ROLE OF INTELLECTUAL PROPERTY RIGHTS IN THE PROTECTION OF BIOLOGICAL DIVERSITY: AN INTERNATIONAL AND NATIONAL PERSPECTIVE

Dissertation submitted to National Law University and Judicial Academy, Assam

in partial fulfilment for award of the degree of

MASTER OF LAWS/

ONE YEAR LL.M. DEGREE PROGRAMME

Submitted by

Archita Jha

ID- SF0222005

I Year & II Semester

Supervised by

Dr. Jupi Gogoi

Associate Professor

National Law University and Judicial Academy, Assam

(July 2023)

CERTIFICATE

This is to certify that ARCHITA JHA has completed his dissertation titled "ROLE OF INTELLECTUAL PROPERTY RIGHTS IN PROTECTION OF BIODIVERSITY: AN INTERNATIONAL AND NATIONAL PERSPECTIVE" under my supervision for the award of the degree of MASTER OF LAWS/ ONE YEAR LL.M DEGREE PROGRAMME of National Law University and Judicial Academy, Assam.

Date:

Dr. JUPI GOGOI
Associate Professor of Law
National Law University and Judicial Academy, Assam

DECLARATION

I, ARCHITA JHA, do hereby declare that the dissertation titled "ROLE OF INTELLECTUAL PROPERTY RIGHTS IN PROTECTION OF BIODIVERSITY: AN INTERNATIONAL AND NATIONAL PERSPECTIVE" submitted by me for the award of the degree of MASTER OF LAWS/ ONE YEAR LL.M. DEGREE PROGRAMME of National Law University and Judicial Academy, Assam is a bonafide work and has not been submitted, either in part or full anywhere else for any purpose, academic or otherwise.

Date:

ARCHITA JHA
SF0222005
National Law University and Judicial Academy, Assam

TABLE OF CONTENTS

Page(s)

ACKNOWLEGEMENT

First and foremost, I am extremely grateful to my supervisor Dr. Jupi Gogoi for her invaluable advice, continuous support, and patience during my Master's Program. Their immense knowledge and plentiful experience have encouraged me in all the time of my academic research and daily life, had she not been available for such support my dissertation would have been incomplete.

Finally, I would like to express my gratitude to my parents and my sisters. Without their tremendous understanding and encouragement in the past few years, it would be impossible for me to complete my study. I have been able to reach this stage due to my brother who always believed in me and my capabilities.

Finally, I would also like to thank the Librarian, Officials, System Administrator, and staff of the NLUJA library, Guwahati for their help and cooperation in making available the relevant materials required for the study. I would also like to appreciate my university friends for helping me in completing my dissertation work in time.

Date:

ARCHITA JHA

UID: SF0222005

National Law University and Judicial Academy, Assam

TABLE OF CASES

TABLE OF STATUTES

1. The Biological Diversity Act 2002
2. Convention on Biological Diversity 2000
3. Patent Act 1970
4. The Protection of Plant Varieties and Farmer's Rights Act 2001
5. Seed Bill 2004
6. Environment Protection Act 1986
7. World Trade Organization 1994
8. Trade Related Aspects of Intellectual Property Rights System (TRIPS) 1994
9. World Intellectual Property Organization (WIPO) 1967
10. The Patent Cooperation Treaty (PCT), 1970
11. Food and Organisation (FAO), 1945
12. Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization (at Hague)
13. United Nations Conference on Trade and Development (UNCTAD), 1964
14. Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization
15. Doha Health Declaration adopted by the 2001
16. The Organization for Economic Cooperation and Development (OECD), 1961
17. Universal Declaration of Human Rights (UDHR), 1948

ABBREVIATIONS

1.	ABS	Access and Benefit Sharing
2.	WIPO	World Intellectual Property Organization
3.	WTO	World Trade Organization
4.	PIC	Prior Informed Consent
5.	TK	Traditional Knowledge
6.	IPR	Intellectual Property Rights
7.	CBD	Convention on Biological Diversity
8.	UPOV	Union International pour la protection des obtentions vegetables
9.	GMO	Genetically Modified Organism
10.	ITPGRFA	International Treaty on Plant Genetic Resources
11.	IUCN	International Union for Conservation of Nature
12.	PPVFR	Protection of Plant Varieties and Farmer's Right
13.	TKDL	Traditional Knowledge Digital Library
14.	TRIPS	Trade Related Aspects of Intellectual Property Rights System
15.	NBA	National Biodiversity Authority
16.	BMC	Biodiversity Management Committee
17.	SBB	State Biodiversity Board

Chapter 1
Introduction

1.1 Introduction

"Look closely at nature. Every species is a masterpiece, exquisitely adapted to the particular environment in which it has survived. Who are we to destroy or even diminish biodiversity?"

- E.O. Wilson

Biodiversity, as the term itself suggests, is made up of two words- 'Bio' and 'diversity', here bio means the whole arena of living organisms and diversity means the variety which we have in them. The diverse organisms live on this planet sharing the ecosystem. All of them have an equal right to access the divine gift of nature in the form of environment we have got. The energy we experience being a part of the ecosystem is magnificent. It is not the human being only but each and every creature present on this mother earth is supported by such power. Mother nature ensures the improvement of human life by providing a rich and varied biodiversity.

"Ether, air, fire, water, earth, planets, all creatures, directions, trees and plants, rivers and seas, they are all organs of God's body. Remembering this devotee respects all species."

The above lines (2.2.41) from the Srimad Bhagavatam reflects the respect and priority which our ancient vedic culture gave to the environment. In the end, all beings—living and inanimate—are a part of God's divine body, which is the source of all sources. This is something we should be aware of and grateful for in everything we experience in life. We are not in any way separate from this divinity; rather, we are a part of it. It is the very foundation of who we are. The nature is at the center of philosophy, Dharma, and customs. For this reason, we regard our rivers, cows, and nation as our mothers. We respect nature as the might of the Lord. Because of this philosophy, we have continued to live in peace with nature for millions of years since the beginning of our civilization. Biodiversity is a

sign of a varied and rich ecosystem. Although our nation ranks seventh on the list of biodiverse nations, biodiversity is not a term that is commonly used there. Our vast biodiversity and the benefits we can derive from it are not well known, and this apathy extends not only to the general populace but also to the governmental, social, political, and administrative levels. The establishment of biodiversity is the foundation for all of the key components and operations of the planet. The air we breathe, the water we drink, and the food we eat are all products of the Earth's abundant biodiversity. Animals and plants both provide food and medicine for people. The ten biogeographic zones of the country contain 47,480 species of flora and around 1,00,690 species of wildlife. Many types of terrestrial and aquatic environments, including forests, wetlands, grasslands, deserts, coastal, and marine ecosystems, support this diversity.[1] Animals and plants keep us alive and healthy, and trees assist in absorbing greenhouse gases, all of which have a big impact on how we live.

The biodiversity of the Earth supports all aspects of living souls, therefore preserving natural resources is essential to the survival of life as we know it. The primary motivation behind biodiversity conservation is to safeguard the continued survival of varied species and ecosystems that are threatened by human activity. Other justifications for biodiversity conservation include preserving essential natural resources for future generations and ensuring the sustainability of eco-systems.

For medical purposes, people have traditionally utilised biological resources. Resources from wild plants, animals, and microorganisms are also quite significant when looking for new medicines. Many medications, including antibiotics, are derived from microbes rather than plants, and novel chemical structures are always being found. New bioresources for enhancing human welfare will be found and developed as knowledge advances. The preservation of biological diversity and the discovery of new biological resources are clearly related.

[1] Implementation of India's National Biodiversity Action Plan An overview 2019 <www.moef.nic.in> accessed 14 April 2023.

1.1.1 Biodiversity Means?

The totality of all life on Earth is referred to as biological diversity, often called biodiversity. Walter G. Rosen coined the term 'biodiversity ' as a short form of Biological Diversity in 1985[2].The term "biological diversity" describes the many types of creatures that exist in the modern world. The living species on the planet, including plants, animals, and microorganisms, are also referred to as biodiversity.[3] All species found on Earth, from genes to ecosystems, are included in the term "biodiversity," which also refers to the evolutionary, ecological, and cultural processes that support life as we know it.

The term "biodiversity" has been recognised by Mr. Kamalnath (ex-Minister of Environment & Forest, GOI) as a synonym for the variety and variability of all species on this planet, which must be carefully protected for our future generations.[4]

Nature is a dynamic equilibrium that is maintained by a partnership of living species that must coexist in order for the ecosystem to function properly. Each species has a certain place in the ecosystem and a specific function to fulfil. Nature is a dynamic system that never stays the same and undergoes constant change, adaptation, and involvement in an equilibrium that, in essence, does not change. This is because it always allows for evolution and diversity.[5]

Conservation can be divided into two categories: in-situ conservation and ex-situ conservation. Animals are preserved in their natural habitats through in-situ conservation. For this reason, habitats where a species' native population still exists are protected. Thus, protected areas are a crucial component of any country's conservation of biodiversity. Ex-situ conservation, on the other hand, involves maintaining species away from their natural habitat. These programmes include things like gene banks, seed banks, zoos, and botanical

[2] Ashish Singh, 'Protection and Conservation of Biodiversity with Special Reference to IPR Laws an Analytical Study on Efficiency Sufficiency of Indian Laws' (Thesis2022) <http://hdl.handle.net/10603/465327> accessed 14 April 2023.
[3] Aman Shakya, 'Role of IPR in Protection of Biodiversity' (2022) 5 International Journal of Law Management & Humanities <https://heinonline.org> accessed 19 February 2022.
[4] N. Ramakrishnan "Biodiversity in Indian Scenarios", Daya Publishing House, (2006) at p. 161
[5] T.N. Khoshoo, "India"s Biodiversity: Tasks ahead" Journal ofCurrent Science, Vol. 67, N0.8, 25th October (1994) at pp.14-17

gardens. “Genetic diversity, species diversity, and ecological diversity are the three types of biological diversity that are commonly taken into account.”

The range of genetic material that each particular plant, animal, and microorganism carries is referred to as "genetic diversity." Both inside and across populations of different species, as well as between different species, there is genetic variety. Species diversity means the variety of living species. The term "ecosystem diversity" refers to both the immense diversity of habitat types and ecological processes present within ecosystems as well as the diverse range of biotic communities, ecological processes, and habitat types that occur within them.

The pursuit for growth and improvement in life puts human beings on different footing in comparison to animals and other living organisms. Man has always struggled for the betterment of life. He is constantly trying new ways and techniques for making smoothness in his life. At times when there were no cell phones, people usually sent letters to communicate with people in distant places. But then came cellphones and now the time of the android phone has arrived which has made communication so easy available even in the remote places of all parts of the world. To improve his life supporting mankind, wonderful inventions have been made in the past century. It is encouraged to do so by providing monopoly rights in terms of intellectual property rights. In the search for betterment of human society, people forgot to keep in mind that the living creatures other than humans are also present and are equally entitled to live their life in the same ecosystem. We have started to expand the scope of Intellectual Property Rights in every direction, exploiting nature to a greater extent which is not only his own creation but a gift of nature to all organisms surviving on this planet. In an effort to enclose the biological and intellectual commons, "Intellectual Property Rights" have been expanded to encompass biodiversity and living things, and this regime has become more global. The scope of granting Intellectual property rights is not confined to only technological inventions, but it has expanded even to the living organisms such as plants by using germplasm technology and making new hybrid forms being patented. Thus it can be said what was once God’s creation is also being encroached by human beings. The patent was granted to Ananda Chakravarthy, in 1972 for genetically engineered pseudomonas bacteria. It was a synthetic

microbe that could disintegrate different parts of crude oil. Oil spils could be treated as a result of this. This was the first attempt to create something living which was for the benefit of society and then there was no looking back.

1.1.2 What is Intellectual Property Rights?

People and organisations are given intellectual property rights largely for innovations and creative works, which gives the inventor/creator the incentive of the right to prevent others from utilising their work without their permission for a predetermined period of time. It enables individuals and organisations to possess their originality and ingenuity in a way that enables them to buy and sell it exactly like real estate. A right to control and compensation for the use of intellectual property belongs to its owner. It is predicated on the idea that a right to ownership and compensation will inspire more innovation and creativity, to everyone's advantage.

The primary statutory instruments for safeguarding IPRs are patents, copyrights, industrial designs, geographical indications, and trademarks. In addition to the types of protection already mentioned, sui generis (Latin for "of its own") types of protection have also emerged to meet the specific demands of knowledge creators. Utility models, plant breeding rights, farmer's rights, and rights to integrated circuits are a few examples.

The various types of IPRs are given below in brief.

a) Patents are the most widely used intellectual property right. An invention's sole legal right to be produced, used, or sold commercially is protected by a patent. In order to use the idea commercially, someone other than the patent holder must acquire authorization from the patentee and will likely need to pay the ip owner royalties. A patent, like the majority of IPRs, gives the owner a brief monopoly as compensation for the innovation and as an incentive to make additional discoveries.

   The salient features of a Patent are:-

   i. Novelty, inventive step and capable of industrial application are the pre requisite for granting patent.
   ii. Both, product as well as process patent can be granted.

iii. The applicant for a patent typically has to reveal to the government's Patent Office how to make the innovation in a way that a knowledgeable expert might replicate it.

b) Trademarks are distinctive indicators, such as phrases, logos, forms, slogans, etc., used to distinguish a certain product or service as being made or offered by a particular person or business. They help consumers differentiate between the products and services of various producers. Trademarks also include brands. The well-known trademarks "Tata Tea," "Microsoft," "Coca-Cola," "Boroplus," and "Godrej" are a few examples.

c) Geographical Indications is essentially a product description that associates the product with a certain geographic region. The location must be connected to the qualities, reputation, and characteristics of the product. The three goals of GI protection are to protect consumers from being misled about the product's quality or origin, to stop producers from engaging in unfair competition by trying to "free-ride" on the hard-earned status of other products, and, finally, to allow producers to command a higher price for their goods due to their geographic distinctiveness.

d) Industrial designs safeguard an item's artistic features, such as its shape, texture, and pattern, as opposed to technical features like the design of jewellery, the precise shape of an automobile, the designs on a wallpaper or carpet, the shape of a watch, etc.

e) Trade secrets- Information that is important for business purposes, such as production techniques and company plans, is covered by trade secrets. They are protected by regulations that forbid acquisition through commercially unfair means and unauthorised disclosure as long as they are kept a secret.

f) Copyright- It is another type of intellectual property which protect the literary and artistic property. Without the creator's consent, it prevents unauthorised copying, translation, broadcasting, etc.

g) Plant Breeders’ Rights- IPRs known as "plant breeders' rights" (PBRs) apply only to certain plant varieties. Within a plant species, a plant variety is a subspecies or type of

plant. New plant varieties are seen as "improvements" rather than "inventions," according to PBRs.

Giving social recognition and financial incentives to the holder of an intellectual property right is the fundamental goal of awarding such a right. Between society and innovators, it functions as a form of social contract for producing advancements as well as creating significant new innovations. IPRs are legally granted to people and businesses so that they can safeguard themselves against the copying of their goods, innovations, and services. The primary driver of their increasing importance in the world economy and in world commerce has been transnational corporations seeking to protect their frequently significant expenditures in R&D. IPR-protected products, technologies, and services account for a sizeable share of the exports of several developed countries.

IPRs were not thought to be a priority for trade negotiations prior to the Uruguay Round. TRIPS, however, has moved IPRs to the forefront of discussions in the age of globalisation. The TRIPS Agreement unifies the fundamental principles of intellectual property law across the globe, and because it is backed by robust enforcement powers, it has significant legal impact. Defying nations risk trade sanctions. IPR policy formulation and implementation at the national and international levels will provide significant problems, which will be more obvious in the case of emerging nations.

The existing IPR framework supports monocultures, the protection of novel plant varieties, genetically modified species, and the monetization of biodiversity and related traditional knowledge. Although the industrialised nations lack a wealth of biological resources, they have greater tools for study and development. They utilise the biogenetic resources that can be accessible from these developing nations, causing a flow of genetic data in the opposite way, protected by IPRs, from poor nations to the capital-rich west.

As a certifier to the numerous international treaties and agreements, India is necessitated to create or modify the necessary domestic laws in order to prepare for and meet the challenges of globalisation. In order to meet the standards of the TRIPS Agreement, Indian laws governing intellectual property rights are being amended.

The important challenges are following:-

At first, it is claimed that each nation's establishment of a robust IPRs framework through TRIPS will grant dominant businesses and private research institutions monopoly powers. This would increase the already high influence of economic and technological power in a small number of corporations, enabling them to monopolise markets at the expense of consumers and small producers, particularly those in developing nations, and impose higher prices on goods covered by IPRs.

Second, under TRIPS, some types of live objects and living processes must be patentable before countries may join the WTO. This has sparked questions regarding morality, religion, the environment, and development. TRIPS and IPRs favour private individuals or businesses and contemporary technology,the lawful interests of farmers, indigenous peoples, and community groups who have committed to information and advances in the efficient utilisation natural resource, and the crucial role that traditional knowledge (TK) plays. Fourth, there is increasing proof that companies and private research institutions have misappropriated traditional knowledge and the interests of farmers and local people by patenting genetic materials and information related to their usage.

Since they encourage economic and technological growth, these initiatives ought to be advantageous to society as a whole. Others contend that intellectual property, including the patenting system, will have a negative impact on the commitment to sustainable development strategies by using the biodiversity of developing countries to raise the prices of seeds and essential medications to a level that the Poor cannot afford, legitimising the biopiracy of traditional knowledge, and undermining the independence of resource-poor farmers. The rights and obligations of producers and users must be balanced with the goals of social, economic, and sustainable development that governments aspire to advance through their IPR laws.

1.2 Statement of Problem

Article 16, para 5 of Convention on Biological Diversity states as:

“The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.”

The Biodiversity Convention requires the contracting parties to cooperate in this area "according to applicable national law and international law to ensure that such rights are supportive of and do not conflict with its aims." This is because the application of the Biodiversity Convention may be impacted by patents and other intellectual property rights. The requirements set forth in the TRIPs agreement, which requires that member nations give patents in every area of technology and Plant varieties may be shielded by sui generis laws, patents, or a combination of both[6], are explicitly included in the reference to international law on patents and other IPRs. The question here is whether, in the event of a conflict between TRIPS and CBD, the latter will take precedence because this aspect of CBD supports IPR. In addition, according to article 22 of the CBD, "the rights and responsibilities of any Contracting Party resulting from any existing international agreement shall not be affected, save where the exercise of such rights and obligations would seriously harm or endanger biological diversity." Together, those clauses make a compelling case for CBD to take precedence over the requirements of any other agreement, including TRIPS.

1.3 Research Aim

The main aim of this research is to understand the relationship between the intellectual property right and biodiversity management and sustainable development. The research also seeks to determine how developed and developing nations can cooperate in order to protect both their intellectual property and their natural resources.

1.4 Research Objectives

The objectives of the research are as follow:-

[6] Art. 27,TRIPS

1. to research the effects of the free flow of genetic material from tropical to Western nations, as well as the reliance of the former on the latter for the transfer of biotechnological goods.
2. to comprehend the issue of biodiversity and to consider necessary preservation measures for nature.
3. prevention of multinational businesses' private capture of local knowledge and protection of that knowledge as common property.
4. to research the impact of Indian law and the International Covenants on IPR on biological diversity.
5. to study the inadequacies of Indian law and the International Covenants on IPRs for the effective preservation of biodiversity
6. to offer solutions to achieve balance between IPRs and biodiversity.
7. examine some of the difficulties associated with extending IPR to new domains, such as plant variety protection and life patents.
8. analyze the issue of "biopiracy" and the protection of TK.
9. to identify potential solutions and the best course of action for each situation at the national and international levels.

1.5 Scope and Limitations

IPRs are to encourage people to invent and create which would bring welfare to the society. But this improvement should not be at the cost of loss of biodiversity. The scope of this research is to understand what should be the aim of Convention of Biological Diversity (CBD) and Trade Related Aspects of Intellectual Property Rights System (TRIPS), in the near future so that we can protect our biodiversity along with giving rights to the intellectual property right holders. But our scope of this study is limited to study of impact of IPRs in the preservation of biodiversity, considering the various national and international legislation in regard to it.

1.6 Hypothesis

The hypothesis proposed is that robust intellectual property rights (IPR) frameworks play a crucial role in the protection of biodiversity. By providing legal protection and incentives

for innovation and research, IPR can promote the creation of sustainable practices, conservation technologies, and the responsible use of biological resources. This, in turn, promotes the conservation and preservation of biodiversity by fostering a collaborative environment between researchers, local communities, and stakeholders. Furthermore, IPR can contribute to the equal allocation of advantages from biodiversity, ensuring that the rights and knowledge of indigenous communities and traditional practitioners are respected and acknowledged. Overall, it is hypothesized that a well-designed and effectively implemented IPR system can enhance biodiversity protection efforts, incentivize sustainable practices, and support the conservation of ecosystems and species diversity.

1.7 Research Questions

1. Whether IP rights are in conflict with rights under biodiversity laws?
2. In the event of conflicts between Conservation of Biodiversity(CBD) and TRIPS, what can be done to resolve it ?
3. Whether Indian legislation is able to resolve the conflict and counterbalance rights of IP and rights of biodiversity ?

