

PATENTABILITY OF GENETICALLY MODIFIED SEEDS

by

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ABSTRACT

There has been happening drastic changes in the field of agriculture since the advancement in Intellectual Property Rights. Agricultural sector has seen a tremendous rise owing to plant breeding, development of fertilizers and by the introduction of genetically modified plants and seeds. In achieving these, biotechnology has got a significant role to play; it has helped in the development of the plant varieties with superior characteristics. Also, Genetic Engineering has helped in getting the desired traits in varieties thereby leading to the development of new varieties with superior traits.

The Indian Patents Act, 1970 does not grant patent protection to plants, its varieties or seeds. However, it does not specifically talk about man made gene sequencing that are found in genetically modified seeds. Because of which many bio-tech companies that may have acquired patent rights on man-made gene sequencing use patent law to claim indirect patent rights over the seeds.

Keywords: Genetically modified seeds, Plant Varieties, Farmers Rights, Breeders Rights, Gene-Sequencing.

Introduction.

Agriculture, though fighting a tough battle, is still contributing to the food chain security and health of the nation. Before the Industrial Revolution, agriculture was the primary source of our economy. We have always been told and taught about sustainable development, nature friendly and peaceful method of livelihood for which our primary duty should be to keep up the agro- economy of our country at par with food requirement, sound health and poverty inclining mass. Protecting the rights of people engaged in agriculture and spreading awareness of the existence of the agricultural laws would ensure constant supply of food to look upon the nutritional index of the population, availability of useful medicines for the health profile of the mass and ensuring employment of the generation. According to the Global Reports on food crisis, lack of developed technologies and inadequate research and protection in the field of agriculture has caused food insecurity among under developed and developing nations. Many factors contribute to food insecurity/crisis, people hoard food crops, mutilate with genes for better production. Agro-market size during 2020-21 crop year, food grain production has been reached a record of 305-308 million tonnes. Agrochemical and pesticides, rice, vegetable, seeds, fruits, tea, pulses, nuts and kernels, dried fruit, cashews, grain, coconut, poultry food, supplements, wheat, coffee, coir product, cereals, animal fodders, plant and animal oil etc. are just to name a few which contribute to the agro- market of our country.¹

Innovation is a perpetual change in any selected field; and agricultural field require innovation for growth, survival and success of human existence. Innovation does not necessarily imply creativity, it indicates changing and improving a process, breed, variety or product. This is how Intellectual property right comes into the sphere of agriculture. Innovation involves for the development of healthier and nutritious food (which is fit for both human and animal consumption), new breeding techniques and fuel for industrial use. Agricultural innovation has the potential to improve the productivity of crops, diversify the agricultural crops and enhance its nutritional value without depleting the land, water and biological diversity resources [Organization for Economic Co-operation and Development (OCED), 2013]

Since innovation requires, intellect, investment, research and development, implementation and management, growth period, collection of results, all at par with the current technologies and

¹ India Brand Equity Foundation (IBEF), Agriculture in India: Information about Indian Agriculture and its importance, <https://www.ibef.org/industry/agriculture-india.aspx> (last visited January 10, 2022).

better than the already established predecessor, single handed rights will protect the originality of an individual's plan to staple the ideas and honour the efforts put into it all the while. In this way IP protection encourages investment in innovation and helps to safeguard the continuous research; as a result acting as a source of support for any developments taking place in the field of agriculture. It helps IPR owners to make their product open to the market without the fear of exploitation and illegal use. IPR is not only restricted to law firms, multinational companies, industrial design rights, trademark, copyrights, patents, but also with the ever changing scenario, its ambit has stretched to primary sector of every economy, i.e., the agricultural sector. Agricultural sector deals with a number of laws for the protection of agricultural goods and services provided by this sector.

Biotechnology and information and communications technologies (ICTs) are anticipated to make dynamic changes by developing modified agricultural crops of better quality which yields high productivity and adaptability with a wider diversity to combat the problems of poverty, food insecurity, malnutrition and diseases.

Patents are generally granted for novel, non-obvious inventions having industrial applications, which generally give the patent holder a legal right to exclude the third party from using or commercially getting benefitted from the product, for a limited period of 20 years. Many countries do not allow patenting on living organisms.

In agriculture, biotechnology patents may cover for instance, plant transformational methods, vectors, genes etc. and patenting transgenic plants and animals. Patents are the most crucial form of protection in agricultural biotechnology.

