



Patentability of Genetically Modified Seeds in India: Doctrinal Ambiguities and Regulatory Interface in the light of Monsanto–Nuziveedu Litigation

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Abstract. This paper examines the legal challenges surrounding the patentability of genetically modified (GM) seeds in India, with specific reference to the Monsanto v. Nuziveedu dispute. It analyses the ambiguity under Section 3(j) of the Patents Act, 1970, which excludes plants, seeds, and biological processes from patent protection, and its interaction with the Protection of Plant Varieties and Farmers' Rights Act, 2001. The study highlights key issues such as the distinction between gene constructs and plant varieties, enforceability of licensing agreements, and the impact of government price regulation. It argues that judicial inconsistency and lack of clear statutory interpretation have created uncertainty, affecting innovation, farmers' rights, and investment in agricultural biotechnology.

Keywords: Patent law, innovation, genetically modified seeds, Monsanto–Nuziveedu litigation., Section 3(j) agricultural biotechnology governance.

1 Introduction

Indian pharmaceuticals and biotechnological inventions got major breakthrough in 2005 when Indian Patent Act, 1970 was amended to align with standards required under TRIPS agreement. This development has raised significant legal concerns regarding whether such innovations can be considered as patentable subject matter or whether they fall within the exclusions under Indian patent law. In the process of genetic engineering genetically modified crops created by altering the structure of genes or introducing genes from other organisms through recombinant DNA technology.

India, being signatory of TRIPS and member of WTO making efforts to harmonize domestic practices with international standards. In this context article 27 of TRIPS agreement [1] is vital, as per provision member states are not bound to protect via patent plants, animals except microorganisms and essential biological processes for production of plants and animals except non-biological and microbiological processes. However, there is obligation to protect plant varieties either via patent,

separate legal system or any combination. The foundation for patentability of biotechnological inventions was laid down in the case of *Diamond v. Chakrabarty* [2] where SC of USA held that anything under the sun is patentable if there is application of human efforts and mind. Invention of genetically modified crops has raised concern about protection through IP laws. Developing nations like India struggle to strike balance between farmers rights and commercial interest of corporate who invest capital in producing better plants that are insect resistant.

India is said to be an agrarian economy where large chunk of population is dependent on agriculture hence when GM crops and seeds are to be considered for commercial exploitation via patents, in this regard two prominent and opposing views need to be considered. First being that it would be harmful to farmers as they would have to pay hefty royalty to seed companies and infringement may lead to action by foreign courts against local farmers. The second view supports research and innovation in the field of agriculture which would increase quality and life span of crops which would ultimately help farmers to yield better returns.

Early 2000s marked acceptance of genetically modified crops in India. However only BT (delta-endotoxins) cotton crop is only permitted genetically modified crop for commercial cultivation by guidelines issued by Genetic Engineering Appraisal Committee in the year 2002. The Bt technology is a technology where a genetic fragment has been derived from *Bacillus thuringiensis*- a bacterium, and inserted into a plant. The main usage of this technology is in the cotton plants which is most prone to pest attack by the boll worms. This technology would make the crops pest resistant resulting in better productivity.

It is insecticide-resistant other crops such as GM mustard and Bt brinjal yet to receive permission for commercial planting. The patentability of plant linked inventions is a controversial domain in India as per section 3(j) of the Patents Act, 1970 plants, animals in whole or part thereof including seeds, varieties, species and essential biological processes cannot be patented this is done to ensure access to food and protecting farmers rights. However, to promote inventions and to protect researchers, breeders and farmers rights India enacted Plant Varieties and Farmers Rights Act, 2001 a sui-generis legislation.

The nexus between biotechnology and agriculture led to genetically modified seeds which uses recombinant DNA technology has given rise to legal concern whether they are patent-able or not.

The current research paper is an analytical study which addresses the legislative obscurity relating to the patentability of genetically modified seeds in India, particularly arising from the interpretation of Section 3(j) of the Patents Act, 1970 and its interface with the Protection of Plant Varieties and Farmers' Rights Act, 2001. This paper examines the legal, policy, regulatory and judicial aspects of biotechnology based agricultural inventions in general and the patentability of genetically modified seeds in the light of *Monsanto-Nuziveedu* litigation in specific while focusing on the implications on farmers rights and agricultural innovations in India.

