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Balancing Innovation and Regulation: GMO Patenting in the Context of International Agreements and National Legislation

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The article delves into the intricate matters related to patents for genetically modified organisms (GMOs). It explains why GMO companies are granted patents, which includes incentivizing innovation and investment in biotechnology. The article analyzes relevant international agreements such as TRIPS, the Convention on Biological Diversity, and the Cartagena Protocol on biosafety. It also examines patent laws in the US and India. While patents aim to encourage essential research and development by biotech firms, critics argue that excessive rights lead to monopolistic control in the seed industry, raise ethical concerns, and risk environmental harm through uncontrolled spread. India balances incentives and access by excluding plants and animals from patents but providing sui generis plant variety protection with exemptions. As GMOs spread globally, it is necessary to have transparent and inclusive multi-stakeholder processes to create policies that uphold scientific progress, farmers' rights, biodiversity, and the greater public good. GMOs and intellectual property can potentially advance sustainable agriculture if carefully regulated through ethical norms and safety mechanisms. However, if left unchecked, they risk exacerbating inequities and environmental damage.

Keywords: *biotechnology, genetic engineering, genetically modified organism, transgenic, germplasm.*

INTRODUCTION

The field of biotechnology comprises diverse technologies that can be employed for an array of objectives. These include the enhancement of plant and animal populations through genetic improvement, the identification and preservation of genetic resources through genetic characterization, the diagnosis of plant and animal diseases, the development of vaccines, and the modification of feeds.[1] In biotechnology, biological systems are manipulated for useful purposes. One important result of using biotechnology to modify an organism's genetic makeup is the creation of Genetically Modified Organisms or GMOs. GMOs are described as organisms (plants, animals, or microbes) whose genetic material (DNA) has undergone modification through natural recombination or breeding in a way that does not occur in the natural environment. It is sometimes referred to as 'modified DNA technology,' 'genetic engineering' or 'modern biotechnology'.[2] Transferring specific genes from one creature to another, including unrelated species, is made possible by it. In 1973, biochemists Stanley Cohen and Herbert Boyer created the first genetically modified creature by transferring DNA from one bacterium into another. This genetic engineering innovation quickly led to the discovery of bacteria that could manufacture human insulin for diabetic patients, and the U.S. Food and Drug Administration (FDA) authorized the first GMO consumer product in 1982.[3]

Agricultural biotechnology encompasses several methods, such as conventional breeding practices, that change or create products from live creatures or their components, enhance plants or animals, or create microbes tailored for certain agricultural uses.[4] Although crossing plant breeds has been a practice for centuries, new technological developments have made it possible to modify genetically modified organisms (GMOs) more precisely and quickly. A commitment

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[1] 'Biotechnology' *(Food and Agriculture Organization of the United Nations)* <https://www.fao.org/biotechnology/en/> accessed 20 January 2024

[2] 'Food, genetically modified' (*World Health Organization,* 01 May 2014) <https://www.who.int/news-room/questions-and-answers/item/food-genetically-modified> accessed 20 January 2024

[3] Gabriel Rangel, 'From Corgis to Corn: A Brief Look at the Long History of GMO Technology' (*Harvard University*, 09 August 2015) <https://sitn.hms.harvard.edu/flash/2015/from-corgis-to-corn-a-brief-look-at-the-long-history-of-gmo-technology/> accessed 20 January 2024

[4] Barrows Geoffrey et al., 'Agricultural Biotechnology: The Promise and Prospects of Genetically Modified Crops' (2014) 28(1) The Journal of Economic Perspectives 99-119 <http://www.jstor.org/stable/43193718> accessed 20 January 2024

to new technologies like agricultural biotechnology is required, as the sources of historic growth mechanization, conventional plant breeding, agrochemicals, and irrigation reach diminishing returns. To provide tolerance to herbicides sprayed on agriculture and protection against insect pests are some typical goals of genetically modifying crops. For example, Bt corn and Bt cotton include DNA from several subspecies of the soil bacteria Bacillus thuringiensis (Bt), which enables plants to produce their insecticide.[5] Crops that are resistant to environmental stresses including cold, drought, boron, salt, and drought have also been developed, enabling plants to survive in environments where they could not otherwise thrive.

