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Legal, Ethical, and Policy Points of View on Governance and Protection of Biological and Genetic Resources

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Biotechnology, agriculture, and pharmaceuticals have collectively increased the global need for biological and genetic resources. This underscores the necessity of setting up robust governance systems that ensure fair access and sustainable resource utilisation. This study examines the complex domain of managing biological and genetic resources. It emphasises access, benefit-sharing (ABS), and protective measures within international, regional, and national legislation. This study utilises the Convention on Biological Diversity (CBD) and the Nagoya Protocol as foundational elements to examine the interconnections among environmental law, intellectual property rights, and indigenous knowledge systems. The study examines the complex challenges associated with the ownership and management of genetic resources, particularly in impoverished nations rich in biodiversity. This examines how contemporary legal systems either uphold or undermine the rights of local and indigenous populations, whose traditional knowledge is often essential for the identification and use of these resources. There is considerable discourse around the perils of biopiracy and the appropriation of genetic material, alongside the necessity for transparent, fair, and legally enforceable Access and Benefit-Sharing agreements. The study evaluates the efficacy of the selected authority and the existing protection mechanism. We analyse the function of intellectual property rights, particularly patent systems, and plant variety protection, and assess their compatibility with biodiversity preservation and fair benefit-sharing. The paper examines the increasing significance of digital sequencing data for genetic resources and its complicating effect on the application of established regulations. This paper advocates for a governance model that is more interconnected, inclusive, and equitable, aiming to integrate domestic policies with international obligations while respecting the rights and contributions of indigenous peoples. It ensures compliance with regulations, safeguards biodiversity, and promotes equitable sharing of benefits derived from genetic resources through the establishment of new laws and policies. In conclusion, the study contributes to the broader dialogue on global equality, environmental justice, and sustainable development by elucidating the legal and ethical frameworks for the use and conservation of biological and genetic resources.

Keywords: Benefit Sharing; Biological Diversity; Convention on Biological Diversity; Genetic Resources; Gene Modifications.

The governance and protection of biological and genetic resources have emerged as critical global concerns in the face of accelerating biodiversity loss, climate change, and rapid advancements in biotechnology. These resources, which include the genetic material of plants, animals, and microorganisms, are fundamental to agriculture, medicine, environmental sustainability, and scientific research. However, their exploitation and management raise complex questions at the

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intersection of law, ethics, and public policy. As nations and international bodies seek to balance conservation with development, the frameworks for regulating access to and benefit-sharing from these resources have become both vital and contentious.

From a legal standpoint, international treaties like the Convention on Biological Diversity (CBD), the Nagoya Protocol, and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) set the foundational principles for how genetic resources are accessed, used, and shared. These instruments aim to ensure that benefits arising from the use of genetic materials are equitably distributed, especially to countries and indigenous communities that have historically conserved these resources. National laws further implement these commitments, often reflecting domestic priorities, indigenous rights, and environmental concerns.

The ethical dimensions of genetic resource governance are equally significant. Issues such as biopiracy, informed consent, cultural sensitivity, and the commodification of life forms demand careful consideration. Ethical debates often revolve around the fair treatment of indigenous knowledge systems, the moral limits of genetic manipulation, and the responsibilities of researchers and corporations when utilizing biodiversity from economically or politically vulnerable regions. Ethics serve as a guiding framework to ensure justice, respect, and equity in all dealings involving genetic resources.

On the policy front, governments and institutions must craft strategies that align conservation goals with socioeconomic development. This includes establishing clear guidelines on research permits, community engagement, benefit-sharing mechanisms, and enforcement structures. Effective policies require a multi-stakeholder approach, incorporating the voices of indigenous groups, scientists, environmentalists, and policymakers. National biodiversity strategies and action plans often reflect this integrative vision, aiming to sustain biodiversity while promoting innovation and access.

In sum, the governance of biological and genetic resources sits at the crossroads of legal mandates, ethical imperatives, and policy innovation. The challenge lies in crafting frameworks that are not only legally enforceable and ethically sound but also adaptable to the evolving realities of globalisation, technological change, and ecological urgency. As the world becomes increasingly interconnected, safeguarding these resources for present and future generations is not only a scientific or environmental concern—it is a matter of justice, equity, and global responsibility.

MATERIAL AND METHODS

The research utilises a blend of qualitative and doctrinal legal methodologies, incorporating aspects of comparative legal analysis and policy assessment. The aim is to analyse the legislation governing access to and protection of biological and genetic resources (BGRs), focusing on the legal, ethical, and governance aspects at international, regional, and national levels. -

Data Acquisition Principal Sources – The study is based on a comprehensive examination of international legal instruments, including: - The Convention on Biological Diversity (CBD) (1992) The Nagoya Protocol on Access and Benefit-Sharing (2010) The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) The TRIPS Agreement and other regulations from the World Intellectual Property Organisation (WIPO) relevant to national biodiversity and intellectual property legislation, such as India's Biological Diversity Act and Brazil's ABS Law.

Secondary Sources

Publications in peer-reviewed journals, legal assessments, official reports, and NGO documents related to biodiversity governance, access, and benefit-sharing (ABS), intellectual property rights (IPR), and indigenous knowledge systems. Analyses of conflicts with biopiracy and benefit-sharing. Policy briefs and position papers from entities such as the World Bank, Food and Agriculture Organisation, and the United Nations.

A Legal Comparison

We analyse certain countries, notably those abundant in biodiversity like India, Brazil, South Africa, and the Philippines, to evaluate the congruence of their national laws with the requirements set forth by the CBD and Nagoya Protocol. The research investigates the efforts

of industrialised and developing countries to integrate innovation promotion with biodiversity conservation.

Analytical Framework

The research investigates the subsequents facts: Doctrinal Legal Analysis - A methodical evaluation of legal texts and concepts to figure out the extent, effectiveness, and shortcomings of existing regulatory systems.

