of the rice but, to not confuse the customers worldwide between the rice grains of Jasmine and Jasmati. This has been later supported by a rice researcher at Thailand's Agriculture Ministry where he criticized the use of the name "Jasmati" used by the Texas company "Rice Tec", as it can stain the popularity and originality of the Thailand's Jasmine rice grain.[211]

2. Bolivian Habanero Pepper

A case with respect to non-patent related biopiracy is the case of Bolivian Habanero Pepper. A pepper variety (*Capsicum Chinenese*) was developed in the USA by crossing an orange breed of pepper from the Yukatan Peninsula and a gene obtained from the United States Department of Agriculture (USDA) that had a plant introduction (PI) number of 5431988[212]. This gene was originally obtained by an USDA official from the borders of Brazil on November 1988 and was then transferred to the USDA gene bank in Georgia from which the gene was collected for cross-breeding[213]. A claim for Plant Variety Protection of the cross-bred pepper was filed and later obtained in 2007. In 2004, the Texas A&M University System Agricultural Program vide a news article stated that

211 Montira Narkvichien, *Thai Farmers Protest Trademark By US Company of Rice Strain,* WALL STREET JOURNAL (Jul. 23, 1998, 12:10 EST) https://www.wsj.com/articles/SB901135675864095500.

212 *Supra* note 168.

213 *Supra* note 198.

a non-piquant variety of pepper has been developed by Texan Plant Breeders. This cross-bred pepper named as the 'TAM Mild Habanero' was obtained after a 5-year breeding program in South Texas. Dr. Kevin Crosby, one of the breeders stated that "It's a beautiful pepper with all the aroma and flavor of the traditional habanero but with just a fraction of the pungency[214]." The issue that arose was that this "TAM Mild Habanero" in fact retained most of the qualities of the Bolivian habanero gene that was one of its parents. The Bolivian Habanero was bred locally in Bolivia for the same reason of it being non-piquant. However, in this case unlike a plant patent, a plant variety protection was obtained[215]. In a plant-patent there is a requirement of non-obviousness and an examination of the prior art is done. There is no such requirement for getting a plant variety protection.

It is to be kept in mind that the 'TAM Mild Habanero' would never have got a plant patent for non-fulfilment of the non-obviousness criteria, however, a plant variety protection was accorded. The cross-bred variety is claimed to be non-obvious because of various data present which suggests the presence of cultivars of *Capsicum Chinenese* in Brazil, Bolivia and the Amazons, particularly the lowland Amazon Basin[216]. There has also been data suggesting medicinal use of this breed. But such data was not considered while granting the plant variety protection. To obtain a plant variety protection

214 *Texas Plant Breeders Develop Mild Habanero Pepper,* AGRILIFE (Aug. 24, 2004) https://agrilifetoday.tamu.edu/2004/08/12/texas-plant-breeder-develops-mild-habanero-pepper/#:~:text=WESLACO%20%E2%80%94%20Texas%20pepper%20breeders%20have,hottest%20pepper%20in%20the%20world.

215 *Supra* note 198.

216 Cecil H. Brown, Charles R. Clement, Patience Epps, Eike Luedeling, Søren Wichmann, *The Paleo biolinguistics of Domesticated Chili Pepper (Capsicum spp.)* 4(1:1-11) J. Ethnobiol 1, 3 (2012) https://pure.mpg.de/rest/items/item_1747089/component/file_1752435/content.

there is little to prove for the alleged innovation. Unlike non-obviousness requirement in Patents, one has to prove distinctiveness of the Plant to obtain a plant variety protection. Distinctiveness is defined in the PVPA as:

> *"The distinctness of one variety from another may be based on one or more identifiable morphological, physiological, or other characteristics (including any characteristics evidenced by processing or product characteristics, such as milling and baking characteristics in the case of wheat) with respect to which a difference in genealogy may contribute evidence"*[217].

The threshold being so low, even though the 'TAM Mild Habanero' retained the non-piquant characteristic and some other novel characteristics of the Bolivian gene, it was granted protection under the PVPA.

217 Plant Variety Protection Act (PVPA) 7 USC §§ 2321-2582 (1970), s 24(a).

PART IV

CHAPTER 9

TRANSFER OF TRADITIONAL KNOWLEDGE AND BIOLOGICAL RESORUCES

9.1. MEANING OF BIOLOGICAL RESOURCES AND ITS CONNECTION TO TRADITIONAL KNOWLEDGE

The term biological resources include all living creatures such as plants, animals, micro-organisms, along with their genetic materials extracted from their genes and the by-products produced out of them. This does not include the genetic materials of humans. Traditional Knowledge (TK) is information that is held by the native individuals, regularly identifying with their encompassing common habitat. At the point when conventional information is utilized without consent by the analysts, or endeavour the way of life they're drawing from – it's called biopiracy.

Turmeric, a notable home cure in Indian houses since ages, had been asserted for enrolment under Patent laws of U.S. It is a tropical spice filled in the east India and has been utilized as a medication, food fixing, a colour, antidote to parasitic

infections, mending wounds, treating skin contaminations, and so on. In 1995, two India based specialists, Suman K. Das and Hari Har P., from University of Mississippi Medical Centre asserted patent over the mending property of turmeric. Later in March 1995, they were allowed patent over it. Notwithstanding, the Indian Council for Scientific and Industrial Research (CSIR) protested the against the grant of this patent. It gave confirmations to the USPTO about the earlier utilization of turmeric and archived confirmations of the earlier craftsmanship. Rather than the way that the utilization of turmeric in Indian houses is a verifiable truth, it was undeniably challenging to track down any archived data on the utilization of turmeric for wound recuperating. After a broad exploration, 32 references were situated in various dialects to be specific Sanskrit, Urdu and Hindi. Thereby, the USPTO denied the patent, expressing that the cases made in the patent were self-evident and expected, and concurring that the utilization of turmeric was an old specialty of recuperating wounds.

The Traditional Knowledge Digital Library (TKDL) is an Indian advanced information storehouse of the traditional knowledge, especially those of therapeutic plants and subtleties used in Indian system for drug. The objective of the library is to prevent traditional knowledge from being abused through biopiracy and unscrupulous licenses, by recording it electronically and ordering it according to global patent arrangement frameworks. Besides that, the non-patent data set serves to cultivate current exploration dependent on customary information as it works on admittance to this gigantic data on fixes or rehearses. As of late, in India, a private bill has been introduced, which after entry will be known as the Protection of Indian Traditional Knowledge Act, 2016. The bill incorporates the attributes of conventional information and what it consolidates, and makes the Central and State

Governments the overseers of all the customary knowledge in India. The turmeric dispute, also known as '*haldighati ki ladai*' illuminates the dire need to secure Traditional Knowledge, the insufficiency in laws encompassing its assurance.

9.2. BIOLOGICAL RESOURCES AND ASSOCIATED TRADITIONAL KNOWLEDGE

The Ambit of Transfer of Result and Patent of Traditional Knowledge:

The Biological Diversity Act, 2002 also covers the transfer of research results and the filing of applications for Intellectual Property Rights (IPRs) relating to biological resources in India.

There is an exclusion established in the Act dealing to protection of plant varieties under IPR whereby, any person who files an application for any right under any law in relation to plant variety protection adopted by the Parliament, is exempted from obtaining National Biodiversity Authority's (NBA) prior permission. Only resident Indian citizen under the Income Tax Act or an Indian legal organisation can freely transfer the results of the study relating to Indian biological resources. However, no such approval is required for publishing such information in papers or disclosing and communicating such knowledge in any seminar or workshop if the publication follows the Central Government's rules. This aspect is covered in Section 4 of the Act.

Under Section 21 of the 2002 Act and Rule 20(4) of the Biological Diversity Rules, 2004, "*the Authority while granting approval to any person for access or for transfer of results of research or applying for patent and IPR or for third party transfer of the accessed biological resource and associated knowledge may impose terms and conditions for ensuring equitable sharing of the benefits arising out of the use of accessed biological material and associated*

knowledge."[218] Despite being enacted in 2002, the link between the Act and patents was not successfully implemented until 2012, when the Controller General of Patents (CG) issued the Guidelines for Processing of Patent Applications related to Traditional Knowledge and Biological Material. In these circumstances, most applicants were unaware of the regulatory linkage under both of these Acts until the CG issued the aforementioned instructions.

In the event of a transfer of research results under regulation 6, the applicant shall be liable to pay the NBA such monetary and/or non-monetary benefit as agreed upon between the applicant and the authority provided, however, that in case of receiving any monetary benefit, if any, on such transfer, the applicant shall transfer to the NBA 3.0 to 5.0 percent of the monetary benefit received by him.

Draft of Guidelines on Access to Biological Resources and Associated Knowledge and Equitable Sharing of Benefits Regulations, 2019:

Under draft Regulation 8, every Indian researcher or scientist, ostensibly referring to residency status, is required to notify the NBA in a new Form B if they want to deposit a novel microbial strain found in India with a repository outside India. The statutory provision equivalent to this responsibility is difficult to identify. Section 3 does not apply because it is confined to an Indian, and Section 7 also does not apply as one is engaged with 'research' despite being an Indian.