Even before the Industrial Revolution, patents were recognized as being crucial for protecting intellectual property. Patents encourage employment by providing an incentive to invest the required time and money. However, indeed, naturally occurring things cannot be patented, a genetically modified organism is not naturally occurring and the fact that it is a living creature is quite irrelevant for patent purposes.[6] Giving innovators a term of exclusivity for the commercial development of items is the goal of the patent system, which promotes innovation. An average of $136 million is required for the discovery, development, and approval of a new genetically modified organism, and businesses would not have been ready to make such an investment without a period of exclusivity.[7] This exclusivity promotes spending on contemporary technologies, which eventually helps customers and farmers. Without patent protection, investors could be hesitant to provide funding for genetic engineering, which would impede the advancement of crop improvement. Furthermore, by mandating thorough disclosure in return for protection, patents promote the sharing of knowledge. This disclosure has the potential to improve science and assist future researchers in expanding on previously discovered information.

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[5] 'The Gene Revolution: Genetically Modified Crops' in Felicia WU and William P. Butz (eds), *The Future of Genetically Modified Crops: Lessons from the Green Revolution* (RAND Corporation 2004) <http://www.jstor.org/stable/10.7249/mg161rc.12> accessed 20 January 2024

[6] *Diamond v Chakrabarty* [1980] 447 U S 303

[7] Wen Zhou, 'The Patent Landscape of Genetically Modified Organism' (*SITN, Harvard University*, 10 August 2015) <https://sitn.hms.harvard.edu/flash/2015/the-patent-landscape-of-genetically-modified-organisms/> accessed 20 January 2024

WHY GMO COMPANIES ARE GRANTED PATENTS

Currently, the annual production of the global biotech market is $5.5 billion.[8] The company that advocates genetically modified crops the most, Monsanto, has reported record earnings and gets 60% of its income from biotech seeds.[9] In order to protect their property rights in this technology, these biotechnology businesses have put pressure on the US government to change the law. Even though the United States is based mostly on natural plant material, it actively promotes and permits the patenting of genetically modified plants. The outcome has been a sharp increase in the number of agricultural biotechnology patents in the US. As of 2000, 2,976 patents had been granted in the field of plant technology.[10] The following points summarize, the granting of patents to GMO companies:

Innovation and Investment: The production of GMOs necessitates extensive biotechnology study, testing, and funding. Patents provide GMO businesses temporary exclusive rights to their ideas, which incentivizes them to spend money on R&D. Without patent protection, businesses could be reluctant to spend money on pricey GMO initiatives because they run the risk of having their work duplicated by rivals for free. Research has indicated that patents promote innovation by yielding a profit and enabling businesses to recover their expenditures associated with research and development.[11]

Research and Development Incentive: Patents provide a monetary incentive for genetically modified organisms (GMOs) to invest in the creation of new technologies and the advancement of old ones.[12] Companies are encouraged to investigate novel approaches to agricultural

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[8] Debra M Strauss, 'The Application of TRIPS to GMOs: international intellectual property rights and biotechnology' (2009) 45(2) Stanford Journal of International Law 287-320 <http://link.gale.com/apps/doc/A216486735/AONE?u=googlescholar&sid=bookmark-AONE&xid=b89adf01> accessed 20 January 2024

[9] *Ibid*

[10] Andres A. Gallo and Jay P. Kesan, 'Property Rights Legislation in Agricultural Biotechnology: United States and Argentina' (2006) 7(2) Minnesota Journal of Law, Science & Technology <https://scholarship.law.umn.edu/mjlst/vol7/iss2/7> accessed 20 January 2024

[11] Michael Heller and Rebecca S. Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 Columbia Law School <https://scholarship.law.columbia.edu/faculty_scholarship/1158> accessed 21 January 2024

[12] *Ibid*

problems, such as insect resistance, drought tolerance, and higher nutritional content, by the possibility of patent protection.

Legal Framework: The patents are used to establish who owns and has control over genetically modified organisms. This guarantees that businesses have the only authority to create, market, and preserve these creatures while also protecting their investment in their development.[13] Patents give GMO businesses legal defense against unapproved use or duplication of their innovations. Without patents, businesses would have few options for retaliating against rivals that improperly use their R&D resources.

Investment in Agriculture: GMOs increase crop yields, insect resistance, and nutritional value, they have the potential to completely transform agriculture. GMO firms are incentivized to persist in creating novel crop strains that tackle worldwide issues like food security and climate change through the issuance of patents. This encourages investment in agricultural biotechnology and results in innovations that benefit farmers and consumers globally.

