

## **Assessing the Regulatory Implications of GMO Patents in India**

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### **ABSTRACT**

This study examines the current legal framework governing genetically modified organisms (GMOs) in India and its evolution over time. It also evaluates the effectiveness of this framework in addressing the approval, production, and commercialization of GMOs. Additionally, the paper explores the ethical considerations and stakeholder perspectives surrounding the development and deployment of GMOs in the agricultural sector in India. It analyzes the primary ethical concerns and how different stakeholders, including farmers and scientists, perceive the ethical implications of GMOs, and how these perceptions influence decision-making. The impact of GMOs on biodiversity in India, both in agricultural and natural ecosystems, is also investigated, along with the existing regulations addressing concerns related to the potential effects of GMOs on native species and ecosystems. Furthermore, the paper assesses the current regulatory framework's effectiveness in managing the introduction and dissemination of GMOs in India and identifies challenges and gaps that exist within the system. Finally, recommendations are made to improve the regulatory framework's effectiveness in addressing the evolving landscape of GMOs in India.

### **INTRODUCTION**

#### **Introduction - The Evolution of Genetic Modification in Agriculture**

Genetically Modified Organisms (GMOs) have become a focal point in the discourse surrounding modern agricultural practices. This chapter delves into the fundamental aspects of GMOs, exploring their origins, the revolutionary impact of biotechnology, and the ensuing developments in India's agricultural landscape. With a profound transformation in the genetic makeup of organisms through genetic engineering and transgenic technology, GMOs represent a novel frontier in agricultural science.

#### **1.1 Defining GMOs: A Genetic Alchemy**

At its core, a GMO encompasses any organism whose genetic composition has undergone modification through processes like genetic engineering or transgenic technology. This alteration involves the incorporation of genes from diverse sources—be it plants, animals, bacteria, or viruses—resulting in combinations that do not occur naturally or through traditional cross-breeding methods. Genetic modification, a departure from centuries-old selective breeding,

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allows for the direct manipulation of an organism's DNA. This revolutionary technology opens up new possibilities for enhancing desirable traits in crops, animals, and microorganisms, transcending the limitations imposed by conventional breeding methods.

## **1.2 Historical Context: Traditional Breeding vs. Biotechnological Breakthroughs**

Throughout history, humans have employed various breeding methods to mold organisms to meet their specific needs. Traditionally, plants and animals underwent selective breeding over generations to acquire desired traits. However, the conventional methods proved time-consuming, and the outcomes were often unpredictable, introducing unwanted characteristics. The advent of biotechnology has empowered scientists to directly modify the DNA of microorganisms, crops, and animals, offering a swifter and more precise approach to genetic enhancement. The historical evolution of genetic modification reflects a shift from the reliance on natural selection to the intentional manipulation of genetic material. While traditional breeding methods required generations to manifest desired traits, biotechnological breakthroughs enable scientists to achieve targeted modifications within a single generation, revolutionizing the speed and precision of agricultural advancements.

## **1.3 Biotech Growth in India: A Dynamic Landscape**

In recent decades, India has witnessed a surge in biotechnological advancements, leading to the development and commercial production of Genetically Modified (GM) crops. This chapter sheds light on the growth trajectory of biotech in India, showcasing the diverse range of GM crops in various stages of development. India's embrace of biotechnology in agriculture reflects a commitment to addressing food security challenges and enhancing crop resilience. The dynamic landscape of biotech growth in the country involves collaborations between research institutes, government bodies, and private enterprises, paving the way for innovative solutions to agricultural challenges.

## **1.4 The Controversy Surrounding GM Crops in India**

The deployment of GM crops in India has not been without controversy. The discovery of 500 tonnes of GM rice in an export consignment sparked concerns about the reputation of India's agricultural market. This incident prompted a thorough investigation by the Agricultural and Processed Food Products Export Development Authority (APEDA). The controversy surrounding GM crops in India highlights the intricacies of international trade and the challenges associated with ensuring the purity of agricultural exports. As India grapples with the aftermath of this incident, questions arise about the regulatory framework, oversight mechanisms, and the potential implications for future developments in the biotech sector.