If the microbial strain is shown to be a "result of research" falling within the definition of Section 4, a prior approval from NBA is still required because the transfer would be to a person (repository) outside India, otherwise, there is no legislative

218 Biological Diversity Rules, 2004, §20(4), No. 18, Acts of Parliament, 2002 (India).

need at all. In the former scenario, there is already an approval system in place, and the new Regulation 8 is an unwanted additional duty that lacks statutory grounding. In the latter example, the drafted Regulation 8 lacks statutory support and looks to be ultra vires.

A value-added product is defined under the 2002 Act in Section 2(p) as products containing portions or extracts of plants and animals in unrecognizable and physically inseparable form219. The proposed guideline reinforces the exception for value-added products created by Section 2(c) read in conjunction with Section 2(p) of the Act. Obtaining value-added products as described in Section 2(p) for any reason, transferring the same, transferring research pertaining to the same, or seeking intellectual property based on research or information of the same, does not require clearance.

The proposed guidelines include a new explanatory note indicating that the exclusion does not hold when such value-added items are utilised as raw materials in the production of another product. This explanatory statement appended to the drafted regulation is unnecessary and excessive. This is due to the fact that the exemption to access to value-added products is unrelated to the aim of such access under the BDA.

9.3. PROCEDURE OF TRANSFER

The National Biodiversity Authority of India (NBA) has the duty and power to grant access to biological resources through requests placed before them from different countries, foreign companies, and foreign institutions. Section 19 of the Biological Diversity Act, 2002 deals with the approval given by the NBA to access the biological resources, while Rule 14

219 Biological Diversity Rules, 2004, §2(p), No. 18, Acts of Parliament, 2002 (India).

of the Biological Diversity Rules, 2004 provides the procedure for accessing the biological resources and related traditional knowledge.

NBA provides that any company, while transferring the biological resources to a laboratory outside India for research purpose, must take permission for the transfer through Form I regardless of whether the control and ownership of accessed biological resources rests with the company in India or with the entity outside. A Form II application has to be made seeking the prior approval of the NBA for transferring the results of research to foreign nationals, companies, NRI's, for commercial purposes. The form has similar sections to Form IV with a sum amount of INR 5000/-.

Form IV application is made for seeking approval of NBA for third party transfer of the accessed biological resources and associated traditional knowledge. The form asks for the Name, Address, Professional Profile and the Organisational Affiliation of the applicant(s). The second column requires the details of the biological material and traditional knowledge accessed including the scientific names, common names, details of the knowledge used and sources of such information. The form also requires a self-attested copy of agreement issued by the NBA under Section 3 of the Biological Diversity Act, 2002. The applicant should provide relevant proof of the benefits and mechanism/arrangement for benefit sharing already implemented and the complete details of the third party to whom these are transferred to and their purpose. Apart from these, the nature of benefits envisages details of any agreement between the applicant and the third party, estimation of benefits that would flow to India and the communities and the proposed mechanism and arrangements for benefit sharing out of such transfer are also to be disclosed. These are to be submitted with a declaration, an authorisation letter for representative and a sum of INR 10,000/-.

These Forms can be filled online through the ABS E-Filling Services. The applicant has to register themself as a new user. After successful registration, they can apply for approval, view or edit applications, download documents which are required and check the status of the application. After signing the declaration, the payment tab opens. After the paying the required amount, the applicant can edit their forms or apply for new ones. The status of the previous applications can be checked through the notifications tab on the home page. The ABS E-Filling website has a helpdesk feature which helps the applicants with any further information required. Once the application is filed, a fee in the form of a cheque or DD drawn in favour of the authority must be submitted. Once the authority is satisfied with the merits of the application along with the applicant's information, they may grant them the approval to access the biological resources and related traditional knowledge. The approval will be given in writing after which the applicant will have to sign the same, thus signifying their acceptance of the terms and conditions laid down by the authority.

9.4 GUIDELINES FOR TRANSFER OF BIOLOGICAL RESOURCES, RELATED TRADITIONAL KNOWLEDGE

- In the case of transfer of biological resources and related traditional knowledge to a third person, the transferor needs to take prior permission from the NBA as well as the third party. The transferee also needs to apply to the authority seeking for approval to access the biological resources and related traditional knowledge.
- The process of granting approval as mentioned under section 19 of the Biological Diversity Act, 2002 should be followed.

- The transfer can be made once the procedure for granting approval to the third party or transferee to access the biological resources and related traditional knowledge is completed according to section 19 of the 2002 Act.
- The NBA will collect information of the transferee and decide upon the application within a time period of six months from the date of receiving the application.
- If the Authority is satisfied with the application, it may grant approval to the third party subjected to such terms and conditions as it deems fit to be imposed in each case.
- The approval will be granted if the transferee or the third party agrees to sign on a return agreement duly signed by the authorized officer of the Authority.
- The form of third party transfers is dealt under section 20 of the Biological Diversity Act, 2002 and Rule 19 of the Biological Diversity Rules, 2004.
- The transfer of research results arising out of using the Indian biological resources and related traditional knowledge, to any person who is of foreign national or foreign company or foreign institution or NRI's, is dealt under the Rule 17 of the 2004 Rules.
- The procedure for transferring the research results is followed by a process where the transferee will have to fill an application under Form II and send it for approval to the NBA.
- The application will either be approved or rejected within a period of three months from the date of filing.
- The person or third party needs to make a payment of Rs. 5000/- to the NBA while filing the application.

Once it is done the Authority will look into the information and related requirements of the third party.

- Once the NBA is satisfied with the third party, they will have to enter into a written agreement signed by the respective Officer of the Authority. After the signing the approval is granted for the transfer of the research results to the respective parties or party.
- The NBA may also revoke or reject the granted approval after providing an opportunity to be heard to the third party.

9.5. REVOCATION OF APPROVAL AND RESTRICTIONS FOR ACCESS TOWARDS RESOURCES BY THE NATIONAL BIODIVERSITY AUTHORITY

Rule 15 of Biological Diversity Rule, 2004 deals with the revocation of granted approval towards accessing biological resources and related traditional knowledge. The NBA can withdraw the granted approval for accessing the biological resources and related traditional knowledge under the following conditions:

- the provisions of the Biological Diversity Act, 2002 or conditions on which the approval was granted to the applicant have been violated.
- Applicant has failed to comply with the terms and conditions of the agreement, and conditions of access to resources between that person and the NBA based on which the approval was granted.
- If the applicant got approval on the account of overriding public interest or is causing risk towards the protection of environment and conservation of biological diversity.

The NBA will send a copy of the revocation order to the applicant, the concerned State Biodiversity Board (SBB) and the Biodiversity Management Committees for prohibiting the access of biological resources and related traditional knowledge and order them to assess the damages, if any, and takes steps to recover those damages.

The NBA can also impose restrictions on access of biological resources for the reasons mentioned under Rule 16 of the Biological Diversity Rule, 2004, which are as follows:

- If the access request is for any endangered taxa (Group of endangered organisms).
- If the access request is for any endemic or rare species.
- If the access request affects the livelihood of local people.
- If the access request causes risk to environment which is hard to control and mitigate.
- If the access request causes genetic erosion or affects the ecosystem functions.
- If the access request is against any interest of India or any international agreements entered into by India.

9.6. HARMFUL EFFECTS OF TRANSFER OF BIOLOGICAL RESOURCES, RELATED TRADITIONAL KNOWLEDGE AND RESEARCH RESULTS

The Preamble of The Convention on Biological Diversity, states that:

"*Noting also that where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should*

not be used as a reason for postponing measures to avoid or minimise such a threat" [220]

There is a precautionary principle involved intending to protect and conserve the biodiversity and also natural resource management. This Precautionary Principle or Precautionary Approach comes into existence when there is an uncertainty about prospective environmental risks and there is no action taking place to protect the environment. The Principle has been founded on the awareness that- a false prediction towards the substantial environmental harm, that will not be caused by human activity, is more destructive to society than a false prediction that it will cause considerable harm to the environment.

Precautionary measures can be relevant only in the following cases:

- In cases of uncertainty wherein the threat is relatively certain, and measures needs to be reserved. However, they are viewed as preventive measures and not precautionary.
- In cases of threat to environment resulting in damages. But if there are no indications of environmental damage, then the principle will not apply.
- It is applicable in cases where the susceptive harm is critical or irrevocable in nature. But the principle will not be applicable if the susceptive damage is trivial.

Precautionary measures are crucial for conservation of biodiversity as loss of species, which are genetically unified, and for the ecosystems which are not interchangeable in nature, will be irreversible. Hence, implementation of this Precautionary

220 Secretariat To The Cbd, Handbook Of The Convention On Biological Diversity (Routledge 2000).

Principle aids in sustainability of the biodiversity assets and ecosystem services.

Implementing the Precautionary Principle entails:

(a) accepting the accountability for our actions, and thus the need to validate our actions in light of ethical principles, public accountability, and available knowledge, and not leaving this to chance.

(b) discovering innovative ways of living that are more redeeming for humans and nature alike, and openly evaluating all alternatives.

(c) safeguarding, at whatever cost, sufficient genetic diversity and resilient natural systems to ensure the flourishing of indefinite evolutionary life on the planet.

(d) implementing the necessary changes in personal, economic, and social life that will ensure the flourishing of indefinite evolutionary life on the planet.

