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PATENT LAW AND GENETIC RESOURCES: A STUDY OF ITS INTERACTION WITH BIOLOGICAL DIVERSITY, BIOTECHNOLOGY, AND AGRICULTURE UNDER INTERNATIONAL TREATIES

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ABSTRACT

The intricate relationship between patent law and genetic resources, particularly in biotechnology and agriculture, warrants a deeper exploration. This includes examining the impact of patenting living organisms and genetic materials on fostering innovation, promoting conservation, and ensuring equitable access to these critical resources. In addition, it pursues studying the legal frameworks related to patenting genetic resources at the national and international level. International conventions, such as the Convention on Biological Diversity (CBD), and more significantly, the Nagoya Protocol, serve to define the legal environment. The paper is on the challenges and opportunities that patenting of genetic resources presents. Although patents can inspire innovation and investment in biotechnology and agriculture, they tend to raise major concerns about biopiracy, monopolization of essential resources, and erosion of traditional knowledge. Such global discourse is assessed in this paper with respect to India's role in the matter. With its high biodiversity and long history of traditional knowledge systems, India can be particularly relevant with regards to genetic resources. The paper analyzes the framework within India: The *Patents Act 1970* and the *Biological Diversity Act (BDA), 2002*; both are looked into along with overall issues of compliance with international treaties in the context. It is hoped that this paper will add to the better understanding of the complex relationship of patent law and genetic resources. That will deeply draw on insights into the challenges and opportunities arising in patenting genetic materials, an issue increasingly pertinent in developing countries like India. It provides the paper recommendations to policymakers and stakeholders in maintaining a balanced approach that is harmonious with innovation in terms of protecting biodiversity and rights from indigenous communities.

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Keywords: Biological Diversity Act (BDA), 2002, Convention on Biological Diversity (CBD), Nagoya Protocol, Patents, Traditional Knowledge.

INTRODUCTION

India is one of the country's sources of the world's most biodiverse countries, with a vast repository of genetic resources that have been used for centuries in agriculture, traditional medicine, and biotechnology[2]. It is a very complex yet basic area of legal study involving patent law and genetic resources. In a nutshell, genetic resources refer to the genetic material of actual or potential value, especially in agriculture and biotechnology. The term biological diversity is used to refer to a variety of life forms on Earth. These include ecosystems, species, and genetic variations. In the fields of agriculture and pharmaceuticals, the developments in biotechnology, especially in genetic engineering, have made remarkable revelations about high potentials. Unquestionably, genetic resources may play a valuable role in new varieties of plants, medicines, and bio-based products. However, commercial exploitation of these resources has resulted in problems in terms of law, ethics, and economy. Patent law, which is directed to the protection of inventions for boosting inventive activity, thus interacts with saving of biological diversity and equitable access to genetic resources, especially for developing nations and indigenous communities.

The research is set on discussing the patents in the biotech and agriculture sectors and their importance within the international legal framework that governs resources, especially the Convention on Biological Diversity (CBD), as well as the Nagoya Protocol, 2010 (hereinafter, "the Protocol, 2010"). It will look into the Indian legislative framework with a special focus on the *Indian Patent Act of 1970,* its amendments*, the* Biological Diversity Act (BDA)*,* and how it plays in the protection of genetic resources particularly in agriculture and biotechnology. At the same time, it speaks about India's obligations in international agreements, the difficulty of implementing this, and finally the matter of biopiracy.

INTERNATIONAL LEGAL FRAMEWORK

A. Convention on Biological Diversity (CBD)

The CBD was established in 1992 on account of the alarming issues about conserving biological diversity. The objectives outlined are conserving biological diversity, using its components in a sustainable manner, and ensuring fair and equitable sharing of benefits arising from such resources. [3] The Convention emphasizes national sovereignty over genetic resources, requiring the countries to control access to those resources and benefit from their use. [4] There are a number of elements of the CBD-mainly: access to genetic resources, benefit-sharing, conservation, sustainable use, and technology transfer. The the Protocol, 2010 is the supplementary agreement to the CBD on the aspect of access to genetic resources and benefit-sharing. The CBD has 196 parties with India, where domestic laws include the BDA*, 2002*, and the *Indian Patent Act,* 1970 to implement provisions under the CBD. The CBD encourages international cooperation, conservation efforts, and sustainable development and was ratified by our country in 1994.