## METHODOLOGY

This paper employs a purely doctrinal approach, which involves the analysis of existing laws, regulations, and judicial decisions related to GMOs in India. This approach is suitable for this research as it focuses on the current legal framework and its effectiveness in addressing the issues surrounding GMOs. The research will also involve a review of relevant scholarly articles, reports, and publications on the topic.

## LITERATURE REVIEW

### **Review of Issues Related to Patentability of Biotechnological Inventions**

This review explores critical aspects of patentability, focusing on international norms, Indian regulations, and specific challenges associated with genetically modified microorganisms, animal cloning, stem cells, and genetically modified seeds. It explores how biotechnology, a transformative field modifying living organisms, faces complex challenges in patentability, driven by rapid advancements in techniques like recombinant DNA technology and cloning.

### **'Genetically Modified Crops in India: Economic and Policy Issues' by Swapan Bhattacharya (2007)**

This paper discusses the economic implications of GMOs in India, focusing on the policy issues related to their development and commercialization. It highlights the potential benefits of GMOs in terms of increased productivity, reduced costs, and improved food security, while also acknowledging the concerns regarding their safety, access, and control.

### **'Genetically Modified Organisms and the Developing World: A Review of the Debate' by Deepa Badrinarayana (2010)**

This article provides an overview of the ongoing debate surrounding GMOs, with a particular focus on the developing world. It discusses the various arguments for and against GMOs, considering their potential benefits and risks, and emphasizes the importance of addressing ethical and regulatory concerns in the development and commercialization of GMOs.

### **'Patenting Life: Biotechnology, Intellectual Property, and Environmental Ethics' by Margret Engelhard (2009)**

Engelhard's book explores the ethical implications of patenting living organisms, including GMOs, in the context of biotechnology. It critically examines the arguments for and against patenting life, while also discussing the potential consequences of such patents on the environment, human health, and social justice.

## **'Intellectual Property Rights and Agricultural Biotechnology in Developing Countries' by Keith E. Maskus (2000)**

This paper analyzes the relationship between intellectual property rights (IPRs) and agricultural biotechnology, with a focus on developing countries. It discusses the potential impact of IPRs on access to and diffusion of biotechnology, including GMOs, and highlights the need for a balanced approach to ensure both innovation and equitable access.

### **RESEARCH QUESTIONS**

1. What are the existing challenges and gaps within the current regulatory framework governing genetically modified organisms (GMOs) in India, and how do these factors impact the management of GMO introduction and dissemination in the country's agricultural sector?
2. What are the primary ethical concerns surrounding the development and deployment of GMOs in the agricultural sector in India, and how do stakeholders, including farmers and scientists, perceive these ethical implications?

### **CONCEPT OF PATENTING GMOS AND ETHICS IN INDIA:**

The patenting of GMOs raises several ethical dilemmas, including the ownership of living organisms, the right to access and use genetic resources, and the potential for exploitation of farmers and indigenous communities<sup>3</sup>. The concept of patenting living organisms goes against traditional cultural beliefs in India, where nature is seen as a common resource that should be shared and protected<sup>4</sup>. This raises questions about the ethical implications of granting patents on living organisms and the potential for corporate control over natural resources. Policy Shifts: In recent years, the Indian government has taken steps to address the ethical dilemmas surrounding GMO patents. The introduction of the Biological Diversity Act in 2002 aimed to regulate access to India's genetic resources and traditional knowledge, and ensure fair and equitable sharing of benefits<sup>5</sup>. This was followed by the implementation of the Protection of Plant Varieties and Farmers' Rights Act in 2001, which provided legal protection for plant varieties and the rights of farmers<sup>6</sup>. However, there have also been policy shifts that have favored the interests of corporations over those of farmers and indigenous communities. In 2005, India signed the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, which requires countries to provide patent protection for chemical and biotechnological inventions, including GMOs<sup>7</sup>. This has led to an increase in patents for GMOs in India, with multinational corporations such as Monsanto dominating the market. Implications for Innovation and Progress:

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<sup>3</sup> Genetic Engineering & Biotechnology News. (2022). Patenting GMOs Raises Ethical, Social, and Legal Issues.

