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BIO-THEFT: THE BATTLE FOR INTELLECTUAL PROPERTY IN NATURE

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ABSTRACT

The term "biopiracy" refers to the unauthorized exploitation of native knowledge about the natural world originating from native communities for financial gain without their permission, often with minimal compensation or recognition. Biopiracy arises from the utilization of indigenous peoples' traditional knowledge and genetic resources from underdeveloped countries by developed nations to obtain patents for their discoveries. This involves the improper patenting of traditional knowledge and genetic resources, particularly concerning plant and biotic materials, leading to acts of "theft or infringement" known as "biopiracy."

For example, indigenous tribes find themselves unable to commercialize their technology when pharmaceutical companies patent medicinal plants derived from traditional knowledge without acknowledging the original creators or source. Various risks are associated with biopiracy, such as the appropriation of ownership over genetic materials or knowledge belonging to nations, communities, or regions; hindering the application of this knowledge in its home country or in alignment with customs; providing unfair profits to patent holders; and disrupting established systems due to unjust and unethical patents. Biopiracy is often intertwined with the process of "bioprospecting," which involves researching, acquiring, and evaluating biological diversity and indigenous knowledge to discover genetic and biochemical resources with commercial value. However, measures have been implemented to address unchecked bioprospecting and tackle issues related to biopiracy.

The collection of biological specimens for scientific research, or "bioprospecting," can advance science in medical and other fields. Nevertheless, biopiracy, or the illegal gathering of biological materials, can have adverse effects, including violating a nation's sovereign rights, harming the economy of indigenous populations, and contributing to species extinction or decline. Maintaining ecological balance relies on preserving biodiversity and using resources responsibly. India has established institutional and legislative measures aligned with international standards to promote preservation, responsible use, and equitable sharing of benefits from the economic exploitation of biodiversity. Despite these efforts, incidents of biopiracy are increasing, with the primary beneficiaries often being the offenders rather than the rightful guardians of biological resources.To effectively tackle this issue, it is crucial to understand the legal and institutional frameworks governing biopiracy and biodiversity conservation in India. This study aims to examine common issues within these frameworks to bridge the gap between intended outcomes and current realities.

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

1. INTRODUCTION

"Biodiversity" was commonly shortened term used to refer to the intricate interactions between living and non-living components in ecosystems. The UN-endorsed Convention on Biological Diversity (CBD) proposed a widely accepted definition of biodiversity in 1992, stating that it encompasses the range of biological systems found in terrestrial, marine, and other aquatic environments, providing essential resources for human survival.[1]

The two major industrial revolutions in chemical and mechanical engineering, marked by the patenting of equipment and molecules in the 20th century, reflected advancements in these fields.[2] The ongoing revolution in genetic engineering further expanded diversity. Threats to biodiversity in that era included species extinction, resource depletion, desertification, deforestation, and a novel concern known as biopiracy.

Biopiracy, involving the acquisition of plant genetic material and indigenous knowledge about plant uses, raised debates on ownership rights. Examples of "biopiracy" included patent claims on biological materials and traditional indigenous knowledge, constituting unlawful utilization of intellectual property rights (IPR) systems to control biological resources. Developed nations often acquired raw materials predominantly held by developing countries, with claims of creative credit.[3]

Risks linked with biopiracy included species endangerment, economic impacts on native economies, and infringements on sovereign rights. Discussions on biopiracy were centered on ownership rights, influenced by historical forces such as capitalism, colonialism, and modern globalization, with multinational corporations (MNCs) issuing patents that shielded biopiracy, widening the gap between developed and developing nations.

Effective regulation of biodiversity necessitated equal access for all. Robust enforcement measures and scientifically based laws were deemed essential to combat biopiracy in India.

Biopiracy and Traditional Knowledge

'Traditional knowledge has long been viewed as an easily accessible and highly valuable resource, making it susceptible to theft.' Specifically, insights into creating physiologically active chemicals have been gained by technologically advanced countries through knowledge of medical treatments. Bioprospecting, reliant on conventional wisdom, further exacerbates this vulnerability.

The assumption that traditional knowledge in the public domain implies communities have relinquished any claims to it exposes traditional knowledge to exploitation. Both codified (written) and uncodified (inherited orally) forms are encompassed within traditional knowledge.

The difficulty for patent offices in searching for codified traditional knowledge in India's regional languages to ascertain its status as prior art before granting patents perpetuates

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

biopiracy. External entities can easily obtain patents for therapeutic formulations derived from conventional medical practices due to the legitimacy of these systems and the lack of information about them in patent offices.

For developing countries, the patenting of non-patentable knowledge, particularly concerning conventional medicines and the risk of biopiracy, has been a significant concern. Numerous instances exist where patents have been granted based on traditional knowledge existing in developing nations or slightly modified versions thereof, leading to disputes and efforts to revoke such patents, which can be challenging and costly.

Patent examiners at foreign patent offices utilize various resources, including searches of relevant non-patent literature sources, to assess patentability. While patent literature is typically well-organized in various databases, there is a recognized need for more accessible non-patent literature resources specialized in Indian traditional knowledge. This would alleviate concerns about the patent system's appropriation of traditional knowledge and facilitate more accurate evaluations of patentability.

The Traditional Knowledge Digital Library (TKDL) plays a crucial role in combating the misuse of traditional knowledge, particularly focusing on publicly available Indian medicinal systems such as Ayurveda, Unani, Siddha, and Yoga. It achieves this by gathering and organizing information from existing literature in regional languages like Tamil, Sanskrit, Urdu, Arabic, Persian, into an electronic format, making it accessible in English, German, Spanish, French, and Japanese.

An innovative hierarchical classification system known as the Traditional Knowledge Resource Classification (TKRC) was developed, encompassing over 5,000 subgroups related to medicinal plants, far surpassing the limited subgroups available in the International Patent Classification (IPC). The TKDL software, along with its corresponding classification scheme, facilitates the translation of text across various local languages. Notably, the program employs a knowledge-driven translation approach using Unicode and metadata to abstract data and translate it into multiple languages. It also modernizes old names into their contemporary equivalents; for instance, "Jwar" becomes "fever," "Curcuma longa" becomes "turmeric," and "Mussorika" becomes "smallpox."

Through the use of "IPC codes and keywords" in several languages, the TKDL's search interface enables the full-text retrieval of conventional knowledge data. Acting as a bridge between local language formulations and international patent examiners, TKDL provides information on current and regional names in a manner comprehensible to them. This project significantly contributes to the protection and preservation of traditional knowledge, addressing challenges in establishing prior art.

“The Traditional Knowledge Digital Library (TKDL) serves as an instrument for preventing the exploitation of traditional knowledge, covering Indian medical traditions like Yoga, Unani, Siddha, and Ayurveda.” The process of documenting this involves selecting and compiling traditional knowledge data from literature written in regional languages such as Sanskrit, Urdu, Arabic, Persian, and Tamil. This information is made readily accessible in five international languages: German, English, French, Spanish, and Japanese, and is digitized for ease of access.

“The Traditional Knowledge Resource Classification (TKRC) is an innovative structured classification system designed to facilitate systematic organization, distribution, and retrieval of information.” It was developed for approximately 5,000 subgroups related to medicinal

plants, contrasting with the International Patent Classification (IPC), which offers a limited number of subgroups.

The TKDL program, along with its associated classification system (TKRC), enables the translation of text from local languages into several languages. This software, not being a 'transliteration tool but-rather a knowledge-based translation tool, translates data abstracted once into several languages using Unicode and metadata.' Additionally, it can convert obsolete terminology into more contemporary terms, like interpreting Jwar as fever, Curcuma longa as turmeric, and Mussorika as smallpox. Full-text traditional knowledge information concerning "IPC and keywords" can be retrieved in multiple languages using the search interface within the Traditional Knowledge Data Library (TKDL).

As the database contains information in a format and language understandable by Patent Examiners, 'TKDL acts as a bridge between formulations existing in local dialects' and the "Patent Examiner" on a global scale. It is anticipated that this will help resolve the gap in accessing existing traditional knowledge.