Food Security: Patents encourage businesses to create genetically modified organisms (GMOs) suited to certain environmental factors and dietary requirements, increasing the supply and accessibility of food.[14] Without patent protection, businesses could be less inclined to spend money creating genetically modified organisms (GMOs) meant to solve problems with food security in underdeveloped nations.

TRIPS

Prior to TRIPS the 1883 Paris Convention[15] established the international foundation for intellectual property but did not prescribe a universal standard for its protection. It mandated the idea of non-discrimination between domestic goods and foreign applications, but individual

[13] Olaitan Oluwaseyi Olusegun and Ifeoluwa Ayokunle Olubiyi, 'Implications of Genetically Modified Crops and Intellectual Property Rights on Agriculture in Developing Countries '(2017) 61(2) Journal of African Law <https://www.jstor.org/stable/26857160> accessed 21 January 2024
[14] Matin Qaim, 'The Economics of Genetically Modified Crops' (2009) 1 Annual Review of Resource Economics 665-694 <https://www.annualreviews.org/doi/full/10.1146/annurev.resource.050708.144203#_i30> accessed 21 January 2024
[15] Strauss (n 8)

countries were allowed to establish their own intellectual property laws. The Uruguay round ends on 1st January 1995 with the establishment of the World Trade Organization (WTO). The Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) is one of the multilateral agreements that come under the WTO Convention. It was set up to strengthen and protect the owner's intellectual property rights on its product and property.[16] Intellectual property rights are given to the person for their unique invention.[17] The TRIPS Agreement stipulates that patents shall be available without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.[18] All new inventions involving creative steps and potential industrial applications are considered patentable subject matter under the TRIPS Agreement. The TRIPS agreement centrally acknowledges that living things can be patented even microorganisms are not generally excluded, and those who create new plant types can avail some kind of intellectual property protection for their 'inventions'. However, regarding the general protection of innovations, TRIPS permits Members to bar inventions from patentability:

Article 27 (2) Excludes plants and animals from patentability for the purpose of upholding morality or the public order, such as to preserve human life or health, preserve animal life or health, preserve plant life or health or prevent grave harm to the environment.[19]

Article 27(3)(b) Excludes plants and animals from patentability, but they must acknowledge patents covering microorganisms, patents covering microbiological processes used to produce plants and animals, and patents covering plant varieties, either through patent or sui generis protection. Regarding the protection of plant varieties, Members may choose to offer new plant varieties either sui generis protection, patent protection, or both sui generis and patent protection.[20]

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[16] *Ibid*
[17] 'Overview: the TRIPS Agreement' (*World Trade Organization)* <https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm> accessed 21 January 2024
[18] Trade Related Aspect of Intellectual Property 1995, s 27(1)
[19] Trade Related Aspect of Intellectual Property 1995, s 27(2)
[20] Trade Related Aspect of Intellectual Property 1995, s 27(3)(b)

Nonetheless, the United States feared the fact that the exception clause diminished the intellectual property rights of their products and coerced developing nations to sign extra treaties, known as 'TRIPS-plus' bilateral accords. These 'TRIPS-plus' agreements impose obligations on poor nations to implement TRIPS faster than the designated transition periods, comply with other international intellectual property agreements, or contain stricter intellectual property requirements.

CONVENTION ON BIOLOGICAL DIVERSITY

Balancing Innovation and Regulation: GMO Patenting in the Context of International Agreements and National Legislation Allowing patents to be granted in respect of genetically modified organisms is itself inconsistent with CBD because they limit access to such genetic material and can conflict with the sovereign rights of nations over its genetic resources. The goals of the CBD are to:

1. Preserve biological variety;
2. Encourage the sustainable use of its constituent parts; and
3. Attain just and equal distribution of the positive benefits resulting from the use of genetic resources.[21]

To achieve these goals, parties have agreed to put in place measures like establishing guidelines for easier access to genetic resources, such as fair benefit-sharing agreements; acknowledging the significance of indigenous and local communities' knowledge, innovations, and practices for biodiversity conservation and sustainable use; encouraging the broader application of genetic resources, subject to the consent of their holders and the fair distribution of benefits resulting from their use.[22] The protection and the implementation of knowledge, such as that related to genetic material, technology, or the biological diversity that local and indigenous cultures possess, is therefore essential to achieving the goals of the CBD. This is inconsistent with the IPRs including TRIPS which hold that genetic material and living organisms are commodities

