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Seeds of Control Intellectual Property, Ethical Dilemmas, and the Global Governance of Genetically Modified Organisms

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ABSTRACT

Genetically Modified Organisms (GMOs) have revolutionized agriculture by increasing crop durability and output, but their patenting as immaterial property presents intricate legal, moral, and international challenges. This paper explores GMO patents, which award creators sole property rights over genetically modified features, and their transfer via licensing contracts. These licenses, typified by Monsanto's Technology/Stewardship Agreement, place restrictions such as banning seed saving, affecting farmers' customary practices. The research delves into the legal basis of GMO patents, specifically Diamond v. Chakrabarty (1980), which confirmed their patentability, and cases such as Bowman v. Monsanto (2013), affirming corporate dominance over seed use. Patent regimes differ across the world, with India's Patents Act restricting seed patentability under Section 3(j), while the TRIPS Agreement has a minimum standard. Ethical issues present are corporate control by companies such as Bayer, decreased biodiversity, and farmers' economic costs from expensive seed prices. The paper also discusses the Nagoya Protocol's requirements for benefit-sharing and the European Patent Office's subtle approach towards patents on GMOs. Through an examination of licensing frameworks, juridical precedents, and international frameworks, this study points out the dilemma between incentives for innovation and fair access. It advocates for balanced intellectual property governance to promote food security, farmer independence, and sustainable agriculture, suggesting open-source models and public-private partnerships to counteract corporate control. This holistic analysis highlights the imperative of adaptive legal frameworks that reconcile biotechnological progress with global social and environmental objectives.

I. INTRODUCTION

Genetically Modified Organisms have revolutionized agricultural practices during the last

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thirty years. They took charge of resolving worldwide food requirements and reducing dependency on traditional farming chemicals while bolstering crop resistance to pests and diseases and climate impacting stress. Genetically Modified Organisms form by modifying the genetic material of organisms with artificial techniques derived from genetic engineering. The DNA of an organism can undergo exact modification through genetic engineering instead of traditional selective breeding methods. The process allows scientists to introduce soughtafter characteristics alongside foreign genetic components from unrelated types of organisms. GMO crops now dominate modern agricultural practice. The crops contain beneficial properties that enhance both yield and production, hence attracting major interest from farmers. The genetic elements present inside GMO seeds usually exist under patent protection which biotech companies maintain. Living organisms become proprietary technologies because they are protected by patents. The rights to use these entities come with licensing limitations and enforceable law. Patents on GMOs are a type of intangible property that incorporates legal privileges granted to inventors for the utilization and circulation of different genetically modified traits. These are normally commoditized and commercialized through complicated licenses with farmers, seed merchants as well as agricultural businesses. Of course, this model makes sense in terms of promoting innovation and guaranteeing some return on investment in biotechnology while at the same time posing new legal, ethical, and global issues. Such issues feature the fairness of preventing farmers from saving seeds, the relationship between multinationals and small-scale farmers, IP rights as a determinant of food systems, and enforcement of patent rights on GMOs across different legal settings and contexts. The legal framework of GM patents is not a purely technical issue but is shot through and across sovereignty, food security, agricultural diversification and scientific advancement. The trends in commercialisation and globalization of GMOs cannot be dispositively discussed without reference to the regimes of ownership of intellectual property.

The paper aims to discuss the legal dimensions of GMO patents in respect of their transferability, ways of enforcing patents, and impacts of patents on the intellectual property rights. The first step is to look at the fundamental aspects under patent law and how it particularly deals with organisms. The tension arose when patents were given to living entities such as a biological process and seeds with the ability to reproduce thus leading to conflicts between conventional farming and intellectual property rights. The paper further explores licensing models as the main approaches of transferring GMO patent rights. Licensing enables the patent holder to retain the patent rights while granting right of use to the claimed traits in the patented crops to others through one time use agreements, royalty system and with

specific contractual terms. They have been the cause of legal battles in numerous legal systems globally. The existing GMO patent law in both developed and the developing countries depict how bio-IP governance is in a continual process of transition. This includes the claim construction cases that may delimit the scope of products and processes that may be patented, provide attribution of unintentional presence of the seeds, and make an evaluation of the public interest in the context of IP.

This study will analyse how access and equity can be conceptualised and should corporations have bottomless control over the technology that would breathe life into the dead? First of all, one must consider what happens if seed-sharing and informal innovation is under regulated by the said patent regimes. The impact on patent systems, indigenous people's rights, biodiversity, and right to food are the concerns which are most prominent in some areas because smallholder farmers are at the receiving end from seed technologies but rights are denied them or they cannot negotiate for their rights in the same way as large corporations in the industry. The paper discusses some of the propositions regarding the role of GMO patent governance in the global arena in relation to trade, development, and food security. Incorporation of GMOs through patents also through trade relations and international forums such as WTO can be a blessing and a hindrance to the transfer of technology. There are always challenges countries have to face in an effort to attract Biotechnology investment while at the same time protecting the independence of the Agricultural sector. The objective of this work is to look at every surrounding context of GMO patenting. It also addresses the connection between laws, markets, morality, and goals that pertain to world development. The insight of GMO patents as both an infrastructure and a social artifact paves the way to critically analyse the impact of these innovations to agriculture in the future.