Human Rights and Environmental Justice Perspective

Assessing the effects of current legislation on indigenous and local communities, whose traditional knowledge often aids in the utilisation and identification of genetic resources. * IPR and Innovation Policy Interface - Evaluating the compatibility and effectiveness of patent systems, plant variety protection, and equitable benefit-sharing mechanisms, and whether they pose challenges. Legal, ethical, and policy points of view on governance and protection of biological and genetic resources.

Beginning

The Convention on Biological Diversity (CBD) from 1992 and the World Trade Organisation Agreement on Trade-Related Intellectual Property Rights (TRIPS)[1] from 1993 have been around for a long time. A lot of the people in TRIPS are also in CBD. India has signed both agreements. Many parts of these papers are connected to one other, but the rights and responsibilities are very distinct. The protection of genetic and biological resources and their availability are two primary areas where these agreements overlap that have become increasingly difficult and alarming. People were worried that the CBD was not doing its job of protecting and supporting biodiversity and the ecosystem, as well as giving people access to biological and genetic resources[2]. But TRIPS says that all states must give Patents, and it should be available across all fields of technology, including biotechnology. Patents, a Sui generis system, or a mix of the two must protect diverse types of plants. State parties with different interests need a clear plan to keep these promises that depend on one other.

There has been a lot of talk in India about the US Patent Office's problematic patents on turmeric and neem basmati, which were all based on known Indian information. Because of this, the Indian government is now putting all its efforts into stopping biopiracy so that it can achieve its international commitments under both agreements. The US and the EU have both said that the neem, turmeric, and basmati patents are not valid.[3] These cases have brought to light problems with the entire process of getting and canceling bioproduct patents. For instance, a patent was given for using turmeric on both acute and chronic wounds to speed up the healing process. The Council of Scientific and Industrial Research (CSIR)[5] said in their patent challenge that the innovation that was claimed was already well-known in India. There was proof that the patent was wrong. Because many non-governmental organizations (NGOs) have claimed they are worried about it, the European Patent Office (EPO) should likewise cancel the Neem patent. You can fight peony patents, but it is not the best way to stop biopiracy because it is hard and expensive to do in another country. These two agreements say that a system must be put in place that fits with what they want to do.[6]

How to use IP rights to keep genetic resources safe

Biodiversity is vitally important for the health of plants, animals, fish, and other living things. The biotechnology[7] industry needs biodiversity to work. The tropics and destitute countries have the most interesting plants and animals. It is well known that most of the world's flora and animals live in countries that are not very developed. In fact, they make up 80% of all land biodiversity.

India has one of the twelve most diverse ecosystems in the world. India has 7–8% of all known species, while it only takes up 2.5% of the world's territory. India has the same amount of informal and formal traditional and indigenous knowledge. Plant genetic resources (PGRs) are the "raw material" for biotechnology.[4] They holds genes, folk variants, and land races that are used to make new varieties. Before molecular biology and genetic engineering, plant breeders had to look for genetic diversity within a species. Genetic engineering can move genes between sexual lines, which has made biodiversity more valuable in terms of money. You can create a new kind of plant with the right genetic components and rDNA technology. In other words, PGRs are particularly important for study on biotechnological plant breeding. These PGRs came from countries that

are not very developed. They are currently being kept safe at ex situ conservation centres, where new types are being grown and further research is being done. Most of the research and development in biotechnology happens in wealthy countries, mostly by private people who work for big firms. Farmers and plant breeders in developing countries could get PGRs for free for research and development until recently. In richer nations, patents and plant breeders' rights (PBRs) protect products or plant varieties that appear from these genetic resources. But it is hard to get these rights in poor countries. After "adding value" to protected goods, they become expensive exports without giving credit or money to the people who made and kept this "raw material." Most of these PGRs came from poor countries, where traditional communities developed, supported, and preserved them. These communities are the rightful heirs, but they have not been rewarded for their work or seen any benefits from it. It is important for developing countries to get paid for the PGRs in question because their genetic resources have made the most money in both developed and global economies. It is also important to remember that genetic resources can teach us things. Plant breeder's rights (PBRs) and patents are about "genotypes," which are bits of information that make up the genetic composition of plants and animals. "They can give someone exclusive rights to something, but there is some disagreement about whether they can be patented because they are new and don't have to be made public." These results show that genetic resources will be a big source of intellectual property rights (IPRs), which is something that article 27 of the TRIPS agreement talks about. To protect the environment and, by extension, biodiversity, Articles 27(2) and (3) of the TRIPS agreement set up important exceptions. Biotechnology, especially rDNA technology, has a significant impact on health and agriculture, which are two incredibly important areas for developing countries. Biotechnology has changed a lot about how we learn about farming.[8]

The Biodiversity Convention's Goals and Areas of Focus

The CBD has three basic goals: to safeguard biodiversity, to use its parts in a way that doesn't destroy them, and to make sure that everyone gets a fair share of the advantages that come from exploiting biodiversity's genetic resources and sharing helpful technology. The several parts of the Convention carry out this order. Article 15 of the Convention says that states own genetic resources and that people must get "prior and informed consent" from states before they can use them[9]. This clause has caused a number of huge problems that need to be carefully thought about for a long time. In 1983, the FAO helped write and put into action Article 1 of the International Understanding on Plant Genetic Resources. It argues that genetic resources are no longer the "common legacy of mankind."[10] In the past, everyone could use genetic resources without restriction. The Consultative Group on International Agricultural Research Work (CGIR) opened its seed banks and research centers to the public because of this. The Green Revolution made it easier to create new types of rice because these resources were available. Also, keep in mind that the TRIPS agreement says that countries must use intellectual property rights (IPRs) in the biotech business. The CBD declared that genetic resources belong to the state, which is not the case here. If we had to employ IPRs, it would be a significant step toward making laws that restrict the flow of knowledge and entirely reject the idea of a common heritage. People are also worried about what will happen to the germ plasm that is kept in agricultural research facilities around the world. There are more than 600,000 plant samples in the "geno-plasmin" banks at these places right now. These groups might need to gain permission from the countries where they get all their materials before they can share these plant genetic resources. Running these centers will also be hard because of money and management issues. Article 15(2) finds a middle ground between the idea of national sovereignty and the requirement for parties to the contract not to put in place rules that go against the aims of the Convention.[11] It also specifies that the people who sign the contract must make sure that the other people who sign the contract can use genetic resources in a way that is good for the environment. States can't unilaterally stop people from getting genetic resources whenever they want. The Article also says that access to a Contracting Party's genetic resources "must be on mutually agreed terms[12] . The country that provides the genetic resources has the right to make money from