1.8 Research Methodology

The doctrinal method has been primarily used by the researcher. The relevant data and information are collected from statutory enactments, published rules of National and International conventions. Secondary sources include books, journals, articles,government reports, thesis and the legal databases such as Scconline, Heinonline of NLU,Assam.

1.9 Literature Review

1.9.1 Research Thesis

Singh Ashish, Protection and Conservation of biodiversity with special reference to IPR laws : An analytical study on efficiency sufficiency of Indian laws (PhD Thesis,Jiwaji University 2022)

The given thesis encompasses the definition of biodiversity through numerous laws, such as the BD Act 2002, and international and national treaties, such as the Rio Convention on

Biodiversity, which was established in 1992. Additionally, it addresses the concern over protected innovation privileges (IPRs) and how it relates to current events, particularly how a changing environment affects people on a global scale. The main goal of granting a protected innovation property is to provide the holder with societal validation and financial stimulus. It draws attention to the dire state of the current IPR system, which promotes monocultures, the production of novel plant varieties and GMOs, as well as the sale of biodiversity and related conventional information. The discussion of the terms "conservation" and "patent" is then carried on through various statutes, legislations, precedents, the BD Act of 2002, the Patents Act of 1970, definitions provided by renowned scholars, and legal cases. Next, it has been extensively explored the authorities granted by the Act, such as the National Biodiversity Authority. The NBA's functions have also been extensively examined. The NBA is the main organisation in charge of directly or indirectly enforcing the Biodiversity Act. The Biological Diversity Regulations of 2004's Rule 12 defines the duties of the NBA. The Act's Section 19 lists the provisions that must receive NBA approval. The State Biodiversity Board (SBB), along with the SBB's functions, has also been covered under the Authorities section.

Naresh, “Intellectual property rights with special reference to biodiversity” management and sustainable development (PhD Thesis, Maharshi Dayanand University 2013)

This thesis deals with the significant issues relating to relationship between the intellectual property rights to biodiversity management and sustainable development. The study focuses on pertinent international legal systems and how they may affect India's evolving legal system. It deals with IPRs and general issues in agriculture which is the main component of agrobiodiversity. Convention on Biological Diversity (CBD) and the WTO’s TRIPS Agreement, International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and International Convention for the Protection of New Varieties of Plants (UPOV), 1961 are the main relevant treaties explained.

Chaudhuri Sabuj Kumar, The impact of Intellectual Property Rights IPR on biodiversity and biotechnology in India and designing a model biodiversity information system (PhD Thesis, Jadavpur University 2006)

This thesis talks initially give brief history of IPR and biodiversity, values of biodiversity. Indian scenario is discussed further. Afterwards legislations, national and international, both related to it is dealt in.

Shah Nileshkumar Pravinchandra, A study relating to intellectual property rights with special reference to biodiversity: A legal appraisal (PhD Thesis, Maharaja Sayajirao University of Baroda 2006)

In-depth discussion is given on how IPRs affect biodiversity.

In order to further "impoverish" or exclude them from technical advancements, industrial and commercial interests take the resources and expertise of resource-rich but economically underdeveloped nations and people. The tendency towards standardising agricultural production and medicinal plant usage systems is anticipated to be considerably intensified by IPRs. The local agricultural diversity would be severely displaced as a result. Farmers who experiment with seed varieties through reuse, trade with other farms, and other methods might come to feel less encouraged to do so. In its new context, a designed creature could have unintended negative effects on other species.

1.9.2 Research Papers

Sahai S, 'TRIPS and Biodiversity : A Gender Perspective' (2004) 12 Gender and Development 58 <www.jstor.org> accessed 7 April 2023

The gender perspective on biodiversity conservation is the primary topic of this article. Cropland, woods, and other natural resources are preserved and conserved primarily by women. They are cited as being the agricultural industry's long-standing stewards of genetic and species variety. Additionally, it discusses the commercialization of bioresources. It discusses the issue that UPOV is not advantageous to developing nations because it lacks any interest for farmers. There is just one right given to breeders, which is increasingly the company in the modern setting. It also discusses UPOV's struggle with agriculture and the security of sources of income. A seed patent would restrict women's ability to develop novel, regionally appropriate kinds for food, medicine, and rituals.

Families' ability to eat healthfully and communities' sociocultural identities would both be harmed by this.

Monagle C, “Biodiversity & Intellectual Property Rights: Reviewing Intellectual Property Rights in Light of the Objectives of the Convention on Biological Diversity” (World Wide Fund For Nature 2001) <www.ciel.org> accessed 18 April 2023

The above paper deals with the key issues in conserving biodiversity. It talks about subsidiary bodies of CBD. The link between the CBD and IPRs has been considered in a number of resolutions adopted by the CBD Conference of the Parties (COP).The COP has created a number of subsidiary groups to consider ABS. It discussed the need to protect and preserve indigenous and local cultures' knowledge, ideas, and practises. Further it encompasses the relationship between IPRs and benefit sharing along with relationship between IPRs and the preservation of and respect for the knowledge, innovations and practices of indigenous knowledge and local communities.

It also suggested a non-IPR based solution for protection of biodiversity which according to author would be more respectful towards traditional knowledge. It further aimed at mutually supportive way between CBD and TRIPS with respect to four areas of access and benefit sharing, respect for and preservation of traditional knowledge, technology transfer and the conservation and sustainable use of biological diversity. Then it elaborates the actions that can be taken at the international and national levels.

Adhikari N, “Towards Effective Protection of Traditional Knowledge: Resolving Conflicts between TRIPS and CBD” <www.cuts-geneva.org> accessed 5 March 2023

The given paper briefly discusses the conflicts between TRIPS and CBD. It says that although WTO’s agreement on Trade Related Aspects of Intellectual Property Rights remains one of the most important yet controversial agreements on intellectual property.It outlines relevant TRIPS issues in relation to traditional knowledge and highlights the need to continue rethinking discussions and agendas on TRIPS so that its benefits are maximized for all countries.

Stilwell MT, “Review of Article 27.3 (B) [2001] Centre For International Environment Law”

The above paper mainly focuses on the link between the provisions of Article 27.3 of TRIPS and the development. Investment, innovation and competition are the three aspects discussed in relation to it. Further it deals with the technical issues relating to sui-generis protection of plant varieties.

“Report of the International Conference on the TRIPS CBD Linkage: Issues and Way Forward (Centre for WTO Studies 2017)”

The given report is an in depth analysis of TRIPS CBD Linkage, issues and what should be the ways forward in the problems relating to it. It was prepared from the international conference organised by WTO Studies, Indian Institute of Foreign Trade at the Indian Institute of Foreign Trade,New Delhi. The objective of the conference was to examine the concerns involved and the views expressed on the subject in the TRIPS Council and in other international organization such as World Intellectual Property Organization (WIPO) and the Convention on Biological diversity (CBD). It looked at possible ways to revive negotiations on the subject in the WTO and explore the role of regional trading agreements and plurilateral treaties on the subject.

It elaborately talks about why the traditional knowledge database library was made and what are the limitations of it. Various initiatives taken by India are also discussed further in the report. It gave a short note of all the conventions and legislations followed from past to present with regard to IPR and biodiversity protection. It widely talks about Nagoya Protocol and its implementation in India. Mandatory disclosure requirement is the new concept in Nagoya protocol which is not being used by all the countries. The given paper talks about including this requirement in the municipal laws regarding IPR protection.

1.9.3 Report

1. Arora DrS and others, “Implementation of India’s National Biodiversity Action Plan an Overview 2019” (2018)

An overview of the National Biodiversity Action Plan's implementation in India is provided in this document. This document includes chapters on the country's biodiversity status, the legal system, different ecosystem types like forests, mangroves, marine, wetland, and fisheries in addition to agro-biodiversity, incorporating biodiversity values into planning and strategies for reducing poverty, TK , ABS.

1.10 Chapterisation

The current work is broken up into five chapters.

Chapter 1: Introduction

This chapter outlines the scope and objective of this research. It examines at first the meaning of biodiversity with different definitions. It also briefly examines the meaning of biodiversity. This includes subtopics such as ‘ Interface between IPR and Biodiversity’ , ‘Impacts of IPR on Biodiversity’ , ‘Contribution of 3rd World’. Further this chapter includes the aims and objectives, scope and limitation along with research problems, literature review and research methodology.

Chapter 2: Challenges And Issues Related To Biodiversity Protection

This chapter describes the various challenges related to biodiversity protection with reference to IPR. It talks about the threats that our biodiversity is facing in recent times along with taking reference with traditional knowledge. The chapter deals with the thoery of TK and the threats associated with it. Further it describes how misappropriation of traditional knowledge takes place which is covered under the term ‘ biopiracy’. Traditional Knowledge Digital Library came into existence for checking the process of misappropriation. How intellectual property protection of traditional knowledge can be done is further discussed. After that global governance of IPR through WIPO is dealt with briefly.

Chapter 3: Conflict of Interest between IPR and Biodiversity: An International Perspective

This chapter presents a global viewpoint on the potential conflict between biodiversity and IPR. It looks at the effects of creating a strong IPR framework by the TRIPS agreement,

which could result in the concentration of economic power in a small number of powerful corporations and the monopolisation of markets, especially affecting consumers and small producers in developing nations. Examining TK and the legal interests of farmers, native communities, and regional populations, we highlight the role of TK and the ethical, religious, environmental, and developmental concerns associated with patenting living organisms and processes under TRIPS. Additionally, it highlights how enterprises and private research institutions are misusing these groups' rights and stealing their traditional knowledge in order to patent genetic information. The chapter expresses worries about the detrimental effects on strategies for sustainable development and highlights the CBD as an international framework to resolve these conflicts and strike a balance between IPR upliftment and biodiversity preservation while taking the interests of society as a whole into account.

Chapter 4: Conflict of Interest between IPR and Biodiversity: A National Perspective

This chapter delves into the conflict that arises between intellectual property rights (IPR) and biodiversity from an Indian perspective. It explores the implications of this conflict and analyzes the unique challenges and considerations faced by India in balancing IPR protection with biodiversity conservation. The chapter begins by providing an overview of the Indian legal framework concerning IPR and biodiversity, including relevant national laws, regulations, and international agreements. It discusses the potential consequences of a robust IPR framework, such as the power dominance in the economy and monopolization of markets, and examines how these aspects impact India's diverse ecosystem and local communities. It explores the initiatives and policies undertaken by the Indian government and other stakeholders to address this conflict of interest, such as the promotion of TK systems, the establishment of sui generis legislation, and the establishment of biodiversity heritage sites. In conclusion, this chapter offers a comprehensive investigation of the conflict of interest between IPR and biodiversity from an Indian perspective. It sheds light on the country-specific challenges.

Chapter 5: Conclusion and Recommendations

In conclusion, the protection of biodiversity is a complicated and diverse issue that involves the use of intellectual property rights (IPR). While IPR can encourage innovation and support economic progress, its effects on biodiversity preservation must be carefully considered. Concerns about the consolidation of economic power, the potential capture of traditional knowledge, and the exclusion of local communities from the advantages of biodiversity resources all contribute to the conflict of interest between IPR and biodiversity. Striking a balance between IPR protection and biodiversity preservation is essential. This can be accomplished by putting in place strong legal frameworks that protect traditional knowledge, indigenous groups' rights, and the sustainable use of biological resources. Achieving effective policies and practises that respect and maintain biodiversity while ensuring equitable ABS requires collaboration between governments, international organisations, and local stakeholders.

Chapter 2

Challenges and Issues Related to Biodiversity Protection

One of the biggest sarcasm for natural resources is that as knowledge of ecology and resource efficiency interests rises, human cultural variety is rapidly declining as the world gradually grows more biologically and culturally homogeneous.[7] One of the principal causes of this scenario is the fact that typical settings have so often been the losers of development, environmental protection, and scientific and commercial research rather than the winners. The exploitation of natural resources and associated knowledge for profit, as well as the loss of biodiversity, have been key concerns, particularly when the IPRs are utilised to enforce monopoly. Traditional knowledge pertaining to biodiversity has been one of the most divisive topics in the current intellectual property rights battles. The crux of the issues is found to be a lack of agreement over how to safeguard indigenous resources, as well as challenges while identifying and categorising these resources within the context of IPRs . Also, the IP protection of TK gained crucial importance and, rather, turned into a difficult topic in the consequence of the signing of international accords like the TRIPS and the CBD. Owing to the expanding demand for bioproducts, traditional knowledge relating to biodiversity has been increasingly being commercialised on a global scale in recent decades. The lives of societies that have traditional knowledge have been negatively impacted by the degradation of TK and bioresources, which has also seriously threatened biodiversity. So, the issue of the necessity to safeguard traditional knowledge and biological resources has been brought up and is now the subject of heated debate on a global scale. India and other developing nations are bio-rich nations with various species of biodiversity that have countless countless applications.

[7] 'Report of the International Conference on the TRIPS CBD Linkage: Issues and Way Forward' (Centre for WTO Studies 2017).

2.1 Threats That Biological Resources Are Facing

2.1.1 Loss Of Biodiversity And Traditional Knowledge

In India, human activities including forestry, infrastructure projects and embankment projects, mining, urbanisation, and the loss of forests to land for agriculture are having a substantial negative impact on the land, forests, and livelihood of indigenous residents and nearby communities. In India, human activities including deforestation, logging, road construction and dam projects, mining, urbanisation, and conversion of forests to land for agricultural plantation all have an impact on a substantial portion of the land, forests, and habitat of tribal people and local communities.[8] Human action directly affects how diverse life is on the planet. The social and ecological framework in which the people have used their traditional knowledge has been altered by the loss of resources and habitat. It is believed that biodiversity is a form of culture.In some of the most challenging environments, millions of humans have persevered for thousands of years. Yet, many TK-based agricultural systems and biological resources have also deteriorated. The traditional methods of life of the indigenous communities have been urbanised as a result of the widespread migration of indigenous and tribal people from rural to urban areas. There are worries expressed due to the depletion of the natural resources on which TK depends. To begin with, conventional knowledge must be comprehended for this.

Traditional Knowledge

Due to millennia of direct contact with nature, the indigenous peoples of the world have a vast understanding of their ecosystems. They have a specific and frequently in-depth awareness of the characteristics of plants and animals, the way that ecosystems work, and the methods for exploiting and managing them since they live in and are a part of the diversity and complexity of complex ecosystems. In rural areas of developing nations, naturally existing species constitute the primary source of many, if not all, products like food, medicine, fuel, construction materials, and other necessities. Due to their long histories of living in close proximity to nature, the indigenous peoples of the world have a

[8] http://envfor.nic.in/soer/2001/ind bio.pdf

vast knowledge of their environs..They live in and are a part of the richness and complexity of complex ecosystems, therefore they have an unique and usually in-depth awareness of the traits of plants and animals, the functioning of ecosystems, and the techniques for utilising and managing them. In rural areas of developing nations, naturally existing species constitute the primary source of many, if not all, products like food, medicine, fuel, construction materials, and other necessities. Likewise, people's understanding of and perspectives on the environment, as well as their interactions with it, are frequently crucial components of cultural identity.[9] Traditional knowledge is a comprehensive notion that encompasses indigenous knowledge in many different domains, such as biodiversity, agriculture, medicine, and folklore expressions including music, dance, songs, crafts, and designs, among others. It has played and continues to play a key role in indigenous cultures' way of life.

Communities can profit from traditional knowledge by creating money. Today's global community is aware that they are not simply outdated and worthless sources of knowledge, but also highly flexible and inventive resources with great commercial value when properly converted. In line with the concepts of self-determination and development, indigenous knowledge must be preserved. Indigenous knowledge holders are unfamiliar of the modern legal system and how to seek restitution if their rights are violated, which makes indigenous knowledge exploitation unfair.

One may say that TK covers a wide spectrum of human interests, including, to name a few, agriculture, biodiversity, and medicine. Communities hold and pass down this enormous cultural and monetary worth over the generations. It includes a broad spectrum of information, such as songs, dances, agricultural techniques, handicrafts, literary, artistic, and scientific works. It also includes medical practices. It has been passed down through the generations as communal property, and indigenous cultures use it in their interactions with one another. TK is a direct descendant of numerous ancestors. When TK is improved and altered, it develops into valuable information that may be used for profit.

[9] United Nations Educational, Scienitific, and Cultural Organization (UNESCO) 1994

In recent years, the scientific community has started to recognise and value TK. Scientists are quickly realising that native tribes possess a wealth of knowledge that, if properly tapped, might produce technologies with high commercial value. Many nations, especially those in the developing world, feel as though they are not benefiting from their vast traditional resources despite their abundance, which is why discussions about the safeguarding of traditional knowledge are currently taking place.

Traditional knowledge contributes significantly to biodiversity conservation, environmental protection, and the satisfaction of human wants for long-term development. Native people have a deep awareness of their complex ecosystems, plant and animal traits, and how to use them as a result of centuries of living in close proximity to nature[10]. This knowledge turns becomes a useful resource once it is formalised into a specification. Nevertheless, many communities are unable to develop their own resources due to widespread poverty and illiteracy. But in today's globalised world, society's common knowledge has been reduced to the exclusive knowledge of a select few.

It is now widely accepted that traditional knowledge plays an important role in human development, notably in relation to food production, agricultural productivity, and health care. For food and medicine, the majority of people still rely on traditional knowledge and practises. Indian medical practises like Ayurveda, Siddha, and Unani draw on a wide range of biological resources as well as ancient wisdom.They are a part of India's established healthcare system. In order to increase agricultural variety and generate higher yield variations, worldwide crop research organisations have taken advantage of plant genetic resources derived from crops grown by local farming populations in developing nations.

The threats to TK are two-fold: one is caused by the improper use of TK (Biopiracy) by native communities, who ought to be its true owners, in which businesses take away the knowledge and resource without the knowledge holder's prior informed consent; the other

[10] World commission on environment & sustainable development (WCED) report, Bruttland (1987)

is caused by the absence of any benefit sharing agreement before putting that information to work.[11]

The existing IPR system prioritises private ownership of native peoples' information and assets, despite the fact that they have freely shared their knowledge on how to use seeds, medicinal plants, production techniques, and genetic material. Another issue that necessitates the preservation of TK is the protection of practises and information related to traditional lifestyles. The preservation of TK aims to give indigenous populations a sense of self-identification in order to preserve their survival. Farmers select the most popular plant species, which seed firms then collect for study and development. Plant genetic resources are preserved and used in this way. Plant breeders' rights benefit and safeguard better varieties, and these companies profit from them. Genetic material provided by farmers is not compensated. Traditional farmers, on the other hand, do not receive compensation for their contributions.

2.1.2 Genetically Modified Crops

An experimental use of biotechnology called genetic modification (GM) of crops includes altering the genetic code of plants to make them produce compounds that they do not naturally produce. The ability to directly alter an organism's genetic code is now possible thanks to advances in genetics technology. With the help of genetic engineering, crop plants can be given simple genetic features from wild relatives, distantly related plants, or practically any other organism.[12] When genes from different creatures are combined using recombinant DNA (rDNA) technology, the the organism that results to as "genetically modified," "genetically engineered," or "transgenic." When genes are transported to new contexts in order to produce new features, genetic engineering is more accurately referred to as genetic re-contextualization. Plant traits can be controlled in a variety of ways through genetic modification, and depending on the modified qualities, the effects of one

[11] Ashish Singh, 'Protection & Conservation of Biodiversity with Special Reference to IPR Laws: An Analytical Study on Efficiency, Sufficiency of Indian Laws' (Thesis 2022) 64 <http://hdl.handle.net/10603/465327> accessed 21 March 2023.
[12] Shah and Nilesh kumar Pravinchandra, 'A Study Relating to Intellectual Property Rights with Special Reference to Biodiversity a Legal Appraisal' (Thesis2006) <http://hdl.handle.net/10603/59930> accessed 12 May 2023.

manipulation may be very different from another. Food that has been genetically modified (GM) is made from plants or animals whose DNA have been altered in a lab by researchers. GM technologies, which were first developed for plants in 1983, can now be used to a range of crop species by plant breeders. The early applications of genetic engineering, or genetic alteration as it is now known, were in human medicine. Today's crops are very different from their wild progenitors in almost every way. Selection-based breeding has been practised for many thousands of years, with the best seeds being saved for the following generation. For thousands of years, farmers have used what we would call "conventional genetics."

2.2 Misappropriation of TK or “Biopiracy”

The misuse of genetic resources is the most complicated set of issues that will affect biological diversity and traditional knowledge in the future, also known as biopiracy. To achieve exclusive use of biological resources, conventional knowledge, or based on these sources or information, commercial products , it also entails obtaining IPRs, commonly patents. In reality, a sizable number of biological resource and knowledge patents have been granted without the knowledge's owner's consent. There is substantial evidence that IPRs have been sought over biological resources produced and used by local populations. Some of the examples are the cases of Neem, Turmeric, Basmati rice in India. It occurs when non-novel ideas receive erroneous patent awards while the knowledge was previously in the public domain as TK. It can also happen when patents are lawfully obtained but based on pre-existing technology or technology that has undergone just minor modifications.

