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# AN ANALYSIS OF THE IMPACT OF THE INTELLECTUAL PROPERTY RIGHTS ON THE DEVELOPMENT & COMMERCIALIZATION OF GENETICALLY MODIFIED SEEDS

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# **ABSTRACT**

Genetically modified (GM) seeds intellectual property rights analysis is a difficult and debatable subject. The Genetically modified seeds concept and its IP Rights are being encouraged and welcomed on one side. On the other side, some contend that IPRs may result in higher seed prices, a less range of options for farmers, and a concentration of power in the hands of a small number of powerful seed businesses. In this paper we will be discussing about the prospects of adopting and using the genetically modified seeds in the agriculture and the difficulties faced by the farmers during the post cultivation. This paper also addresses the problems faced by the farmers and the seed manufacturing companies in relation to the agreement clauses agreed upon by the farmers without proper knowledge. Still the many MNCs are exploiting the breeder's right without their knowledge and there is in an alarming situation in the society to spread the awareness about the GM seeds its application and its statutory rights. Patents on GM seeds, however, might also have a variety of disadvantages. They may first result in higher seed prices. This is due to the ability of corporations holding GM seed patents to set monopolistic prices for their seeds. Second, GM seed patents may limit farmers' options. This is due to the possibility that farmers will only be able to cultivate GM seed kinds that have been patented by a select few sizable seed companies. Thus this paper covers the aspects relating to the patent of GM seeds and the Intellectual rights derived from the statutes to the farmers or the breeders and also the current regulatory framework of GM seeds & crops.

Keywords: Modified Seeds, Farmer's rights, Crops, Gene, Intellectual Property Rights.

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#### INTRODUCTION

Agriculture, which continues to be the main source of income for around 58% of the population, is essential to India's socioeconomic development. The rapid development of genetic modification (GE) for improving agriculture production and quality over the past few decades has led to the development of intellectual property rights, or IPRs, for plant kinds, including GM (genetically modified) seeds and plants. The World Trade Organization (WTO)'s global intellectual property framework mandates that member nations extend IPRs over biotechnology used in agriculture by enacting suitable legislation that takes into account the technology's socioeconomic goals.

So this paper mainly focusses on the importance of genetically modified seeds and its effective use in current era and also how it contributes to the development of agriculture and economy. Despite strong opposition to GM agricultural technologies, the government's policies appear to be in favor of GM crops. The NITI Aayog has recently argued in favor of expanding the usage of GM seed varieties to boost agricultural growth. The term "Agri-Tech" is frequently used to describe this combination of agriculture and technology. A number of businesses are currently emerging in this industry, investigating and creating novel methods to improve agricultural practices and goods. This essay also analyses the rights to intellectual property associated with genetically engineered seeds and the effects they have.

# **Research Objectives:**

- > To evaluate how intellectual property rights affect the creation and marketing of genetically modified seeds.
- > To explore the various rights available for the Farmers.

# **Research Methodology:**

The research has embraced the doctrinal method of research relying mostly on secondary sources. The Sources include Government reports, Journals, Websites, Books, Articles, and other mass media sources. Therefore, the pertinent information on Genetically Modified Seeds has only been evaluated and interpreted from the sources and used in accordance with the requirements of the research.

# **BACKGROUND & HISTORY OF GENETICALLY MODIFIED SEEDS**

Genetically modified (GM) seeds are those that have undergone laboratory modification to add particular traits, including pest or herbicide tolerance. Recombinant DNA technology, which enables scientists to insert genes from one organism into another, is one of many methods used to make GM seeds. The earliest techniques for genetically altering microorganisms were created by scientists in the 1970s, which is when GM seeds first became popular. The first genetically IP Bulletin Volume IV Issue I Jan- June 2023

modified plant, a tobacco plant designed to withstand antibiotics, was developed in 1983. The first GM food crop, a tomato, received U.S. government approval for commercial sale in 1994. These Genetically modified seeds and food crops resulted in greater economic development to the society as well as economy. Since then, GM crops have proliferated throughout the agricultural sector. In over 25 nations now, GM crops are grown, and they contribute significantly to the world's production of soybeans, corn, cotton and canola. The majority of GM crops have been modified to resist pesticides or herbicides. Crops that can withstand herbicides, like Roundup With ready soybeans, farmers may destroy weeds with herbicides without endangering their harvests. Crops and seeds that are resistant to pests, like Bt maize, release proteins that are poisonous to some insects. For farmers and consumers, GM crops may offer a number of advantages. Herbicide-resistant plants can assist farmers in lowering their herbicide usage, which can help them save money and lessen environmental harm.