I. EXAMPLES OF TRADITIONAL KNOWLEDGE BIO-PIRACY

A. **Turmeric (Curcuma longa Linn)[4],** a common rhizome used to enhance the flavor in Indian cuisine, has a history of being used for centuries to treat burns and rashes, in addition to its culinary benefits. In 1995, Indian expats Suman K. Das and Hari Har P. Cohly from the "University of Mississippi Medical Center were granted US patent No. 5,401,504 for utilizing turmeric in wound treatment." The Council of Scientific & Industrial Research (CSIR) from India, headquartered in New Delhi, challenged this patent during re-examination, citing prior art to question the invention's novelty. CSIR argued that turmeric had been used for millennia in traditional Indian medicine to heal rashes and wounds, thus its medical application was not novel. To support their argument, CSIR provided documentary evidence such as an old Sanskrit text and a 1953 Journal of the Indian Medical Association article, demonstrating the longstanding understanding of turmeric's therapeutic benefits. Despite appeals from the patent holders, the US Patent and Trademark Office (US PTO) upheld CSIR's concerns and invalidated the patent in 1997. This case was a landmark, showcasing the importance of acknowledging and defending indigenous knowledge by successfully challenging a patent based on traditional knowledge from a developing nation.[5]

B. **Neem seed oil[6],** known for its therapeutic properties including treating colds, preventing pests in crops, and addressing various ailments, was at the center of a patent dispute. "In 1994, the European Patent Office (EPO) granted a patent (EPO patent No. 436257) to the US Department of Agriculture and W. R. Grace Company for using neem oil to control plant fungus." However, international NGOs and attorneys defending Indian farmers contested this patent in 1995, demonstrating that neem's fungicidal properties were well-established and used in Indian agriculture, making them ineligible for patenting. The EPO revoked the neem patent in May 2000 based on the lack of an innovative step, despite subsequent appeals from the patent holders in 2001 and 2006. This legal battle underscored the importance of safeguarding

[4] Turmeric Case (Judgement) [1997] U.S. Patent No. 5401,504.

[5] Prof. S. C Santra, Biopiracy, 19 ENVIS Centre on Environmental Biotechnology, 1, 7 (2011), available at http://deskuenvis.nic.in/pdf/Newslet19.pdf

[6] Neem Patent Case (Judgement) [2000] E.P.O. Patent No. 436257.

traditional knowledge and opposing the unjust patenting of natural resources and indigenous practices.

C. In a related case involving **basmati rice**[7], Rice Tec sought to register "Texmati" for Oryza sativa Linn. at the 'United Kingdom Trade Mark Registry, which was successfully opposed by the Agricultural and Processed Food Exports Development Authority (APEDA).' Subsequently, on September 2, 1997, Rice Tec was granted a US utility patent for a rice plant with characteristics akin to Indian traditional Basmati rice lines, including coverage of certain geographical areas. However, a re-examination request in April 2000 led Rice Tec to withdraw specific claims from its patent application.

D. The kava case highlights biopiracy concerns surrounding kava, scientifically known as "**Piper methysticum Forster**," a significant cash crop in the Pacific region renowned for its use in the ceremonial kava drink. Originating in Vanuatu and Fiji thousands of years ago, kava is cultivated in over a hundred varieties. It is now sold in North America and Europe for various purposes. L'Oreal, a French corporation with annual sales of $10 billion, has patented kava for preventing hair loss and promoting hair growth.

E. **The Ayahuasca case** involves Native American tribes in the 'Amazon basin processing the bark of Banisteriopsis caapi Mort to create Ayahuasca, a ceremonial drink known as the wine of the soul, used by shamans for religious, medicinal, and divination purposes.' In 1986, American Loren Miller was granted a "US Plant Patent (No. 5,751)" for Ayahuasca. The US Patent and Trademark Office (USPTO) revoked the patent on November 3, 1999, following concerns raised by the "Coordinating Body of Indigenous Organizations of the Amazon Basin (COICA) and other groups against the unjust patenting of a plant species." However, on April 17, 2001, the inventor successfully reinstated the patent rights. These cases raise concerns about the unfairness and immorality of exploiting native genetic resources for patented products, risking the survival of indigenous civilizations. Moreover, restrictions on indigenous communities' use or export of their biological resources and traditional knowledge further endanger traditional wisdom. Preserving traditional knowledge, especially recognizing the legal rights of India's aboriginal and indigenous communities rich in traditional knowledge, is crucial. These communities should receive recognition and compensation for their contributions, often safeguarding ecological diversity through sustainable practices. Raising awareness about the challenges of protecting and preserving this invaluable knowledge is essential, given the general lack of understanding about traditional wisdom.

I. The patent dispute between Haldi and Turmeric raised serious issues with biopiracy. The US Patent Office granted a patent to two Non-Resident Indians (NRIs) working at the 'University of Mississippi Medical Center in 1995' for turmeric, also known as haldi, which has been used for millennia in Indian traditional medicine. Biopiracy allegations against this patent were bolstered by evidence of traditional knowledge (TK), which included old manuscripts and a '1953 Journal of the Medical Association article.' The case was recognized as biopiracy by the United States Patent Office, which invalidated the patent's validity and accepted the objections

[7] India-US Basmati Rice dispute, [2001], U.S. Patent No 5663484 A.

made by ICAR and CSIR. This court case established a standard for handling biopiracy concerns.[8]

II. The US obtaining a neem patent caused a stir in the Neem controversy. The utility of neem was first recognized in 1971, when an American timber importer started bringing seedling for the W.R. Grace Company. Three parties, namely 'Aelvoet, Vandhana Shiva, and the International Federation of Organic Agriculture Movements (IFOAM),' filed a lawsuit opposing this patent. Based on information acquired in 1999, the European Patent Office (EPO) finally revoked the patent in May 2000. 'The US Department of Agriculture and W.R. Grace' filed a petition in 2001, but the EPO ruled in March 2006 that the patent was totally void. Since the patent covered a traditional technique that had been around for a while in India and lacked novelty in accordance with patent laws, it was considered to be biopiracy.[9]

III. A disagreement arose between India and the US in 1997 over an American patent on "Basmati rice Lines and grains," that was secured by Rice Tec. Inc., a Texas-based corporation. The TRIPS agreement prevents Geographical Indication (GI) items, such as Basmati rice, from being patented, which is why this patent grant created controversy. According to the Indian government, more than 90% of the world's Basmati germplasm is found in India, and the US Patent Office has awarded numerous patents for rice varieties that bear Indian Basmati rice characteristics. In 2008, India asked for the patent grant to be reexamined in order to resolve this issue. In response to that request, Rice Tec withdrew claims 15–217 and 4. Farmers viewed this action as a huge win because it kept their traditional knowledge intact and avoided possible financial losses from the patent grant.[10]

IV. A patent application was submitted in February 2011 by Pangaea Labs Ltd., a UK-based company, regarding a "Hair Building Solid agent." After examination, it was discovered that the hair styling spray contained extracts of turmeric, pine bark, and green tea—ingredients that are typically used in Ayurvedic and Unani medicine to treat hair issues. According to the Council of Scientific and Industrial Research, India has been using this recipe from ancient times. The Traditional Knowledge Digital Library (CSIR-TKDL) contested the patent application in 2014, claiming that the blend was originally from India. June 2015 saw the voluntary withdrawal of the application after it was reviewed and then faced opposition.[11]

V. In 2010, the Colgate-Palmolive Company[12] submitted a patent application for the use of myristica, or Indian nutmeg, in toothpaste and mouthwash recipes for dental care. Nonetheless, nutmeg has long been utilized traditionally for medicinal purposes. The company's concept was to make oral care products by simply combining nutmeg extract with different ingredients. The European Patent Office was contacted in August 2014 by CSIR-TKDL (Traditional Knowledge Digital Library) to review the claim. They provided proof of the historic usage of nutmeg in the treatment of dental problems, gum blisters, and bad breath. According to an

[8] Prof. S. C Santra, Biopiracy, 19 ENVIS Centre on Environmental Biotechnology, 1, 7 (2011), available at http://deskuenvis.nic.in/pdf/Newslet19.pdf

[9] Ibid, at 8.

[10] Ibid, at 9.

[11] India foils UK Company's Bid to patent use of turmeric, pink bark and tea, AIR WORLD SERVICE http://www.tkdl.res.in/tkdl/PressCoverage/image/Airworldservices_03082015.jpg.

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

examination published in October 2014, there was not much originality or ingenuity in the invention. Consequently, by June 2015, the Colgate-Palmolive Company has withdrawn the patent proposal.