The CBD, although emerging, faces setbacks in the effectiveness of its implementation, balancing the provision with development, realizing benefit-sharing equity, and ensuring it addresses biopiracy. Beyond environmental conservation, the CBD plays an instrumental role in the sectors of agriculture, pharmaceuticals, and biotechnology. Because it serves as a global framework, the CBD is significant; it plays an important role in furthering biodiversity protection and for the development that should be achieved today so that future generations can enjoy it. Its importance is acknowledged through growing

2 Ministry of Env't, Forest & Climate Change, https://www.cbd.int/doc/world/in/in-nr-05-en.pdf.(last visited on Jul. 2024)

3 Convention on Biological Diversity, Art. 2, 1760 U.N.T.S. 79 (1992).

4 *Id.* Arts. 1–3.

recognition of its importance to humanity's well-being, its contribution to climate change, and its ability to generate resilient ecosystems.

B. Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits (The Protocol of 2010)

It was adopted back in 2010 with the primary purpose of providing a clear and predictable framework for access to genetic resources as well as benefit-sharing. The protocol recognizes the sovereignty of countries over their genetic resources and ensures equitable and fair benefits arising from their use. Key areas of this Protocol include 1) Access permits for countries, they are expected to give PIC before allowing access to their genetic resources; 2) Benefit-sharing agreements, mutual terms accepted between providers and users of genetic resources; 3) Compliance and dispute settlement rules to enforce the protocol. The protocol covers all types of genetic resources, including plants, animals, microorganisms and traditional knowledge associated with the said resources. India is among the 133 signatories.

National laws and regulations have to be interpreted, institutional frameworks and capacity building involved in the implementation of the Protocol, 2010. Countries have to clearly appoint national focal points, competent national authorities, and establish checks to prevent biopiracy. The Protocol, 2010 promotes transparency through the Access and Benefit-Sharing Clearing-House, (ABSCH). Royalties, technology transfer, joint research, and capacity building are all potential benefits that can be shared. One of the practices that will ensure effectiveness in the implementation of Protocol, 2010 is making sure that sharing benefits is fair, equitable, and promotes sustainable development, contributing towards biodiversity conservation.

The Protocol, 2010 is an international supplementary agreement to the CBD, access to genetic resources as well as fair benefit-sharing resulting from their use. It renders conditions under which prior informed consent (PIC) will be given by the country of origin for acquiring its genetic resources and that benefit-sharing will be equitable. It has been operational since 2010.[5] Although its framework is theoretically sound, many countries face problems of capacity, resources, and vagueness over the regulatory framework.[6] In 2012, India ratified Protocol, 2010. The protocols put India to the test in accessing its genetic resources with equitably sharing the benefits with such communities. To fulfill those obligations, the *Biodiversity Act, 2002* has been enacted to regulate the use of biological resources and to have ABS mechanisms.

C. Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

The TRIPS Agreement[7] went into force in 1995, imposing on all member countries obligations to provide patent protection for inventions in as wide a range of areas of technology as there are-and, of course, including biotechnological innovations. This agreement specifies minimum standards for patent protection: namely, novelty, inventive step, and industrial application. However, and equally importantly, it provides exceptions to patentability-in particular, indigenous knowledge and genetic material, where countries can indicate variations in meaning.

India passed the *Patents (Amendment) Act, 2005*, bringing within the patent regime product patents for biotechnological inventions but excluding from the ambit of patent protection the exclusive biological processes.[8] The above amendment brought into balance protection extended for patents with public interest as well as national policy considerations. The *Patents*

5 CBD, https://www.cbd.int/abs/default.shtml#:~:text=The%20Nagoya%20Protocol%20on%20Access%20to%20Genetic%20Resources%20and%20the,a%20fair%20and%20equitable%20way (last visited on 12 Jun. 2024).

6 M. L. C. de Jonge, *The Nagoya Protocol: The Way Forward*, 17 AUSTL. INT'L L.J. 69, 75 (2011).

7 WTO, https://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm (last visited on 12 Jun. 2024).

8 P. G. F. W. Chandra, Patents and Traditional Knowledge: The Indian Perspective, 43 IND. J. INT'L L. 407, 411 (2003).

Act, 1970 was amended to include almost all the excluded subject-matters provided under Article 27.3 of TRIPS, thus making India a part of international protection standards in patents.