Plant breeder's right was originally initiated to protect traditional breeding methods used to develop new plant varieties. Sui generis is a relatively weaker mode of protection as it does not exclude other breeders from using the subject matter for further development. Geographical indications is a protection of the geographically produced materials which have a distinct quality relating to the geographical area.²

² The Innovation Policy Platform, IP and innovation in Agriculture, <https://www.innovationpolicyplatform.org/www.innovationpolicyplatform.org/content/ip-and-innovation-agriculture/index.html> (last visited January 10, 2022).

Steps taken by the Government for the Protection of the Seeds Varieties.

Ministry of Agriculture, vide Letter No.11-71/88-SD-1 dated September 16,1988, brought out 'New Policy on Seed Development', with the goal to provide the farmers the best planting materials available in the world so as to increase the productivity and thereby increasing farm income and export earnings. Soon the private sector started demanding for rights in agriculture which smoothly got the public sector and the government to discuss about the same (which was earlier opposed by the public sector as they held the conviction that the private companies would encroach upon their breeding material). Reports and discussions suggested that India should implement rights for the farmers and the breeders in accordance with the International Union for the Protection of New varieties of Plants (UPOV). Massive protest against implementing Trade-Related Aspects of Intellectual Property Rights (TRIPS) were held with a cogent argument that it only encompasses agricultural innovations of breeders and corporations, and overlooks the informal innovations of the farmers and communities, especially in developing countries. In the background of this debate on plant breeders' right in India, the government formulated a draft of a bill to grant Plant Breeder Rights in 1993/94.

The bill provided for plant breeders' rights through provisions based on UPOV. However, the farmer's right under this draft was defined as-

- 1) Farmers' privilege as a right not only to save and exchange seeds but also to sell seeds (except branded).
- 2) Benefit sharing based on compensation and operating through a mechanism where communities/farmers can make claims for such compensation.
- 3) Farmers Rights as ownership: the idea that farmers must be able to register their varieties.³

Patentability of Seeds.

Patent gives exclusive right for a stipulated period of time through legal systems to have a control over one's invention and prevent the exact duplication of the invention by a third party.

According to the Indian Patent Act, 1970 and subsequent Patent (Amendment) Act, 1999 and

³ https://seednet.gov.in/PDFFILES/NEW_POLICY_NPSD.pdf (last visited January12, 2021).

2002, patents might be applied mainly for agricultural tools and machinery or the processes for the development of agricultural chemicals. Agricultural and horticultural methods which are Process Patent are products of agriculture which brings about rise in economic value of the country. It also helps in the nutritional index of the mass, contains medicinal values and holds the potential to combat diseases. This went on until the Patent Amendment Act, 2005 was passed, which gave the rights to patent over the products of agricultural inventions (Product Patent). Later as a signatory of TRIPS, *sui generis* system of protection of plant varieties was adopted which enables an owner to design the own way of protection of a plant variety and product. Since then patents were granted for seeds, plants, micro-organisms, cells, and even genetically modified organisms. Agricultural patents constitutes less than 2% of the total patents of Indian patents.

Patents can be levied upon genes of a plant which are novel. International Patent Classification (hereinafter referred as IPC) as a tool has been availed to obtain a specific level of precision in relation to activities related to agriculture. The bibliographic references contain information on patent number, publication date, IPC number, inventor's name, applicant's name, inventor's country, title, etc.

IPC class A01H (new plants or processes for obtaining them, plant reproduction by tissue culture techniques)- 8 patents were granted to India for nutrient medium composition for enhancing shoot sprouting from bamboo species and excised embryo-axis of cotton, transformation of plant/ tissue, rhizobial preparation for enhancing nodulation activity and grain yield in legumes, cold extruded composition, and synergistic composition as growth medium for fungi and bacteria.

According to the recent trend witnessed in agricultural patenting, major patents were done in the field of herbicides, pest-repellents or attractants. The Patents (Amendment) Act, 1999 offers Exclusive Marketing Rights (EMR) in agricultural chemicals, which helped foreign multinationals to exclusively market their agricultural chemicals in India for a period of 5 years, subject to the right granted in the country and marketing approval on/after 1 January 1995.

Patenting of DNA genes.

Patenting of DNA genes were, nonetheless, pointed out to be objectionable by many for it indicated life (DNA - Hereditary material from one generation to another) as a commodity and

a 'gene machine' which could be exploited for profit. Nevertheless, novel genes, plants processing it, seeds and their progenies are all being patented. According to Section 3(i) of the Indian Patent Act⁴ the following is not an invention: It states, "any process for the medicinal, surgical, curative, prophylactic [diagnostic, therapeutic] or other treatment of human beings or any process for a similar treatment of animals or plants to render them free of disease or to increase their economic value or that of their products."

