A Review on Intellectual Property Rights of Biosafety

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Abstract: The interconnection between intellectual property rights (IPRs) and biosafety has become increasingly significant in the era of biotechnology and genetic modification. While IPRs aim to promote innovation and economic development by protecting new biotechnological inventions, they also raise complex ethical, environmental, and social challenges. This review explores the delicate balance between the protection of genetic innovations through patents and the preservation of biodiversity and environmental safety. It examines global & Indian legal frameworks, including the TRIPS Agreement, the Cartagena Protocol on Biosafety, and national legislations such as the Biological Diversity Act (2002), the Patent Act (2005), and the Seeds Bill (2004). The study highlights how biosafety regulations are essential in managing the potential risks posed by GMOs to human health and ecosystems. Furthermore, it discusses the need for aligning intellectual property regimes with sustainable development goals, emphasizing liability, public participation, and the precautionary principle. The review concludes that an integrated approach combining biosafety governance and intellectual property protection can promote responsible innovation while safeguarding environmental and social interests.

Keywords: Biosafety, Biological Diversity Act, Patent Act, Intellectual Property Rights, Regulations.

1. INTRODUCTION

There are several linkages between IP protection and environmental conservation and utilization. Biotechnology and its ability to manufacture GMOs threaten environmental protection. Biosafety addresses environmental issues about GMOs. The TRIPS Agreement allows patentability restrictions due to environmental concerns. The Biodiversity Convention goes farther in mandating governments to support its goals with intellectual property rights. The connection between biosafety, the subfield of environmental law that guarantees GMOs do not cause harm to the environment, and IPR as incentives for genetic engineering is an issue that requires attention beyond these broad statements on IP rights and environmental management. Therefore, meeting national and international biosafety standards is essential when employing a patented GMO. Those responsible for discharging harmful compounds into the environment should face legal consequences. [1]

Transboundary genetically modified organism movement would harm biodiversity conservation and sustainable usage, according to the Cartagena Protocol on Biosafety.

The government of India has taken measures in light of this and the importance of biosafety. Risks associated with the use and release of BTOs that could damage biodiversity and human health must be regulated, managed, and controlled by the Central Government in accordance with the Biodiversity Act.

India acknowledges the significance of biosafety in biodiversity protection with BDA, 2002, which restricts the transfer of genetically modified organisms. Environmental governance is advanced in this way.

Intellectual property rights are contrary human rights since they focus primarily on economic gains without social consideration. Because intellectual property rights are arguably underappreciated compared to human rights. Socially conscious intellectual property regimes reconcile the moral and economic rights of creators and inventors in patents with society's demands. The basic argument for patents is that they compensate innovators and help society. The human rights approach to intellectual property makes the underlying balance between inventors and creators' rights and society's interests more apparent and rigorous.

2. SAFEGUARDING GM CROPS' IP

The protection of IPR for GM crops is derived from TRIPS Agreement Article 27(3) (b). The commercial sector makes extensive use of genetic engineering. Investment in Research & Development is necessary for the creation of genetically modified seeds by private enterprises. Because of this, the Intellectual Property Regime has become more important in preventing the unauthorized duplication of goods. The pursuit of germplasms by multinational corporations (MNCs) for the purpose of engineering and creating new goods is sparked by the need to safeguard intellectual property in the biotechnology industry. Foreigners gained control of the farmers' carefully guarded variety and used it to their advantage, eventually pressuring the farmers to pay a premium for their genetically modified seeds.

The topic of IPR in connection to commerce and technological transfer is one of the most fascinating and significant concerns concerning genetically modified crops. Properly managing the IPRs linked to the increase of commercial biotech research is crucial to ensure that public and non-profit research institutions have access to new innovations. This is especially the case when it comes to emerging nations. In particular, while thinking about problems related to genetically modified organisms (GMOs), a number of WTO global accords are pertinent. [2]

When it comes to agricultural biotechnology, TRIPS permits the patenting of plant types but not plants themselves. The status of crops and plants as patentable is an open and contentious topic. In order to ensure that biotechnology is used appropriately, intellectual property rights provide the necessary legal framework. The Food & Agriculture Organization is now working on a set of thorough biosafety laws that will safeguard the public. This decision-making process demonstrates a strong commitment to social and ethical considerations. In the end, research and development capability is what matters most for a nation and its customers when it comes to making educated decisions concerning biotechnology. The scientific capacity to absorb new technologies & adapt them to local circumstances is crucial for emerging nations, especially when national technology strategies are focused on importation or domestic generation.[3]

3. BIOSAFETY IN BIOTECHNOLOGY

When people talk about biosafety, they're really referring to a more general concept that encompasses worries about how different activities could harm the ecosystem. The environmental impacts of introducing genetically modified organisms into the ecosystem have come to be closely linked with biotechnology and biosafety in recent years. The fact that patents or other forms of intellectual property protection cover the vast majority of commercially produced and released genetically modified organisms establishes a connection between biosafety and IP rights.

