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Combatting Biopiracy for the Protection of Natural Resources and Biodiversity in India

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Abstract

The term "biopiracy" is the unauthorised exploitation of native knowledge about the natural world that comes from native communities for financial advantage without the native people's permission, frequently with very little payment or acknowledgment. Biopiracy results from developed countries using indigenous peoples' genetic resources and traditional knowledge from underdeveloped countries to secure patents for their discoveries. This entails the improper use of patents on genetic resources, and traditional knowledge especially when it comes to plant and biotic materials, which leads to "theft or infringement" referred to as "biopiracy."

For instance, indigenous tribes are prevented from commercializing their technology when pharmaceutical manufacturers (companies) patent medicinal plants derived from traditional knowledge without giving credit to the original founders or source. A number of risks are associated with biopiracy, such as the assertion of ownership over genetic materials or knowledge that belongs to countries, communities, or regions; impeding the application of this knowledge in its native country or in accordance with customs; providing patent holders with unfair profits; and upsetting established systems as a result of unjust and unethical patents.

The collection of biological specimens for scientific research, or "bioprospecting," can enhance science in the medical and other domains. Biopiracy, or the illegal collecting of biological materials, can, however, have negative consequences, including the violation of a nation's sovereign rights, the detriment to the economy of indigenous people, and the extinction or reduction of species. Maintaining ecological equilibrium depends on protecting biodiversity and using resources responsibly. In order to encourage preservation, “responsible utilization, and fair distribution of the benefits from the economic exploitation of biodiversity,” India has put in place a number of legislative measures that are in line with international norms. Biopiracy occurrences are on the rise despite these efforts, and the main beneficiaries are frequently the culprits rather than the legitimate stewards of biological resources.

To successfully address this issue, it is imperative to comprehend the legal and institutional frameworks that govern biopiracy and biodiversity conservation in India. The purpose of this study is to examine common issues within these frameworks in order to close the gap between intended results and existing conditions.

KEYWORDS: Bioprospecting, Traditional Knowledge Protection, Theft of Genomic Content, Preservation of Environmental Balance, Utilization of Patents on Gene Resources, etc.

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INTRODUCTION

"Biodiversity" refers to the complex web of interactions between living and non-living elements in ecosystems. Biodiversity is the usual way that this phrase is shortened. The most commonly accepted definition of biodiversity was proposed by the UN-endorsed Convention on Biological Diversity, or CBD, in 1992. This definition of biodiversity states that it includes the variety of biological systems that are present in terrestrial, marine, and other aquatic settings and that provide fundamental resources for the survival of humans.[3]

Through the patenting of machinery and molecules, the two great industrial revolutions in chemical and mechanical.[4] The issuance of patents in the 20th century to signify new materials and gadgets reflected the two great industrial revolutions in chemical and mechanical engineering, which led to the patenting of equipment and molecules. Diversity is encompassed by the ongoing revolution in genetic engineering. Threats to biodiversity today include the extinction of species, resource depletion, desertification, deforestation, and a relatively new problem called biopiracy.

The acquisition of plant genetic material and indigenous knowledge about the uses of plants is known as biopiracy, and it gives rise to discussions concerning ownership rights. Patent claims on biological materials and traditional indigenous knowledge are two examples of "biopiracy," which is the unlawful utilization of intellectual property rights, or IPR, systems to exert control over biological resources. This kind of exploitation frequently occurs when developed nations obtain raw materials mainly held by developing countries, with industrialized nations claiming creative credit.[5]

Risks associated with biopiracy include endangered species, economic harm to native economies, and violations of sovereign rights. Ownership rights are at the center of discussions about biopiracy, which has been made more common by historical forces including capitalism, colonialism, and modern globalization. Patents issued by multinational corporations (MNCs) shield biopiracy, maintaining the gap between populously varied developed and developing countries.

In order to effectively regulate biodiversity, everyone must have equal access. Strong enforcement procedures and laws based on scientific principles are needed to combat biopiracy in India.

Examiners of patents at foreign patent offices use various resources, such as a search of pertinent non-patent literature sources, to determine whether a claimed subject matter is patentable. Although patent literature is usually well-organized in different databases, there is an acknowledged need for more easily available non-patent literature resources that are specialized in Indian traditional knowledge. This would help allay worries about the patent system's capture of traditional knowledge and enable more precise evaluations of patentability.

