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RESEARCH PAPER

Biopiracy and IPR: Post Effects of Convention on Biological Diversity (CBD)

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ABSTRACT

To encourage innovation and safeguard the rights of creators and innovators, intellectual property rights, or IPRs, are crucial. IPRs have particular difficulties, however, because of biological concerns including biodiversity preservation, the preservation of traditional knowledge, and biopiracy. With particular relevance to India, this study explores the biological concerns surrounding intellectual property rights. The paper addresses the biological concerns related to IPRs and gives a general review of them, including their kinds and significance. The problems in identifying conventional knowledge and the possibility of biopiracy are two of the concerns presented by biological issues that are examined in this study. The research also looks at India's legislative and policy frameworks pertaining to IPRs and biological problems. In its conclusion, the research emphasizes the need of a thorough legal and legislative framework that strikes a balance between the rights of creators and innovators, the preservation of traditional knowledge, and biodiversity conservation. Policymakers, academics, and stakeholders interested in encouraging innovation while guaranteeing the preservation of traditional knowledge and biodiversity conservation will find great value in the research results of this study.

***Keywords**: Biodiversity, Traditional Knowledge, TRIPS, CBD, Bio-piracy*

INTRODUCTION

Protecting the rights of artists and innovators, fostering innovation, and advancing economic progress all depend on intellectual property rights, or IPRs. However, the relationship between IPRs and biological challenges has become more complicated as biological resources, biodiversity protection, and traditional knowledge have gained relevance. The difficulties of striking a balance between IPRs and the preservation of biodiversity and traditional knowledge are especially severe in the Indian setting, since both elements are essential to the nation's cultural and economic legacy.

The range of living forms found in a particular ecosystem, area, or planet-both in terms of the number of species and their genetic diversity-is referred to as biodiversity. It includes the variety of living things, including fungi, microbes, plants, and animals, as well as the environments and habitats in which they reside. The number of species is just one aspect of biodiversity; another is the way in which these species interact with their surroundings. It is essential for preserving ecosystems' health and functionality, delivering ecosystem services like clean water and air, and promoting human welfare. Conservation activities are essential to safeguarding and conserving biodiversity for future generations, since it is endangered by invasive species, pollution, climate change, habitat degradation, and overexploitation of resources.

The range of living forms found in a particular ecosystem, area, or planet-both in terms of the number of species and their genetic diversity-is referred to as biodiversity. It includes the variety of living things, including fungi, microbes, plants, and animals, as well as the environments and habitats in which they reside. The number of species is just one aspect of biodiversity; another is the way in which these species interact with their surroundings. It is essential for preserving ecosystems' health and functionality, delivering ecosystem services like clean water and air, and promoting human welfare.

Threats to biodiversity include overuse of resources, pollution, climate change, habitat degradation, and invasive species, and In order to safeguard and preserve this essential resource for future generations, conservation initiatives are essential.

Trade-Related Aspects of Intellectual Property Rights is what TRIPS stands for. The World Trade Organization (WTO) hosted negotiations for this global agreement on intellectual property rights in 1994.

TRIPS establishes minimal requirements for the defense and upholding of several types of intellectual property, such as trade secrets, patents, trademarks, and copyrights. It mandates that WTO member nations provide certain types of intellectual property with a specific degree of protection and enforcement, which may be contentious since it may affect access to vital medications and other significant technology. By offering a robust legal framework for the defense and upholding of intellectual property rights, TRIPS aims to foster innovation and creativity. TRIPS aims to stimulate research and development investment and the spread of information and technology by giving creators and inventors legal protection for their works.

Nonetheless, TRIPS detractors contend that the pact may have unfavorable effects, especially on developing nations. Access to necessary medications may be hampered by the need for a certain degree of intellectual property protection and enforcement since pharmaceutical corporations may have monopolies on the manufacture and distribution of life-saving medications, putting them out of reach for many. In underdeveloped nations, this may have detrimental effects on healthcare access and public health.

