



# Patenting of Genetically Modified Organisms (GMOS): A Critical Analysis

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## **Authors' contributions**

*This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.*

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## **ABSTRACT**

Genetically modified organisms (GMOs) are subject to patent law, biotechnology, and ethical concerns, making it a complicated and contentious topic. The development of genetically modified organisms has become integral to improvements in environmental sustainability, agriculture, and medicine. GMO patents grant companies and inventors the exclusive right to use their innovations, encouraging creativity and financial investment in the field of biotechnology. However, the patenting process brings up ethical and legal issues, especially when it comes to who owns living things, possible control of the food supply, and the effects on farmers and agricultural biodiversity. Detractors assert that the commercialization of living organisms could inhibit technological advancement and grate customary farming methods, whereas proponents underscore the significance of patents in promoting scientific inquiry and innovation. This abstract discusses the trade off between innovation and societal impact when it comes to patenting GMOs, looking at significant legal decisions, regulatory frameworks, and righteous discussions related to this significant area of biotechnology.

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## 1. INTRODUCTION

The rapid advancements in the field of biotechnology have led to the development of genetically modified organisms (GMOs), organisms whose genetic material has been artificially manipulated through genetic engineering. As these innovations hold significant commercial value, the question of patenting GMOs has become a critical issue in intellectual property law. This article explores the difficulties surrounding the patenting of GMOs, the ethical implications, and the legal frameworks that govern this practice. Genetically modified organisms (GMOs) represent one of the most significant advancements in biotechnology, offering the potential to address global challenges in agriculture, medicine, and environmental management [1]. Through the precise manipulation of genetic material, scientists have created organisms with enhanced traits such as pest resistance, increased nutritional value, and adaptability to harsh environmental conditions. These innovations have sparked a global debate not only on the safety and ethics of GMOs but also on the legal frameworks that govern their ownership and commercialization.

The patenting of GMOs is a particularly contentious issue, as it involves granting exclusive rights to companies or individuals over the use and distribution of genetically altered seeds, animals, and microorganisms. Proponents argue that patents incentivize innovation by providing a mechanism for inventors to recoup their investments in research and development. Critics, however, raise concerns about the monopolization of essential biological resources, potential threats to biodiversity, and the ethical implications of owning life forms. This article seeks to explore the complexities surrounding the patenting of GMOs by examining the legal precedents, regulatory frameworks, and the impact of such patents on agriculture, research, and global food security. Through a critical analysis of case studies and international patent laws, the article aims to provide a comprehensive understanding of the current landscape and future directions of GMO patenting.

## 2. CONCEPTUAL FRAMEWORK

Before discussing the patenting of GMOs, it is crucial to clearly understand the concept. GMOs

have emerged as a significant technological advancement in the field of biotechnology. Their impact can be observed in various areas such as agriculture, medicine, and environmental preservation [2]. The process of genetically modifying organisms generally entails modifying the genetic material of living organisms to introduce favorable traits, resulting in the creation of crops that are resistant to pests, diseases, and environmental conditions. This process has also contributed to advancements in medical research. [3]

### 2.1 Defining GMO

An organism whose genetic material has been altered using genetic engineering techniques is known as a Genetically Modified Organism. This method, which is not traditional, involves selective breeding and genetic modification to directly manipulate an organism's DNA in order to achieve desired traits rapidly and precisely. For instance, it is possible to modify crops to be more nutritious, resistant to pests, or tolerant to herbicides. GMOs have significantly contributed to improving agricultural productivity, addressing food security, and creating therapeutic products in medicine.[4].

### 2.2 Defining the Terms used

'Intellectual Property Rights (IPR)' refer to the legal protections granted to authors, inventors, creators, and artists for their intangible works, inventions, or creations. These rights empower them to control the usage of their works and protect them from unauthorized use or replication.

'Biotechnology' involves utilizing organisms, cells, or biological systems to develop products and technologies that offer improved sustainability, production, and other advantages for various applications, including medical, agricultural, and environmental uses.

'Monopolization' is the process through which a single company, entity, or organization obtains exclusive control over an industry or market, leading to unfair competition and distribution.

'Commercialization' entails the introduction of a product or service to the market and may encompass stages such as research, testing, devising a marketing strategy, production, and distribution.