Table 1. TRIPS vs. CBD – Legal, Ethical, and Policy Perspectives

Issue/Perspective	Obligation under TRIPS	Obligation under CBD	Legal, Ethical, or Policy View
Patentability of Life Forms	Allows patents on microorganisms and potentially life forms (Art. 27.3b)	Encourages protection of biodiversity, not commodification	Legal: Conflict over scope of what can be patented
Traditional Knowledge (TK)	No explicit recognition	Recognizes TK and promotes respect for indigenous rights (Arts. 8j, 10c)	Ethical: TK holders should be recognized and rewarded
Access and Benefit Sharing (ABS)	No clear requirement for ABS	Mandates fair and equitable benefit sharing (Art. 15)	Policy: National ABS laws needed to implement fair use
Disclosure of Origin in IPR Applications	Not required (under Art. 29)	Encouraged as part of access conditions	Legal/Policy: Amendment to TRIPS proposed to include disclosure
Prior Informed Consent (PIC)	Not mandated	Required before accessing genetic resources (Art. 15.5)	Ethical: Ensures community autonomy and informed choice
Technology Transfer	Limited provisions (Art. 7, Art. 66.2)	Strongly promotes access to technologies (Art. 16)	Policy: Promote South-South and public-private partnerships
Farmers' Rights & Land Races	Not recognized	Recognized through sustainable use and in PGRFA (e.g., Nagoya Protocol)	Ethical/Policy: Support in-situ conservation and agro-biodiversity
Sovereignty over Resources	Does not acknowledge explicitly	CBD asserts national sovereignty over biological resources	Legal: Countries can regulate access under national laws
Harmonization of IPR and Biodiversity Laws	TRIPS enforces minimum IPR standards	CBD emphasizes community rights and conservation	Policy: Need for integrated legal frameworks aligning TRIPS with CBD goals

Table 2. International Case Laws

Case	Facts / Issue	Decision & Reasoning	CBD / TRIPS Conflict
1. Havasupai Tribe v. Arizona Board of Regents(2010)	DNA samples from tribe given for diabetes study were used in unrelated research (e.g., mental health, migration) without consent	Court ruled in favor of the Havasupai tribe: awarded $700,000 compensation, returned samples, and required transparency	Contravenes CBD Article 15 on Prior Informed Consent (PIC) and ABS obligations; also conflicts with TRIPS-related biotech norms on permissible use and benefit-sharing.
2. Hoodia (San people) Biopiracy Case	South African CSIR patented appetite-suppressing component from Hoodia (used by San people), without PIC or benefit sharing	Parties eventually agreed to a benefit-sharing arrangement in 2002, granting royalties to the San	Highlights violation of CBD Articles 8(j) (traditional knowledge) and 15 (PIC & benefit-sharing), and lack of mandatory disclosure as TRIPS lacks such requirements.
3. Neem & Turmeric Patents (India / US Patent Revocations)	Traditional Indian knowledge of turmeric (wound healing) and neem (pesticide properties) were patented in US.	USPTO revoked these patents citing prior art and lack of novelty.	Demonstrates conflict: TRIPS allows patenting unless novelty is absent; CBD principles (prior art, TK protection) must be considered.
4. Basmati Rice & Wheat Varieties Cases	Patents granted to foreign entities for Basmati rice and Indian wheat strains (Nap Hal series), falsely claiming novelty.	Indian objections led to revocation or narrowing of patents; generic/pseudo-generic Basmati excluded; wheat patents revoked.	Reflects conflict: TRIPS minimum patent standards vs. CBD emphasis on sovereignty and TK (Art. 15, 8(j)).
5. Dcm Shriram Ltd v. National Biodiversity Authority (India, 2023)	A breeder claimed benefit-sharing exemptions under Plant Varieties Act, conflicting with Biodiversity Act's access rules	Court upheld Biodiversity Act: access and benefit-sharing obligations stand even where plant variety registration exists; no double exemptions	Illustrates conflict between domestic implementation of CBD-based ABS statutes and TRIPS allowing plant variety regimes; need for harmonization.

their use in business. Because of this, Article 15 says that genetic resource owners have two duties: to keep them safe and to let others utilize them on terms that both sides agree on.

The Convention's main goal is to protect and promote the rights of communities, farmers, and indigenous peoples when it comes to their biological resources and knowledge systems.[13] This means that the agricultural sector in most developing countries is mostly stable and successful in the long term because of the informal innovations that farmers come up with. People are worried about how traditional knowledge and genetic resources are connected because of Article 8(j) of the CBD. It also recognizes the part that traditional knowledge, practices, and new ideas from indigenous and local communities play in protecting and using biological diversity in a way that is fair for everyone. The agreement says that the parties must, as much as possible and in a way that is legal in their own countries, respect, preserve, and uphold the knowledge, innovations, and practices of indigenous and local communities that are part of traditional lifestyles that are important for protecting and using biological diversity in a way that is sustainable. They should also try to make sure that everyone gets a fair part of the benefits of employing these new ideas, methods, and information.

The text makes it clear that the States parties need to pass laws about three important but hard-to-coordinate issues that is-

1. Setting rules for how rights (including IPRs and suit generic systems) can be used, how they can be used, and how they can be protected in aboriginal and native communities' knowledge, inventions, and implementation connected to maintaining biological variety as well as using it sustainably.
2. Getting a lot of people to use these new ideas, methods, and information with the help and support of the people who own them; and
3. Encouraging everyone to get their fair share of the benefits that come from using them.
4. Moving technology from one part of biotechnology to another.

