IPR-PATENTABILITY OF GENETICALLY MODIFIED PLANTS IN INDIA

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ABSTRACT

The status of patent protection for Genetically Modified plants is presently uncertain in India as there have been Patents registered on Genetically Modified plant varieties in India but there is ambiguity whether they would be protected under the Patents Act. The problem had come to a head in the *Monsanto Technology LLC v Nuziveedu Seeds Ltd*[1] but the question regarding patentability has been left unresolved with the compromise and withdrawal of the case by the parties. This has resulted in a lacuna with respect to the IP regime in India which has led to confusion regarding enforcement of these rights and is detrimental to the steps that India is taking in its move towards an economy based on Research and Innovation. The project also discusses the difference in the protection given to an IP under the Patents Act and the Plant Varieties Act and what would be the effect on the Rights of farmers in India if GM plants are allowed to be Patented.

Keywords: Intellectual Property, Genetically modified plants, transgenic variety, Bt Cotton.

[1] 2019(3) SCC 381.

INTRODUCTION

Since the start of the 2000s, Genetically Modified plants have been introduced into the Indian Agricultural space and have seen widespread adoption by the farmers in the country. But till date, Bt Cotton is the only Genetically Modified plant that is allowed to be planted in the country as per the directive of Genetic Engineering Appraisal Committee.[2] Strains of the bacterium Bacillus Thuringiensis (Bt) produce toxins that are harmful for a variety of insects and it has been found to combat bollworm – moth larvae that commonly attack cotton crops. The aim of introducing Bt cotton in India was to reduce the amount of insecticide needed in farming cotton.[3]

In Diamond v. Chakrabarty[4], the United States Supreme Court laid the legal foundation for the Patenting of Genetically Modified plants and animals. With a five-Judges comprising the majority, in a bench of nine Judges, the US Supreme Court gave the ruling that 'anything under the Sun is patentable' provided that there is some human intervention or input and this lead to the US becoming the forerunner in Biotechnical engineering and research.

Introduction of Genetically Modified crops has brought with it a host of Intellectual Property issues. The agricultural companies put a huge amount of capital into their research for newer and better methods of seed production and expect returns on them through IP protection, through Patents. This protection is well provided for in the Western world but there is still a lot of debate in the developing countries regarding the balancing of the right of these seed companies and the poor farmers in these countries who in most cases are the ones who need these advanced plants the most as these plants bring certain advantages such as protection from pests or a better growing season for the crop.[5]

In India, introduction of GM crops since the early 2000s and their patentability have been matters of controversy with civil society groups and several NGOs protesting against such steps by the Government, one of their main qualms being the excessive royalties asked for by the

[2] Parthsarthi Biswas, "GM seeds: the debate, and a sowing agitation", *Indian Express,* June 12, 2020, *available at:* https://indianexpress.com/article/explained/gm-seeds-the-debate-and-a-sowing-agitation-6452999/ (last visited on December 21, 2024).
[3] Ian Plewis, "Modelling long-term impacts of Bt cotton. Nature Plants", *Nature* October 20, 2020, *available at:* https://doi.org/10.1038/s41477-020-00789-7 (last visited on January 28, 2025).
[4] 447 U.S. 303 (more) 100 S. Ct. 2204.
[5] Lodewijk Van Dycke and Geertrui Van Overwalle, "Genetically Modified Crops and Intellectual Property Law: Interpreting Indian Patents on Bt Cotton in View of the Socio-Political Background", 8 *JIPITEC* 151 (2017).

foreign corporations and a sense of impending danger keeping in view the patent infringement actions taken by seed companies in foreign jurisdictions against the farmers.[6] On the other hand, domestic seed companies and researchers in the field consider patentability and grant of royalties as necessary to ensure research and innovation and also to ensure that multinational seed companies are not run off from the Indian markets which would be detrimental to the interests of the Indian farmers in the longer run.[7]

However, it is a general view that these campaigns against the GM plants has by and large been written off as more than 80 percent of the cotton being planted in India today is one or the other variant of the Bt gene and a large number of other GM crops are being grown in India without the approval of the Government such as Bt Brinjal and Bt Mustard. It seems that the views of the groups leading this campaign are not in line with the farmers that they seem to represent.[8]

In this Article, the Author discusses the controversy regarding the Patenting of plants in India and the need for a deliberative debate on the relation between GM plants and rural development and the civil society opposition regarding the same.