Bioprospecting is the methodical discovery, categorization, and study of new sources of chemical substances, genes, proteins, and microorganisms having actual or possible economic worth that is done for commercial objectives. Bioprospecting is the methodical search, classification, and study of fresh chemical material sources, genes, proteins, and microorganisms with real or prospective economic value that are found in biodiversity for commercial purposes.[13] Bioprospectors rely on the expertise of indigenous and local people

[13] Article 7(3) of Costa Rica 7788 Biodiversity Law

since they have been managing these resources for a long time and are the best at understanding them to uncover economically significant genetic resources. A fundamental aspect of the growth of the world's economies and societies has been the exploration of biological resources for novel commercial applications. When bioprospecting results in biopiracy or environmentally harmful methods, a problem occurs. Biopiracy is the term used to describe this process of taking biodiversity and knowledge. The term "biopiracy" was created by Canadian activist Pat Mooney as a response to charges made by industrialised nations that third world nations countries were stealing their inventions. The term "biopiracy" was created by Canadian activist Pat Mooney in an effort to refute charges made by industrialised nations that developing nations were stealing their innovations.[14] The willful misappropriation of this prosperity, which is evident on a national and international basis, poses a severe threat to it. The main issue is that, although information generated in laboratories is acknowledged, it is not the local communities' property who have cared for it for years and are its real owners.

Most traditional communities have no idea of privately owning resources like seed varieties, which makes it difficult for them to fully understand the dangers and ramifications of an IPR. Most traditional societies have no idea of privately owning resources like seed varieties, which makes it difficult for them to fully understand the dangers and ramifications of an IPR regime.[15] Low levels of awareness and literacy are another factor contributing to traditional societies' susceptibility. The law and the IPR system in place are unknown. Even though they are aware of the law, traditional societies are increasingly more susceptible to biopiracy due to the evolving norms and principles of international IPR regimes. The controversy over safeguarding traditional knowledge and its subset, traditional medicines, has intensified due to the widespread commodification of TK through its exploitation and appropriation. The majority of the time, developing nations were the targets of these thefts committed by academics, researchers, and organisations from outside the community.

[14] Krishna Dronamraju , “Emerging consequences of biotechnology: biodiversity loss and IPR issues”, World Scientific Publishing Company (2008)
[15] Vandana Shiva, “US Monopolists Continue Biopiracy against India", (2003)

Numerous firms in the industrialised world have copyrighted the therapeutic qualities of plants, fruits, and vegetables that have been used by South Asian traditional healers for ages. Many firms in Western nations have copyrighted the therapeutic qualities of plants, fruits, and vegetables that have been used by South Asian traditional healers for ages.[16] Companies and organisations, mostly from the US, Europe, and Japan, have filed patents for 65 neem properties, 2 bitter gourd properties, 6 turmeric properties, and 3 jackfruit properties. One of these, the patent on the use of turmeric for wound healing, caused quite a stir when it was later overturned by the concerned companies and organisations, mostly from the US, Europe, and Japan, have filed patents for 65 neem properties, 2 bitter gourd properties, 6 turmeric properties, and 3 jackfruit properties. Among these, the patent on the use of turmeric for wound healing caused quite a stir, not the least because it was subsequently overturned by the relevant body[17]. The submission of a patent application implies that something other than knowledge about the genetic resource has been created, specifically an invention. These organisations will ultimately hinder or deter parties from even attempting to produce benefits that could be shared under the CBD by targeting the innovative process itself, including efforts to gain intellectual property protection for discoveries resulting from the exploitation of genetic resources. These organisations will ultimately block or hinder parties from even attempting to generate benefits that may be shared under the CBD model by targeting the innovative process itself, including efforts to gain intellectual property protection for discoveries made using genetic resources.[18] If the CBD doesn't mandate an equal distribution of the profits from such an invention, this could be considered bio-piracy. The error is not in submitting the patent application, but rather in failing to treat those who contributed to the chance for innovation properly.

A Case on Bio-Piracy

The cases of bio-piracy and the legalisation of it through sanctions in developed nations, particularly the US, have been very upsetting to developing nations with a wealth of

[16] Adhikari, Ratnakar; Rajesh Khanal and Navin Verma (2001)
[17]Ratnakar Adhikari, 'Emerging Issues Relating to Conflicts between TRIPS and Biodiversity: Development Implications for South Asia'
[18] Mathew and Basil B, 'Trade Related Intellectual Property Rights TRIPS versus Convention on Biological Diversity CBD: A Study on the Traditional Knowledge Related Intellectual Property IP Protection in India' (Thesis2015) <http://hdl.handle.net/10603/49080> accessed 11 May 2023.

biological diversity. Diamond v. Chakrabarty, 447.US.303(1980), which established the precedent for Chakrabarty, led to the PTO's adoption of the practise of determining patentability on a case-by-case basis. Chakrabarty, a genetic engineer working for General Electric, developed a Pseudomonas bacteria that could break down crude oil. The possibility of using the bacterium to clean up oil spills was raised. The creature was initially disallowed as patentable subject matter by the PTO, and the case ultimately reached the Supreme Court. In the end, the Court ruled 5-4 in Chakrabarty's favour, saying an active, man-made microorganism qualifies as patentable subject matter under Section 35 USC 101. Living organisms are not automatically ineligible for patent protection as the subject matter of a patent. The Chakrabarty ruling by the Supreme Court was crucial for the development of the biotechnology sector. The majority of the brand-new items that the sector creates each year incorporate a wide variety of natural discoveries, notably those involving living things. The active components of many of the most spectacular creations, from medications to agricultural engineering, come from plants and organisms found in the varied ecosystems of smaller, less industrialised countries.

2.3 Traditional Knowledge Digital Library

It was established with the intention of developing a prior art tool to prevent the grant of incorrect patents. It aims to give information about TK and GR in digital form in a language and structure that patent examiners around the world can comprehend. Under the terms of the access agreement, TKDL is made available to patent offices for prior art search and review, but any third-party disclosure is not permitted. As a follow-up action, the TKDL unit has consistently attempted to make cases of rejected/cancelled patents public. However it has certain limitations.It only covers conventional drugs, and even these are not completely covered. The TKDL is made available to patent offices for prior art search and evaluation in accordance with the conditions of the access agreement, but no third-party disclosure is allowed. The TKDL unit has continuously made an effort to make cases of rejected/cancelled patents public as a follow-up step. It does have some restrictions,

though. It only addresses conventional medicine, and even this is not fully covered.[19] Connecting TK with the indigenous communities that retain the knowledge is crucial.

North- South Division

Another area where industrialised nations with abundant technology and developing nations with abundant biodiversity are at odds is the preservation of ancient traditions and diversity. Collaboration between these two groups could lead to considerable innovation in a variety of goods, including pharmaceuticals, food, and cosmetics. Nevertheless, such collaboration has hardly ever brought in money for developing nations. Due to the contracting parties' unequal negotiating power, unfair licencing policies frequently result, when native communities are only paid for their biological resources and not compensated for their intellectual contributions. The results of the subsequent research are often not shared with the indigenous tribes. Frequently, no agreement is reached between the nations. In some cases, it is easy to see how TK and genetic resources are related since indigenous populations have come to understand the special functions of the germplasm. Foreign companies simply separate the molecules in this case, combine them with a usable product, and file for patent protection. Due to the unequal bargaining positions of the parties involved in a germplasm transfer, unfair licencing agreements frequently result in enterprises only paying local communities for the genetic resources in the form of lump sums or royalties. It too is occasionally disregarded. TK is undervalued in terms of importance.

2.4 IP Protection of TK

One of the most challenging topics in the discussions under the WTO and the CBD is the difficulties surrounding the conservation of biodiversity and the associated traditional knowledge. In fact, the TRIPS Agreement's provisions for the patenting of living forms have created a serious issue in the protection of such resources. The biotechnology industry's meteoric ascent over the preceding 20 years has led many countries to realise the huge possibilities for economic gain from their natural diversity and indigenous

[19] 'Report of the International Conference on the TRIPS CBD Linkage: Issues and Way Forward' (Centre for WTO Studies 2017).

knowledge. This realisation has been fueled by the growing demand for innovative biotechnological products. The global community is attempting to balance the needs of host nations, who want payment for providing genetic resources and traditional knowledge, and those of biotechnological innovators, who demand unrestricted access, open markets, and stronger IP protection. Several developing countries' desires to exert sovereign control over their resources were seen as impediments to free trade by industrialised countries, which sought to retain incentives for new breakthroughs through a strict IPR regime. To create novel medicines and GM crops for the global market, pharmaceutical businesses and agribusiness firms increasingly rely on these resources. On the other hand, intellectual property rights are often seen as a tool for wealthy nations and multinational firms in poor countries to utilise their resources without paying a cent and keeping none of the financial advantages connected with such resources. Pharmaceutical and agricultural companies increasingly rely on these resources to develop breakthrough drugs and GM crops for the worldwide trade. Almost 80% of the world's biodiversity may be found in underdeveloped nations, making them a haven for bioprospectors searching for the newest breakthrough in medicine or agriculture. The CBD and the TRIPS both represent the divergent perspectives of both developed and emerging nations on IPR. Industrialized countries view the CBD with scepticism because it skillfully strikes a balance between state sovereignty rights and intellectual property protections. On the other side, developing countries generally perceived TRIPS as a means of allowing multinational corporations access to local resources while retaining any gains from them to themselves. The conflict over intellectual property is fueled by the unequal economic distribution and location of the world's biodiversity.

2.5 Global Governance of IPR

Regarding the international regulation of IPR is dealt in, the WTO is the leading institution equipped with, among other things, a successful dispute resolution system. The World Intellectual Property Organization (WIPO), however, dealt with IPR as its primary duty long before the WTO. Prior to the creation of the WTO, the International Union for the Preservation of New Varieties of Plant (UPOV), a separate organisation headquartered

within the WIPO, dealt with one specific type of IP protection, namely plant breeders' rights.

World Intellectual Property Organization

There were other IPR-related documents, such as the Paris Convention for the Protection of Industrial Property (1883), Berne Convention (1886), and Rome Convention, even before TRIPS came into effect (1980). To better manage these instruments, WIPO was founded as a specialised agency of the United Nations in Stockholm on July 14, 1967. WIPO's dual goals are to improve intellectual property protection globally by collaborating with other international organisations and, when necessary, governments, and to (a) maintain administrative coordination among the several unions addressing IPR issues.

WIPO's duties include overseeing international IPR treaties, giving governments and commercial organisations technical and legal support, and keeping an eye on IPR trends globally to harmonise IPR standards. The primary objective of WIPO is to advance the protection of intellectual property around the globe, and despite the organization's absence from the biodiversity discussion, its agreements are significant. The World Intellectual Property Organization's (WIPO) intentions to strengthen the "Intergovernmental Committee on Intellectual Property and General Resources, Traditional Knowledge and Folklore" are becoming increasingly clear.The motivation behind the formation of a separate body was the realisation that problems with conventional knowledge cover numerous existing WIPO entities. The main goal was to create a forum for discussing issues related to how intellectual property interacts with traditional knowledge, genetic resources, and traditional cultural manifestations, much as what had recently been accomplished within the context of the TRIPS discussions. Three interrelated issues are of interest to the Intergovernmental Committee. The issues that need to be addressed are as follows: sharing the benefits of genetic resources; maintaining traditional knowledge; and third, safeguarding folkloric expressions.

The proponent for IPR inclusion in the WTO claims that WIPO fell short of expectations due to two significant flaws. Firstly, there were no specific guidelines on how to enforce rights before national legal and administrative authorities, which made national authorities,

especially in developing nations, uninterested in pursuing those responsible for IPR violations. Second, there was no effective and binding dispute resolution process in place on a global scale.[20]

[20] Vijay Katti, and Somasri Mukhopadhyay (2000), 'Intellectual Property Rights under World Trade Organisation' in B. Bhattacharyya, (ed.) Seattle and Beyond: The Unfinished Agenda, Indian Institute of Foreign Trade (IIFT), New Delhi

Chapter 3

Conflict of Interest Between IPR and Biodiversity: An International Perspective

Intense conflict has been produced between industrialised countries and developing nations, as well as between multinational enterprises and indigenous people, as a result of the advent of new generic technologies and the rising value of traditional knowledge connected to biodiversity. On the other hand, it seems that the presence of conflicting elements in the agreements, declarations, and other legal instruments limiting access to and control over biodiversity have made debates over the management of local bioresources and knowledge even more severe. The Trade Related Aspects of Intellectual Property Rights (TRIPS) and the Convention on Biological Diversity (CBD), both of which are international treaties that try to assuage the concerns of both developed and less developed nations, are at the centre of the arguments over traditional knowledge that is tied to biodiversity. While the CBD promotes the fair and equitable distribution of biological resources, the TRIPS Agreement encourages stricter legal safeguards for intellectual property rights. In contrast to TRIPS, which is an agreement whose requirements are implemented by the WTO, the International Convention for the Conservation of Biological Diversity (CBD) is an agreement whose provisions are normally not enforceable. CBD stands for the Convention on Biological Diversity. This chapter compares and contrasts the historical development, prominent characteristics, and conditions that led to the acceptance of the CBD with the background, features, and guiding principles of the TRIPS agreement. In addition to this, it investigates the core concepts of the CBD. This chapter also details the events that led to the creation of TRIPS Plus and makes an effort to identify any possible problems that may arise during the implementation of the CBD. This is done so that the possible repercussions may be weighed against the interests of the many parties.

The adoption of the CBD took place against the background of a rising threat to the world's genetic resources presented by recent developments in biotechnology, namely rDNA technology (recombinant deoxyribonucleic acid). This threat was the impetus for the adoption of the CBD. Despite the position taken by the CBD that intellectual property

rights (IPRs) must not be in conflict with the conservation and sustainable use of, conflicts will always arise. The acceptance of the CBD took place against the background of a rising danger to the world's genetic resources (recombinant deoxyribonucleic acid) presented by recent advancements in biotechnology, especially rDNA technology. This threat was posed by recent breakthroughs in biotechnology. Conflicts will inevitably develop, and states should work together to ensure that intellectual property rights support and do not conflict with the organization's purposes. In spite of the CBD's stance that intellectual property rights must not conflict with the conservation and sustainable use of biodiversity, conflicts will arise.[21]

3.1 Convention On Biological Diversity (CBD)

The agreement on Biological Diversity (also known as CBD) is, without a shadow of a doubt, the most all-encompassing agreement that has ever been ratified. It is the goal of this initiative to maintain the genetic, populational, speciesal, habitatal, and ecological variety of life on all scales in order to guarantee that the many forms of life that exist on earth will continue to sustain the various life support systems that are housed within the biosphere. It recognises that establishing social and economic objectives for the use of biological resources and the benefits obtained from genetic resources is at the heart of the process of sustainable development and that doing so will help conservation efforts. These goals may be created for the use of biological resources and the advantages derived from genetic resources.

After deliberations that had began in November 1990 under the aegis of the United Nations Environment Programme (UNEP), the Convention on Biological Diversity (CBD) was the end product of the United Nations Conference on Environment and Development that took place in Rio de Janeiro in 1992. On June 5 of that year, the conclusion of the meeting was announced (Adair, 1997). The Convention on Biological Diversity (CBD), which is administered by UNEP, defines standards for environmental protection while also promoting continuous economic development. The CBD places an emphasis on the

[21] Article 16.5

preservation of biodiversity, sustainable usage, and fair and equitable benefit sharing from the use of genetic resources.

The Convention on Biological Diversity (CBD) acknowledges that the depletion of natural resources, which is mostly caused by activity in economic sectors such as agriculture, forestry, fisheries, water supply, transportation, urban development, or energy, is one of the primary contributors to the loss of biodiversity. This is particularly true of endeavours that prioritise short-term profits above those that are sustainable over an extended period of time. Therefore, addressing institutional and economic concerns is very necessary in order to accomplish the goals of the convention. The Convention recognises the significance of traditional knowledge for the very first time in a global legal document. Traditional knowledge refers to the richness of information, innovations, and practises that are held by indigenous and local communities. This information is important for the preservation and sustainable use of biological variation.

The Convention is made up of around forty separate articles. The primary sections, which include Articles 5 to 17, cover a wide variety of issues that are associated with biodiversity. Some of these issues include the following: identification and monitoring; conservation in natural and human-modified environments; rational or substantial use; awareness-raising; impact assessments of actions that might have an impact on biodiversity; access to genetic material; preservation of relevant traditional knowledge and practises; sharing of benefits derived from the use of biological resources; and exchange of information. The outstanding significance of this treaty may be attributed to the fact that it addresses political issues on both the national and international levels in addition to the scientific concerns about the conservation of biodiversity.

3.1.1 The CBD Principles

The Convention on Biological Diversity (CBD) acknowledges a number of fundamental ideas in order to provide a description of the types of rights a state has over its genetic resources and the legal framework it can build in order to govern access to those resources. A few of them are as follows:

a) Each state should have sovereign rights over the biological and genetic resources that are situated on its land, and each state should have the capacity to pass laws that control how such resources may be used.[22]

b) Access to such material should only be granted in line with the "Prior Informed Consent" requirements established by the resource provider and on conditions that have been mutually agreed upon by both parties. In addition to this, it acknowledges the responsibility of ensuring a "fair and equal" distribution of benefits that are related to the use and availability to resources.[23]

c) Each country that is a contractual party to the CBD need to make an effort to develop and carry out scientific research that is based on the genetic resources with the full involvement of, and, to the extent that it is practicable within, the countries that are donating the genetic resources.[24]

d) The Parties to the Contract ought to adopt legislative, administrative, and policy measures that could guarantee that those parties to the Contract, particularly those in developing nations, who provide the genetic resources for such research actively engage in such activities and, where it is practical to do so, in such Contracting Parties. These measures could be in the form of anything from a policy to a piece of legislation or an administrative directive.[25]

e) Contracting Parties should put into effect the necessary legislative, administrative, and policy measures to guarantee that other Contracting Parties, particularly those that are developing countries and who contribute genetic resources, have access to the transfer of technology that makes use of those resources on terms that are mutually agreeable. This access should include technology that is protected by patents and other intellectual property rights.[26]

[22] Article 15, CBD
[23] Article 15 CBD
[24] Article 15 CBD
[25] Article 19 CBD
[26] Article 16 CBD

f) Each Contracting Party shall implement such legislative and administrative policy measures as may be required to give access to cooperative development and the transfer of technology for the benefit of governmental institutions and the business sector in developing countries. This access would be to the advantage of both of these groups.[27]

g) The state should

   (i) respect, maintain, and promote the indigenous people's and local people's knowledge, ideas, and practises that serve as examples of traditional ways of life. This is essential for the preservation and sustainable use of biological variation.
   (ii) with the approval and involvement of the owners of such knowledge, inventions, and methods, promote the wider application of such knowledge, inventions, and techniques.
   (iii) support the fair distribution of gains that are the outcome of the use of such knowledge, innovation, and approaches.[28]

h) It is recommended that patents and other intellectual property rights support and do not conflict with the organization's aims. This is due to the fact that patents and other intellectual property rights may have an effect on how the CBD is implemented.[29]

3.1.2. Salient Features of Convention on Biological Diversity(CBD)

The Convention on Biological Diversity (CBD) is now the most active international legal framework for promoting the preservation of Traditional Knowledge. This is due to the fact that its scope is confined to regions associated to biodiversity. The following is a list of the essential components of the CBD that are responsible for the preservation of biodiversity and traditional knowledge:

[27] Article 16 CBD
[28] Article 8(j) CBD
[29] Article 16.5 CBD

In accordance with the provisions of Article 8(j),

a) The Conference of the Parties (COP) and the Working Group on Article 8(j)

An institutional structure for controlling the Agreement's implementation and its ongoing extension has been established by the Agreement. The CBD process is governed by the Conference of the Parties, often known as the COP. The link that exists between the CBD and IPRs has been taken into consideration by the CBD Conference of the Parties (COP) in a number of its decisions. Convention Parties participate in its meetings, which take place once every two years or more often if deemed necessary. It develops work schedules, as well as debates changes to the Convention and the adoption of Protocols to the Convention, with the goal of achieving the goals of the Convention. The Conference of the Parties has created a number of subsidiary organisations in order to investigate access and benefit sharing. To get things started, a "Panel of Experts" has been assembled to discuss benefit sharing and access.It is tasked with determining a shared understanding of fundamental concepts, as well as exploring all of the potential avenues for benefit-sharing and access on conditions that are acceptable to both parties. This investigation is to include determining guiding principles and the most effective procedures for such agreements. The plan of work emphasises a number of different areas under which extra specific tasks are indicated in an attempt to provide assistance to Parties in the process of fulfilling their commitments as stated in Article 8(j). The project acts as a framework for the implementation of TK protection within the context of the CBD, taking into consideration the essential role that local communities and indigenous peoples play in the conservation of TK. The primary objective of the work programme is to ensure that all of those groups engage in an active and beneficial manner throughout all of its phases and levels of execution.