The main features of the amendment were the extension of product patent protection in every field of technology and changes in the *1970 Act.* Here, Section 3(j) of the Indian Patent Act particularly states that "no plant, animal, or micro-organism or any element thereof, or any isolated and purified full-length polypeptide or the regulating thereof or any similar or derivative thereof can be patented." This includes India's pursuit of patent laws to become in tandem with international agreements and also protect national interest along with providing impetus to biotechnological innovation.

PATENT LAW AND GENETIC RESOURCES

a. Definition of Genetic Resources

The genetic resources are all the products from plants, animals, microbes, or otherwise derived sources of hereditary function units which have proximal as well as possible use. Those are the basis on which innovations in agriculture, biotechnology, and medical sciences are developed.

b. Criteria for Patentability

There should be novelty, an inventive step, and industrial applicability for it to be patentable. Applications submitted under international standards have to satisfy all of the three basic requirements.[9] It had rather been designed to weigh the interest of innovation against the interest of protecting genetic resources and traditional knowledge.

c. Challenges of Biopiracy

The issue of biopiracy has been defined as the unauthorized appropriation and commercialization of genetic resources and traditional knowledge without the consent or equitable compensation to indigenous communities or nations of origin. This matter raises major ethical and legal issues.[10] It is also one of the most serious disputes between companies operating globally and local people. Over thousands of years, Indian villages have used traditional knowledge to grow medicinal plants and herbal medicines. That is, multinational pharmaceutical firms exploit that traditional knowledge by not giving due credits to the owners of the sources or compensating them. That does not only systematically violate the rights of indigenous communities but also deny them the economic benefits that often accrue to owners of that kind of knowledge. Biopiracy may also have a negative impact on the biodiversity. Impoverished regulation and conservation measures of genetic resources, for instance, may lead to loss of biodiversity and erosion of ecosystems. Through their know-how of local ecosystems, indigenous communities play a crucial role in conserving biodiversity. Biopiracy, along with undermining their rights and ignoring their traditional knowledge, contributes to degrading ecosystems. Few of the challenges include:

d. Exploitation of Indigenous Knowledge and Resources

This is one of the critical flaws that biopiracy has, as indigenous knowledge is utilized and gains no attention to legitimate claims or compensation. For generations, developing nations' communities have developed subtle knowledge about local biological resources' medicinal, agricultural, and ecological uses. The corporations or the researchers from the developed world patent their products or processes once they rely on such knowledge, however, leaving no share for the community in financial benefits in most cases.

e. Shortfalls in Legal Protection Over Traditional Knowledge

Traditionally, patent law does not apply to this kind of traditional knowledge-speak, that is, oral. Patent law stipulates that the invention be novel

9 *Id.*

10 J. T. H. Newell, Biopiracy and the Role of Intellectual Property Law in Conservation, 29 J. ENVTL. L. 455, 463 (2017).

and documented. This leaves enormous areas for shortfalls in legal protection, which allows foreign multinationals to patent inventions based on some generations' traditional knowledge.

f. Asymmetric Power Differentials Between Developed and Developing Nations

Biopiracy usually arises from an imbalance of power between resource-rich poor countries and the powerful corporations or developed states who want to exploit their rich resources. There is a high incidence of inability in developing countries to reassert sovereignty over their genetic resources due to inadequacies in intellectual property infrastructure, lack of legal professionals, and the weight of economic force to open up resources in return for development aid or trade terms.

g.Challenges in Monitoring and Enforcing Regulations

Monitoring the use of genetic resources and enforcing regulations are gigantic challenges that many states face. Genetic resources are easily relocated from one country to another and reproduced, and thus it becomes virtually impossible for countries to trace them once they have left their countries of origin. Additionally, most third world countries are disadvantaged to litigate against foreign states when biopiracy is involved.

In the Ayahuasca plant, while the U.S. has patented its isolation of active ingredients without any regards to indigenous tribes in South America who used this plant in medicinal practices over centuries, challenging such patents in foreign legal systems is expensive and time-consuming.[11]

i. Inadequate Mechanisms of Access and Benefit-Sharing.