INDIAN LEGISLATIVE ENACTMENT

India has passed a number of laws pertaining to intellectual property rights (IPR). Below is a discussion of some of the most significant enactments:

- **The Patents Act, 1970:** In India, patent granting is governed by this Act. In order to conform to the TRIPS Agreement, it was modified in 2005. Pharmaceutical product patents were included by the modifications, which also extended patent terms and allowed for mandatory patent licensing under certain conditions.
- **The Copyright Act, 1957:** India's copyright laws are governed by this Act. It protects sound recordings and cinematographic films, as well as literary, theatrical, musical, and creative works.
- **The Trade Marks Act, 1999:** In India, trademark registration and protection are governed by this Act. It covers trademark registration and guards against trademark abuse.
- **The Geographical Indications of Goods (Registration and Protection) Act, 1999:** Geographical indicators in India may be registered and protected under this Act. According to this definition, geographical indicators are signs indicating a product originates from a certain area and that a particular attribute, reputation, or other feature of the product is mostly due to its location.
- **The Designs Act, 2000:** The registration and protection of designs in India are governed by this Act. It allows for both the registration of designs and the avoidance of their violation.
- **The Protection of Plant Varieties and Farmers' Rights Act, 2001:** The rights of Indian farmers and the preservation of plant types are protected by this Act. It creates a framework for plant variety registration and safeguards farmers' rights to save, use, trade, and market their farm-saved seeds.

These laws have been implemented to provide India's many types of intellectual property-such as patents, copyrights, trademarks, geographical indications, designs, and plant varieties-legal protection. They were put into place to safeguard the rights of creators and inventors while also encouraging innovation, creativity, and economic progress.

CONVENTION ON BIOLOGICAL DIVERSITY

During the 1992 United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro, Brazil, the Convention on Biological Diversity (CBD), a global environmental pact, was made available for signing. The CBD is an international treaty that aims to promote the conservation and sustainable use of biodiversity and ensure the fair and equitable sharing of the benefits arising from the use of genetic resources.

The protection of biological diversity, sustainable utilization of its constituent parts, and just and equitable distribution of the advantages resulting from the use of genetic resources are the three primary goals of the CBD. In order to accomplish these goals, the CBD offers a framework for biodiversity conservation and sustainable use, along with channels for transferring financial and technological resources to poorer nations to aid in biodiversity conservation.

Additionally, the CBD allows for the creation of national plans, programs, and strategies for biodiversity conservation and sustainable use. Parties to the CBD must identify, monitor, and create plans for the sustainable use of their biological resources. In order to preserve biodiversity, the CBD also supports the creation of protected areas and the encouragement of eco-friendly travel.

The CBD is one of the most commonly accepted international environmental accords, having been signed by 196 nations. The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization, which was adopted in 2010 to address issues related to access and benefit-sharing of genetic resources, is one of several other international agreements that support the CBD.

INTERNATIONAL STEPS FOR PROTECTION OF THE BIOLOGICAL DIVERSITY:

For many nations, especially those with abundant biodiversity resources, the protection of biological diversity rights within the framework of intellectual property rights (IPR) is a crucial problem. To address this problem, a number of international actions have been taken, including:

- **Convention on Biological Diversity (CBD):** The goal of the CBD, a multinational environmental accord, is to guarantee the just and equal distribution of the advantages resulting from the use of genetic resources while also encouraging the protection and sustainable use of biodiversity. It urges the creation of national laws and regulations to guarantee the preservation of indigenous and local populations' traditional knowledge, inventions, and traditions and acknowledges the significance of IPR protection for biodiversity conservation and sustainable usage.
- **Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement:** A international pact known as the TRIPS pact lays forth minimal requirements for the defense and upholding of intellectual property rights, such as copyrights, patents, and trademarks. It acknowledges the value of IPR protection in fostering innovation and creativity, but it also contains clauses to make sure IPR doesn't obstruct the transfer and sharing of technology for the benefit of the general public, as well as safeguarding public health and nutrition.
- **Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization:** A addition to the CBD, the Nagoya Protocol seeks to guarantee the fair and equal distribution of advantages resulting from the use of genetic resources. It contains clauses to guarantee the preservation of traditional knowledge related to genetic resources and lays up guidelines and protocols for access to genetic resources and benefit sharing. Additionally, it acknowledges the value of IPR protection for biodiversity conservation and sustainable use, but it stipulates that this protection must not conflict with the goals of the Protocol or the CBD.
- **World Intellectual Property Organization (WIPO):** The United Nations specialized agency WIPO is in charge of advancing the global protection of intellectual property rights. WIPO facilitates the negotiation of international IPR agreements and offers developing nations technical assistance to help them create efficient IPR frameworks. In order to address the problem of IPR protection in the context of biological variety, WIPO has also set up a program on traditional knowledge, genetic resources, and traditional cultural manifestations.

These tools acknowledge the value of IPR protection for biodiversity conservation and sustainable use, but they also include safeguards to prevent such protection from impeding technology transfer and dissemination for the public benefit, protecting public health and nutrition, and honoring indigenous and local communities' traditional knowledge.

