THE INDIAN LEGAL REGIME'S PREVENTION OF BIOPIRACY FOR BETTER CONSERVATION OF BIODIVERSITY

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ABSTRACT

Biodiversity is the most important component for maintaining ecological balance, and it must be conserved and used sustainably. Recognizing such demands, India has taken several legal and institutional measures in accordance with the standards established by International Instruments to achieve the core objectives of conservation, sustainable utilization, and equitable sharing of benefits from commercial utilization of biodiversity. However, rather than decreasing, cases of biopiracy are increasing, while the true beneficiaries of biological resources are mostly on the receiving end. It is thus necessary to investigate the legal and institutional frameworks in India that govern such matters in order to comprehend the disparity between the desired outcomes and the practical reality. This paper therefore highlighted some of the common issues in the legal and institutional frameworks related to biopiracy and biodiversity conservation.

INTRODUCTION

Biodiversity refers to the entire ecosystem and is comprised of a complex set of relationships between living and non-living organisms. The abbreviation for biological diversity is biodiversity. The United Nations sponsored the first widely used definition of biodiversity, which was included in the 1992 Convention on Biological Diversity (CBD). Biodiversity is defined as variability among marine, terrestrial, and other aquatic systems, as well as ecological complexes.[1]

As a result, the natural environment provides the fundamental conditions for human survival.

The use of IPR systems to legitimize control over biological resources is referred to as biopiracy. Patent claims over biological resources and indigenous traditional knowledge that are based on the creativity and innovation of Third World people are examples of biopiracy. Raw materials or genetic resources are primarily owned by poor least developed countries in the phenomenon of biopiracy, whereas the necessary biotechnology or technical skills are owned by firms in the developed world. Whatever benefit accrues from such commercial exploitation of natural resources must be shared in a way that is acceptable to both local communities and the firm. However, the firms are unwilling to share profits. Biopiracy can violate a nation's sovereign rights, harm the economic health of indigenous communities, and deplete or destroy species. The primary rights at stake in biopiracy debates are ownership rights. Biopiracy thrived during colonialism, capitalism, and, most recently, globalization. Biopiracy promotes inequality between developing and less developed countries rich in biodiversity by being covered by patents granted by MNCs.

INTERNATIONAL PROTECTION AGAINST BIOPIRACY

Some of the international measures taken to combat biopiracy include:

The UN Convention on Biological Diversity (CBD)

The UN CBD was signed at UNCED in 1992 during the Rio Earth Summit, and it entered into force on December 29, 1993. This Convention represents a new approach to genetic resources, codifying a balance between the competing self-interests of various developing and developed countries, with the goal of preserving global biodiversity. On June 5, 1992, the Convention was

[1] United Nations Convention on Biological Diversity, 1992, Art. 2

open for signature at UNCED or the Earth Summit. To date, 196 countries have signed the Convention.

The US is not a signatory to the Convention on Biological Diversity. The Convention's primary goal has been to promote sustainable development, and its underlying principles are consistent with those of the other Rio Agreements. One major objection to CBD is the unequal distribution of the benefits resulting from the commercial use of genetic and biological resources. CBD supports the general principle of international law that states have national sovereignty over genetic resources and that national governments have the sole authority to determine resource access.

The relationship between IPR and access to genetic resources was one of the most contentious aspects of the Convention. As a result, the third objective of the Convention was adopted: access to genetic resources and benefit sharing. The goal was to consider the need for developed and developing countries to share the costs and benefits of commercialising genetic resources. Furthermore, the emphasis was on finding ways and means of assisting the local people.

Article 15 is the central provision governing 'Access and Benefit Sharing;' other provisions include Articles 8(j), 10(c), 16, 17, and 18.

Developments under CBD

BONN GUIDELINES[2]

The Convention did not elaborate on the three principles of prior consent, fair and equitable benefit sharing, and mutually agreed terms. This caused confusion among nations regarding the practical implementation of the Convention's objectives. Thus, in April 2002, the Bonn Guidelines were adopted to assist governments in developing legislative or policy measures on access and benefit-sharing. Bonn guidelines were adopted to educate both users and providers about access and benefit-sharing arrangements, to transfer technology to developing countries, and to have a positive influence on the development of laws that protect indigenous people's customary laws.

Except for the human genetic resources, all other genetic resources covered by CBD, and benefits arising out of commercial utilization of such genetic resources are covered by Bonn

[2] Bonn Guidelines, (2005), UNCBD

Guidelines.