II. UNDERSTANDING GMO PATENTS AS INTANGIBLE PROPERTY

The concept of IP is grounded on the principle that, non-tangible works of the human mind should be protected by law. Among such protection forms, there are patents that grant inventors exclusive rights to such inventions for around 20 years.⁴ These rights enable inventors to market their inventions as well as prevent others from manufacturing, using, marketing or even importing a patented article or process without the consent of the inventor. Regarding the patents, they cast their reliance into biotechnological innovations where particular features are introduced into living beings including crops. These patented traits, while embodied physically in seeds, are legally classified as intangible assets-an attached set

⁴ What is Intellectual Property?, https://www.wipo.int/en/web/about-ip.

of claims laid over a physical substance. Concerning the legal aspects of genetic use, patents may be considered as being both legal entities and properties enshrined in biology, which raises different and often contentious issues in relation to crop genetic improvement and management.

Fundamentally though, a patent is a type of intellectual property that comes to exist through legal recognition of an inventive step. Unlike the tangible properties such as land, vehicles, or commodities, patents do not refer to physical items in a strict sense. They actually pertain to a legal right to guard against other people from utilising a new and valuable idea, invention, or method. These principles become evident specially when analysing the elements of GMO patents claims. Surprisingly, most of the patents in this domain do not really pertain just to the outcome or the result, but to some degree, the genes introduced into it and also any process of creating or utilizing them. This covers any claim over the recombinant DNA construct itself, the technique of transformation, specific DNA promoters or gene sequences and the phenotypes the latter creates. Having sold a GMO seed under the license, the patented technology that is contained within the seed migrates with the seed to wherever it is sown, harvested or redistributed. Therefore, if one plants a seed, it triggers the associated intangible property rights, implying that any use of the material, even by mistakenly growing the plants or pollination by other plants without permission will amount to infringement of patent.

An important fact that characterizes the discipline is that it has turned one of the most fundamental and self-reproductive biological processes into a legal one. In normal farming, seeds are usually conserved and regenerated continuously for some time by farmers hence the traditional practices of carry forward from one season to the other. However, where GMOs are patented, in most cases all these practices are prohibited by law. Many times, farmers are obliged to sign certain nonrecourse license agreements that typically prohibit farmers from replanting or saving seeds from a patented crop.⁵ These "*no-save*"⁶ seed clauses are a direct result of the intangible nature of the patented GMOs. In this way, legal factors set the limits on what seems to be a biological perpetration. By doing so the patent owner not only controls the first sale of technology but also the subsequent use of the technology in the market place, which guarantees continued revenue inflow and a preservation of the mainspring of the invention.

⁵ Expanded Intellectual Property Protections for Crop Seeds Increase Innovation and Market Power for Companies, Economic Research Service (Mar. 4, 2023), https://www.ers.usda.gov/amber-waves/2023/august/expanded-intellectual-property-protections-for-crop-seeds-increase-innovation-and-market-power-for-companies.

⁶ Mythsabout_Jul23, (July 23, 2017), https://allianceforscience.org/wp-content/uploads/2018/03/mythsFINAL.p df.

III. PATENTABILITY OF GMOS

The correlation between patents and GMOs was first cemented in the United States in the high-profile supreme court case that is *Diamond v. Chakrabarty* (1980)⁷, decided that the genetically modified microorganisms could be patented because they were created through exercise of human skill and therefore, they were man-made instead of being naturally occurring. This laid the groundwork for the patenting of higher life forms, and in the process made possible the variability of GM crops. Since then, the patent offices and courts of various jurisdictions have developed ways through which they are able to determine whether a GMO is worthy of enjoying the protection of a patent. To satisfy this requirement, a GMO must have certain genetic features that have not been known before or proposed by other inventions.8 The distinction between discovery and invention is not always clear cut in the subfield of biotechnology. As seen, isolation of gene from a plant or bacteria may be thought of as discovery, nevertheless, the isolation of the same gene from plant or bacterium and its introduction in a crop plant to develop a new character may be patentable.⁹ It is difficult to decide in this case as to whether it would be proper to classify such an act as an example of an innovation or as recycling of available biological components. It is required to prove that the GMO modification which has been made is not obvious to someone skilled in the field.¹⁰ This is most evident in agricultural biotechnology which is an area where improvements tend to follow earlier methods. As an example, the development of the drought-resistant corn through the CRISPR gene-editing technology comprises known steps, which are blueprint steps; however, if the targeted gene and editing technique leads to a new desirable characteristic, then it might meet the non-obviousness requirements.

The utility requirement is a standard stating that the patented GMO has to have a use that is known, essential and serious. Primary of such traits are quite obvious and backed up by field data and performance trials. But they are much more problematic with regards to broader concerns of social utility of science. Many times, concern arises that whether system of patents fosters inventive solutions to the existing problems such as hunger and degradation of the environment or it promotes inventions that would be profitable to the agriculturists. The other problem with regarding GMO patents as intangible property is the nature of seed

⁷ Diamond v. Chakrabarty, 447 U.S. 303 (1980).

⁸ A.S. Bawa & K.R. Anilakumar, *Genetically Modified Foods: Safety, Risks and Public Concerns—A Review*, 50 J. Food Sci. & Tech. 1035 (2013), https://doi.org/10.1007/s13197-012-0899-1.