There is ambiguity in the Indian Intellectual Property regime as to the Patentability of Genetically Modified plants in India as plants are not patentable under the Patents Act, where section 3(j) explicitly excludes patentability of plants but seed companies submit that the process of insertion of a microorganism in the seed satisfies all the conditions of patentability. This particular lacuna was a question in a Patent Infringement suit between Monsanto and Seed Companies in India which had licensed the Bt Cotton seed from Monsanto. That dispute has been settled between the parties and the question regarding the patentability of GM plants has been left open.

- The general objective of the Research is to determine whether GM plants are Patentable in India

[6] Karine Peschard and Shalini Randeria, "Taking Monsanto to court: legal activism around intellectual property in Brazil and India", 47 *The Journal of Peasant Studies* 792 (2020), DOI: 10.1080/03066150.2020.1753184 < https://www.tandfonline.com/doi/full/10.1080/03066150.2020.1753184 >.
[7] Gayatri Vaidyanathan, "Indian court's decision to uphold GM cotton patent could boost industry research", *Nature* January 30, 2019, *available at:* https://www.nature.com/articles/d41586-019-00177-y (last visited on June 2, 2025).
[8] *Supra* note 5.

- To compare the Rights given to the Intellectual Property holder under the Patents Act and the Plant Varieties Act

- To analyse the effect that the Patenting of GM plants would have on the farmers in India

2. PATENTABILITY OF GM PLANTS IN INDIA

The status of Genetically Modified Plant Patents is still ambiguous in India. The Monsanto Technology LLC v Nuziveedu Seeds[9] case had brought the issues to the fore but the case having been settled in the Delhi High Court in 2021 has ensured that the controversy will simmer on until there is another round of litigation or the Government of India steps in to clarify the issue.

The Indian Patents Act, 1970 has been revised a number of times to make it compliant to the obligations under TRIPS (The Agreement on Trade-Related Aspects of Intellectual Property Rights). It is important to go through these provisions under TRIPS to have a better understanding of the question regarding patentability of GM plants in India.

Article 27.1 of TRIPS requires, "…patents shall be available for any inventions…in all fields of technology…."

Article 27.3 of TRIPS states, "Members may also exclude from patentability… (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes."

A combined reading of Article 27.1 with Article 27.3 of TRIPS would render biotechnological inventions in agriculture patentable and not excluded subject matter, provided they would otherwise qualify to be patentable. [10]

However, Section 3(j) of the Patents Act excludes "plants and animals in whole or any part thereof other than micro-organisms, but including plants, varieties and species and essentially biological processes for production or propagation of plants and animals" from patentable

[9] 2017 (70) PTC 145 [Del].
[10] Lakshmikumaran M., *Genetically Modified Plants: The IP and Regulatory Concerns in India* in Liu KC., Racherla U. (eds) "Innovation, Economic Development, and Intellectual Property in India and China" (ARCIALA Series on Intellectual Assets and Law in Asia. Springer, Singapore, 2019).

subject-matter. This section of the Indian Patents Act makes it clear that methods of 'production of plants or animals' is not patentable under the Indian Patents Act, 1970.

Transgenic plants are plants that have had their genomes modified through genetic engineering techniques either by the addition of a foreign gene or removal of a certain detrimental gene.[11] Due to fundamental differences in biology, if the gene is obtained from a completely unrelated species (e.g., a bacterium), it cannot be successfully inserted into a plant with any success. Significant human intervention in the form modifying the gene for it to be suitable for a plant genome and adding several other components is required. Further, the insertion of the DNA constructs into the plant can occur at different locations in the plant genome, but not all of them will result in a desired trait. Only through significant human intervention can one select one of these "events" that will result in the transgenic plant expressing the desired trait at the optimal level. The recombinant DNA constructs developed in-vitro, the method for developing the genetically modified plants using that gene, and the integration of the DNA construct into the plant genome at a specific location in the plant genome cannot be termed as "essentially biological processes" and should be considered as a patentable subject matter.[12]