[21] Convention on Biological Diversity 1992, art 1
[22] Convention on Biological Diversity 1992, art 15

that may be altered and that the products of this labor are property whose ownership needs to be exclusive.[23]

CARTEGENA PROTOCOL ON BIOSAFETY

Cartegena protocol on biosafety is a supplement to the Convention on Biological Diversity and aims to ensure the safe handling, transport, and use of organisms that have been modified using modern biotechnology.[24] It was entered into force in 2003 and now has 170 signatories. The protocol was established under CBD and is regarded as the first multilateral international treaty dealing with the transboundary movement of living modified organisms. The goal of the Protocol accordance with principle 15 of the Rio Declaration on Environment and Development is to help ensure an adequate level of protection in the area of the safe transfer, handling, and use of living-modified organisms resulting from modern biotechnology that may have negative effects on the conservation and sustainable use of biological diversity, taking into account risks to human health and with a particular focus on transboundary movements. [25]Consequently, the global regulatory protocol pertaining to genetically modified organisms (GMOs) has adopted a cautious approach that serves as a lens, prohibiting the entry of GMOs into the food chain in situations where the potential dangers to human health and the environment are not sufficiently mitigated. A number of multinational environmental agreements additionally incorporate the precautionary concept

US PATENT ACT

Once an invention is patented, the inventor alone reaps the benefits of his creation and has the right to exclude others from using his invention and in return for this period of exclusive use, the inventor fully discloses his invention to the public. The US Constitution grants patent rights

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[23] Debra M Strauss, 'Defining nature: The Ethical Implications of Genetically Modified Plants' (2008) 3(1) Journal of Food Law and Policy <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1302506> accessed 22 January 2024

[24] 'About Biosafety' (*UN Environment Programme*) <https://www.unep.org/explore-topics/biosafety/about-biosafety#:~:text=The%20Cartagena%20Protocol%20on%20Biosafety,been%20modified%20using%20modern%20biotechnology> accessed 22 January 2024

[25] 'United Nations Conference on Environment and Development, Rio de Janerio, Brazil, 3-14 June 1992' (*United Nations*) <https://www.un.org/en/conferences/environment/rio1992> accessed 24 January 2024

to protect ideas and promote research and innovation.[26] Until 1930, plants and seeds were not seen as patentable material because they were a product of nature and not amenable to the written requirement description for patents. Congress passed the Plant Patent Act, of 1930 as the only source of intellectual property rights for innovations including living organisms, particularly plants. According to its text, protection for plant breeders is restricted to asexually reproducing plants those that procreate by budding, grafting, or roots of cuttings that reproduce differently from seeds.[27] However, discontented with the limitation of asexually reproducing plants, companies pushed for the extension to sexually producing plants too. In the U.S. Patent Act of 1952, Congress introduced the wide protection of 'utility patents,' granting the patent holder the exclusive right to use the invention for twenty years, if the invention satisfies the criteria of innovation, non-obviousness, disclosure, patentable subject matter, and usefulness. [28] Enacted by Congress in 1970, the Plant Variation Protection Act of 1970 grants breeders of 'any sexually reproduced or tuber propagated plant variety (other than fungi or bacteria)' twenty-five years of protection, provided that the variety is novel, unique, uniform, and stable.[29] The Plant Variety Protection Act protects the intellectual property of sexually reproducing plants and their seeds, in contrast to the Plant Protection Act, which solely protects asexually reproducing plants and their progeny. The Plant Variety Protection Act, even though it broadens protection, has two important exclusions. In one, producers are permitted to preserve seed from crops grown with the protected variety and replant them without paying the breeder (the 'saved-seed exemption'); in the other, breeders are permitted to utilize protected seed to generate new kinds (the 'research exception').[30]

Interestingly, businesses don't go for plant patents, instead, they get utility patents, which are a distinct kind of patent requiring a more detailed description of the invention. These conditions are frequently not met by plants that are accidentally found or produced by crossbreeding, but

[26] Constitution of United States 1787, art 1
[27] US Patent Act 1952, s 161
[28] US Patent Act 1952, s 101 (US)
[29] Plant Variety Protection Act 1970, s 24
[30] Plant Variety Protection Act 1970, s 254

comprehensive information on genetically modified organisms at the molecule level is typically available.[31] Utility patents are advantageous over plant patents in a number of ways:

- Aside from plants, inventions can be covered under utility patents.
- If a genetically modified organism (GMO) incorporates new, foreign DNA into the plant genome, the specially created DNA can also be covered by utility patents.
- Greater protection against infringement is offered by a utility patent.