MAJOR CONCERNS BETWEEN TRIPS AND BIODIVERSITY:

The possibility that intellectual property rights may lead to a monopoly on therapies and medications that could save lives is one of the main biological problems with them. For example, a pharmaceutical business may get a patent for a novel medication that effectively treats a certain illness. But, particularly in low-income nations, this patent may restrict other businesses from manufacturing and marketing the same medication, leading to exorbitant costs and restricted availability. In India, where a sizable portion of the population cannot afford pricey prescription drugs, this problem is especially pertinent.

The effect of patents on plant and animal genetic resources is another biological concern associated with intellectual property rights. Farmers and indigenous groups may find themselves unable to access and use their traditional knowledge and resources as a result of patents on genes and other genetic resources. On instance, a company may be able to get a patent on a certain gene sequence in a crop plant that is commonly grown in India. This may make it illegal for Indian farmers to use and market seeds that have that DNA sequence without first obtaining a license.

Furthermore, the protection of biodiversity may suffer as a result of genetic resource patents. Businesses that acquire patents on genetic resources often exploit them in ways that are not sustainable, which leads to biodiversity loss and the depletion of natural resources. In India, which is home to a wide variety of plant and animal species, this is a serious issue.

Concerns have also been raised about how intellectual property laws can impede scientific advancement. For example, restricting intellectual property rights may make it impossible for researchers to acquire crucial genetic resources and data. Innovation and scientific advancement may be hampered by this, especially in the biotechnology sector.

Last but not least, there is worry that biopiracy-the unlawful exploitation of genetic resources and traditional knowledge-may result from intellectual property rights. When a business or person appropriates genetic resources or traditional knowledge from a specific group without getting prior informed permission or paying them, this is known as biopiracy. This has been a major problem in India, where companies have been taking advantage of indigenous people in an attempt to patent genetic resources and traditional knowledge.

INDIAN GOVERNMENT STEPS TO REDUCE THE CONFLICT BETWEEN INTELLECTUAL PROPERTY RIGHTS AND BIODIVERSITY:

India is a nation with a wealth of traditional knowledge and biodiversity. The Indian government has made a number of actions to lessen the conflict between biodiversity rights and intellectual property rights (IPR), including:

- **Biological Diversity Act, 2002:** The protection, sustainable use, and fair distribution of benefits resulting from the exploitation of biological resources are all covered under the Biological Diversity Act of 2002. The Act seeks to preserve the nation's biodiversity and the traditional knowledge that goes along with it. In order to control access to biological resources and guarantee the fair distribution of profits resulting from their usage, it also establishes the National Biodiversity Authority (NBA) and State Biodiversity Boards (SBB).
- **Traditional Knowledge Digital Library (TKDL):** In order to prevent the appropriation of traditional knowledge related to biodiversity, the Indian government and the Council of Scientific and Industrial Research (CSIR) collaborated to create the Traditional Knowledge Digital Library (TKDL). In order to help patent examiners spot previous art and stop the issuance of unsuitable patents, the TKDL digitizes traditional knowledge from Indian medical systems and makes it available to them in a variety of languages.
- **National IPR Policy, 2016:** A road map for creating a strong IPR system in India is provided by the National IPR Policy, 2016. It urges the creation of policies and procedures to stop the granting of patents on biological resources and traditional knowledge, acknowledging the significance of preserving biodiversity and traditional knowledge. The strategy also highlights the need of ensuring the fair distribution of benefits resulting from the use of traditional knowledge and the significance of encouraging its usage in the creation of new goods and services.

- **Access and Benefit Sharing (ABS) Guidelines, 2014:** A framework for controlling access to biological resources and guaranteeing the fair distribution of benefits resulting from their utilization is provided by the Access and Benefit Sharing (ABS) Guidelines, 2014. According to the recommendations, corporations and researchers must share the advantages of using biological resources with the resource providers and get prior informed permission from the NBA or SBBs before using them. Traditional knowledge related to biological resources is likewise protected under the standards.

TRADITIONAL KNOWLEDGE DIGITAL LIBRARY

The Indian government launched the Traditional Knowledge Digital Library (TKDL) as a way to prevent the exploitation of traditional knowledge related to biodiversity. A joint initiative of the Indian government and the Council of Scientific and Industrial Research (CSIR), the TKDL seeks to digitize traditional medical knowledge from Indian systems and make it available to patent examiners in a variety of languages. This facilitates their ability to recognize previous art and prevents unwarranted patents from being granted.