- **Rules for Biosafety**

Direct and indirect effects of releasing GMOs or LMOs into the environment, including but not limited to:

a) How likely is it that the GMO's traits will be passed on to the species' wild relatives?

b) The degree to which unrelated species may acquire the toxin-producing or other genes that were introduced into the organism.

c) Are there any known allergies or other health risks associated with consuming GMOs?

d) Whether GMOs have the potential to introduce new weeds, alter biological vectors, or cause systemic disruptions

In this respect, the global trade regime must address a number of interconnected issues, such as the capacity of the importing or host country to evaluate and manage risks, rules for the labeling of GMO products to enable customers to make educated decisions, limitations on GMOs that could jeopardize food security (e.g., through terminator gene technology), etc.[4]

- **Biosafety Of Genetically Modified Organisms**

New challenges to biodiversity conservation have emerged from GM plant and animal species. The release of organisms with changed genetic code into the wild poses a new threat of industrial pollution known as genetic contamination.

India is home to a wide variety of plant & animal species and is known as a megadiverse nation. Furthermore, local populations rely on biodiversity for their livelihoods and daily survival. Prohibiting genetically modified organisms is, thus, crucial in India.

Because the consequences of GM goods are not immediately apparent, addressing the environmental safety issues associated with them is challenging. Critics of this innovation claim that GM species represent a threat to non-GM species via the possibility of hybridization. A shift in the ecology may occur if these hybrids become the dominant species. There are other worries about the potential negative impacts on other species, including soil flora and animals, butterflies, and Bt crops. Some worry that the target pests might develop a tolerance to Bt crops. GM crops are already a part of today's farming practices and will likely remain so to some extent. The public's reaction and viewpoints will determine their level of acceptance, and legislators are obligated to consider these factors. Before we wrap up, it's important to note that GM crops have both proponents and detractors. [5]

4. BIOSAFETY-RELATED INTERNATIONAL INSTRUMENTS

The regulation of biosafety on a global scale is influenced by six different groups:

- **The Convention on Biological Diversity, 1992**

The topic is with preserving biological resources, making responsible use of them, and ensuring that everyone benefits fairly from their use. As stated in Article 19(3) of the CBD, the Parties:

“Is required to think about how to establish a protocol that lays out the proper steps to take, such as getting people's permission before using any biotechnologically altered organism that could harm efforts to preserve and use biodiversity sustainably.”

An Open-Ended ad hoc Group on Biosafety was established at the second COP to the CBD in 1995 to implement Article 19(3) and create a protocol "particularly concentrating on transboundary movement," including "suitable mechanism for advance informed.

Live genetically engineered organisms (LMOs) are governed by the Cartagena Protocol on Biosafety when they cross international borders. As a result, the Convention on Biological Diversity has approved the Protocol.[6]

- **The World Trade Organization (WTO)**

Trade in products and services as well as the resolution of disputes are covered. Procedures for risk assessments of plant and animal pests, illnesses, and food safety are addressed in the World Trade Organization Agreement on Application of Sanitary and Phytosanitary (SPS) Measures.

- **The International Plant Protection Convention (IPPC), 1952**

It creates ISPMs, or International Standards on Phytosanitary Measures, to combat pests that affect plants and plant products, including genetically modified organisms (GMOs).

- **The Codex Alimentarius Commission (CAC), 1972**

It creates norms for things like food labeling and food safety on a global scale. Any living thing with a unique mix of genes produced by contemporary biotechnology is considered a "living modified organism" (LMO or GMO) according to the Protocol.

- **The World Organization for Animal Health (OIE), 1924**

Standards for animal health, including contagious animal illnesses, are developed, and trade restrictions pertaining to animals and animal products are standardized.

- **The Organization for Economic Cooperation and Development (OECD), 1961**

It sets out to harmonise policies, norms, and laws on a global scale.

- **Cartagena Protocol on Biosafety, 2000**

The United Nations Convention on Biological Diversity ratified the Cartagena Protocol on Biosafety in 2000; In the month of September in 2003. The majority of the Asia-Pacific region's nations are among the 143 that have ratified the Protocol as of January 2008. Since these nations' biosafety regulatory systems are either already in place or are being built to meet the requirements of the Protocol.

When it comes to concerns about the release of genetically modified organisms (also known as "living modified organisms" in the Protocol) into the environment, the primary international legal instrument is the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. [7] Typically, it's a reaction to worries about biotechnology's possible harmful impacts on people's health and the environment. The precautionary principle, a cornerstone of international environmental law that allows conservation efforts to be carried out even when full scientific knowledge about possible negative impacts on the environment is lacking, is emphasized throughout the Protocol. This makes it stand out.

