

HOLISTIC STUDY ON GENETICALLY ENGINEERED CROPS: AN INDIAN PERSPECTIVE

MS. ANJALIKA SOAM

Maharashtra National Law University, Nagpur, India

Abstract:

Patent grant and use of genetically engineered crops is a worldwide debate. In India picture is not clear on the usage and patentability of these artificially engineered crops. On one hand patent act explicitly excludes animal and plant varieties from purview of IP protection whereas on other hand Supreme Court of India upheld the patent of Bt cotton in recently rendered judgment. Law is not clear on the point whether genetically engineered crops are subject matter of patent protection in India or not. Since, the monopoly protection to these transgenic crops very much depends upon facts that are they environment friendly and is their produce is fit for human consumption? Though, Agricultural biotechnology have a great potential to increase food productivity and yield better food production but inherent risk of environmental and health, impact on agricultural market and further on lives of farmers in India are the aspects that cannot be ignored. So, a detailed analysis is required into the provision of patent act to know how law in India will deal with GM crops and what are the risks associated with usage of GMO. This study focus on biosafety challenges of these products, and then analysis on patentability aspects of GM Crops.

Key Words: Genetically Modified Crops, BT. Cotton, Patentability, Indigenous population, Environment and Health

Definition:

Through genetic engineering, DNA of one organism is inserted into genes of unrelated species, generating the desired trait in every trait of target organism and producing genetically modified food¹. In case of genetically modifies plant, the desired trait is typically a resistant to sprayed pesticides or a toxicity towards predatory insects.² Through genetic engineering one can give desirable properties to targeted organism or plant variety result of this entire processes is known as a genetically modified organism, plant produce through this gene manipulation technique are known as genetically modified crops or genetically modified products.

Scope:

This process of gene manipulation or modification is so much technologically advanced that it is now possible to manipulate genes of any organism, plants, bacteria or animal. This technology got potential to produce compounds like food, pesticides, tissues, cells, organs and other bio-chemicals for commercial usage. The ability to manipulate genetic material, and transfer it from one species to another for some economic purposes,

¹ Debra M. Strauss, the international regulation of genetically modified organisms: importing cautions into the U.S. food supply, 61 Food and Drug LJ 167, 167 (2006), available at <https://core.ac.uk/download/pdf/268549743.pdf> (last visited December 30, 2020)

² World Health Organization, 20 Questions on Genetically Modified (GM) Foods, <http://www.who.int/foodsafety/publications/biotech/20questions/en/index.html> (last visited on December 30, 2020)

is the bedrock of the biotechnology industry.³ The ability to manipulate genetic material is now used to modify plants and animals we use today in our diets and has also made possible cloning of organism and livestock.

Historical Development:

Genetically engineered food has been with man since time immemorial. Forms of genetic engineering have been practiced by resourceful farmers by breeding plants and animals to emphasize certain attributes, by gathering and planting the seeds of fatter grains, by selecting meatier and hardier animals for breeding, and by cross-fertilizing different species of plants to create new varieties that exhibit the most desirable characteristics of the parent plants (Schardt, 1994). But the traditional methods of modification used to take years to give desirable results and also it was applicable upon certain close relative varieties and thus was not much developed system. Direct application of genetic engineering techniques including traditional breeding started in the 1960s, has continued in the 1990s, and will perhaps proceed into the 21st century (Phillips, 1994).

This gene modification technique globally was introduced in 1960 but Bt. Cotton was the first GMO introduced in India in the year 2002. This affected India's capability of producing cotton and which now is world's largest cotton producer. GM Mustard is the new GM crop in the block that is doing the rounds of constant speculation and has been cleared by the Genetic Engineering Approval Committee (GEAC), the biotech regulator in India under the Ministry of environment and forests with no such bio safety or public health concerns.⁴ Dhara Mustard Hybrid-11 or DMH-11 is a genetically modified variety of mustard developed by the Delhi University's Centre for Genetic Manipulation of Crop Plants.⁵ This variety could be seen very soon in markets of India by the due approval of central government.