Questions arising on when to apply precautionary principle:

Many people have a false perception that scientific knowledge is not necessary, but it is not true. For practical application of a precautionary principle, it needs scientific knowledge. In reality, the principle can only be applied if there is a reasonable expectation that a particular course of action will result in "a considerable reduction or loss of biological variety." There will almost certainly be disagreement as to what would constitute a sufficient reason to expect such a threat. Even scientific scholars disagree on a competent evaluation of probable hazards to biological diversity, which policymakers will discover. There is a lot of disagreement in the scientific literature on how to properly assess biosafety. For example, some experts argue that genetic modification is simply a more accurate and safer method for improvement of agricultural

products. Other qualified specialists with same level of expertise argue that the current understanding of genome and ecosystem dynamics is insufficient to define the term "precision" in the given context. It can't be expected that the contracting parties could reach a consensus in the face of scientific disagreement without prior clarity on the research topics that are deemed to be significant and that form the methodological basis for prudence in regards to biodiversity protection.

The biosafety evaluation of Genetically Modified Organisms (GMO) solves the problem behind the actual application of the principle. Since experts are divided amongst themselves, one expert may highlight few potential benefits from GMOs, while another may highlight few of potential problems. Prospective benefits include results such as augmented production of food; reduction in usage of pesticides; built in resistance against the diseases; insects, drought, or frost in crops; treating environmental pollution biologically; production of medicines, etc. However, there is an equivalently extensive list of probable risks involved, such as loss of effective herbicides and pesticides at an accelerated rate; disruption in the ecosystems; genetic pollution; negative impact to human health, etc. The question then arises, on what basis can a person consider whether it poses a potential threat or a potential benefit?

This list of important research questions could cover a wide range of topics, including non-target organism sensitivity and potential biodiversity repercussions, along with the predicted augmentation of genetic engineering to long-term development. It would be a significant step forward if such sets of relevant questions were available for specific purposes. Hence, these sets of relevant questions are crucial for understanding whether a particular biological resource is a risk to significant reduction or loss of biological diversity.

CHAPTER 10

RECENT TRENDS ON BIODIVERSITY AND BENEFIT-SHARING

10.1. INTRODUCTION TO BIODIVERSITY ACT AND PROTECTION OF PLANT VARIETIES AND FARMERS RIGHTS ACT

The Liberalization, Privatization and Globalization model of 1991 mandated major changes in the functioning of the Indian economy. This in turn required a change in laws, there was more emphasis on private property and entrepreneurship, and adapting to this change was necessary for India to better integrate with the globalised world economy.[221] In 1993, after Convention on Biological Diversity (CBD) was sanctioned, the Trade Related Intellectual Property Rights (TRIPs) agreement of the World Trade Organisation (WTO) was also passed. The most important feature of the TRIPS Agreement is that it requires all WTO member nations to adopt a minimum degree of IPR protection, including patentability for living forms that may be viewed as invented. Patents and "sui generis systems" for plant variety preservation are examples of IPR

221 Philippe Cullet and Jawahar Raja, *Intellectual Property Rights and Biodiversity Management: The Case of India,* 4 GLOB. ENV. POL. 97, 101 (2004).

that have an impact on biodiversity conservation under the TRIPs Agreement.[222]

In India, a number of specific TRIPS agreement obligations influenced the country's biological resource management regime. The most important change is the expansion of the scope of patentability, which requires, for example, the introduction of patent protection to new sectors such as health and agriculture, as well as the necessity for intellectual property protection for plant types. The Patents Act of 1970, which needed to be amended for this requirement, limited patentability and rights conferred in the areas of health and agriculture, explicitly disallowed the patentability of living organisms, and upheld the colonial-era patent regime while subordinating it to larger social concerns such as food security and access to affordable drugs. In 1999 and 2002, two TRIPS-compliant amendments were passed.

Separate plant variety protection legislation was presented in parliament in 1999 to fulfil the TRIPS deadline of 1st January 2000, but it was only enacted in 2001. The Biodiversity Act was enacted as a result of this, to give effect to India's biodiversity convention commitments. The processes that led to the passage of the other two pieces of legislation, on the other hand, determined the framework in which the biodiversity act was passed. Instances of asserting intellectual property rights on knowledge in the public domain in India in foreign countries known as "biopiracy" were added to the mix.

When taken together, the statutes point to a state under international pressure to give greater protection to commercial intellectual property rights through organisations such as states and multilateral agencies. The Act also addresses concerns

222 Stephen B Brush, *Indigenous Knowledge of Biological Resources and Intellectual Property Rights: The Role of Anthropology,* 95 Am. Anthro. Assoc. 653, (1993).

about biopiracy. The government's answer is to acknowledge private property rights while also giving itself the ability to decide the limitations of such rights within its sovereign jurisdiction through these three acts.

10.2. BIOLOGICAL DIVERSITY ACT

The 'United Nations Convention on Biological Diversity' (CBD), differentiates between 'Biodiversity' and 'Biological Resources', it can be said that biodiversity consists of the variables of all the living organisms which come from all ecological complex systems they have been a part of, and their different species in the ecosystem includes diversity. Whereas the biological resources consist of all the living creatures such as plants, animals, micro-organisms, along with their genetic materials extracted from their genes and the by-products produced out of them. This does not include the genetic materials of humans.[223] The CBD emphasizes on the recognition and protection of the sovereign rights of States over their biological resources, this led India to protect and preserve the biodiversity of the country along with provision of equal benefits to the traditional knowledge holders, through a legislation.

The Parliament of India therefore enacted the Biological Diversity Act (BD Act) in 2002. It provides guidelines and mechanism to protect biodiversity and to enable sharing of benefits arising out of the biological resources. India is one of the world's 12 mega biodiversity countries and one of 194 signatories to the Rio Earth Summit Convention on Biodiversity. This Act brought the principles of Access and Benefit Sharing to the country.[224] The Act was made with the

223 United Nations Convention on Biological Diversity, 1992, Art. 8.

224 Ruchir Mishra & Rajshree Mishra, *Protection of Environment Through Biodiversity Act*, 2 Jusimperator (2019).

help of guidelines given under the Convention on Biological Diversity (CBD), of which India is a part. This Act lays down certain objectives to protect the overall biodiversity so that the coming generation can benefit and enjoy the same quality of biological/natural resources we have today. The primary objectives of the Act, which are consistent with the convention, are the protection of biological variety and the sustainable use of biological resources. On similar principles, it seeks fair and equal distribution of genetic resources. This has been accomplished through the mechanism of access and benefit-sharing agreements for research or commercial use.[225]

It lays down three main objectives which are a very clear and concise reflection of the legislative intent:

- To conserve the biological resources of the country
- To manage the sustainable use of these resources, and,
- To enable and provide equitable and fair sharing of the benefits which arise from the use of knowledge of these biological resources with the people forming the local communities.

When we look into the laws relating to biodiversity, mainly the BD Act and National Biodiversity Authority (NBA) through the lenses of IPR, we see very clearly that IP aspects related to these legislations mainly revolves around, patents and traditional knowledge. This can be seen when one closely examines the objectives laid down by the BD Act. The third objective of this Act talks about Traditional Knowledge under the ambit of IPR which states that when certain benefits arising from the use and production of the biological resources, these benefits are the forms of outcomes of the traditional knowledge, the people of the local community

225 Kanchi Kohli & Shalini Bhutani, *The legal Meaning of Biodiversity*, 48 Eco. & Pol. Week. 15, 16 (2013), https://www.jstor.org/stable/23528081.

people hold and the sole right and reward of this knowledge is vested in the individuals who hold such knowledge which can help process and extract benefits from the biological resources of the country to help the public at large.

A national level statutory body, NBA, and various State level Boards i.e., the State Biodiversity Board (SBB), have been established under the Act in order to ensure its proper implementation. Various Biodiversity Management Committees (BMC) have also been set up as local bodies. The State level Biodiversity boards have been established in 29 states, with a total of 2,68,639 biological Management committees, and an additional 4,812 committees in Union Territories.[226] The main functions of these bodies include regulation of the Act and providing advice along with measures which have to be taken by the government.

The main function of the bodies is to take appropriate steps to protect Intellectual Property Rights arising out of biological resources. They have the right to oppose and cancel intellectual property rights if they are detrimental to nature and are destroying biodiversity. There are certain regulations given under the Biological Diversity Act 2002, for the protection of biodiversity in the country.

No one can apply for a patent or any other form of intellectual property rights based on the research conducted on biological diversity without the permission of the National Biodiversity Authority. The national biodiversity authority must give permission and may order the benefit-sharing for utilization of the country's biodiversity. The NBA is also protecting the interests of tribal people in the forest who are dependent on these biological resources. Article 6 of the CBD gives guidelines for National Biodiversity Strategy and Action

226 *Biodiversity Management Committees*, accessed at http://nbaindia.org/content/20/35/1/bmc.html.

Plans (NBSAP). These strategies are the main instruments for implementing CBD at the National level. The NBSAP is useful in implementing and integrating various plans to save biodiversity throughout the world.227

10.3 BIODIVERSITY AUTHORITIES IN INDIA

National Biodiversity Authority:

The National Biodiversity Authority is the nodal body which oversees the implementation of the Act, and issues guidelines for access to and equitable benefit sharing of genetic resources. Many applications before the NBA seek clearance for use or transfer of genetic material from India for developing products through modern biotechnology.[228] Without the Authority's consent, no transfer of biological resources or the knowledge are transferrable. While granting approval, NBA under Section 21, shall ensure equitable sharing of benefits based on mutually agreed-upon terms and conditions between the person applying for such approval, the local bodies involved, and benefit claimants. The NBA, in case of benefit sharing, needs to consult with the local bodies to impose terms and conditions for securing equitable sharing of benefits arising from the use of accessed biological resources, innovations, knowledge, and practices associated with their use. It also requires depositing monetary benefits into the National Biodiversity Fund, except where biological resources and knowledge are acceded to.