“With a focus on publicly available Indian medicinal systems including Ayurveda, Unani, Siddha, and Yoga, the Traditional Knowledge Digital Library (TKDL) is an essential instrument in the fight against the misuse of traditional knowledge. It accomplishes this by gathering and arranging information on traditional wisdom from literature that already exists in regional tongues, such as Tamil, Sanskrit, Urdu, Arabic, Persian, and Sanskrit, into an electronic format. After that, this data is accessible in English, German, Spanish, French, and Japanese, five foreign languages. The Traditional Knowledge Resource

[3] United Nations Convention on Biological Diversity, 1992, Art. 2.
[4] VANDANA SHIVA, PROTECT OR PLUNDER? UNDERSTANDING INTELLECTUAL PROPERTY RIGHTS; https://books.google.co.in/books?id=ghoTDbc4uYoC&dq=protect+or+blunder&source=gb_navlinks
[5] ibid.

Classification (TKRC) was created as an innovative hierarchical classification system that includes over 5,000 subgroups relating to medicinal plants, as opposed to the few subgroups accessible in the International Patent Classification (IPC). The TKDL software, together with its corresponding classification scheme, makes it easier to translate text across numerous local languages. Notably, the program translates data into several languages after it has been abstracted using a knowledge-driven translation approach that makes use of Unicode and metadata. Additionally, it converts old names into their contemporary equivalents. For example, Jwar becomes fever, Curcuma longa becomes turmeric, and Mussorika becomes smallpox. Using IPC codes and keywords in several languages, the TKDL's search interface enables full-text retrieval of conventional knowledge data. TKDL acts as a link between local language formulations and international patent examiners by offering information on current and regional names in a manner that is comprehensible to them. With the help of this project, traditional knowledge will be better protected and preserved as it attempts to overcome the difficulty in obtaining prior art."

Examples of Traditional Knowledge Bio-Piracy

A. A typical rhizome used to improve flavor in Indian cuisine is turmeric (Curcuma longa Linn). Turmeric has been used for millennia to cure burns and rashes, but it also has medical, cosmetic, and coloring benefits outside of its culinary uses. Indian expats Suman K. Das and Hari Har P. Cohly of the University of Mississippi Medical Center were awarded a US patent (No. 5,401,504) in 1995 for the application of turmeric to the treatment of wounds. The Council of Scientific & Industrial Research (CSIR) (India), which is headquartered in New Delhi, challenged this patent during re-examination, citing previous art to contest the invention's novelty. According to the CSIR, turmeric has been used for millennia in traditional Indian medicine to heal rashes and wounds, therefore its medical application was not new. In order to bolster their argument, CSIR produced documentation proof, such as an old Sanskrit text and a 1953 Journal of the Indian Medical Association article that demonstrated the customary understanding of turmeric's therapeutic benefits. The US Patent and Trademark Office (US PTO) sustained CSIR's concerns and invalidated the patent in 1997, despite appeals from the patent holders. This case was a landmark one, demonstrating the value of acknowledging and defending indigenous knowledge by being the first to successfully challenge a patent based on traditional knowledge from a developing nation.

B. The Neem patent case and its eventual revocation or cancellation Neem seed oil is well-known for its therapeutic uses, including curing colds and the flu, preventing pests and fungal infections in crops, and treating meningitis, malaria, and skin ailments when mixed with soap. The European Patent Office (EPO) awarded the patent (EPO patent No. 436257) to the 'US Department of Agriculture' and the Corporation W. R. Grace Company in 1994 for a method of controlling plant fungus using hydrophobic neem oil. However, a group of international NGOs and attorneys defending Indian farmers challenged this patent in court in 1995. They proved that the fungicidal qualities of neem seed extracts were well-established and used in Indian agriculture to safeguard crops, therefore they could not be patented. The claimed invention was found to lack an innovative step by the EPO in 1999, based on the data that was submitted. May 2000 saw the revocation of the neem patent as a result. The EPO denied the USDA's and W. R. Grace's further attempts to contest this ruling in 2001 and 2006. This lawsuit brought to light the significance of preserving traditional knowledge and opposing the illegitimate patenting of natural assets and native customs.

C. Retracted claims for basmati rice not entirely revoked Before the United Kingdom Trade Mark Registry, Tec Rice filed an application to register the name "Texmati" in relation to Oryza sativa Linn., or rice basmati. The "Agricultural and Processed Food Exports Development Authority (APEDA)" successfully opposed this application. On September 2, 1997, the US Patent and Trademark Office (US PTO) awarded Rice Tec a US utility patent. The patent applied for the protection of a rice plant with characteristics similar to those of Indian traditional Basmati rice lines. This patent included the Caribbean Islands as well as any part of Central, North, or South America. Later, on the 28th of April 2000, a request for re-examination of this patent was filed. Rice Tec decided to withdraw claims 4 and 15 through 17 from its patent application in response to this request.