Controversies associated with GM crops in India:

Controversies with GM crops in India started from year 2002 with the introduction of Bt. Cotton. PIL was filed against this crop in year 2006 in Supreme Court by many activist groups. Since matter was sub judice in SC, environmental minister Jairam Ramesh blocked the release of Bt. Brinjal in market until further notification and lack of consensus among scientists. New trials on these crops were suspended till 2012 by Supreme Court until regulatory and monitoring mechanisms could be strengthened in country. In 2014 UPA government approved trials for 11 crops and in 2014 21 new varieties of GM had been approved for field trials by NDA government. In year 2016 GEAC gave green signal to Bt. Mustard but Supreme Court stayed the same and sought public opinion on it.

Health Effects of GMOs

Genetically engineered crops are known for reduced susceptibility to pests and insects and are further promoted as a solution to low yield of crop in developing countries. There are undeniable possibilities that

³ Stella G. Uzogara, The impact of genetic modification of human foods in the 21st century: A review, *Biotechnology Advances* 18 (2000) 179–206, available at <https://www.researchgate.net/publication/9057337> last visited February 8, 2021.

⁴ Sudha Rani M, Satish Y, Rani C, Prasad NVSD, Bharthi S, Sri Lakshmi B and Ratna Kumari S, "History, status and impact of genetically modified crops in India", *International Journal of Chemical Studies* 2018; 6(5): 2735-2739, available at <https://www.chemijournal.com/archives/2018/vol6issue5/PartAV/6-5-6-713.pdf> last visited February 8, 2021.

⁵ id

motive of these promoters is profit not altruism. In light of this unbridled commercial approach to these transgenic crops it would not be surprising that these giant corporations might have paid little attention towards potential hazards of these food products. In 1992 the U.S. Food & Drug Administration (FDA) ruled, without any substantial scientific basis, that these genetically engineered foods present no different risks than traditional foods products.⁶ FDA's own scientists ridiculed this unscientific agency view of genetic engineering. "What happened to the scientific elements in [the] document?" one asked. FDA scientists consistently stated that "[t]here is a profound difference between the types of unexpected effects from traditional breeding and genetic engineering. ... [T]his difference should be and is not addressed."⁷ Also, other scientist Arpad Pusztai, from Rowett Research Institute, UK announced on television that experiments undertaken on GM potatoes produced intestinal effect on rats, and thus he himself will never consume these modified food products. The result of this statement was, he removed from his office and statement in press was released that his gesture was flawed. The British Medical Association issued notification for a moratorium on planting of genetically modified food. British government acting on this came out with proposal of research on potential health risks on genetically modified food.

Following are the potential health risk of GM crops”

- **Antibiotic Resistance:**

One of the prominent risks associated with genetically engineered food is that it makes disease causing bacteria resistant to antibiotics, resulting in a significant spread of infections and particular disease in human population. Since all genetically engineered food contains “antibiotic resistance markers” which eventually help producers identify and confirm whether the new genetic material is being successfully transferred to host food or not. Large scale transfer of these genes in food can render antibiotics ineffective in fighting diseases and thus could decrease immunity.

However there are many studies which identified that there exists no evidence to support these risks till date. Scientists and researcher do have acknowledge that there is possibility of such kind of antibiotic resistance bacteria may develop in human body but lack of evidence to support these claims make this theory less acceptable is substance. There were claims made in USA that over period of time variety of cancer types in country has changed and it is associated with switch to consumption of GE food. But these claims have been discarded in a research, where researchers observed the pattern of change in cancer incidence in the United States are generally similar to those in the United Kingdom and Europe, where diets contain much lower amounts of food derived from GE crops. The data do not support the assertion that cancer rates have increased because of consumption of products of GE crops.⁸

- **Variations in Nutritional Quality of Food**

There is a possibility that food produced by bio-tech may have modification in nutritional contents and can differ in food quality and produce, from traditional methods. Foreign genes introduced by artificial techniques might alter value of food in unpredictable ways by varying the nutritional contents. There the difference may arise in traditional counterparts and GM counterparts. But again there is little data available to support this claim. There is not substantive data that might prove the effects of change in nutritional composition. There is

⁶ <https://www.centerforfoodsafety.org/issues/311/ge-foods/ge-food-and-your-health> last visited February 8, 2021

⁷ id

⁸ The National Academy of Press members, *Genetically Engineered Crops: Experiences and Prospects*, 2016, available at <https://www.nap.edu> last visited February 9, 2021.

lack of information in terms of, nutrient interaction, nutrient potency, nutrient gene interactions, nutrient metabolism and nutrient bioavailability. There is also a paucity of information on situations in which these altered nutrients are involved in the complex regulation of gene expression (Young and Lewis, 1995).