No matter how it is done, technology transfer always involves three steps: understanding, communicating, and absorbing.

To create a new and valuable product, it is important to properly write down all of the existing information so that someone who wants to use it can do so according to a defined set of rules. Countries don't have to give up their technological know-how or let other countries access their genetic resources unless both parties agree to do so. Article 16 of the CBD talks about intellectual property rights (IPRs) and how to move technology that has to do with genetic resources. This convention says that the Contracting Party agrees that technology, including biotechnology, is necessary to reach the goals of this Convention.[14] The Consented contracting Party also agrees to provide and help other Contracting Parties get and use technologies that are useful for protecting biodiversity and using it in a way that does not hurt the environment too much. It tells you how to get and move technology the right way. It needs fair and good terms for transferring technology and letting low- and middle-income countries use it, like preferential and concessional terms. But when the technology is protected by patents or other types of intellectual property rights, access and transfer must be done in a way that respects those rights. Countries are expected to recognise and protect the ownership of new ideas that use genetic resources, either through patent systems or other legal mechanisms that operate.

A Contracting Party that uses genetic resources from a developing country, on the other hand, should provide "access to and transfer of technology, [by a Contracting Party] which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights" through the implementation of legislative, administrative, or policy measures. So, both parties benefit from being able to use genetic resources and share technologies. Businesses also have this duty, which should help "access to, joint development, and transfer of technology" for the benefit of both government organisations and the commercial sectors of developing countries. The people who signed the contract need to work together on this issue since patents and other intellectual property rights could change how the CBD is put into reality, especially when it comes to transferring technology. This is "subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its

objectives." The reference to international law on patents and other IPRs includes the duties outlined in the TRIPS agreement.

Article 16, paragraph 5 says that IPRs promote the aims of the CBD, but it's not clear which will come first if the two dispute. Is it allowed to break an IPR responsibility if it won't help the CBD attain its aims, like the one in article 8(j)? The provision is considerably weaker because the people who signed the contract merely have to "cooperate," and it's not obvious what the substantive commitment is in this circumstance. Article 22 specifies that the CBD won't change the rights and duties of any Contracting Party that come from an existing international agreement, unless doing so would seriously harm or threaten biological diversity. This is another reason why it matters. Both sections offer a strong case for CBD to have priority over any other agreement, even TRIPS. "Can the rules of one Convention tell the members of another Convention what to do?" is a good question. In this case, can TRIPS members be subject to CBD? Is it not reasonable to say that living things should not be included by TRIPS because genetic resources and biotechnology are so closely related, especially when they hurt the environment, which is what TRIPS says in article 27(2)? It is usually straightforward to say that laws like these should be construed in a way that takes all relevant events into account. For instance, the IPR system should be connected to issues like trade, the environment, farmer rights, and the rights of local communities. These arguments, on the other hand, are utopian because they suggest that things "ought to be," yet they could also just be hopes because there is no clear idea of who should make decisions or what should come first. It is usually better to have a stronger legal basis. The hardest parts of the whole CBD idea are finding the right technology and coming to an agreement on how to share profits. The CBD says that the Contracting Parties must "take all practicable measures to promote and advance priority access." This is to make sure that poor nations have fair and equal access to the advantages and consequences of biotechnologies that use genetic resources contributed by those Contracting Parties. Both sides need to agree on the rules for this kind of access. Because of this, people who exploit genetic resources to make new medicines, chemicals, or plant or animal species must share their earnings with the owner of the resources on conditions that all parties agree on. Sharing information on the findings of technical, scientific, and socio-economic research..

Article 17 of the CBD also talks about "specialised knowledge, indigenous and traditional knowledge in combination with the technologies referred to in Art. 16(1)." This means that both sides are making a pledge. The United States has not yet approved CBD. The biotechnology industry has opposed the Convention, saying that it (1) lets signatories, especially poor countries, weaken intellectual property protection and (2) lets them sign compulsory license agreements. There are worries that biotechnology would be used to coerce licensing of biotechnology-related patents because it has such great promise to help developing countries with their food and health problems. When writing or changing national laws and regulations, Article 8(1) of TRIPS lets members "adopt measures necessary to protect public health and nutrition, and to promote public interest in sectors of vital importance to their socio-economic and technological developments" as long as those measures are in line with other TRIPS provisions. Members can also take acts that are against competition or require approval for non-commercial public use. However, according to Article 7 of the TRIPS Agreement, IPR protection and enforcement must encourage technological innovation, transfer, and dissemination to the mutual advantage of producers and users of technological knowledge and in a manner conducive to socio-economic welfare and balance of rights and obligations." Furthermore, industrialised states are required by Article 66(2) of the TRIPS agreement to establish incentives for domestic companies and organisations. These TRIPS clauses are in line with CBD articles 16.4, 17, and 19, which talk about transferring technology to developing nations. This is mostly the job of the private sector in affluent countries. Article 16 of the CBD is based on the idea that countries with a lot of biodiversity that don't have access to the right technologies to accomplish the Convention's goals are missing out on opportunities to safeguard biological variety. It sets up a legal framework that protects the global intellectual property system while lowering these costs. First and first, access to technology transfer should be based on fair and just terms. Most people

think that technology transfer agreements should not be based on pricing or market segmentation but should instead be based on the conditions of the global technology market. The phrase "mutually agreed" does not apply to compulsory licensing because it is not "mutually agreed." When a country gives out compulsory licenses, the payment it makes for access to protected technology must be fair for each case, taking into account the economic value of the authorisation.

Article 31 of the TRIPS agreement and Article 5 A of the Paris Convention for the Protection of Industrial Property say that patenting environmentally friendly inventions must be done in a certain way. The rules for restricting the transfer of biotechnology are the same as the rules for controlling the transfer of technology in general. One of these rules is the amount of royalty. Another important thing to keep in mind. The industrialised world sees sharing genetic resources and transferring technology as a violation of economic responsibilities and an invasion of private technologies and expertise. People in the developed world think that these kinds of government acts in developing countries make international investors less likely to want to invest there. These affluent countries' viewpoints show that poor countries without the right intellectual property rights won't be able to get technology in the future. In these situations, it is hard to honour the rights of indigenous peoples and pay them for their work to promote, protect, and conserve genetic resources as required by the CBD.