Prior informed consent is required under the guidelines for access to genetic resources. The consent is tied to the specific use for which it is granted. The Guidelines also require that contractual agreements include provisions for the use of intellectual property rights, such as joint research, obligations to implement invention rights, and the grant of joint licences. The Bonn Guidelines encouraged countries to adopt measures to disclose the country of origin of genetic resources and local community practises in IPR applications. Finally, the disclosures would aid in the investigation of cases of improper patent grant while also assisting in the revocation of patents based on traditional knowledge.

NAGOYA PROTOCOL

The Nagoya Protocol is a legally binding international protocol. It is an addition to the UN CBD Treaty. The protocol aims to provide a legal framework for implementing one of the UN CBD's most important goals: fair and equitable benefit sharing.[3]The protocol establishes a framework for regulating how users of genetic resources or traditional knowledge associated with genetic resources can gain access to such knowledge.

Article 5 of the Protocol also states that the benefits derived from commercial use of genetic resources must be shared fairly and equitably, on mutually agreed terms, with the provider party, the party with genetic resources, or an indigenous community. Furthermore, the Article empowers State Parties to enact legislative or administrative measures to ensure equitable resource sharing. The Nagoya Protocol reiterates the CBD's third goal. Within the framework of Article 15 of the CBD, the protocol applies to genetic resources and traditional knowledge associated with genetic resources.

Article 8 of the protocol encourages research activities that contribute to the conservation and sustainable use of developing countries' biological resources. Furthermore, the party gaining access to the resources must consider any emergencies that may arise and endanger human, animal, or plant health both nationally and internationally. Furthermore, the protocol calls for the establishment of focal points to provide necessary information to parties seeking access to genetic resources or knowledge related to them. Article 13 also provides for the establishment of one or more national authorities on access and benefit-sharing. These authorities will be in

[3] Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity

charge of granting access to resources and issuing written evidence that the access requirements have been met. Another important theme of the protocol is the global Multilateral Benefit-Sharing Mechanism,22 transboundary cooperation, and compliance with domestic legislation on access and benefit-sharing clearing house mechanism, which is part of the Clearing House Mechanism under Article 18 of the CBD. The Nagoya Protocol imposes binding and enforceable obligations on States that ratify or accede to it.

THE TRIPS AGREEMENT

Trade-Related Aspects of Intellectual Property (TRIPS) is a World Trade Organisation (WTO) Agreement that was signed in 1994. TRIP establishes intellectual property rights protection as an essential component of the multilateral trading system. The agreement went into effect on January 1, 1995[4]. The agreement's main goal is to promote trade, protect property rights, standardise IPRs, and provide extended protection to IPR holders. TRIPS requires that all members of the agreement follow the obligations of the World Trade Organization's main conventions, namely the Paris Convention and the Berne Convention. The member states must include these minimum standards in their national laws governing intellectual property rights. Intellectual property rights are recognised as private rights in the agreement.

There was no global standard for patentability of inventions prior to the TRIPS agreement. Article 27 of the aforementioned agreement can be regarded as a global standard on patentability, establishing a minimum yardstick for the patentability of all inventions. Article 27 of the agreement states that member countries must protect intellectual property rights in genetic resources. The Article also states that patents are available for all inventions, whether products or processes, as long as they are capable of industrial application.

There is one exception to this rule. Article 27(3)(b) of the TRIPS Agreement states that signatories can exclude plants, animals, other microorganisms, and biological processes other than nonbiological processes from patentability. In other words, Article 27(3)(b) of the TRIPS Agreement mandates that each Member State establish a patent system, an effective sui generis system, or a combination of the two to protect plant varieties. As a result, Article 27(3) is permissive, allowing member states to choose whether or not to grant patents for biological matters or processes. Typically, the duration of protection is 20 years. The TRIPS Agreement,

[4] Lorna Dwyer, Biopiracy, Trade and Sustainable Development, Col. Jou. Int. Envr. Law & Policy, 220, 238 (2008).

as well as minimum standards for intellectual property protection, call for their implementation. IPR holders can enforce their rights and protect their interests through civil courts or administrative proceedings. The member states are not required to establish special courts for IPR related issues.

INTERNATIONAL TREATY ON PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE

The primary goal of the treaty is to conserve and sustainably use plant genetic resources for food and agriculture. The treaty also calls for an equitable distribution of the benefits derived from the use of genetic resources. This treaty is consistent with CBD's provisions. The IT PGFRA treaty was adopted by the FAO Conference in November 2001.28 The treaty was ratified by 40 governments and entered into force in 2004. The treaty was open for signatures until November 4th, 2004. There are a total of 146 contracting parties to the treaty of IT PGFRA.