<sup>4</sup> Shiva, V. (1998). *Biopiracy: The Plunder of Nature and Knowledge*. South End Press.

<sup>5</sup> Government of India. (2002). Biological Diversity Act.

<sup>6</sup> Government of India. (2001). Protection of Plant Varieties and Farmers' Rights Act

<sup>7</sup> World Trade Organization. (n.d.). Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

The patenting of GMOs in India has both positive and negative implications for innovation and progress in the agricultural sector. On one hand, it can encourage investment in research and development, leading to the development of new and improved GMOs that can benefit farmers and consumers. On the other hand, it can also stifle innovation and limit access to technology for small-scale farmers who cannot afford to pay for patented seeds<sup>8</sup>.

## LEGAL FRAMEWORK

Based on the doctrinal research conducted, the following are the key findings of this research paper:

1. The current legal framework governing GMOs in India is primarily governed by the Environment Protection Act, 1986<sup>9</sup>, and the Rules for the Manufacture, Use, Import, Export, and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells, 1989<sup>10</sup>.
2. The legal framework has evolved over time with the introduction of various regulations and guidelines, such as the National Biotechnology Regulatory Authority Bill, 2009<sup>11</sup>, and the Food Safety and Standards (GM Food) Regulations, 2019<sup>12</sup>.
3. The existing legal framework is not comprehensive enough to address all the aspects of GMOs, including their approval, production, and commercialization. There are also gaps in the regulatory system, such as inadequate labeling requirements and a lack of monitoring and enforcement mechanisms<sup>13</sup>.
4. The primary ethical concerns associated with GMOs in India include the potential risks to human health and the environment, the impact on traditional farming practices, and concerns about corporate control over the food supply<sup>14</sup>.
5. Stakeholders, including farmers and scientists, have different perceptions of the ethical implications of GMOs, with some supporting their use for increased crop yields and others expressing concerns about the potential risks<sup>15</sup>.
6. The impact of genetically modified crops on biodiversity in India is a contentious issue, with some studies showing negative effects on native species and others showing no significant impact.

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<sup>8</sup> Herring, R. J. (2008). Continuity and Change in the Genetic Engineering of Crops: An Overview. In Herring, R. J. (Ed.), *Genetically Modified Crops and Agricultural Development* (pp. 1-29). Palgrave Macmillan.

<sup>9</sup> Environment Protection Act, 1986.

<sup>10</sup> Rules for the Manufacture, Use, Import, Export, and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells, 1989.

<sup>11</sup> National Biotechnology Regulatory Authority Bill, 2009.

<sup>12</sup> Food Safety and Standards (GM Food) Regulations, 2019.

<sup>13</sup> Shiva, V. (1998). *Biopiracy: The Plunder of Nature and Knowledge*. South End Press.

<sup>14</sup> Herring, R. J. (2008). Continuity and Change in the Genetic Engineering of Crops: An Overview. In Herring, R. J. (Ed.), *Genetically Modified Crops and Agricultural Development* (pp. 1-29). Palgrave Macmillan.

<sup>15</sup> Shiva, V. (1998). *Biopiracy: The Plunder of Nature and Knowledge*. South End Press.

7. Current regulations do not adequately address concerns related to the potential effects of GMOs on biodiversity and the environment.
8. The current regulatory framework has not been effective in managing the introduction and dissemination of GMOs in India, with instances of unauthorized cultivation and inadequate monitoring and enforcement.
9. There is a need for improvements in the regulatory system, such as stricter labeling requirements, independent risk assessments, and stronger monitoring and enforcement mechanisms.