It was requested that the Working Group study the prospects of defining technological criteria for collecting and recording traditional knowledge, as well as evaluate any potential threats that such documentation may represent to the rights of traditional knowledge holders. Additionally, it is the responsibility of the Working Group to generate numerous sets of suggestions with the goal of simplifying the process by which parties and

governments are required to meet the duties outlined in article 8j and other connected laws. The drafting of legislation that would allow for equitable access to TK has been one of the primary priorities of the programme. These rules need to guarantee that the use of TK is done so with the permission of its holders and that those holders get a fair share of the advantages derived from its usage.

b) Recognition of Traditional Knowledge

In accordance with the CBD's Article 8(j), parties are required to, in accordance with the laws of their respective nations, respect, preserve, and maintain indigenous and local communities' knowledge, innovations, and practises that represent traditional lifestyles that are important for the conservation and sustainable use of biological diversity, as well as promote the equitable sharing of the benefits resulting from their use. In addition, parties are required to promote the equitable sharing of the benefits resulting from the use of indigenous and local communities' knowledge.

c) The Protection of Biological Diversity while Ensuring Its Long-Term Utilisation

One of the primary objectives of the CBD is to encourage the conservation of biological variety as well as the responsible use of its component parts. The Convention on Biological Diversity requires that Parties weigh in issues of conservation and sustainable use when making decisions at the national level[30]. Moreover, Parties are urged to include the preservation and sustainable use of biological variety in pertinent sectoral or cross-sectoral plans, programmes, and policies. Parties are in charge of determining the procedures and groups of actions that have or are expected to have a significant negative impact on biological variety and keeping track of those outcomes.[31]

d) Transfer of Technology

IPRs have the potential to have an effect not just on the kinds of technologies that might be produced using genetic resources, but also on how such innovations can be transferred and used. Additionally, they have the ability to promote Access and Benefit Sharing (ABS),

[30] Article 10(b)CBD
[31] Article 7(c) CBD

in addition to the conservation of traditional knowledge. The development and dissemination of appropriate technologies are essential to the effective accomplishment of the objectives set out by the CBD. The United Nations Conference on Trade and Development (UNCTAD) defines technology transfer as the organised dissemination of knowledge for the aim of manufacturing a product, operating a process, or delivering a service. The transmission of technology may take place either from one part of a country to another or from one state to another.[32] Article 16, which addresses access to and the transfer of technology, has the only explicit reference of intellectual property rights in the CBD. State parties have agreed, as stated in paragraphs 1 and 2 of Article 16 of the CBD, to provide access to and facilitate the transfer of technology to other parties on terms that are both equitable and as advantageous as possible.[33] Because patents and other intellectual property rights commonly apply to technologies, it is essential that such technologies be made accessible under conditions that acknowledge and are consistent with adequate and effective intellectual property rights protection. This is because those technologies are frequently the subject of intellectual property rights. A number of developing countries mentioned patent applications and patent databases as significant potential sources of technological information in a proposal for technology transfer to the WTO. They also mentioned that the sharing of information and regulatory standards between patent offices would increase the positive effects of such tools. They might provide assistance in the building of databases for certain less developed nations, particularly those that do not have access to the internet.[34] Article 17 of the CBD addresses the dissemination of information gleaned from any and all sources that are open to the general public and that is vital to the conservation of biodiversity and the practise of sustainable use. Article 17, paragraph 2, makes an explicit reference of the use of specialist knowledge, indigenous knowledge, and traditional knowledge to biotechnology, in addition to the potential of information repatriation. This article suggests that material that is already accessible to the general

[32] Lyle Glowka et al "A Guide to the Convention on Biological Diversity"" IUCN Environmental Policy & Law Paper 30.(1994)
[33] Ashish Singh, 'Protection & Conservation of Biodiversity with Special Reference to IPR Laws: An Analytical Study on Efficiency, Sufficiency of Indian Laws' (Thesis 2022) 64 <http://hdl.handle.net/10603/465327> accessed 21 March 2023.
[34] India, Pakistan and the Philippines, "Steps that Might be Taken within the Mandate of the WTO to Increase Flows of Technology to Developing Countries", Submission to the Working Group on Trade and Transfer of Technology, WT/WGTTI/W/10(13 October 2005), Para 13

public ought to be freely released after receiving the appropriate authorization. However, intellectual property rights linked to indigenous and traditional knowledge were gathered, recorded, and made available to the public without their knowledge or agreement. Therefore, the application of this article ought to be in conformity with Article 8(j) of the Convention and ought to support it. The owners of traditional knowledge, for example, should not be intimidated or mislead into making their knowledge available to the general public. Instead, they should be provided with accurate information on the intellectual property rights (IPR) and other implications of doing so.

a) Access and Benefit Sharing (ABS)

As part of its mission to promote the conservation of biodiversity, the CBD provides strong encouragement to the parties involved to support the provision of access to genetic resources and the equitable distribution of the benefits that result from their use. The Convention on Biological variety (CBD) is based, first and foremost, on the basic principle that nation states have sovereign rights over the biological variety within their territory. The CBD recognises that national governments have the capacity to limit access to natural resources in line with national law. Access to genetic resources must be achieved with the prior informed consent (PIC) of the CBD party and on circumstances that are mutually acceptable in order to comply with Article 15(4) and Article 15.

b) Prior Informed Consent (PIC)

Prior Informed Consent A claim of sovereignty over genetic resources may be made with the least amount of time and effort required with prior informed consent. In principle, one cannot have access to genetic resources without first obtaining prior informed permission. In accordance with Article 15 of the CBD, national governments have the discretionary power to choose who is allowed access to whose genetic resources. Additionally, the nation that is supplying it must first offer its prior, informed consent in order for this access to be granted. The CBD does not define the concept of prior informed consent. Prior informed consent is the agreement of a party to an activity after the complete disclosure of the rationale for the action, the specific processes that the action would require, any potential

dangers that would be involved, and the full extent of the consequences that may be conceivable.[35]

Basic Principles of an effective PIC are-

i. Clarity and certainty of the law
ii. Clear establishment of Competent National Authorities (CNAs) that have the authority to issue PIC
iii. Clearly stated deadlines and timing
iv. Method for involving relevant stakeholders in consultation

c) Mutually Agreed Terms (MAT)

Conditions for accessing the genetic resources of a Contracting Party must first be discussed and agreed upon by both parties. In addition, the Convention imposes an obligation on the Contracting Parties "to take all practical measures to promote and advance priority access by Contracting Parties, particularly developing countries, on a fair and equitable basis to the outcomes and the benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties." This obligation applies to the outcomes and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties.[36] This access is going to be contingent on both parties coming to an agreement. The Biological Diversity Regulations (BD Rules) from 2004 detail the procedure that must be followed to get approval. The consent is given in the form of a contract, and the terms of the contract have been mutually agreed upon before the contract is signed. One of the most important provisions of the agreement is that benefit-sharing be implemented after the commercialization of patents.[37] In addition to providing specifics on the benefit-sharing ratio and other access-related conditions and limits, the 2014 Guidelines on Access to Biological Resources and Related Knowledge and Benefits Sharing Regulations provide an overview of the biological resource access landscape. The

[35] Sarah A. Laird (ed.) "Biodiversity and traditional knowledge, equitable partnership in practice," Earthscan Publication London (2002)
[36] Article 15(4) CBD
[37] Article 19 CBD

final agreement, which has been accepted, is uploaded into the ABS-Clearing House (ABS CH), which is a system that allows the interchange of information on ABS.[38]

Bonn Guidelines

The adoption of the Bonn Guidelines in 1993 marked the beginning of the process that would eventually lead to the provisions of the CBD being put into action. The Bonn Guidelines are non-mandatory guidelines that have been provided to governments that have ratified the CBD. The guidelines provide assistance to the parties, the government, and other stakeholders in drafting comprehensive plans for access and benefit sharing as well as detailing the steps that are required to accomplish this goal. According to paragraph nine of the CBD, which also defines the scope of the guidelines, all genetic resources, associated traditional knowledge (TK), innovations, and practises that are covered by the CBD, as well as the benefits that result from the commercial and other uses of such resources, should be covered by the guidelines. The only genetic resources that are exempt from this rule are human genetic resources. According to the recommendations, in order for access and benefit sharing systems to have a solid basis, comprehensive access and benefit sharing plans at the national or regional level are required to function in this capacity. This access and benefit sharing strategy should encourage equitable benefit sharing with a focus on the preservation and sustainable use of biological diversity. It may be included in a national biodiversity strategy and action plan.

The most essential goals are

a) to encourage the conservation of biological diversity and to promote the responsible use of its products.

b) to provide Parties and Stakeholders with a transparent framework that will facilitate simpler access to genetic resources on their part and ensure that benefits will be distributed fairly to all parties involved.

[38] 'Report of the International Conference on the TRIPS CBD Linkage: Issues and Way Forward' (Centre for WTO Studies 2017).

c) In order to provide guidance to the Parties on the establishment of access and benefit-sharing schemes with the purpose of educating the practises and tactics of stakeholders about access and benefit-sharing agreements

d) To offer capacity development in order to assist the negotiation and implementation of effective access and benefit sharing agreements, notably for developing nations, particularly the least developed countries and small island developing states among them. This is specifically for the benefit of developing countries.

e) For the purpose of increasing awareness on the implementation of essential CBD criteria

f) To encourage the efficient and orderly transfer of relevant technology to those who provide access, with a particular focus on less developed and emerging nations

g) To stimulate the availability of critical financial resources to reach countries that provide to enhance the functioning of the clearing house mechanism as a tool for access and cooperation among profit-sharing parties

h) In line with both domestic laws and other international instruments, the parties involved should make it a priority to negotiate and put into effect benefit-sharing agreements and other procedures that understand the need to conserve the indigenous and local communities' traditional ways of knowing, inventing, and carrying out their daily lives.

The recommendations recommend that the overall access and benefit-sharing strategy of a country or region should serve as the foundation upon which the access and benefit-sharing systems of an area or nation should be constructed. This access and benefit-sharing mechanism might be included into a national biodiversity strategy and action plan as a means of fostering fair benefit distribution while simultaneously maintaining biological variety and making use of it in a manner that is ecologically responsible.

3.1.3. Nagoya Protocol

In 2002, there was a movement to implement the Comprehensive Biological Diversity Act's (CBD) exceedingly specific benefit-sharing provision. In 2004, a directive was published that called for the development of worldwide standards in this area. Following that, the Nagoya Protocol was ratified in 2010, and it became legally binding in 2014. The three primary components of the NP are referred to together as ABC, which stands for access, benefit sharing, and compliance. Article 6 of the NP mandates the adoption of certain legal, regulatory, and administrative measures concerning PIC in the countries that supply the service. The NP, on the other hand, was quite precise on the type of the steps that were necessary for compliance with the CBD, while the CBD did not require the implementation of particular measures. Article 6 of the NP stipulates that the provider countries are obligated to put into effect certain legal, policy, and administrative measures in regard to PIC. In contrast to the CBD, which did not specify any particular law as being necessary for the implementation of PIC, the NP was quite specific on the kinds of steps that needed to be taken.[39] According to the NP, parties are required to employ legislative, regulatory, and administrative measures to fairly and evenly share benefits, with the party contributing resources serving as the party that is responsible for providing such benefits. The usage of GR, as well as its commercialization and any applications that may follow, will bring about the benefits that will be distributed. The relevant compliance requirements had a multitude of qualifiers and different words that were quite similar to best effort provisions. In addition, these limitations are not specified, and it is up to the user country to determine whether or not they apply. The establishment of efficient monitoring, tracking, and reporting procedures was a goal that developing countries strove hard to achieve. In addition to this, they have proposed the establishment of checkpoints at which users would be required to disclose pertinent information. The use of biochemical compounds is at the root of a significant number of allegations of biopiracy; hence, emerging countries insist on the incorporation of derivatives.

[39] 'Report of the International Conference on the TRIPS CBD Linkage: Issues and Way Forward' (Centre for WTO Studies 2017).

As it is, the scope primarily encompasses derivatives for anti-money laundering and compliance purposes. But this might have a variety of various connotations depending on the person reading it. The World Health Organisation (WHO) was in the process of negotiating a framework for influenza viruses that had the potential to trigger a pandemic at the time, and the European Union (EU) attempted to have pathogens removed from the debate. Pathogens are covered by ABS regulations and are included in them, except that Article 8(b) of the NP has a compromise that requires each party to take current or imminent crises that jeopardise or damage human, animal, or plant health into account when formulating national ABS legislation. This compromise is included because the NP contains a compromise that requires each party to take into consideration current or impending emergencies that risk or harm human, animal, or plant health.[40] The demand for rapid access as well as rapid fair and equitable benefit sharing that results from the usage of GR may be taken into account by the parties. This criterion may include access to inexpensive treatments. It is also important to emphasise benefit sharing, in particular access to low-cost medicines.

The outcomes of the seventh meeting of the Working Group on ABS give more detailed information about TK's ABS device, which, in this regard, strengthens and extends Article 8(j) as well as the Bonn Guidelines. The responsibilities and obligations that fall on national authorities as well as those who possess TK have been thoroughly stated. The purpose of the proposal is to improve the standing of native and local inhabitants in terms of access to TK by underlining their right to be consulted by authorities, in particular on issues pertaining to prior informed consent, mutually agreed-upon conditions in benefit sharing, and effective engagement.[41]

Goals of Nagoya Protocol

a) establishing more stable conditions for access to genetic resources

[40] 'Report of the International Conference on the TRIPS CBD Linkage: Issues and Way Forward' (Centre for WTO Studies 2017).
[41] Mathew and Basil B, 'Trade Related Intellectual Property Rights TRIPS versus Convention on Biological Diversity CBD: A Study on the Traditional Knowledge Related Intellectual Property IP Protection in India' (Thesis2015) <http://hdl.handle.net/10603/49080> accessed 11 May 2023.

b) assisting in the distribution of rewards once genetic resources have been contributed by a contractual Party have left. Through aiding in benefit sharing, the Nagoya Protocol provides incentives to protect and responsibly exploit genetic resources, so improving biodiversity's contribution to growth and human well-being. Key obligations for contracting parties are outlined in the Nagoya Protocol with regard to benefit sharing, access to genetic resources, and compliance.

c) Provide transparency, clarity, and legal certainty

d) Verify that the procedures and guidelines are reasonable and not arbitrary.

e) Provide down precise standards for prior knowledge consent and amicable agreements.

f) Provide provisions for the issuance of a permit or an equivalent when access is authorised.

g) Establish conditions that encourage and support research that supports long-term use and biodiversity conservation.

h) Pay great attention to any situations that could endanger the health of people, animals, or plants.

i) Reflect about how important genetic resources are to agriculture and food security.

Obligations of Nagoya Protocol

a) Cooperate when it appears that the requirements of another contractual Party have been breached.

b) Promote the use of contracts that are mutually agreed upon to resolve disputes.

c) Ensure that they have the choice to use their own legal systems to seek redress when issues arise from mutually agreed-upon agreements.

d) Improve access to justice by taking action.

e) Create a reliable checkpoint to keep an eye on the usage of genetic resources at any step in the value chain, including pre-commercialization, research and development, innovation, and commercialization. The Nagoya Protocol provides rules on access, benefit sharing, and compliance and addresses traditional knowledge related to genetic resources. It also includes genetic resources, to which native and local populations are legally entitled.

f) Establishing national focal points (NFPs) and competent national authorities (CNAs) to collaborate on compliance concerns, act as information hubs, and offer access.

g) Negotiate Mutually Agreed Terms (MAT)

3.2 Trade Related Aspects Of Intellectual Property Rights (TRIPS)

The Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement of the World Trade Organisation is the most important international agreement dealing with intellectual property rights. Trade-Related Aspects of Intellectual Property Rights (TRIPS) (1986-1994) was the product of the most recent round of GATT talks, which lasted for a total of eight years and was successfully concluded. During the course of the negotiations, intellectual property rights emerged as a brand-new subject for debate. The United States of America campaigned for its inclusion despite being put under pressure to do so by the pharmaceutical industry, whose representatives drafted the essential language for the discussions. Establishing uniform, fundamental principles for the protection and enforcement of intellectual property rights by all WTO Members, this Agreement was reached during the trade discussions that took place during the Uruguay Round.[42] These aims are to "promote effective and adequate protection of intellectual property rights" and "eliminate distortions and impediments to international commerce" brought about by the enforcement of IPRs, as stated in the preamble to the TRIPS Agreement. According to Article 7 of its aims, it wants to stimulate technological innovation and transfer in a manner that is "conducive to social and economic advantage and to a balance of rights and duties."

[42] Shah and Nilesh kumar Pravinchandra, 'A Study Relating to Intellectual Property Rights with Special Reference to Biodiversity a Legal Appraisal' (Thesis2006) <http://hdl.handle.net/10603/59930> accessed 12 May 2023.

Specifically, it wants to do this in a way that balances rights and responsibilities. Patents and "sui generis systems" for plant variety protection are two examples of IPRs that are included in the scope of the TRIPS Agreement and that may have an effect on the conservation of biodiversity. The objective of the TRIPS Agreement is to bring the laws and regulations that pertain to intellectual property into conformity throughout the globe. The Agreement achieves this goal by specifying the essential conditions that must be met in order to protect diverse types of intellectual property. The countries that have signed on to the TRIPS Agreement are obligated to make these minimum standards a part of their national intellectual property legislation. The TRIPS generally provides down the basic grounds for awarding rights to the owner of IP, the criteria for enforcement under national laws, the settlement of disputes, and remedies for people whose IP rights have been infringed. These are all important aspects of intellectual property rights.

The World Trade Organisation (WTO) is in charge of supervising the global trade system, which includes the TRIPs agreement as one of its fundamental building blocks. The TRIPS Agreement lays forth the basic requirements for the protection of intellectual property rights (IPR) for all 164 members of the World Trade Organisation (WTO).

According to Section 5, which discusses patents, every technical breakthrough should be eligible for legal protection via the use of a patent. This includes items with a life of their own.

The agreement addresses the majority of these concerns.-

a) Implementation of key principles governing the trading system and other international accords pertaining to intellectual property

b) How to most successfully protect one's rights to intellectual property

c) How governments may most successfully preserve such rights inside the borders of their own countries

d) How to find common ground among WTO members about intellectual property disputes

In the second part of the TRIPs agreement, several types of intellectual property rights and methods for protecting them are analysed and discussed. The purpose of this endeavour is to ensure that all member countries are in compliance with appropriate protection standards. The responsibilities that were outlined in the key international agreements of the WIPO, which were in place prior to the establishment of the WTO, serve as the point of departure for this circumstance.

These are-

a) The Paris Convention

b) The Berne Convention

The TRIPs Agreement mandates that member countries shall offer patent protection for all innovations, including goods and processes, across all technical sectors, without exception, and subject to the standard conditions of novelty, originality, and industrial utility. This obligation applies to all inventions, regardless of the technological field in which they are developed. In addition to this, it is essential that patents be granted and that patent rights be exercised regardless of the country in which the innovation was made or the place where the products were manufactured.[43]

There are three exceptions to the rule that governs patentability, which is the basic concept. Inventions that are damaging to people's health or well-being, as well as the health or well-being of animals, plants, or the environment are specifically included in this category. The first category is for innovations that violate morality or public order. The application of this exception is subject to the condition that the invention's commercial exploitation must also be stopped, and that this prohibition must be essential to protect public order or morality in order for the exception to be applicable.[44] The second exception is that members are not permitted to allow the patenting of techniques that are used to treat either people or animals, including diagnostic, pharmaceutical, or surgical procedures.[45] The third provision stipulates that members have the authority to prohibit the creation of plants and

[43] Article 27.1 of Trade Related Aspects of Intellectual Property Rights (TRIPS)
[44] Article 27 2, ibid
[45] Article 27 3(a), ibid

animals by the use of microorganisms or fundamentally biological processes in lieu of non-biological and microbiological techniques. Any country that chooses to exclude some plant species from the protection offered by patents is nonetheless required to have a robust "sui generis" strategy of defence. In addition, the whole of the Article is subject to evaluation four years after the Agreement has been brought into effect.[46] The agreement lays forth the bare minimum of rights and responsibilities that are expected of patent owners. However, it does provide room for certain exceptions. It is possible for the owner of a patent to abuse the rights afforded to him, such as by failing to bring the patented goods to market. According to the terms of the agreement, governments may provide "compulsory licences" in order to mitigate the risk of situations like these, which would allow a competitor to legally produce the item or carry out the method in question. However, in order to safeguard the patent holder's lawful rights, there are some conditions that must be fulfilled before the patent may be granted.

Recently, the issue of how to preserve the role of the patent system as a method of motivating the production of innovative drugs while simultaneously ensuring that patent protection for pharmaceutical goods does not prevent people in poor countries from gaining access to medicines has emerged as an important topic of discussion.

Some nations were unsure about how these provisions would be interpreted and how much their right to use them would be respected, despite the fact that the TRIPs Agreement includes flexibility options such as accelerated licensure.

When the WTO ministers met in Doha for their ministerial conference in November of 2001, they released a special statement that addressed a significant portion of this problem. They reached a consensus that members should be unrestricted in their ability to pursue programmes that safeguard the general public's health and shouldn't be held back by the TRIPs Agreement. They stressed the several ways in which countries may take use of the TRIPs Agreement's built-in flexibility. In addition, it was decided to keep the current exclusions for the least developed nations from the protection offered by pharmaceutical patents until the year 2016. They assigned the TRIPs Council additional responsibilities to

[46] Article 27 3(h) of TRIPS

fulfil in order to address an additional issue, which was how to offer greater flexibility so that nations who are unable to manufacture medicines on their own might import copyrighted products produced under compulsory licence. On August 30, 2003, approval was given for a waiver that would allow for this degree of freedom.[47]

3.2.1 Problem Embedded in Art 27.3(b)

There is a consensus among most people that the TRIPs agreement, in its present form, should not be implemented since it violates the basic rights of individuals. TRIPs is fraught with problems on several fronts. It goes against every chance and violates every privilege that local communities have been granted in the central business district.