INDIAN LEGISLATIONS / INITIATIVES FOR PROTECTION ON BIOPIRACY

India has enacted the following legislation to combat biopiracy and preserve biodiversity. These laws are related to the conservation and sustainable use of biological resources, either directly or indirectly. The following are some examples of important legislation:

The Protection of Plant Varieties and Farmer’s Rights Act, 2001

The Government of India passed this Act to protect new plant varieties. In 2003, rules for protecting new plant varieties were issued. To administer the Act, an authority known as "The Protection of Plant Varieties and Framer's Rights Authority" was established under the Act. The Act was passed by the government because it is a requirement of every member of the TRIPS Agreement to protect new plant varieties. India ratified the TRIPS Agreement and enacted the said Act to give effect to Article 27(3)(b) of the TRIPS Agreement.

The Act's main goals are as follows:

1. To promote new research activities in both the public and private sectors for the development of new plant varieties.
2. To ensure that planting materials and high-quality seeds are available to Indian farmers, as well as to facilitate the growth of the seed industry through both foreign and domestic

investment.

3. To acknowledge farmers', local and tribal communities', and their contributions to the country's agrobiodiversity. The Act also recognises and protects farmers' rights in terms of their contributions to conserving or improving a new plant variety.

Other significant aspects of the Act include:

- Section 26 of the Act[5] discusses the Benefit Sharing concept arising from the use of plant genetic resources. However, there is no requirement for benefit sharing between breeders and farmers, and the Act makes no mention of the Priority Principle. Farmers' permission to use their genetic material or traditional knowledge for commercial purposes.
- Breeder's Rights, Framer's Rights, and Researcher's Rights are also recognised by the Act. Breeders have exclusive rights under the Act to produce, sell, and distribute protected varieties. In the event of an infringement of Breeders Rights, they may seek civil redress in the District Court under Section 65 of the said Act.
- The rights of farmers are recognised in Chapter IV. A farmer who has developed a new variety may register it under Section 39 of the said Act. Under the Act, the farmer is entitled to the same protection as the breeder. Farmers who work to conserve genetic resources of landraces/domesticated animals and economic plants will be recognised and rewarded by the Gene Fund.
- Concerning Researcher's Rights, Section 30 of the aforementioned Act states that a researcher may use variety registered under the Act for conducting research, which may include using variety as an initial source to generate another variety. However, the researcher must obtain the breeder's permission before using the same variety again.

Biological Diversity Act, 2002[6]

In 1992, India became a signatory to the UN Convention on Biological Diversity. In response to UN CBD obligations, India enacted the Biological Diversity Act in 2002, after ten years of negotiations with all stakeholders. The Act applies to the entire country of India, including the state of Jammu and Kashmir.

[5] The Protection of Plant Varieties and Farmer's Rights Act, 2001, No. 53 of 2001, Acts of Parliament (India), S. 26.
[6] Biodiversity Act 2002, No. 18 of 2003, Acts of Parliament (India).

The Act's main goal is to promote the conservation of biological and genetic resources, as well as the equitable distribution of benefits resulting from commercial use of biological resources.

The following are some of the most important features of the Biological Diversity Act, 2002:

1. The Act provides for the sustainable use of biological resources, their conservation, and the equitable distribution of benefits among all stakeholders. The objectives of the BD Act, 2002 are consistent with the goals of the UN CBD.
2. The Act also recognises and reaffirms countries' sovereign rights over their biological resources and protects indigenous communities' knowledge about biodiversity conservation.
3. The Act also emphasises equitable benefit sharing from commercial exploitation of genetic or biological resources.

Patents Amendment Act, 2005

The term patent acquired statutory meaning under the Patents Act of 1970. With the implementation of TRIPS, India amended its patent laws solely to meet the TRIPS agreement's obligations. The Patents Act of 1970 was amended in 1995, and again in 2002. To fully comply with the provisions of the TRIPS Agreement, the Patents Act of 1970 was amended in 2005, and the amended Act became effective on January 1, 2005. The amended Act included provisions for product patents as well as traditional knowledge. The first change that was bought concerned the definitions of patent and invention. The amended definition of invention in Section 3(p) states that an invention that is traditional knowledge, duplication of TK, or known properties of traditionally known components shall not be considered an invention.