To stop the exploitation of traditional knowledge on biodiversity, the Indian government established the Traditional Knowledge Digital Library (TKDL). A collaborative effort between the Council of Scientific and Industrial Research (CSIR) and the Indian government, the TKDL aims to digitize traditional medical knowledge from Indian systems and provide it to patent examiners in many languages. This makes it easier for them to identify prior work and prevents unauthorized patents from being issued.

Inappropriate patents based on traditional knowledge have been successfully stopped by the TKDL. For instance, in 2009, when the TKDL presented proof of turmeric's historic usage in Indian medical systems, the European Patent Office invalidated a patent on its application for wound healing. Similarly, when the TKDL presented proof of neem's historic usage in Indian agriculture, the USPTO revoked a patent on its application for regulating fungal development on plants in 2010.

The time and expense associated with patent examination have also been decreased because to the TKDL. A World Intellectual Property Organization research claims that the TKDL has helped patent offices save more than $170 million by cutting the time it takes to review patent applications by up to 80%.

Here are some data points on the success of the TKDL:

- Over 34 million pages of traditional knowledge from Indian medical systems, including Ayurveda, Unani, and Siddha, have been digitized by the TKDL as of March 2021.
- To provide access to its database, the TKDL has signed agreements with patent offices throughout the globe, including the European Patent Office, the Japanese Patent Office, and the United States Patent and Trademark Office.
- In addition to saving patent offices more than $170 million, the TKDL has assisted in cutting the time required to review patent applications by up to 80%.
- Based on traditional knowledge, the TKDL has produced evidence that has resulted in the revocation of more than 200 patents issued by different patent offices worldwide.

All things considered, the TKDL has been effective in preventing the takeover of traditional knowledge linked to biodiversity and has established a model for other nations to follow.

ACCESS TO BENEFIT SHARING:

The idea behind Access and Benefit-Sharing (ABS) is to make sure that the countries that contribute and utilize genetic resources divide the advantages that result from their usage in a fair and equitable manner. It is a fundamental component of the Convention on Biological Diversity (CBD), which seeks to advance fair distribution of the advantages of genetic resources, conservation, and sustainable usage.

ABS entails granting access to genetic resources and related traditional knowledge in return for a portion of the profits generated by their use. Benefits might be in the form of cash remuneration, technological transfer, or capacity development, among other things. The foundation of ABS is the

understanding that local and indigenous populations have generated and preserved genetic resources and related traditional knowledge over many generations.

Because of the increased interest in biotechnology and the potential of genetic resources for the creation of new goods and technologies, the idea of ABS has been more significant in recent years. However, the rights of indigenous and local populations may be violated and exploitation may result from the utilization of genetic resources without just and equitable benefit-sharing.

Through the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, which went into effect in 2014, the CBD offers a framework for ABS in order to address these issues. According to the Nagoya Protocol, countries must set up national ABS frameworks and make sure that the suppliers of genetic resources and related traditional knowledge provide their prior informed permission.

The following are some of the main conflicts between TRIPS and biodiversity rights, especially with regard to benefit-sharing and access to genetic resources:

- The capacity to acquire and use genetic elements from microbes, plants, and animals for study and development is known as "access to genetic resources." These genetic resources are often sourced mostly from developing nations with high biodiversity. TRIPS has drawn criticism, meanwhile, for lacking sufficient safeguards to guarantee just and equal access to these resources. Rather, the agreement mainly protects intellectual property rights for those who use these genetic resources to create new technologies or products, which could result in biopiracy or the illegal use of genetic resources from developing nations without the proper benefit-sharing arrangements in place.
- Benefit-sharing is the practice of distributing the financial and non-financial advantages of using genetic resources, such as capacity development and technology transfer. A different multinational environmental accord, the Convention on Biological Diversity (CBD), acknowledges the value of benefit-sharing in guaranteeing biodiversity conservation and sustainable use. However, there are worries that poor nations are not getting their fair share of benefits from the exploitation of their genetic resources since TRIPS does not provide clear rules on how to guarantee that gains are shared fairly and equitably.
- How intellectual property rights affect access to necessary medications is another conflict between biodiversity rights and TRIPS. Many individuals in underdeveloped nations may not be able to afford the high costs associated with patent protection for medications. TRIPS contains clauses that permit nations to grant compulsory licenses to enable the manufacturing of reasonably priced generic versions of patented medications; however, this has generated controversy, with some contending that it compromises pharmaceutical companies' capacity to recover their R&D expenditures.