The following are the main arguments against biopiracy:

- Inequitable, Illegal, and Endangering Indigenous Cultures: By taking advantage of indigenous cultures' knowledge and resources without their consent or just compensation, biopiracy is accused of being unethical and unjust, endangering their survival.
- Indigenous Genetic Resource Patents: Businesses frequently patent products made from traditional genetic resources, depriving those groups of control and financial gain from their own resources and knowledge.
- Prohibition on Use and Export: Indigenous peoples are frequently forbidden from using or "exporting their biological resources and traditional knowledge, which causes them to lose their indigenous knowledge and ultimately lose important cultural assets."

PROTECTION OF TRADITIONAL KNOWLEDGE IS NEEDED

- Immediate Legal Acknowledgement of Indigenous Rights: Since traditional knowledge is mostly held by India's tribal & indigenous peoples, it is critical that their rights be duly acknowledged.
- Recognition and Recompense for Conservation Efforts: Native and tribal communities making sustainable contributions to biodiversity conservation need to be recognized and given due recognition for their vital role.
- Public Education about Traditional Wisdom: Education campaigns are desperately needed to bring attention to these issues and the contributions made by indigenous and tribal cultures, as there is a dearth of knowledge regarding traditional wisdom among the general public.

WORLDWIDE PROTECTION AGAINST BIOPIRACY

The United Nations Convention on Biological Diversity (CBD)

During the Rio Earth Summit in 1992, the Convention on Biological Diversity (CBD) was ratified at the UNCED and went into effect on December 29, 1993.[6] To protect biodiversity worldwide, it seeks to find a middle ground between the goals of different developing and developed countries. Additionally, the CBD offers a fresh method for managing genetic resources. 196 parties have approved it as of right now, and it was up for signing at UNCED (the Earth Summit on June 5, 1992). Remarkably, as a result of its withdrawal from the CBD, the USA is now no longer acknowledged as a party. Promoting sustainable development is one of the Convention's main goals, and its tenets are consistent with other accords reached during the Rio Summit.

[6] Report of the Nairobi Act, Conference on Adoption of the Agreed Text of the Convention on Biological Diversity, Nairobi, Kenya, May 20- 21, 1992, UNEP/Bio.Div/CONF/L.2 https://www.cbd.int/doc/handbook/cbd-hb-01-en.pdf.

Developing nations have been pushing for changes within the Convention on Biological Diversity (CBD) to create a more fair framework for sharing benefits from the exploitation of genetic resources.[7] The equitable sharing of profits from the commercial use of biological and genetic resources is one of the main arguments made against the CBD. The CBD preserves a cornerstone of international law by stating that national governments have the sole right to control access to genetic resources and that states retain national sovereignty over these resources. According to the 15th article of the Convention, the contracting parties must give their prior consent before accessing genetic resources.

Contracting parties shall also adopt laws or other policies to guarantee a fair and reasonable allocation of research advantages and commercial revenue resulting from the use of genetic resources.[8] The Convention includes a number of clauses pertaining to the transfer and access of technology, in-situ and ex-situ methods of preservation, sustainable utilization, and resource conservation.

The relationship between genetic resource access and intellectual property rights (IPR) is one of the Convention's most disputed subjects. Consequently, the need for equitable cost and benefit sharing between industrialised and less developed nations that result from the commercial exploitation of genetic resources was identified, and access to "gene resources and benefit-sharing" became one of the three objectives of the Convention. Another important goal was to facilitate support for the local population. The central provision pertaining to "Access and Benefit Sharing" is found in Article 15. It is supplemented by "Articles 8(j), 10(c), 16, 17, and 18," when taken together provide guidance for the application of the access and benefit-sharing procedures within the CBD framework.

“Historically, community involvement—especially that of women—has been essential to promoting biodiversity. In contrast to ex-situ conservation techniques like gene bank preservation, in-situ conservation—which emphasizes local conservation initiatives—is thought to be more ecologically sustainable. Policies and programs that support the preservation and sustainable use of biological resources must be put in place.”