Although the Protocol, 2010 is aimed at making both governments and local communities benefit fairly from genetic resources exploited in any given area, the ABS mechanisms are implemented very weakly or not at all. Most companies do not enter into fair contracts or bypass ABS altogether by obtaining genetic resources through intermediaries and countries that are lax about their laws.

ii. Threat to Biodiversity and Sustainable Development

Biopiracy undermines biodiversity conservation efforts and sustainable development efforts in a number of ways. For example, commercial harvesting of genetic resources with inadequate safeguards can result in overexploitation of resources, degradation of the environment, and loss of species. Additionally, bioprospecting without compensation can result in marginalization or economic disadvantage to indigenous communities often serving as custodians of biodiversity.

Unchecked extraction of biological resources can destroy ecosystems and eventually imperil biodiversity balances. For example, overcollection of wild medicinal plants for pharmaceutical use has imperiled several species.[12]

iii. Ethical and Cultural Issues

Biopiracy raises several ethical and cultural issues, especially when the sacred plants or traditional practices are commodified for gain by outsiders. Generally, indigenous people consider exploitation of their traditional knowledge without permission as a form of cultural theft. Furthermore, a patent of genetic resources might not permit indigenous groups to use these resources in the same way they have been doing them for decades.

Many indigenous peoples perceive specific plants and animals as being an essential part of their culture and religions. The commercial use of such resources against their will can be considered

11 M. J. Case, Ayahuasca and Intellectual Property: The Biopiracy of Indigenous Medicinal Knowledge, 32 AM. INDIAN L. REV. 517, 530 (2007).

12 P. O. Westerhaus, *The Exploitation of Medicinal Plants and Its Effect on Biodiversity: A Legal Perspective*, 24 NAT. RESOURCES J. 239 (1984).

not only a violation of intellectual property rights but also cultural ones.[13]

iv. Fragmented International legal framework.

International treaties like the CBD and the Protocol, 2010 exist to fight biopiracy; however, it has a problem as there is not a comprehensive worldwide framework. Intellectual property standards and the access given regarding genetic resources vary from country to country, with one country treating it lightly and another is quite serious about it. That's why it becomes problematic in achieving uniform legislation when it comes to biodiversity protection and fair benefit-sharing.

Although some countries, like India, maintain robust home laws that prevent biopiracy, others lack such legality or have it very weak. The result is that corporations take advantage of these loopholes in exploiting legal lacunas by sourcing genetic resources from these jurisdictions.

Biopiracy poses significant legal, ethical, and environmental challenges to developing countries and indigenous communities. Despite the existence of international treaties, like the CBD and Protocol, 2010, many of the challenges identified above persist because of enforcement that is weak, lack of legal protection to traditional knowledge, and an imbalance between resource-rich and technology-rich countries. It requires greater international co-operation, better monitoring mechanisms, and an enabling environment in which indigenous communities can protect and profit from their genetic resources.

CASE STUDIES

i. The Neem Tree Patent Case

The Neem Tree Patent Case may be one such notable case seeking light between intellectual property rights and traditional knowledge. In 1995, W.R. Grace & Co., a U.S. multinational obtained a patent for a method of using neem extract to protect plants from pests. Neem is a native tree that mainly grows in South Asia, especially in India. It is a shrub that has been of long-standing use because it repels pests as it cures diseases. The neem patent of course sparked a public outcry and the critics felt that the company had reaped the traditional knowledge without crediting the origin. They felt that neem-based plant protection was an age-old practice in India and yet not such a common knowledge as it had become in the last couple of centuries. This really raised the issues of biopiracy whereby genetic resources and traditional knowledge were being used and traded in an unauthorized manner.