Crops that are resistant to pests can let farmers use less insecticides, which can save them money and lessen the harm done to the environment. Additionally, there may be a variety of advantages for consumers of GM crops. GM crops, for instance, can be modified to be more nutrient-dense or to have a longer shelf life. Additionally, new meals and products can also be created using GM crops, such as soybean oil that is rich in omega-3 fatty acids which is good for people who are suffering from heart diseases.

Nevertheless, there may be some hazards connected to GM crops. The possibility that GM crops could cross-pollinate with wild plants and produce new pests or weeds that are resistant to insecticides or herbicides is a source of concern. Another worry is that GM crops can have unforeseen effects on the environment or human health. GM crops have been thoroughly investigated and confirmed to be both safe for consumption by humans and the environment. According to a report published in 2016 by the NASEM, "there is no convincing evidence that GMOs pose any unique risks to human health." Although GM seeds are still a contentious issue, they are becoming more crucial to world agriculture. GM seeds may make it possible to raise more food with less resources as the world's population continues to rise.

# ADVANTAGES AND DISADVANTAGES OF GENETICALLY MODIFIED SEEDS

Genetically modified seeds (GM Seeds) provide more resilient and superior plant breeds. The usage of GM seeds is done to boost the yield and profit of a particular crop. The only GM crop legal in India is Bt Cotton. It possesses alien genes from the Bacillus thuringiensis (Bt) soil

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<sup>&</sup>lt;sup>2</sup> Committee on Genetically Engineered Crops, Genetically Engineered Crops: Experiences and Prospects (Washington, DC: National Academies Press, 2016).

bacterium, enabling the crop to produce a protein harmful to the widespread pest pink bollworm. There are various advantages and disadvantages of genetically modified seeds. But however, GM seeds are seen to be the good one to the current era.

#### Pros:

- ❖ Higher Agricultural yields: Most agriculture experts believe that farmers using genetically modified seeds will see higher yields. Even though there hasn't been a lot of research done on how biotechnology affects crop yields and returns, what has been done so far is consistent with this expectation. The ERS study discovered that farmers' use of Bt cotton and herbicide-tolerant cotton "significantly increased" crop output.<sup>3</sup> Crop yields experienced a "small increase" as a result of using soybeans that are herbicide tolerant.
- ❖ Fewer pesticide and herbicide applications: If GM seeds are more broadly accepted, farmers also expect a decrease in the use of synthetic herbicides and pesticides (and the associated costs). According to the ERS study, farmers that used GM seeds used fewer pesticides and herbicides overall. Use of pesticides was significantly reduced. Except for the herbicide glysophate, for which the investigation showed a large rise, this drop in herbicide use was also statistically significant.
- ❖ Human Health Benefits: GM seeds are beneficial to the human health as compared to other seeds. As during the use of those modified seeds there is a comparatively less need for chemicals and other fertilizers as in turn it's prosperous and helpful to human health.
- ❖ Increased revenue: Most studies indicate that using GM seeds increases farmers' profits. The ERS analysis indicates that a rise in net revenue from agriculture generally corresponds with a boost in the usage of GM seeds in a statistically meaningful way. For example, the service found that GM soybeans produced a median net value per planted acre of \$208.42, whereas other crops created an overall net value of \$191.56. The service also found "an important factor increase" in net profits for crops of herbicide-tolerant cotton and Bt cotton.

#### Cons:

❖ Limited rights to retain and replant seeds: A confidential agreement between the producer and a biotech firm severely limits the grower's rights regarding the purchased seed. Usually, these contracts contain a "no stored seed" disclaimer. This provision prohibits farmers from storing and/or repurposing genetically modified crop seed. The clause essentially requires GM crop growers to purchase GM seeds annually.

<sup>&</sup>lt;sup>3</sup> Economic Research Service, United States Department of Agriculture, Genetically Engineered Crops for Pest Management (2000).