As demonstrated by the Supreme Court decision ***Bowman v Monsanto*** utility patents forbid replanting seeds taken from sources in contrast, plant patents allow licensees to sexually reproduce indefinitely, as long as they don't provide or sell the seeds to others for planting.[32] Therefore, utility patents provide more extensive protection for GMO plants

JUDICIAL RULING

***Diamond v Chakrabarty*:** The Supreme Court establishes a complex and sophisticated framework by including living organisms in the ambit of patent protection. Justice Burger stated in a 5-4 ruling that an organism's patentability depended more on whether it was an invention of humans or a result of nature than on whether it was inanimate. The court then held, reading the legislative language broadly, that a live, artificial bacteria capable of digesting multiple components of crude oil was patentable under the PPA.[33] Although a particular type of bacteria was the subject of this case, there were obvious consequences for plant life. A new criterion for invention was set by the Court's lenient reading of the PPA and the passing of the PVPA, which concentrated on 'natural' and 'human' items.

Ex Parte Hibberd Case: The Board of Patent Appeals and Interferences *r*eversing the USPTO's refusal of a patent application for a maize plant, suggested that plants constitute a patentable life form. As a result, more sophisticated living things in the above case, a novel plant variety

[31] Elizabeth A. Rowe, 'Patents, Genetically Modified Foods, and IP Overreaching' (2011) University of Florida Levin College of Law Research Paper 24/2010 <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1683481> accessed 23 January 2024
[32] *Bowman v Monsanto* [2013] 569 US 278
[33] *Diamond v Chakrabarty* [1980] 447 US 303

with a remarkably high concentration of amino acids might be eligible for a utility patent.[34] The applicant made more than 260 distinct claims for a single item containing genes and DNA sequences. More than 1800 broad utility patents for germplasm were granted by the PTO after Hibberd.

***Asgrow Seed v Winterboer*:** in this case, a seed corporation for violating the PVPA sued an Iowa farming couple. The couple sold second-generation seeds to a third party and kept the trademarked PVPA seeds they had purchased from the business. In an 8-1 ruling, the Supreme Court denied the farmers' contention that they were protected under the PVPA seed-saving exemption.[35] The seed-saving exemption was limited by this ruling to farmers who conserved seeds for further planting on their own land.

INDIAN PATENT LAW

India's policy on granting intellectual property rights (IPRs) related to biotechnology has been generally restrictive. The country's patent law of 1970 did not allow patents on products such as plant varieties and tissue cultures. However, after joining the World Trade Organization (WTO) in 1995, India was required to comply with the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. This agreement mandates that member countries grant patents for all inventions, including both product and process patents, irrespective of the field of technology, provided they meet the patentability criteria.[36] To comply with TRIPS, India amended its Patent Act in 1999, 2002, and 2005. In order to obtain a patent on genetically modified (GM) crops, the invention must pass a triple test of novelty, inventive step, and capability of industrial application. The invention should also not fall under any patentability prohibition listed under Section 3 of the Indian Patent Act. However, India's Section 3(i) removed the term 'or plants' from its scope and excluded agricultural methods from patentability under the Indian Patent Act.[37] This was done to ensure that seeds, which are the first link in the food chain, remained a common property resource in the public domain. A new

[34] *Ex parte Hibberd* [1985] 227 USPQ 443
[35] *Agro Seeds v Winterboer* [1995] 513 US 179
[36] Agreement on Trade-Related Aspects of Intellectual Property Rights 1995, art 27(1)
[37] Patent Act 1970, s 3(i)

section 3(j) was also introduced to the 2002 Amendment Act,[38] which considers the generation or multiplication of genetically modified plants as an innovation.[39] However, 'plants and animals in whole or in any part thereof, seeds, variations, and others are not considered inventions.' On January 1st, 2005, the Third Amendment to the Patents Act 1970 came into effect. The provisions for awarding product patents in all areas of technology, such as chemicals, food, pharmaceuticals, and agrochemicals, were included.[40]