Following several years of a legal wrangle, the U.S. In fact, USPTO finally revoked the neem patent in 2005. Under its decision, this method of neem extract was not novel and prior art describes it. India and others who defend the traditional knowledge had an important victory here. The Neem Tree Patent Case provides a very enlightening lesson as far as the respect with which traditional knowledge ought to be treated is concerned. This was one of the most flamboyant examples of biopiracy which has sparked widely heated protest and prodded the debate to call for stronger protection of genetic resources.[14] Already in the 1990s, the neem-an Indian traditional medicine plant-has had patented products both in Europe and in the United States.[15] In 2000, it was revoked by Office of the European Patent after a long legal battle owing to grounds that prior indigenous traditional knowledge existed in India.

ii. Golden Rice

The Golden Rice case best depicts the complicated interaction between biotechnology, intellectual property, and humanitarian considerations. Golden Rice is a genetically engineered variety of rice that yields beta-carotene, a precursor to vitamin A. It was developed to combat vitamin A deficiency, a major public health problem in many developing nations, such as in South Asia and Southeast Asia.

13 G. R. Pal, *Global Justice and the Ethics of Biopiracy*, 11 INT'L J. HUM. RTS. 613 (2007).

14 R. D. Anderson, The Neem Tree Patent: The Fight Against Biopiracy, 2 HASTINGS SCI. & TECH. L.J. 1, 8 (2010).

15 *In re* Neem Tree Patents, E.P.O. 0436257, O.J. E.P.O. 1999 (European Patent Office, 2000), supra note 10.

Development of Golden Rice On the other hand, although this was a scientific breakthrough, many challenges faced the commercialization and distribution of this new food variety. One of the most primary concerns was that of intellectual property. Research technology used in developing the golden rice was patented by institutions such as the International Rice Research Institute, Thailand, and the Swiss Federal Institute of Technology. These institutions granted the technology to many organizations such as the Philippine government and humanitarian organization Syngenta Foundation for Sustainable Agriculture.

Although, the technology for Golden Rice could not be commercially utilized as early as it was planned due to safety issues and other regulatory hurdles but there were also apprehensions regarding utilizing the product for the commercialization of genetically modified crops in developing nations, where they may not even be viable. Despite all these, there are still several countries that have given permission to cultivate Golden Rice commercially. It is being cultivated in the Philippines and Bangladesh. Millions of children who lose their sight and die due to vitamin A deficiency have also received humanitarian aid.

This is why the Golden Rice case matters: it deals with the relative trade-off between the need for innovation and the need for intellectual property protection that reflects the greater goals of public health or food security.[16] It also questions the role of multinational corporations and humanitarian organizations in developing and disseminating genetically modified crops. It was designed to solve vitamin A deficiency, rampant in most developing countries. Having promised an approach towards food security, however, it has also generated debating issues on issues concerning ownership of genetic resources and risks to smallholder agriculturalists.

iii. Turmeric Case

The U.S. Patent and Trademark Office granted a patent in 1995 on an application of turmeric for wound healing, which has been used for age-old times in Indian traditional knowledge. The researchers argued this patent. This work was revoked in 1997 after some evidence was presented as proof of past use, which was a great victory against biopiracy.

iv. Patenting of GM Crops and Farmer Rights

Genetically modified crops like Monsanto's Roundup Ready soybeans have raised alarms concerning farmer rights to keep and sow seeds. Patent prohibitions usually remove farmers' access rights to seed sown from their fields and utilizes for later planting. Such has been seen to cause patent disputes and disputes over the rights of farmers.[17]

INDIAN LEGISLATIVE FRAMEWORK

a. Overview of Patent Law in India

i. Patents (Amendment) Act, 2005

The 1970 Act is the main legislation that governs patent law in India. This act describes the requirements for patentability but keeps in mind global standards while still addressing national concerns of access to genetic resources.[18]

ii. Criteria for Patentability in India

As compared to the international norms, in India, the 1970 Act holds that, inter alia, an invention in order to be patentable shall possess novelty, an inventive step, and industrial applicability.[19] It is a matter of debate whether genetic material naturally occurring in the environment can fulfill these criteria. For example, though patents on GMOs or separated genetic sequences are granted in the United States, control measures are more stringent in application on those.[20]

16 P. P. S. Kumar, *The Golden Rice Controversy: Between Ethics and Technology*, 48 IND. J. AGRIC. ECON. 327 (2008).

17 Monsanto Co. v. Bowman, 569 U.S. 278 (2013).

18 Patents Act, No. 39 of 1970, India (as amended).

19 *Id*.