VI. In a case brought 'before the Chief Judicial Magistrate in Darjeeling,' two citizens of the Czech Republic[13] were accused of unlawfully gathering insects in Singhalila National Park in West Bengal. They were found guilty on September 8, 2008, of failing to seek prior authorization from the National Biodiversity Authority (NBA) in violation of Sections 19 and 3 of the Act on Biological Diversity (BD Act). They stated that they would only use the materials they collected for research and not for profit. They were also found guilty of trespassing into forested regions in violation of Sections 29 and 27 of 'Wildlife Protection Act of 1972.' The NBA made clear who has the authority to deal with BD Act infractions after this case. S.O. 2708(E), published November 17, 2008, empowered "regional NBA officials, State Biodiversity Boards (SBBs), and the Ministry of Environment (ranked no lower than Scientist "C") to enforce acts." In addition, as of January 12, 2009, forest officials who hold a position higher than Range Officer are authorized to file complaints under 'the Biodiversity Act.'

VII. After being detained in Kerala, a state in southern India, 2 Japanese nationals were charged with violating the Act on Biological Diversity (BD Act) of 2002. They were charged with taking reptiles from the Athirapally forest in Kerala without first getting the National Biodiversity Authority's (NBA) approval. The trials for the the accused involved an application to both the 'Wildlife Protection Act of 1995 and the Biological Diversity Act, 2002,' after a complaint filed by the the Kerala state Forest Department in the month of July 2015.[14]

VIII. The Environment Support Group petitioned the Karnataka High Court in a 'Public Interest Litigation (W.P. No. 41532/2012)' to compel regulatory agencies to handle biopiracy concerns, bolster regulatory processes, and guarantee Biological Diversity Act compliance. “The National Biodiversity Authority (NBA) with the Karnataka State Biodiversity Board (KBB) then filed a criminal charge in the Bt Brinjal biopiracy case following the involvement of the High Court.” The complaint was filed on November 24, 2012, in spite of the Karnataka Government's attempts to stop the criminal case from being filed by moving officers. Until the criminal investigation was started, Mr. K. S. Sugara, IFS, the Member Secretary of KBB at the time, refused to fire the officers who filed the complaint. 'On October 11, Justice Mr. A. S. Pachhapure of the Karnataka High Court' denied petitions attempting to stop the criminal prosecution of M/s Mahyco/Monsanto, M/s Sathguru, and senior representatives of the University of Agricultural Sciences, Dharwar (UAS). The NBA and KBB accused them of engaging in biopiracy by marketing Bt Brinjal, the nation's first genetically modified produce. Among the applications that were dismissed were those from UAS representatives and Dr. S. A. Patil, the former vice-chancellor who was also the director of the Indian Agricultural Research Institute in New Delhi and the chairman of the Karnataka Krishi Mission. They were accountable. A major change in the legal landscape of India concerning biopiracy has occurred with the National Biodiversity Authority's (NBA) decision to prosecute foreign entities and

[13] Czech Scientists Case, COUNTERVIEW https://counterview1.files.wordpress.com/2016/12/bd-litigating-report-final-5-12-2016.pdf .

[14] P.V. Shyam, Japanese Duo sentenced to one year imprisonment in Kerala for smuggling reptiles, TIMES OF INDIA https://m.timesofindia.com/city/kochi/japanese-duo-sentenced-to-one-year-imprisonmentin-kerela-for-smuggling-reptiles/articleshow/50049251.cms.

their Indian accomplices engaged in the illegal activity. This ruling makes it clear that biopiracy operations could result in legal repercussions in the nation. Future developments will provide light on the results of this new legislative initiative and what may be anticipated in terms of tackling and avoiding biopiracy in India.[15]

IX. A U.S. corporation unjustly filed a patent for Brahmi, which an Ayurveda medicinal herb with strong cultural ties to India, in the Brahmi Patents Biopiracy Case. The exploitation of native resources, biopiracy, and the commercial theft of traditional knowledge were among the issues brought up by this. India disputed the patent's validity, arguing that it was not novel because Brahmi is used in traditional ways. The complexity of rights to intellectual property in relation to indigenous knowledge and the preservation of biodiversity was brought to light by this case. After protracted court cases and arguments, the Brahmi patent ultimately was withdrawn.

X. The case of Rooibos Patent Biopiracy concerned the unapproved patenting of Rooibos, a native plant of South Africa that has been traditionally used by nearby populations, by a Japanese corporation. Significant issues about biopiracy, the exploitation of native resources, and the necessity of fair benefit-sharing were brought up by this case. Rooibos was widely used in conventional medicine and was being sold without the right license, according to South Africa, which challenged the patent. This case shed light on the complicated issues involving biodiversity and intellectual property rights, especially in cross-border settings. This Rooibos patent was deemed void after protracted legal actions and widespread worldwide scrutiny for lacking innovative step and failing to adequately acknowledge traditional knowledge.

The aforementioned incidents highlight how important it is to preserve indigenous knowledge, protect cultural heritage, and make sure that the advantages of natural resources are distributed fairly. It established a standard for handling biopiracy issues globally.

The following are the main arguments against biopiracy:

- Inequitable, Illegal, and Endangering Indigenous Cultures: The exploitation of indigenous cultures' knowledge and resources without their consent or fair compensation has been accused of being unethical and unjust, endangering their survival.
- Indigenous Genetic Resource Patents: Products derived from traditional genetic resources are often patented by businesses, leading to the deprivation of control and financial benefits for these groups over their own resources and knowledge.
- Prohibition on Use and Export: Indigenous peoples frequently face restrictions on using or exporting their biological resources and traditional knowledge, resulting in the loss of their indigenous knowledge and valuable cultural assets.

The need for the protection of traditional knowledge is emphasized:

- Immediate Legal Acknowledgement of Indigenous Rights: Given that traditional knowledge is primarily held by India's tribal and indigenous peoples, there is a critical need for their rights to be officially acknowledged.
- Recognition and Recompense for Conservation Efforts: Native and tribal communities that contribute sustainably to biodiversity conservation should be acknowledged and compensated for their significant role.

[15] Environment Support Group & Another versus NBA amd Others, INDIAN ENVIRONMENTAL PORTAL http://www.indiaenvironmentportal.org.in/files/file/esg-pil-biopiracy-hc-karnataka.pdf.

- Public Education about Traditional Wisdom: Education campaigns are urgently required to raise awareness about these issues and highlight the contributions made by indigenous and tribal cultures, as there is a lack of public knowledge regarding traditional wisdom.

II. WORLDWIDE PROTECTION AGAINST BIOPIRACY ICESCR

Worldwide protection against biopiracy is being addressed by various global organizations, with the International Covenant on Economic, Social, and Cultural Rights (ICESCR) standing out as a significant example.[16]

Enacted by the United Nations General Assembly (UNGA) on December 16, 1996, the ICESCR is a global agreement aimed at curbing biopiracy and the trade of its derivatives. Article 1[17] of the Covenant imposes a duty on individuals to conserve natural resources while emphasizing people's rights to utilize and manage these resources. It also ensures that everyone has access to means of sustenance.[18]

Furthermore, Article 15 of the Covenant affirms every State Party's right to benefit from scientific discoveries and their applications, acknowledging the private rights of investors. Article 15(c) specifically recognizes the material and moral interests of indigenous communities, highlighting the international community's commitment to balancing technological progress with cultural heritage conservation.[19]

The guiding principles of the Convention on Biological Diversity (CBD) stress the importance of community involvement, particularly highlighting women's contributions to biodiversity conservation. The preference for in-situ conservation methods, which prioritize local conservation efforts over ex-situ techniques like gene bank conservation, is emphasized for its sustainability. Comprehensive strategies and initiatives are deemed necessary to support the sustainable use and preservation of biological resources.

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 came into effect on December 29, 1993.[20] The protection of biodiversity worldwide was sought through a middle ground between the goals of different developing and developed countries. Additionally, a fresh method for managing genetic resources was offered by the CBD. It has been approved by 196 parties as of now, and it was available for signing at UNCED (the Earth Summit on June 5, 1992). Remarkably, due to its withdrawal from the CBD, the USA is no longer acknowledged as a party. One of the Convention's main goals was promoting sustainable development, and its tenets were consistent with other accords reached during the Rio Summit.

[16] ibid.
[17] ibid.
[18] ibid.
[19] ibid.
[20] 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.