### 2.3 The Concept and Importance of GMOs in Recent Times

In recent years, GMOs have gained prominence due to their potential to address global challenges. In agriculture, GMOs contribute to increased crop yields, reduced reliance on chemical pesticides, and improved resistance to environmental stresses such as drought and salinity [5,6]. These advancements are particularly significant in the face of population growth, climate change, and the depletion of arable land. In the medical field, GMOs have enabled the production of life-saving drugs, such as insulin and recombinant vaccines, which are more accessible and cost-effective.

Despite the benefits, the development and commercialization of GMOs are hindered by ethical, environmental, and socio-economic concerns. Critics argue that GMOs may lead to unintended environmental consequences, such as the loss of biodiversity and the potential for cross-contamination with non-GMO species [7]. There are also concerns about the monopolization of the agricultural industry by corporations that hold patents on GMOs, which could undermine the livelihoods of small-scale farmers.

### 3. THE CONCEPT OF PATENTING

Patents provide legal protection for intellectual property, giving the holder exclusive rights to an invention for a specific period. The primary goal of patent protection is to encourage innovation by allowing inventors to recover their investment in research and development. For an invention to be eligible for a patent, it must meet specific requirements, including being new, non-obvious, and useful [8].

In the context of genetically modified organisms (GMOs), patenting involves obtaining legal rights over organisms that have been genetically altered, such as plants, animals, and microorganisms. This means that the patent holder has the sole authority to produce, use, sell, or distribute the GMO [9]. The patenting of GMOs is a controversial issue because it raises questions about the ownership of living organisms and the ethical considerations of modifying these organisms.

#### 3.1 The Importance of Patenting GMOs

Patenting GMOs is crucial for many reasons. Firstly, it provides an incentive for innovation in

biotechnology. Developing GMOs requires substantial investment in research, development, and regulatory approval. Companies and researchers may be reluctant to invest in such costly and time-consuming endeavors without the promise of patent protection. Patents ensure that innovators can recover their investments and earn profits, which in turn encourages further advancements in the field [10].

Secondly, patents enable the commercialization and spread of GMOs. Patent holders can regulate the manufacturing and distribution of GMOs by obtaining exclusive rights, thereby guaranteeing that they are produced in accordance with rigorous standards of quality and safety [11]. This is especially crucial in the agricultural industry, as the utilization of inferior or unauthorized GMOs could pose significant risks to food safety and environmental sustainability.

Thirdly, patents play an important role in fostering competition and collaboration in the biotechnology industry. By allowing companies to license their patented GMOs to others, patents encourage the sharing of knowledge and technology, which can lead to the development of new and improved products. This can also help to address concerns about the monopolization of the industry, as patents provide a legal framework for competition and innovation [12,13].

#### 3.2 The Need to Patent GMOs

The patenting of GMOs is a controversial issue. Proponents say GMO foods have been proven safe, whereas anti-GMO groups claim that GMOs cause health problems for both humans and animals, destroy the environment, and only benefit large corporations. There are also concerns about the impact of GMO patents on farmers, particularly in developing countries, where access to patented seeds may be limited due to high costs [14]. Additionally, the concentration of patent ownership in the hands of a few large corporations has raised concerns about the potential for market monopolies and the erosion of traditional farming practices.

However, the need to patent GMOs can be justified on several grounds. Firstly, patent protection is necessary to ensure that the benefits of GMO technology are realized. In the landmark case of *Diamond v. Chakrabarty* (1980), the U.S. Supreme Court ruled that a

genetically engineered bacterium, which can break down various components of crude oil, is eligible for patent protection [15]. The Court recognized that this bacterium was not naturally occurring and its unique capabilities were not found in any naturally existing bacteria. Furthermore, the Court emphasized that the bacterium met the essential criteria for patentability, as it was a product of human creativity and intellect, possessing its own distinct identity, characteristics, and specific applications [16]. This decision significantly stimulated patent activity within the genetic engineering sector. Without patents, there would be little incentive for companies to invest in the development and commercialization of GMOs, which could stifle innovation and limit the availability of these technologies. Patents also provide a legal framework for regulating the use of GMOs, ensuring that they are developed and used in a manner that is safe and beneficial to society.