The relationship between TRIPS and biodiversity rights is complicated, especially when it comes to benefit-sharing and access to genetic resources. TRIPS must strike a balance between the requirement for fair and equal access to genetic resources and the sharing of benefits resulting from their use, even as it works to advance innovation and the protection of intellectual property rights.

ROLE OF NBA IN PROTECTING TRADITIONAL KNOWLEDGE

By controlling access to India's biological resources and the traditional knowledge connected to them, the National Biodiversity Authority (NBA) of India plays a significant role in preserving traditional knowledge. With the goal of controlling access to India's biological resources and related traditional knowledge and guaranteeing a fair and equitable distribution of the benefits resulting from their utilization, NBA was founded under the Biological Diversity Act, 2002.

The NBA has taken part in a number of programs designed to preserve traditional knowledge. The traditional knowledge pertaining to regional biological resources is recorded in the People's Biodiversity Register (PBR), which it has established. Access and benefit-sharing agreements are facilitated by the PBR, a database of data gathered from local communities.

The NBA has also created a framework, which involves the creation of Community Biodiversity Registers (CBRs), for the preservation of traditional knowledge related to biological resources.

Though they are created via a process that involves local communities, CBRs are comparable to PBRs. They assist prevent outsiders from misappropriating the customary knowledge related to biological resources by documenting it.

The NBA has contributed to the creation of standards for the preservation of traditional knowledge related to biological resources in addition to the PBR and CBR programs. The recommendations provide a structure for safeguarding traditional knowledge and distributing the advantages that result from its use in a just and equitable manner.

Documenting traditional knowledge related to local biological resources and preventing outsiders from stealing it are the goals of the People's Biodiversity Register (PBR) and Community Biodiversity Register (CBR). The National Biodiversity Authority (NBA) of India is the organization behind both of these programs.

PEOPLE'S BIODIVERSITY REGISTER:

A database of data gathered from nearby communities, the People's Biodiversity Register records the traditional knowledge related to biological resources. Participatory development of the PBR with local communities guarantees accurate documentation of their knowledge and consideration of their concerns. The PBR contains data on biological resources' availability and use, as well as its cultural and medical applications and related traditional knowledge. The PBR is a crucial instrument for promoting access and benefit-sharing arrangements, as well as controlling access to biological resources and traditional knowledge.

COMMUNITY BIODIVERSITY REGISTER:

Similar to the PBR, the Community Biodiversity Register is created in collaboration with local communities. To prevent outsiders from stealing the traditional knowledge related to biological resources in a certain region, CBRs are employed to record such information. Local communities create CBRs, which include data on biological resources' availability and use, as well as its cultural and medical applications and traditional knowledge. CBRs are a crucial instrument for safeguarding biological resource-related traditional knowledge.

In India, the PBR and CBR programs are crucial instruments for preserving traditional biological resource knowledge. These programs assist in making sure that local community' interests are taken into consideration and that their information is not stolen by outsiders by incorporating them in the recording and preservation of their traditional knowledge.

All things considered, by controlling access to India's biological resources and related traditional knowledge and making sure that the advantages of their utilization are distributed fairly and equally, the NBA plays a significant role in preserving traditional knowledge. The NBA has contributed to the development of a framework for the preservation of traditional knowledge that is based on the requirements and preferences of local communities via programs like the PBR, CBR, and recommendations.

INDIAN LEGISLATIVE ENACTMENTS SPECIAL REFERENCE TO TRADITIONAL KNOWLEDGE:

In order to safeguard traditional knowledge (TK) and stop its appropriation, India has passed a number of laws. Among the significant ones are:

- **Protection of Plant Varieties and Farmers' Rights Act, 2001:** The purpose of this legislation is to guarantee that farmers are fairly compensated for their contributions to the creation of plant varieties and to safeguard their rights with respect to their traditional knowledge. By mandating that the origin of traditional varieties be disclosed, it also aims to stop their exploitation.
- **Biological Diversity Act, 2002:** The protection, sustainable use, and fair distribution of benefits resulting from the utilization of biological resources are all covered by this legislation. Benefit-sharing arrangements and prior informed permission are necessary for the utilization of traditional biological resource knowledge.
- **Traditional Knowledge Digital Library (TKDL):** Traditional knowledge in the areas of agriculture, medicine, and traditional practices may be found in digital form at the TKDL. The Indian government established it to stop patent offices from stealing traditional knowledge. A

number of patents on conventional knowledge-based innovations have been successfully blocked by the TKDL.