In general, Article 27.3(b) gives governments the authority to prevent some ideas from being copyrighted. These inventions may include plants, animals, and processes that are "basically" biological. On the other hand, microorganisms and processes that are not biological or microbiological must be eligible for patents. However, in order to be eligible for protection, plant varieties must fall under one of the following categories: a system that is specifically created for the task (also known as "sui generis"); patent protection; or a combination of the two.[48] Two important review procedures are the review of Article 27.3 and the review of the whole TRIPS Agreement under Article 71.1 for policymakers who are interested in ensuring that the CBD goals that are specified in the TRIPS Agreement are achieved. The TRIPs Agreement mandated that the review of Article 27.3(b) be underway no later than the year 1999. During the review session that took place in July 1999, India presented a report in which it discussed its core understanding of Article 27.3(b) and the challenges that it presents to developing countries. According to India, there are two difficulties that need to be addressed: the need to reevaluate whether or not it is ethically proper to patent live things, and the demand to recognise both official and informal innovation systems, especially in connection to biodiversity. Both of these issues are particularly important since India is concerned about biodiversity. India stressed how

[47] Shah and Nilesh kumar Pravinchandra, 'A Study Relating to Intellectual Property Rights with Special Reference to Biodiversity a Legal Appraisal' (Thesis2006) <http://hdl.handle.net/10603/59930> accessed 12 May 2023.
[48] www.wto.org

important it is to strike a balance between the TRIPs agreement and the CBD. The support that India got came from other developing countries. The industrialised countries kept their distance from India.[49]

During the debate held by the TRIPS Council, a number of topics were brought up, including the best way to put into practise the existing TRIPs rules on whether or not to patent plants and animals, as well as the question of whether or not such standards need to be updated. In addition, it addressed what should be done when traditional knowledge and genetic material are used for profit by individuals outside of the communities or countries from which they originally came, particularly when those items are the focus of patent applications, and it also addressed how to make sure that TRIPS and CBD complement one another.

3.2.2 The Doha Mandate

In accordance with the Doha Declaration of 2001, the TRIPs Council should place primary emphasis on the following issues: the interaction between the TRIPs Agreement and the CBD; the preservation of traditional knowledge and folklore; and any other pertinent recent developments that member governments bring up during the review of the TRIPs Agreement. The Doha Declaration from 2001 (WTO2001) gave the TRIPS Council the mission to explore the links between the TRIPS and the CBD, in addition to the question of traditional knowledge. This was particularly important in light of bio-piracy and the patenting of biotechnology. In addition, the Declaration stipulates that the TRIPS Council must investigate the preservation of traditional knowledge in regard to biotechnology (TRIPS Art. 27.3)(b). Technically, Doha mandates that TRIPS be assessed within the context of the already-established international system. Article 27.3(b) of the TRIPS regulations provides member states with certain leeway regarding the manner in which they regulate the patenting of plant and animal products. The origin of any material that may be included in a patent, including biological material that might have been obtained from traditional cultures, is not needed to be disclosed either. This applies even if the item

[49] Mathew and Basil B, 'Trade Related Intellectual Property Rights TRIPS versus Convention on Biological Diversity CBD: A Study on the Traditional Knowledge Related Intellectual Property IP Protection in India' (Thesis2015) <http://hdl.handle.net/10603/49080> accessed 11 May 2023.

in question was acquired from traditional cultures. A state's right to exercise sovereign control over its own national biological resources is recognised and protected by the CBD. When it comes to making use of traditional knowledge and resources, the CBD grants the state the ability to establish the norms that regulate the notions of prior informed consent, mutually acceptable conditions, and fair distribution. This authority was granted by the CBD.

It is necessary to discuss the relationship between the Convention on Biological Diversity and the Trade-Related Aspects of Intellectual Property (TRIPS), as well as the specific tensions that arise between these documents and the obligations they create in member countries, in order to gain a full understanding of the international intellectual property issues that are raised by the Doha Mandate. These issues are particularly concerning with regard to traditional knowledge and biodiversity.

3.3 Conflict Between TRIPS and CBD

The TRIPS Agreement was the first international agreement of its kind to manage the protection of intellectual property. Historically, only national law applied to patents, but the World Intellectual Property Organization (WIPO) unified the diverse national laws and imposed national treatment. National jurisdiction was responsible for determining the requirements, restrictions, and rights of patents, as well as their exact nature.

CBD and TRIPS in brief[50]

No.	Issue	TRIPS Agreement	CBD
1.	Date of entry into force	1994	1992
2.	Governing Body	WTO	UNEP
3.	Main Mandate	Trade and IPRs	Environment Conservation

[50] Mathew Basil, B (2013), Conflicts and Divergent Perspectives to Protect Traditional Knowledge and Indigenous People, International Research Journal of Social Sciences, Vol. 2(11)

4.	Emphasis on	Protection of IP as a private property	Protection of Genetic Resources(GR) and Traditional knowledge as public goods
5.	Access and Benefit Sharing of GR and TK	Not addressed	Addressed

In the preamble to the CBD, it is stated that in order to satisfy the requirements of an ever-increasing global population, it is necessary to have access to and be able to interchange both technological and genetic resources. This is because the preservation and responsible use of biological diversity are of the utmost significance. This statement makes the link between sufficient access to genetic resources and the appropriate transfer of technology, including that which is protected by patents and other intellectual property rights. It also establishes the relationship between adequate access to genetic resources and the appropriate transmission of knowledge. The clause is an effort to establish a middle ground in the ongoing battle between developed countries and developing nations over the availability, use, and preservation of the world's genetic resources. The issue centres on whether or not wealthy nations should have more control over the use of genetic resources than poor nations have. In the preamble to the CBD, it is stated that in order to satisfy the requirements of an ever-increasing global population, it is necessary to have access to and be able to interchange both technological and genetic resources. This is because the preservation and responsible use of biological diversity are of the utmost significance. This statement makes the link between sufficient access to genetic resources and the appropriate transfer of technology, including that which is protected by patents and other intellectual property rights. It also establishes the relationship between adequate access to genetic resources and the appropriate transmission of knowledge. The clause is an effort to establish a middle ground in the ongoing battle between developed countries and developing nations over the availability, use, and preservation of the world's genetic resources. The issue centres on whether or not wealthy nations should have more control

over the use of genetic resources than poor nations have. The preamble makes a number of proclamations, one of which is that states have sovereign rights over biological resources and are responsible for ensuring the preservation of their biological variety and the sustainable management of their biological resources. According to the information presented in the article, in order to ensure the protection of this sovereign right, the national governments possess the discretionary power to choose who is allowed access to genetic resources, and their choice must be in accordance with the laws of each respective country. As a direct consequence of this, genetic resources are now seen as belonging to the state. Genetic resources are no longer the "common heritage of mankind," as stated in article 1 of the International Agreement on Plant Genetic Resources, which was enacted in 1983 under the auspices of the FAO and had the consequence of enabling everyone to access genetic resources for free in the past. According to this article, genetic resources are no longer a "public good.[51]

a) The Contracting Parties are required to work together in this regard, subject to national law and international law, to ensure that such rights are supportive of and do not conflict with the objectives of the Biodiversity Convention because patents and other intellectual property rights may affect how the Biodiversity Convention is implemented.[52] The reference to international law on patents and other IPRs specifically mentions the obligations outlined in the TRIPs agreement, which calls for members to grant patents in every area of technology and to protect plant varieties either through patents, a sui generis system, or a combination of both. The major issue to consider is which should take precedence in the event of a disagreement between the two because IPRs promote CBD goals according to paragraph 5 of article 16 of the CBD.

b) In addition, according to article 22 of the CBD, "the rights and responsibilities of any Contracting Party resulting from any existing international agreement must not be affected, save where the exercise of such rights and obligations would seriously harm or endanger biological diversity." Together, those clauses make a compelling

[51] Joseph Straus, *The Rio Biodiversity Convention and Intellectual Property* (1993).
[52] Article 16 para 5

argument for CBD to take precedence over the requirements of any other agreement, including TRIPS.

c) The Convention further obligates Contracting Parties "to take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and the benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms"[53]. So, on mutually agreed-upon terms, individuals who create new plant or animal kinds, medications, or chemicals based on genetic resources must split their revenues with the owner of those resources. But TRIPS lack this mutually agreed terms.

d) The most significant aspect of the CBD, which contradicts the monopolistic notion of IPR, is that it formally acknowledges the crucial role that indigenous and local communities, as well as women, play in biodiversity conservation through their traditional and sustainable practises and cultural knowledge systems. Also much of discussions are done for the betterment of MNCs in plant breeding and seed industry rather than emphasising on protection of biodiversity, implementing the treaty obligations of CBD. However, due to the complicated quantitative and qualitative aspects of recognising the inventive and value-adding components of their contribution as well as the precise location from which the crucial genes responsible for the distinctiveness of the new variety came, the administrative implementation of the concept of indigenous and local communities rights is plagued with many problems.

e) The IPR framework has to be changed in order to be more CBD-friendly since key aspects of the CBD, such as the recognition of the state's sovereignty over its biological resources and the fair sharing of benefits with indigenous populations, are not included. But, the best way to resolve this issue is through the equitable

[53] Article 19 CBD

distribution of wealth. The CBD states that cooperation, not conflict, is the best course of action.

f) Whereas TRIPS grants IPRs to businesses or people, CBD recognises local communities for their contributions to conservation and sustainable development.

g) CBD requires prior informed consent of the nation states or the local communties who are identified as custodians of the biodiversity for any use of genetic materials whereas according to TRIPS, patent holders need not disclose the source of genetic materials on which a patent have been granted.

h) The CBD and the TRIPS Agreement have different purposes, histories, and overarching structures. TRIP'S is a trade agreement having commercial goals that primarily benefit powerful private organizations and businesses. Yet, the fast loss of biodiversity across the world, the acknowledgement of the value of traditional knowledge, and the rights of local people were the key drivers for the creation of the CBD.

i) Based on the CBD's recognition of national sovereignty, nations have the authority to control outsiders' access to biological resources and knowledge as well as to decide how benefits will be shared. The TRIPS will allow individuals and organisations to patent a nation's biological resources outside of the country where the resources or knowledge originated. In this way, the TRIPS Agreement makes it easier for living things to be misappropriated, as well as knowledge and methods for using biodiversity. In turn, developing nations' sovereignty over their resources, including their ability to exploit or utilise them and to choose access and benefit-sharing agreements, would be jeopardised.

j) Intellectual property rights are acknowledged as private rights in the TRIPS' preamble. Patents grant the owner of the patent the only right to stop anyone from creating, utilising, offering for sale, selling, or importing the patented product as well as from applying the patented technique. The grant of IPRs over items or processes under TRIPS provides private ownership over the rights to create, market, or utilise the

product or process. This makes it unlawful for anyone to do so, unless the owner first grants permission, which is often granted only in exchange for a licence or payment of royalties. IPRs therefore have the effect of restricting the free flow of information, as well as the use and manufacture of its products. The traditional social and economic structure, in which local communities make use of, develop, and nurture biodiversity, is at conflict with this system of exclusive and private rights. Many sections of the CBD both recognise this and work to defend community rights. However, the TRIPS agreement does not acknowledge the value or nature of collective knowledge or collective rights. Instead, the TRIPS-endorsed patent system favours private persons and organisations by allowing them to gain rights, even rights over goods or information that were primarily developed by local communities. The TRIPS and certain countries' adoption of biological material patent laws have made it easier for indigenous and local groups to have their expertise and resources misused, and the number of bio-piracy cases has been rising quickly. The CBD's principles and rules, which require nations to acknowledge local community rights and equitable benefit sharing, are violated by this theft. In fact, one of the primary goals of the CBD was to prevent misappropriation or bio-piracy, but TRIPS has had the consequence of facilitating the practise of such misappropriation.

k) Only inventions with a known creator are eligible for patent protection under the TRIPS agreement. The likelihood of recognising the contribution of traditional knowledge is greatly reduced since it is the result of the combined efforts of several individuals and groups. Moreover, TRIPS mandates that an invention have a chance of finding an industrial use before it can be protected by a patent, whereas TK ideas are more implicit in nature and rarely have a direct industrial application. The CBD appropriately recognises Traditions and practises, but the TRIPS encourage the expansion of knowledge through the use of contemporary technologies.

l) Article 15.4 of the CBD stipulates that access to genetic resources shall be contingent on the approval of the PIC of the Contracting Party that supplies such resources, unless the providing Party establishes some alternative protocol. Therefore, before commencing their work, individuals who wish to collect biological resources or

knowledge about them must get permission and present sufficient information about their work and how it is intended to be used. This is because consent is required in order to acquire biological resources or knowledge about them. In the draught law of many countries, it is essential to ensure that both the state and the local populations that are directly affected have given their prior informed consent. This indicates that authorization to collect is contingent on agreements for benefit sharing between the collector, the state, and the local communities, and that authorisation may be withheld if these arrangements are deemed unacceptable. It was decided to make the PIC requirement mandatory in order to deter dishonesty in resource and information acquisition as well as to promote fair benefit sharing.

m) In general, the phrase "access and benefit sharing" refers to the institutional frameworks that are in place to facilitate the use of genetic resources, the acquisition of access to those resources, and the distribution of the advantages that result from their utilisation in a manner that is both fair and equitable. The acknowledgement by the CBD of the sovereign rights of states over their own biodiversity and knowledge is an essential component, given that this bestows upon such nations the authority to restrict access and, as a result, the ability to defend their claims about benefit-sharing agreements. If access is granted, the conditions under which it is granted must be mutually agreed upon, and prior written agreement is required (Article 15.4) and (Article 15.5). The Trade and Investment Partnership Agreement (TRIPS) does not have a condition that would permit the holder of a patent to share earnings from claims concerning biological resources or associated knowledge with the government or native populations in the country of origin. If a person or company in one country obtains a patent in another country based on a biological resource or associated information that is held in the country of origin, the country of origin truly does not have many tools available to protect its benefit-sharing rights in this scenario. Regardless of whether or not such legal actions might be challenged in court, the associated costs are prohibitive.

Ethiopia, which was one of the early countries to join the CBD, proposed that the organisation investigate the relationship between the TRIPS and the CBD. Ethiopia

requested that the WTO/TRIPS Council take into consideration and settle the concerns of the CBD Contracting Parties before making any decisions or taking any measures related to the TRIPS Agreement that may have an affect on the innovations and traditions of local and indigenous groups. This would be done before the WTO/TRIPS Council made any decisions or took any steps related to the TRIPS Agreement. In 1996, India was the first nation to officially propose that the World Trade Organization's Committee on Trade and the Environment (CTE) investigate whether or not the CBD and TRIPS are compatible with one another. The argument that the TRIPS Agreement would result in minimal competition for "environmentally sound technology and goods," hence driving up prices and reducing the availability of such technologies, was the basis of India's case against the agreement. As a result of this, India has proposed that the CBD and TRIPS Agreements be harmonised by means of an amendment to the TRIPS that would compel applicants for patents to disclose any genetic resources they intend to use in their inventions. At the global level, there is still a large amount of discussion concerning the nature of the relationship between TRIPS and CBD, as well as the areas in which the two don't agree with one another. TRIPS seems to consider the strengthening of IPRs as a goal in and of itself, in contrast to the CBD, which sees IPR protection as a means of accomplishing biodiversity conservation, sustainable use, and fair benefit sharing. This is evident from the stated aims, which make it apparent that TRIPS appears to view the strengthening of IPRs as a goal in and of itself. The United States, Japan, and a few other countries are among the minority of governments that maintain that the TRIPS and the CBD do not conflict with one another. However, knowledgeable individuals such as Bowman are of the opinion that the goals of the CBD may be achieved via the implementation of an expansive interpretation of TRIPS Articles 7 and 8, which call for the consideration of welfare improvement.

Article 27, the most contentious provision of the TRIPS-CBD controversy, provides a broad range of protection by allowing the patenting of any invention—products or processes—in all technological disciplines as long as they are unique, include an innovative step, and are applicable to the industrial sector. This provision provides a broad range of protection by permitting the patenting of any invention—products or processes—in all technological disciplines. The CBD's competing goals make it more difficult to achieve its goals.

The TRIPS agreement does not require anybody who seeks patents or other intellectual property rights (IPRs) over biological resources to first get informed prior consent. In contrast, the TRIPS do not acknowledge the rights of the nation in which the biological resource or the knowledge of its utilisation is located. Applicants for patents may thus submit claims on biological resources or knowledge to patent offices situated in any country, and such offices may grant such claims without even obtaining the consent of the relevant government(s) of the nation(s) in question.

Conclusion

The Convention on Biological Diversity (CBD) is the result of ongoing demand from throughout the globe to take action in response to the unequal revenues and loss of biodiversity in the southern hemisphere. The establishment of an international framework is one of the goals of the Agreement, which seeks to both preserve the world's biological resources and increase their use. The Convention on Biological Diversity (CBD) recognises that human activities in economic sectors such as agriculture, forestry, fisheries, water supply, transportation, urban development, and energy, in particular those that place a greater emphasis on obtaining short-term benefits than on long-term sustainability, are largely to blame for the depletion of nature, which in turn leads to the loss of biodiversity. This is one of the key points that the CBD emphasises. It is consequently necessary to address both the economic and institutional concerns in order to achieve the goals of the convention.

On the other hand, the TRIPS is an international agreement between members of the WTO. The purpose of the TRIPS Agreement is to standardise the rules and regulations that pertain to intellectual property on a worldwide basis. This purpose is achieved via the TRIPS Agreement, which establishes fundamental rules for the protection of diverse types of intellectual property (IP). The countries that have signed on to the TRIPS Agreement are obligated to make these minimum standards a part of their national intellectual property legislation.

Article 27.3 of the TRIPS Agreement, which specifies that governments must include plants and animals in innovations that are eligible for patenting, is the component of the

TRIPS Agreement that has generated the greatest controversy. During the discussions that have taken place under the auspices of the WTO and the CBD with respect to issues concerning the protection of traditional knowledge and biodiversity, there has been a substantial amount of dispute. The terms of the TRIPS Agreement on the patenting of life forms have generated a significant problem with regard to the protection of such resources.

Both the goals of the CBD and those of the TRIPS, which aim to preserve intellectual property rights, are in fundamental disagreement with one another. Both the TRIPS Agreement and the CBD have diverse origin tales, organisational structures, and philosophical underpinnings. As was previously mentioned, the TRIPS are a set of commercial goals that are largely geared towards serving the interests of powerful private enterprises. The requirement to manage access to and distribution of benefits resulting from biodiversity conservation and sustainable use, as well as a growing understanding of the significance of Traditional Knowledge and the rights of local communities that produce and hold it, were the primary drivers behind the creation of the CBD.

The issue of state sovereignty and the rights of individuals who have intellectual property rights is one of the primary points of contention between the CBD and the TRIPS. As a result of the Convention on Biological Diversity (CBD), governments have the authority to choose the arrangements for benefit-sharing and to limit the access of non-natives to their biological resources and knowledge. People or organisations are allowed to patent biological resources outside of the nation in which the resources or knowledge were first found in order to comply with the TRIPS agreement. Therefore, TRIPS establishes the requirements for the incorrect acquisition of property rights or ownership over living things, in addition to the knowledge and practises for making use of biodiversity. The rights of developing nations to manage their own resources, to exploit or utilise those resources, and to determine which access and benefit-sharing agreements to join into are put in jeopardy as a result of this. The owner of a patent has the exclusive right to prohibit anyone else from creating, making use of, offering for sale, selling, or importing the patented product or using the patented technique. It is consequently against the law for anybody to engage in such conduct without first obtaining permission from the proprietor, which is often granted only in return for the purchase of a licence or the payment of royalties.

The international intellectual property framework known as TRIPS safeguards intellectual property all across the globe by maximising the economic benefits that may be derived from both long-held conventional knowledge and the most recent and groundbreaking scientific discoveries.

As part of the Trade Related Intellectual Property Rights (TRIPS) amendment, obligatory disclosure requirements for patent applications are now mandated. It is imperative that the wording of Article 27.3(b) be modified in order to guarantee that patents on biological objects, including bacteria, are never granted. The advantage of the disclosure method is that it would assist in preventing the theft of GR and associated TK. This is because patent applicants would be required by law to declare the source/origin of the information as well as the approved access to the information. Additional benefits include eliminating the possibility of erroneous patents being granted, improving the openness of the ABS, increasing the degree of legal predictability and clarity, and enforcing CBD requirements throughout all relevant countries. However, industrialised countries like as the United States support a policy known as the No Disclosure Requirement, which is also supported by other developed nations. The "No Disclosure Requirement" method, which is advocated by the United specifies and is supported by other developed countries, advocates for sticking to the present standard patent law, which specifies that disclosure is only necessary if it is important for a person of ordinary ability in the art to put the invention into practise. Other industrialised nations are in favour of the "No Disclosure Requirement" approach. The proponents of this viewpoint argue that information should only be divulged if it is required to test the standards for patentability and only after the patent has been awarded. If disclosing the innovation is not necessary in order to create or use the invention, then there should be no obligation for disclosing the invention. Additionally, the United States of America makes the request that the applicant be given the opportunity to correct incorrect or inadequate information.[54]

[54] 'Report of the International Conference on the TRIPS CBD Linkage: Issues and Way Forward' (Centre for WTO Studies 2017).