The second amendment of the above act deleted the term 'plant'. Thus, genetically engineered plants have got the allowance to be patented. Article 27.3 (b) of TRIPS states that: "Parties may exclude from patentability 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. However, parties shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. This provision shall be reviewed four years after the entry into force of the Agreement establishing the WTO."⁵

This is considered as a loophole for our country in the name of scientific boon as Monsanto being a drafting hand in TRIPS agreement, has made its way to India's patent laws.

Plant Breeder's Rights.

The Plant Breeder's Right provides for a patent like system which allows the plant variety owner to prohibit specific unauthorized users of the variety. Plant Breeders' Rights (hereinafter referred to as PBR) law applies only to plants, and hence are among the class of *Sui generis*. In many countries PBR lasts for up to 25 years for trees and vines and 20 years for other species. To qualify itself for the protection, the new variety must be distinct, uniform and stable. If a comparative study is to be done, this variety must be distinguishable from the other varieties.

Article 27.3(b) of TRIPS, permits for protecting of plants and creatures and fundamentally natural procedures for their generation, regardless of whether such innovations are generally qualified for licenses. It may require the protecting of qualified creations covering 'microorganisms' and 'microbiological' or 'non-organic' procedures and items thereof. These terms are not characterized, leaving extensive degree for understanding. Exclusions, likewise,

⁴ The Patents Act, 1970, § 3(j), No. 39, Acts of Parliament, 1970 (India)

⁵ Laurence R. Helfer, Intellectual Property Rights in Plant Varieties, ISBN 92-5-105222-0, FAO 2004, <https://www.fao.org/3/y5714e/y5714e.pdf> (last visited January 13, 2022)

requires the organization of a 'powerful' *sui generis* law for the insurance of plant assortments. PBR under the TRIPS Agreement is a component of World Trade Organization (WTO) and the signatories of WTO are committed to comply with the TRIPS requirements with a harmonized minimum level of IP rights protection. Article 27.3(b) in part, states that WTO must provide plants variety patents “an effective *sui generis* system”, and now many countries have taken the initiative to opt for PBR over patents, as PBR is a *sui generis* system but what constitutes ‘effective’ is yet uncertain.⁶

Seed Act, 2004: Seed act, 2004 aims at preventing the farmers from saving/hoarding seeds from the private seed industries, dealing in seed exchanging and seed reproduction. The motive behind this act was to foster the rise of high quality seeds at the community level. The act regulates by imposing fine of upto Rs.25000/- on the farmers who have unregistered seeds and rights to the Seed Police to break into the huts and fields of the farmers for checking of their unregistered possession. Thus, this act proved to be beneficial solely for the private seed industries without doing any good to the farmers, eventuating in the loss of seeds and suicide committed by the farmers as they were drowned in debt.

Farmers’ rights in the Indian **Protection of Plant Variety and Farmers Right Act (PPVFRA), 2001**, are as follows:

1. Denied right to sell a branded seed of a variety under this act. They are free to save, sow, re-sow, and use the seeds and the products of the seeds, including seeds of protected varieties.
2. The legal Indian bodies which provide growth hormones for the making the crop disease resistant and giving better yield should be benefited in the gain of the farmer, thus benefit- sharing should be practiced.
3. The farmer is eligible of obtaining compensation if the seed received from the seed industry fails as was stated to give results.
4. Farmers have the right to access registered seed of varieties at a fair price.
5. Farmers who have contributed positively to crop improvement strategies are rewarded from the national gene fund.
6. If a farmer’s variety is to be used by the third party, authorization from the farmer is

⁶ IP Handbook blog, <http://www.iphandbook.org/handbook/ch04/p05/> (last visited January 12, 2022)

mandatory.

7. A farmer is well protected from accidental infringement if proven that he is unaware of the existing rights.

Along with the private sectors, farmers are being promoted to conserve and make use of the rights made for them and effectively contribute to the balance in private sectors and farmer's rights.

Case Study:

Nuziveedu Seeds Ltd and Ors. vs. Monsanto Technology LLC and Ors.

Contentions of National Seed Association of India (hereinafter referred as NSAI) - NSAI accepts that GM traits are patentable, but argues that once they are introgressed into a cotton genome the resulting transgenic variety is not patentable due to Section 3(j).