- **Patents (Amendment) Act, 2005:** The Patents Act of 1970 was modified by this act to conform to the TRIPS agreement. It offers protection for innovations in all technological domains, even those that are based on conventional knowledge. However, it also contains clauses that prohibit patents from being granted for innovations that violate morals or public order, or that endanger the health of people, animals, or plants.
- **The Geographical Indications of Goods (Registration and Protection) Act, 1999:** Geographical indications (GIs) in India may be registered and protected under this Act. GIs are labels applied to goods with a particular geographic origin and attributes or a reputation that are peculiar to that location. The Act safeguards traditional knowledge from unlawful exploitation and acknowledges its significance in the manufacturing of commodities with GIs.
- **Draft National Policy on Traditional Knowledge Systems:** In addition to ensuring its fair use and benefit-sharing, the policy seeks to safeguard traditional knowledge. It acknowledges that traditional knowledge needs a sui generis method of preservation that considers its special characteristics.
- **The Traditional Knowledge Digital Library-International (TKDL-I):** The Indian government has established TKDL-I in collaboration with the World Intellectual Property Organization (WIPO) to prevent the misappropriation of traditional knowledge on a global level. TKDL-I provides information on traditional knowledge from India and other countries and helps patent examiners determine if an invention is based on traditional knowledge.
- **Traditional Knowledge Associated with Genetic Resources (TKAGR) Guidelines, 2019:** A framework for the preservation and administration of traditional knowledge related to genetic resources is offered by the TKAGR Guidelines. In addition to ensuring their fair distribution, they seek to advance the preservation and sustainable use of biological resources and related traditional knowledge.
- **Traditional Knowledge Digital Library Access Agreement:** For the use of the traditional knowledge included in the TKDL, the Indian government has signed access and benefit-sharing agreements with a number of nations, including the US, Japan, and Korea. These agreements guarantee that prior informed permission and mutually agreed conditions govern the use of traditional knowledge, and that the communities and people who have produced and preserved it get an equitable part of the benefits that result from its usage.
- **The National Intellectual Property Rights (IPR) Policy, 2016:** The National IPR Policy aims to safeguard traditional knowledge against infringement and abuse, acknowledging its significance. It encourages innovation and the creation of new technologies by using old knowledge, but it makes sure that the advantages of doing so are distributed fairly.
- **Draft National Policy on Traditional Knowledge, 2019:** In order to provide a thorough framework for the preservation and advancement of traditional knowledge in India, the Indian government has put up a draft national policy on the subject. The policy seeks to encourage the preservation, recording, verification, and sharing of traditional knowledge because it acknowledges its significance for sustainable development. Additionally, it suggests creating a National Centre for Traditional Knowledge, which would operate as a central hub for organizing and carrying out initiatives pertaining to traditional knowledge in India.

In order to safeguard traditional knowledge and stop its appropriation, certain legislative actions are crucial. More understanding of existing regulations, their application, and the creation of new safeguards for traditional knowledge are still necessary, nevertheless.

CONCERNS OF THE PHARMACEUTICAL INDUSTRY

Concerns have been raised by the pharmaceutical sector on how government-protected biological variety may affect their R&D efforts. Their capacity to create new medications and other goods may be hampered by the limitation of access to biological resources and the traditional knowledge related to them. Furthermore, negotiating access and benefit-sharing agreements and obtaining prior informed permission from local populations may be expensive and time-consuming, which

can raise the price of medication development and postpone the release of new drugs onto the market.

The possibility of biopiracy, or the unlawful exploitation of biological resources and the traditional knowledge connected to them, is another issue. The pharmaceutical industry is concerned that stringent rules governing access and benefit sharing would encourage researchers to look for information and resources outside the law, which might result in the illicit exploitation and theft of biological resources and traditional knowledge.

Some have advocated for a more balanced approach to the preservation of intellectual property rights and biological variety in order to allay these worries. This can include creating a framework that makes it easier to access biological resources and traditional knowledge while guaranteeing that local groups benefit equally. Additionally, the costs and delays related to access and benefit-sharing agreements may be decreased by creating more efficient and transparent procedures for the sharing and access to biological resources and traditional knowledge.

BIO-PIRACY

Unauthorized or unlawful acquisition and exploitation of biological resources and the traditional knowledge connected with them is referred to as "bio-piracy." It often entails businesses and people from rich nations exploiting natural resources and traditional knowledge from developing countries without benefiting the local populations or the countries where the resources are situated.