Fair access to and exchange of genetic resources

To stop biopiracy and make sure that genetic resources are available, a system must be put in place that helps both the owners of genetic resources and the people who need them for biotechnology research and development. "A strong international framework for intellectual property could help solve this problem." There are two parts to the link between access to genetic resources, benefit sharing, and intellectual property rights. First, it's possible that genetic materials that have been kept in place or moved to a different location have been changed by humans to have traits that don't happen naturally. If these changes are new, inventive, and useful in business, they may be able to be patented (but only if they meet certain standards set by the laws of the country where the patent is sought). Plant genetic resources (PGRs) are new, unique, stable, and consistent types of plants that may be able to get national legal protection through patents, a sui generis system, or a mix of the two. When it comes to traditional knowledge, other modified resources like landraces and traditional varieties that are important for the survival of local communities and maybe for the preservation and advancement of plant genetic resources but don't fall under the current intellectual property laws may be considered protected by national laws. You can only get to privately held genetic resources with the permission of the right holders and through license agreements. Recording interests in inventions made possible by using traditional knowledge and genetic resources is the second situation in which intellectual property rights might help with benefit sharing and access to genetic resources. Many national and regional laws have made it necessary for patent documents to show where the genetic resources used to make inventions came from and to show that traditional knowledge holders and relevant authorities have given their informed consent. The goal of this declaration is to give people a way to prove that they are following the rules and contracts that regulate benefit sharing and access to genetic resources.

"The CBD lets people who own biological knowledge get these benefits in exchange for the old, non-patented base that a patented product is built on." This base could have truths, like the Indian idea that neem leaves can be used as insecticides on grains that are stored or that turmeric can kill bacteria. It could also be a group that the government pays for to help it flourish and safeguard it, like the Indian Council of Agricultural Research. Or it may be information that an MNC utilised to produce a new type or compound by expanding on what they already knew and adding a little bit of newness without providing the public any advantages or shares. Plant breeders' rights damage farmers' rights because they don't think about the labor that farmers do as breeders. Patents work the same way: they help a multinational corporation gain local knowledge by making tiny changes or translating it. However, putting the idea of indigenous and local communities' rights into practice at the international level is very difficult because it is hard to measure and recognise the

new and valuable parts of their contributions." Also, it's hard to figure out exactly where the important genes that give the new variety its unique traits came from. Will all the countries that got the news benefit from it? Even though it isn't very old, the word "traditional knowledge" needs to be clearly defined. The national legal system's suggested remedies to these difficulties must be clear, easy to understand, and fair in terms of recognition and payment. Also, it shouldn't be much difficult for the foreign patent holder or the plant breeder or researcher. Everyone should agree on the basic rules for access and benefit sharing that the law should spell out. International efforts to work together to find new kinds of plants and animals might be the answer in this scenario. But developing countries need to take the initiative and take on more risk by undertaking more "value adding" at the local level, where they can decide what appropriate recompense for indigenous people or rural communities should be. This is the only way they can protect and benefit from their great biological variety. But there are challenges with sharing benefits at the national level, which will be dealt about later. Also, biotechnology research is usually site-specific, especially in agriculture, and needs to take into account the soil and climate conditions in each area. A deal with a foreign partner should include a quid pro quo system in which access to genetic resources is traded for local research and manufacturing facilities and training for people. This is likewise in line with Article 8(j) of the CBD. Such an agreement would help both domestic and foreign parties by setting up a system for making the most of genetic resources in exchange for a high enough price for access to such resources. Governments in developing countries could set up a fund by taxing manufacturers for extra output based on how close the trademarked or protected living form or folk rendition is. The money might be used to help fix problems with the environment in poor countries. These countries need to boost their own biotechnology research and development, especially in agriculture, to make new types of crops because their populations are growing quickly and their farms aren't doing well. "The national interest should be protected by requiring licenses for any misuse of the rights granted by national law."

To help the CBD meet its aims, such making sure that benefits are shared fairly, the law should require IPR applications to include the nation of origin and the community that taught them about the resources that can be copyrighted, as well as proof of consent from that country. In other words, the individual who filed the petition needs to prove that the CBD's requirements have been met. National laws give us a way to figure out the specifics of benefit sharing. A good crop's pedigree can include land races, or "folk varieties," that come from diverse sections of a country or even more than one country. Even while national laws safeguard farmers' rights, it is important to make sure that farmers from other nations are adequately paid for their labor in preserving, protecting, and creating diverse types of germ plasm. It's also crucial to realise what conventional wisdom can do. The host country and the foreign agency or corporation need to agree on how to share benefits based on general rules. The best thing to do is to pass a law that creates a sui generis system to address these needs that emerge from farmers' rights, the CBD, and fair pay systems.

How to Make the Law Work in India

India has lately passed three laws that are all about genetic resources and biodiversity. These are the Plant Variety Protection and Farmers Rights Act of 2001[14] , the Patents Act of 1999[15], and the Biological Diversity Act of 2000[16]. The Ministry of Industry and Commerce is in charge of patents, the Ministry of Agriculture is in charge of plant varieties, and the Ministry of Environment and Forests is in charge of biodiversity. It looks like the people who made these regulations didn't work together well enough, which is why the bodies and their functions are the same. The definitions of biological resource intellectual property rights and resource access plans in the three proposed statutes are very similar. The Patent Act, the Plant Variety Protection Act, and the Biological Diversity Act will all build up an IPR system, so these three proposed laws are all connected. The proposed Plant Variety Protection Act creates a new way to protect plant breeders' rights (PBRs) that is based on TRIPS article 27.3(b). The proposed Patent Act, on the other hand, allows biotechnology patents. These laws are meant to help India follow the rules set out in the TRIPS agreement and the CBD.