The changes in food and diet through biotechnology occur at a pace far greater than the scientists' ability to predict the significance of the changes on pediatric nutrition. Critics therefore advise that caution should be exercised regarding use of GM food products in infant foods.⁹ In 1992, FDA's Division of Food Chemistry and Technology and Food Contaminants Chemistry examined the problems of nutrients loss in GE food but and scientists from the department warned the agencies that genetically engineered foods can result in "undesirable alterations in level of nutrients in food" and yet the same is being ignored.

- **Toxicity**

Genetically engineered foods can be claimed as unstable because of novel gene insertion processes, presence of anti-biotic resistant markers and vectors. There's an added possibility that formerly non-toxic elements of food might become toxic by these gene insertions. This situation can occur when gene inserted plays with food safety roulette and can turn it hazardous for human consumption. Genes for some natural toxins such as protease inhibitors in legumes, cyanogens in cassava and lima beans, goitrogens in canola species, and pressor amines in bananas and plantains, may be turned on and lead to an increase in levels of these toxins which can pose a peril to the consumers of these crops.¹⁰ Consumers from many parts of the world have raised questions on safety of these crops and demanded for their bans in the domestic and international markets. Wide range of debates took place at international level in WTO and other industry discussion by posing the argument that there's need of systematic investigation over these products.

- **Risk of Allergic Reactions:**

GE food products have potential to cause allergenic reactions amongst masses. These allergenic reactions can take place because of two situations. One, is when consumer consume the food which he think does not contain any such substance to which he is allergic too, but ultimately because of gene modification that food turns into allergenic one as the gene, inserted are those to which individual consumer is allergic. This happens because of negligent marketing by companies eventually rendering consumer less informed and affected. This situation is not hypothetical in nature. Pioneer Hi-bred International (a seed company now owned by Dupont) incorporated Brazil nut genes into soybeans to increase the protein content of its animal feed. This gene modification caused allergic reactions in consumers who were allergic to Brazil nut, so this product was voluntarily recalled.¹¹

Secondly, threat of allergy is posed when allergenic potential of micro-organism is either untested or it's unknown by the companies. When these unknown allergens are transferred from donor to recipient plant or animal they trigger allergic reactions or might exacerbate already existing ones. Though regulatory bodies ask for full disclosure by the companies but there might occur situations when companies itself are not aware of these allergens. This can be really hazardous for human health and specially children.

⁹ Supra note 3.

¹⁰ Supra note 9.

¹¹ Julie A nordlee, Steve Taylor, Jeffrey A. Townsend, Laurie A. Thomas & Robert K. Bush, "Identification of a Brazil-Nut Allergen in Transgenic Soybeans", 1996, New England Journal of Medicine 334 (11):688-92, available at : <https://www.researchgate.net> last visited February 9, 2021.

All above mentioned risks are potential risk by their very nature. Scientists and other scholars globally do have accepted possibility that they might appear in system of genetically modified crops and food. But, there are no studies and evidence to prove their existence or occurrence till date. One reason for this can be that conducting such research studies is time consuming affair and it need years to conclude whereas on the contrary genetically modified food has already acquired larger portion of individual diet. This is making difficult now to conduct such studies. This area of GM crops requires more detailed analysis and empirical research.

Environmental Concerns Associated with GM Crops

Global debates on genetically engineered crops on world forum are usually concentrated to food security issue or environmental issues. Though environmental issues differ from food security issue, as assessing the impact of transgenic crops on environment requires experience, build up from decades of studies since no change in environment could be perceived in a day or two. Largely environmental concerns can be categorized under two heads: Direct and Indirect concerns.