At the same time, this paper argues that due to lack of clear and unambiguous statutory interpretation regarding patentability of genetically modified seeds the

intellectual property regime of India facing uncertainties which is ultimately affecting equitable access in the agricultural sector and technological developments. Also, this paper critically analyses the overlaying between Indian plant varieties protection laws and patent law by examining the efficacy of current Indian legal framework in balancing commercial interests with socioeconomic issues. This research followed doctrinal and analytical methodology by studying legal provisions, judicial pronouncements, policy documents and related academic literature relating to the patent law and biotechnology.

2 Monsanto Technology LLC v. Nuziveedu Seeds Ltd: Brief Analysis

The case of Monsanto Technology LLC v. Nuziveedu Seeds Ltd [3] is vital as it deals with patentability of genetically modified seeds. It counters the question whether protected genes and modified seeds to be considered on equal footing. It decided whether Bt cotton seeds gene are patentable or excluded under section 3(j). The case further decided whether Patents Act, 1970 or Protection of Plant Varieties and Farmers Rights Act, 2001 will be taken into account when it comes to protection of plants genes. The issue in question in the current case pertains to whether genes and genetically modified organisms or crops can be patented in India. The case addressed multiple issues like the agricultural biotechnology, farmers rights and complex legal issue of patentability of genes in seeds.[4]

The dispute was between two parties Monsanto Technology LLC, a US based company dealing in agriculture biotechnology and chemicals. It was acquired by a German Firm Bayer A.G which holds patent in India for its invention named “method for transforming plants to express Bt delta endotoxins” and Nuziveedu Seeds Ltd., Indian company dealing with hybrid seeds.[5]

Monsanto developed patented Bt technology, where Nucleotide Acid Sequence was inserted in cotton seeds which would protect cotton crops from boll worms and enhance quality of crops. It was decided that Monsanto will give this Bt cotton technology to licensed seed companies which produces cotton seeds and they will further pass it to the farmers.[6] To this effect in the year 2004 a sub-license agreement was entered between Monsanto Technology and Nuziveedu seeds Ltd and its subsidiaries. As per this agreement Indian companies were entitled to use Bt technology into cotton seeds in exchange of trait value (license fee).[6]

The dispute started to take shape in the year 2015, where government intervened by fixing minimum support price for cotton seeds which led to reduced trait value for Bt technology. The Indian companies asked Monsanto to reduce the trait value as per state government rules which it refused and the license agreement was terminated. Plaintiff filed suit in Delhi HC for obtaining injunction against use of their registered trademark and preventing defendant from using Bt technology. Defendant retaliated by questioning patentability of subject matter under section 3(j) and took a stand that they are bound by trait value decided by government.

The legal issues regarding patentability of genetically modified seeds in India are multifolded as they lie at the intersection of contract law, patent law, and agricultural regulations. The primary issue is whether such seeds fall within the statutory exclusion under Section 3(j) of the Patents Act, 1970, which bars patentability of plants, seeds, and essentially biological processes. The case of Monsanto Technologies also highlighted the concerns regarding breach of conditions of the licensing agreement. In addition to this Hon'ble Court have also debated on whether the inventions made in plants and seeds will fall under the regime of Plant Varieties and Farmers' Rights Act, 2001 or it shall be considered as a mere micro biological process, which is patentable under the Patent Act, 1970. It is required to examine the intervening powers of the Government in price regulation of these seeds. Ultimately, the conflict between the Patents Act and the PPVFR Act raises the question of legislative primacy and the appropriate balance between intellectual property protection and farmers' rights in India.

2.1 Analysis of Relevant Legal Provisions

The dispute between Monsanto Technology and Nuziveedu Seeds Ltd paved way for multiple legal ambiguities. The claim of Monsanto was that the patent claim is out of scope of patentability and it was a man-made DNA that does not exist in nature and does not otherwise form a part of the plant as existing in nature and therefore it is not an exception as per Section 3(j) of the Indian Patents Act and that their patent is valid. On the other hand, Nuziveedu raised the issue that the utilisation of the impugned Bt trait is only when it is introduced in to the seed (which is covered under Section 3(j)) and that it is inert and inanimate otherwise. The function of the patented subject matter is considered a part of the seed. For the country like India, addressing these ambiguities are extremely crucial for the Indian farmers rather discussing them in a leisure manner as the at the end farmers will be liable to for royalties, licenses etc. The current case have discussed an important legal complexities of the patentability of genetically modified (GM) seeds in India under the Patents Act, 1970 and the relevant international agreements. [7]. Discovery of natural living or non living things have been kept outside the scope of patentability under section 3 (c) of the Patent Act. However, it must be noted that GM seeds are created by human intervention and biotechnological process and they are not mere discovery. Moreover, according to section 3 (j) plants, seeds, animals and essential biological processes cannot be patented as to protect traditional farming practices and to prevent commercialization of GM seeds in India. The legal ambiguity arises when scientists design genetic seeds by applying advanced scientific process and technology, they are uncertain to decide whether these seeds are patentable as biotechnological invention or non-patentable seeds. This ambiguity raises several more uncertainties regarding the process they followed or novelty and inventive step incorporated in the process.[8]. Section 48 grants exclusive rights to the patentee to prevent unauthorized use, sale, or import of patented inventions, which can give strong control over agricultural technologies. At the international level, Article 27(3) of the TRIPS Agreement requires member countries to provide protection to plant varieties either through patents, a separate legal system, or a combination of both.[9] In India, this protection is mainly provided