The Patents (Second Amendment) Act of 1999

The Act allows for the patenting of

biotechnological methods." The new change to Section 5 of the Amendment Bill says, "For the purposes of the section, chemical process includes biochemicals, biotechnological, and microbiological process." When someone wants to patent biological material, they have to put both the biological material and the requirements in a depository institution. This will show where and when the biological material used to make the invention came from. Clause 28 of the Act provides that the patent will not be awarded or taken away if the application incorrectly indicates where the biological material came from or where it was found. The Act also provides rules to protect biodiversity and traditional knowledge. People in the country where the invention was developed must be able to get to the information that led to it in order for a patent to be taken away. The goal of this project is to keep the traditions and knowledge of native or local people safe.

The Plant Variety Protection and Farmers' Rights Act of 1999

The major goal of the Act is to create plant breeders' rights (PBRs). The new law would cover all plants except for microbes. Even if it is missing some portions, the UPOV Convention is the foundation for everything else. For example, it gives farmers their regular rights and shares benefits and pay with them. This shows how important traditional, rural, and tribal populations are to the country's agro-biodiversity. It also understands that farmers have to develop crops and protect them. It has a section (clause 3) that lets the Plant Varieties and Farmers' Rights Protection Authority set up benefit sharing, among other things. People or groups get paid when their genetic material is utilised to generate a protected variety. This is called benefit sharing. The authorities will decide how much to provide based on the type and amount of genetic material the claimant used to generate the variant, as well as how helpful it is for business and how much people want it (section 26). Additionally, the National Gene Fund, which it set up (article 52), will get benefit sharing accruals. Article 52 specifies that the Fund's money will be used for a number of ways, include giving the claimant a share of the benefits and paying the village community for using its variety to safeguard and exploit genetic resources in a way that doesn't harm them. The name of the Bill also protects farmers' rights, as you might expect. Clause 31 solely safeguards farmers' rights to keep, use, trade, give away, or sell farm products that are protected. This is in conformity with Article 15(2) of the UPOV Convention, which became law in 1991. But this privilege doesn't apply to the farmer if the consumer is buying the goods to make copies of them for sale. Instead of breeders, the Act usually labels farmers agrobiodiversity growers and managers. According to Clause 48 of the Draft Act, the following groups enjoy rights: -

1. Anyone can register a claim in any centre mentioned in the Official Gazette by the Authority for this reason, as long as they have the Central Government's consent. This includes individuals, groups of people (whether or not they are actively farming), government organisations, and non-governmental organisations. This is to make a claim for a village or local community.
2. The centre that was told about the claim can check it on its own if someone makes a claim under sub-section (1). This can be done by a government or non-government organisation, or by a person or group of people from the village or local community. If it thinks that the village or local community had a big effect on the evolution of the variety designated by this Act, it will tell the Authority what it found.
3. The Authority can pay the person, group of people, or government or non-governmental organisation that reported to it the amount of money it deems is reasonable, as long as it is within the limits set by the Central Government. After then, the Authority can send the breeder of that variety a notice in the way shown, and they will be able to complain and have their case heard.
4. Any money that breeders of variants get from subsection (3) must go to the Gene Fund.

"This line just says what the community will get if their work on producing a variety is recognised; it doesn't give them any rights. The Biodiversity Act of 2000 also agrees with this. But granting the community a monopoly on intellectual property rights will make things very difficult for the law and for running things. Communities can get credit for their work on developing a protected variety under a different article (clause 26). Article 14 further stipulates that you can't register any variety that has a gene or gene sequence that could hurt or kill people, animals, or plants.

Another exception is Clause 29, which says that a variety can't be registered if ceasing its commercial use is necessary to protect public morals, public order, the health of people, animals, or plants, or to avoid serious damage to the environment. In the public interest, the federal government could choose not to conserve any species or genus. If the right-holder doesn't set up seed production and sale, the proposed law says that protected varieties can be required to be licensed in the public interest. This makes sure that farmers can get protected seeds (article 41). According to patent law, the proposed law says that the Authority must define the terms and conditions of the license, such as the royalty and other payments to the variety's breeder, as well as the length of the license, which may change depending on the situation. In addition, it says that the variety's required licensee must have enough resources to give farmers seeds or other materials for growing them at a fair market price (article 45).

The 2000 Biological Diversity Act

One of India's biggest problems is finding a way to use a tool to help achieve the CBD's goals of fair benefit sharing." The main goals of the proposed law to implement the CBD are to limit access to genetic resources and related knowledge in order to protect local communities' knowledge of biodiversity and to make sure that the local population, who are biological resource conservers and know how to use them, gets a fair share of the benefits that come from using them. The National Biodiversity Authority, State Biodiversity Boards, and Biodiversity Management Committees shall be in charge of carrying out this duty under the Act. The National Biodiversity Authority is in charge of making sure that the Act is followed and that there are rules for fair access to and distribution of genetic resources (Article 18). It is also suggested that Biodiversity Funds be created at the federal, state, and local levels. The money from the fund will be utilised to improve and protect sites that have run out of resources. It is a good idea to keep traditional knowledge alive.

Also, state governments should tell National Heritage Sites that are essential for biodiversity after talking to local self-government groups (article 37). The proposed law says that Indians who don't live in India, foreigners, corporations, associations, or organisations that aren't registered in India or are registered in India but have non-Indian citizens managing their shares can't do anything related to biodiversity without the National Biodiversity Authority's permission (clause 3). This is meant to stop anyone from getting genetic resources without permission and to fight biopiracy. Likewise, no one may exploit study results about biological resources found in or obtained from India without the Authority's permission. If they follow the central government's policy criteria (clause 4), publishing research papers and sharing expertise through seminars and workshops are not subject to these rules.