20 Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).

iii. Exclusions from Patentability

The *Indian Patent Act* has introduced various provisions through which some inventions are excluded from patent protection. These include inventions concerning genetic resources. Section 3 lists various types of inventions that are not liable to be patented and includes:

a. **Section 3(b):** This excludes any invention whose primary application would be against public order or moral principles or that could seriously injure human, animal, or plant life or adversely affect the environment.

b. **Section 3(j):** It squarely prohibits any patents on plants and animals, including any biological process to obtain them. This section is hence of particular significance especially in agricultural biotechnology wherein GMOs generally become the subject matter for patent claims. Instead of providing plant patents, India follows the *Protection of Plant Varieties and Farmers' Rights Act, 2001 (PPVFR Act).*

iv. Biotechnological Patents

Section 3(j) of the system excludes patents on plants and animals, but biotechnological inventions are allowed under certain conditions. For example, such criteria allow patents on isolated DNA sequences, microorganisms and other materials containing genes. Normally, patents application occurs on the processes of biotechnology. Such processes in some instances include gene-editing technologies or methods of producing GMOs.

b. Protection of Biodiversity

i. Biological Diversity Act, 2002

This is a very significant legislation to regulate the access of biological resources and any associated traditional knowledge. Reflecting on the commitment of India towards the CBD lies in the fact that it ensures the sustainable access of genetic resources so that there is equitable benefit sharing. This act is an important legislation to protect India's biological diversity and regulate access to genetic resources. It institutionalizes the National Biodiversity Authority (NBA) and gives facilities for an access and benefit-sharing mechanism, through the equitable view sharing of benefits with local communities from genetic resources.[21]

ii. Access and Benefit Sharing (ABS) Mechanisms

Applicants would have to take prior permission from the NBA before patents could be granted on any inventions concerning Indian genetic resources. In fact, the BDA puts in place legal provisions about obtaining prior informed consent from local communities and sharing of benefits derived from the utilization of biological resources.[22]

1. Prior Informed Consent (PIC)

PIC has consequently been defined as the core requirement for ABS. It obliges researchers, companies and states first of all to obtain the consent of the country or community providing the resources so that the rights of the holders of the resources can be respected, and equitable negotiations may begin.[23]

2. Mutually Agreed Terms (MAT)

The terms and conditions agreed on by the provider and user of genetic resources are usually termed as MATs. They cover modalities of sharing monetary and non-monetary benefits, especially technology transfer, capacity building, and joint ownership of patents.[24]

3. Challenges in Implementing ABS

Even with the frameworks provided by the Protocol, 2010, much challenge lies

21 Biological Diversity Act, No. 18 of 2003, India.

22 *Id*. § 7.

23 CBD, supra note 5, art. 15(5).

24 Nagoya Protocol, supra note 6, art. 5.

in implementing ABS. Most countries lack legal and administrative capability to enforce PIC and MAT, leading to imbalances in negotiation power between MNCs and states. Additionally, enforcement across international borders, especially to non-CBD signatories, adds another layer of complication.

iii. Interface of Patent Law and Biodiversity

Recent Indian developments in patent law remind one further of an increase in the recognition of a need to protect indigenous rights and traditional knowledge, especially with regard to biotechnological innovation. Yet problems persist concerning practical implementation and the promise of fair benefit-sharing.[25]

iv. Traditional Knowledge Protection

India has been a forerunner in protecting TK from biopiracy. The Biodiversity Act has strengthened the patent law by making source and origin obligatory disclosures of genetic resources used in inventions. India has also established a Traditional Knowledge Digital Library (TKDL) for documentation and protection of TK from getting patented abroad. The TKDL has already played a critical role in demonstrating the invalidity of patents on Indian genetic resources-think neem and turmeric. Already, patents granted abroad have been revoked due to existence of pre-existing traditional knowledge.