In simple terms, NBA's approval is needed for accessing the Biological Resources or Traditional Knowledge associated

227 J.S. Singh and S.P.S. Kushwaha, *Forest biodiversity and its conservation in India*, 10 Int'l For. Rev. 292 (2008).

228 Shalini Bhutani and Kanchi Kohli, *Ten Years of the Biological Diversity Act,* 47 Eco. & Pol. Week. 15, 17 (2012), https://www.jstor.org/stable/41720181.

with it, making any application for the intellectual property rights and lastly, transfer of any results of such research. Section 3 of the BD Act provides that, any person who is (i) a non-citizen or (ii) a citizen but non-resident or (iii) a body corporate in India having non-Indian participation (i.e., shareholding from entities/ individuals who are non-citizens, or is a non-resident, or is a body corporate not incorporated or registered in India), is required to obtain prior approval from the NBA.[229] In case such prior approval is not taken from the authority, section 4 prohibits such a person from transferring the result of such research to any person. On similar grounds, section 6 says that such person would also be prohibited from making an application for any intellectual property in or outside India for any invention based on any research or information on a biological resource obtained from India.

Unlike Sections 3, 4 and 6 of the 2002 Act which require prior approval of the National Biodiversity Authority, Section 7 of the Act provides for prior 'intimation' to State Biodiversity Board (SBB) for obtaining biological resource for certain purposes.[230] Only prior notification to the concerned SBB is necessary for operations pertaining to commercial utilisation, or bio-survey and bio-utilization for commercial utilisation, for entirely Indian entities or non-Section 3(2) entities. Thus, a cursory reading of the Act's provisions reveals that no approval or notification to the SBB is required for Indian entities to access biological resources for the purpose of research. There is no overlap in the functions of NBA and SBBs on issues of

229 The Biological Diversity Act, 2002, § 3, No. 18, Acts of Parliament, 2003 (India).

230 Geethanjali K.V. Namrata Rawat, *Role, Powers & Functions of State Biodiversity Boards to Collect Access & Benefit Sharing Amount from Indian Entities*, NLSUI, (27 Jul. 2021, 17:53), https://nlspub.ac.in/role-powers-and-functions-of-state-biodiversity-boards-to-collect-access-and-benefit-sharing-amount-from-indian-entities/.

ABS. Their domains and functions are very distinct from each other. All matters relating to requests by foreign individuals, companies or institutions and all matters relating to transfer of results of research to any foreigner, approvals for intellectual property protection where biological resources and associated knowledge are involved will be dealt with by NBA. All matters relating to access by Indians for commercial purposes will be under the purview of the concerned State Biodiversity Boards. However, the benefit sharing guidelines are to be issued by the NBA.[231]

Even though the SBBs have very less involvement in transfer of Biological Resources, they are indirectly related with transfer of traditional knowledge and transfer of technology which is considered under the Access and Benefit Sharing. Under the Biological Diversity Act, industry individuals who are dissatisfied with any benefit-sharing determination or order of the National Biodiversity Authority or a State Biodiversity Board may seek redress. According to Sections 52 and 52A, such aggrieved parties may file an appeal with the High Court within 30 days of such communication (or by a further extension of up to 60 days if the Court is satisfied of the sufficient cause for delay) and the National Green Tribunal (established under Section 3 of the National Green Tribunal Act, 2010), respectively.

However, in this section, there should be concentration on the fines and remedies available to SBBs where prior intimation under Section 7 is not provided and/or other ABS requirements are not met.

But apart from the NBAs, the SBBs of certain states have set their own terms.

231 National Biodiversity Authority, http://nbaindia.org/content/19/16/1/faq.html (Last visited 28 July 28, 2021).

According to Sikkim Biodiversity Rule 17(1), any individual requesting access to or collection of biological resources and associated information for research or commercial use must submit an application to the Board in Form-1 as specified in the schedule. Every application must be accompanied by a charge of Rs. 100/- for research purposes and Rs. 1000/- for commercial use, in the form of a cheque or demand draft.

In the case of Arunachal Pradesh, the Rule 17(1) of the state's Biodiversity Rules states: "Any person seeking access to/ collection of biological resources and associated knowledge for research or commercial utilisation shall make an application to the Board in Form-1 Part A and B appended to these rules." Every application must be accompanied by a charge of Rs. 100/- per species/item for government institutions and Rs. 500/- for others, payable in cash, cheque, draft, or Treasury Challan. The Board will determine the commercial use cost for biological resources (other than scheduled flora, fauna, and microorganisms) on an ongoing basis.

Similar to these states, Tamil Nadu, Jharkhand, Rajasthan, Goa, Assam, West Bengal, Orrisa, and Chhattisgarh also have rules and regulations similar to these. When seen from transfer of Biological Resources, they don't have any other guidelines as the approval is completely in the hands of the NBA. But when it is seen from the perspective of accessing the traditional knowledge and technology, they have their own roles.

Biodiversity Boards in different States:

The State Biodiversity Boards are for the conservation of biodiversity. Accordingly, in all 29 States, SBBs have been established by the act. The major responsibilities of the SBBs are to advise the State Governments, regarding the guidelines which have been issued by the Central Government, on matters regarding the protection of biodiversity and the overall

environmental ecosystem. To perform such other functions as necessary to carry out the provisions of this Act or as prescribed by the State Governments.

State Biodiversity Board of Uttar Pradesh:

Uttar Pradesh State Biodiversity Board, has its existence under Section 22 of the Biological Diversity Act, 2002, was constituted on 28th September 2006 by the Government of Uttar Pradesh. The State of Uttar Pradesh has one National Park and 23 Wildlife Sanctuaries covering 5,712 km which is 2.37% of the state's geographical area. The official website for the Board provides the following main functions -

1. Advising the State Government, subject to any guidelines issued by the Central Government, on matters relating to the conservation of biodiversity, sustainable use of its components and equitable benefit sharing which arises from biological resources utilization.
2. Performing such other functions as may be necessary to carry out the provisions of this Act as may be prescribed by the State Government.

In 2010, the governor of Uttar Pradesh in the exercise of the powers under section 63(1) of the BD Act, 2002 made certain rules which came into force under the name of The Uttar Pradesh Biological Diversity Rules, 2010.

State Biodiversity Board of Andhra Pradesh:

The state of Andhra Pradesh has its own State Biodiversity Board which is governed by Andhra Pradesh Biological Diversity Rules, 2009. The Boards general functions are discussed under section 13 of Andhra Pradesh Biological Diversity Rule, 2009. The functions of this board are: Advising the state government relating to matters concerning conservation of biodiversity

sustainable use of biological resources fair and equitable sharing of the exclusive benefits which arise from the usage and utilization of the biological resources present in the state. The board should provide technical assistance and guidance to the state government. Regulating the access of biological resources 2 Indian nationals for commercial utilization or bio survey or bio utilization. One of the main Functions is updating and implementation state Biodiversity conservation strategy and action plans. The board can Commission and sponsor investigations, studies, research, ETC. Giving directions to biodiversity management committees towards management and conservation of biological diversity.

The state biodiversity board collects ₹1000 for research being done using the biological resources and ₹10,000 for commercial utilization after biological resources. Once the payment is done, and the application is filed the board will do a background concerning the persons' local biodiversity management committee and after collecting such additional information the board shall decide on the application within three months from the date of receiving the application. Once the approval is granted the person will get access to the biological resources and associated knowledge. Before giving the access, the board will ask for the person to enter into an agreement and once will get access to the biological resources the agreement is duly signed by the person then that person will get access to the biological resources. This procedure to grant access is discussed under section 16 of Andhra Pradesh Biological Diversity Rules, 2009. The revocation of access approved but bored is discussed under section 17 of Andhra Pradesh Biological Diversity Rules, 2009.

State Biodiversity Board of Jharkhand:

"Jharkhand" as the name suggests in Hindi, it translates to English as "Parts of Forests" is a state filled up with nature

consisting of a lot of greenery in the form of forests and water bodies. This states that the state consists of a huge amount of the components of biodiversity which needs to be conserved and protected by the state government.

The major legislation or set of rules which governs and regulates the protection of biodiversity in the state of Jharkhand is called "Jharkhand Biological Diversity Rules, 2007". This is a documented legislation which was formed and functions by and under the state government and authorities of Jharkhand. It consists of a total of 21 rules and various sub-rules or sub-sets under them. This set of rules was formulated and established by the Government of Jharkhand originally in Hindi which is called "Jharkhand Javikiya Vividhata Niyamawali, 2007" and was also translated in English for better flexibility of its interpretation.

Same as other authoritative bodies, the Jharkhand state authorities also requires one to take prior approval from the state authority to get access to the biodiversity of Jharkhand. This authority works under the direct regulations and governance of the "Biological Act, 2002." Same as any codified law it consists of preliminaries and definitions of the Rules established which are divided into various serial numbers.

Also, certain models of livelihood production that assists in the conservation of biodiversity in the states such as AP, Chhattisgarh, Jharkhand, and Orissa are provided in the scope of "Forest Act, 1927." Also, a committee has been set up in Jharkhand to regulate the proper functioning of the Biodiversity Rules and this body is called the "Jharkhand Biodiversity Board."