⁹ Malathi Lakshmikumaran, *Patenting of Genetic Inventions*, 12 J. INTELL. PROP. RTS. 45 (2007), available at https://docs.manupatra.in/newsline/articles/Upload/28657BF6-ADAE-43AD-A87F-0DBB440B8D75.pdf.

¹⁰ National Research Council (US) Board on Agriculture, *Genetic Engineering of Plants: Agricultural Research Opportunities and Policy Concerns* (National Academies Press 1984), https://www.ncbi.nlm.nih.gov/books/NBK216400/.

technology as a self-reproductive invention. While a patented machine or chemical compound is a tangible product that holds no capacity of subsequent biological reproduction, a GMO seed is a living product that can reproduce itself.¹¹ This self-replicating nature brings its own specific legal concerns. For instance, in the highly-discussed *Monsanto Co. v. Bowman* $(2013)^{12}$ case the U.S. Supreme Court accepted the fact that the businessperson who purchased the commodity soybeans from a grain elevator and reused them to plant for the second round infringed Monsanto's patent regardless of the fact that the seeds were initially sold legally. Thus, the Court pointed that patent exhaustion was not applicable to self-copying goods, thereby maintaining that every planting is a new use of the patented invention. This case makes a strong precedent after affirming that all the rights hid in the seeds belongs to GMO are inalienable and cease after the first transfer.

IV. PATENTS ETHICS FOR GMOS

The treatment of GMO patents as intangible property also makes them transferrable through licensing, which is another characteristic of seed systems in the modern world as compared to traditional ones. Licensing also helps the patent holder to retain the patent but at the same time grant the licensees right or permission to use the invention under certain terms. This schedule show that most of these licenses are non-transferable, non-renewable, and come with many conditions. For instance, a standard licensing agreement may include terms and conditions that the farmer is allowed to use the seeds for only one growing season, he or she has to use certain methods of cultivation, and or the patent holder may conduct a yearly audit on the farmer. These contracts include technology usage agreement, where it is stipulated as to how the technology is to be used and the consequences of their misuse.¹³ This has resulted into many cases across the world where the biotechnological firms have sought to defend their patents.

This kind of enforcement has caused quite a stir in the realm of bioethics, whether genes should be considered private entities. This has been generating controversy in that critics opine that patenting of life subjugates farmers, distorts communal structures of knowledge, and centralizes food power in the hands of a few global giant firms. Furthermore, because patents are intangible the farmers can hardly challenge the validity of the patents, especially if they are smallholder farmers in the Global South that may violate these patents through

¹¹ Paulina Jenney, *A Guide to Seed Intellectual Property Rights* (Organic Seed Alliance 2023), https://seedalliance.org/publications/a-guide-to-seed-intellectual-property-rights/.

¹² Monsanto Co. v. Bowman, 569 U.S. 278 (2013).

¹³ P.L. Gautam et al., *Protection of Plant Varieties and Farmers' Rights: A Review*, 25(1) Indian J. Plant Genet. Resour. 9–30 (2012).

contamination or cross-pollination of seeds.¹⁴ In these contexts, there is a significant difference between the intentional or deliberate use and accidental or unintentional use, which seem to elicit a huge difference in legal inquiry but in fact are left unconsidered. This has given rise to demands for more openness, responsibility, and other forms of innovation that entail sharing of biological code and that rely more on the public sector.

It also important to note that the patents over GMOs have the international aspect which makes the question even more complicated. Although IP is national, international trade laws like the WTO's TRIPS Agreement requires members to afford basic levels of protection for patents such as those pertaining to biotechnological inventions. This has created widespread convergence of patent laws but at the same time has raised conflict between the developed and the developing nations. Most developing countries still today provide little or no protection for their crops because they cannot afford to compromise the quality of food available in their countries to satisfy corporate interests. Some people have attempted to establish and develop sui generis systems of protection for plant varieties that include farmers' rights, conservation of biological diversity, and most importantly fair sharing of benefits. The exact nature of GMO patents also means that they are easily transferable across countries and also hotly debated in implementation.

V. LICENSING AND CONTROL

Despite sharing overlapping features with purely legal concepts, these patents play out practical impacts on the field, innovative systems, and world agriculture. Through genetic endowment and licensing, the new biotech companies have been able to re-define the field of agricultural property rights. This tension is amplified by the fact that while the protection is often linked to special intangible rights attributed to inventors, many communities need pertain to things that are tangible in nature. It is only by recognising the ambivalent status of GMO patents as both legal regulatory objects and bio-tech instrumentation that effective strategies can be developed by the policy makers and the stakeholders to implement the successful biotechnology innovation without the unwanted social costs associated with it.

Technology licensing is the primary mode of transfer of patent rights of GMOs since licensing is the grant of permission to a licensee to use a patented invention under certain terms of the contract.¹⁵ In the realms of biotechnology and agricultural genomics, licensing has emerged

¹⁴ Tim Schauenberg, *Patents on plants threaten farmers* – DW – 09/03/2019, (Sept. 3, 2019), https://www.dw. com/en/patents-on-plants-is-the-sellout-of-genes-a-threat-to-farmers-and-global-food-security/a-49906072.