To get biological resources or information about them for research, commercial use, bio-survey, or bio-utilisation, or to send the results of any study that used biological resources found in or obtained from India, any of the people listed above must fill out a specific form and pay the required fee (clause 19). Article 20 says that a person who has received approval cannot give away any biological resources or knowledge about them without the Authority's authorisation. When the Authority gives its permission, it will make sure that benefits are provided evenly and on terms and circumstances that everyone agrees on to help claimants, local entities, and the individual making the request (article 21). The Authority will work with local groups to set up rules for sharing benefits that will make sure that the benefits of using biological resources, inventions, knowledge, and practices related to their use are shared fairly. In accordance with the terms of any agreement and in whatever way it sees fit, the Authority will oversee the distribution of monetary advantages to providers (clause 21). This includes giving money to the National Biodiversity Fund, but only when biological resources and knowledge are obtained from a certain person, group of people, or organisation.

You can share benefits in one or more of the following ways:

1. Chosen NBA or benefit claimants share IPRs.
2. Technology changed.
3. Setting up areas for production, research, and development in regions that will make life better for people who get benefits.
4. A group of Indian scientists, local residents, and

people who get benefits are working on biological resource research and development, bio-survey, and bio-utilisation.
5. Setting up a venture capital fund to help people who get benefits.
6. The NBA decides how much money and other benefits to give to people who apply for benefits (article 21(2)).

These rules don't apply to government-approved cooperative research projects, though." Article 5 says that research projects that were started before the new law went into effect must be adjusted to meet its standards. Clause 18 says that the Authority can help state governments figure out which areas should be designated as heritage sites, give the federal government advice on how to protect biological diversity and use it in a sustainable way, and come up with rules for fair distribution of benefits and access.

The proposed law says that anyone who wants to get intellectual property rights (IPR) in India or anywhere else for an invention based on biological research or data on an Indian biological resource must first get NBA clearance. The body must give the applicant permission before the patent is sealed by the appropriate patent body. The Authority can set restrictions when it gives permission, like a share of the money made from commercial use of the rights, or it can charge a royalty, a benefit sharing fee, or both. This part (clause 6) doesn't apply to anybody who want rights under the plant variety protection act. According to clause 18(4), the NBA may also take the right steps to stop any country outside of India from giving intellectual property rights (IPRs) to any biological resource or related information that comes from India. Violating these rules could result in a fine of up to Rs. 1,000,000, a maximum five-year prison sentence, or both (article 53). Clause 56 says that infractions of the Act are cognizable and don't need bail.

One of the things the National Biodiversity Fund will do is
(a) Help folks who need it.
(b) Keeping safe and expanding sites where biological resources or information about them can be found.
C) The government will try to protect and keep local biodiversity information by making a unique system based on NBA standards [article 36(4)] and registering it at the municipal, state, and federal levels.

State Biodiversity Boards will be in charge of allowing Indians to use genetic resources for business purposes, but they will not allow any usage that goes against conservation, sustainable use, or fair benefit sharing. When the NBA and State Boards make decisions about how to use biological resources and related knowledge in their area, they must talk to these committees. The Biodiversity Management Committee may charge a fee for collecting or accessing biological resources from their area (clause 41).

It also says that every local government must set up a Biodiversity Management Committee to keep track of, maintain, and use biodiversity in a way that doesn't hurt it. The proposed law aims to bring India's legal system in line with its obligations under the CBD. The goal is to "provide for the conservation of biological diversity, the sustainable use of its components, and the equitable sharing of the benefits arising from the use of biological resources and for matters connected therewith or incidental thereto." But the proposed law doesn't give any practical ways to reach these goals.

The Bill talks a lot about benefit sharing and biopiracy, but it doesn't talk about how using IPRs in biotechnology might hurt biodiversity by making monoculture more common. Clause 21 includes benefit-sharing provisions, but the last amendments must be made after the law goes into effect. You need to know a lot about the following: teaching the local scientific community; getting more money; transferring technical tools, with or without patent or sui generis system protection; the amount of royalties, which is set by a formula that everyone agrees on; and so on. But private multinational biotechnology businesses are unlikely to agree to the proposed article 21(2) (a), which would allow for shared ownership of intellectual property rights. So, the agreed-upon terms will decide what happens next. The proposed Act creates the National Biodiversity Fund to help "conservers of biological resources, creators, and holders of knowledge." In some aspects, the fund idea supports the idea that people who create and possess knowledge don't have a right to their information. The only good thing about them is that they can get money from this fund, which

will be decided by higher-ups. It doesn't take into account the common intellectual property rights that come with biodiversity. A sui generis system could be used to set up such a privilege. A sui generis system is a more relaxed, community-based way for farmers and indigenous people to create, choose, improve, and raise different types of crops and animals. This is different from individual IPRs like patents. Several people in India have suggested giving patents to local groups, but there are certain problems with this idea. Even if they stop biopiracy, the difficulties caused by official breeders may be too much for the local people to deal with. Community rights should be properly taken into account under a sui generis system. It seems that the patent system can't protect the intellectual property rights of those who live there.

Keeping an eye on biodiversity

The hardest part is that local biodiversity management committees must keep track of biodiversity (article 41) so they can fight biopiracy and effectively dispute intellectual property rights that were earned in other nations.

Some areas of Kerala, one of India's most biologically diverse states, are actively experimenting with ways to keep track of biodiversity and make lists of it. The registers' objective is to safeguard and foster the growth of relevant ecological knowledge in local communities. They can help plan and manage the environment in a specific area. They help you get knowledge that can be utilised to manage biological resources in a way that is favourable for the environment. People and communities can also utilise them to back up their claims that they know how to exploit biodiversity resources. Biodiversity registries are a great tool to stop people from applying for patents without authorisation and to charge bioprospecting fees or royalties for using biological resources or knowledge for business. They give textual proof that knowledge can't be trademarked as ultramodern because it already exists in some parts of the world. This is especially useful when a patent application is based on knowledge from outside the US, because published resources are the sole way to determine innovation. They might also help bring back the function of the farmer as a breeder, and they could be a highly useful source of knowledge for all farmers if People in India's rural areas are trying out innovative techniques to catch creatures. As part of the experiment, the hamlet of Pattuvam in Kerala opted to keep track of all of its natural resources and other information related to them.