The introduction of patent opposition proceedings under Section 25(1) of the said Act was the second most significant change brought about by amendment. According to the new amended Section 25, when an application for patent grant is pending, any person may write to the Controller and express their opposition to patent grant. Third, the amendment included a provision in Section 25 (3) (d) that allows for the opposition of a complete patent specification for an invention that was publicly used in India prior to the priority date of that claim.

CASES OF BIOPIRACY

Turmeric Patent Dispute[7]

Indians have used turmeric for thousands of years because of its numerous health advantages and anti-inflammatory characteristics. It is one of the most well-known herbs that is reputed to miraculously treat practically all health issues.[8] In 1994, a patent was issued to the University of Mississippi on the use of turmeric for its abilities to treat wounds. There is no evidence to support the university's assertion that turmeric is primarily used in India to heal sprains and as an anti-inflammatory, although it is also stated that turmeric is used to treat exterior wounds.[9] Sanskrit tests and other documents were submitted in opposition to the patent by the Indian Council for Scientific and Industrial Research, including a study that demonstrated the utility of turmeric in healing wounds and was published in 1953. The Mississippi University's patent on the use of turmeric for the treatment of external wounds was cancelled by the US Patent and Trademark Office based on the provided proofs.[10]

The Neem Dispute

The patenting of the neem plant's anti-fungal characteristics is one of the most well-known instances of bio piracy in India. Native to the Indian subcontinent, the neem tree is widely recognised for its wide range of medical and agricultural uses. [11]A patent was granted to W.R. Grace and the US government in 1994 for a specific method of preventing fungal infection on plants using neem oil, which contains 0.1 to 10% neem oil that is extracted using a hydrophobic method and is largely free of azadirachtin, 0.005 to 5.0 percentage emulsifying surfactant, and 0.1% water. he granting of patent of the anti-fungal properties of the neem plant was opposed, as neem was an indigenous plant variety of India and the traditional knowledge to use neem for medicinal purposes and anti-fungal application in agriculture started in India centuries before itself. Hence, the patent cannot be granted since it does not fulfil the two important essentials for granting patent, i.e., innovation and novelty. Due to inflaming protest from

[7] Prof. S. C Santra, Biopiracy, 19 ENVIS Centre on Environmental Biotechnology, 1, 7 (2011)
[8] United Nations Development Programme, "Biopiracy and the patenting of staple food crops", Human development report, 1999.
[9] Rakesh Kalshian, Turmeric Biopiracy, available at: http://www.outlookindia.com/article/TurmericBiopiracy/20184
[10] Divya Bhargava, Patent Act: Biopiracy of Traditional Indian Products-an overview, available at: http://www.countercurrents.org/bhargava140709.htML
[11] Ibid 8

several Indian farmers, political and social activists, scientists, the granted patent was revoked in May, 2000.

Basmati Rice Dispute

Another well-known example of bio piracy was the basmati rice lines and grains. This was the country's second biopiracy triumph. Basmati rice is a native rice type of India and one of the most widely consumed grains in the country. On July 8, 1994, Rice Tec Corp, a Texas-based firm, filed a generic patent on basmati rice. At the United States patent and trademark office, the firm was attempting to get a monopoly on the basmati rice lines and grains for planting, harvesting, and cooking. The corporation also went forward with the claim that they invented the rice, despite the fact that it was taken from other rice successions in India. The corporation also claimed that they are patentable since they created a unique type of basmati lines and grains. After widespread opposition to the issuance of a patent to the business Rice Tec Inc, the United States Patent and Trademark Office invalidated the majority of the terms of the Basmati patent. [12]

The Indian Wheat Case

In the year 2004, the European patent office which was situated in Munish struck down the patent that was granted to Monsanto for Nap Hal, an Indian wheat variety. The patent was granted to Monsanto, a company which is known as one of the biggest seed corporations on May 21 in the year 2003 by the European patent office by giving a title "plant".[13] The institute of RFST along with various other organizations filed a petition, Research Foundation for Science, Technology & Ecology & Another V. U.O.I & Other [14]against the granting of patent of Nap Hal to the Monsanto corporations which resulted in the revocation of the patent.