through the Protection of Plant Varieties and Farmers' Rights Act rather than full patent protection. Further, disputes have also emerged under the Contract Act where private licensing agreements between seed companies and farmers conflicted with government regulations controlling seed prices.

Above critical interrogation reflects the attempts made by Indian Patent law to maintain balance between encouraging innovation while protecting farmers' interests, but this balance is often uncertain in the case of GM seeds. Section 3(c) rightly prevents monopolies over natural discoveries, yet it does not clearly explain the extent to which human modification can transform a seed into a patentable invention. Section 3(j) reflects India's policy of protecting agriculture and farmers from corporate dominance, but its broad wording creates ambiguity for biotechnology inventions that involve substantial scientific intervention. Section 48 gives extensive powers to patentees, which may promote research and investment, but it can also increase farmers' dependence on multinational seed companies and reduce seed-saving practices.[10] Although TRIPS allows flexibility in protecting plant varieties, India's dual system of patent law and plant variety protection has led to overlapping rights and legal uncertainty. Similarly, conflicts between patent rights, contractual agreements, and state price control measures raise questions about whether private commercial interests should prevail over public welfare and food security. Therefore, the present legal framework reflects an ongoing tension between technological advancement, farmers' rights, and national agricultural policy. [11]

2.2 Arguments of the Parties

Monsanto argued that Patentability was never in question the action was brought for patent infringement because respondent used Bt technology ever after termination of licensing agreement. The subject matter of patent has a DNA which is inserted into cotton seeds. The nucleic acid sequence is not a mere discovery of living organism but it is invented chemical. The gene construct is not equivalent to plant variety hence it is not eligible for protection under Protection of Plant Varieties and Farmers Rights Act. Since human efforts were involved in gene sequence creation it is to be protected under Patents Act. Patented NAS is not normal biological process but scientific invention. The case involved question of facts and law requiring expert opinion hence summary judgement was not suitable. It was argued that reading section 2(j) with section 3(j) jointly GM plants and plants created through biological process both are excluded from patentability under section 3(j).

Nuziveedu argued that, Section 3(j) prohibits patenting of plants and seeds hence there is statutory exclusion of patenting any linked invention. It was argued that GM Bt cotton seeds were produced via traditional method hence it cannot be patented. When NAS was mixed with cotton plant it became inseparable part of cotton seed through biological process which is not patentable. It was submitted that plant varieties cannot be protected under patents act but under Protection of Plant Varieties and Farmers Rights Act. The claims from 25-27 are essential biological processes not product claims. The respondent argued that they committed no infringement as they used traditional breeding method for Bt traits. It was argued that monopolization of plants and seeds may restrict access to food and detrimental to local farmers. The

royalty to be paid to Monsanto must be regulated as per state's pricing policy guidelines. It was argued that there were no inventive step and industrial application of gene sequence NAS unless it is mixed with cotton plant otherwise making it mere biological thing. [12]

2.3 Judgement and Reasoning

At the initial stage court has not addressed the patentability of the subject matter. It held that both parties are bound by sub licensing agreement and the termination was arbitrary. It permitted seed companies to use Bt cotton in exchange of trait value. Both parties appealed the decision in division bench of Delhi HC. It was held that the invention falls within the purview of section 3(j) which prohibits patenting of plants, animals, seeds, varieties, species and essential biological process for production of plants and animals. The court directed invention to be protected under Protection of Plant Varieties and Farmers Rights Act within the 3 months. The seed companies were held liable to pay trait value as per sub license agreement.[13]

The Supreme Court of India, upheld the decision given by single judge bench regarding compliance with sub-license agreement and injunction order was imposed again and redirected matter to single judge bench for disposal. It set aside decision given by division bench regarding patentability of the invention asserting that expert opinion and evidences are required to deal with such complex issue. [14]

Whereas in India the Monsanto case failed to clarify domains of Patents Act and Protection of Plant Varieties and Farmers Rights Act when it comes to protection of seeds. If genetically modified seeds are protected under Patents Act it might lead to monopolization of seeds hampering access to food and farmers right. If genetically modified seeds are protected under Plant Varieties and Farmers Rights Act it might hamper research, development and investment in biotechnological inventions. Unfortunately the SC failed to highlight whether the Acts are interdependent or discrete.