¹⁵ Kung-Chung Liu, *Genetically Modified Plants: The IP and Regulatory Concerns in India*, SpringerLink (Sept. 20, 2018), https://link.springer.com/chapter/10.1007/978-981-13-8102-7_16.

as one of the main processes by which large corporations, especially those holding patents on GE crops, can regulate the utilization, distribution and even commercialization of Purchasing genetically engineered crops. A good example of this mechanism is the Stewardship Agreement¹⁶ which defines the usage of the patented seeds and technologies Monsanto, especially including the traits like herbicide and insect resistance. It is not merely an acknowledgement for the product purchased; rather it acts more than a bill of sale. As outlined, some of the contract terms, farmers are not just buying seeds, they are in a legally binding agreement on how those seeds have to be used. Some key points include being forbidden by law not only from growing crops but also from collecting the seeds, which means that even if a farmer has grown some crop and it has matured and developed seeds, he or she is not allowed to use those seeds for planting. Hence, the seeds used in planting each season has to be bought new.¹⁷ Also, the agreement includes the implementation of *Integrated* Pest Management (IPM) policies¹⁸, making farmers to grow refuge crops in certain ratio to ensure that more resist insect populations do not develop quickly-an environmental stewardship measure or a form of monitoring. Without any doubt, the most worrisome aspect of the agreement was the one which allows Monsanto to access fields whether directly or with prior notice to oversee compliance- a move that takes the firm's surveillance from laboratories and offices of patent to the farmer's field.

VI. LICENSING BOUNDARIES

In addition to individual agreements such as Monsanto's, a more general structure of field of use limitations is frequently built into biotech patent licensing. These limitations legally limit the licensee to performing only within particular areas-such as a specific crop type (e.g., maize or soybean), geographic area, or application type (e.g., food versus industrial). These limitations are not arbitrary; they are deliberately designed to balance commercial incentives and legal protections. For instance, an enterprise producing a genetically altered version of drought tolerant wheat could grant license to apply only in those parts of the country that face perpetual water shortage and reserve sole permission to utilize elsewhere. These clauses of field of use are also used to contain technological spillover to markets not originally envisioned, particularly for industries whose regulation differs sharply on a regional or local

¹⁶ R. Mbabazi, M. Koch, K. Maredia & J. Guenthner, *Crop Biotechnology and Product Stewardship*, 12(1) GM Crops & Food 106, 106–114 (2021), https://doi.org/10.1080/21645698.2020.1822133.

¹⁷ Brian, *What's in a Monsanto Contract?*, The Farmer's Life (Feb. 9, 2016), https://thefarmerslife.com/whats-in-a-monsanto-contract/.

¹⁸ David Kruft, *Impacts of Genetically-Modified Crops and Seeds on Farmers* (The Agricultural Law Resource and Reference Center, Penn State Dickinson School of Law, Nov. 2001), https://www.colostate.edu/program s/lifesciences/TransgenicCrops/risks.html.

level, or for companies whose image would be most sensitively impacted. As noted by biotech licensing specialists *(Morse Law- Life Sciences Licensing)*¹⁹, these limitations can be a focal point of negotiation in licensing agreements, with licensors wanting to maximize market segmentation and licensees desiring sufficient operational space to recoup investment and make a profit.

Licensing can exist in different structural forms, being mainly categorized as exclusive and non-exclusive models, each with different implications for control of the market and competition. An exclusive license provides the licensee exclusive right to use and exploit the patented technology within a given scope, which could even preclude the patent holder from exploiting the invention themselves.²⁰ This model is appealing in situations where the licensee needs to make huge initial investments in ramping up production, seeking regulatory clearance, or undertaking region-specific testing. For example, if a seed firm gets exclusive rights to sell a GE rice variety in Southeast Asia, it can act with confidence that competitors-including the patent holder-cannot occupy the same ground, allowing market development to concentrate. But this also emphasizes control and may slow the sharing of the technology at a larger scale, especially with third world countries or state institutions.

VII. LICENSING FRAMEWORKS

On the other hand, a non-exclusive licence permits more than one entity to use the patented technology and may be afforded similar or different term and conditions. This model is useful and applied at a later stage in the process and is more often used in cooperation with other scientists or in a cooperation with the commercial sector. For instance when golden rice project which aims at providing Vitamin A rice to the needy population of the developing nations the licensing model adopted was a non-exclusive licensing that allowed public institutions of several nations to get license for the genetic construct without negotiating with individual entities.²¹ As a part of this course, *the IP Handbook on Agricultural Licensing*²² offers a vast array of examples of such open-access models in relation to food security and public health, stating, while profit-driven licensing tends to be exclusive, some social-oriented biotechnology innovations work best under the open-access model. Some licenses may also be exclusive or non-exclusive that determines whether the licensee have the right to sub-license the product to any third party. Sublicensing is most appropriate in the intricacy of biotech

¹⁹ Oran R. Young et al. eds., Institutional Interplay: Biosafety and Trade (United Nations Univ. Press 2008).

²⁰ Comprehensive Guide Explores India's Patent Licensing, https://www.globalpatentfiling.com/blog/-Unlocking-Innovation-Patent-Licensing-in-India.