Hair Loss Dispute[15]

Pangaea Laboratories Ltd., a UK-based company, filed a patent in February 2011 titled "Hair Building Solid agent." Close inspection revealed that the hair spray is made up of turmeric, pine bark, and green tea extracts. According to the CSIR, the composition has been used for

[12] Shiva V, "Bio piracy: The plunder of Nature and Knowledge" , South end press, 2006
[13] Suvarna Pandey, "Biopiracy related to traditional knowledge and patenting issues", Patent Attorney, S. Majumdar & Co., New Delhi, available at: http://www.birac.nic.in/webcontent/dib.pdf
[14] WP (Civil) No. 64 of 2004.
[15] India foils UK Company's Bid to patent use of turmeric, pink bark and tea, AIR WORLD SERVICE

the treatment of hair problems in Ayurveda and Unani since ancient times. CSIR-TKDL filed a patent challenge in 2014, claiming that the composition is of Indian origin. In June 2015, the application was withdrawn based on the application and examination.

Jaiphal/ Nutmeg Dispute (Colgate-Palmolive Bid to Patent Nutmeg) [16]

In 2010, the Colgate- Palmolive Company filed a patent application. Myristica, also known as nutmeg, is of Indian origin and has traditionally been used for medicinal purposes. In this invention, the company simply added nutmeg extracts to various agents to make toothpaste and mouthwash for the treatment of oral diseases.

CSIR-TKDL requested that the claim be examined by the European Patent Office in August 2014. Several documents supporting the origin and use of nutmeg were submitted, demonstrating the use of nutmeg in the treatment of oral diseases such as bad breath, gum boils, and other oral diseases. Based on the findings of the investigation, a report was published in October 2014 stating that invention was not noble or inventive. By June 2015, the application was withdrawn by the Colgate- Palmolive Company.

CONCLUSION AND SUGGESTIONS

Given the growing issue of biopiracy, it can be argued that policy development and change are required. Biopiracy remains a major concern for all developing countries, and the looming question is how to address the growing problem while respecting Western patent rights in order to promote innovation that benefits all societies. Traditional knowledge is an essential component of Indian culture. A large number of people's livelihoods are dependent on it. As a welfare state, India should provide protection and equality to all of its citizens, including indigenous people. The current legal framework is insufficient and inadequate to protect traditional knowledge.

Though the concept of benefit-sharing has been echoed in some acts, the country requires a centralised Act to protect traditional knowledge. The action that must be taken to ensure proper protection of Traditional Knowledge, conservation of biological resources, and prevention of biopiracy is that local communities or TK holders must be appropriately educated and made

[16] Intellectual Property Rights and India, INSIGHT ON INDIA https://www.insightsonindia.com/2016/03/21/intellectual-property-rights-india/.

aware of their rights. Another step that can be taken is to allow local communities to participate effectively and actively in all discussions about biological resources and traditional knowledge.

Based on the observations, the following measures can be proposed for the protection of indigenous peoples' traditional knowledge and the prevention of biopiracy:

- To strengthen the TK base, the TKDL should be made more effective and collaborate with an increasing number of NGOs. Indigenous communities should be encouraged to participate in the fight against biopiracy, and free legal aid should be provided to these communities if they wish to challenge a case involving a violation of their TK.
- Specific criteria should be established to ensure that local indigenous communities receive the greatest benefit from resource access.
- Non-governmental organisations (NGOs) should be allowed to participate in policymaking and communicate directly with communities on a local level.
- Provisions in the BDA must empower citizens to file suits in the High Court in the event of a claim for bio-piracy, any unauthorised use of biological resources, unauthorised use of indigenous people's innovations, or violation of BDA/BD rules. Thus, rather than simply filing an appeal with the High Court after the unauthorised use, the unauthorised use can be prevented by filing a suit for injunction.
- State governments must include protection of natural resources and associated traditional knowledge in their plans and policies, as well as protection of the rights of the community that holds it.
- At the local level, communities can best protect their knowledge and resources. Traditional knowledge holders should be properly educated at the local level so that they are aware of their rights and responsibilities regarding the protection of their biological resources and the knowledge associated with them.
- The government should learn about local traditional knowledge practises and take appropriate steps to incorporate them into research projects so that indigenous people who hold TK can benefit. It will foster trust and respect among the government, researchers, and indigenous peoples.
- Non-governmental organisations (NGOs) act as a warning system to protect indigenous peoples' traditional knowledge. As a result, for the protection of indigenous people's rights, the Acts are silent in some areas that need to be addressed, and only the work of

NGOs does not suffice to fulfil the purpose of the act for the protection of indigenous knowledge, necessitating the need for a clearer form of legislation.