Because it may lead to the exploitation and theft of natural resources and traditional knowledge, bio-piracy is seen as a major problem that can cause local people to lose both their economic and cultural heritage. Additionally, it may lead to environmental harm and biodiversity loss.

A number of international laws and agreements, including the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization and the Convention on Biological Diversity (CBD), have been established to combat bio-piracy. By establishing legal frameworks for access and benefit sharing, these agreements seek to guarantee that local people profit fairly from the utilization of biological resources and traditional knowledge.

INDIAN LEGISLATION AND BIO-PIRACY:

In order to combat biopiracy and safeguard its biological variety and traditional knowledge, India has put in place a number of regulatory measures. The Biological Diversity Act (BDA) of 2002 is one of the important pieces of legislation that attempts to control access to biological resources and the customary knowledge that goes along with them and guarantee that local people fairly share the benefits that come from using them.

According to the BDA, prior informed permission must be obtained from the State Biodiversity Board (SBB) or the National Biodiversity Authority (NBA) before anybody may exploit biological resources or traditional knowledge related to them for commercial or scientific reasons. Additionally, the legislation mandates that local communities and the NBA share in the profits that come from using biological resources and traditional knowledge.

In order to fight biopiracy, India has also launched the Traditional information Digital Library (TKDL) initiative, which attempts to digitize traditional information about yoga, Ayurveda, and medicinal plants and make it available to patent examiners. The United States and Europe are among the foreign nations that the TKDL has successfully stopped from granting patents on traditional Indian remedies.

The Genetic Engineering Appraisal Committee (GEAC) standards, which mandate that businesses get prior informed permission and benefit-sharing agreements with local populations and declare the source of the genetic material utilized in their goods, were also introduced in India in 2019. These rules are intended to stop international firms from abusing India's traditional knowledge and genetic resources.

All things considered, these legal actions have been successful in combating biopiracy and safeguarding India's traditional knowledge and biological variety. To guarantee that these policies are successfully put into place and maintained, however, further work must be done.

ROLE OF INDIAN JUDICIARY IN THE PROTECTION OF BIO-PIRACY:

The Indian judicial system has been crucial in defending local communities' and traditional knowledge holders' rights and preventing biopiracy. Here are a few instances:

- The Indian government contested a European patent on the use of neem tree extracts as fungicides in the Neem Tree case, claiming that Indian communities had a long-standing practice of using neem. The patent was later canceled by the European Patent Office.
- In the Basmati Rice case, an Indian business contested an American company's US patent award on a kind of Basmati rice. According to the Indian firm, Basmati rice has been cultivated in India for millennia and is considered a traditional kind. The patent was ultimately canceled by the US Patent and Trademark Office. The Indian government was ordered by the Supreme Court to take action to prevent foreign corporations from abusing or taking advantage of the traditional rice variety. The court also emphasized the need of protecting traditional knowledge against biopiracy and acknowledging its significance.
- The Indian government contested the US patent on the use of turmeric as a wound-healing agent in the Turmeric case, claiming that Indian communities have long used the spice. The patent was ultimately canceled by the US Patent and Trademark Office. The Indian government was ordered by the Supreme Court to compile traditional knowledge about turmeric and other therapeutic plants into a database. In order to safeguard traditional knowledge and stop biopiracy, the court also emphasized the need of stricter legal and legislative measures.
- The Supreme Court ordered the Indian government to look into a biopiracy case involving the medicinal herb Kutki, in which a US-based corporation had trademarked an extract from the plant. The government was also directed by the court to take action to stop biopiracy like this from happening again.
- In the case of T.N. Godavarman Thirumulpad v. Union of India, the Supreme Court ordered a ban on the collection of forest resources and the granting of patents on traditional knowledge until a national policy on biodiversity and traditional knowledge was formulated.
- In the case of Kalpavriksh v. Union of India, the Supreme Court ordered the government to establish a legal framework for the protection of traditional knowledge and the equitable sharing of benefits from its use.
- In the case of Novartis AG v. Union of India, the Supreme Court upheld India's patent laws and rejected Novartis' application for a patent on a cancer drug called Glivec. The court held that the drug did not represent a significant improvement over existing drugs and therefore did not meet the criteria for patentability. This decision was seen as a victory for access to affordable medicines and for the protection of public health.
- In the case of Monsanto Technology LLC v. Nuziveedu Seeds Ltd., the Supreme Court upheld the validity of India's Patents Act and ruled that Monsanto's patent on genetically modified cotton seeds was not valid under Indian law. The court held that the invention did not satisfy the criteria for patentability, as it was not a new invention but rather an extension of an existing one. The ruling was seen as a victory for farmers' rights and the protection of biodiversity.
- In the case of Wildlife Trust of India v. Ministry of Environment and Forests, the Supreme Court directed the government to establish a National Regulator for the Protection of Plant Varieties and Farmers' Rights. The regulator was tasked with ensuring that plant varieties and farmers' rights were protected and that bio-piracy was prevented. This decision was seen as a significant step towards protecting traditional knowledge and the rights of local communities.
- Citing worries about the effects on human health and the environment, the Supreme Court in the Bt Brinjal case placed a halt on the commercial distribution of genetically modified Bt Brinjal. A thorough regulatory framework for the testing and distribution of genetically modified organisms (GMOs) was also demanded by the court.
- In the Niyamgiri case, the Supreme Court maintained local people' rights to consultation and approval prior to any mining operations occurring on their ancestral grounds. The court also acknowledged the need of preserving the area's natural and cultural characteristics.