- ❖ Acceptable arbitration clauses are commonly found in contracts between private farmers and seed firms. These clauses require that any issues pertaining to the technological features or performance of the seed must be resolved by arbitration. Under this clause requiring binding arbitration, growers may not file claims. Because of their near-monopoly on availability, these seeds are always expensive to buy.
- ❖ Harm to other living things: The potential harm that genetically modified (GM) crops and seeds may do to other living things, including beneficial ones, is a concern associated with the consequences of biotechnology. Very little research exists to support this concern.⁴ The media gave a Cornell University research a lot of coverage. This study suggests that when a gene from Bt corn is carried onto milkweed plants by the wind, it may pose a risk to the larvae of monarch butterflies. Other research, however, has demonstrated that the real amount of Bt on plants of milkweed in a natural setting does not come close to the concentrations that are detrimental to the larvae.
- ❖ Challenges with international markets: GM crops are not universally accepted. Trade blocs such as the European Union (EU) have prohibited the importation of crops that have been genetically modified because of concerns about the environment and public health. The EU is not yet forced to accept GM crops since it has alternative supply sources besides the US. Brazil, which outlaws the use of genetically modified crops, remains a dependable supply source for countries that refuse to import GM products

#### GM SEEDS IN INDIA: REGULATORY FRAMEWORK

The only GM crop legal in India is Bt Cotton. The variety Bt Cotton is a kind of cotton plant that has been genetically modified to include a bacillus thuringiensis gene extract. The widespread pink bollworm, a pest that hampers cotton agriculture, is poisonous to a plant protein that is developed by the plant with the help of this extract (Bt). *The Genetic Engineering Appraisal Committee (GEAC)* is the supreme body in India that approves the release of GM crops for commercial use.

In 2002, the Genetic Engineering Appraisal Committee (GEAC) gave its approval for *Bt Cotton* to be grown commercially in India. Since then, Bt cotton has been planted on more than 95% of the country's cotton land. After BT Cotton, the GEAC also gave its approval *to BT Brinjal* and *HT Mustard* in 2007 and 2017, respectively. However, the release of HT Mustard was postponed in

<sup>&</sup>lt;sup>4</sup> Colorado University, Transgenic Crops: An Introduction and Resource Guide available at (http://www.colotate.edu/progms/lifesciees/TransgnicCrops/risks.html).

2017<sup>5</sup> after the Supreme Court sought public feedback, while BT Brinjal was stopped in 2010.<sup>6</sup> Currently in effect are two regulations that regulate genetically modified crops: the Environmental Protection Act of 1986 and the Rules for the Production, Use, Import, Export, and Storage of Harmful Micro-Organisms/Genetically Engineered Micro-Organisms or The cells, 1989 ("the Rules, 1989"), both of which were notified under the Act. These laws cover the widespread use of genetically modified crops. The Environment Protection Act also specifies the compositions of the relevant agencies for addressing certain parts of the Rules. Moreover under the Environment Protection Act of 1986, using the authorized GM variant might result in a 5-year prison sentence and a fine of Rs. 1 lakh. The Recombinant DNA Advisory Committee is a body under the Ministry of Science and Technology's Department of Biotechnology. The RDAC is in charge of reviewing biotechnology policy at the national and world levels. Also in Addition to that the Review Committee on Genetic Manipulation (RCGM) Department of Biotechnology, Ministry of Science and Technology executive branch. The safety and protocol are observed by the RCGM. Additionally, it offers the GMO regulations. Additional organizations, such as *Institutional* Biosafety Committees (IBSC), are responsible for putting these regulations into practice.<sup>7</sup> According to the Rules for the Manufacture/ Use/ Import/Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells (Rules, 1989), which were notified under the Environment (Protection) Act, 1986, all GMOs GMSs, including GM crops, are subject to regulation in India. The 1989 Rules cover a wide range of activities relating to genetically modified organisms (GMOs), including as manufacturing, packing, exporting, importing, selling, and storing. These regulations are implemented in collaboration with the Indian Department of Biotech (DBT), Department of Science & Technology, Ministry of India, and State Governments.

#### INTELLECTUAL PROPERTY RIGHTS AND GM SEEDS

Patentability is specifically restricted to plants, either whole or in particular, seeds, varieties of plants, and nearly all of the biological mechanisms for plant growth and multiplication under *Section 3(j) of the Indian Patent Act*.<sup>8</sup> In order to fulfil India's commitments under **Article 27** of TRIPS Agreement, this provision was added as part of the Patents Act's 2002 modification.