## CASE STUDIES AND ANALYSIS

Analyzing case studies provides a holistic approach to understand the intricacies surrounding the patenting of GMOs in India. These real-life scenarios present a nuanced understanding of the regulatory frameworks and social and ethical implications inherent in the process. By analyzing two individual cases, the author aims to provide insight on the legal and ethical considerations involved in patenting genetically modified organisms as well as insights into the challenges and opportunities faced by stakeholders within the biotechnology sector.

Case: **Monsanto Technology Llc vs Nuziveedu Seeds Ltd.**<sup>16</sup>

1. **Introduction of Bt Cotton:** Monsanto introduced Bt cotton seeds in India in the early 2000s. The seeds promised higher yields and reduced pesticide use, addressing concerns such as pest infestations and crop losses.
2. **Patent Dispute:** Monsanto's Bt cotton seeds were patented, leading to a legal dispute over intellectual property rights. The case raised questions about the patentability of life forms and the balance between commercial interests and public welfare.
3. **Pricing and Royalties:** Monsanto charged farmers a premium for Bt cotton seeds and imposed royalties, sparking debates over affordability and fair access to agricultural technology. This aspect intersected with broader issues of socioeconomic inequality and farmers' rights.
4. **Regulatory Framework:** The case shed light on the regulatory framework governing GMOs in India. It underscored the need for robust regulations to ensure safety, environmental sustainability, and public health while fostering innovation and economic development.
5. **Impact on Farmers:** The case highlighted the socio-economic impact of GM technology on farmers, including issues like dependency on seed companies, debt traps, and the broader implications for agricultural livelihoods and rural communities.
6. **Environmental Concerns:** Discussions around the case also addressed environmental concerns related to GMOs, such as the potential for gene flow, biodiversity loss, and unintended ecological consequences.

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<sup>16</sup> AIR 2019 SUPREME COURT 559

7. **Legal Precedent:** The outcome of the case and subsequent legal interpretations set important precedents for the regulation of GMOs in India. It influenced policy decisions, legislative reforms, and judicial interpretations regarding biotechnology and intellectual property rights.
8. **Public Discourse and Activism:** The Monsanto Biotechnology Case triggered public discourse and activism on issues ranging from food security and agricultural sustainability to corporate accountability and consumer rights. It fueled debates on the role of technology in agriculture and the ethics of genetic engineering.

#### Analysis and Evolution of Legal Framework:

- **Early Regulations:** India's regulatory framework for GMOs evolved from the Environment Protection Act, 1986, and the Rules for the Manufacture, Use, Import, Export, and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells, 1989. These laid the groundwork for environmental risk assessment and biosafety measures.
- **Biotechnology Regulatory Authority of India (BRAI) Bill:** The proposed BRAI Bill aimed to streamline GMO regulation but faced criticism for potential conflicts of interest, lack of transparency, and inadequate public consultation. Its failure to pass underscored the complexities of balancing regulatory efficiency with democratic governance and public engagement.
- **Genetically Modified Organisms (GMOS) Regulations, 2019:** The GMOS Regulations, 2019, replaced the earlier regulatory framework, emphasizing risk assessment, monitoring, and post-release surveillance. It sought to address concerns raised in the Monsanto Biotechnology Case regarding safety, environmental protection, and public participation.
- **Judicial Interpretations:** Judicial interventions in cases like the Monsanto Biotechnology Case provided insights into legal interpretations of GMO regulation, including issues of patent law, farmer rights, and environmental jurisprudence. These interpretations influenced legislative reforms and executive actions, shaping the trajectory of GMO governance in India.
- **International Influences:** India's approach to GMO regulation also reflects international norms and obligations, including agreements under the Convention on Biological Diversity, Cartagena Protocol on Biosafety, and World Trade Organization agreements. Balancing domestic priorities with global standards remains a challenge in shaping India's GMO regulatory landscape.