The SC overturn the erroneous judgement of division bench and restored the order of injunction of single judge bench ensuring fairness in justice which would require in future expert opinion and evidences to decide patentability, however the need for better legal system to address core issue of patentability of biotech inventions is not adequately taken into account. [15]

This case attempted to strike balance between farmers right and interest of patentees however as seen in Novartis case and Natco pharma case where public access to life saving drugs was given importance than patent monopoly in this case access to food was not properly addressed.

If this case clarified the patentability of biotech invention it would have increased R&D and investment in agro-biotech, to the contrary it left the grey area of GM seeds unanswered creating legal unpredictability and instability.

It exposed the lacunas of current patent regime where GM seeds are not protected adequately and there is absence of experts who would strike balance between legality and technicality of the inventions. [16]

2.4 Doctrinal Ambiguities in the Patentability of GM Seeds

Monsanto- Nuziveedu dispute relates to the issue of distinction between product and process patent. Monsanto argued that, the patented invention was not the product that is seed but the microbiological process that is used to create a plant which is insect resistant. Whereas, Nuziveedu contended that, once gene becomes part of seed and plant, it will fall within the scope of section 3(j) and so it will be non-patentable. In this regard the Delhi High Court highlighted issue like whether a gene construction process can be separately patent able after its incorporation into a living plant. Therefore, the case did not conclusively uphold patent ability of genetically modified seeds, but instead exposed the uncertainty surrounding biotechnology patents in India.[17]

Section 3(j) of the Patents Act excludes plants, seeds, varieties, species and essentially biological processes from patentability. The ambiguity arises while determining whether the GM are technological inventions which formed with the involvement of human intervention or it is merely a biological process. [18]

Indian Courts have developed multiple approaches while addressing this ambiguity, which again added into more uncertainties and dilemmas for the farmers, researchers and biotechnological companies. The broad wording of Section 3(j) has therefore become one of the central reasons for doctrinal ambiguity in biotechnology patent law.[19]

2.5 Interface Between the Patents Act and PPVFR Act

The interrelationship between the Patents Act, 1970 and the Protection of Plant Varieties and Farmers' Rights Act, 2001 (PPVFR Act) is central debate in the current case. The PPVFR Act have provided right to save and reuse the seeds to the Indian farmers. The relationship between patent rights and plant breeders' rights (PBRs) lies at the intersection of innovation, agriculture, and social justice. Patents protect technological inventions that demonstrate novelty, inventive step, and industrial applicability. In contrast, PBRs (or plant variety protection laws) safeguard breeders' efforts to develop new, distinct, uniform, and stable plant varieties. The conceptual difference lies in the type of innovation—technical invention versus biological creation—but the policy objectives often overlap: both aim to encourage research and reward creativity. However, their coexistence frequently creates legal and ethical tensions, particularly regarding farmers' rights, access to genetic resources, and biodiversity conservation. [20]

The overlap between these two legislations has created uncertainty regarding whether plant-related inventions should be protected under patent law or under the plant varieties framework. This conflict becomes more significant when multinational corporations seek stronger intellectual property rights over genetically modified seeds.[21]

2.6 India's Sui Generis Framework and TRIPS Compliance

TRIPS permitted the member states to to exclude plants and animals from patentability under Article 27(3)(b), however it asked the countries to develop an effective sui generis system to protect plant varieties through patent. In order to

comply with the conditions of Article 27(3)(b) India enacted sui generis framework under PPVFR Act. With this law India attempted to maintain balance between farmers rights, innovatoion and biodiversity conservation. However, there has been always overlap between traditional rights of farmers and commercial interests of biotechnological companies. Protecting inventions as patent fosters investment and research in the agricultural biotechnology, however, excessive patent control may increase farmers' dependence on seed corporations. On the other hand, the PPVFR Act recognizes farmers not only as cultivators but also as conservers and breeders of plant varieties. Therefore, Indian law attempts to balance innovation with social justice and food security concerns.[22]