According to the Bonn Guidelines, access to genetic resources requires prior informed consent, with that consent being linked to a particular use.[9] Contracts must contain provisions pertaining to intellectual property rights, such as obligations for cooperative research, the application of invention rights, and the granting of cooperative licenses. Countries are urged to put policies into place for disclosing, in Intellectual Property Rights (IPR) applications, the nation of origin of genetic resources and customs from the local community.[10] The purpose of these disclosures is to help with the revocation of patents based on conventional knowledge and to rectify improper patent issuance.[11]

As an addition to the United Nations Convention on Biological Diversity, or CBD, treaty, the Nagoya Protocol is an international accord having legal force. One of the main goals of the CBD is to create a strong legal framework that guarantees just and equitable benefit sharing.[12] This is what this protocol attempts to do. It controls how genetic resources and the traditional knowledge connected to them are accessed and used.

[7] HANDBOOK OF THE CONVENTION ON BIOLOGICAL DIVERSITY INCLUDING CARTEGANA PROTOCOL ON BIOSAFETY, (3rd ed., 2005).
[8] Fair and equal distribution of the knowledge obtained from the gains-ibid.
[9] Ibid.
[10] Ibid.
[11] Ibid.
[12] 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 : text and annex, CBD www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf

In accordance with mutual agreement on the conditions for benefit sharing with the indigenous communities or entities providing the resources, the fifth article of the Nagoya Protocol promotes the fair and equitable treatment of parties holding or donating genetic resources. It gives State Parties the authority to pass legislation or implement administrative rules to guarantee the fair allocation of resources. Furthermore, the protocol supports benefit sharing, which is the third objective of the CBD.

Research projects that enhance the preservation and sustainable utilization of biological assets in underdeveloped nations are encouraged under Article 8 of the agreement.[13] When utilizing these resources, parties must take into account any potential domestic or international emergencies that could harm the health of people, animals, or plants.

Establishing focal points to enable information sharing for parties requesting access to genetic materials or associated knowledge is another requirement of the Nagoya Protocol. The establishment of national authority on benefit sharing and access is outlined in Article 13. These authorities are in charge of approving resource access and furnishing documentation attesting to adherence to access regulations.[14]

This 'Global Multilateral Benefit-Sharing System,' encouraging cross-border cooperation, and respect for national benefit-sharing and access legislation are important elements of the treaty. Additionally, the protocol improves compliance and transparency by integrating with the CBD's clearinghouse mechanism as per Article 18.

Enforceable commitments bind states who "ratify or accede" with the Nagoya Protocol, highlighting the protocol's importance in advancing fair resource use and benefit sharing worldwide.

The TRIPS Agreement: Encouraging Trade and Intellectual Property Rights in the World Trade Organization[15]

'The Trade-Related Aspects of Intellectual Property (TRIPS) Agreement' was introduced by the World Trade Organization (WTO) in 1994, and it came into effect on January 1st, 1995. Since intellectual property rights (IPR) protection is a key component of this agreement, it plays a critical role in the international trading system. Its main goals are to promote trade, preserve property rights, harmonize laws pertaining to intellectual property, and provide IPR holders more time to protect their rights.

All parties to the TRIPS agreement must ensure that their national laws uphold the minimal criteria for protecting intellectual property rights by adhering to the Paris and Berne Conventions, which are fundamental WTO agreements. Intellectual property rights are recognized as private rights under the TRIPS Agreement, highlighting their importance in promoting creativity and innovation.

There was no global standard for an invention's patentability prior to the TRIPS Agreement. Nonetheless, the 27th article of this agreement sets a worldwide minimum criterion for the patenting of all inventions. In addition to requiring member states to safeguard genetic resource ownership, Article 27 of the TRIPS Agreement permits patents on inventions pertaining to goods or processes that can be used in the 'industrial sector,' with some biological processes being exempted under Article 27(3)(b).

“Under Article 27(3)(b)[16], member states are free to decide whether to grant patents on biological products or processes, such as microbes, plants, animals, and biological processes. To preserve plant species, they must either create an efficient sui generis system, a patent structure, or an amalgamation of the two.”

[13] ibid.
[14] Ibid.
[15] Lorna Dwyer, Biopiracy, Trade and Sustainable Development, Col. Jou. Int. Envr. Law & Policy, 220, 238 (2008). 24 Ibid
[16] Ibid.

The TRIPS Agreement describes the basic conditions for intellectual property protection, including a 20-year protection period, as well as the steps IPR owners must take when defending their rights in administrative or civil courts. Member nations may choose to strengthen IPR enforcement by establishing specialist courts for IPR cases, even if doing so is not required.