The People's Biodiversity Declaration, which is now on the Register, promises that people in the area would not let any biological forms have a monopoly. The communities have also promised to keep the registry secret and only disclose information when it is needed. The major goal of the registry is not to limit how local resources may be used for business, but to avoid those from outside the area from claiming rights to historical local knowledge. There are some issues with the way the registration is currently set up. First, registers can assist prohibit people from gaining patents on knowledge that is maintained in a certain area. However, they can't stop other people from exploiting DNA from plants that grow in that area. Once they uncover these genes, they can get patents on new things and ways to do things. This has to do with the latest EU directive that protects bio-technological ideas by law. This rule says that an innovation can be made from biological material that has already existed in nature but has been taken out of its natural environment or made through a technical procedure. A registration doesn't prove that someone knows their rights. But the contrary is true. The registries reveal that this knowledge is already out there and can't be patented. The only method to keep ideas or knowledge safe is via patents. This means that farmers and others in the area can't get to their information. The registers keep other individuals from claiming ownership of this data, but they aren't a smart concept for new property rights that would aid the original owners of the rights. Third, open registers would be like a research grant for scientists because anybody could see the information and it could be sold. People who possess the rights right now would not be able to stop this kind of agreement.

This argument doesn't apply to closed registers, like the ones in Puttuvam village, because they preserve the information rights of local communities. In this case, the people in the community choose who can see the registration data, not a company from outside. If someone doesn't know about any IPRs, the register only lets them share benefits in a very restricted way. Also, there is no indication that the individuals who make biological resources, protect them, or know

how to use them own them and can decide whether to sell them. Benefit sharing is a way to make up for the harm done to current rights holders by not letting farmers and locals own their knowledge and discoveries in order to stop bio-piracy. Also, benefit sharing has a number of problems. The Aarogyappacha (Trichopus Zeylanicus tramancoricus) is the experiment in dispute. The Kani people grew this herb in southern Kerala. The Tropical Botanical Garden and Research Institute (TBGRI) in Kerala produced the anti-fatigue drug Jeevani using its active ingredients. A private company was given the rights to make Jeevani in exchange for a 2% royalty on sales and a license fee of about $24,000 for seven years. The Kanis were supposed to collect half of the TBGRI's fee and royalties. Some people in the community didn't want the deal to go through, but others did. The people who were against it thought that Kanis hadn't been involved in the negotiations and that TBGRI had written the benefit-sharing agreement on its own. If TBGRI had given the Kanis the technical know-how to create the medicine instead of just money, they may have been more involved in the process. This agreement also dealt with worries about how profits would be shared and other things. A trust fund was set up in late 1997 to help the Kanis share the money. The trust's money was meant to improve the Kani tribe's quality of life. There were still problems, such dealing with a lot of cash in a mainly denominated economy and making sure that all Kanis, even those who didn't agree with the deal, were included. In addition, there was a lot of debate about the legal status of Kanis' land when it came to getting and producing raw materials. The Kanis can only get rid of small amounts of forest goods, and they live in officially designated forest zones.

The Forest Department is in charge of Aarogyappacha because it doesn't fit into this group. The company has tried to collect leaves from the area utilizing Kanis because scientists think that the therapeutic chemicals in Aarogyappacha work better in their natural setting. The Forest Department has not allowed the Kanis to collect the leaves for commercial purposes, though, because they are worried about overusing resources. In addition to the disadvantages mentioned in the previous example, there may be problems at the benefit-sharing level that can't be fixed, especially if the germplasm of a certain plant has spread to more than one country. In this case, it's not clear if one society has a better claim to a given plant than another. To fix this problem, it is best to name the players who really care about these resources in a certain country as the germplasm's source instead of people from other countries. A time frame should also be set to find out where the germplasm came from and nothing else.

Insight and Analysis

• CBD Priorities vs. TRIPS Structures: The table cases highlight the tension between CBD mandates (PIC, benefit-sharing, protection of traditional/designated knowledge) and TRIPS standards (patent eligibility, minimal IP rights framework).

• Ethical and Legal Gaps: Many decisions underscore striking ethical concerns—such as consent and acknowledgment—missing in traditional IP law unless supplemented by CBD-aligned policy.

• Forward Steps: These cases illustrate the growing trend toward embedding CBD principles into governance practices, often via national legislation or court judgements.

CONCLUSION

While both the TRIPS Agreement and the Convention on Biological Diversity (CBD) are legally binding, their obligations often conflict. For instance, a government implementing CBD-based policies to protect community rights may unintentionally violate TRIPS provisions. This legal tension reflects a broader divide: developed countries and multinational corporations (MNCs) emphasise global recognition of intellectual property rights (IPRs), while developing nations—home to most of the world's genetic resources—demand fair compensation and benefit-sharing.

To resolve this, a balanced framework is needed—one that safeguards biodiversity and respects both IPRs and the rights of local communities. Meanwhile, biodiversity-rich nations should create domestic systems to meet both TRIPS and CBD obligations compatibly. Wealthy countries must facilitate access to biological resources and associated technologies. At the same time, policies should encourage conservation of traditional varieties (land races), perhaps by

mandating their cultivation on designated land areas.

A CBD- centred global approach to benefit-sharing should include these actionable steps:

Actionable Policy Recommendations

A) Recognise CBD primacy over TRIPS in matters concerning biological resources and traditional knowledge. This requires clarifying CBD Articles 16(5) and 22 to prevent legal conflicts.

B) Amend TRIPS Article 27(3)(a) to allow countries to exclude all biological forms and traditional knowledge from patentability.

C) Legally prioritise indigenous and local communities' rights to use, trade, and manage biodiversity over private IPRs.

D) Establish binding global and national rules on access and benefit-sharing (ABS) for genetic resources. These must include prior informed consent and mutually agreed terms.

E) Revise TRIPS Article 29 to mandate disclosure of:

• The country of origin of biological resources,
• The indigenous or local community providing associated knowledge,
• Proof of consent and benefit-sharing agreements.

These reforms will harmonise the goals of TRIPS and CBD while promoting equity, innovation, and conservation.

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