THE PLANT VARIETY PROTECTION AND FARMERS RIGHTS (PVPFR) ACT, 2001

The PVPFR Act was created to protect the rights of various stakeholders, such as farmers, researchers, and plant breeders, who contribute to the preservation, enhancement, and availability of PGR for the development of new plant varieties. As per the TRIPS Agreement's Article 27(3),[41] member nations must establish an effective system, either through patents, a sui generis system, or a combination of both, to safeguard their varieties.[42] India opted for the sui generis system to protect its plant varieties. The Act mandates that plant varieties must meet four requirements for protection: distinctiveness, originality, uniformity, and stability (NDUS).[43] The Act offers different levels of protection based on the type of plant variety. Registered varieties such as trees and vines are protected for 18 years; other field crops are protected for 15 years, and extant/notified varieties are protected for 15 years from the date of notification by the Central Government under the Seed Act of 1966.[44]

JUDICIAL RULINGS

Navbharat Seeds Pvt. Ltd. v Monsanto Technology LLC: This was a legal dispute between the American agrotech multinational Monsanto, and the Indian seed producer Navbharat Seeds Even after Monsanto cancelled the licensing agreements for breach of contract, Navbharat Seeds

[38] Patent Act 1970, s 3(j)
[39] *Ibid*
[40] Patent (Amendment) Act 2005
[41] Agreement on Trade-Related Aspects of Intellectual Property Rights 1995, art 27
[42] Agreement on Trade-Related Aspects of Intellectual Property Rights 1995, art 27(3)(b)
[43] Plant Variety Protection and Farmers Rights Act 2001
[44] *Ibid*

proceeded to sell cotton seeds infused with the company's proprietary Bollgard II Bt cotton technology. Consequently, Monsanto sued Navbharat Seeds in the Delhi High Court for patent violation. The Court imposed an injunction against Navbharat Seeds and found in favor of Monsanto, recognizing the validity of its patent for the Bt cotton technology. [45]The lawsuit emphasized Monsanto's stringent infringement of its patent rights over Bt cotton technology in India and strengthened its hold on the country's cotton seed industry.

Monsanto v CCI: In the Monsanto v CCI case, the CCI looked into claims that in sublicensing agreements with Indian seed businesses, Monsanto had placed unreasonable restrictions. The Bt cotton technique is patented by Monsanto in India, and in return for royalties, the company licenses the technology to indigenous seed firms.[46] The Supreme Court maintained CCI's jurisdiction to look into patent abuse from the standpoint of competition policy, despite Monsanto's challenge. The case served as a warning that if healthy market competition is hampered, restrictive patent regimes invite scrutiny of patent abuse.

CHALLENGES IN PATENTING GMOs

There is a high projection that GMOs will serve our long-term objectives of preserving the ecosystem's integrity and improving food security, concomitantly patentability of life presents moral and legal dilemmas. They also call into question whether it is appropriate from a public policy standpoint to award such property rights.

Monopoly and Control: Companies that get GMO patents frequently acquire exclusive rights to the modified organisms, creating monopolies. This kind of regulation may restrict access to genetic resources and discourage competitiveness. Monsanto v Bowman When a farmer in this case utilized second-generation seeds without buying new ones, Monsanto filed a lawsuit against him for patent infringement.[47] The decision in favor of Monsanto highlights the

[45] *Navbharat Seeds Pvt. Ltd. v Monsanto Technology LLC* AIR 2019 SC 559
[46] *Monsanto v CCI* (2020) 272 DLT 61
[47] *Bowman v Monsanto* [2013] 569 US 278

possibility for businesses to exercise monopolistic control over the application of genetically modified organisms.

Dependency of Farmers: Farmers that use genetically modified seeds run the risk of becoming reliant on a small number of powerful patent-holding companies. This dependence may limit farmers' options and flexibility when choosing seeds, which may influence the variety of agriculture. Brazil v Monsanto. Monsanto and Brazilian farmers engaged in legal disputes over claimed patent infringements. This case demonstrated worries that farmers would become legally reliant on patented seeds and suffer financial penalties, which might put more strain on farming communities.