5. THE BIOSAFETY LAWS OF INDIA

India has a clear procedure for controlling the production and evaluation of GMOs and their derivatives. The DBT and the MoEF are the two highest regulatory bodies. In 1989, MoEF published regulations under EPA, acknowledging that the government should take the lead in protecting and conserving the environment. These rules control the manufacturing, importing, using, researching, and releasing of GMOs and products made from them. The regulation's stated goal is to protect both people and the environment against potentially harmful products or organisms.

Since India adopted the Protocol on January 23, 2003, the responsibility for implementing its terms lies with the MoEF of the Indian government. One of the many measures launched by the MoEF to meet its Protocol obligations is the capacity building of various stakeholders to guarantee the protocol's effective implementation throughout the country. The MoEF is now running a Biosafety Capacity Building Project with funding from the World Bank. The primary focus of this project is to enhance the regulatory framework for the following areas: risk assessment and management; information sharing; training and human resource development; and the transboundary movement of LMOs/GMOs.

- **The Patents Act, 1970**

The 1970 Patent Act was amended in 2002 and 2005. Pre-2002 modification, Section 3(i) of the Patent Act prohibited patents on "any medical, surgical, creative, prophylactic & other treatment of human beings or all that can be done to treat plants or animals similarly, heal them, or increase their economic value. Section 3(j) makes patents on "plants or animals or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals," as well as other biological objects, illegal. Current Patent Act of 2005 incorporates these revisions. [8] The 2005 Patent Act does not define "microorganism" or "biological process" and still prohibits patents on plants, animals, and seeds. Some argue that only human-created germs should be patented, not natural ones. [9] After 3(j) and 3(i) changes, processes like introducing the Bt gene into cotton may be patentable, but Bollgard is not. Another change in the 2005 Act is the switch from process to product patents.

- **The Biological Diversity Act, 2002**

"Conservation of biological diversity, sustainable use of its components and equitable sharing of the benefits arising out of the use of biological resources" are what the Biological variety Act of 2002 aims to achieve, according to its preamble. Section 36.4 of the Act specifies the responsibilities of the federal & state governments with respect to genetically modified organisms (GMOs).

Environment Impact Assessment: Integrating biodiversity concerns into environmental impact assessments of projects is addressed in Section 36(4) of BDA 2002. The provision reads as follows: "36(4) (i) wherever necessary, for assessment of the environmental impact of that project which is likely to have adverse effect on biological diversity, with a view to avoid or minimize such effects and, where appropriate, provide for public participation in such assessment."

While Section 36(4) (ii) addresses the steps the federal government must take to safeguard against the potentially harmful effects of biotechnology, this section details how to conduct an Environmental Impact Assessment (EIA) of a project that could threaten biodiversity conservation efforts. Local communities and civil society organizations must use these rights to stop the irreversible loss of biodiversity. It suggests that public involvement and evaluations should be conducted if the government believes there could be an effect on wild or agro-

biodiversity. One of the biggest dangers to biodiversity is the way things are now being developed. It is important to consider the potential effects on wild and agro-biodiversity when planning development and industrial initiatives. This is also handled under the Environmental Protection Act of 1986, which establishes a process for EIAs and the environmental clearance for industrial and development projects. But keep in mind that when it comes to incorporating biodiversity considerations, the EIA notification implementation is severely lacking. Regarding public involvement, EIA report quality, and other metrics, the previous thirteen years of EIA notice implementation have been very disheartening. There was a lot of pushback from civil society groups in 2006 about the notification's substance and the way it was redrafted. Both the substance and the redrafting procedure go against the spirit of the parent civilization. Several reasons, such as the lack of openness and public involvement, make it very weak, but it is still being implemented despite this. It goes against the spirit of the parent Act.

Biosafety: To ensure the safe use and release of GMOs that pose a threat to human health, biodiversity preservation efforts, and ecological sustainability, Section 36(4) (ii) establishes guidelines for their regulation, management, and control.

There is a great need for Section 36(4) (ii) because biotechnology poses serious, perhaps permanent dangers to human and environmental health. The biosafety-focused Cartagena Protocol of the CBD has India as a signatory. However, the Environment Protection Act of 1986 (EPA) of 1989 issued biosafety regulations that are now out of date in India. Amid public demonstrations against genetically modified (GM) crops, the biosafety regulatory system is undergoing a revision. [10]

- **Seeds Bill, 2004**

In addition to easing the production and delivery of high-quality seeds and resolving associated matters, the Bill specifies standards for the quality of seeds with respect to sale, import, and export. Specific rules for the registration of transgenic varieties are included in the Bill, along with other measures pertaining to seeds. The draft bill's clause 15 details the procedures for transgenic varieties that need permission under the 1986 Environment (Protection) Act.