Changes within the Convention on Biological Diversity (CBD) have been pushed for by developing nations to create a fairer framework for sharing benefits from the exploitation of genetic resources. “The equitable sharing of profits from the commercial use of biological and genetic resources is one of the main arguments made against the CBD.” A cornerstone of international law is preserved by the CBD, stating that national governments have the sole right to control access to genetic resources, and states retain national sovereignty over these resources. According to the 15th article of the Convention, prior consent must be given by the contracting parties before accessing genetic resources.[21]

Laws or other policies shall also be adopted by contracting parties to guarantee a fair and reasonable allocation of research advantages and commercial revenue resulting from the use of genetic resources. 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 industrialized and less developed nations resulting 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.[22] 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.

Here are the key CBD principles:

Historically, community involvement—especially that of women—has been considered essential in promoting biodiversity.

- In contrast to ex-situ conservation techniques like gene bank preservation, in-situ conservation—which emphasizes local conservation initiatives—is considered to be more ecologically sustainable.

- Policies and programs supporting the preservation and sustainable use of biological resources must be implemented.

CHANGES AND DEVELOPMENTS MADE UNDER CBD

The Bonn Guidelines[23]

The guidelines adopted in April 2002 aimed to address issues related to prior consent, fair and just distribution of benefits, "mutually advantageous arrangements, access and benefit-sharing

[21] HANDBOOK OF THE CONVENTION ON BIOLOGICAL DIVERSITY INCLUDING CARTEGANA PROTOCOL ON BIOSAFETY, (3rd ed., 2005).

[22] Fair and equal distribution of the knowledge obtained from the gains.

[23] Bonn Guidelines, (2005), UNCBD https://www.cbd.int/doc /cbd-bonn-gdls-en.pdf.

arrangements," transfer of technology to developing countries, education regarding access and benefit-sharing, and the preservation of customary laws of indigenous peoples. These guidelines, except for human genetic resources, fall under the purview of the CBD and benefit from their economic utilization.[24]

According to the Bonn Guidelines, access to genetic resources necessitates prior informed consent, which must be linked to a specific use.[25] Contracts must include provisions concerning intellectual property rights, such as obligations for collaborative research, the application of rights to inventions, and the granting of collaborative licenses. Countries are encouraged to establish policies for disclosing the nation of origin of genetic resources and customary practices from local communities in Intellectual Property Rights (IPR) applications.[26] The purpose of these disclosures is to aid in revoking patents based on traditional knowledge and rectifying improper patent grants.[27]

The Nagoya Protocol: Reinforcing Legal Frameworks for Fair Benefit Distribution and Resource Availability

The Nagoya Protocol serves as an additional legal framework to the United Nations Convention on Biological Diversity (CBD) treaty, aiming to ensure just and equitable benefit sharing. It specifically regulates 'the access and utilization of genetic resources and associated traditional knowledge.'[28]

The fifth article of the Nagoya Protocol promotes fair and equitable treatment concerning benefit sharing with indigenous communities or entities providing genetic resources. It empowers State Parties to enact legislation or establish administrative rules to ensure fair resource allocation. Additionally, the protocol aligns with the third objective of the CBD, which is benefit sharing.

'Under Article 8 of the Nagoya Protocol, research projects that contribute to the conservation and sustainable use of biological resources in underdeveloped nations are encouraged.' Parties using these resources must consider potential domestic or international emergencies that could endanger human, animal, or plant health. The Nagoya Protocol mandates the establishment of focal points to facilitate information sharing for parties seeking access to genetic resources or associated knowledge. Article 13 outlines the creation of national authorities on benefit sharing and access, responsible for approving resource access requests and providing documentation confirming compliance with access regulations.

[24] Ibid.
[25] Ibid.
[26] Ibid.
[27] Ibid.
[28] 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

The protocol emphasizes a 'Global Multilateral Benefit-Sharing System,' promoting international collaboration and respect for national benefit-sharing and access laws.[29] It also enhances compliance and transparency by integrating with the CBD's clearinghouse mechanism, as specified in Article 18.[30] Enforceable commitments are imposed on states that ratify or accede to the Nagoya Protocol, underscoring the protocol's pivotal role in promoting fair and equitable utilization of resources and benefit sharing on a global scale.

The International Treaty of Plant Genetic Resources for Agriculture and Food[31]

"The conservation and sustainable utilization of plant genetic resources for food and agriculture, along with the assurance of fair benefits from their utilization, are governed by the provisions of the International Treaty on Plant Genetic Resources for Food and Agriculture (IT PGRFA)." This treaty, which adheres to the principles of 'the Convention on Biological Diversity (CBD),' was accepted by 40 countries and subsequently approved and ratified by the FAO Conference in November 2001, coming into effect in 2004. Currently, the treaty has been signed by 146 parties.

Some important clauses of the agreement include:

- Local people and farmers were encouraged and aided in protecting 'plant genetic resources for food and farming, especially untamed plants growing in their native environments' (Article 5).
- The need for sustainable utilization of genetic resources from plants was highlighted in Article 6, along with the support of research programs aiming to conserve biodiversity and maintain soil fertility through ecological principles.
- The rights of farmers, including their ability to maintain customary knowledge and participate in decisions concerning the preservation and sustainable utilization of genetic resources of plants, were acknowledged and defended (Article 9).
- States' sovereign rights over genetic material from plants were preserved, and a global framework for their access was created to ensure fair and equal distribution of benefits from their use (Article 10).
- Access to plant genetic materials for food and agricultural conservation, breeding, and research purposes was limited, with access for non-food or commercial objectives being outlawed. The beneficiaries of the international system were not allowed to impose any limits on access to these resources, including intellectual property rights.
- The overall goals of the IT PGRFA treaty were to support farmers, preserve traditional knowledge, and provide responsible access to these essential resources while also encouraging the conservation, sustainable utilization, and fair sharing of benefits obtained from the genetic resources of plants for food and agriculture.

Other initiatives-

[29] Ibid.
[30] Ibid.
[31] International Treaty on Plant Genetic Resources for Food and Agriculture

TRIPS[32]

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

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

Before the TRIPS Agreement, there was no global standard for an invention's patentability. Nevertheless, the 27th article of this agreement set a worldwide minimum criterion for the patenting of all inventions. In addition to requiring member states to safeguard genetic resource ownership, patents on inventions related to goods or processes that can be used in the 'industrial sector' were permitted under Article 27 of the TRIPS Agreement, with some biological processes being exempted under Article 27(3)(b).[33]

Under Article 27(3)(b), it is within the discretion of member states to decide whether patents should be granted on biological products or processes, such as microbes, plants, animals, and biological processes. To preserve plant species, they must either establish an efficient sui generis system, a patent structure, or a combination of both.

The TRIPS Agreement outlines the fundamental conditions for intellectual property protection, which include a 20-year protection period and the procedures IPR owners must follow when defending their rights in administrative or civil courts. Member nations have the option to enhance IPR enforcement by establishing specialized courts for IPR cases, even though it is not mandatory to do so.

The Intergovernmental Committee on Traditional Knowledge (TK), Folklore, and Intellectual Property (IP) and Genetic Resources[34]

WIPO, with 192 member states, is seen as a specialized organization of the UN that plays a vital role in assisting member states in the creation and promotion of harmonization in the field of intellectual property rights (IPR) law. "The Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore (IGC) was established by WIPO in 2000, aiming at preventing biopiracy, defending traditional knowledge and

[32] Lorna Dwyer, Biopiracy, Trade and Sustainable Development, Col. Jou. Int. Envr. Law & Policy, 220, 238 (2008). 24 Ibid
[33] Ibid.
[34] Lorna Dwyer, Biopiracy, Trade and Sustainable Development, Colorado Journal of International Environmental Law and Policy

folklore, and advancing the preservation of biodiversity.[35]" The IGC serves as a forum for debating issues related to biodiversity, proposing solutions, encouraging technical developments such as TK publications and records, endorsing the preservation of TK, and advocating for the use of patent laws to preserve genetic resources and traditional knowledge. Additionally, the dissemination of traditional wisdom in TK publications and journals is promoted by the committee, which also seeks to enhance cooperation across patent offices.[36]

Examining and contrasting-TRIPS and CBD[37]

In the early 1990s, it was acknowledged by the international community that the industrial system posed threats to the environment and endangered the rights and knowledge of indigenous inhabitants, crucial for maintaining biological abundance. This realization led to the establishment of the Convention on Biological Diversity (CBD) by the United Nations in 1993, aimed at addressing these concerns and safeguarding biological resources. Around the same time, the 'World Trade Organization (WTO) developed the Trade-Related Aspects of Intellectual Property (TRIPS) Agreement, specifically focused on regulating the global trade framework.'