In comparison with Section 3(j) and Art. 27.3(b), India has inserted two clauses. In the first, a further restriction is added by saying that "living things and animals in part or any portion thereof"

<sup>&</sup>lt;sup>5</sup> Karnika Bahuguna, "Supreme Court stays commercial release of GM Mustard, DownToEarth," – last accessed on 28th Sep, 2023.

<sup>&</sup>lt;sup>6</sup> Outlook Article, "Putting moratorium on Bt Brinjal was a right decision: Jairam Ramesh," - last accessed on 28th Sep, 2023.

<sup>&</sup>lt;sup>7</sup> Saksham Caturvedi and Chanchal Agarwal, "Analysis of farmer rights in the light of Plant Varieties and Farmers' Rights Act in India", 33(11) EIPR 709-710 (2011).

<sup>&</sup>lt;sup>8</sup> Maslkar and others, Report of Technical issue Group on the Patent Law Issues (2007). IP Bulletin Volume IV Issue I Jan- June 2023

are to be barred; in the second, the group to be excluded is expanded to include seeds specifically. Consequently, under Indian law, no variety of seed or variation will be entitled to patent protection. Patents do not protect genetically engineered or organic seeds. Therefore, it is not possible to directly patent GM seeds. The Patent Act does not cover the idea of patentability for genetics and genomic order and sequences. However, the limitation in section 3(j) applies to every part without exception. Natural genes, cells, tissues, and nucleic acids will so continue to be excluded. However, a gene may be eligible for patent protection if it is "recombinant and having inventive step and industrial application" in addition to "substantial human intervention." Therefore, a separate sequence that is inserted into the vector and subsequently transferred into a cell of the host to generate a desired characteristic would be considered a patentable gene. These recombinant genes are described as "chemical compositions" in the Mashelkar Committee Report, and such "incremental innovations" should be supported.

As a result, there is some uncertainty regarding what happens when recombinant genes are added to various plant parts, including cells, tissues, and processes. Although it is illegal to explicitly patent plants in India, the owner of a patent may covertly claim ownership of the plant by patenting the altered gene that causes the plant to grow. In India, for instance, Bt Cotton was granted a patent in this way.

A further law protecting plant varieties is PPVFR act. Implementing farmer's rights is one of the primary objectives of the legislation known as the Protection of Plant Variety and the farmer's Rights Act, 2001, which aims to treat farmers similarly to commercial breeders and grant them the same protection for the species they produce. The Act designates the farmer as a breeder who has created several successful varieties, a grower, and a guardian of the agricultural genetic pool. The Act also includes 'researcher's rights,' which enable a breeder to grant a local source a license to use their variety as a new source for the development of modern and new varieties without seeking prior consent. Only the transgenic seed is subject to rights held by the research business. The company sells mutant seed to local businesses as a starting point for producing more hybrid varieties but does not hold the intellectual rights to the variations that follow. These businesses have rights to benefit sharing under the PPVFR Act. The corporation is permitted to get a portion of the profit generated by these kinds for the breeder.

#### **FARMERS' RIGHT & IPR**

The Protection of Plant Variety and Farmer's Rights Act, (PPV&FR Act), 2001 is the first piece of legislation to provide farmers with legal protection and acknowledges the role that local

<sup>&</sup>lt;sup>9</sup> Dr. Philippe Cullet & Kolluru, "Plant Variety Protection And Farmers Rights- 60 Towards A Broader Understanding", 24 DL 55

<sup>10</sup> Sec 30. Researcher's rights, The PPVFR Act, 2001 (ACT NO. 53 OF 2001).

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communities and the nearby people played a vital role in the creation of new plant varieties. The matter concerning farmers' rights or the farmers' rights over their traditional varieties is the most contentious problem that arises as a result of the establishment of IPR in Plant Genetic Resources (PGRs). With the aid of NGOs, the law allows farmers to register their different kinds, protecting them from being scavenged by official breeders. According to a recent study, despite the fact that the PPVFR Act of 2001 permitted for the registration of over 600 farmer's varieties, not a single variation has yet been incorporated into the official seed chain. Also the introduction of genetically modified (GM) seed protected by various forms of intellectual property has changed the structure of farming practices, and 65 farmers have reduced to being simply consumers of developers. Moreover, Breeders are permitted to create new kinds using even protected varieties under the purview of PPV&FR Act whereas as per the patent laws allows only for experimental use.