Direct Concerns:

Liberating genetically modified crops into environment can cause direct impact to same. These impacts can be listed as gene flow through pollinations, mixed mating and dispersal, weediness, traits flow to non-target species, impact on soil microbial population, and unintended effects on bio-chemistry etc. Although scientists differ in their views on these risks, they agree that environmental impacts need to be assessed on a case-by-case basis and recommend post-release ecological monitoring to detect any unexpected events (ICSU, Nuffield Council, GM Science Review Panel).

- **Gene Flow:**

It is the process by which genetic material is introduced from one population of a species to another, thereby changing the composition of the gene pool of the receiving population.¹² If this gene flow occurs naturally without human intervention it got possibility of impact ecological environment balance. Scientists have admitted the possibility that gene flow from transgenic crops can occur when pollens from open pollinated varieties cross with wild or local crops. In such cases the resultant transgenic wild hybrid may result in disturbed ecosystem. Whether this gene flow can result into an environmental problem is further issue and requires detailed analysis.

Bio-tech companies globally have adopted measures to restrict this process of gene flow but actual effectiveness of those measures is yet to be look upon.

One of the impacts of gene flow is weediness, where hybrid crop becomes established as a weed in other crop field. There are theories given by scientists that there is very low possibility of a domesticated crop growing as a weed, because they cannot survive and reproduce there. Other group of scientists which advocate benefits of GM crops opine that hybridized weeds can be advantageous to agriculture practices as they are already insects and pest resistant. But there are no evidences to support such claims. Opponents of GM crops want regulations to demand proper studies to assess the risks of GM crops on the environment. They believe that Bt. toxin, for example, can threaten beneficial insects by entering the food chain.¹³

¹² <https://www.britannica.com/science/gene-flow> last visited February 10, 2020.

¹³ Supra note 10

- **Hybridized trait effects on non-target species:**

Some genetically engineered traits such as pesticidal toxins by Bt. Genes may impact non targeted species along with targeted along with targeted crops they are particularly intended to control. A case study i.e. Monarch Butterflies demonstrated this, and concluded with the note that it is difficult to assess every condition with reference to GM crops, because laboratory studies are different from actual world implication. In Monarch butterfly controversy John Losey in 1999 published a result which stated that pollens from Bt. Maize killed monarch butterflies; he validated his research on the basis of his friend's laboratory study. Result of this publication lead to formation of 6 independent researchers' teams to study impact of Bt. Maize on butterflies in year 2001. The team was formed from National Academy of Science from USA. The team accepted the fact that pollen used in the original study was toxic at high doses, they found that Bt maize pollen posed negligible risk to monarch larvae under field conditions.¹⁴ Though the team clarified that the impact on butterflies by bt maize is negligible in comparison to threats from conventional pesticide but this controversy questioned the usage of GM food by masses.

Indirect Impacts:

The indirect impacts of transgenic crops can be like change in agricultural practices, use of herbicides and pesticides, changing dimensions of agricultural conditions etc. Though scientists acknowledge these impacts but have state that these impacts can be negative of positive in nature. They acknowledge that more comparative analysis of new technologies and current farming practices is needed.¹⁵

- **Changing agricultural practices:**

By the introduction of transgenic crops traditional agricultural practices has witnessed a shift. Farmers adopt those methods of agricultural which are more suited to these artificially engineered seeds. They adopt changing chemicals, different sowing techniques and varied land use patterns. Net result of these changed agricultural practices need to be assessed yet. But applying the general economics, we may come to a point a farmer will always choose those crops and seeds which will give him better yields and higher profits. This can lead to growing of selected crops and can cause serious threat to food security. More detailed data based analysis is needed to look upon this area.¹⁶

- **Use of pesticides and herbicides:**

Though liberation of genetically modified crops in agricultural market has led to less usage of pesticides in quantity and less toxic herbicide use but overall consumption of these have increased in past. This increased use can have hazardous impact on human health. The main concern here is even more use of less toxic herbicide will have negative impact on health and environment.

The other concern associated with usage of herbicides and pesticides is development of more pest resistant weeds in field. One cannot assume the fact that spraying of pesticides and herbicides will provide a robust protection because there is no reason to believe that it will take away every possibility of development of resistant pests.