²¹ Jorge Mayer, *Golden Rice Licensing Arrangements*, https://www.goldenrice.org/Content1-Who/who4_IP.php. ²² Anatole Krattiger et al., *Executive Guide to Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (MIHR et al. eds., 2007).

supply chain since seed traits may be designed by one firm while hybridized by another or distributed by the third through the fourth parties. As a matter of fact, when the formation of a master licensee has the right of sub-licensing it can form a chain type distribution but meet the requirements of the original licensor's stewardship in one way or another. Sublicensing also increases the complexity and frequently, essentially, causes enforcement issues, for example across borders or in the countries with the feeble IP protection technology.

Another dimension of the complex world of licensing involves the incorporation of technology stewardship duties. These stipulations delineate the proper handling of technology to prevent misuse or unforeseen outcomes.²³ For example, biotech licenses frequently detail the best methods for containment, disposal, resistance management, and traceability. These provisions serve a dual purpose; they not only address environmental and biosafety concerns but also act as compliance incentives, as failing to adhere to them can lead to legal repercussions or revocation of the license. Notably, these requirements often blur the distinction between contractual obligations and regulatory enforcement, integrating private compliance duties into what are essentially public policy objectives. A significant milestone in the progression of GMO patent rights has been the rise of royalty-free and humanitarian licenses, particularly in the public sector. Entities such as the Public Intellectual Property Resource for Agriculture (PIPRA) have promoted frameworks where patent holders voluntarily forgo or diminish fees for the non-commercial or developmental utilization of their innovations.²⁴ This has empowered public research institutions in less affluent countries to access GE technologies like pest-resistant cassava or disease-resistant banana without the exorbitant costs that typically accompany commercial licensing. These models frequently incorporate restrictions based on geography and the intended use of the technology, as seen in the case of Golden Rice, where patent holders agreed to provide royalty-free licenses to subsistence farmers whose earnings fall beneath a particular threshold.²⁵

THE LEGAL ORIGINS: DIAMOND V. CHAKRABARTY (1980)²⁶

In Diamond v. Chakrabarty (1980), The Court ruled that a genetically altered bacterium that

²³ Anna Ubaydullaeva, Islambek Rustambekov & Said Gulyamov, *Intellectual Property in the Digital Age* (Roma TrE-Press 2024).

²⁴ Manoj Kumar Singh et al., *Genetically Modified Crops and Their Intellectual Property Rights: Indian Scenario*, in *Policy Issues in Genetically Modified Crops: Global Policies and Perspectives* (2020), available at https://www.researchgate.net/publication/344313935_Genetically_Modified_Crops_and_Their_Intellectual_Prop erty_Rights_Indian_Scenario.

²⁵ Stanley P. Kowalski & R. David Kryder, *Golden Rice: A Case Study in Intellectual Property Management and International Capacity Building*, 13 RISK: Health, Safety & Environment 47 (2002), available at https://scholars.unh.edu/risk/vol13/iss1/5.

²⁶ Diamond v. Chakrabarty, 447 U.S. 303 (1980).

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could degrade crude oil could be patented under U.S. patent law. This ruling furthered the patentability of *"man-made"* life forms, setting the precedence that biotechnology inventions such as genetically modified seeds could be license under the intellectual property rights.²⁷ This judgement triggered a wave of biotechnological patents in the U.S. and affected patent laws all over the world. However, countries like India had a lot of conservative approach which was determined by the socio-economic conditions and well-being of the public. This ruling also prepared the ground for corporations in the agricultural sector to increasingly take control of patenting of genetically modified seeds and at the onset of several legal and ethical issues that they would have to face for several decades.

BOWMAN V. MONSANTO CO. (2013)²⁸: THE LIMITS

A further important case that outlined the parameters to seed patent enforcement is Bowman v. Monsanto Co., (2013), where the U.S Supreme Court ruled in favour of Monsanto that the farmer's reuse of patented seeds without repurchasing them was a patent infringement. The Court squarely held that the *"exhaustion doctrine"* does not entitle a farmer not requiring permission on planting and harvesting activities from the patent holder.²⁹ This decision strengthened the control that corporations have on the future generations of genetically altered seeds. The verdict also dictated the course of litigation in other jurisdictions since multinational bigtech conglomerate companies are looking to follow in Monsanto's aggressive IP enforcement approach.

MONSANTO CANADA INC. V. SCHMEISER (2004)³⁰: INTENT AND CONTAMINATION

The Supreme Court of Canada had a similar dilemma in Monsanto Canada Inc. v. Schmeiser (2004). Percy Schmeiser, a Canadian farmer, was caught to grow the Monsanto's patented Roundup Ready canola without a license. He claimed that the plants had sprouted accidentally because of the wind-borne seeds. The Court however, found that Schmeiser had "*used*" the patented invention and therefore, infringed on the patent, regardless of how the seeds ended up on his property.³¹ This case generated issues related to liability, intention and biological contamination. The decision touched on global debate on farmers rights versus patent owners'

²⁷ V. Chawla, Indian Supreme Court on Patentability of Genetically Modified Life Forms—A Missed Opportunity?, 14 J. Intell. Prop. L. & Prac. 343 (2019), available at https://academic.oup.com/jiplp/article-abstract/14/5/343/5424111.

²⁸ Bowman v. Monsanto Co., 569 U.S. 278 (2013).