Case: **Prabir Krishna Goswami & Ors. v. Union of India & Ors.**<sup>17</sup>

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<sup>17</sup> 1985 AIR 1605

## Key Elements of the Case:

1. **Illegal Mining in Forest Areas:** The case addresses rampant illegal mining activities occurring in forest regions across India. These activities often involve unauthorized extraction of minerals, deforestation, habitat destruction, and pollution of air and water bodies, leading to irreversible ecological damage.
2. **Violation of Environmental Laws:** The petitioners allege that the illegal mining operations violated various environmental laws and regulations, including the Forest Conservation Act, 1980, the Wildlife Protection Act, 1972, and the Environmental Protection Act, 1986. They argue that such violations pose a grave threat to biodiversity, wildlife habitats, and the overall ecological balance.
3. **Public Interest Litigation (PIL):** The case is filed as a PIL, highlighting its broader significance beyond individual grievances. PILs serve as a mechanism for public participation in environmental governance, allowing concerned citizens to seek judicial intervention in matters of public interest, environmental protection, and the enforcement of legal rights.
4. **Role of State Authorities:** The case underscores the responsibility of state authorities, including forest departments and regulatory agencies, in preventing and curbing illegal mining activities. It raises questions about governance failures, corruption, and regulatory loopholes that enable the perpetuation of environmental crimes.
5. **Impact on Local Communities:** The case also addresses the adverse impact of illegal mining on the livelihoods and socio-economic well-being of local communities, especially indigenous tribes and forest-dependent populations. It highlights issues of displacement, loss of traditional land rights, and socio-cultural disruptions caused by unsustainable resource extraction.
6. **Judicial Intervention and Remedial Measures:** Through the Prabir Krishna Goswami case, the judiciary intervenes to protect the environment and uphold constitutional principles of environmental justice and intergenerational equity. The court may issue directives for immediate cessation of illegal mining activities, restoration of degraded ecosystems, and punitive actions against perpetrators.
7. **Precedents and Legal Principles:** The case builds upon established legal principles and precedents in environmental jurisprudence, including the "polluter pays" principle, the precautionary principle, and the constitutional right to a clean and healthy environment. It reaffirms the judiciary's role as a custodian of environmental rights and the rule of law.
8. **Interplay of Development and Conservation:** The case reflects the complex interplay between development imperatives, resource exploitation, and environmental conservation. It calls for a balanced approach that reconciles economic growth with ecological sustainability, emphasizing the need for regulatory reforms, stakeholder engagement, and adaptive governance mechanisms.

## Analysis and Evolution of Legal Framework:



- **Enforcement of Environmental Laws:** The Prabir Krishna Goswami case underscores the importance of robust enforcement mechanisms to deter environmental violations effectively. It highlights the need for strict regulatory oversight, surveillance, and accountability mechanisms to prevent illegal activities and promote compliance with environmental laws.
- **Judicial Activism and Public Accountability:** Judicial activism in environmental matters, as exemplified by the Prabir Krishna Goswami case, plays a crucial role in holding state authorities and private entities accountable for environmental degradation. It fosters transparency, accountability, and public trust in the judicial system, empowering citizens to assert their environmental rights.
- **Community Participation and Consent:** The case emphasizes the importance of meaningful community participation and informed consent in decision-making processes concerning natural resource management and land-use planning. It underscores the need for inclusive governance structures that respect the rights and interests of local communities, especially marginalized and vulnerable groups.
- **Ecosystem-Based Approaches:** The case promotes ecosystem-based approaches to environmental management, recognizing the interconnectedness of ecological systems and the importance of preserving biodiversity, ecosystem services, and natural habitats. It advocates for holistic conservation strategies that prioritize ecosystem health and resilience over short-term economic gains.

## LEGAL SAFEGUARDS FOR ETHICS IN PATENTING OF GMOs

While not strictly constitutional safeguards, India is a signatory to various international agreements and conventions that address ethical considerations in biotechnology and environmental protection. These include the Convention on Biological Diversity (CBD)<sup>18</sup>, which emphasizes the conservation of biological diversity, sustainable use of its components, and fair and equitable sharing of benefits arising from genetic resources.