The question of patentability of transgenic plants or Genetically Modified plants has been discussed in cases in front of the Controller of Patents and the Intellectual Property Appellate Board(IPAB). In the case of Monsanto Technology LLC. v. Controller General of Patents[13], after the Controller had rejected Monsanto's claim for a heat resistant variety citing Section 3(j) of the Patents Act, Monsanto appealed to the IPAB. The IPAB accepted Monsanto's argument that since the production of the transgenic variety being claimed involved substantial human intervention, it could not be considered as an "essentially biological process" and, thus, was not hit by Section 3(j) of the Patents Act.

Following the above interpretation of the IPAB, there have been many decisions by the Indian Patent Office, wherein the objection under Section 3(j) of the Patents Act has been set aside on account of the inventions having a substantial human intervention, and therefore resulting in the patent application being allowed. This controversy was brought to the fore in the case of Monsanto v. Nuziveedu at different stages of the litigation in different Legal Fora, from the

[11] Jhansi Rani S, Usha R., "Transgenic plants: Types, benefits, public concerns and future. Journal of Pharmacy Research" *Science Direct* August 2013 *available at:* https://www.sciencedirect.com/science/article/pii/S0974694313003289 (last visited on June 1, 2025).
[12] *Ibid.*
[13] IPAB Order No. 146 of 2013 dated 5 July 2013.

single Judge of the Delhi High Court in a patent infringement case to the Appeal to the Supreme Court.

2.1 Monsanto Technology LLC v Nuziveedu Seeds Ltd[14]

Monsanto Technology LLC had a patent for Nucleotide Acid Sequence (NAS) containing the Bacillus thuringiensis (Bt) gene. NAS when inserted into the cotton plants worked as a defence against insects and therefore the need for pesticides for protection of the cotton crop from insects was reduced thereby decreasing the cost of production.

The dispute between Monsanto and Nuziveedu Plants Limited started in 2016 when Nuziveedu seeds and other seed companies sought for Monsanto to decrease the royalties which they were paying to Monsanto for license of the technology and did not further pay the agreed royalties. Against this, Monsanto terminated the royalty agreements and started proceedings in the Delhi High Court for patent infringement against Nuziveedu and the other seed companies. In reply, Nuziveedu filed a counter-claim challenging the validity of the patent. The trial court at this stage did not delve into the question of the validity of the patent and held that the termination of the royalty agreement by Monsanto was illegal and allowed the seed companies to continue using the Bt gene provided they paid the agreed trait fees.[15]

This Order by the single bench was appealed to the Division Bench by both the parties. The Court revoked the patent on the ground that the said invention was not patentable subject matter under Section 3(j) of the Patents Act, 1970, which excludes from patentability "plants and animals in whole or any part thereof other than micro-organisms but including plants, varieties and species and essentially biological processes for production or propagation of plants and animals". The Division Bench also allowed Monsanto to get their Intellectual Property under the PPV Act as it was a long time holder of the patent.[16]

Monsanto's claim was that NAS is a micro-organism and, hence, patentable under the Act. It was argued by Monsanto that the patent claim was not for the plant itself but for NAS and the process of introducing it into the plant which fulfilled all the conditions of patentability under

[14] *Supra* note 1.
[15] *Supra* note 1.
[16] Nuziveedu Seeds Ltd v. Monsanto Technology LLC 2018 (74) PTC 12 [Del].

the Act. It was argued that this was not a biological process but needed human intervention and, hence, should be Patentable.

The Supreme Court set aside the order of the Division Bench of the Delhi High Court and remanded the matter back to the Trial Court (Single Judge of the Delhi High Court), restoring the Injunction Order that was set aside by the Division Bench, on the grounds that the issue of patentability was a complicated issue of fact and law and could not be decided in a summary manner without taking the opinion of experts and careful consideration of the different submissions by the parties.

This questions of law pertaining to the Patents Act, 1970 and Protection of Plant Varieties and Farmers' Rights Act, 2001 remanded to the single Judge of the Delhi High Court have been left unanswered as the dispute has since been settled between the parties vide order of the Delhi High Court dated 09.04.2021.