Transgenic Varieties: Provisions for the temporary two-year registration of transgenic types are included in the bill. This clause ignores the fact that the transgenic variety must undergo rigorous field testing to establish its safety before being released into the wild. Significant

threats to ecological systems and the food chain are posed by the introduction of GMO into the environment. Through natural processes, transgenic material from foreign sources may diffuse into the agro-ecological system in the form of seeds. Through the process of cross-pollination, the foreign genes may be passed on to other crops and even wild species. Genetic contamination may therefore become more severe with the passage of time. A worsening of the problems may occur if genetically modified seeds were to be accidentally released, mingled with non-genetically modified seeds, or grown illegally. There are many environmental, health, & economic reasons why GM contamination is important. Public safety is greatly concerned about the possibility of genetically modified crops used to make pharmaceuticals contaminating food supply. [11]

Community agency over biological resources, environmental sustainability, human and animal health, and agro-biodiversity conservation are all profoundly affected by the Seeds Bill.

- **PVPFR Act, 2001**

India passed PVPFR in 2001; it was formally announced in 2005 in response to the TRIPS need for plant variety protection under Article 27.3(b). In section 29, which forbids the official registration of GURTs, sometimes called "Terminator" technologies, the PVPFR lays down the essentials of GMOs.

6. BIOSAFETY, IP RIGHTS, AND SUSTAINABLE DEVELOPMENT

Biotechnology and the awareness of the health and environmental risks of transgenic organism release led to biosafety frameworks. India led biotechnology and biosafety advancements. [12] Biosafety links technological expansion to environmental issues and sustainable development by addressing health and socioeconomic concerns regarding GMO in the environment. Biosafety and IP rights are linked since patents and other intellectual property protect most commercially accessible GMOs. IP rights and sustainable development are linked in one location, even if biosafety is seldom considered. This missing link must be made. The legal system must acknowledge the relationship between biosafety, which governs the potential damage of genetically modified organisms, & IPR, which encourage their development. One method to do this is to require biosafety compliance for patentability. As proven in Monsanto vs. Schmesier, biosafety and IP rights at the liability level are linked. This chapter highlights that pre-commercialization testing and the liability regime should be included. This expands on past studies on prior informed consent and traditional knowledge's geographical origin as

patent requirements. Most countries have biosafety regulatory frameworks, thus biosafety disputes should end. Just their link is missing.

Formally integrating the biosafety licensing procedure and intellectual property rights should not cause any debate as all stakeholders currently accept them. Liability regime linking will also be difficult. However, GMOs' particular traits and capacity to propagate make this necessary. The precedent provided by Monsanto v. Schmeiser shows that the legal system should allow competing culpability systems.

The Cautious Principle Must Be Followed

Recognizing that every country and community has the freedom to set its own standards for risk and to reject the release or transfer of any LMO or its product if they feel the level of danger is too high;

- The commercial creator and/or exporter of the LMO or its product is obligated to invest in the execution of the protocol and strict responsibility according to the polluter-pays principle.
- Following a release or transfer, there must be continuous monitoring of LMO performance, effects, and habitat range.
- There must also be national reporting, compliance checks, enforcement measures, and dispute resolution procedures.

7. CONCLUSION

The intricate relationship between intellectual property rights and biosafety underscores the need for a balanced approach that promotes both innovation and environmental protection. While IPRs incentivize biotechnological research and development, they must operate within a framework that prevents ecological harm and ensures social accountability. India’s regulatory structure comprising the Biological Diversity Act, the Patent Act, and biosafety guidelines under the Environment Protection Act reflects growing awareness of the importance of biosafety in biotechnology governance. However, outdated biosafety regulations and weak enforcement continue to pose challenges. To ensure sustainability, it is essential to integrate biosafety compliance as a prerequisite for patentability and to strengthen liability mechanisms for genetically modified organisms. Following the precautionary and polluter-pays principles, biotechnology must advance with responsibility, transparency, and public participation. A

cohesive linkage between IPRs and biosafety will not only secure innovation but also uphold ecological balance and human welfare, contributing to the long-term goal of sustainable development.

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8. Note that this language is almost a verbatim transfer from article 27.3(b) of TRIPS, where these terms are similarly left undefined. Apart from WTO obligations, the amendments also reflect obligations to the WIPO Patent Cooperation Treaty (PCT). Briefly, the PCT aims to facilitate a process whereby parties wishing to invoke a patent in many countries can do so with one application, though WIPO itself cannot grant protection.

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