¹⁴ Conner, Glare and Nap, The State of Food and Agriculture, 2003-2004, available at <https://www.greenfacts.org/en/gmo/3-genetically-engineered-food/5-gene-flow.htm> last visited February 10, 2021.

¹⁵ id

¹⁶ The State of Food and Agriculture, 2003-2004, available at <https://www.greenfacts.org/en/gmo/3-genetically-engineered-food/5-gene-flow.htm> last visited February 10, 2021.

Indian Seed Market

Portion of commercialized seeds in Indian markets is 30%¹⁷ which is lower than developed countries and much higher most developing and under developed countries like Africa, where these seeds acquire 10% of market. Though market domination presently of GM seeds in India is quite low but this has witnessed massive increase in past few years. Seed industry today is more concentrated those earlier times. The ten largest seed corporations dominate three quarters of the commercial seed market. The top three of these, Monsanto, DuPont and Syngenta, represent more than half (53 percent) of the market.¹⁸ Even more figures reported by Greenpace that Monsanto in 2009 sold 90% of its GM seeds globally. This increase can be a threat to small and medium scale farmers of India. The commercial seed market and Monsanto in particular have had a devastating effect on Indian farmers as Cotton farmers in India have been strained since Monsanto controls 95 percent of the cotton seed market.¹⁹

- **Impact on Farmers:**

Commercialization of these seeds leads to concentration in hands of few companies. For example Monsanto in partnership with Indian based Mahyco Company is the owner of the four varieties of Bt cotton approved for use in India.²⁰ Monsanto asserted the claims that particular variety of Bt. Cotton can yield higher results and is more cost efficient than the existing hybrid indigenous variety of cotton as farmers need not to spray pesticides to ward off pests. Eventually farmers in India shifted towards this variety of Bt. Cotton. But, this shift comes with the issue that farmers in India can no longer save seeds from their yearly crops for re sowing. Thus, farmers are apparently forced to buy new seeds every year from the company at a fixed price. As number of farmers growing Bt. Seeds seeing the advantage of same made the indigenous variety to disappear from the markets. Ultimately, farmers in the country are left with no choice other than buying seeds from Monsanto-Mahyco. This is where monopoly of particular company established in the country.

This established monopoly has two fold disadvantages. First, they are detrimental to interest of farmers and secondly they took away indigenous variety from the market. This entire process has jeopardized the long term biological diversity of the country. This was merely an example of cotton but this could be taken as a lesson to control future demon.

Other concern associated with the problem is that earlier pesticidal cost wasn't born by the farmers but continuous use of these seeds leads to attacking of crop by, "Lalya" or "reddening," a disease unseen before, which affected the GM acreage more than the non-Bt cotton crops.²¹ So, now farmers are overburdened with extra cost in terms of pesticide usage. The failure or low yield coupled with high input costs has left farmers in a debt trap and with reduced income, thereby affecting their income levels and access to adequate food.²² As

¹⁷ Reset Digital for Good, "The Privatisation of seeds", available at <https://en.reset.org/knowledge/privatisation-seeds> last visited February 10, 2021.

¹⁸ id

¹⁹ id

²⁰ Anitha Ramanna, „Bt cotton and India“s policy on IPRs,“ Asian Biotechnology and Development Rev., 2005.

²¹ Anuradha Mittal, Harvest of suicides: how global trade rules are driving Indian farmers to despair, 2008, available at www.freelibrary.com last visited February 10, 2021.

²² Anagh Mishra, "Intellectual Property Rights Regime Vis-A-Vis Food Security- Ironing Out The Creases", International Journal of Law and Legal Jurisprudence Studies, Volume 4 Issue 3, available at: <http://ijlljs.in/> last visited February 10, 2021.

a result of the high price of Bt cotton seeds and the failure of Bt cotton in various parts of India, thousands of farmers have committed suicide in the last few years.²³

The monopolization of market by these giant corporates is causing gross fundamental rights violation to Indian farmers. It is directly affecting farmers right to livelihood enshrined under Article 19 (1) (g) of Indian constitution. Article 21 of Indian Constitution i.e. “Right to life” and “Right to food” is also being violated by the acts of agricultural bio-tech corporations as farmers are left with minimal choices of survival and are unfortunately forced to attempt suicides.