Secondly, patenting GMOs can help to address some of the ethical concerns associated with genetic modification. By providing a legal framework for the ownership and control of GMOs, patents can ensure that these technologies are used responsibly and ethically. This includes ensuring that GMOs are produced and distributed in a manner that is consistent with environmental sustainability and social justice. In *Monsanto Co. v. Schmeiser* (2004), the Supreme Court of Canada addressed the patentability of genetically modified organisms (GMOs) and affirmed that patent rights extend to the genetic modifications, regardless of how they entered Schmeiser's fields. This landmark decision reinforced the protection of intellectual property in biotechnology, establishing that patent holders can control the use of their inventions, even in cases of unintentional contamination [16].

Thirdly, the patenting of GMOs has the potential to boost the economic progress of nations such as India. The Food and Agriculture Organization (FAO) underscores the dual impact of GMOs in improving food security while also prompting ethical concerns related to biodiversity and the rights of farmers. The Indian Patent Office guidelines stress the importance of striking a balance between innovation and the public interest in agricultural practices [17]. By promoting innovation and competition within the biotechnology industry, patents can facilitate the emergence of new sectors and drive economic

expansion. This is particularly important in developing countries, where the biotechnology industry has the potential to play a significant role in addressing challenges such as food security, public health, and environmental sustainability [17].

#### **4. THE LEGAL LANDSCAPE OF GMO PATENTING**

The patenting of GMOs is governed by various international and national legal frameworks. The European Patent Convention (EPC), for instance, includes specific provisions for biotechnological inventions, which encompass GMOs. According to Kishkevich, the EPC's Chapter V "Biotechnological inventions" outlines the criteria for patentability, emphasizing that biotechnological inventions must be novel, involve an inventive step, and be industrially applicable [18]. The legal framework in Indonesia, as discussed by Sari & Mawardah, also highlights the importance of agricultural biotechnology products, underscoring the advantages and challenges of patenting GMOs in the agricultural sector [19].

##### **4.1 Ethical and Economic Considerations**

The ethical implications of patenting GMOs are significant. Patents serve as an incentive for innovation by granting inventors exclusive rights to their creations. However, the exclusive control of genetic resources through patents can give rise to ethical dilemmas, particularly concerning access to vital resources like food. Eneh & Sowunmi suggest that the patenting of life forms, including GMOs, might worsen food security problems, especially in developing nations where access to patented seeds and crops could be limited [20].

Furthermore, the commercialization of GMOs through patents can lead to economic disparities. Marques et al. discuss how patents on GMOs have resulted in legal battles and increased litigation, particularly in the Global South, where seed activism has become a prominent response to the monopolization of genetic resources.

##### **4.2 Challenges in Patenting GMOs**

Patenting GMOs is fraught with challenges, both legal and technical. The development of biotechnological products involves complex processes that often blur the lines between natural and human-made inventions. Kumat

highlights the complications in patenting biotechnology, particularly when it comes to genetically engineered organisms. The Supreme Court's decision to grant patent rights to genetically engineered microorganisms has set a precedent, but it also opens the door to debates on the ethical implications of such patents [21].

Moreover, the criteria for patentability, such as novelty and inventive steps, are often contested in the context of GMOs. The intricate nature of genetic modification makes it difficult to determine whether a particular GMO meets the patentability requirements. This has led to legal disputes and challenges in enforcing patents, particularly in jurisdictions with different interpretations of patent law.

## 5. CONCLUSION

The patenting of genetically modified organisms (GMOs) represents a complex and contentious issue at the intersection of science, law, and ethics. On one hand, patents can drive innovation by providing financial incentives for research and development, leading to advancements in agriculture, medicine, and environmental management. Patents protect intellectual property, allowing inventors to recoup their investments and fostering a competitive marketplace that can spur further technological progress.

On the other hand, the patenting of GMOs raises significant concerns. The commodification of living organisms challenges traditional notions of biological and intellectual property. There are fears that patenting may lead to monopolistic practices, restrict access to essential technologies, and disproportionately benefit large corporations over small-scale farmers and researchers. Additionally, ethical considerations arise regarding the extent to which human intervention should alter the natural world and control its genetic makeup [22].

To address these issues, a balanced approach is needed. Policy-makers must ensure that patent laws evolve in a way that promotes innovation while safeguarding public interests. This includes implementing measures to prevent monopolistic practices, ensuring equitable access to patented technologies, and fostering transparent and inclusive dialogues about the ethical implications of genetic modification. By navigating these complexities thoughtfully, it is possible to harness the benefits of GMOs while mitigating potential

risks and ensuring that their development serves the broader good of society.

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## COMPETING INTERESTS

Authors have declared that no competing interests exist.

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