Environment Issues: The creation of crops enhanced for particular characteristics, such as insect or herbicide resistance, may be encouraged by GMO patents. The development of pest resistance and possible damage to non-target creatures are two examples of how this might result in environmental issues. The introduction of genetically modified Bt cotton to India initially produced positive results. However, worries surfaced regarding the development of resistant pests, leading to increased pesticides and potential environmental harm.[48]

Considerations for Ethics: It is believed that because patenting biological forms entails ownership of living things, it presents ethical issues. This can conflict with traditional agriculture practices and indigenous knowledge. Schmeiser v Monsanto (2004) is an example of a case where a Canadian farmer named Percy Schmeiser accidentally had Monsanto's patented Roundup Ready canola seeds on his property.[49] He was sued by Monsanto for patent infringement, raising moral questions and possible legal conflicts with unintended impact.

Problems with Seed Contamination: Unintentional genetic modification in nearby fields may result from cross-pollination between genetically modified and non-modified crops. Farmers who want to continue growing non-GMO crops face difficulties since contamination might make those products less marketable and result in disputes for patent infringement. The

[48] *Navbharat Seeds Pvt. Ltd. v Monsanto Technology LLC* AIR 2019 SC 55
[49] *Schmeiser v Monsanto* [2004] 1 SCR 902

StarLink corn controversy [50]arose when genetically modified maize, engineered to withstand insect damage, was discovered in human food supplies. This led to product recalls. The occurrence brought to light the difficulties in preventing GMOs from accidentally finding their way into non-GMO items.

CONCLUSION

Genetically modified organisms (GMOs) have the potential to revolutionize agriculture and help resolve global issues such as food security, climate change adaptation, and nutritional deficiencies in crops. However, giving intellectual property rights over living organisms raises complex legal, ethical, economic, and environmental concerns that must be carefully balanced. On one hand, patents aim to incentivize private sector investment in developing innovative GMOs by granting a period of market exclusivity to recoup research and development costs. This temporary monopoly seeks to encourage scientific progress into enhanced seed varieties and crop improvements that benefit agriculture. The patent system has successfully catalyzed substantial R&D investment in agricultural biotechnology. Companies argue that without patent protections, they would not undertake the long, costly process of discovering, testing, and commercializing new genetically engineered crops. However, critics argue that extensive patent rights have also allowed a few large biotechnology firms to gain excessive control over the global seed industry. Currently, only three companies account for over 60% of global proprietary seed sales. Farmers face restricted choices and lack bargaining power in negotiations with these influential patent holders. Consumer groups raise concerns over the consolidation, market dominance, and anti-competitive behavior enabled by patent protections in the GMO industry. Moreover, while GMOs may offer agricultural benefits, their widespread adoption could pose ecological risks in terms of pest resistance, increased pesticide use, biodiversity loss, and unintended contamination through cross-pollination. Several cases highlight how extensively patented GM crops may spread quickly and inadvertently transmit genetically engineered traits to non-target species across natural landscapes. The patent system aims to

[50] Colin Carter and Aaron Smith, ‚Estimating the Market Effect of a Food Scare: The Case of Genetically Modified StarLink Corn' (*IDEAS*) <https://ideas.repec.org/p/ags/iaae06/25447.html> accessed 22 January 2024

encourage innovation but needs to strike a careful balance between incentives for biotechnology firms and considerations for agriculture, the environment, and the greater public good.

In light of these issues, India has tried to find a pragmatic middle ground in its approach to GMOs. By excluding plants and animals from patentability under TRIPS, while establishing a sui generis system of plant variety protection with exemptions for research and seed saving, India has tried to enable access and availability of genetic material. However, India has faced pressure from the US and agribusiness to implement higher IP standards. Many complex ethical, legal, and scientific questions around GMO patents remain disputed globally. As research on agricultural biotechnology continues to rapidly progress, inclusive and transparent policymaking processes are needed at national and international levels to determine appropriate protections that balance the interests of all stakeholders. Achieving consensus between biotechnology companies, governments, scientific experts, farmers, and civil society on issues of ethics, safety, market competition, international law, and sustainable development will be critical for guiding responsible development and use of GMO technologies going forward. Continuing efforts are vital to ensure GMO policies keep pace with emerging technologies, balance moral concerns over patenting forms of life with incentives for vital R&D, uphold farmers' rights, and prioritize environmental protection and the greater common good.

With carefully crafted regulations and participatory decision-making, biotechnological advances and intellectual property systems can potentially be harnessed synergistically to further food security and agricultural innovation in line with broader social and ecological objectives.