State Biodiversity Board of Kerala:

There are five national parks in Kerala namely Silent Valley, Eravikulam, Mannavan Shola, Pambadaum Shola

and Mathikettan Shola. The Kerala State Biodiversity Board (KSBB) is based in Thiruvananthapuram. It is initially attached to Kerala State Council for Science, Technology and Environment (KSCSTE). The Board now functions under the Environment Department of the state of Kerala. The major aim of KSBB is to provide technical support and guidelines for the bodies of protection of biodiversity in preparing biodiversity registers and their legal protection. This body is providing guidelines and support for the collection of biodiversity and to collect tax on it. This body is providing support and directions for the formation of district technical support groups and forums to preserve and protect biodiversity.

There are also activities aimed at making bodies under Panchayat, Block, District, municipality, and Corporation level to make the preservation and protection of biodiversity at its best level. There is a People's Biological Diversity register for the operation and restoration of biodiversity. It is made with the help of the local community. Identification and documentation of biodiversity are done by the People's biodiversity register. Using the help of people's biodiversity register research is done on biodiversity and discoveries are taking place to make commercial products, patent such products and provide equitable distribution of benefits etc. Several programs have been made in the state of Kerala with the use of the biological diversity Act 2002 and biological diversity rules 2004.

KFRI provides instruction and Advises to the local people in the preparation of PBR and implementation of programs. There will be technical and other preparation activities. The progress of activity will be examined at the ward level every three months. Monitoring is also done at the district level and block level every six months. It is a comprehensive database recording people's knowledge and insight of the

status, uses, history, ongoing changes and forces driving these changes in the biological diversity resources of their localities.

The Environmental policy of 2010 in Kerala also has provisions for the protection of biodiversity. The conservation of western Ghats is a primary concern in the policy. Some of the effective methods in the Environment policy are the Intensification of surveys inside and outside the Protected Areas for complete documentation of biodiversity, including microbes. Inventory of biological resources in different parts of the State through People's Biodiversity Register at Panchayat, Municipality and Corporation levels. Conservation of biodiversity through a network of protected areas including biosphere reserves, national parks, sanctuaries, gene conservation centres, wetlands, mangroves, sacred groves, heritage sites and such other natural habitats of biodiversity. Protection and conservation of domesticated species/varieties of plants and animals to conserve indigenous genetic diversity. Maintenance of corridors between national parks, sanctuaries, other protected areas, forests and, animal habitats for ensuring the natural movement of animals

To get permission to use biodiversity in Kerala an application should be given with required documents. The application should contain a copy of the project document, with objectives, methodology and expected outcomes especially for the conservation of Protected Area, approved by the funding agency or by the Head of Institution may be enclosed. In case of applications involving the collection of specimens which are listed in the Schedules of Wildlife (Protection) Act, 1972, their species, conservation status and their position in the Schedules of Wildlife (Protection) Act, 1972 should be specifically and mandatorily mentioned thereof. Justification for the collection of specimens from the Protected Area/s should be given.

10.4. CRITICAL ANALYSIS OF PVP AND FARMERS' RIGHTS

India enacted Protection of Plant Varieties and Farmer's Rights Act, 2001 (PPVFRA) in compliance to the TRIPS requirement. The Act provided both PVP and farmers' rights. This sui generis system followed in India is very unique as it has taken the concept of farmers' rights far ahead and genuinely deals with the concerns and issues faced by farmers as breeders, innovators, conservers, etc. The Act has tried to be in accordance with the features of both UPOV and the International Treaty on Plant Genetic Resources for Food and Agriculture. It also embodies few of its own distinctive features as per necessities of farmers. The PPVFRA recognizes various farmers' rights as per Section 39.[232]

In India, the PPVFRA authority serves as the institutional mechanisms for the protection of rights of the farmers and ensures that farmers are provided with the variety which is of reasonable price and quantity. The PPVFRA Act states that the revenue gained from the farmers' use of the plant variety has to be utilized by gene fund, where a part of it is used for administrative maintenance of gene fund.

In case the seeds sold by the breeders to the farmers are not of sufficient quality, then there is no fixed amount of compensation specified that has to be rewarded to farmers. This would be the sole discretion of authority, and as it is discretionary, it is also arbitrary in nature. Another disadvantage is that the burden of proof to show that the infringement of right of breeder was an innocent mistake falls on the farmers.

232 Anshu Pratap Singh, Padmavati Manchikanti, and Hardeep Singh Chawla, *Sui Generis IPR Laws vis-à-vis Farmers' Rights in Some Asian Countries: Implications Under the WTO*, 16 J. OF INTELLECT. PROP. RIGHTS, 107 (2013).

Although the general rule is that the person who makes the allegations has the burden of proof on themselves.

There is a contention that as the property rights of farmers to use, exchange, sow, share, or sell their own properties were clearly not permitted. However, this was later amended and currently farmers have the same property rights as before the Act. The Act obligates the farmers to be diligent and file applications to the authority within the concerned local area. Moreover, they also have to fight against big corporations with great financial resources.

In the case of *PepsiCo v. Bipin Patel*[233], the corporation alleged that the farmers were using some potato hybrids which were similar to those used to manufacture 'Lays' chips without prior authorization of the corporation. The court held that a farmer planting a registered variety does not exactly constitute as an offence because the Act allows the farmers to reuse such varieties and also to distribute it to their neighbors, on the basis of the conditions that farmers are not permitted to sell 'branded seeds'. According to PPVFRA, it means that a protected variety includes any seed put in a package or any other container and labeled in a manner which shows that such seeds are a protected variety.[234]

The Court also made another observation that the variety in contestation was an extant variety which is a 'variety of common knowledge'. Therefore, the Court ruled in the farmers favour and found out that the big corporations and politicians took advantage of the loopholes of law and disrupted the farmer community. Then PepsiCo proposed an out of court settlement to the farmers whom it had sued.

233 PepsiCo India Holdings Pvt Ltd v. Bipin Patel, Suit no. 23 of 2019, Commercial Court at City Civil Court, Ahmedabad.

234 Simran Bais, *Protection of the Breeders & Farmers Rights-UPOV & PPV-FRA*, Ssrn (Jul. 10, 2021, 9:10 PM), https://ssrn.com/abstract=3836067.

A commonly suggested alternative would be to establish an international system that is more farmers friendly and more adapted to states with increased number of small-scale farmers who also engage in plant breeding. Critics have pointed out that the PVP system is inconsistent with the modern technological and scientific developments which has invented new and better ways to develop and breed new plant varieties, and thus that a fundamentally new system should be sought. There are also those who defend the rights to traditional knowledge and community rights, who state that plants belong to the communities that breed and maintain them, and should only be protected, if at all, by collective user rights defined by these communities, not by property rights that are privately held.[235]

10.5 ACCESS AND BENEFIT SHARING

Access and Benefit Sharing essentially implies that when bio-resources or people's technologies related to such resources are accessed, the user/accessor must either compensate the supplier community financially or recognise the source. According to International treaties, biodiversity laws must be drafted in a manner which will deliver proper justice, when access is granted to the genetic resources and traditional knowledge of a particular area or community, a part of the benefits that the users derive from the utilization of such resources should be shared with the holder of such traditional knowledge for the overall development of that area or community. However, either of the terms "fair" and "equitable" have not been defined anywhere in the international conventions or treaties. In the Indian Scenario, this concept is reflected in the Biodiversity Act, Patents

235 Graham Dutfield, *Food, Biological Diversity and Intellectual Property: The Role of UPOV*, Global Economic Issue Publication (Jul. 11, 2021, 11:30 AM), http://www.ip4growth.eu/sites/default/files/GD%20UPOV%20QUNO%20English.pdf.

Act, and Biotechnology Laws and it is upon them to ensure proper regulation of the 'Access and Benefit Sharing of Biodiversity.'[236]

Following Article 8 (j) of CBD, the NBA undertakes duties such as establishing processes and standards to oversee activities such as access and benefit-sharing and IPR. The authority also manages the Access and benefit-sharing operations of SBB and local BMC by offering technical support and direction.

The NBA guides the government on matters relating to biodiversity conservation, sustainable use of its components, and equitable sharing of benefits arising from biological resources, selects and notifies areas of biodiversity significance as Biodiversity Heritage Sites under the BD Act, and performs other functions as required. On behalf of the Government of India, the NBA takes steps to safeguard the country's biological diversity and opposes the transfer of intellectual property rights to any foreign government on any biological resource derived from India or information related to such resources.

SBBs deal with issues with Indians' commercial access to bio-resources and prohibit any action that violates the principles of conservation, sustainable use, and fair benefit sharing. Established under section 41 of the Act, the mandate of the BMCs is conservation, sustainable use, and documentation of biodiversity and chronicling of knowledge relating to biodiversity in Panchayats.[237] As of 2020, 29 states of India have established SBBs, and there are 2,44,727 BMCs and an additional 4,371 BMCs in two Union Territories.

236 Hamdallah Zedan, *Convention on Biological Diversity*, WIPO (May 22, 2021, 12:20 PM), https://www.wipo.int/edocs/mdocs/mdocs/en/isipd_05/isipd_05_www_103974.pdf.