In addition, According to **Section 64** of the Indian PPV&FR Act,<sup>12</sup> selling, importing, and producing a variety that has been registered under the PPV&FR Act without the registered breeder of that variety's permission or a registered breeder's registered licensee is regarded as violating the legally protected variety.

The clauses in relation to "benefit sharing," "rights of researchers," and "protection of the public interest" are quite significant. Now is the time for the Government and NGOs to take the proper action to inform the populace on the country's legal system and regulatory framework. Thus the farmers should also be made educated about their rights which are exclusively available to them.

# **CHALLENGES: GENETICALLY MODIFIED SEEDS**

The Most primary challenge faced by the genetically modified seeds is the problem and inability of reproduction. As far as concerned nowadays the GM seeds are found to have the inability to reproduce further seeds from the plants which grown out of GM seeds. Also additional the problem faced is the offspring produced from the cross-pollination of GM seeds with other plants could lack the same desirable characteristics as the plants that were originally planned. This may be due to some fact that the genetic changes are not always transmitted to subsequent generations in a predictable manner.

Thus Farmers who save seed from GM crops can consequently have a crop that is less fruitful, less resistant to pests and illnesses, or of worse quality. It is crucial to remember that at present there are no sterile GM crops available on the market. However, research has been done to create

<sup>&</sup>lt;sup>11</sup> Shalini, Intellectual Property Rights Policy Fails to Address Farmers' 83 Rights and Needs" THE WIRE (May 30, 2016),

<sup>&</sup>lt;sup>12</sup> Section 64 of the PPV&FR Act, "Infringement", PPVFR Act, 2001 (ACT NO. 53 of 2001).

such crops, also referred to as "terminator seeds." Farmers would have to buy fresh seed every year since Terminator seeds would turn out to be unable to create viable offspring. Due to widespread public opposition, it is highly unlikely that Terminator seeds will ever be sold commercially.

#### SUGGESTIONS & RECOMMENDATIONS

Indian in current era is in a magnificent technological development in all the prominent areas. But still there exist a gap in the proper awareness of the developments and the use of new inventions. The government should take step to provide awareness to the general public about the various rights available to them and the access to justice in case of any violation of their rights. The government should also assist farmers in saving and exchanging seed by educating them about their rights and responsibilities under IPR legislation.

The government should make sure that labelling regulations are transparent and explicit while empowering consumers to make knowledgeable decisions about GM food products. The Indian government must analyze its IPR rules and regulations to make sure they are fair and encourage the creation and use of GM seeds in a way that benefits all parties involved, including farmers, consumers, and the environment. The government should also help Indian seed firms develop their own GM technologies, reducing their dependency on foreign seed corporations.

#### **CONCLUSION**

Property and state governance have increasing relevance in light of the issues raised by technological advances and intellectual property rights. The global intellectual property framework and the privatization of agriculture mandate the protection of intellectual property for plant varieties, including genetically modified seeds. The legal acknowledgment of farmers' rights is crucial because it addresses some of the bigger issues related to the introduction of IPRs in agriculture. Genetically modified seeds may be the least ideal choice for farmers who significantly depend on a stable market. For some farmers, the danger of GM crops' unpredictable consumer acceptability, especially in global markets, may be too great. Genetically modified seeds are without a doubt an innovative agricultural technology.

Thus, In order to meet the needs of Indian farmers and consumers, the government should investin GM technology research and development. In Addition, Public-private collaborations should be encouraged by the government in order to create and market GM seeds. The government should also try to educate farmers, consumers, and the broader public on the advantages and dangers of GM seeds. Without a doubt, these seeds provide a plethora of potential benefits as well. Nonetheless, farmers shouldn't embrace new technology blindly.

Before entering into a contract with the corporate GM seeds companies the farmer should be informed thoroughly of every clause of the contact. Before deciding to plant genetically modified seeds, farmers should familiarize themselves with the technology and carefully go over all pertinent legal documentation.

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