Mandatory Disclosure Requirements

In order to enhance compliance with CBD access and benefit-sharing duties, eliminate exploitation of the intellectual property system, and prevent theft of genetic resources and associated traditional knowledge, a worldwide system of required declaration of origin regulations is essential. The declaration of origin requirements for intellectual property applications are recognised as an integral component of the CBD access and benefit-sharing regime by the Bonn Guidelines. This demonstrates the relationship between the CBD legislation and the global system of intellectual property law. In spite of the fact that several nations have passed legislation at the national level that mandate the disclosure of origin, a significant number of other nations in which intellectual property may be sought after do not at this time have such standards in place. It is necessary to add additional clauses to existing international treaties in order to make certain that the disclosure of origin rules are adhered to everywhere in the world.

Advantages-

a) To improve substantive examinations and ensure the integrity of determinations in accordance with traditional intellectual property legal requirements;

b) to increase the likelihood that improperly granted intellectual property will not need to be revoked;

c) to provide greater certainty regarding the validity of granted rights or privileges;

d) to increase the likelihood that improperly granted intellectual property will not need to be revoked.

e) May be of assistance in identifying instances in which access to genetic resources and related traditional knowledge has been obtained without agreements stipulating prior informed consent and equitable benefit sharing, or in which intellectual property has been wrongfully granted, and may be of assistance in facilitating corrective actions in the event that such circumstances arise.

f) are obligated to put a halt to the theft of economic gains that have been obtained in an unethical manner as a consequence of applying for, owning, or transferring intellectual property. Those profits might be gained either legally or illegally.

It is possible that current and prospective national laws pertaining to appropriation that puts at risk the integrity of intellectual property or the right to access or keep the advantages derived from intellectual property may have their integrity improved as a result. It is possible for there to be less ambiguity and greater clarity within a global system of regulations regarding national access, benefit-sharing, and intellectual property.

Disclosure of origin regulations need to include the power to reject rights to apply for, own, or enforce intellectual property in order for them to be effective in deterring breaches of access and benefit-sharing duties and preventing misappropriation. This will allow the rules to successfully prevent misappropriation. In a manner comparable to this, they need to provide national intellectual property offices the authority to postpone the processing of intellectual property applications or even consider them withdrawn if the relevant information isn't given on time. Disclosures of origin should be required early on in the application process for intellectual property.

Applicants should be required to reveal:

a) where genetic resources originate from and what customary knowledge goes with them.
b) the country that provides genetic resources and the corresponding traditional knowledge
c) proof in the form of documentation indicating the requirements for access and benefit-sharing have been satisfied
d) The information that the applicant is aware of about the persons who are involved in the subject matter of the application, the location of origin of genetic resources, and relevant traditional knowledge.

During both the international and the national stages of the application process, the mandatory disclosures should be reviewed to ensure that they follow to the established

processes in a formal manner and that they include all of the necessary information. Concerns raised by the CBD about the need of include a statement of origin in the paperwork necessary to apply for intellectual property are warranted. Only traditional knowledge that is significant for the preservation and sustainable use of biological variation in terms of equitable benefit-sharing is particularly addressed in Article 8(j) of the CBD. Contracts for access and benefit-sharing may impose responsibilities to do so wherever intellectual property applications are filed, even if such national laws do not require the disclosure of origin as their national laws currently do in some countries. This is the case even if such national laws do not require the disclosure of origin. It is possible that the information that is disclosed in accordance with the national disclosure of origin requirements will not be able to be utilised to prevent the improper issuance of intellectual property without mandatory obligations. Additionally, it is possible that the national disclosure of origin requirements will not be recognised and enforced by other nations in which intellectual property is applied for. On the other hand, mandating that origin information be disclosed would result in a variety of positive outcomes for both the CBD regime and the system of intellectual property law. One of these outcomes would be an improvement in the recognition and implementation of the disclosure of origin duties that are already in place. Mandatory requirements may also improve evaluations of inventorship or other ties to the subject matter, aid in identifying parties who should participate in equitable benefit-sharing, make it easier to use the subject matter of the intellectual property, encourage adherence to access and benefit-sharing laws, and aid in tracking intellectual property commercialization to promote more effective use of the property. Mandatory requirements may also improve evaluations of inventorship or other ties to the subject matter. The CBD framework and the system of intellectual property law, on the other hand, would gain in a number of ways by requiring obligatory disclosure of origin, including better recognition and enforcement of present disclosure of origin responsibilities. One of these ways is that demanding mandatory disclosure of origin would make required disclosure of origin mandatory. Additionally, mandatory requirements have the potential to: improve evaluations of inventorship or other connections to the subject matter, thereby assisting in the identification of parties who should participate in equitable benefit-sharing; facilitate the use of the intellectual property's subject matter; encourage

adherence to access and benefit-sharing laws; and aid in tracking intellectual property commercialization in order to promote more effective intellectual property commercialization. While deciding the way forward for TRIPS- CBD linkage, various aspects which require consideration are as follow-

a) Cases of Biopiracy- The importance of exposing bio-piracy incidents goes beyond only gathering evidence; it also plays a crucial role in maintaining public awareness of the problem and fostering political commitment. It may be difficult to spread information about these biopiracy situations, thus additional effort is needed.

b) Initiatives like TKDL- TK database is an important complementary tool for preventing bio-piracy. However Information from the database may be accessed, which might encourage appropriation. Not all nations have pre-grant opposition systems, and others may not have the resources to carry out such a procedure. TKDL is so challenging to reproduce for other nations.

c) Visibility of Bio- piracy issue- WIPO, the CBD process, and country level laws would all benefit from the WTO putting more emphasis on patent-linkage issues.

d) WIPO- The role of WIPO should go beyond patents. Protection of plant varieties should be included (PVP). PVP is dealt with by the International Union for the Protection of New Varieties of Plants (UPOV), although it has clarified that disclosure requirements will not be included. Moreover, the UPOV system is inadequate and insufficient for the agricultural needs of emerging nations.

e) Inter-Forum Interaction: On the subject of bio-piracy and disclosure requirements, there must be interaction between the WTO, WIPO, and CBD-Nagoya Protocol. This will help people comprehend how distinct forums are related to one another.

f) Nagoya Protocol- The Nagoya Protocol still has room for improvement, and choices made by the COP MOP can address its problems.

Chapter 4

Conflict of Interest between IPR and Biodiversity: A National Perspective

After signing the CBD in 1992, it took another decade for India to finally enact the Biological Diversity Act of India in 2002. This was after India had signed the CBD in 1992. In the year 1997, the Ministry of Environment and Forests was in charge of putting together the initial draughts of the Biological Diversity Bill, and they did so by assembling a working group consisting of sixteen different people. Professor M.S. Swaminathan, who also served as head of the committee, was the leader of the group.[55] The draught legislation was developed after an extended period of public comment and discussion. Participation from the Central Government, State Governments, institutions of local self-government, scientific and technical institutes, experts, non-governmental organisations, the business sector, and other relevant players was required for this process.[56] Ultimately, on December 2 and December 11, 2002, the Lok Sabha and Rajya Sabha respectively passed The Biodiversity Act 2002.[57]The Biological Diversity Act, which was passed in 2002, is a significant and forward-thinking piece of legislation in India. It provides solutions to a wide range of new problems that have recently arisen, such as those that have been brought about by recent developments in technology—particularly in the domains of biotechnology and information technology—as well as those that have been brought about by the ongoing degradation of the environment, which is inextricably tied to the loss of biological diversity.In 2002, it enacted a law known as the Biological Diversity Act (BD Act), with the intention of achieving the following three particular goals: the preservation of biological diversity, the sustainable use of its component components, and the fair and equal sharing of benefits stemming from the use of biological resources. These objectives are derived from the CBD. The Convention on Biological Diversity has two primary stipulations that Bharat is working to progress and make effective. One of these

[55] Kanchi Kohli, Understanding the Biological Diversity Act 2002: A Dossier (2006).
[56] Pratibha Brahmi, R. P. Dua and B. S. Dhillon "The Biological Diversity Act of India and agrobiodiversity management" CurrentScience, Vol. 86, No. 5,10 March (2004)
[57] The Biological Diversity Act, 2002

requirements is the Biological Diversity Act of 2002, which was passed in 2002. The Act was enacted with the intention of regulating the access of non-natives to biological resources for the sake of study and business, and it provides severe punishments for its violation.[58] This ambitious Act seeks to promote the preservation, wise utilisation, and equitable distribution of the advantages of Bharat's biodiversity resources, which include ecosystems, crops, domesticated animals and their breeds, and microorganisms. A National Biodiversity Authority (NBA), State Biodiversity Boards (SBB), and Biodiversity Management Committees (BMC) at the level of Panchayats (village committees) and Municipalities are all provided for in this context.[59] It was originally conceived of as an umbrella Act that would replace a number of older Acts, one of which being the Forest Act, which was enacted during the time period of the colonial government. However, in its current form, the Act only has the status of a complementary Act, and it is required to cohabit with a number of other Acts, in particular those dealing to patents, plant varieties, farmers' rights, panchayati raj (village government), and the environment. Moreover, the Act cannot be amended in any way. There are a number of probable conflicts in the operation of these multiple Acts that need to be appropriately handled in order to ensure that the Biological Diversity Act of 2002 can effectively manage the numerous new and crucial concerns brought on by breakthroughs in scientific and technical fields. This Act is a key step in the people of India's attempts to establish their sovereign rights over their genetic and biological variety resources and to claim a part of the benefits that follow from the use of genetic resources. These goals can only be accomplished by claiming a portion of the advantages that come about as a direct consequence of the utilisation of genetic resources.

India became a Party to the Convention on Biological Diversity (CBD) in 1993 so that it could fulfil its responsibilities under the CBD. It drafted its own NBAP in 1999 and dubbed it "National Policy and Macro Level Action Plan on Biodiversity." The Strategy, 1999 was developed as a result of in-depth conversations held with stakeholders at all levels. The

[58] Ashish Singh, 'Protection & Conservation of Biodiversity with Special Reference to IPR Laws: An Analytical Study on Efficiency, Sufficiency of Indian Laws' (Thesis2022) 64 <http://hdl.handle.net/10603/465327> accessed 21 March 2023.
[59] Garg Ritu, 'Conservation of Biodiversity under Biodiversity Act 2002 and the Patent Laws in India Problem and Issues' (Thesis2010) <http://hdl.handle.net/10603/132524> accessed 17 May 2023.

consultation process increased people's knowledge of the CBD throughout the nation and spurred aspirations for the effective implementation of the CBD.[60]

4.1 Important Features of BD Act, 2002

The following is a list of some of the most important provisions that are contained in the Biological Diversity Act, which regulates access to biological diversity, its protection, and the use of it in a sustainable manner:

a) Conservation of biodiversity and environmentally responsible use.

b) Preserving and restoring the health of endangered animal and plant species.

c) Regulation of access to the nation's biological resources is carried out with the goal of guaranteeing that everyone will get an equivalent portion of the benefits derived from the utilisation of such resources, in addition to the information that is associated with those resources.

d) To guarantee that local residents who safeguard biological resources and who possess expertise and information about the use of biological resources all get a fair share of the benefits.

e) Regions that are noteworthy from the standpoint of biological variety may be conserved and promoted if they are designated as sites of biological diversity heritage in order to respect and safeguard the knowledge held by local people in relation to biodiversity.

f) Establishment of committees to facilitate the participation of entities exercising self-government in the overall process of putting the Act into effect.

At the local level, the Indian government formed something called Biodiversity Management Committees (BMC). At the state level, they built State Biodiversity Boards

[60] Dr Sujata Arora and others, 'Implementation of India's National Biodiversity Action Plan an Overview 2019' (2018).

(SBB), and at the national level, they established the National Biodiversity Authority (NBA).

a) The National Biodiversity Authority: sits atop the hierarchy as the most powerful organisation. The National Biodiversity Authority was established as the country's highest administrative tier. On October 1, 2003, in order to fulfil the requirements of Section 8(1) of the Act, the government of India created the National Biodiversity Authority (NBA) in the city of Chennai in the state of Tamil Nadu. The National Basketball Association (NBA) is a body corporate that has the capacity to enter into contracts, acquire, hold, and dispose of real estate (both movable and immovable), as well as to sue and be sued. The NBA also has perpetual succession, a common seal, and the ability to acquire, possess, and dispose of real estate (both movable and immovable). The National Basketball Association is composed of a chairman, ten ex-officio members from various locations, and five unofficial members. At the moment, the position of Chairman of the National Biodiversity Authority is held by Mr. C. Achalender Reddy. Additionally, the National Biodiversity Fund, which will be maintained by the NBA, will be utilised to promote the protection of biological resources, transmit benefits to stakeholders, and create socioeconomic development in regions where biological resources are used. The Biological Diversity Act mandated that the National Academy of Sciences form a number of Expert Committees in order to handle the many different aspects of the Act's overall aim.

Functions of NBA

The Biodiversity Act and the CBD's goal are both in line with the NBA's mandate. The Both the Biodiversity Act and the purpose of the CBD are congruent with the mission statement of the NBA. The NBA is principally responsible for carrying out the Biodiversity Act's provisions, either directly or indirectly. The following is a list of some of the roles that the NBA plays:

i. Advise the government of India on matters pertaining to the conservation of biological diversity, the ethical use of its components, and the equitable sharing of the benefits derived from the exploitation of biological resources.[61]

ii. Help state governments choose places of ecological significance that should be preserved as historic sites, and provide ideas for how such areas should be managed after they are protected.[62]

b) State Biodiversity Board (SBB): State Biodiversity Boards (SBBs) have been established at the state level, with the power to address issues pertaining to Indians' access for commercial purposes and the ability to prohibit any action that is in conflict with the goals of conservation, sustainable use, and fair benefit sharing. State Biodiversity Boards (SBBs) have the ability to address issues pertaining to commercial access for Indians. In accordance with the provisions of Section 22 of the Act, the SBBs are established by the respective state governments via the publication of official gazette announcements. In the same way as the NBA is a body corporate, so is the SBB. Both organisations have the ability to acquire, possess, and dispose of property, both movable and immovable, as well as the capacity to contract, and both organisations have the ability to sue in their own names and be sued in their own names.[63].

Function of SBB

In accordance with instructions from the Central Government, advise the State Government on matters relevant to biodiversity protection, sustainable use of its components, and equitable distribution of benefits from the use of biological resources. These functions are specified in Section 23 of the Biological Diversity Act.

i. impose limitations on the commercial exploitation, biosurveillance, and biouse of any biological resource by Indians by allowing or refusing requests for such activities.

[61] Section 18(3) (a) the Biological Diversity Act
[62] Section 18(3) (b)
[63] Section 22(3) BD Act

ii. Carry out any further activities that may be necessary to satisfy the requirements of the Biological Diversity Act.

c) Biodiversity Management Committees: The most laudable action taken by this Act is the attempt to implement the Act at the local level with the help of the local populace by setting up Biodiversity Management Committees (BMC) at the local level. Local bodies constitute the BMC in accordance with Section 41 within their respective areas of jurisdiction in order to promote the conservation, sustainable use, and documentation of biological diversity, including the preservation of habitats, folk varieties and cultivars, domesticated stocks and breeds of animals and microorganisms, and the chronicling of knowledge relating to biological diversity. The NBA and the SBB must engage the BMC before making any decisions involving the utilisation of biological resources and related information that fall under their purview. Every region that receives a notification from the State Government will establish a fund called the Local Biodiversity Fund.

Functions of BMC

i. The BMC's members In conjunction with locals, create, update, and certify the People's Biodiversity Registry (PBR). The BMC is required to keep a Registry detailing the access to biological resources and traditional knowledge granted, the collection fees levied, the benefits received, and the method of sharing those benefits.[64]

ii. Advise on any item the State Biodiversity Board or Authority refers to it for permission, to keep records of the local herbalists and practitioners who use the biological resources, and to grant approval.[65]

[64] Rule 22(6) of Biodiversity Rules 2004.
[65] Rule 22(7) of Biodiversity Rules 2004

4.2 Relevant Definitions used in the Act

Some of the definitions used in relation to the Act include:

a) Biological Resources:

The Act states that human genetic material is not included, but includes plants, animals, and microbes or sections of them, their genetic material, and byproducts (excluding value-added goods.[66] Bio resources are certainly not all parts of biodiversity; they are just parts of biodiversity that are currently or potentially valuable to humans. Examples include natural byproducts, crops, vegetables, ornamental orchids, animals, seeds, eggs, germplasm, and plant leaves, flowers, fruits, bark, and roots. It's important to note that the bio resource preview expressly excludes human genetic material. As a result, the biodiversity Act does not apply to access to human genetic material for research, commercial purposes, or intellectual property rights. The Central Government is empowered to exempt specific biological resources from the Act's limitations under Section 40 of the Act.

b) Bio- survey and Bio- utilization

Characterization, inventory, and bioassay are all included in bio-survey and bio-utilization, as well as the survey or collection of species, subspecies, genes, components, and extracts of biological resources for any application.[67] Since both bio-survey and bio-utilization are defined as surveys of gathering for any purpose, this is a broad term. Many foreigners and Indians have undertaken bio-surveys without any limitations on the extraction process and, frequently, without the knowledge of the local communities.

c) Commercial Utilization

Commercial utilisation is defined as the use of biological resources for products that are intended to be sold, such as pharmaceuticals, industrial enzymes, food flavours, fragrances, cosmetics, emulsifiers, oleoresins, colours, extracts, and genes used to improve crops and

[66] Section 2(c) of Biological Diversity Act
[67] Section 2(d) of Biological Diversity Act

livestock through genetic intervention. Conventional breeding and customary practises in any area of agriculture, horticulture, poultry, dairy farming, animal husbandry, or beekeeping are not considered to be commercial utilisation.[68] The phrase has been defined in a way that exempts local communities from regulation by regulatory authorities (who historically used these and depend on them for their livelihood). The pharmaceutical and biotechnology sectors' uses, among others, would all fall under its purview.

d) Equitable Benefit Sharing

Sharing of benefits as assessed by the National Biodiversity Authority under section 21 of the Act is what is meant by fair and equitable benefit-sharing.[69] This is one of the main objectives of both the Biodiversity Act and the CBD. The idea behind this is that communities or individuals who have helped conserve biodiversity should be compensated with ongoing access to the resources rather than merely a share of the money made from the sale of related knowledge and bio-resources. Communities that donate biological resources and associated traditional knowledge for research, economic use, or intellectual property rights may benefit-share in a variety of ways.

e) Sustainable Use

It refers to using biological diversity's components in a way and at a rate that prevents the long-term deterioration of biological diversity, preserving its capacity to satisfy the needs and ambitions of both present and future generations.[70]

4.3 Provisions for Access and Benefit Sharing

Access to biological resources and people's knowledge for research and commercial reasons, including Intellectual Property Rights (IPR), was virtually "unregulated" in India prior to the Biological Diversity Act of 2002. While the Biodiversity Convention acknowledges states' sovereign rights over their natural resources, it also establishes standards for the interesting and fair distribution of benefits from the use of genetic

[68] Section 2(f) of Biological Diversity Act
[69] Section 2(g)
[70] Section 2(o)

resources to the countries that provide these resources. Access and advantage sharing (ABS), which is frequently mentioned, creates a new framework for the use of genetic resources in the twenty-first century. In an era where money is the primary factor in international relations, the rich biodiversity found in needy countries is a crucial asset that might propel their economic and social growth.

a) Access Procedure under the Act:

Chapter II of the Biological Diversity Act, titled "Regulation of Access to Biological Diversity," addresses the regulation of access to biological diversity. For the purposes listed below, "access" means gaining access to any biological resource located in Bharat or information relating to it, as per Section 3 of the Act. These are-

i. Research or
ii. Commercial utilization
iii. Survey or assortment of species, subspecies, qualities, parts and concentrates of organic assets for any reason, including characterisation

The Biological Diversity Act principally deals with the fair distribution of benefits resulting from the use of these resources and related data by the country and its residents. It also handles the access of foreign nationals to genetic resources and related data.

b) Revocation of Access or Approval:

Only on the basis of a suo motto or complaint and in accordance with the following conditions may access or authorisation for an application be revoked. These are-

i. violation of the Act's rules or the conditions set forth in the authorization's grant
ii. Upon the terms of the Agreement being complied with
iii. Failing to follow any requirements for authorised access

c) Restriction for Access to Biological Resources:

The Act imposes some restrictions on request related to access to biological resources and traditional knowledge if the request is on-

i. endangered taxa
ii. endemic and rare taxa
iii. likely adverse effects on the livelihood of the local people
iv. adverse and irrecoverable environmental impact
v. cause genetic erosion or affect ecosystem function
vi. purpose contrary to national interests and other related international agreements to which India is party[71].

d) Procedure for Prior Approval of Transfer of Research Results:

Guidelines for cooperative research initiatives between institutions, including government-sponsored institutions of India and such institutions in other countries, involving the transfer or exchange of biological resources or information relevant thereto have been prepared and announced.[72] The Act prohibits anybody from disclosing research findings using biological resources obtained from India to foreign individuals or organisations, including NRIs, for financial gain without the authority's prior authorisation.[73]

e) Other Laws on Access and Benefit Sharing

In addition to the BD Act, the following Acts have effectively safeguarded the national system of benefit sharing for plant genetic resources and traditional knowledge:

i. The Authority must promote benefit-sharing claims for the applicant variety to be registered in the way specified, according to Section 26 (1) of the Preservation of Plant Varieties and Farmers' Rights (PPVFR) Act 2001.
ii. Section 10.4 of the Patent (Amendment) Act of 2002 - When a biological material is mentioned in the specification of a patent application, the applicant must deposit the material with an authorised depository institution and fulfil other requirements, such as disclosing the biological material's source and place of origin when it is used in an invention. The biological sample must be delivered before the filing date

[71] Rule 16(1) of Biodiversity Rules 2004
[72] www.nbaindia.org
[73] Section 4 of Biological Diversity Act

of the patent application. The depository institution will make the biological material accessible to the general public after the patent is published.[74]

4.4 Socio- Economic Concerns of Conservation

From the time it was a Bill, society's concerns about the law were pervasive. From the time it was a Bill, society's concerns about the law were pervasive. Criticizing Biological Diversity Act, Scientist Suman Sahai comments [75]. It is regrettable that the Biodiversity Act lacks a defined position on intellectual property rights, especially given that IPRs relating to biological materials are currently the most contentious topic in the IPR debate as a whole. The Act is unclear in this particular area, which is also the subject of a fierce international debate. This ambiguity is concerning because it could result in never-ending legal disputes about what would qualify as a legitimate IPR for the purposes of this law.