237 Ruchir Mishra & Rajshree Mishra, *Protection of Environment Through Biodiversity Act*, 2 JUSIMPERATOR (2019).

Section 21 of the BD Act and Rule 20 of the BD rules, 2004 necessitates appropriate benefit-sharing provisions to be incorporated in access agreements and mutually agreed terms relating to access and transfer of biological resources or knowledge occurring in or obtained from India for commercial use, bio-survey, bio-utilization, or any other monetary purposes. Therefore, NBAs apply certain restrictions While granting access clearances, NBA will apply restrictions and conditions to ensure equitable benefit sharing, which include the following:

a. grant of joint ownership of intellectual property rights to the NBA, or where benefit claimers are identified, to such benefit claimers;

b. transfer of technology;

c. location of production, research and development units in such areas which will facilitate better living standards to the benefit claimers;

d. association of Indian scientists, benefit claimers and the local people with research and development in biological resources and bio-survey and bio-utilization;

e. setting up of venture capital fund for aiding the cause of benefit claimers;

f. payment of monetary compensation and other non-monetary benefits to the benefit claimers as the NBA may deem fit.[238]

The Access and Benefit sharing guidelines:

After the establishment of Nagoya Protocol, the 'Guidelines on Access to Biological Resources and Associated

238 K. Venkataraman, *India's Biodiversity Act 2002 and its role in conservation,* 50 Int'l Soc, Trop. Eco. 23, 28 (2009).

Knowledge and Benefits Sharing Regulations, 2014', also termed as 'ABS Regulations' was issued by NBA on November 21, 2014. The ABS Regulations objective is to provide a particular procedure by which the financial obligations of those who use the genetic resources can be determined along with a process through which these benefits can be shared. The benefits arising out of the use of biological resources and traditional knowledge should be shared uniformly with the one holding that knowledge. The Traditional Knowledge of a particular tribe should be used fairly for a particular purpose and after taking permission from relevant authorities. Equitable Benefit comes in when that particular purpose is achieved and the benefits arising from it is shared equally and fairly with that particular tribe from whom that traditional knowledge was taken for the overall development of that particular area or community. Under the ABS Regulations, its provided that the obligation of benefit sharing on the trader and the manufacturer will be 1.0 to 3.0% and 3.0 to 5.0% respectively. It is also decided that if the economic value of biological resources than their derivatives, where these resources can be red sanders, sandalwood, etc. the sharing of benefit should include an upfront payment which should not be less than 5%. In such cases, the auction or the sale amount can be decided by the NBA or SBB. The judicial decision of *Environment Support Group Represented by Ms. Bhargavi S. Rao and Mr. Leo F. Saldanha V. National Biodiversity Authority, Represented By its Chairman and Ors.*[239], in the High Court of Karnataka at Bangalore further clarified the grey areas regarding the laws of access and benefit sharing of the biological resources.

When it comes to commercialization of IPR which is obtained through inventions (Patents) which are related to

239 Environment Support Group and Ors. v. National Biodiversity Authority and Ors., Writ Petition No. 41532 / 2012.

the genetic resources, the stakeholders are required to pay a monetary or non-monetary benefit to NBA as decided between the applicant and the applicant.

The ABS Guidelines further state that the benefits arising out of the utilization of biological resources and the associated knowledge can be shared in monetary/non-monetary forms. The benefits sharing is determined on the basis of considerations made such as, commercial utilization of biological resource, research stages and its development, amount of investment made, nature of the technology, risks involved in the commercialization of that particular product, etc. A special consideration is provided when a technology or a product is developed to control an epidemic, or disease, or for control of environmental pollution which are affecting the life of humans, plants, and animals on earth. Furthermore, in cases, where the biological resources used in a product are accessed, used or sourced, from two or more SBB's jurisdiction, the total amount of the benefit is to be shared in a proportion which is decided by the NBA or SBB.

10.6. COMMUNITY BENEFIT SHARING

It is essential that for bioprospecting to be a success, the local people should be compensated for the utilization of biodiversity and resources and such utilization should be regulated. There should be equitable sharing of benefits and a bioprospecting agreement between the countries to enable such equitable sharing.

The first instance of the concept of benefit sharing can be seen in the Universal Declaration of Human Rights (UDHR) under Article 27(1) states that every person has the right of participation and enjoy the cultural life, arts of the community and share the scientific advancements made and the benefits received.

Certain guidelines were developed based on The Pacific Model Law, 2002[240] for the protection of TK and Traditional Cultural Expressions (TCEs) works by the secretariat of the Pacific Community in 2006. Since TK and TCE works are a result of the collective product of the community, the rights are considered to be vested with the community. The Pacific Model Law, 2002 also brings forth this point under Section 4 where it recognizes the owners of TK and TCE works to be "the group, clan or community, or individual recognized as part of group, clan or community, in whom the custody or protection of the traditional knowledge or expressions of culture are entrusted in accordance with customary law and practices." The guidelines discuss the need for setting up of "relationship linkages" i.e., establishing a relationship between the community that claims to be the owner and the subject matter of the protection. This could be done through proving customary practices or traditions. The objective behind this being to prevent individuals or other communities claiming rights over rights held that may belong to another community. Another method of proving it could be through examining who has custody or is in charge of safeguarding such TK and TCE works, or whether such representations form an integral part of their identity and heritage. The communities can be further represented by their traditional authorities or leaders like the Panama Law No. 20 prescribes or choosing their own representatives based on their community customary practices. The guidelines also discuss how in the event that the determining of one particular community as the owners is impossible, then the State can take on the role of the beneficiary (receiving the benefits from the use of TK and TCE and its

240 Secretariat of the Pacific Community, *Guidelines for Developing National Legislation for the Protection of Traditional Knowledge and Expressions of Culture Based on the Pacific Model Law 2002*, Wipo (Jul. 23, 2021, 9:30 PM), https://www.wipo.int/edocs/lexdocs/laws/en/spc/spc001en.pdf.

protection) and instead use the proceeds for the upliftment of such communities to which it may have potentially belonged to.

The Model Provisions of 1982 state that the rights are either to be vested with a 'competent authority' or with the 'community concerned'. Section 10 states that if any person is inclined to use any Traditional Knowledge or folkloric expressions of such community then they must seek authorization either from the competent authority or the community concerned, and such authorization must be in writing.

10.7 OFFENCES AND PENALTIES UNDER THE BIODIVERSITY ACT

All offences under the Act are cognizable and non-bailable, which means that any accused offender can be arrested without a warrant and could face a maximum sentence of three years imprisonment. Any violation of Sections 3, 4, or 6 of the Act, or attempt or abetment thereof, is punishable by 5-imprisonment, a fine of INR 1 million (note: if the damage inflicted is larger than INR 1 million, the fine would be proportionate with the harm caused), or both. Any violation of Section 7 of the Act, or attempt or abetment thereof, is punishable by a three-year jail sentence or a fine of INR 0.5 million, or both. Furthermore, if the perpetrator is a firm, the company's directors and senior management people would be judged guilty of the crime unless they can establish that the crime was done without their knowledge.

Bioresource, 'Smuggling' and Biopiracy:

Bioresource, 'smuggling' or 'biopiracy' is one of the first examples to arise under the biodiversity policy. One of the key motivations for the 'global South' to embrace the CBD is biopiracy of bioresources or associated people's knowledge.

Owing to the global scale of the issue, biodiversity-rich countries such as India have argued for an international legal regime to prevent the appropriation of their biological heritage without due acknowledgement of the source, without the assent of local communities, and without sharing any 'benefits' with them. As a result, when the CBD was enacted, and then the BD Act was approved, there were expectations from various movements that it would be utilised to combat biopiracy. However, this did not occur as quickly or as frequently as expected.

Sections 3, 4, 5 and 6 of the Act dealing with biopiracy were successively announced to take effect on July 1, 2004[241]. Following that, there were a slew of practical concerns to address, including increasing customs authorities' capacity to prevent the unlawful export of Indian bioresources and raising public knowledge about CBD and the BD Act. Parallel to this, the NBA's Expert Committee (EC) on ABS was formed to expedite procedures and applications for access to bioresources and the issuance of IPR. The inaugural meeting of the EC took place in 2006. The assumption is that 'biopiracy' will be contained if the proper access procedures are followed.

Under the BD Act, it will be a punishable offence for all the Indian individuals/citizens, and associations or organizations registered in India according to the Indian law to obtain access to any of the biological resources for bio-utilization, bio-survey, and commercial utilization without a prior communication to the SBB which is concerned for that. This includes all the local communities, local people, growers, and cultivators of biodiversity. The Vaids and Hakims are exempted here. It is also an offence for them to go against any of the orders passed

241 Ministry of Environment and Forest Notification S.O.(E) dated 1 July 2004, http://nbaindia.org/uploaded/pdf/notification/6%20%20Sec%20 3-7%2018%2047.pdf.

by the SBB post advisement with the local bodies restricting or prohibiting any of the activities when it receives a warning. The punishment for these offences imposed is imprisonment of up to three years and a fine up to Rs. 5 lakhs.

It is also an offence for any person to transfer the research results related to the biological resources to any foreign individual or any foreign organization without prior authorisation from the NBA. But this excludes the activities or works such as the publication of the research papers or dissemination of traditional knowledge to any workshop/ seminar. It is also an offence to apply for IPRs such as patents, GIs, etc. in or outside the country of India without prior approval from the NBA. The punishment imposed for these offences is imprisonment up to five years or a fine of up to Rs. 10 lakhs. Here also, in cases where the damage exceeds the amount of Rs. 10 lakhs, the fine will be equal to that damage caused. These punishments/penalties also apply to the entities/ persons who try to infringe or aid such actions as mentioned above.