- **Impact on Indigenous people:**

The dominance enjoyed by these corporates has also affected indigenous population of country. The dreams of high yield and lower costs shown by these seed companies lead to destroyed indigenous culture. Before the Green Revolution in India there were roughly 50,000 rice varieties, and within twenty years this number dropped to a mere 40 - 40 from 50,000.²⁴ This mono-cropping culture adopted by Indian farmers and indigenous people has severely affected indigenous crops which used to be diet of particular community, country or India as a whole. The resources to which indigenous populations once had right to consume has also been disturbed by this techno based agriculture.

In indigenous communities across the world, the overall sentiment toward GMOs and intellectual property patents is a negative one.²⁵ The idea that a person can reduce a complex life form to a set of trademark genes to be controlled in labs away from a natural growing environment is abhorrent to most people who share a deeper connection to the earth, both ancestrally and spiritually.²⁶ For indigenous peoples, GMOs pose a particular threat to the very foundation of many tribes, not only is it a health issue, but it is also a sovereignty issue.²⁷

Seeing the concerns around world India should take lessons from case studies like Native Hawaii and Brazil where many lives were found in health hazards because of transgenic crops experiments. What applicable to natives across the globe might not affect exactly in same manner and degree to Indian people but impact being a part of world cannot be avoided.

Patentability of GM Crops

The Uruguay round led to conclusion of TRIPS in year 1994 and it came into force in year 1995. While the Trade-Related Aspects of Intellectual Property Rights Agreement of the Uruguay Round has been controversial, Article 27 (3) (b) of this agreement is more so which pertains to patenting of biotechnology inventions.²⁸

²³ id

²⁴ Supra note 17.

²⁵ Global Struggle, Native Americans Denounce Genetically Engineered Foods, Nw Resistance Against Genetic Engineering (2002), <http://nwrage.org/content/native-americans-denouncegenetically-engineered-foods> last visited February 10, 2021.

²⁶ Tauli-Corpuz, Genetic Engineering, Biosafety and Indigenous Peoples, in Biosafety First - Holistic Approaches To Risk And Uncertainty In Genetic Engineering And Genetically Modified Organisms 303, 304-06 (ed. 2007).

²⁷ Casandia Bellevue, GMOs, International Law and Indigenous Peoples, 30 Pace Int'l L. Rev. 1 (2017) Available at: <https://digitalcommons.pace.edu/pilr/vol30/iss1/1> last visited February 10, 2021.

²⁸ C. Niranjan Rao, Patents for Biotechnology Inventions in TRIPS, Economic and Political Weekly, Jun. 1-7, 2002, Vol. 37, No. 22 pp. 2126-2129, JSTOR, available at: <https://www.jstor.org> last visited February 10, 2021.

Article 27 attracts the most attention because it stipulates the technology fields to be covered and exceptions to patentability.²⁹ Article 27 (3) (b) in specific provides provision to protect bio-technological inventions, it states that ‘Members may also 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, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof’. This is very complex provision by very nature. It includes provisions within provisions and thus need careful interpretation. The provisions can be deciphered in following ways:

- Members may exclude from patentability plants and animals perse.
- Micro-organisms are patentable subject matter but only those which are artificially created by human invention.
- Essential biological process for production of plants and animals can be excluded from patentability.
- Non biological and micro-biological processes are patentable under this provision.
- Members are obliged to protect plant varieties either by patents or by effective sui generis system.

Indian Patent Act, 1970

India when it comes to granting patent to inventions affecting agriculture has always adopted restrictive policy measures. India’s Patent law 1970 did not allow patents on products including plant varieties, tissue culture etc.³⁰ Though, India has adopted many revisions to its Patent Regime. The first amendment took place with The Patents Amendment Act 1999, Second with Patent Amendment Act 2002 and third was The patent Amendment act of 2005.³¹ These amendments were mostly on pharmaceutical patents but had some impact on agricultural biotechnology patents too.