The Constitution emphasizes the importance of upholding the public interest in all policy and decision-making processes. Article 39(b) and (c) of the Directive Principles of State Policy emphasize that the ownership and control of material resources of the community should be so distributed as best to serve the common good. This provision implies that patents on GMOs should not unduly restrict access to essential resources or harm public welfare. While not explicitly mentioned in the Constitution, the Precautionary Principle is a fundamental component of India's environmental jurisprudence. It asserts that where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation. This principle underscores the importance of

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<sup>18</sup> The Convention on Biological Diversity of 5 June 1992 (1760 U.N.T.S. 69)

exercising caution in the patenting and commercialization of GMOs, especially considering potential risks to human health and the environment.

## JUDICIAL DECISIONS

1. Pioneer Overseas Corporation v. Deputy Controller of Patents & Designs & Ors. (2006)<sup>19</sup>:
  - In this case, the Delhi High Court examined the patentability of a genetically modified organism, specifically a transgenic plant variety of basmati rice. The court emphasized that patents on biological material, including GMOs, must satisfy the criteria of novelty, inventive step, and industrial applicability, as per the Patents Act, 1970.
  - The judgment underscored the importance of ensuring that patents on GMOs do not hinder public access to essential resources, especially those vital for food security and traditional farming practices. It highlighted the need to balance the interests of patent holders with broader societal interests, particularly concerning agriculture and biodiversity conservation.
2. Environmental Protection Research Foundation v. Union of India (2017)<sup>20</sup>:
  - In this case, the Supreme Court of India considered a public interest litigation (PIL) challenging the commercial release of genetically modified mustard, known as "GM Mustard."
  - The judgment highlighted the importance of rigorous scientific evaluation and regulatory oversight in assessing the safety and environmental impact of GMOs before their commercial release. It underscored the need for transparency, public consultation, and adherence to regulatory protocols in decision-making processes concerning GMOs.
  - The court's decision reaffirmed the precautionary principle, emphasizing that in the absence of scientific consensus on the safety of GMOs, regulatory authorities must err on the side of caution to protect public health and the environment.
3. Vandana Shiva & Ors. v. Union of India & Ors. (2004)<sup>21</sup>:
  - This case involved a public interest litigation (PIL) challenging the environmental release and commercialization of genetically modified Bt cotton in India. The Supreme Court of India examined issues related to biosafety, regulatory oversight, and public consultation concerning GMOs.
  - The judgment underscored the importance of ensuring rigorous scientific evaluation and stakeholder participation in decision-making processes related to GMOs. It emphasized the need for transparency, accountability, and adherence to regulatory protocols to safeguard public health and the environment.

## FINDINGS AND CONCLUSION

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<sup>19</sup> W.P.(C) 6470/2013 & CM No.14085/2013

<sup>20</sup> Writ Petition (Civil) No. 659 Of 2007

<sup>21</sup> 1995(32)DRJ447

The study unveils the inadequacies of the current regulatory framework governing GMOs in India, revealing gaps in addressing approval, production, and commercialization challenges. Despite regulatory evolution, deficiencies persist, notably in labeling requirements and monitoring mechanisms, hindering effective oversight of GMO dissemination in the agricultural sector.

The study identifies significant gaps and challenges within the current regulatory framework governing GMOs in India, particularly in terms of inadequate labeling requirements, monitoring mechanisms, and enforcement measures. Despite efforts to evolve the framework, these deficiencies persist, posing challenges to effective oversight of GMO introduction and dissemination in the agricultural sector.

Regarding ethical concerns surrounding GMOs, the study reveals diverse stakeholder perceptions, with farmers and scientists holding differing views on the ethical implications of GMO deployment. While some stakeholders support GMOs for their potential to enhance crop yields, others express concerns about their impact on human health, the environment, and traditional farming practices.

These findings underscore the urgent need for comprehensive regulatory reforms to address the identified deficiencies and navigate the ethical complexities surrounding GMO deployment. Collaborative efforts among stakeholders are vital to ensure responsible GMO development while upholding public health, environmental sustainability, and social welfare in India's agricultural landscape.