INDIAN LEGISLATIONS / INITIATIVES FOR PROTECTION AGAINST BIOPIRACY[17]

The 2001 Protection of Plant Varieties and Farmers' Rights Act:[18]

The objectives of this act are to safeguard farmers' rights regarding plant varieties, promote the creation and application of novel plant varieties, and guarantee just remuneration for the contributions that farmers have made to plant genetic material.

The Indian government protected new plant varieties and encouraged agricultural biodiversity via the Protection of Plant Varieties and Farmer's Rights Act, 2001. As per Article 27(3)(b) of the TRIPS Agreement, it creates the Protection of Plant Varieties and Farmer's Rights Authority to oversee the Act. Among the Act's goals are:

1. Encouraging fresh plant variety research projects in both the public and private sectors.
2. Encouraging the domestic and international establishment of seed businesses by making sure Indian farmers have access to 'premium seed and planting supplies.'
3. Respecting the rights of farmers with regard to novel plant kinds and recognizing and preserving the contributions made by 'farmers, local populations, and indigenous cultures to the country's agrobiodiversity.'

The following are some significant facets of 'the 2001 Protection of Plant Varieties and Farmer's Rights Act':

1. The Act's Section 26 explores the idea of benefit sharing resulting from the use of genetic resources from plants. However, breeders and farmers are not required to participate in benefit sharing, and the Act does not address the issue of farmers' prior authorization for the use of their 'genetic material or traditional knowledge' for commercial purposes.[19]
2. The Act appropriately acknowledges the rights of farmers, researchers, and breeders. According to the Act, breeders have "exclusive authority" to develop, put on the market, and distribute protected varieties. In the event that their rights are violated, breeders continue to be able to file a lawsuit in the appropriate district court according to 'Section 65[20] of the Act in question.'
3. Farmers' rights are recognized in Chapter IV. Section 39[21] of this Act allows a farmer that has created a 'novel variety' to register it. The Act states that the farmer has the same rights for safeguarding as the breeder. The Gene Fund[22] will recognize and compensate farmers who work to protect landraces, domesticated plants, and animals' genetic resources.
4. In terms of the rights of researchers, 'Section 30'[23] of the Act's provisions grants them the right to carry

[17] K. Venkataraman, Intellectual Property Rights, Traditional Knowledge and Biodiversity of India, 13 Jou. Intel. Prop. Rhts., 326, 331 (2008).
[18] ibid.
[19] The Protection of Plant Varieties and Farmer's Rights Act, 2001, No. 53 of 2001, Acts of Parliament (India), S. 26.
[20] id., S. 65.
[21] id., S. 39.
[22] id., S. 39 (1) (iii).
[23] id., S. 30.

out research using variations that are registered within the Act, including the ability to use one variety as a starting point for the creation of another variety. However, before utilizing the same variety again, the researcher needs to obtain the breeder's approval.[24]

5. Local communities' rights are also acknowledged by the Act. 'Any individual, non-governmental organizations organization, or governmental body may make a claim on the behalf of a local group or village about its contribution to the development of a particular variety in accordance with Section 41[25] of the Act. After confirming the allegation and proving that the town or village contributed to the development of the variety, the authorities could let the breeder know. The authorities will provide the breeder with a fair chance to voice their concerns and be given due consideration. But the Section also deals with paying out compensation to private citizens, non-governmental groups, or public authorities who have filed "claims on behalf" of a town or village.

Biological Diversity Act (2002):[26]

In order to preserve biological diversity, encourage the sustainable use of its constituent parts, and guarantee the just and equal distribution of benefits resulting from the use of biological resources, the Biological Diversity Act was enacted.

The TKDL is an important project that records traditional knowledge about medicinal plants and formulations, even though it is not a legal requirement. By giving patent examiners access to a database, it lessens the likelihood that traditional knowledge would be misappropriated and prevents patents from being granted for recognized traditional knowledge.

India responded to its duties according to the UN Convention on Biological Diversity (CBD), which it ratified in 1992, by enacting the Biological Diversity Act, 2002. The Act, which aims to safeguard biological and genetic resources and guarantee equitable sharing of profits from their commercial exploitation, was passed in 2002 following ten years of talks. The Act addresses the issue of corporations, individuals, and organizations' access to biological and genetic resources and is applicable to entire India, including the state of Jammu and Kashmir.

“The equitable benefit-sharing, sustainable use, and conservation of biological resources in accordance with the goals of the CBD. The safeguarding of indigenous knowledge about biodiversity and the acknowledgement of nations' 'sovereign authority over their biological resources.' A focus on equitably allocating the financial gains from the use of genetic or biological resources.”