ETHICAL AND SOCIAL CONSIDERATIONS

Perhaps the most important question at the crossroads of patent law and genetic resources in ethics is how best to balance innovation with conservation. On this score, the role of indigenous knowledge cannot be under-valued for the simple reason that, more often than not, knowledge with regard to the sustainable use of genetic resources is held by local communities. Global justice and equity demand equal benefits derived from the said advancement in biotechnology among the parties.[26]

i. Exploitation of Indigenous Communities

Indigenous communities have many times been the custodians of valuable genetic resources and traditional knowledge. It is the misuse by multinational corporations or research institutions of such resources without the indigenous communities' permission that is characteristic of the exploitation of such communities. Such communities have often been deprived of compensation for the use of their knowledge and resources. Indigenous communities often lack adequate legal frameworks or mechanisms to enforce their law. For example, Article 6 of the Protocol, 2010 states that "there is a requirement for PIC before accessing genetic resources." Ethically, communities providing genetic resources have to benefit from the commercialization of such resources. The principles of equitable benefit-sharing are laid out by the CBD and the Protocol, 2010 but often not practiced.

For example, the Arogya Pacha Case of India is one in which a multinational company patented a plant used by the Kani tribe, and public protests resulted in it being one of the earliest instances of a benefit-sharing agreement.

ii. Commodification of life forms

Patenting of genetic material and life forms as commodities is another serious ethical issue. The patenting of living things gives rise to primary ethical issues over the privatisation of elements of life. It is most controversial in agriculture and medicine where saving drugs and food crops become patented to make them relatively unavailable. On ethical and religious grounds, wide opposition goes for the patenting of life forms. The argument is against patenting life mainly on the moral ground-the ultimate position on what should and should not be patented: that life cannot be claimed as an invention, that life should not be a thing owned, manufactured afterwards with

25 R. C. Patil & S. R. Gupta, *Recent Developments in Patent Jurisprudence in India*, 6 J. INTELL. PROP. L. & PRAC. 81 (2011).

26 G. R. Pal, *Global Justice and the Ethics of Biopiracy*, 11 INT'L J. HUM. RTS. 613 (2007).

possible subsequent commercialisation. These groups insist that genetic resources, particularly those on food security or health, should remain in global commons.

For example, the patentability issue related to genetically modified crops, like the patents owned by Monsanto over BT cotton[27], raises the issue of granting monopolies over resources in agriculture with ethical concerns.

Genetic modification patents on seeds mean the livelihoods of farmers may be undermined in developing countries. Saving seeds for the following season, as was traditionally done, may become illegitimate and puts them under pressure to purchase new seeds every season, from corporations that now hold patents on these seeds. Connected to these patented seeds is a loss of food sovereignty as well as agriculture practice locally.

iii. Environmental and Biodiversity Concerns

Also, many patents and commercialization of genetic resource activities have severe impacts on the environment, more particularly to biodiversity. Pursuing profit may even encourage biological resource exploitation, which can bring consequences that involve the depletion of biodiversity, habitat destruction, and ecological imbalance. Such focus on genetically modified crops or patented plant varieties would lead to genetic erosion in the replacing of traditional varieties. Loss of genetic diversity impacts ecosystems while also undermining food security because the diverse plant varieties are better able to resist pests and adapt more easily to environmental changes.

For instance, traditional varieties of rice were substituted with high-yielding IR-8 developed during the Green Revolution. This resulted in loss of biodiversity in Asia. Latin America has witnessed the degradation of local indigenous farming practices and biodiversity loss as a result of the introduction of genetically engineered patented crops.

FUTURE DIRECTIONS AND RECOMMENDATIONS

International cooperation should be strengthened to handle biopiracy and arrangements for fair benefit-sharing. The establishment of new legal frameworks incorporating the rights of indigenous peoples and traditional knowledge, while meantime strengthening national laws and policies, will also be of some importance to the effective management of genetic resources.[28]

Lawmakers and Policymakers

i. These national laws should ideally reflect the provisions of the Protocol, 2010- that is, transparent rules with regard to prior informed consent (PIC) and benefit-sharing-clearly so for any foreign entity wishing to gain access to genetic resources.

ii. A sui generis system should be developed for the protection of the traditional knowledge that does not come under the formalities of patent law. Necessary feature is another important tool in digital libraries like India's Traditional Knowledge Digital Library (TKDL).[29] The TKDL is a repository of traditional medicinal knowledge, which prevents the misuse of the same in patent applications.

iii. Regional treaties will have a balance of ABS regulations in order to effectively combat biopiracy across borders and biodiversity-rich regions from coordinated enforcement actions. For example-the Swakopmund Protocol on the Protection of Traditional Knowledge[30] adopted by the African Regional Intellectual Property Organization (ARIPO).