Here are the principal issues to be worried about during implementation:

a) Ethical issues on Transferring Genetic Material

The Biological Diversity Authority, State Biodiversity Boards, and Biodiversity Management Committees should all have an ethical committee. When negotiating the transfer of rights to national and international organisations and people, the Committees should make sure that the cultural, religious, and other values of significant biological resources and materials are not disregarded. The Committees should ensure that genetic materials have important ecological benefits in addition to being used for human benefit.[76]

b) Lack of Basic knowledge

The majority of the community members, officials from different organisations, and State Biodiversity Boards have stated that they require additional information. Also Government agencies should demonstrate a willingness to share information with the public in order to

[74] Section 11(A) Of Patent Act
[75] Ashish Kothari, '"A Submission to the Standing Committee Examining Biological Diversity Bill 2000"' [2000] Understanding the Biological diversity act 2002 a dossier".
[76] Garg Ritu, 'Conservation of Biodiversity under Biodiversity Act 2002 and the Patent Laws in India Problem and Issues' (Thesis2010) <http://hdl.handle.net/10603/132524> accessed 17 May 2023.

increase awareness of the problems with the Biological Diversity Act and to enable genuine participation in various conversations. The Act has primarily only been discussed in "professional" and scientific circles. It has to be discussed with local communities in their respective regional languages as they are the vital component for the protection of biodiversity and without expressing themselves in their own language, its impossible to gather information completely.

c) Focus on other Relevant Parallel Sectors

The difference between market and non-market prices of forest products must be closed in order to negotiate the trade of forest products. Today's gatherers still primarily depend on forests and other types of biodiversity. Indian studies show that international organisations and middlemen obtain the majority of the revenue generated by products derived from biodiversity. As a result, the bioprospecting process should be linked to the village committees' identification of knowledge and talent, and appropriate rewards for already-existing local knowledge should be developed through benefit sharing, based on the circumstances of each individual case. Specifically, Constituted valuation committees established for various regions under the Biological Diversity Authority should look into the discrepancy in information about their value-added utilities and traditional selected applications. Local communities must be aware of who has the right to utilise their natural resources because they are significant owners of biological resource rights. Civil society organisations working at different levels must monitor this and take appropriate action since local populations would not typically have access to information like applications made for using their resources or getting IPRs. The Committee should see to it that the prices are paid by the community organizations. The market price itself needs to be based on the availability of water resources, land, and extraction rates that are sustainable.

Conservation Through "Biodiversity Heritage Sites

One of the most specialised and cutting-edge conservation strategies under the Act has been marketed as biodiversity heritage sites (BHS). With regard to the declaration of Biodiversity Heritage Sites, Section 37 of the Act mandates that state governments notify the federal government. According to this Act, sites of high biodiversity value will be

published in the Official Gazette as biodiversity heritage sites. In order to achieve in-situ conservation, this section discusses how areas with a high biodiversity might be named "Biodiversity Heritage Sites." The objective of developing this new classification is to enable the preservation of biodiversity hotspots. Notwithstanding the fact that section 37 of the Act requires local bodies to be notified before biological heritage sites are chosen and declared, local communities are not required to provide their consent if the sites are to be designated. The State Government Regulations are intended to consider the significant role of locals when declaring Biodiversity Heritage Sites. The NBA has created guidelines for selection and upkeep of Biodiversity Heritage Sites.

4.5 The Patents Act, 1970

In 2002 and 2005, the Patent Act of 1970 underwent revisions. Section 3(i) of the Patent Act, which previously forbade patents on any process for the medical, surgical, creative, prophylactic, or other treatment of human beings, or any process for rendering animals or plants free of disease, or any process to increase their economic value or that of their products, was amended to remove the term 'plants' in 2002.[77] Clause 3(j), which prohibits patents on, among other things, plants and animals or any portion of them, other than microorganisms, was also enacted. This section covers species, varieties, seeds, and essential biological processes for the production or multiplication of plants and animals.

Salient Features of the Act

a) The Patent Act of 2002 made significant changes to Section 3 of the 1970 Act, opening the way for the patenting of microbes. Traditional knowledge, however, is exempt from patent protection.
b) The new Act of 2002 revised Section 52(1) of the Indian Patent Act of 1970, extending the time a patent may be held to twenty years from the filing of the patent application.
c) The modified Act's Chapter XVI, which runs from Sections 82 to 94, has extensive provisions on mandatory licencing. Any interested party may submit an application to

[77] Ashish Singh, 'Protection & Conservation of Biodiversity with Special Reference to IPR Laws: An Analytical Study on Efficiency, Sufficiency of Indian Laws' (Thesis2022) 64 <http://hdl.handle.net/10603/465327> accessed 21 March 2023.

the Controller for the issuance of a Compulsory licence in accordance with Section 84 at any time following the passing of three years following the date of the sealing of a patent.

d) The modified Act's section 92 expressly states that compulsory licencing may be granted in cases of national emergency, exceptional urgency, or public non-commercial use that may result from or be necessary as a result of a public health catastrophe. This covers treatment for hepatitis, TB, malaria, AIDS, and HIV, among other epidemics.

e) Provisions stating exceptions to patentability (or what cannot be patented) have been appropriately updated to avoid "ever greening" of patents for medicinal compounds. This eliminates all doubt regarding the range of patentability because India has a very rich tradition and legacy. Long-term protection of traditional knowledge would benefit from clear guidelines about what cannot be patented. Ayurveda, Siddha, and other well-established ethnic systems of medicine, as well as their formulations, are not subject to patent protection.

4.6 Provisions Under BD Act with Respect to Intellectual Property Rights and The Conflict between BD Act and IPR Protection

Regardless of nationality, any applicant for IPR on biological resources or traditional knowledge from India must submit an application to the NBA for approval of an IPR application, according to Section 6 of the Act, which is the applicable law in this respect. The NBA has the authority to accept or reject an IPR application. An application may be approved by the NBA with restrictions.[78] Before making a decision about the application, the NBA is required by Rule 14 of the Biological Diversity Guidelines to consult the local people. Rule 18 also stipulates that although the NBA determines the specifics of benefit sharing, the relevant local communities must be engaged. Section 55 of the Act imposes penalties for any violations of these rules.

Despite the fact that rule 18 mandates that communities be engaged before NBA establishes the specifics of benefit sharing. Section 55 of the Act also makes appropriate punishment

[78] Section 21(2) of BD Act

provisions. But, the Indian government is unable to prosecute and punish a foreign offender. The sole remedy proposed for this is for every nation to adopt laws requiring patent applicants to reveal their nation of origin and to confirm that they have the community's and nation's permission, or prior informed consent.

Section 6 of the BD Act forbids acquiring IPR for inventions based on any research or information on a biological resource obtained from India without first receiving NBA consent. It is restricted to innovations that are founded on study of, or knowledge of, an Indian biological resource. It demands prior clearance for patent applications filed both inside and outside of India. The approval process is outlined in the 2004 Biological Diversity Regulations (BD Rules). The consent is granted in the form of a contract with conditions that have been mutually agreed upon. Benefit-sharing following patent commercialization is one of the agreement's crucial requirements. The benefit-sharing ratio and other access-related conditions and limitations are also included in the 2014 Guidelines on Access to Biological Resources and Related Knowledge and Benefits Sharing Regulations. The final agreement (approved) is sent to ABS-Clearing House (ABS CH), a mechanism that facilitates information sharing on Access and Benefit Sharing.

The Indian Patents Act, 1970 was amended in 2005 to require the declaration of the origin and source of biological components utilised in biotechnological innovations. The Act also requires a certification of the receipt of the required consent from the authorised authority, in this case the NBA. In addition, the 2012 standards for patent examination provide that without NBA's consent, patent examiners must not award patents for inventions based on biological resources received from India. This has been successfully applied while examining patents. The priority standards of the patent system are also taken into consideration by the Biological Diversity Act, and the NBA's prior approval can be needed before a patent is issued. The Biological Diversity Act and the Patent Act are compatible, as further evidenced by the fact that failure to properly disclose the source and origin of biological material in a patent application is one of the grounds for pre-grant and post-grant opposition as well as for the revocation of patents in India.

1200 ABS applications were submitted to the NBA, and 85% of those have been reviewed and contacted by the applicants. With the applicants, it has signed more than 400 agreements, 265 of which are related to IPRs. In order to streamline the procedure, it has also created an online application system, and its beta version is now in use. Additionally, it offers a phone service to help applicants complete out the approval form and an online fee payment option. These facilities are designed to increase the system's effectiveness in obtaining the necessary data from the applicant, enabling timely disposition of the applications submitted.[79]

Section 3 of Indian Patent Act 1970 talks about what does not comes under invention. Section 3(j) encompasses seeds, varieties, and species, as well as virtually all biological processes used in the production or propagation of plants and animals, excluding microorganisms. It means only microorganisms are allowed to be patented. The problem with the section is that it don't specifies which are essential biological process. The act do not defines essential biological processes. Which are to be kept in the purview of essential biological process is not given anywhere in the act so that they can be kept outside the purview of giving intellectual property rights. Neither section 6 of the BD Act defines essential biological resources although biological resources are defined in it.

Plant Varieties Protection and BD Act

BD Act Section 6 applies to the acquisition of breeder's rights outside of India. It requires previous NBA authorization. It does not, however, apply to registration in India. The Preservation of Plant Varieties and Farmers' Rights Authority (PPVFRA) stipulates in S. 18 (1)(h) that the genetic/parental material must be legally acquired if it is to be used for breeding, evolution, or development of the protected variety.

The registration may be revoked for incorrect disclosure under Section 34 of the PPVFRA. Hence, it is hoped that these PPVFRA provisions will enable the Biological Diversity Act's need for the lawful acquisition of biological material, particularly section 3, to be met. Due to the PPVFRA's built-in ABS mechanism and the aforementioned restrictions, the BD

[79] 'Report of the International Conference on the TRIPS CBD Linkage: Issues and Way Forward' (Centre for WTO Studies 2017).

Act's regulations are not made applicable to the filing of applications for any rights covered by the PPVFRA. To be exact, the BD Act's ABS rules apply to gaining similar rights outside of India. The NBA's ability to intervene on behalf of the national government to take action to oppose the issuance of IPR on any biological resource received from India or related knowledge derived from India is one of its most significant responsibilities. The NBA may do this in accordance with Section 18(4) of the BD Act. The NBA's goal is not to stop patent applications; rather, it is to guarantee that the BD Act's rules are followed and to make it possible for the community and local residents who provided the biological resources to share in the advantages.

Challenges

Due to its collaborative working relationship with the Indian Patent Office and Plant Variety Protection Authority, the NBA has been able to carry out its duties effectively. On the other hand, the NBA faces significant threats from operations outside of India.

First, access is the main emphasis of user country measures outside of India. Due to the absence of enabling elements in other nations' patent laws, the NBA is ill-equipped to deal with biotechnological patents in an effective manner.

Second, obtaining biological material illegally and using it in the innovation is still not grounds for contesting and revoking the patent.

Thirdly, it is exceedingly expensive and time-consuming to oppose and revoke patents in other jurisdictions.

Fourthly, there haven't been many findings from outside observers. There hasn't been much of a response.

Finally, third-party views tend to focus on originality and inventiveness rather than the issue of the lawful acquisition of biological resources.

Misappropriation of biological resources in India could be reduced by collaboration and cooperation with the appropriate agencies (PPVFRA, IPO, NBA). Yet, there are no coordination channels for the applications submitted in other nations, which makes it

difficult for NBA to do its duties. Hence, a worldwide disclosure system is necessary for the efficient prevention of the theft of biological resources and related information.

Criticism

Leading environmental groups have criticised the Biodiversity Act, claiming that it distances indigenous farmers from their resources and encourages "biopiracy." The Act pretends to usurp these resources - and all knowledge thereof - by corporate organisations with the government's sanction, essentially negating the CBD's fundamental goals. When it was passed on December 11, Union Environment and Forests Minister T.R. Baalu asserted that the legislation would control foreign individuals' and institutions' access to genetic resources and related knowledge and ensure fair sharing of benefits resulting from their use with the nation and its people.

Indian corporations and residents are free to use the nation's biological resources for study, but they are not permitted to share their discoveries with other countries without the NBA's permission. Yet all of these regulations merely serve to bury biodiversity behind a mound of red tape that can only serve to cut off small-scale farmers from their resources while facilitating global bio-piracy.

The Act aims to deny the people access to their regional biological resources and requires all Indian nationals to request NBA approval before even submitting a patent application based on any study of or knowledge of Indian biological resources. Before even submitting a patent application, Indian corporations would now need to butter the palms of a growing bureaucracy.

The inevitable result of the legislation as suggested would be the theft of the rich biodiversity by MNCs (like Monsanto) with the complicity of government officials. The CBD was developed in response to demand from MNCs for more "access" to the world's resources. Its declared goal was to protect biodiversity for the benefit of local populations. Non-Indian nationals, non-residents, and corporate entities not registered in India are prohibited from obtaining any biological resource found in India or information related to it for study, commercial use, bio-survey, or bio-utilisation, according to Section 3.

Yet this prohibition is neatly bypassed by section 5 which states that the above provisions "shall not apply to collaborative research projects...if such projects...

(a) conform to the policy guidelines issued by the Central Government in this behalf;

(b) be approved by the Central Government."

In other words, with the government's endorsement and sanction, everything is therefore feasible.

The Act not only makes it possible for researchers to work together, but it also gives multinational corporations free rein to fully exploit India's agricultural sector. This suggests that the global seed industry, including Cargill, Monsanto, and others, can freely assert patents or "breeders' rights," take Indian seeds and modify them, and use specialised "exterminator pesticides" to eradicate all plants other than those based on specially-treated imported seeds in order to maximise their profits at the expense of the majority of Indian farmers.[80]

On the subject of intellectual property rights, the Act is inadequate (IPR). The only requirement is that IPR applications must go via the NBA, which runs improperly into national and worldwide campaigns against patents on biological forms. At a time when academics are already complaining the loss of crucial time due to time-consuming procedures, research proposals will now not only need to be reviewed by the NBA but publications will also need to adhere to government criteria. Local communities, on whose behalf the law was implemented, will not really have a voice in the awarding of patents on biological material or in the determination of what constitutes "equitable" benefit distribution. Now, the NBA's bureaucrats will determine this.

Considering the significance of IPR, Section 6 of the BDA specifically mentions how the BDA's rules apply to IPR. The very broad scope of the BDA's IPR authority is made clear by a thorough reading of Section 6. First of all, it should be recognised that Section 6 does not just apply to Indian nationals and residents (as defined in the Income Tax Act, 1961).

[80] Garg Ritu, 'Conservation of Biodiversity under Biodiversity Act 2002 and the Patent Laws in India Problem and Issues' (Thesis2010) <http://hdl.handle.net/10603/132524> accessed 17 May 2023.

Every natural or legal person, regardless of country, may be included in the phrase "no person" as used in Section 6, subclause 1. Second, the law's application is extra-territorial in that it also applies to the intellectual property rights legislation of other foreign nations. Lastly, it's interesting to notice that the stated section's reach extends beyond biological material just "existing" in India. In reality, the phrase "obtained" from India is used, which has the broadest possible suggestion that everything, including exotic material, would fall under the umbrella as long as it is acquired from India.

The BDA's Section 6 has a lot of ambiguous terminology, and since India's judiciary has not yet set any precedents, many of these problems lack clear solutions. For instance, Section 6 specifies that the NBA must provide its consent before IPR is used for research or information based on a biological resource derived from India. The NBA's interpretation of the meaning of "obtained" is not quite clear. Would "obtaining" be confined to only those biological resources that are really sourced from within India as the NBA's goal is to protect Indian biodiversity. What about Indian biological material that was originally collected there but was afterwards transported and acquired abroad (outside of India). Do the terms "obtained" and "occurring" imply that the biological resource must also be discovered to be present in India? Does "occurring" solely refer to biological resources that are sufficiently unique from those found abroad or will it cover foreign-origin biological resources that are also present in India, independent of any unique characteristics.

Another instance is where Section 6 expressly stipulates that any application for IPR rights must get prior NBA approval before being submitted to any foreign jurisdiction. The first proviso states that if an application is made, NBA authorization may be requested after the patent has been accepted but before to grant by the relevant patent body. Whether the foreign patent office is legally required to postpone the patent issuance until NBA permission is given is a clear question in this situation. The BDA's Section 2(c) provides a definition of "biological resource." The definition's broadness may be shown by expressly eliminating value-added goods and human genetic material. The language in Section 2(c) makes it abundantly evident that the Act is primarily intended to patent biological innovations, which imposes an extra burden on the Applicant to comply with that is mostly regulatory in nature.

According to current Indian Patent Office (IPO) procedure, it has been noted that it is essentially routine to run into an objection requiring clarification regarding the provision of NBA approval in the case of use of any biological resource obtained from India for patent applications that disclose any biological material in the First Examination Report (FER). As previously stated, in accordance with Section 6 of the NBA, the issue of the patent would be postponed until evidence of NBA clearance was supplied. It should be noted that the implementation of NBA regulations under the IPO does not just apply to claimed biological resources for patenting purposes. Instead, it covers the usage of any such resource or knowledge of it in any application component. For instance, the NBA would apply to the utilisation of any biological resource for a claimed product's validation.[81]

When national phase or convention applications receive precedence from another country, a confirmation that no biological resource from India was used in the invention is typically required. It might be difficult for an Indian candidate to do this, though.

It's interesting to notice that the BDA must be complied with even if the IPO does not need proof of compliance with any other local laws before granting patents!.This collaboration between the IPO and the NBA is admirable because it serves as an example of a relationship between the Ministry of Commerce and Industry and the Ministry of Environment and Forests, under which the NBA operates as an independent legal entity (Department of Industrial Policy & Promotion, which houses the Office of the Controller General of Patents, Designs, and Trademarks). Therefore we can see that there are various types of disparities along with the act and the process which has to be overcomed.

Conclusion

Even if the Act should have been tougher, it can still be a positive move if strict and precise standards are now outlined in accordance with it. If the Act is to accomplish its declared goal, there must be "full public engagement." It was up to the government and the people

[81]Amitavo Mitra, 'Biological Diversity Act, 2002 and Patenting of Biological Inventions in India – Part I (Section – 6) - Patent - India' (*www.mondaq.com*27 Summer 2017) <https://www.mondaq.com/india/patent/589566> accessed 21 May 2023.

to actively employ the framework that the legislation had merely established. Also the provisions are left over very wide which should be narrowed down such as terms used in section 6 which have been discussed above so as to narrow the interpretation and it would be easy for using these provision balancing with the rights of intellectual property holders' rights.

Chapter 5
Conclusions and Recommendations

5.1 Conclusion

The value of intellectual property rights (IPRs) has dramatically increased recently all around the world. Intellectual property is the term used to describe human creativity. Its protection is mainly meant to support artistic endeavours.

The value of intellectual property to a country's industrial and economic development cannot be overstated. The reason why wealthy nations are prosperous is because their intellectual property is exploited. The protection of intellectual property also contributes to the transfer of technology from developed to underdeveloped countries.

It is consequently necessary to defend intellectual property because it is essential to a nation's industrial and economic progress. But at the same time, this area of law is necessary and attempts to promote and safeguard an individual's interest in obtaining a fair price for his or her labour, money, or intellectual endeavour. But, new TRIPs rules and subsequent court rulings have enlarged the scope of patentability beyond human comprehension and brought all living things, including plants, animals, and humans, under the purview of intellectual property rights. The issuance of patents on living things has made people aware of the terrible consequences of IPRs on living things and biotechnologies. The biodiversity itself is now being threatened by this new IPR framework. Creating property rights over living things has also brought up significant environmental challenges. Patenting biological forms could result in the demise of several species of flora and wildlife, which would eventually disrupt the natural order of things. According to the Indian Constitution Review Committee, the fundamental "right to life" guaranteed by Article 21 of the Indian Constitution should include the "right to live in a healthy environment." This fundamental right may be violated in any attempt to disturb the environment.