This law also penalizes persons who go against any of the directions or orders passed by the Central Government, State Government, NBA or SBB. However, it should be noted that there is no distinguished penal sanctions prescribed or provided under this law other than the punishments mentioned above. The amount of Rs. 1 lakh is fined as a penalty for the first offence which can be extended up to Rs. 2 lakhs when the second offence takes place. If the offences are continuous, then this fine can go up to Rs. 2 lakhs per day of the default continuation. In cases where the offence has been committed by a company i.e., a corporate body including an association or a firm, then an action can be taken against both that company and the involved persons.

All the offences under the BD Act, aim to penalize the activities of the individuals that have the capacity of threatening all the biological resources occurring within the national boundaries of India. Therefore, it is stated within this law that any of the act or the activities which seek/attempts/tries to illegally obtain/access; unsustainably exploit/use, or unjustly enrich or benefit the person/individual using or accessing it completely evades or breaches the fair and equitable benefit sharing and violates the procedure of law which operates the genetic and biological resources occurring in India is a punishable offence under this Act. These offences are punishable with considerable imprisonment and penalty.

The BD Act: The Scenario of Offences embedded under the Provisions:

The Act itself conveys that "Any contravention of provisions of Sections 3,4,6,7 and 24(2) are all cognizable and non-bailable." This makes it clear that all the offences committed under the ambit of this Act are cognizable offences having the capacity of a criminal procedure and trial to be carried on and are also non-bailable. And the offences are punishable with an imprisonment of 3 or more years and the police officer in a case relating to these offences may arrest the alleged person or the offender without the need of a warrant. A penalty in the form of a fine up to Rs. 10 lakhs and/or imprisonment up to 5 years is imposed for the violations of Sections 3,4, and 6. Whereas, a penalty in the form of a fine up to Rs. 5 lakhs and/or imprisonment which may be extended up to 3 years is imposed for the violations of sections 7 and 24(2). Let's understand the nature of these offences better in a detailed form.

It has been observed that any of the offences under this Act can be brought to a court of law only by the Central Government at the first instance. This can take place when a

complaint is filed by the Central Government or an authorized officer or an authority of that government. This also includes all the officers of the State Forest Department. Action to bring the offence to the court can also be taken when the complaint is filed by a "benefit claimer" and this complaint can be raised after giving official notice to the central government or the NBA or any officer authorized by the government. This should be done within the time frame of 30 days of the occurrence of the offence.

On another perspective, it should be noted that if the citizen is not a direct "benefit-claimer" of the biological resource regarding which the offence or violation has occurred, then they won't be in a position or capable of challenging that offence or the offenders. For instance, if a company or a person has accessed the species of a particular insect, animal, or plant partly or wholly in an illegal manner, then another individual can challenge this offence if he proves to be the "benefit claimer" following the definition prescribed under the BD Act.

Finally, it should be noted clearly that the BD Act does not allow *Public Interest Litigation* by any ordinary concerned person. And the Act also provides immunity to the Central and State Government officials and the members of the NBA and the SBBs from any kind of legal proceedings for any of the acts sone with an intention of "good faith."

It is also stated that in cases where the offender is a company, the key managerial personnel or the directors of that company will be assumed or deemed to be guilty of that offence until and unless they prove that the concerned offence was committed without their knowledge, or they were not aware of that offence being committed.

Section-Wise Penalties [The Penalties following the Provisions]:

It is observed that the definition of the penalties for the persons who contravenes or attempts to contravene Section 3 has been provided under Section 55(1) of the Act.

Section 55(2) of the Act lays down the definition for the penalties for those individuals who contravene or attempts to contravene Section 7.

These penalties spell out the importance of taking approval or permission from the NBA which is the implementing body of the BD Act before accessing or obtaining the biological resources to carry out the research or commercialization purposes.

10.8 OFFENCES AND PENALTIES UNDER PPVFRA

The PPVFR Act provides punishment and fine for several offences. According to Section 68 of the Act, no one other than the breeder of a registered variety, a registered licensee, or a registered representative thereof may use the denomination of that variety. The subsequent Section 69 states that it is an offence under this Act to falsely apply a variety's denomination or a deceptively similar denomination to any variety or package containing that variety without the breeder's consent, or to use any package bearing a denomination that is identical to or deceptively similar to the denomination of such variety registered under this Act for the purposes of packing, filing, or labelling therein any variety other than such variety registered under this Act.

Thereby, Section 70 provides that such act shall be penalised through imprisonment for a term not be less than three months but may be extendable to two years, or with fine not less than fifty thousand rupees but extendable to five lakh rupees, or with both. The same punishment is applicable also

in cases where the person provides false information regarding the country or name and address of the breeder of a registered variety in the course of trading such variety.

The Act prohibits the sale of any seeds or other propagating material to which a false or deceptive denomination has been applied in order to prevent anyone from attempting to claim credit for the reputation of a registered breeder and to safeguard fanners from receiving substandard seeds. The Section 71 makes the sale of such seeds illegal. It states that, unless a person can prove he acted innocently, anyone who sells, exposes for sale, or has in his possession for sale or for any purpose of trade or production any variety to which any false denomination is applied, or to which an indication of the country or place of its origin, or the name and address of the breeder of such variety has been falsely made, will be punishable with imprisonment for a term not less than six months but extendable to two years, or with fine not less than fifty thousand rupees but extendable to five lakh rupees, or with both.

According to Section 72, anyone who, in any way, falsely represents that a variety not registered under the Act is a variety registered under the Act shall be punishable with imprisonment for a term not less than six months but extendable to three years, or with the fine not less than one lakh rupees but extendable to five lakh rupees, or with both.

Section 77 states that when a company is the perpetrator of a crime, the company and every individual in charge of and accountable to the company for the conduct of its business at the time of the crime will be considered guilty of the crime, unless he can establish that the crime was done without his knowledge or that he took all reasonable precautions to stop it from happening. However, if it is established that the offence was committed with the knowledge or complicity of, or that

the offence was result of the neglect of, any official of the corporation, that officer will also be held accountable for the offence. Lastly, Section 73 provides for greater punishment in cases of repeated offences under this Act.

10.9 DRAWBACKS OF LAWS RELATING TO BIODIVERSITY

In 2010, Maharashtra Hybrid Seeds Company (Mahyco) and American seed giant Monsanto allegedly exploited the local eggplant variety for development of Bt Brinjal, which was not approved by the competent authorities. This came out as India's first legal action against Biopiracy. Biopiracy is the illegal annexation of biodiversity and traditional knowledge of local communities from developing countries by multinational corporations and research institutions.[242]

It all started, when Environment Support Group (ESG), a Bangalore based NGO, raised a complaint that Monsanto and Mahyco used several local varieties of brinjal to develop Bt brinjal without seeking authorization from any national or local biodiversity authority. Following this, the Board conducted an investigation and discovered that the firms utilised "six local varieties" of eggplants without prior clearance from the NBA. In 2011, NBA charged them with allegedly violating the Biological Diversity Act, *"for acquiring and using the local brinjal varieties for development of Bt brinjal without seeking prior approval from the competent authorities."*[243] In 2013, the Karnataka High Court asked the NBA and Karnataka SBB to pursue criminal proceedings against the accused after hearing a public-interest petition filed by ESG in 2012,

242 Walid Abdelgawad, *The Bt Brinjal Case: The First Legal Action Against Monsanto and Its Indian Collaborators for Biopiracy*, 31 Biotech L. Rep. 136, 136 (2012).

243 *Id.*

accusing authorities of delaying criminal prosecution against Monsanto and other accused in the case.

Divya Pharmacy v. Union of India (2018)[244]

Divya Pharmacy is a business undertaking of Divya Lok Mandir and manufactured Ayurvedic medicines and Nutraceutical products, with its manufacturing unit located at Haridwar. Swami Ramdev and Acharya Balkrishna were the founders of the trust and the pharmacy.

The petitioner raised an argument that sharing of profits with local and indigenous communities is a part of FEBS provisions of the 2002 Act. Prior approval from NBA is a requirement only under sections 19 and 20 of the Act. Therefore, only foreign entities using biological resources were liable to share the profits or pay the fees as per Sections 2(g) and 3. The counsel for the petitioner mentioned that the plain reading of the Act provides a clear understanding that only a foreign entity required permission from the NBA before they undertake any activity using any bioresource or knowledge. The respondents contended that FEBS regulations make no distinction between a foreign and an Indian entity, and that equitable benefit sharing with local and indigenous groups was one of its goals.

The Uttarakhand High Court gave comprehensive interpretation in its judgement. It mentioned that when it comes to India's international obligations, interpretation of the FEBS require entities to share the benefits with the local and indigenous communities irrespective of it being an Indian or foreign entity as its their resources which are exploited. It clarified that SBBs could raise the demand for FEBS while harnessing biological resources for commercial use. It laid emphasis on the need for creation of deterrence

244 Divya Pharmacy v. Union of India, (2018) Scc Online Utt 1035.

against avoidance of FEBS by user companies in the name of nationalistic policies.[245] Thus, the Petition was dismissed by the court.