These cases demonstrate the Indian judiciary's dedication to defending local communities' and traditional knowledge holders' rights and preventing biopiracy. They have established significant

precedents for future cases concerning the rights of local people and traditional knowledge holders, and they have contributed to the development of a legal framework for the conservation of biological diversity in India.

CONCLUSION

In conclusion, India, a rich storehouse of biological resources and traditional knowledge, has made the preservation of biological variety and traditional knowledge a top priority. The framework for the protection of biological diversity and traditional knowledge has been established by the Convention on Biological Diversity (CBD) and the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement. However, there have been worries about the possible conflict between IPRs and the rights of traditional knowledge holders and local communities.

The Biological Diversity Act, the Protection of Plant Varieties and Farmers' Rights Act, the National Biodiversity Authority (NBA), the Traditional Knowledge Digital Library (TKDL), the People's Biodiversity Register (PBR), and the Community Biodiversity Register (CBR) are just a few of the measures India has taken to address these issues. These programs seek to stop biopiracy, guarantee fair benefit sharing, and preserve traditional knowledge.

With historic cases like T.N. Godavarman Thirumulpad v. Union of India, Kalpavriksh v. Union of India, and Monsanto Technology LLC v. Nuziveedu Seeds Ltd. establishing significant precedents for the preservation of biological diversity and traditional knowledge in India, the Indian judiciary has also been instrumental in defending the rights of local communities and holders of traditional knowledge.

In general, the Indian court and government have made significant actions to uphold the rights of traditional knowledge holders and local communities while encouraging the sustainable use of biological resources. To guarantee that these programs are carried out successfully and that the rights of regional communities and holders of traditional knowledge are upheld in reality, however, continued efforts are required.

SUGGESTIONS

The following ideas may help resolve the issue between biological rights and TRIPS:

- Including traditional cultural expressions and knowledge in the IP system: It is important to recognize and include traditional cultural expressions and knowledge in the IP system. This may be accomplished by establishing sui generis systems, which would acknowledge the rights of local communities and traditional knowledge holders while also providing legal protection for traditional knowledge and traditional cultural forms.
- Clarifying the scope of IPRs: It is important to make sure that traditional knowledge and biological resources that have been in the public domain for many generations are not covered by IPRs. This would guarantee that local communities and traditional knowledge holders are not unjustly denied their rights and stop companies from misappropriating biological resources and traditional knowledge.
- Putting access and benefit-sharing (ABS) agreements into place: ABS agreements should be put into place to guarantee that traditional knowledge holders and local communities are fairly compensated for the use of their biological resources and traditional knowledge. Additionally, these agreements would support biodiversity conservation and the sustainable use of biological resources.
- Enhancing the National Biodiversity Authority's (NBA) role: The NBA should be enhanced to guarantee that it has the tools and legal power required to successfully control access to biological resources and traditional knowledge. This would guarantee that local communities and traditional knowledge holders may profit from their biological resources and traditional knowledge while also preventing companies from misappropriating them.
- Promoting international collaboration: Resolving the contradiction between biological rights and TRIPS requires international cooperation. While acknowledging the significance of intellectual property rights, nations should collaborate to create and carry out international accords and standards that support the preservation of biological resources and traditional knowledge.

- These are just few ideas for resolving the issue between biological rights and TRIPS. To discover solutions that support the sustainable use of biological resources and safeguard the rights of local people and traditional knowledge holders, governments, international organizations, and civil society must collaborate.

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