27 Monsanto Co. v. Nuziveedu Seeds Ltd., (2019) 3 S.C.C. 381 (India).

28 D. S. P. Anand, *Future Directions in Access and Benefit Sharing*, 16 J. BIOETHICAL INQUIRY 119 (2019).

29 S. K. Verma, *Protecting Traditional Knowledge in India: Recognizing the Role of the TKDL*, 13 J. WORLD INTELL. PROP. 255 (2010).

30 WIPO, https://www.wipo.int/wipolex/en/treaties/details/294 (last visited on 12 Jun. 2024).

iv. Funding through the national government on legal education campaigns targeting the indigenous populations over rights available under ABS frameworks should be observed. The United Nations Development Programme has used local capacity-building efforts to educate communities about their rights in the Protocol, 2010.[31]

v. Patent law should therefore be given the strength of ABS mechanisms that rewards the providers of the resources. Cross border patenting and bioprospecting will require legal frameworks to determine benefits that are equitable.[32]

Indigenous Communities

i. Such indigenous communities should also be represented before national and international forums such that their concerns are heard and thus dealt with accordingly. This declaration under the United Nations[33] states that indigenous peoples have right to participation in decisions regarding resources.

ii. The indigenous communities should collaborate with the governments in documenting and protecting their traditional knowledge. In India, indigenous groups have collaborated with the government to contribute to TKDLs, where some patent applications have been successfully repelled.

iii. Collaboration with NGOs and legal organizations is of essence for indigenous groups to be availed legal aid when making claims against biopiracy. International organizations range from the World Intellectual Property Organization (WIPO)[34] that gives technical assistance towards indigenous groups in developing countries.

Multinational Corporations

i. Companies must also comply with Protocol, 2010, to request, and acquire PIC, before accessing any genetic resources. For instance, Companies engaging themselves in the collection of genetic material from Brazil must adhere to the country's Biodiversity Law, which implements ABS rules.[35]

ii. Thus, the benefit sharing among corporate corporations should be just and genuinely representative of the contribution made by the communities that provide the genetic resources.

iii. Corporations should make transparent reports of all uses of genetic resources as well as adherence to ABS rules. For instance, it should also include CSR Reports from companies dealing with biotechnology which will reveal their level of compliance with the ABS regulations, such as compliance with the Protocol, 2010.

International Organizations

i. The salient task then is to harmonize patent law with international treaties such as the CBD and TRIPS in conditions where national laws need to be set forth in full consonance with innovation but still within the frames of principles for international ABS.[36]

ii. Technical assistance and funding by the organizations such as UNEP and Global Environment Facility (GEF)[37] would strengthen the ABS frameworks in developing nations.

iii. The GEF supports the capacity-building projects, thereby helping nations implement the Protocol, 2010.

31 *Id.* at 4

32 Graham Dutfield, Protecting Traditional Knowledge and Folklore: A Review of Progress in Diplomacy and Policy Formulation, U.N. Conf. on Trade and Dev., Doc. UNCTAD/DITC/TED/10 (2003).

33 United Nations Declaration on the Rights of Indigenous Peoples, G.A. Res. 61/295, U.N. Doc. A/RES/61/295 (Sept. 13, 2007).

34 WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, WIPO Doc. WIPO/GRTKF/IC/34/INF/9 (2017).

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CONCLUSION

These linkages between patent law and genetic resources are complex, sourced from international treaties and national legislations. Patents encourage innovation but, on the other hand, restrict access to core genetic resources while infringing on the rights of indigenous people. International instruments such as the CBD and the Protocol, 2010 provide a framework for how this can be balanced between innovation and conservation of biological diversity and equitable benefit sharing. Therefore, greater harmonization would be required between patent law and principles of ABS keeping in view the sustainable and equitable use of genetic resources. This can be done by ensuring that such genetic resources would promote innovation by being used sustainably. It is on this backdrop that a balance of interests with concerns for ethical practices and an inclusionary approach in respecting rights of indigenous communities becomes highly crucial in such interests. This means policymaking and stakeholders need to co-work in developing frameworks that protect biodiversity along with the rights of those who conserve it.

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