The NBA, or National Biodiversity Authority[27]

In compliance with the third chapter of the Biological Diversity Act, 2002, the Central Government of India formed the 'National Biodiversity Authority (NBA).' It has all the ‘characteristics of a company and operates as a body corporate.’[28] The NBA was established in 2003 to carry out the Act on Biological Diversity, 2002's provisions. Its main function is advisory, particularly in relation to counseling the Central Government on matters pertaining to the preservation of ecological assets and their sustainable use.[29]

[24] id., S.30 (b).
[25] id., S. 41.
[26] Biodiversity Act 2002, No. 18 of 2003, Acts of Parliament (India).
[27] Supra, 50.
[28] Ministry of Law and justice, The Biological Diversity Act, 2002, GOVT. OF INDIA http://nbaindia.org/uploaded/Biodiversityindia/Legal/31.%20Biological%20Diversity%20%20Act,%202002.pdf.
[29] About National Biodiversity Authority, NBA INDIA http://nbaindia.org/content/22/2/1/aboutnba.html.

1. forming committees to look into problems related to agrobiodiversity.[30]
2. limiting "access to biological materials" by demanding permission before using them for study or business.[31]
3. providing guidance on biological resource protection, sustainable use, and fair benefit distribution to the state and federal governments.[32]

Biodiversity state boards (SBB)

The fourth chapter of the 2002 Biological Diversity Act requires State Governments to create State Biodiversity Boards (SBB). Nonetheless, the National Biodiversity Authority (NBA) has appropriate authority in Union Territories.[33] Like the NBA, SBBs carry out comparable responsibilities, such as counseling the state's government on issues pertaining to biological resource conservation.

Committees for Biodiversity Management (BMCs)

Under the provisions of Chapter XI of the Act on Biological Diversity, 2002, local self-government establishes "committees for managing biodiversity (BMCs)" with the purpose of safeguarding and preserving biological resources. '1,55,868 BMCs at the local level as well as State Biodiversity Boards in 29 States' have been established thanks to assistance from the National Biodiversity Board.[34]

The National Biodiversity Authority (NBA) implemented a number of biological resource conservation efforts, including:[35]

1. 42 applications for patents for Indian biological resources—including the Red Sanders, a vulnerable species that is native to India—were rejected by NBA.
2. After receiving about 450 applications, NBA formed the "Expert Committee on Access and Benefit Sharing (ABS)" to review requests for prior authorization pertaining to biological resources and traditional knowledge (TK).
3. In 2017, the NBA received $12.49 crores in benefit-sharing payments, which it then gave to the Tamil Nadu Biodiversity Board and the Andhra Pradesh Forest Department.
4. NBA gave stakeholders training courses aimed at enhancing their capacity in TK and IPR.
5. NBA assisted in the creation of 'People's Biodiversity Registers (PBRs)' and BMCs in several States in order to record traditional knowledge and biodiversity.
6. In accordance with the BD Act of 2002, benefits were distributed and resource preservation was encouraged through the use of federal, state, and local monies for biodiversity.
7. The Department of AYUSH and CSIR in India collaborated to create the 'Traditional Knowledge Digital Library (TKDL),' which focuses on Indian medicine. It digitally gathers traditional knowledge from traditional literature and converts it into five foreign languages in patent format so that patent examiners may easily understand it. TKDL organizes data, which covers about 2 lakh drug formulations, using the TKRC program in accordance with the International Patent Classification. The 'Nutmeg Patent Case (2010), the Curcumin Pine Bark Case (2015),' among other cases where TKDL

[30] Supra 59, S. 13
[31] Supra, 59, S.18 (1).
[32] Supra, 59, S. 18 (3).
[33] Supra, 59, S. 22.
[34] Supra, 63.
[35] ibid.

acted as a preventive safeguard for the nation's traditional knowledge are notable examples of TKDL's victories.

The 2005 Patents Amendment Act

The Patents Act-1970, established the formal definition of the term "patent" in India. The TRIPS agreement served as the impetus for later modifications to India's patent rules, which were made in order to comply with its requirements. The initial 1970 Act was amended in 1995, and once more in 2002. To fully comply with TRIPS regulations, the Patents Act -1970 underwent significant revisions=only in 2005; the revised Act became operative on January 1st, 2005.[36]

"Patent and invention definitions were updated by the Act, which stated that under Section 3(p),[37] traditional knowledge, reproductions of traditional knowledge, and known characteristics of traditional elements (inventions involving TK)[38] are not considered inventions."