While the CBD prioritized the rights of local populations to benefit from biological resources and worked on preserving biodiversity with fair benefit sharing, TRIPS placed more emphasis on protecting intellectual property rights (IPR) for "commercial interests." Despite their differing objectives, both agreements impose legally binding obligations on countries.

The most contentious issues revolve around the "areas of interest" and the interaction between CBD and TRIPS. While TRIPS views IPR protection as a means to an end, CBD sees IPR as a tool for biodiversity protection and equitable benefit sharing. TRIPS has faced criticism for allegedly not doing enough to protect biodiversity. Although the standards set by CBD are not legally enforceable, TRIPS' provisions are enforced by the WTO. Some nations argue that there is no conflict between TRIPS and CBD, while others believe that understanding CBD's objectives requires an understanding of TRIPS' Articles 7 and 8, which focus on welfare enhancement.

- A comparison of the Convention on Biological Diversity (CBD) and the Trade-Related Aspects of Intellectual Property Rights (TRIPS) reveals several significant differences and points of conflict between the two international agreements.
- In terms of competing goals, the Convention on Biological Diversity (CBD) emphasizes transferring technology from developed nations to developing ones and granting more authority to developing countries over their natural resources. Its goal is to enhance these countries' abilities to utilize and conserve biological resources sustainably. On the other hand, the Trade-Related Aspects of Intellectual Property Rights (TRIPS) focuses on

[35] id, at 244
[36] id, at 245
[37] TRIPS versus CBD, GAIA, available at https://www.grain.org/article/entries/20-trips-versus-cbd

providing corporate entities with intellectual property rights to protect commercial interests globally.[38]

- Regarding their origins, the CBD was established to restrict access to and utilization of biological resources while preserving biodiversity. In contrast, TRIPS was designed to benefit private companies and has economic objectives.
- Concerning national sovereignty over resources, the CBD empowers nations to manage and exploit biological resources while maintaining sovereignty over them. However, TRIPS undermines national sovereignty by allowing the patenting of biological materials in countries other than their country of origin.[39]
- Regarding benefit-sharing requirements, the CBD emphasizes benefit-sharing from the economic exploitation of biological resources as a measure to prevent biopiracy. TRIPS lacks such benefit-sharing clauses, which could potentially encourage biopiracy.
- In terms of enforceability, the CBD focuses on objectives and goals without globally enforceable rights, lacking legal authority for enforcement.[40] In contrast, TRIPS requires member governments to establish procedures to protect the interests of intellectual property rights (IPR) holders and enforce IPR rights in civil courts. [41]
- Regarding the requirement for previous consent, the CBD mandates collectors of biological assets to obtain prior informed consent to ensure transparency and community involvement. Conversely, TRIPS does not have such prior consent requirements, which could lead to the improper use of biological assets.[42]
- In terms of individual rights and community rights, the Convention on Biological Diversity (CBD) recognizes the significance of community knowledge [43] and places a strong emphasis on protecting traditional knowledge and communal rights.[44] On the other hand, the Trade-Related Aspects of Intellectual Property Rights (TRIPS) acknowledges intellectual property rights as private property rights, which can sometimes hinder the free flow of customary knowledge and communal rights.

In summary, TRIPS focuses on protecting intellectual property rights and benefits for private enterprises, while CBD aims to safeguard biological resources and empower local communities. To align more closely with the goals of the CBD, TRIPS should acknowledge and respect community rights and autonomy over natural resources, legally protect traditional knowledge, and include provisions for benefit-sharing and prior consent. This approach could help alleviate tensions between the two agreements and promote a more harmonious relationship.

[38] TRIPS versus CBD, GAIA, https://www.grain.org/article/entries/20-trips-versus-cbd
[39] UNCBD, Art 15.
[40] Cynthia M. Ho, Biopiracy And Beyond: A Consideration Of Socio-Cultural Conflicts With Global Patent Policies
[41] Supra, 43.
[42] Supra, 45, Art. 15(4).
[43] Supra 45, UNCBD Art. 8(j).
[44] Marcia Ellen DGeer, Biopiracy: The Appropriation of Indigenous Peoples' Cultural Knowledge Law https//: heinonline.org/HOL/Page?public=true&handle=hein. journals/newenjic9&div=11&start_page=179&collection=journals&set_ _cursor=0&men_tab=srchresults.

The main clauses that TRIPS might have contained to lessen conflict between CBD and the TRIPS Agreement were:

Sovereignty of the State:

The state's sovereign authority over biological assets was to be clearly acknowledged in TRIPS, aligning it with CBD's objectives and preventing disputes over national sovereignty.

Legal Defense of Customary Knowledge:

Traditional knowledge was to be legally protected within TRIPS, addressing issues related to biopiracy and misuse while upholding traditional knowledge within the framework of intellectual property rights.

Prioritizing the Rights of Communities:

TRIPS clauses were to emphasize and recognize the rights of communities to their resources, highlighting the importance of community involvement and knowledge in sustainable resource utilization.

Benefit-sharing and Prior Consent:

Guidelines for benefit-sharing and prior informed consent were proposed to be included in TRIPS, aligning it with CBD's goals of transparency, community inclusion, and fair distribution of benefits from commercial exploitation of biological resources.

By incorporating these clauses into TRIPS, the agreement would have been better positioned to support CBD's objectives, reduce conflicts, and promote cooperation in addressing issues related to biological resources, traditional knowledge, and intellectual property rights.

III. INDIAN LEGISLATIONS / INITIATIVES FOR PROTECTION AGAINST BIOPIRACY

India has put in place several significant laws aimed at combating biopiracy and safeguarding biodiversity. Key legislation concerning the conservation and responsible utilization of biological assets, either directly or indirectly, includes the following:[45]

The 2001 Protection of Plant Varieties and Farmers' Rights Act:[46]

'The Protection of Plant Varieties and Farmer's Rights Act, 2001,' was established by the Indian government with the following objectives: safeguarding farmers' rights concerning plant varieties, promoting the development and utilization of new plant varieties, and ensuring fair compensation for farmers' contributions to plant genetic material.

This Act, in accordance with 'Article 27(3)(b) of the TRIPS Agreement, established the Protection of Plant Varieties and Farmer's Rights Authority to oversee its implementation.' The Act aims to:

- Foster new plant variety research initiatives in both public and private sectors.
- Facilitate the domestic and international growth of seed enterprises, ensuring Indian farmers' access to high-quality seeds and planting materials.

[45] K. Venkataraman, Intellectual Property Rights, Traditional Knowledge and Biodiversity of India, 13 Jou. Intel. Prop. Rhts., 326, 331 (2008).

[46] ibid.

- Uphold farmers' rights regarding new plant varieties and acknowledge and preserve the contributions made by farmers, local communities, and indigenous cultures to the country's agricultural biodiversity.

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

I. Section 26 of the Act addresses benefit sharing arising from the use of genetic resources from plants. However, participation in benefit sharing is not mandatory for breeders and farmers, and the Act does not cover farmers' prior authorization for commercial use of their genetic material or traditional knowledge.[47]

II. The Act acknowledges the rights of farmers, researchers, and breeders. Breeders have exclusive authority to develop, market, and distribute protected varieties. If their rights are violated, breeders can file a lawsuit in the appropriate district court under Section 65 of the Act.[48]

III. Chapter IV of the Act recognizes farmers' rights. Section 39[49] allows a farmer who has developed a new variety to register it, granting the farmer the same protection as the breeder. The Gene Fund[50] compensates farmers for protecting landraces, domesticated plants, and genetic resources of animals.

IV. Researchers' rights are addressed in Section 30[51] of the Act, allowing them to conduct research using registered variations and create new varieties based on existing ones with the breeder's approval for repeated use of the same variety.[52]

V. The Act acknowledges the rights of local communities. Under Section 41, any individual, NGO, or governmental body can claim on behalf of a local group's contribution to developing a variety. After verification, the authorities inform the breeder, who has an opportunity to voice concerns and receive compensation as per the claims made on behalf of a town or village.[53]

Biological Diversity Act (2002):[54]

'The Biological Diversity Act was enacted 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 TKDL, although not a legal requirement, is an important project that records traditional knowledge about medicinal plants and formulations. By granting patent examiners access to a database, the likelihood of misappropriation of traditional knowledge is reduced, and patents for recognized traditional knowledge are prevented from being granted.