Drawbacks of the Biodiversity Act:

It has been observed that the Biological Diversity Act, 2002 faces a complete absence of a proper exhaustive way for dealing with the security and preservation of the country's biodiversity and this hinders the overall protection procedure of the biodiversity. The Act instructs about 'benefit sharing' but it has been noted that the Act focuses more on the 'benefit' but remains completely silent on 'sharing' of these 'benefits'. Since the implementation of this Act, there has been no proof or evidence that the benefits which arose were ever fair and equal. The high court's decision in the Divya Pharmacy case clarified the question in regard to the interpretation as well as implementation of the Access and Benefit Sharing regime. However, the real test is to ensure that the amount collected in the guise of fees is put towards the conservation of the biodiversity. If the said purpose is fulfilled then the rationale behind fair and equitable sharing shall be achieved. Or else, the fees will only end up as a means to exploit the resources.

Another major flaw is that this Act focuses more on business utilization and profit sharing of the biological and organic resources instead of giving an adequate amount of thought to conservation. The Act is highly focused on the license to the biological resources and its related issues, instead of providing a complete comprehensive regime for sustainable use and conservation of biological resources. Its responses to the current issues and challenges are to completely rely upon the time-tested principles of the permanent sovereignty over

245 Zafar Mahfooz Nomani, *Case Comment: Divya Pharmacy v. Union of India High Court of Uttarakhand*, 39 Biotech L. Rep. 122, 127 (2020).

the natural justice. The significant purpose of this Act to protect the biodiversity seems to have been forgotten. There is a deficiency of mechanisms to deal with biodiversity offences as well.

Further, the Act does not have an over-riding effect on the already pre-existing laws, like the laws on forests and wildlife. This makes it unclear as to which law will be applicable and will supersede in the case of a dispute.

The Act, to create a three-tier system, has instituted an NBA at the national level and a SBB at the state level. These authorities have been established to oversee and keep a check on the use and sharing of benefits arising out of the biological resources; and the traditional knowledge and its conservation. The severe drawback here is the absence of extraterritorial jurisdiction of the NBA which creates makes in incapable to operate and monitor the application overseas. The NBA is also criticized of not being able to satisfactorily perform its functions. The Central Government Agency Comptroller & Auditor General of India says that the authority is not working efficiently. The major factor responsible for such flaws is the government apathy. Some of the functions of this authority was affected due to a recent incident wherein the post of NBA's Chairperson was held for some time, on an extemporary basis, an added responsibility of a senior officer in the Ministry of Environment & Forest.

The Act does not provide a legal framework in favour of the rights of all the other holders of biological resources and the related knowledge. So, the outcome of this is that all the biological resources and the associated traditional knowledge, which are not allocated to the private entities through IPRs or have been appropriated by the state itself, will be assumed or deemed to be freely available to be utilized, leading to the

keepers of such knowledge and resources losing out on the benefits they should have otherwise received.

Criticism of Biological Diversity Rules, 2004:

In April 2004, the Ministry of Environment and Forests, Government of India notified about the new Biological Diversity Rules, 2004 under the 2002 Act. This new set of rules were criticized by most of the civil society. This criticism was due to the undermining of the role of the Gram Sabhas and Gram Panchayats in the implementation of the Act. It was alleged by the civil society that these new rules impose risk of dilution of the Biological Diversity Act, 2002 in spirit and in letter and will further weaken the already weak and deficient provisions of the Act which are related to rural community powers and rights. When the civil society facilitated various Panchayats, Gram Sabhas, NGOs, the individuals and citizens groups wrote to the Ministry of Environment and Forests, and they even wrote to the Prime Minister, and pointed towards the fact that that these Biodiversity Rules would have adverse impact on their livelihood, conservation, and rights.

They also heavily criticized the procedure through which the Rules had been finalized. Several groups and citizens sent in detailed comments after the draft rules were put up for public comment in the year 2003. But these public comments were completely ignored during the finalization of these Rules. When the draft rules in final form were notified on 15th April 2004, it was almost indistinguishable to the draft which was put up for public comment in the past year and it included repeating scientific mistakes. All the contents included in these rules consisted of several problems. Instead of looking upon the conservation and an overall protection of the Indian biodiversity, they only facilitated privatization of the biological resources and the associated traditional knowledge, give allowance to biopiracy, weaken the rights of the communities,

including the tribal people over the natural resources of the country, and allow the vested interests to exploit the biodiversity of India. There were many ways in which these Rules did not facilitate the decision making power of the community and control over their resources and the traditional knowledge. This was against the community sovereignty.

It should be noted that both the Biological Diversity Act, 2002 and the Biological Diversity Rules, 2004 were an essential response to the responsibilities imposed by the international treaty under CBD, but they did not act to protect the nation's interests relating to its biological resources and the indigenous knowledge systems. Thus, over 220 Gram Panchayats and Gram Sabhas all over India signed the declarations and rejected these new Rules and stated that implementation of the same would not be done. There were certain core reasons and critical problems with these rules which attracted such huge amount of criticism and outright rejection.

Judicial Perspective on Biodiversity Act:

As a result of the 'constitutionally protected environmental rights' discussion, top courts have issued judgements and directives based on 'collective biodiversity concerns.' The judicial rulings defined 'environment' as biological or natural resources, forest cover, illicit mining, and the devastation of marine life and animals, all in light of constitutional duties. The usage of PIL to the interpretation of three constitutional clauses (Articles 21, 48A, and 51A(g)) ushered in a paradigm change that aided in comprehending the significance and relevance of biodiversity protection. The basic right to life is enshrined in Article 21. This refers to more than just existence; it also refers to and involves the quality of life. This includes environmental conservation and preservation, balance in the ecosystem, free of air and water pollution, and sanitation, without which life cannot be enjoyed. Article 48A, a state

policy directive, requires the state to maintain and develop the environment, as well as forests and animals.

The Supreme Court concluded in T. N. Godavarman v. Union of India[246] that preserving and enhancing forest cover as a natural gene pool reserve is a fundamental requirement. The diversity of India's forest cover reflects its biodiversity. Ecosystems, species, and all forms of life must be managed for the sake of both current and future generations. Following that, a number of key rulings were issued in Godavarman's case, including forest management planning, no non-forestry activities in a national park or animal sanctuary, and a prohibition on tree and wood felling.

The Japanese Nationals Case:

Two Japanese individuals were arrested in 2015 for unlawfully accessing fragile reptile species in Kerala's Western Ghats Mountain region, a biodiversity hotspot. This was a problem that developed in Kerala, India's southernmost state. Bioprospecting and wildlife smuggling are particularly prevalent in forest regions such as those found in the Western Ghats. The two Japanese individuals had gathered reptiles in Kerala's Athirappally jungle. In July 2015, a case was filed against the two Japanese citizens by the Kerala FD. The trial was based on the provisions of Wildlife (Protection) Act and the BD Act.

Section 59 of the BD Act, states that "he provisions of this Act shall be in addition to, and not in derogation of, the provisions in any other law, for the time being in force, relating to forests and wildlife". Under the BD Act express prohibition is placed on foreign nationals from collecting bioresources without first obtaining authorization from the NBA. In the event of no NBA consent, this serious offence carries a

246 T. N. Godavarman v. Union of India, (2006) 1 SCC 1.

punishment of either a five-year prison sentence or a fine of 10 lakh Indian Rupees. The BD Act is seldom implemented to deal with smuggling of bioresources, such as exotic wild species by field-level forest officers, despite the fact that forest authorities normally staff the SBBs. In reality, despite the fact that the Act was enacted many years ago, the newspaper report stated that it was not well-known or understood. As a result, it is only "rarely invoked."[247]

R. Muralidharan v. The Secretary, Ministry of Law & Justice, New Delhi & Ors, 2015:

In this petition, a reference had been drawn with respect to certain provisions which necessitate a person, whether an Indian resident or a foreign national, to comply with specified obligations as mentioned under Sections 6 and 19(2) of the Act, to obtain permission preceding to or succeeding to the use of biological material for research, while making an application for patent before the Indian Patent Office. Section 19(1) casts an obligation on Indian National to take permission prior to transferring findings of research relating to biological material endemic to India and Section 20 casting an obligation to seek for another permission before actual transfer of biological material.248 The petition was however dismissed on the basis of it being misconceived.

The economic sustainability of TKDL has to be examined in an era of "absolute uniqueness," when prior public use/ sale internationally equates to invalidating prior art if done before the filing date, yet the government's strict, route

247 K.S. Sudhi, Japan nationals to be booked under Biodiversity Act, The Hindu, (Jun. 24, 2015 12:00 am), https://www.thehindu.com/news/cities/Kochi/japan-nationals-to-be-booked-under-biodiversity-act/article7348752.ece.

248 R. Muralidharan v. The Secretary, Ministry of Law & Justice, New Delhi & Ors., W.P. No. 13840 of 2015.

dependant approach has led to additional money being put into the programme. In order to combat biopiracy, India must not overcompensate, since this would result in significant expenditures for scientific research and development in the agriculture industry.

About the book

'Handbook on Biodiversity Protection in India' focuses on Intellectual Property laws and their role in the protection of traditional knowledge, genetic and biological resources. It also discusses the issue of biopiracy and bioprospecting of traditional knowledge and biological resources. This handbook serves as a testament to the need of the world to transition to sustainable innovation and development while ensuring the protection of biological diversity, traditional knowledge and the affected communities.

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