Patent Opposition Procedures: A significant modification was the inclusion of patent opposition procedures in Section 25(1), which permits anybody to challenge a patent's award in writing to the Controller while the application is still ongoing.

Apart from the main objectives, the biological diversity act - 2002 has provisions that correspond with CBD requirements, specifically binding Sections 22 and 8:[39]

1. 'The National Biodiversity Authority (NBA), State Biodiversity Boards, and BMCs (Biodiversity Management Committees)' were established to supervise biodiversity management at different levels.
2. Acknowledging and conserving the customary knowledge about biodiversity that local communities possess, while guaranteeing that their contributions and rights are honored and safeguarded.
3. Designating locations as heritage sites of biological diversity in order to preserve and further establish them as important areas for the conservation of biological diversity and sustainable use.
4. The Biological Diversity Rules, 2004 and the Biological Diversity Act of 2002 are to be implemented by the 'Biodiversity Management Committees (BMCs) at the municipal, state, and federal levels, the State Biological Boards (SBB), and the National Biodiversity Authority (NBA) at the national level.' These authorities carry out a number of vital duties, such as:
5. Overseeing, supporting, and counseling the Indian government on projects aimed at conserving biodiversity, making sustainable use of its components, and distributing benefits fairly.
6. Granting permissions in accordance with the guidelines provided in the 2002 Biodiversity Act's Sections 4, 3, & 6.
7. Carrying out further tasks as required to meet the requirements of the Act, such as locating and designating areas of biodiversity value as 'biological diversity heritage sites.'
8. Preserving the nation's biodiversity and avoiding the export of Indian biological resources' intellectual property rights to other countries or the import of biological resources.
9. Requests regarding access to biological resources and information about traditional knowledge to foreign people, groups, and companies are handled by the 'National Biodiversity Authority (NBA).' This comprises actions taken to stop intellectual property piracy within and outside of India, protecting

[36] Supra, 50.
[37] ibid.
[38] Traditional Knowledge Digital library, Available at http//:www.tkdl.re.in/tkdl/langdefault/Commo/Biopiracy.asp?GL=Eng.
[39] Biodiversity Act-Bare Act https://www.indiacode.nic.in/bitstream/123456789/2046/1/200318.pdf.

the local populace from exploitation.

10. The establishment of a "designated National Repository (DNR)" according to the provisions of section 39 of the Act on Biological Diversity, 2002, is one of the latest steps toward the implementation of the NBA. With services for preserved specimens including animals, the herbarium (the dried plant material used for research), live cells, organism genomes, and information on hereditary and biological system function, this repository plays a critical role in the conservation of biodiversity.

The biological diversity legislation of 2002 was created ten years after 'the United Nations Convention on Biological Diversity' was ratified, although there are still certain issues with the law. During this time, government officials, academics, and non-governmental organizations (NGOs) may engage in in-depth discussion and research. The Biodiversity Rules were then passed in 2004, which led to the establishment of the 'Biodiversity Management Committee' & gave local and indigenous groups the ability to share their views on the preservation, use, and fair distribution of biodiversity. As for the Act itself, it is noteworthy that there is a gap wherein the prohibition of 'profit-sharing from commercial exploitation' is given more weight than the prioritization of conservation. Although one of the Act's main goals is to stop rich countries from taking biological resources, it's also important to focus on protecting and conserving biodiversity. Sustainable biological resource utilization and efficient biodiversity management depend on striking a balance between these objectives.

An Analysis of Prior Informed Consent Under the Biodiversity Act

The Biodiversity Act's clauses pertaining to "consultation" with indigenous communities bring up significant issues. It is more important to obtain "permission of the local body" rather than just "consultation," which might not ensure consent. A lot of the time, "consultation" is taken to mean interacting with a select number of people, village chiefs, or city corporations. True consultation ought to involve every member of the affected community or settlement, using the languages and modes of communication that they find most comfortable. People must be fully informed about the benefits and drawbacks of giving consent in order for them to make an informed decision about whether to say "yes" or "no." However, there is flexibility for interpretation in the legislation/Act and Central Rules, which makes it difficult for indigenous communities to take an active role in the process.

The Act addresses PIC in a number of places, emphasizing how crucial it is to guarantee fair benefit-sharing from the utilization of biological resources.

Penalties are given under section 55-57 of the abovesaid act.