[47] The Protection of Plant Varieties and Farmer's Rights Act, 2001, No. 53 of 2001, Acts of Parliament (India), S. 26.
[48] id., S. 65.
[49] id., S. 39.
[50] id., S. 39 (1) (iii).
[51] id., S. 30.
[52] id., S.30 (b).
[53] id., S. 41.
[54] Biodiversity Act 2002, No. 18 of 2003, Acts of Parliament (India).

India fulfilled its obligations under the UN Convention on Biological Diversity (CBD), ratified in 1992, by enacting the Biological Diversity Act in 2002. The Act aims to safeguard biological and genetic resources and ensure equitable sharing of profits from their commercial exploitation. It was passed following ten years of discussions and addresses issues related to access to biological and genetic resources by corporations, individuals, and organizations, applying to the entirety of India including the state of Jammu and Kashmir.

Key features of the Biological Diversity Act of 2002 include:

1. Emphasis on equitable benefit-sharing, sustainable use, and conservation of biological resources in line with CBD objectives.
2. Protection of indigenous knowledge regarding biodiversity and recognition of nations' sovereign control over their biological resources.
3. Focus on fair distribution of financial benefits derived from the utilization of genetic or biological resources.

"The Act also mandates the establishment of the following procedures and structures by local, state, and municipal governments: The National Biodiversity Authority (NBA), Committees for the Management of Biodiversity (BMCs), State Biodiversity Boards (SBBs)."[55]

The NBA, or National Biodiversity Authority

'The National Biodiversity Authority (NBA) was established by the Central Government of India in accordance with the third chapter of the Biological Diversity Act, 2002.' It possesses all the characteristics of a company and functions as a body corporate.[56] Formed in 2003, the NBA is tasked with implementing the provisions of the Biological Diversity Act, 2002. Its primary role is advisory, particularly in advising the Central Government on matters concerning the conservation of ecological assets and their sustainable utilization.[57]

1. The NBA creates committees to address issues related to agrobiodiversity.[58]

2. It regulates "access to biological materials" by requiring prior permission before their use for research or commercial purposes.[59]

3. The NBA provides guidance to both state and federal governments on the protection of biological resources, sustainable utilization, and equitable distribution of benefits.[60]

Biodiversity state boards (SBB)

[55] Supra, 50.
[56] 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.
[57] About National Biodiversity Authority, NBA INDIA http://nbaindia.org/content/22/2/1/aboutnba.html.
[58] Supra 59, S. 13
[59] Supra, 59, S.18 (1).
[60] Supra, 59, S. 18 (3).

The fourth chapter of the 2002 Biological Diversity Act mandates State Governments to establish State Biodiversity Boards (SBBs). However, in Union Territories,[61] the National Biodiversity Authority (NBA) holds relevant authority. Similar to the NBA, SBBs undertake similar responsibilities, including advising the state government on matters related to the conservation of biological resources.

Committees for Biodiversity Management (BMCs)

"Committees for managing biodiversity (BMCs) are established by local self-government under the provisions of Chapter XI of the Act on Biological Diversity, 2002, with the purpose of safeguarding and preserving biological resources. Assistance from the National Biodiversity Board has facilitated the establishment of '1,55,868 BMCs at the local level as well as State Biodiversity Boards in 28 States."[62]

Several biological resource conservation efforts were implemented by the National Biodiversity Authority (NBA), including:[63]

1. Rejection of 42 patent applications for Indian biological resources, including the Red Sanders, a vulnerable species native to India.
2. Formation of the "Expert Committee on Access and Benefit Sharing (ABS)" after receiving approximately 450 applications to review requests for prior authorization related to biological resources and traditional knowledge (TK).
3. Receipt of $12.49 crores in benefit-sharing payments in 2017, subsequently disbursed to the Tamil Nadu Biodiversity Board and the Andhra Pradesh Forest Department.
4. Provision of training courses by NBA to stakeholders aimed at enhancing their capacity in TK and IPR.
5. Assistance provided by NBA in creating 'People's Biodiversity Registers (PBRs)' and BMCs in several States for recording traditional knowledge and biodiversity.
6. Distribution of benefits and promotion of resource preservation in alignment with the BD Act of 2002, utilizing federal, state, and local funds for biodiversity conservation.
7. Collaboration between the Department of AYUSH and CSIR in India to establish the 'Traditional Knowledge Digital Library (TKDL)' focused on Indian medicine. TKDL digitally compiles traditional knowledge from traditional literature and translates it into five foreign languages in patent format for easy understanding by patent examiners. TKDL organizes data covering about 2 lakh drug formulations using the TKRC program as per the International Patent Classification. Notable examples of TKDL's successes include the 'Nutmeg Patent Case (2010)' and the 'Curcumin Pine Bark Case (2015),' where TKDL served as a preventive safeguard for India's traditional knowledge.

The 2005 Patents Amendment Act

[61] Supra, 59, S. 22.
[62] Supra, 63.
[63] ibid.

The 2005 Patents Amendment Act brought about significant changes to India's patent rules to ensure compliance with the TRIPS Agreement.[64] The main modifications included:

- Updated Definitions: The Act revised patent and invention definitions, specifying under Section 3(p)[65] that traditional knowledge, reproductions of traditional knowledge, and known characteristics of traditional elements (inventions involving TK) [66] are not considered inventions.

- Introduction of Product Patents: The amended Act introduced product patents, aligning with global norms and departing from previous rules, in accordance with TRIPS.

- Patent Opposition Procedures: Section 25(1) now includes patent opposition procedures, allowing anyone to challenge a patent's award in writing to the Controller during the application process.

- Opposition of Complete Patent Specifications: Section 25(3)(d) enables opposition to a complete patent specification for inventions that were in use in India before the claim's priority date. This provision allows contesting patents based on earlier use (prior art or prior publication) in India.

The **'Wildlife Protection Act of 1972'** was created as a legislative tool to protect and maintain species and their habitats. Its purpose is to ensure the sustainable protection of wildlife species by regulating activities related to poaching, hunting, trading, and transportation.

Similarly, the **'Forest Conservation Act**,' passed in 1980, serves as a legislative act to protect forests and wildlife. It aims to promote the sustainable utilization of forest resources by regulating activities such as deforestation, the conversion of forest lands for uses other than forests, and mining activities within forested regions.

Additionally, the **'Environmental Protection Act of 1986'** establishes an extensive legislative framework for improving and protecting the environment. It addresses a wide range of environmental issues and promotes sustainable development through strategies for pollution management, the completion of environmental impact assessments, and the preservation of natural resources.

The Biodiversity Act of 2002 was enacted for several key reasons:

Inadequate Coverage in Existing Legislation: Prior environmental laws such as 'the Indian Forest Act of 1927, the Wildlife Protection Act of 1972, and the Environment Protection Act of 1986' did not comprehensively address the protection of ecology and biodiversity. This legislative gap became more apparent with India's participation in various international

[64] Supra, 50.
[65] ibid.
[66] Traditional Knowledge Digital library, Available at http//:www.tkdl.re.in/tkdl/langdefault/Commo/Biopiracy.asp?GL=Eng.

environmental agreements, highlighting the global concern for environmental and wildlife conservation.

International Frameworks and Concerns: India's transition from a closed to an open economy in the 1990s coincided with its participation in the UN Convention on Biological Diversity. This convention provided a comprehensive framework for biodiversity protection. However, it also raised concerns about bio-piracy, necessitating stringent regulations to prevent the exploitation and theft of indigenous resources.

Development of National Strategy: A civil society organization was tasked with creating "India's National Biodiversity Strategy and Action Plan" between 2000 and 2002. However, when the government rejected this plan, a technocrat-drafted version was created instead. 'This process led to the enactment of the Biodiversity Act of 2002, which aimed to address the objectives of biodiversity preservation, sustainable utilization of biodiversity components, and equitable distribution of benefits derived from genetic materials.'[67]

The Biological Diversity Act of 2002 includes provisions that align with CBD requirements, particularly in Sections 22 and 8:[68]

1. The supervision of biodiversity management at various levels was entrusted to the "National Biodiversity Authority (NBA), State Biodiversity Boards, and Biodiversity Management Committees (BMCs)."

2. Customary knowledge about biodiversity possessed by local communities was acknowledged and conserved, ensuring that their contributions and rights were honored and safeguarded.

3. Locations were designated as heritage sites of biological diversity to preserve and establish them as crucial areas for biodiversity conservation and sustainable use.