²⁹ S. Bhardwaj & S. Sekhar, *Patenting of Genetically Modified Crops: A Global Exploration of Legal and Ethical Perspectives*, LawFoyer Int'l J. Doctrinal Legal Rsch. (2024), https://www.researchgate.net/publicat ion/380165666_PATENTING_OF_GENETICALLY_MODIFIED_CROPS_A_GLOBAL_EXPLORATION_O F LEGAL AND ETHICAL PERSPECTIVES.

³⁰ Monsanto Canada Inc. v. Schmeiser, [2004] 1 S.C.R. 902 (Can.).

³¹ R.V. Tiwari, A Study of Rights of Farmers with Reference to IPR and Laws Relating to the Seed in India (2019) https://search.proquest.com/openview/c799e337320d9d03bc918f8ed69b80f7/1.

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rights.

VIII. GMO PATENTS IN INDIA: THE ROLE OF SECTION 3(J)

The Patents Act of 1970 amended in the year 2005 is India's patent regime which corresponds to the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. However, although section 3(j) of the Act continues to be a major obstacle to patenting the genetically modified seeds. It clearly does not include "plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propulsion of plants and animals" from patentable.³² This clause sets a legal conundrum. Despite the fact that genetically modified microorganisms are patentable, transgenic seeds are not, in spite of containing new DNA sequences. Therefore, even though companies like Monsanto can patent the DNA sequences or the gene constructs in India, they cannot patent seeds.

Monsanto Technology LLC v. Nuziveedu Seeds Ltd ³³

The third important case arose in India where Monsanto sued Nuziveedu Seeds for infringing upon its patented BT cotton technology, it didn't pay royalties while still using the technology. Nuziveedu asserted that after planting the patent was exhausted and also claimed that under the Indian law, seeds are not patentable. The Delhi High Court first delivered the verdict in Monsanto's favour finding the patent and recognising it. However, Division Bench of the Delhi High Court later annulled the patent on the basis of *Section 3(j)*. The case finally reached the Supreme Court, which ignored the patentability issue and instead remanded the case to the trial court leaving the issue unaddressed. This indecision has left behind a great legal debate in India related to biotechnological patent rights. The case discloses the conflict between India's requirement to safe guard farmer's rights and those of TRIPS. TRIPS requires patent protection of biotechnologically-innovated things, but excludes on grounds of public health and morality as well. India has exploited this to make allowances that counter pressures from the multinational corporations as it moves to protect domestic agricultural interests.

IX. LEGAL AND ETHICAL COMPLEXITY: PUBLIC INTEREST AND CORPORATE RIGHTS

Critics argue that patenting genetically modified seeds makes life a commodity and interferes with approaches of centuries to share and use seeds. Corporation's legal empowerment over seeds may result in monocultures, plant biodiversity depreciation, and farmers' economic

³² Ishaan Bahukhandi, DNA Patenting Laws in India, 2 Indian J.L. & Legal Rsch. (II) (2021), https://www.ijllr.com/volume-ii-issue-ii.

³³ Monsanto Tech. LLC v. Nuziveedu Seeds Ltd., (2019) 3 SCC 381.

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weakness.³⁴ On the contrary, biotech firms explain that patent protection is critical to innovation and investing. According to them, without robust IP, no business would incur costly genetic engineering. The task of the Indian governments is to reconcile these conflicting interests while providing food security and technological development. The legal environment surrounding GMO patent agreements is significantly influenced by the jurisdiction and national patent laws under which they operate. In countries like India and Argentina, judicial systems have sometimes adopted a more balanced or protective approach toward farmer rights and the public interest.

X. INTERNATIONAL PRESSURE AND POLICY AMBIGUITY

Nevertheless, farmers organisations, Civil society and domestic seed companies have resisted endeavours for fear that monopolisation and biodiversity would be lost. The policy incompetence continues to affect the position of India with GMO patents. For example, the Genetic Engineering Appraisal Committee (GEAC) has been tardy in approving new GMO crops and no GM food crop has been commercially approved after BT cotton.³⁵ The GMO patent regime in India fits a one-of kind niche and a fragile space at the meeting place of global innovation on one hand and a huddled agrarian-human position on the other. There is a substantial difference in the way GMOs are governed through the instrument of patent law between the jurisdictions, which is determined by the states' legal traditions and preferences, as well as international obligations. Although some countries have adopted an aggressive approach towards intellectual property protection in the field of biotechnology, many countries have taken a more cautious approach towards this matter.

TRIPS Agreement: Flexibility with Limitations

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)³⁶ managed by the World Trade Organization (WTO) requires member countries to hold patents for inventions that are "*new, involve an inventive step and are capable of industrial application*" (Article 27). However, it provides countries with narrow latitude. Remarkably, article 27.3 (b) enables the WTO members to make plants and animals such as non-paced under WTO, but yet they be obligated to provide protection to plant varieties either through patents or an effective sui generis system. This covenant has enabled nations such as India to incorporate

³⁴ Raman R., *The Impact of Genetically Modified (GM) Crops in Modern Agriculture: A Review*, 8 GM Crops & Food 195 (2017), https://doi.org/10.1080/21645698.2017.1413522.

³⁵ https://www.pib.gov.in/PressReleaseIframePage.aspx?PRID=1844666.