Many developing nations, like India, have attempted to establish legislation to stop the onslaught of IPRs on biodiversity in light of the impact that IPRs have on it. Yet, the current laws are insufficient to safeguard biodiversity because of the shortsightedness of the nation's lawmakers, who act in response to pressure from profit-driven MNCs that have always put profits before people. It is crucial that the use of intellectual property ensures the safeguarding of fundamental human values since it is critical to human growth and a necessary component of economic development in a global setting. Advantages of intellectual property should be distributed equally to producers and users without distinction or discrimination of any type, and resource allocation should be done in a way that gives all countries an equal chance to benefit from knowledge-based advancement. Documentation of our knowledge system is urgently required to stop piracy and to safeguard our knowledge system. Also, a system for distributing the gains from the commercial exploitation of biological resources using such Traditional Knowledge must be put in place. India might be a prime location for activities of research and development, clinical studies, and patent protection if IPR regulations are carefully crafted and put into place. India is seen as the hub for clinical research by both national and international contract research organisations. The availability of large numbers of patient volunteers, skilled labour, and English proficiency will pave the way for previously unheard-of chances for local manufacturers. In addition to having a large domestic market, India also possesses a sizable pool of technical, managerial, and entrepreneurial capabilities. It is in our long-term best interests to have a system of intellectual property protection that acknowledges both the importance of fostering and rewarding innovation as well as our most important public interest concerns.

It is important to keep in mind that if more nations adopt international norms and standards for the protection of intellectual property rights, India won't be able to export goods to those nations that are infringing on those rights. Human activity globalisation is an inevitable outcome. We shouldn't take an isolationist posture but rather be a part of this globalisation. It will be prudent for us to establish internationally recognised guidelines and standards for the defence of intellectual property rights while adding safeguards for biodiversity. But, in order to take part in a global partnership as extensive as that described in the Dunkel Draft, we must consider the short-, intermediate-, and long-term elements

from the perspective of various sectors, as well as the benefits and drawbacks in these various time horizons. There is no denying the value of belonging to an international organisation, but membership must be for the common man's benefit rather than the interests of profit-driven businesses or to appease industrialised nations. Undoubtedly, one cannot have everything go one's way, but overall, there must be a definite sign that the losses won't be so great as to amount to another round of colonising. Deep reflection on social justice and equality issues must accompany globalisation. Without a question, each nation will have to give up some of its national sovereignty in order to participate in the global society. Yet, the poor world shouldn't be expected to shoulder all of the costs.

All humans share a common heritage in science and technology. Equal involvement from all has shaped our past in this domain, and the united efforts of many different people around the world will shape our future. The fact of the matter is that in the modern world, the creation, mastery, and use of science and technology are essentially what set the Third World apart from the industrialised nations. The best and arguably most accessible chance for transforming undeveloped countries into prosperous, developed ones is provided by modern technology, which dismantles all development impediments. Thus, it is not surprising that national development strategies focus on ways to advance both locally based and imported technical expertise. It is therefore vital to reduce IPR law inequalities to a minimum in order to foster international understanding and goodwill in light of the recent worldwide trend in IPRs. It's possible that this is the first step in creating a global IPR system that safeguards biodiversity.

The WTO needs to reevaluate and work on the patenting of goods found in the diverse tropical ecosystem, according to the final analysis of the ongoing negotiations. India, along with other developing nations, must make its case for permanently excluding the so-called invention of Traditional Knowledge based on Indian traditional history from the existing ambit of patenting through a thorough review of the TRIPs agreement. That would be the greatest strategy to guarantee safety and combat bio-piracy of developing country products and processes by governmental and non-governmental dominant firms in the western countries. The study's whole focus is on biodiversity and intellectual property rights, two crucial challenges for the survival and advancement of humanity. The former, which is a

gift from God to everyone who lives on the planet, cannot be exploited only by humans but must be distributed fairly among all living things. Since it is the only thing that mankind has produced, it should ideally only be utilised to advance and preserve mankind.

It is unquestionably important to protect intellectual property rights because they can advance development and improve human life, but this study raises the question of whether such rights can be extended to biodiversity, including life forms for which man has either no role at all or a very limited role.

The initial purpose of a mechanical innovation was to provide legal protection to a creator of a novel indigenous gadget. Today, however, the scope of granting intellectual property rights has been expanded to include plants, biological material, and living organisms as well as mere technological creations and inanimate objects, turning what was once God's creation into a person's business endeavour. There is no denying the significance of IPRs in the fields of communications and medicine. IPR protection encouraged scientists and researchers to create a newer, better technology, which ultimately altered every aspect of human life. For their tireless and rigorous efforts, the scientists and researchers must receive fair compensation.

Although one of the planet's greatest resources, biodiversity does not always receive the credit and importance it deserves. The daily existence of the entire human race depends heavily on biodiversity. Regrettably, a significant loss of biodiversity has resulted from human activity, especially in the last several decades. There is no question that more groundbreaking discoveries, such as treatments for different types of cancer, are in store because a large portion of the world's species have yet to be fully studied for their potential. But only if we can initially conserve these species will we be able to use their potential. Knowledge, creativity, and biodiversity have all developed via community rights and responsibilities, and the acknowledgement of these rights is a prerequisite for the preservation of both biodiversity and human rights. Resources and knowledge are freely exchanged between developing and developed nations. The theft of their intellectual and biological resources as well as the subsequent payment of royalties for goods and services produced from their innovations and biodiversity cause two losses in the world's poorest

nations. Developed nations are trying to seize traditional knowledge. There are ongoing biopiracy cases involving traditional knowledge-based goods like neem, karela, turmeric, etc. We shall eventually be required to pay royalties for things that are our property and essential for daily living if IPR policies are not altered to stop bio-piracy. Biodiversity knowledge systems that are held and used by communities must be recognised legally as "common property" owned by the communities in question. The environment and human health are both at risk from genetic alteration. But, they also have the ability to reduce widespread hunger and lengthen the shelf life of goods. With the recent granting of patents on living things, substantial thought must be given to issues like ownership of genetic material, the safety of genetically modified creatures, and the misuse of genetic data. People will be viewed as "inventions" and the "intellectual property" of the scientists involved if patents are awarded for human cloning techniques.

Protecting intellectual property and preserving biodiversity must coexist in harmony. The present laws must be amended in order to achieve this goal, and not just at the national but also at the international levels. Even if they must be developed from a more global perspective, these rules must take into account the unique requirements of each nation.

It is crucial that the use of intellectual property ensures the safeguarding of fundamental human values since it is critical to human growth and a necessary component of economic development in a global setting. Advantages of intellectual property should be distributed equally to producers and users without distinction or discrimination of any type, and resource allocation should be done in a way that gives all countries an equal chance to benefit from knowledge-based advancement.

5.2 Recommendations

The following ideas are provided to conserve the earth's rich biodiversity and to support innovators by safeguarding their intellectual property.

At first it is necessary to limit the application of IPRs to biological materials. Traditional farmers should be permitted to keep their gathered seeds and trade them. In order to preserve traditional knowledge and prevent its piracy, it must be documented as soon as

possible and acknowledged as the property of the respective communities. In order to use biological resources commercially based on traditional knowledge, a suitable mechanism for benefit distribution must be put in place.

In accordance with the TRIPs agreement, a member state should demand that anybody submitting an application for a patent covering biological material or traditional knowledge declare the source and country of origin as well as give proof of the relevant national regimes' prior informed permission. In other words, mandatory disclosure requirement provision is must in TRIPS Agreement. TRIPs must undergo a thorough assessment, which should aim to harmonise them with the CBD. It is necessary to alter the Indian Patent Act to include infringement on intellectual property rights as a reason for canceling the patent. To regulate the release of genetically modified systems into the environment, an international, binding protocol needs to be created.

The TRIPs Agreement should state that Members shall require applicants for patents relating to biological material or traditional knowledge to disclose the source and country of origin of the biological resource and of the traditional knowledge used in the invention as a condition of acquiring patent rights. It is necessary to provide proof of prior informed agreement through the authority's validation under the applicable national regimes. It is required to provide proof of equitable benefit sharing under the applicable national regimes. Such actions are entirely in accordance with the Convention on Biological Diversity's guidelines for access to genetic resources and the just and equitable distribution of the benefits resulting from their use. To prevent potential systemic conflicts between TRIPs and the CBD, such provisions would be introduced to the TRIPs Agreement. Practically speaking, it would be more economical to develop the aforementioned internationally accepted strategy to combat bio-piracy than to divert national resources to pricey legal actions for the cancellation of patents that contain illegal genetic components. Poor nations, in particular, lack the means to monitor every patent dispute involving the usage of their resources outside of their borders. The crucial issue of coherence between two legally binding international accords would also be addressed by this. As a result, the proposed amendment would have the undeniable benefit of creating a predictable climate for governments, investors, traditional groups, and academia. Hence, supporting

biotechnology research and development in underdeveloped countries would be consistent with the TRIPs Agreement's objectives to promote technical innovation and the transfer of information.

WTO Members shall take into account the following to make sure that the TRIPS Agreement supports and does not obstruct governments' capacity to carry out their commitments under the CBD:

a) the TRIPS Council granting the CBD permanent observer status- If the WTO members award the CBD, permanent observer status in the TRIPS Council right now, both in the General Council and the TRIPS Council, it would be better to analyse the problems regarding biodiversity protection coming across.

b) Modifying the conditions for patent applications to maintain conformity with the CBD's access and benefit-sharing regimes and to help prevent the misappropriation of genetic resource knowledge- To ensure that patent applicants state the country of origin of claimed subject matter and prove legitimate access to the knowledge or resource (in accordance with national law, or in the absence of national law, in accordance with international guidelines), WTO Members should consider revising Article 27.3 (b) or Article 29 of the TRIPS Agreement, "Conditions on Patent Applicants." These requirements will also assist patent offices in determining whether the applicant has satisfied the novelty requirement for the issuance of a patent.

c) Increasing the limitations on patentability set forth in Article 27.3 (b)- Many WTO Members are worried that a few wealthy nations may try to compel them to adopt life patenting by pushing for the elimination or restriction of the TRIPS Article 27.3(b) exemptions. These countries should at the very least insist on keeping the freedom under Article 27.3(b) to refuse to grant patents for plants and animals. They should make the case that biological and primarily microbiological processes should be included in the exceptions. Members who are also CBD Parties must have the freedom to reject patents over life in order to experiment with different CBD implementation strategies.

d) Fighting against attempts to lessen the flexibility in defining sui generis systems- Members of the WTO should reject any efforts to establish UPOV 91 as the standard "effective sui generis system." Sui generis systems give Members the flexibility to carry out their duties under other international agreements and to safeguard other economic and social interests in the ways that they consider fit.

e) Carrying out a "sustainable review" in accordance with TRIPS Agreement Article 71.1- The assessment should make sure that the TRIPS Agreements' goals, as stated in their preamble and Article 7, are supported by its implementation, as well as the WTO's overarching goal of promoting trade "in conformity with the objective of sustainable development." If the TRIPS Agreement is found to fall short of these goals or to be incompatible with the effective implementation of international agreements like the CBD, WTO Members should think about changing it, as allowed by Article 71.1. According to Article 16(5) of the CBD, Parties are obligated to work together to make sure that IPRs promote and "do not run counter" to the goals of the convention.

f) Article 27.3(b) must be reviewed in a substantive manner, not just for implementation's sake. Instead of just creating a chart showing which countries have implemented what, we need to review the regulations and address the basic injustices they contain. It will be necessary to include a disclosure clause to TRIPs. Members should amend Article 27.3 (b) and/or Article 29 of the TRIPs Agreement to require the disclosure of the source of any patented material. Biopiracy would be avoided in this way. To avoid the improper use of genetic resource knowledge and to ensure compliance with the access and benefit-sharing provisions of the CBD, the procedures for patent applications should be amended.

g) The WTO dispute settlement procedure must take CBD goals into account. The TRIPs Agreement must not conflict with a Party's rightful performance of its CBD responsibilities in the event of a conflict.

h) It is important to consider the TRIPs-related human rights issues that have been raised. The TRIPs agreement needs to be changed so that it doesn't infringe on the rights of regular people.

i) By compiling a list of specialists who could serve on panels when disputes concern CBD objectives, WTO Members should make sure that dispute panels are aware of, comprehend, and assist in the enforcement of the duties of the CBD. In the event that Members are brought before dispute resolution both during and after the transitional period, this will aid in protecting them. The dispute panel should take enough time to create TRIPS legislation that is compliant with the CBD.

j) Members of the WTO should state that in the event of a conflict, the TRIPS Agreement shouldn't obstruct a Party from properly carrying out its CBD commitments.

The following suggestions offer ways for national government to make use of the TRIPS Agreement and the CBD's flexibility to carry out their commitments in ways that best promote the CBD's goals. Other policy actions that could be implemented in support of the CBD goals are also included in the recommendations. To ensure that the TRIPS Agreement promotes and does not impede the attainment of the CBD's goals, it will be necessary to use mechanisms to facilitate communication between ministries and departments and to ensure the development of integrated policies. Policy makers should consider -

a) Creating Access and Benefit Sharing Plans and putting them into action- They should contain minimal requirements that are legally obligatory under national law.

b) Making plans for prior informed consent- These protocols must to be created in collaboration with regional and indigenous populations.

c) Clearly defining fundamental ideas of intellectual property in national legislation- When determining whether a claim is "new," patent offices should use sources like oral testimony, visual evidence, and information stored in gene bank deposits in order to safeguard conventional knowledge from unauthorised use. A thorough characterization of fundamental ideas will prevent IPRs from being strengthened beyond what is necessary by the TRIPS Agreement and lessen the likelihood that the CBD will be compromised.

d) Using the exemptions from life patenting described in Article 27.3(b) Policymakers should consider prohibiting life patenting in order to fulfil their obligations under the

CBD, which include developing national policies to conserve traditional knowledge and provide fair and equitable access and benefit sharing.

e) ensuring full participation of indigenous and traditional local community representatives in the development of plans for the preservation and protection of traditional knowledge The preservation and protection of traditional knowledge should be a priority for governments, thus they should consider taking steps to ensure that local leaders from indigenous and traditional communities are actively involved in the development of IPR strategy. Indigenous and traditional local groups should be represented in any international conferences on traditional knowledge, according to national delegations.

f) Taking into account the creation of traditional knowledge databases- The creation of traditional knowledge registries on a national or international scale, as well as the dissemination of this data to patent offices around the world, may help to stop the misappropriation of traditional knowledge. It is only acceptable to include traditional knowledge in these registries with the previous informed agreement of the community in issue.

g) Guaranteeing enough funding for national intellectual property agencies- Patent offices must have adequate resources in order to carry out their duties in a way that advances the CBD's objectives. They must be well-equipped to conduct a thorough investigation of "prior art" and to prevent granting improper or excessively broad patents.

h) The flexibility provided by the TRIPs agreement for revising the Patents Act of 1970 has not been fully utilised by India. To exclude lower-level innovations, such as new dosage forms or new formulations, from the grant of patents, the terms "new" and "inventive" should be stated. As a result, there will be a cap on the number of patents. In Article 30 of the TRIPs agreement, specific restrictions on patent rights are listed. As they are unable to do it themselves, this should be used to provide non-patent holders in India authorization to produce and export patented medicines to least developed countries. Both India and these countries would benefit from this.

BIBLIOGRAPHY

Books

Agarwal & Aradhana, (2007). *The Anti-Dumping Agreement and Developing Countries: An Introduction*. Oxford University Press, New Delhi

Agrawal, K, C. (2002). *Global Biodiversity: Conservation, Indigenous Rights and Biodiversity*. New Delhi, Nidhi Publication

Alikhan & Shahid. (2004). *Intellectual Property and Competitive Strategies in the 21 Century*. New Delhi, Kluner Law International

Anuradha, R.V. (2000). *Sharing the Benefits of Biodiversity: The Kani TBGRI Deal in Kerala*. India, Kalapavriksh Publisher

Ashish, Anuradha, R.V & Kothari. (2001). *Experience with Biodiversity Policy – Making and Community Registers in India*. New Delhi, IIED Publishers

Bagchi, J.K. (2007). *Intellectual Property; Global and Indian Dimensions.* Manas Publications, New Delhi.

Bibek & Debroy, (1998). *Intellectual Property Right.* B.R. Publishing Corporation, New Delhi.

Bird, C., Subash, Robert & Jain C. (Ed).(2009). *The Global Challenge of Intellectual Property Rights*. New Delhi, Edward Elgar Publication.

Dhar, Biswajit & Anuradha, R.V. (2001) *Regime of Intellectual Property Protection for Biodiversity: A Developing Country Perspective*. RIS and IUCN Publication, New Delhi.

Dutfield, Graham. (2000). *Intellectual Property Rights, Trade and Biodiversity, Seeds and Plant Varieties.* IUCN, World Conservation Union.

Gupta, V.K. (2007). *Intellectual Property: Biodiversity, Genetic Resources and Traditional Knowledge*. World Trade Centre, 24 July.

Kannaiyan, S. (2007). *An Over View on Biological Diversity Act 2002*. National Biodiversity Authority, Neelagari.

Karki, M.M.S. (2009). *Intellectual Property Rights; Basic Concepts*. Atlantic Publisher

Koul, A.K. & Ahuja, V.K. (edt). (2001). *The Law of Intellectual Property Rights: In Prospect and Retrospect.* Faculty of Law, University of Delhi.

Laird, Sarah, A. (Ed). (2006). *Biodiversity and Traditional Knowledge, Equitable Partnership in Practice*. Earth Scan Publishers

Articles

Adhikari N, 'Towards Effective Protection of Traditional Knowledge: Resolving Conflicts between TRIPS and CBD' <www.cuts-geneva.org> accessed 5 March 2023

Avinahs K, 'Economics and IPR System in India' (*www.heinonline.org*) <https://heinonline.org/HOL/License> accessed 19 February 2023

Arjun Prasad Nagore, *Biological Diversity and International Environmental Law* (APH Publishing Corporations New Delhi 1996)

Adhikari R, 'Emerging Issues Relating to Conflicts between TRIPS and Biodiversity: Development Implications for South Asia'

Arora DrS and others, 'Implementation of India's National Biodiversity Action Plan an Overview 2019' (2018)

Jackson JT, 'A Biodiversity Approach to Cyber Security' (*wrap.warwick.ac.uk*1 May 2017) <http://wrap.warwick.ac.uk/106820> accessed 20 March 2023

Kohli K, *Understanding the Biological Diversity Act 2002: A Dossier* (2006)

Kothari A, '"A Submission to the Standing Committee Examining Biological Diversity Bill 2000"' [2000] Understanding the Biological diversity act 2002 a dossier"

Mathew and Basil B, ‘Trade Related Intellectual Property Rights TRIPS versus Convention on Biological Diversity CBD: A Study on the Traditional Knowledge Related Intellectual Property IP Protection in India’ (Thesis2015) <http://hdl.handle.net/10603/49080> accessed 11 May 2023

Mitra A, ‘Biological Diversity Act, 2002 and Patenting of Biological Inventions in India – Part I (Section – 6) - Patent - India’ (*www.mondaq.com*27 Summer 2017) <https://www.mondaq.com/india/patent/589566/biological-diversity-act-2002-and-patenting-of-biological-inventions-in-india--part-i-section--6> accessed 21 May 2023

MONAGLE C, ‘Biodiversity & Intellectual Property Rights: Reviewing Intellectual Property Rights in Light of the Objectives of the Convention on Biological Diversity’ (World Wide Fund For Nature 2001) <www.ciel.org> accessed 18 April 2023

Ramakrishnan N, *Biodiversity in Indian Scenarios* (Daya Books 2006)

‘Report of the International Conference on the TRIPS CBD Linkage: Issues and Way Forward’ (Centre for WTO Studies 2017)

Ritu G, ‘Conservation of Biodiversity under Biodiversity Act 2002 and the Patent Laws in India Problem and Issues’ (Thesis2010) <http://hdl.handle.net/10603/132524> accessed 17 May 2023

Sahai S, ‘TRIPS and Biodiversity : A Gender Perspective’ (2004) 12 Gender and Development 58 <www.jstor.org> accessed 7 April 2023

Sarnoff JD and Correa CM, ‘Analysis of Options for Implementing Disclosure of Origin Requirements in Intellectual Property Applications - a Contribution to UNCTAD’s Response to the Invitation of the Seventh Conference of the Parties of the Convention on Biological Diversity’ [2006] SSRN Electronic Journal

Shah and Pravinchandra N kumar, ‘A Study Relating to Intellectual Property Rights with Special Reference to Biodiversity a Legal Appraisal’ (Thesis2006) <http://hdl.handle.net/10603/59930> accessed 12 May 2023

Shakya A, ‘Role of IPR in Protection of Biodiversity’ (2022) 5 INTERNATIONAL JOURNAL OF LAW MANAGEMENT & HUMANITIES <https://heinonline.org> accessed 19 February 2022

Shiva V, ‘Farmers’ Rights, Biodiversity and International Treaties’ (1993) 28 Economic and Political Weekly 555 <https://www.jstor.org/stable/4399549> accessed 20 March 2023

Singh A, ‘Protection & Conservation of Biodiversity with Special Reference to IPR Laws: An Analytical Study on Efficiency, Sufficiency of Indian Laws’ (Thesis2022) 64 <http://hdl.handle.net/10603/465327> accessed 21 March 2023

Stilwell MT, ‘Review of Article 27.3 (B)’ [2001] Centre For International Environment Law

Straus J, *The Rio Biodiversity Convention and Intellectual Property* (1993)

Wable S, ‘IPR and BIODIVERSITY: AN AMALGAMATION"’ 13 supremo amicus

Legislations

CBD (2000)

Food and Agriculture Organization (2004)

United Nations Environment Programme (2008)

UPOV (1970)

Indian Patent Act (1970)

World Trade Organization (1994)

World Intellectual Property Organizations (1883)

Trade Related Aspects of Intellectual Property Rights (1994)