4. The implementation of the Biological Diversity Rules, 2004, and the Biological Diversity Act of 2002 was tasked to the Biodiversity Management Committees (BMCs) at municipal, state, and federal levels, as well as the State Biological Boards (SBB) and the National Biodiversity Authority (NBA) at the national level. These authorities carried out essential duties such as:

5. Supervising, supporting, and advising the Indian government on projects aimed at conserving biodiversity, utilizing its components sustainably, and ensuring fair benefit-sharing.

6. Granting permissions in accordance with the guidelines outlined in Sections 4, 3, & 6 of the 2002 Biodiversity Act.

[67] Biodiversity Act-Bare Act https://www.indiacode.nic.in/bitstream/123456789/2046/1/200318.pdf.
[68] Biodiversity Act-Bare Act https://www.indiacode.nic.in/bitstream/123456789/2046/1/200318.pdf.

7. Undertaking additional tasks as required to fulfill the Act's requirements, such as identifying and designating areas of biodiversity significance as 'biological diversity heritage sites.'

8. Preserving the country's biodiversity and preventing the transfer of Indian biological resources' intellectual property rights to other countries or the importation of biological resources.

9. Requests concerning access to biological resources and traditional knowledge information by foreign individuals, groups, and companies were managed by the National Biodiversity Authority (NBA), including measures to prevent intellectual property piracy both within and outside India, safeguarding the local population from exploitation.

10. The establishment of a "designated National Repository (DNR)" as per the provisions of Section 39 of the Biological Diversity Act, 2002, marked a recent step toward NBA implementation. This repository, which includes preserved specimens like animals, herbarium materials (dried plant material for research), live cells, organism genomes, and information on hereditary and biological system function, played a critical role in biodiversity conservation.

The Biological Diversity Legislation of 2002 was enacted a decade after the ratification of the United Nations Convention on Biological Diversity. Despite this, certain issues persist within the law. During this period, in-depth discussions and research were undertaken by government officials, academics, and non-governmental organizations (NGOs). The passing of the Biodiversity Rules in 2004 resulted in the establishment of the Biodiversity Management Committee, empowering local and indigenous groups to express their perspectives on biodiversity preservation, utilization, and fair distribution.

Concerning the Act itself, there exists a noticeable gap where the prohibition of profit-sharing from commercial exploitation is prioritized over conservation. While one of the Act's primary objectives is to prevent wealthy countries from exploiting biological resources, it is equally crucial to emphasize the protection and conservation of biodiversity. Achieving sustainable utilization of biological resources and effective biodiversity management relies on striking a balance between these objectives.

The Constitutional Position- Article 14: Assessment of Classification's Alignment with Objectives of the Act

The Indian Constitution's Third Part delineates fundamental rights applicable to both citizens and non-citizens. Articles 21 and 14 are particularly crucial, extending to everyone irrespective of nationality. However, a review is warranted to assess whether the Biological Diversity Legislation of 2002 violates Article 14 by creating legal distinctions based on citizenship and residency status, potentially leading to unfair treatment.

Legally, there are two avenues to evaluate a law's compliance with Article 14:

The "Intelligible Differentia" criterion necessitates that the legal framework differentiate between various groups using rational and clear-cut standards.

Regarding the legal doctrine of "Intelligible Differentia," a law's classification does not automatically render it ultra vires, or beyond the scope of legal authority. However, if the classification lacks substantial differences, it may be deemed ultra vires. Both "citizenship and place of residence" serve as factors in the classification process of the relevant act. Furthermore, the legislation must establish a logical connection between the act's objectives and the classification to satisfy the "Rational Nexus" test. The act aims to ensure fair distribution of profits from genetic resources, promote equitable resource utilization, and safeguard biodiversity. Nevertheless, these objectives do not logically correlate with the classification of individuals based on their “citizenship and residency status.”

The "Rational Nexus" criterion necessitates a rational and logical relationship between the distinctions made by legislation and the objectives it aims to achieve.

In the context described, the "rational nexus test" emphasizes the need to establish a reasonable and sensible link between the goals of a law and its classification. Strict prohibitions on even minor ownership shares in a company can impede international partnership agreements, joint ventures, and scientific collaborations with foreign counterparts. Larger corporations may find such restrictions impractical, especially if foreign entities hold only a small percentage of shares. Restrictions should be limited to non-Indian shareholders who have the capacity to influence the management and decision-making processes of the company.

The potential environmental impact caused by Indian corporations and residents, particularly those residing overseas, should also be considered under the Biological Diversity Act. Legislators should consider factors such as supporting individuals with traditional knowledge and preventing harm to biodiversity when granting access or intellectual property rights.

When authorizing access or granting permission for intellectual property rights (IPRs) under the Biological Diversity Act, several considerations should be taken into account:

I. Does the access provide new opportunities that empower holders of traditional knowledge to innovate.
II. Does the authorized access pose a threat to biodiversity.

The constitutional essence and spirit of the federal structure play a crucial role in biodiversity conservation. As per the CBD, state governments should have greater flexibility and discretion in managing biodiversity-related matters. However, the current legislation establishes state biodiversity authorities that primarily function as advisory bodies following directives from the Central Government, lacking complete autonomy. It is recommended to grant state governments more flexibility to address biodiversity issues effectively. Additionally, state

governments impacted by biodiversity concerns should be notified, along with Biodiversity Management Committees (BMCs), particularly concerning critically endangered species and biodiversity heritage sites.

The Purpose and Significance of Local Communities

The purpose and significance of local communities in biodiversity management are often understated in current provisions. Decision-making authority predominantly rests with entities like the National Biodiversity Authority (NBA) and State Biodiversity Boards (SBB), sidelining local governments. The NBA engages with communities primarily after access has been granted to establish benefit-sharing arrangements, excluding them from initial access approval decisions. Moreover, local communities have limited knowledge about intellectual property rights (IPRs), their entitlements, and how to commercialize traditional knowledge under this centralized approach, leaving them disempowered.

Notably, individuals cannot directly seek remedies from the court in cases of perceived unfair benefit denial. Claimants must first notify relevant parties of their intent to file a complaint, and if unresolved, the NBA is approached for further action. However, not all citizens have locus standi, creating hurdles for those seeking recourse. Local communities, being closely attuned to the utilization of biological resources in their surroundings and vigilant against external exploitation, play a vital role in preventing biopiracy. Relying solely on official channels may impede their ability to timely access assistance and support.

Prior Informed Consent (PIC)

The principle of Prior Informed Consent (PIC) was regarded as a cornerstone of environmental governance and international law in this research. Emphasis was placed on the necessity of obtaining express consent from relevant parties, such as native communities or groups of indigenous peoples, before their biological assets or traditional knowledge could be used or accessed.

Under the Prior Informed Consent (PIC) approach, the acquisition or use of knowledge or resources required the consent of the owner or holder before any action could proceed. This approach ensured that applicants for access submitted all pertinent information, thereby enabling local populations to make informed decisions.

The "right to Free, Prior, and Informed Consent (FPIC)" for indigenous peoples has been acknowledged by various international accords, human rights laws, state laws, and intergovernmental organizations to varying extents. Development initiatives, judicial systems, administrative procedures, and other activities have often negatively impacted the ability of indigenous people to maintain their physical and cultural identity.

Certain Details were provided regarding a report on free, prior, and informed consent (FPIC) presented by the ‘Inter-Agency Support Group on Indigenous Issues at the May 2004 Permanent Forum by the United Development Programme (UNDP)’ (E/C.19/2004/11). It was noted that several UN agencies have partially incorporated FPIC into their policies and guiding

principles to enhance cooperation with Indigenous peoples (IPs). However, a universally recognized definition, interpretation, or method for FPIC implementation remains absent.

The 1992 Convention on Biological Diversity (CBD) was mentioned, highlighting its 'call for member states to preserve, protect, and uphold the knowledge, inventions, and customs of indigenous and local groups under Article 8(J).' This article also supports the broader use of these innovations, practices, and knowledge, provided that the owners agree and participate.

Additionally, the 'Cartagena Protocol on Biosafety, a part of the United Nations Convention on Biological Diversity (2000), was referenced.' It introduces the concept of Free, Prior, and Informed Consent (FPIC) concerning the transboundary 'movement, transit, handling, and exploitation of all living organisms.' The "CBD's 5th Conference of Parties (COP) decision, V/16, was mentioned as reaffirming the core principles of Prior Informed Consent (PIC)." It emphasizes the importance of granting indigenous and local community members with traditional knowledge, innovations, and practices the opportunity to provide their "prior informed consent or authorization" before sharing such information or knowledge with others.