3. DIFFERENCE BETWEEN PROTECTION UNDER PATENT ACT AND PPV&FR ACT

The PPV & FR Act is a *sui generis* legislation created by India for the fulfilment of its obligations under TRIPS. The creation of a new plant variety is protected under the PPV Act. The new variety may be created by a biotech research corporation, a breeder of plants or a farmer himself.

However, one is to note here that the PPV & FR Act awards protection to the commercial growers/breeders/seed companies for specific varieties in terms of Distinctness, Uniformity and Stability (DUS) testing to distinguish and identify a new extant, essentially derived variety and farmer's variety.

Moreover, Section 2(za) of the PPV & FR Act defines a "variety" as "a plant grouping except microorganism within a single botanical taxon of the lowest known rank."

Considering the aforesaid, a gene can never be equated to be a variety, wherein a trait is determined by the expression of one or more genes. Thus, a gene made of nucleic acids is a chemical compound within a plant which may confer a specific trait or characteristic to a plant but cannot be considered a variety under PPV & FR Act. Moreover, when a gene or DNA molecule is inserted into a plant species through the transformation method, such method

cannot get protection under PPV&FR Act. Such methods can only be protected under the patent regime, since there is no provision of protecting a method of transforming a plant or regeneration of plant using tissue culture methods under PPV & FR Act.[17]

Under the Patents Act, the patents can only be used for experimental use and not for further development or proliferation without the license from the Patentee whereas under the PPV & FR Act, persons are free to breed protected varieties and to develop new varieties through this process.

In case of any infringement under the PPV & FR Act, Section 64[18] of the PPV&FR Act states that the sale, import, and production of a variety registered under the PPV&FR Act by a person who is not the breeder of the said variety or the registered licensee of a registered breeder, without the permission of the registered breeder of the said variety, shall constitute as infringement of the registered variety.

Thus, it can be seen that the PPV&FR Act only provides for a legal recourse when either the variety registered under the PPV&FR Act or any right relating to such a registered variety is infringed by any person who is not authorized to use such a registered variety. The recourse to proceedings against infringement would be limited only to the case of a registered variety and not with respect to the trait or microbiological sequence which would prohibit any protection for Genetically Modified plants. [19]

Section 30[20] of the PPV&FR Act reads that nothing in the Act would prohibit the use of a variety by any person as an initial source of variety for the purpose of creating other varieties once new varieties are created from a variety and if these varieties are not registered then, they

[17] *Supra* note 10.
[18] Section 64 of the PPV&FR Act reads: "Infringement.— Subject to the provisions of this Act, a right established under this Act is infringed by a person— (a) who, not being the breeder of a variety registered under this Act or a registered agent or registered licensee of that variety, sells, exports, imports or produces such variety without the permission of its breeder or within the scope of a registered licence or registered agency without permission of the registered licensee or registered agent, as the case may be; (b) who uses, sells, exports, imports or produces any other variety giving such variety, the denomination identical with or deceptively similar to the denomination of a variety registered under this Act in such manner as to cause confusion in the mind or general people in identifying such variety so registered."
[19] *Supra* note 10.
[20] Nothing contained in this Act shall prevent –
(a)the use of any variety registered under this Act by any person using such variety for conducting experiment or research; or
(b)the use of a variety by any person as an initial source of variety for the purpose of creating other varieties: Provided that the authorisation of the breeder of a registered variety is required where the repeated use of such variety as a parental line is necessary for commercial production of such other newly developed variety.

can be used in an unauthorised manner. In other words, the PPV&FR Act regime does not offer any protection against the unauthorized use, sale, export, import, and production of the specific distinct trait, e.g., insect resistance, which may have been inserted into another plant variety by conventional breeding methods using the initial transgenic plant.[21]

Therefore, the protection against infringement given under Section 64 of the PPV&FR Act cannot be used by an innovator or researcher to protect a specific genetic mutation or trait that has been brought into the plant through transgenic mutation. Thus, the PPV & FR Act does not provide any efficacious remedy or protection against infringement of the GM Plants and hence a protection under the Patents Act, 1970 is necessary so as to ensure that the research and innovation in the particular area are sufficiently encouraged and the capital invested is compensated.