I present the argument as follows – “While the biotechnologies required for developing Genetically-modified (GM) traits are patentable under Indian Patent Act, after the transgene gets integrated in the genome and the GM traits expresses itself in a plant variety, such transgenic varieties are therefore not patentable”. Moreover it says that, under the Indian Patents Act, “there is no such provision to gather a trait value by enforcing patent rights on seeds and plant varieties to recover the investment and efforts put in to develop a new GM trait and to get approvals under the Environment Protection Act (EPA) despite having a patent for technologies which have been used for developing the GM trait, because it becomes a part of the plant variety”. The second stage of NSAI's argument is centered on the PPVFRA – it argues that any variety containing the Bt. Trait will then be subject to the limitations and exceptions listed under the PPVFRA. If the variety is not registered under the PPVFRA then any person is free to use such varieties. But what happens if the variety containing the Bt. Trait is registered? In such a case NSAI argues that a combined reading of Section 30, followed by Section 26 of the PPVFRA, gives any Indian seed company the right to conduct research on any registered variety to develop a new variety and subsequently commercialize that new variety subject to the benefit-sharing requirements.⁷

⁷ Prashant Reddy, The NSAI's new IP strategy in its dispute with Monsanto, Spicy IP (last visited January 15, 2022) <https://spicyip.com/2016/08/the-nsais-new-ip-strategy-in-its-dispute-with-monsanto.html>

Contentions of Monsanto - Monsanto's patent has two claim sets that are directed towards nucleic acid or gene sequences (Claims 25-27) and methods for producing transgenic plants (Claims 1-24). Both the claims viz. the man-made nucleic acid or gene sequences and the man-made processes (not a significant biological process) of transferring the man-made gene sequences (a novel product) into the genome of a plant, emanate from human ingenuity. Monsanto transformed Coker variety of cotton seed with the man-made gene sequences and claimed it within the impugned patent thereby conferring Bt. trait to the Coker variety. The novel gene sequences were then transferred from the Coker variety through conventional breeding by the intended party (sub-licensees in this case) into their desired cotton variety fit for Indian agro-climatic conditions. Here, both the novel products and processes are protected as a patent by the inventor (Monsanto in this case) under the IPA 2005, and the resultant desired cotton variety with novel gene sequences is protected by the owner of variety (sub-licensee Nuziveedu in this case) under the PPVFRA 2001. Both PPVFRA 2001 and IPA 2005 clearly demarcates what is patentable under IPA 2005 and what are often protected under PPVFRA 2001, and any other interpretation is erroneous and misleading.⁸

Delhi High Court's Judgment - Court said that the matter is not patentable under section 3(j) of the Patents Act, 1970 and it can apply for registration under Protection of Plant Varieties Act.

To conclude with:

Here I would like to present my opinion: The Single Judge Bench of the Delhi Court has interpreted it in the favour of the small seed companies and therefore the farmers who are literally the benefit derivers out of such invention and low cost of seeds. When the inventor company demands for royalty or licensing fee, these local seed companies' charges more from the farmers which is adversely affecting the economic growth of not only the farmers but also the country, hence it becomes mandatory for the Government to step in and pull some triggers to regulate the monopoly of the seed companies. However, this manifests that the Defendant Monsanto is not satisfied with this judgment and has moved to Supreme Court for appeal. Whatever be the judgment of the Supreme Court, the farmers and the people who depends solely

⁸ Pankhuri Agarwal, NSAI's Lopsided take on Patenting of Biotech Innovation in Agriculture, Spicy IP (last visited January 15, 2022) <https://spicyip.com/2018/05/nsais-lopsided-take-on-patenting-of-biotech-innovation-in-agriculture.html>

on agriculture and whose income is much less than these big MNCs, their right should get protected and they should be guaranteed to get it at a reasonable price under subsidized scheme from the government.

PepsiCo vs. Gujarat Farmers.

A very big controversy arose, when recently in April 2019 the multinational PepsiCo was in news all over for suing the farmers in Gujarat for cultivating the variety of potato which the company claimed that it owns.

Gujarat farmers sow potato seeds that was registered under the name of the multinational company PepsiCo. The patent is for the potato plant variety FL-2027 (commercial name FC-5). Pepsi's North America subsidiary company "Frito Lay" which has the patent until October 2023 and for India PIH has patented FC-5 until January 2031 under the Protection of Plant Varieties and the Farmer's Rights Act (PPVFRA), 2001.