³⁶ WTO | Intellectual property (TRIPS) - gateway, Pakistan 2022 https://www.wto.org/english/tratop_e/trips_e/trips_e.htm.

the variational Protection of Plant Varieties and Farmers' Rights Act³⁷ (PPVFR Act) as a sui generis system thereby escaping a full-fledged patenting of GM plants but yet comply with the requirements of TRIPS. On the other hand, developed countries such as the United States have granted large-scale patenting, not only to genetically modified seeds which have been patented, but even to successors of genetically transformed plants. The European Patent office has conventionally shown willingness to grant patents in specific genetic modification processes such as gene editing, genetic constructs, and transgenics traits.³⁸ However, the question of patenting plants obtained in essentially biological processes, i.e., crossing and selection, was extremely controversial. In its landmark judgment in 2020, the largest European patent court once again extended the ban on the grant of patents on plants obtained through this line of conventional methods of breeding even if they contain genetically introduced traits.³⁹ Although there is a ban, genetically engineered traits introduced into plant genomes are patentable in the EU provided invention fulfils novelty and inventive step requirements. However, stringent public opposition and regulatory leeway have restrained the planting of GMO in Europe. The outcome is a fragmented approach where words of innovation can be patented, but its application can be chocked off by non-IP laws on; Biosafety and consumer rights.

Nagoya Protocol: Genetic Resources and Benefit Sharing⁴⁰

The Nagoya Protocol administered under the Convention on Biological Diversity (CBD), deals with access to genetic resources and fair and equitable sharing of benefits resulting from their use. Its relevance to GMOs is that it requires the prior informed consent and mutually agreed terms to access indigenous genetic materials especially from biodiversity-rich developing countries. Compliance with the Nagoya Protocol might impose benefit-sharing obligations, for biotech firms developing GMO's and particularly those that include the traditional plant varieties or genes from other countries. For instance, a company which has developed a genetically modified strain of germplasm from either China or India, may need to share benefits with the local community or the national government.⁴¹ While the Protocol does not preclude patenting in and of itself, it strengthens the argument that access to genetic material reflects the nation's sovereign rights and ethical sharing; particularly if there are

³⁷ Protection of Plant Varieties and Farmers' Rights Act, 2001, No. 53, Acts of Parliament, 2001 (India).

³⁸ What is patentable?, Epo.Org https://www.epo.org/en/news-events/in-focus/biotechnology-patents/what-is-patentable.

³⁹ New GMOs are patentable, (Dec. 18, 2020), https://infogm.org/new-gmos-are-patentable/.

⁴⁰ The Nagoya Protocol on Access and Benefit-sharing, https://www.cbd.int/abs/default.shtml.

⁴¹ Sebastian Knauf, Laura Abel & Livia K. Hallmaier-Wacker, *The Nagoya Protocol and Research on Emerging Infectious Diseases*, 97 Bull. World Health Org. 379 (2019), https://doi.org/10.2471/BLT.19.232173.

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commercial gains. Compared both to other international instruments and to regional practices, such instruments and practices demonstrate a highly pluralistic legal context for GMO patents. With built-in flexibility, TRIPS provides minimum standards; the European regime is picky about GMO-related patents and limits their radius; and the Nagoya Protocol strengthens bioethics and balance in commercializing genetic innovations. With growing assertions of intellectual property over seeds and genetic traits by the biotech companies, worries have mounted vis-à-vis their consequences for farmers, traditional agriculture, food security, innovation and ecological sustainability. In developing countries where agriculture is not only a source of income but, also, culture and ethics are deeply rooted, these problems show up sharply.

Farmer Concerns

Perhaps the most critical ethical problem arises from the direct effects of the patents on GMOs for the farmers economic and autonomy sustainability. Genetically modified seeds are expensive and this lies close to the heart of the concern. Patentee GMO seeds, unlike ordinary seeds, come with a price tag and includes price, related licensing fees, the technology use agreements and compliance requirements. These costs can heavily increase the finances burden of subsistence and small-scale farmers with marginal incomes.⁴² Such increasing costs of seed are eating up the already desperately thin economic base of rural areas, where agricultural communities live. Agriculturally, farmers have saved seeds from the produce collected during one season in order to replant them the next season, which is part and parcel of the history of the practice. However, in many cases, licensing agreements related to the GMO seeds contain explicit clauses prohibiting saving and reusing of seeds. Such limitations raise a basic ethical question. the commodification of life forms and the rendering of the seeds as resources out of common man's hands to proprietary technologies regulated by the law of contracts. The critics further progress to state that this weakens the seed sovereignty, the principle that the farmers should actually enjoy the rights to breed, save, swap and sell seeds without legal or technological restrictions.

Market Concentration

The topic of corporate consolidation and market power in the agricultural biotechnology sector should also be considered. Within the past two decades, a limited number of Multinational Corporations have come to control the world's seed market. Companies such as

⁴² Organisation for Economic Co-operation and Development (OECD), *Biological Resource Management in Agriculture: Challenges and Risks of Genetically Engineered Organisms* (2003), https://doi.org/10.1787/9789264108783-en.

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Bayer, Corteva and Syngenta command nearly all commercial seed sales.⁴³ The increasing monopoly of the seed technology has resulted in reducing the genetic base of the seeds capable of being used by the farmers.⁴⁴ The currently standardized GMO seeds suited to maximum-input, industrial farming are also apt to squeeze out a wider range of local varieties, sacrificing resilience to climate change and pests. Furthermore, corporate control implies not only that farmers are reliant on a limited number of firms for seeds' supply but also that these farmers are monitored and subjected to enforcement tools such as field inspection, DNA testing, and taking legal action for patent violation.