4. EFFECT OF PATENTABILITY OF GM PLANTS ON FARMERS IN INDIA

The PPV & FR Act allows the farmers to 'save, exchange, use and sell' seeds under Section 39(1)(iv) of the Act which reads as under-

> "a farmer shall be deemed to be entitled to save, use, sow, re-sow, exchange, share or sell his farm produce including seed of a variety protected under this Act in the same manner as he was entitled before the coming into force of this Act: Provided that the farmer shall not be entitled to sell branded seed of a variety protected under this Act."

This provision was brought into the Act explicitly to ensure that the farmer's rights cannot be encroached upon and that the practice of store and propagation of seed which is essential to traditional farming can continue. There is no such identical provision in the Patents Act, 1970 and it is a genuine concern of Civil Society and Farmers' Associations that patenting of GM Plants would result in Biotech Companies bringing infringement action against individual farmers and force them to pay royalties.

Although at present, Biotech Companies have not been especially critical of the judgment against GM Plant Patents in India or the lowering of trait fees by the Government fearing backlash, Biotech Companies have been litigating in various countries against farmers for

[21] *Supra* note 10.

patent infringement in jurisdictions, such as Brazil and Canada, which brings to light the intention of these companies to enforce their proprietary rights even directly against single cultivators in case circumstances demand in the future.[22]

If the GM plants are allowed to be patented under the Patents Act without there being any protection to the farmers for selling and distributing the seeds, then it would be to the detriment of the farmers and against the spirit in which Section 39 of the PPV & FR Act was enacted. A rights comparable to the farmer's rights can be introduced into the Patents Act so as to protect the rights of farmers to save and exchange farm produce.

A comparable 'copy-paste' approach was adopted by the EU in its Biotech Directive (Article 11 Directive 98/44/EC), which copy-pastes the farmers' privilege, i.e. farmers' rights to replant the product of their harvest on their own farm, from the EU Regulation on Community plant variety rights (Article 14 Regulation (EC) No 2100/94) to the patent laws of the EU Member States.[23]

5. CONCLUSION

From the discussion in the above sections, the author is of the view that GM plants should be patentable in India as Transgenic Plants fulfil the criteria of patentability under the Patents Act and they do not fall under the restriction under section 3(j) of the Patents Act, 1970. Patentability would ensure that the Biotech companies bring their product to the Indian market as it has been seen in recent years that although the biotech companies have not been explicitly critical of the Indian Government's policy towards GM plants but Multinational Biotech Companies have been reticent to bring their product to India.

The Monsanto case would have brought this question in dispute to a solution but the Supreme Court remanded the case back to the Delhi High Court in 2019. Now, in 2021, the case has been settled by the parties with all questions with regard to the Patents Act, 1970 and the Protection of Plant Varieties And Farmers' Rights Act, 2001 remaining open. It is the opinion of the author that the Supreme Court should not have remanded the whole matter to the single Judge but should have decided the matter as to patentability itself. This would not have been

[22] Adarsh Ramanujan, "Patents and Plant Variety: Development from Brazil", *Spicy IP* December 13, 2019 *available at* https://spicyip.com/2019/12/patents-and-plant-variety-development-from-brazil.html (last visited on June 5, 2025).
[23] *Supra* note 5.

unprecedented as the Supreme Court had taken this approach in the Novartis Ag v. Union of India[24] case also keeping in mind that the intellectual property disputes have a lot of commercial interest dependent on their outcome and the need for efficacious resolution of such disputes. Now, currently the controversy with respect to the patentability of GM plants in India is back to where it started after many rounds of litigation.

[24] (2013) 6 SCC 1.

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LIST OF ABBREVIATIONS

ABBREVIATION	FULL FORM
Bt	Bacillus thuringiensis
GM	Genetically Modified
IP	Intellectual Property
IPR	Intellectual Property Rights
LLC	Limited Liability Company
NAS	Nucleic Acid Sequence
PPV & FR Act	Protection of Plant Varieties and Farmers' Rights Act

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