The sharing of benefits and Access Provisions under the Biodiversity Act's Section 21

A practice known as "access benefit sharing" requires accessors of biological assets or indigenous knowledge to either credit the source or pay the provider communities for their labors. When access is allowed, regulatory frameworks must guarantee both the identification and claim of one's just share of the benefits as well as their fair distribution. The Convention on Biological Diversity's Article 16 describes the protocols for obtaining and sharing technology.

Through sovereign appropriation, the state's or private inventors' monopoly on intellectual property rights, or both, the Act unifies all property rights. It does not, however, include a framework for handling the legal assertions made by other proprietors of biological assets and related data. As a result, part of the

knowledge and resources are made available to the public and are not disseminated in compliance with intellectual property rights.

“The Indian Biodiversity Act's benefit-sharing access provisions are principally delineated in Sections 3, 4, 6, 7, 20, 21, 22, 24, and 41.”

India is having difficulty drafting and putting into effect legislation and regulations pertaining to access benefit sharing (ABS). Among these difficulties are:

Inadequate Distinction Between Biological and Genetic Resources: There is no distinction made in the Act between "biological resources" and "genetic resources." This implies that access to genetic resources is granted by the acquisition of a single bio specimen via collection, sale, or purchase, which may be in opposition to the Act's stated goal of controlling access. This makes the use of natural resources easier.

Difficulty in Monitoring and Enforcing Compliance: It might be challenging to monitor genetic resources and make sure users of those resources are following the law. The right to ownership of genetic material is not specifically addressed by the statute. Furthermore, the ABS law does not distinguish between different stakeholders who use genetic resources for various reasons, such as researchers, collectors, and multinational corporations.

Few Bio Prospecting Bids: Only a few bio prospecting bids have been received and approved by India. Additional barriers to the application of current biodiversity legislation include the lack of information regarding the negotiation processes, which leaves the efficacy of the Act in practice uncertain.

Two strategies can be employed to tackle the difficulties that have been highlighted.

1. Using suggestions derived from the most successful biodiversity laws in the world's most productive biodiversity zones.
2. Putting into action comprehensive policies that support the Biodiversity Act's primary goals in their most unadulterated form.

CONCLUSION AND SUGGESTIONS

“To strengthen the TK basis, improve the Traditional Knowledge Digital Library (TKDL) in association with NGOs. Encourage Indigenous communities to take an active role in anti-biopiracy campaigns by offering them free legal assistance to challenge infringements on their traditional knowledge. Define precise standards to enable the most advantageous access to local indigenous populations' resources. Permit non-governmental groups to engage directly with neighborhood communities and to participate in the formulation of public policy. Include clauses in the Act on Biodiversity (BDA) that allow citizens to sue in the high courts for alleged breaches of BDA/BD regulations, illegal utilization of indigenous innovations, unauthorized exploitation of biological resources, and biopiracy. With this method, unauthorized use can be quickly stopped by injunctions. Ensure that state governments incorporate community rights and traditional knowledge into their plans and activities in addition to the conservation of biological resources. Provide local communities with the necessary education to ensure that they are aware of their rights and duties and can properly protect their knowledge and resources. Recognize and respectfully integrate regional traditional knowledge methods into research initiatives that will benefit indigenous communities and build confidence between the government, academics, and indigenous people. Boost legal safeguards for the rights of indigenous peoples by passing more precise legislation, since the existing Acts are vague in many areas and relying solely on the work of NGOs is insufficient. Give indigenous groups free legal aid to contest patents or other infringements on their traditional knowledge. Considering the unique nature of traditional knowledge, develop a sui generis framework

devoted to its protection. Create special courts for expeditious dispute resolution in order to address the lack of specialized legal skills in traditional knowledge. To stop big companies from acquiring patents in an unethical manner, experts should be included in these tribunals.

The increasing difficulties caused by biopiracy have led to the need for new rules and revisions. This is a problem that worries developing countries a great deal, and the key question is how to solve it while maintaining "Western intellectual property rights" to promote innovation that benefits all communities. Traditional wisdom is highly valued in Indian culture and is essential to many people's means of subsistence. India must guarantee equality and safety for all citizens, especially indigenous groups, in its capacity as a welfare state. However, the current legal system does not provide traditional knowledge with enough protection. Although there is some benefit-sharing mentioned in the current legislation, the recommendation is to create a centralized Act aimed at protecting traditional knowledge in India. In order to safeguard traditional knowledge, preserve biological resources, and stop biopiracy, it is imperative that local communities and those who possess traditional knowledge are made aware of their rights. It is also advised to facilitate the active involvement of local populations in talks concerning the availability of natural resources and indigenous wisdom.

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