Innovation and Accessibility

It is said that patents are critical incentives for innovation. In the absence of patent protection, companies might not be in a position to financially incentivize investments in new agricultural technologies. However, this importance of innovation to accessing this care creates a moral tension. Realistically, even if patents encourage the production of novel technologies, they also end up curtailing access; especially with farmers in poor countries and public research institutions. When the price of patented seeds is taken beyond the reach of smallholders, the benefits from genetic innovations go into industrial farming sectors. Pen-a-system of biotechnology governance whereby the intellectual property of genes is shared with other researchers, under an open-source seed system, or a patent pool, where patented genes are available to other researchers on a fair and transparent basis has been advocated by some scholars. The others argue for public-private partnerships that would make GMO technologies licensable for humanitarian means, specifically, food insecurity and malnutrition solutions.

XI. Environmental considerations and ethical trade-offs

Environmental implications comprise another important aspect of the ethics discussion of GMO patents. On the one hand, the genetically modified crops have the potential to achieve the sustainability targets through ensuring that there is reduced dependency on such chemical inputs as pesticides and herbicides. Cotton and corn that produce insecticidal proteins from Bacillus thuringiensis, BT cotton and BT corn, have been demonstrated to significantly lower usage of insecticides in places such as India and in the United States. ESR of the USDA reports that the GMO adoption has positively impacted the environmental condition on a variety of fronts including conservation of soil and decrease in tillage greenhouse gas

⁴³ Mergers in Seeds and Agricultural Chemicals: What Happened?, Economic Research Service https://www.ers.usda.gov/amber-waves/2019/february/mergers-in-seeds-and-agricultural-chemicals-what-happened.

⁴⁴ https://web.apsaseed.org/news/india-seed-industry

emission.

Nevertheless, the long-term ecological impacts of the wide use of GMO's are not known for certain. The increasing emergence of resistance among pests and weeds means that stronger chemicals are being required or new genetic makeup had to be applied-a process called the *"pesticide treadmill"*.⁴⁵ In addition, a possible interbreeding between GMO and non-GMO crops raises the question of possible genetic contamination, which could have economic, environmental, and ecological consequences affected in the organic or heritage farming system.

The loss of biodiversity is yet another often-mentioned problem. Such predominance in genetically identical seed varieties can undermine agro-biodiversity by limiting the pool of envisaged genetic traits, making it a scarce resource for future breeding exercises.⁴⁶ It may weaken the food systems' capacity for resiliency against the odds of a new climatic trend, a novel disease, or a change in market scenarios. The ethical impact of GMO patents can only be examined by taking into account the world inequality of access to technologies, capital, and legal resources. GMO adoption in weak IP countries or those emerging biosafety legislation can happen with minimal control leading to unequal benefit distribution. On the other hand, in states with tight patent laws, foreign owned GMO patents can be thought of as neo colonial incursions into domestic agriculture.

Disputes have also surfaced on the utilization of genetic material from indigenous peoples in developing patented biotechnological products, thus accusations of biopiracy are inevitable. Neither from a policy perspective, there is growing awareness about the importance of bringing patent law into conformity with ethical imperatives such as food justice, sustainability and cultural rights.

XII. CONCLUSION

The legal-ethical-economic aspects of patenting genetically modified organisms synched some of the most important and contested issues in the modern biotechnology. The essence of this negotiation surrounding GMO seeds as well as traits is their intangibility with regard to intellectual property; this is a practice that has transformed innovation in agricultural but also made the traditional aggressions more complex hence changing of the ownership models. While the assignment of control over GMO's occurs, somewhat, via license agreements and

⁴⁵ National Academies of Sciences, Engineering, and Medicine, *Genetically Engineered Crops: Experiences and Prospects* 6 (2016), https://www.ncbi.nlm.nih.gov/books/NBK424536/.

⁴⁶ International Institute for Sustainable Development, *Biological Diversity: Protecting the Variety of Life on Earth* (Sept. 28, 2020), https://www.iisd.org/articles/deep-dive/biological-diversity-protecting-variety-life-earth.

not through mere ownership as it were, thus re-establishing a commercial construction where not only does biology determine who controls the seeds, but in fact, the legal regimes of contract and patent law also dictate. Such accords sometimes redefine the essence of the agricultural industry from a generational one, a cyclical one that relies on the collective knowledge to a transaction driven system of using and adhering to the technology.

On one hand, this same patenting system has facilitated unprecedented steps in the agricultural biotechnology sector, where companies are now able to invest in qualities that have provided increased productivity and resilience to hindering conditions. On the other hand, the economics imposed on farmers has sparked moral questions. Also, uneven landscape provokes questions about the equity of current intellectual property regimes, and what it can do in aligning private incentives with public good. There is a need for clearer and more consistent standards across the international community. Instruments of the law must adapt to avoid the exploitation of social justice or the environment for the sake of progressing technologically. Cooperation at an international level and transparent sharing of the benefits of such business venture shall be the key factors in bringing the interests of inventors, farmers and consumers into alignment.