Prior Informed Consent (PIC)" is very important for the following reasons:

1. Empowering Indigenous Communities: PIC gives traditional knowledge holders or local communities the ability to make well-informed decisions about who gets access. Before granting access requests, it enables them to evaluate the commercial worth of their conventional knowledge or goods.

2. Making Informed Decisions: PIC makes sure that national and local governments can decide what resources or genetically engineered (modified) organisms (GMOs) are safe for using by providing them with thorough and accurate information. This supports attempts to conserve biodiversity and manage resources responsibly.

An Analysis of Prior Informed Consent Under the Biodiversity Act

The significant issues brought up by the clauses of the Biodiversity Act pertaining to "consultation" with indigenous communities were highlighted. The importance of obtaining "permission of the local body" rather than relying solely on "consultation," which may not ensure consent, was underscored. Often, "consultation" is interpreted as engaging with a limited number of individuals such as village chiefs or city corporations. True consultation was argued to necessitate the involvement of every member of the affected community or settlement, utilizing their preferred languages and communication methods. It was stressed that people must be fully informed about the benefits and drawbacks of granting consent to make an informed decision about whether to agree or decline. However, the flexibility for interpretation within the legislation and Central Rules was noted, making it challenging for indigenous communities to actively participate in the process.

The Act addressed Prior Informed Consent (PIC) in multiple instances, emphasizing the critical nature of ensuring fair benefit-sharing from the utilization of biological resources.

Penalties were stipulated under sections 55-57 of the aforementioned act.

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

The practice known as "access benefit sharing" requires accessors of biological assets or indigenous knowledge to either credit the source or compensate the provider communities for their contributions. Regulatory frameworks must ensure both the identification and assertion of one's fair share of benefits, along with their equitable distribution, when access is permitted. Article 16 of the Convention on Biological Diversity outlines protocols for acquiring and sharing technology.

The Act consolidates all property rights through sovereign appropriation, encompassing the monopoly on intellectual property rights by the state or private inventors, or both. However, it lacks a framework for addressing legal claims by other owners of biological assets and associated data. Consequently, some knowledge and resources are made public without adherence to intellectual property rights.

“The 2001 Tokyo signing of the Nagoya Protocol, or Agreement on Access and Benefit Sharing, aims to ensure the fair and equitable distribution of benefits arising from the utilization of genetic resources.” This promotes sustainable use practices and biodiversity conservation. Genetic resources from animals, microbes, and plants are utilized for various purposes, including product development and scientific research. Researchers often obtain traditional knowledge from indigenous and local populations directly related to these genetic resources.

The benefit-sharing access provisions of the Indian Biodiversity Act are primarily outlined in 'Sections 3, 4, 6, 7, 20, 21, 22, 24, and 41.

India's scenario

India has faced difficulties in drafting and implementing legislation and regulations related to access benefit sharing (ABS). Among these difficulties are:

Inadequate Distinction Between Biological and Genetic Resources: The Act does not make a clear distinction between "biological resources" and "genetic resources." This lack of distinction implies that access to genetic resources can be obtained through the acquisition of a single bio specimen via collection, sale, or purchase, which may contradict the Act's goal of controlling access. This loophole makes it easier to use natural resources without proper regulation.

Difficulty in Monitoring and Enforcing Compliance: Monitoring genetic resources and ensuring compliance with the law can be challenging. The statute does not specifically address the right to ownership of genetic material. Additionally, the ABS law does not differentiate between different stakeholders who use genetic resources for various purposes, such as researchers, collectors, and multinational corporations.

Few Bio Prospecting Bids: India has received and approved only a few bio prospecting bids. The limited number of bids reflects additional barriers in applying the current biodiversity legislation. One such barrier is the lack of information about the negotiation processes, which creates uncertainty about the Act's effectiveness in practice.

To address the highlighted difficulties, two strategies can be employed:

1. Drawing on successful biodiversity laws from highly productive biodiversity zones worldwide for suggestions and best practices.
2. Implementing comprehensive policies that fully support the primary goals of the Biodiversity Act in their purest form.

CONCLUSION AND SUGGESTIONS

The increasing difficulties caused by biopiracy had necessitated the need for new rules and revisions. This problem was a cause of concern for developing countries, and the key question was how to solve it while maintaining "Western intellectual property rights" to promote innovation benefiting all communities. Traditional wisdom held high value in Indian culture and was essential to many people's means of subsistence. India had to guarantee equality and safety for all citizens, especially indigenous groups, in its capacity as a welfare state. However, the current legal system did not provide traditional knowledge with enough protection.

Although some benefit-sharing was mentioned in the current legislation, the recommendation was to create a centralized Act aimed at protecting traditional knowledge in India. To safeguard traditional knowledge, preserve biological resources, and halt biopiracy, it was imperative that local communities and those possessing traditional knowledge were made aware of their rights. It was also advised to facilitate the active involvement of local populations in discussions concerning the availability of natural resources and indigenous wisdom.

The following actions are recommended to combat biopiracy and preserve the traditional knowledge of indigenous people:

1. Strengthen the TK basis by improving the Traditional Knowledge Digital Library (TKDL) in collaboration with NGOs. Encourage Indigenous communities to actively engage in anti-biopiracy campaigns by providing them with free legal assistance to challenge infringements on their traditional knowledge.
2. Define precise standards to facilitate the most advantageous access to local indigenous populations' resources.
3. Allow non-governmental groups to directly engage with neighborhood communities and participate in the formulation of public policy.
4. Integrate clauses into the Act on Biodiversity (BDA) that empower citizens to file lawsuits in high courts for alleged breaches of BDA/BD regulations, illegal utilization of indigenous innovations, unauthorized exploitation of biological resources, and biopiracy. This approach can swiftly halt unauthorized use through injunctions.

5. Ensure that state governments incorporate community rights and traditional knowledge into their plans and activities alongside the conservation of biological resources.
6. Provide comprehensive education to local communities to ensure they are aware of their rights and responsibilities and can effectively protect their knowledge and resources.
7. Recognize and respectfully integrate regional traditional knowledge methods into research initiatives that benefit indigenous communities and foster trust between the government, academics, and indigenous people.
8. Strengthen legal safeguards for the rights of indigenous peoples by enacting more precise legislation, as the current Acts are often vague, and relying solely on the efforts of NGOs is inadequate.
9. Offer indigenous groups free legal aid to contest patents or other infringements on their traditional knowledge.
10. Develop a sui generis framework dedicated to the protection of traditional knowledge, considering its unique nature and importance.

Special courts should be established to expedite dispute resolution and address the lack of specialized legal skills in traditional knowledge cases. These courts should include experts who can effectively adjudicate cases and prevent big companies from acquiring patents in an unethical manner.

REFERENCES

[1] Access and Benefit Sharing Experience from India. National Biodiversity Authority.
[2] Biodiversity Access and Benefit –Sharing Policies for Protected Areas. United Nations University, Institute of Advance Studies.
[3] Bonn Guidelines on Access and Fair and Equitable Sharing of the Benefit Arising out of their Utilization. Secretariat of CBD.
[4] Buchs, A. K., & Jasper, J. (2007). For whose benefit?: Benefit Sharing Within Contractual ABS Agreements from an Economic Perspective ; the Example of Pharmaceutical Bioprospection.
[5] Chasing Benefits: Issues on Access to genetic Resources and Traditional Knowledge with reference to India's Biodiversity Regime. Kohli K. and Bhutani. S.
[6] Convention on Biological Diversity. United Nations, 1992.
[7] Customary Law and Traditional Knowledge, Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions: An Overview. WIPO. (All other sources have already been mentioned in the footnotes).
[8] Dennis, D. (2007). Global biopiracy: patents, plants, and indigenous knowledge. Culture & Agriculture, 29(1), 55–56. https://doi.org/10.1525/cag.2007.29.1.55
[9] Living in Harmony with Nature. CBD publication.
[10] Nagoya Protocol. Secretariat of CBD.
[11] Shiva, V. (2007). Bioprospecting as sophisticated biopiracy. Signs, 32(2), 307–313. https://doi.org/10.1086/508502
[12] Shiva, V. (2016). Biopiracy: The Plunder of Nature and Knowledge. North Atlantic Books.
[13] The Biological Diversity Act, 2002.

[14] Wynberg, R. (2023). Biopiracy: Crying wolf or a lever for equity and conservation? Research Policy, 52(2), 104674. https://doi.org/10.1016/j.respol.2022.104674