The Allegations were that: Pepsico India Holdings [PIH] which has a buyback agreement with the Gujarat farmers, accused the 11 farmers – of illegally growing, producing and selling of the variety without the permission of the PIH.⁹

The Controversy: The PPVFRA provides for the establishment of an effective system for the protection of the plant varieties while developing the new varieties of plants. The PepsiCo instituted a suit for permanent injunction to restrain the infringement of the variety FC-5 seeds and also wanted to seek damages worth Rs. 1.5 crores each from the 4 farmers for illegally producing and selling the variety without any permission from the company and violating their statutory rights. PepsiCo uses the potatoes grown from FC-5 seeds to make its popular product 'Lays Chips'. The company claims to have firsthand knowledge about the production of the FC-5 variety by the farmers in January 2019, following which samples were collected and those were then sent for testing which matched, confirming a possible infringement resulting in PepsiCo being granted ex-parte ad interim injunction and thereby restraining the farmers from producing, growing and

⁹ Sohini Ghosh, PepsiCo. Vs. Gujarat Farmers: case, its withdrawal. The Indian Express (last visited January 16, 2022) <https://indianexpress.com/article/explained/pepsico-vs-gujarat-potato-farmers-case-its-withdrawal-5707731/>

selling the variety that has been registered until the next hearing.¹⁰

Following PepsiCo's move, the farmer's organization in Gujarat and all over the other states and along with them the politicians and activists started a campaign/ protest against the multinational company and demanded for the Government intervention. PepsiCo was portrayed as a tyrannical capitalist who was trampling upon the rights of the poor peasants and farmers.

However, there were many such people who stood in the support of PepsiCo claiming it to be an intellectual property right which was violated by the farmers. They said that the company had filed for an application for registration of a variety of seeds as a new variety on 2nd February 2012 and was subsequently granted registration by the Plant Variety Registry and therefore making PepsiCo the owner of the variety.

But on the flipside, the farmers claimed to have bought the potato seeds from a local market called gray market, in addition to this the farm activists also claimed that the potato variety was introduced in India in 2011 and was registered five years later in 2016 and that there was no contractual agreement with the company PepsiCo.

Here a significant matter in question is that who can grow what crops, as IPR is invoked under the law governing the rights of breeders and farmers in India.

Section 39(1)(iv) of the PPVFRA¹¹ begins with the words "Notwithstanding anything contained in the Act" which implies that this Section has precedence over all other sections from the Act. Moreover, it entitles a farmer to do all the things mentioned therein in the same way as he was entitled to do before the Act came into force, meaning thereby that the 'Act of the Farmers' shall remain unaffected.

Whereas on the other hand, PepsiCo was relying his claim on Section 64, which states that a right established under this Act is infringed when a person who is not a breeder, registered agent or licensee for that matter who is involving in selling, importing, exporting, which is causing confusion in the minds of general public. However, it is to be seen whether the farmer sold potato seeds which is to be cultivated, or they sold the unprocessed potato produce which is used in the

¹⁰ Vidhushi Trehan, PepsiCo vs. Farmers (A Case Of Misplaced Priorities Or Possibility Of Laying Down A New Precedent, Mondaq.com (last visited January 16, 2022) <https://www.mondaq.com/india/corporate-and-company-law/829552/pepsico-vs-farmers-a-case-of-misplaced-priorities-or-possibility-of-laying-down-a-news-precedent>

¹¹ The Protection of Plant Varieties and Farmer Rights Act, 2000, § 39(1)(iv), No. 53, Acts of Parliament, 2001 (India)

making the lays chips. Plus, the farmers claimed protection under 39 (1)(iv) claiming that the seed was already available in the market much before the registration was done by PepsiCo, raising question why PepsiCo took action at such a later stage, when the same thing could have been done earlier.

But soon after the Government stepped in the issue, the company withdrew its case against the farmers under intense political pressure; and the matter remained unsolved. But the question here is why did the company decide to take such a step when this variety of potato is the main essence of their product Lays?

Farmer's organization ASHA (Alliance for Sustainable and Holistic Agriculture) soon thereafter filed an application for the revocation of the certificate granted to the PepsiCo under Section 34(f) of the PPVFRA which allows registration to be revoked on the grounds that the breeder has not complied with the provisions of the Act, and furthermore, accuses PepsiCo of obtaining the breeder's certificate of FC-5 variety by fraud. That this variety has already been grown by farmers and that PepsiCo's registration is unethical and fraudulent.

As under Section 28 of the Act which provides an exclusive right to the breeder, but there is Section 39 of the Act which provides for the rights to the farmers to grow and sell a plant, if they have developed the same. However, law on this point is still ambiguous.

Conclusion.

However, the Authority's acceptance of the Revocation Application (inclusive of the ground that it was against public interest) gives us an explicit signal that the Farmer's Rights should not be taken lightly by the Intellectual Property Rights holders.

Moreover, when it comes to the PPVFRA, 2001 efforts should be made by concerned authority to ensure that the Applicant for Registration is not superseding the Rights of the Farmers.