The Mashelkar Committee has been constituted to study patentatibility new chemical entity involving more than one inventive steps. the Committee observed that it would not be TRIPS compatible to limit the grant of patent for pharmaceuticals to NCEs alone, thereby indirectly supporting the argument for section 3 (d).The Committee Report played vital role in shaping India's biotechnology patent policy. It has recommended that microorganisms involving human intervention may be patentable, but it also emphasized the need to protect farmers' interests and public welfare. The report reflected India's cautious approach towards biotechnology patents and highlighted the need for balancing innovation with food security. However, the recommendations dose not clarify the patentability of genetically modified seeds. [23]

3 Judicial Perspectives in India

Besides Monsanto Technology LLC v. Nuziveedu Seeds Ltd case there are several other cases through which Indian judiciary have been interrogated issue of patentability and public interest.[24]

It is pertinent to note that the Supreme Court of United States have laid down the foundation for biotech innovations through the landmark judgement in *Diamond v. Chakrabarty* by recognizing patentability of genetically modified microorganism on the ground that it was a product of human ingenuity. This judgment have impacted global biotechnology patent law and is frequently referred to in discussions relating to genetically modified organisms.

In India, *Novartis AG V. Union of India* dispute highlighted the strict approach of Indian judiciary towards petantability standards of drugs. This case reflected Governments wider approach of protecting public interest by preventing monopolistic practices. This reasoning is relevant while interpreting biotechnology patents and genetically modified seeds.[25]

The *Natco Pharma* case reflected India's commitment toward balancing patent rights with public welfare through compulsory licensing. Even though the dispute related to pharmaceuticals, the principles relating to accessibility, affordability and public interest are relevant in the context of agricultural biotechnology and genetically modified seeds.[26]

The Indian legal framework for GM seeds reflect the contradictions among and between patent law. Farmers rights, plant variety protection and public policy. The

Monsanto dispute revealed India's unclear and ambiguous approach towards biotechnological inventions particularly inventions in seeds and plants. While patent law aims to encourage innovation and investment, agricultural policy in India also seeks to protect farmers, biodiversity and food security. This overlap has resulted in judicial inconsistency and uncertainty regarding the scope of intellectual property protection available to biotechnology companies.[27]

4 Conclusion and Recommendations

The Monsanto–Nuziveedu Litigation litigation have been established that though Indian patent law is successful and clear in excluding plant varieties and seeds from patentability and effectively protect them under an independent sui generis legislation, however, this law is in adopting technological advancements in patents. Despite the enactment of the Protection of Plant Varieties and Farmers' Rights Act in 2001, Monsanto managed to obtain a patent for its Bt. technology in the year 2008 under the Indian Patents Act rather than obtaining protection under the former.

The existing Indian legal framework of GM seeds remained uncertain and ambiguous because of inconsistent interpretation of section 3 (j) and overlapping objectives and operations of PPVFR Act and Patent Act. The legislative clarity regarding patent protection for microbiological processes and GM seeds will encourage investment and research in this area. Clear statutory guidelines should be introduced to distinguish patentable biotechnology inventions from non-patentable plant varieties.

The Monsanto dispute addressed several issues relating to regulation of trait value and patentability of GM seeds, enforceability of sub-licensing agreement. This recent Supreme Court Order, recognized the responsibility of every single individual to think wisely over the issue and a greater responsibility lies on the legislature of the country to make necessary amendments and provisions in law in par with the advancements in science and technology keeping in mind the welfare of the nation. There should be clearer provisions with respect to patentability of DNA sequences and genes.

The Supreme Court of India ensured justice and fairness, however failed to address core issue of patentability of biotechnological inventions leading to legal unpredictability and instability about GM seeds exclusion. Whereas the Supreme Court would have taken firm stand and sets judicial precedent, this would not only foster investments but also Research and Development in Indian agro-biotech industry.

Policy reforms should also ensure that innovation in agricultural biotechnology does not adversely affect farmers' traditional rights. The law must maintain balance between technological development, public welfare and food security. India may consider adopting a more harmonized framework that clearly defines the relationship between patent law and plant variety protection while remaining compliant with TRIPS obligations. Further judicial interpretation and legislative reform are necessary to reduce doctrinal ambiguity and promote certainty in biotechnology regulation. India needs a strong legal system that would balance corporate interest with farmers

rights and protect genetically modified seeds with clarity leading to adoption of eco-friendly agricultural practices.

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