Since legal regime in reference to plants and particularly transgenic crops is in developmental stage globally and in India as well. The patent amendments act 1999 and 2002 allowed for process patent in case of plants but no protection was attributed to plants per se. Protection can be granted for treatment of plants, which renders them free of disease or increase their economic value.³² Some author point out, however, this may de facto end up in patent coverage for plants. 2002 Amendment act bought section 3 (j), which avoid any possibility of patenting life forms specially plant varieties and seeds. Argument given for Section 3 (j) and non-patenting life forms is that “life form per se was not an article of substance that could be produced by manufacture or a composition”³³ and thus is not an invention within Section 2 (1) (j). Also, it can be subject to rejection under ethical ground within the provision of Section 3 (b).

²⁹ id

³¹ Anitha Ramanna, Bt. Cotton and India’s Policy on IPRs, Asian Biotechnology and Development Review, available at: <https://ris.org.in/> Last visited at February 10, 2021.

³² Ramakrishna, “Globalisation and International Governance of Modern Biotechnology Development of IPR Regime In India with Reference To Agricultural Biotechnology”, (2003), Sussex UK.

³³ Suresh Kumar K, “The Current Indian Patent Regime and the Scope of Protection in Agricultural Biotechnology: Some Issues and Considerations”, Journal of Intellectual Property Rights Vol. 12, May 2007, pp. 341-348, Available at: <http://nopr.niscair.res.in/> last visited February 10, 2021.

Any new plant variety arising out of an innovation use of conventional technique as well as modern biotechnology is not a subject matter of patent. Any innovation which can be categorized as biological intervention will attract provision under this act and will be excluded from patenting. However processes of modern biotechnology will escape the branding of “essential biological” clause under the section and thus can be granted patent.

Bt. Cotton case³⁴ study

Background:

Monsanto Technology is a US based company which have registered patent for Nucleotide Acid Sequence (NAS) which contains genes *Bacillus thuringiensis* (Bt gene). The contention was centered around the introduction of the Cry2Ab gene from the DNA of a naturally occurring bacterium, *Bacillus thuringiensis*, into a cotton plant cell to synthesise a nucleic acid sequence.³⁵ This process breeds a cotton plant variety resistant to bollworms. Monsanto claimed patent rights over the identification of the gene and over the method of inserting the nucleic acid sequence into the plant cell.³⁶ Nuziveedu argued that when a nucleic acid is introduced into any plant cell, Indian law prohibits patenting the cell.³⁷

Delhi High Court:

The case before Delhi High Court was appealed by Monsanto against Nuziveedu Seeds, along with Prabhat Agri Biotech and Pravardhan Seeds, Monsanto in the appeal claimed injunction for using their patented technology and trademark infringement by Indian companies. Delhi High Court said that Monsanto’s patent cannot be upheld under Indian Law, it falls under the exception of Section-3 (j) of Patents Act, Indian companies are lawful in using the technology and further court upheld payment of licensing fee by the Indian companies.

Supreme Court:

Court held that division bench should have restricted their jurisdiction in deciding the matter especially in a summary procedure. Since matter involves complex question of facts that like whether the DNA sequence is part of seed, whether the nucleic acid gene sequence can be eliminated from plant or not, etc. Court further iterated that division bench should have restricted their jurisdiction to the extent of deciding the grant of injunction, not beyond that without any expert public opinion considering the complexity of issue involved. It also establishes that summary adjudication of any technically complex suit without formal proof, particularly by way of expert opinion is neither desirable, nor permissible under the law.

Conclusion

Agricultural biotechnology have great potential to increase food productivity and yield better food production but inherent risk of environmental issues and health concerns, impact on agricultural market and further on lives of farmers in India cannot be ignored. Biggest danger to grow these crops is the impossibility of follow up. Another important aspect is regulatory framework of these products. Since genetically modified crops by

³⁴Monsanto Technology LLC v. Nuziveedu & Ors AIR 2019 SC 559.

³⁵ The Wire Staff, ‘What the Supreme Court Said in Its Bt. Cotton Judgment’, available at: <https://thewire.in/> last visited February 10, 2021.

³⁶ id

³⁷ id

applying current patent law provision cannot be protected under IP laws as a plant variety. We need to give close look on challenges this technology will bring to our country if granted patent protection. Are we economically and socially ready to face those challenges? This study focus on biosafety challenges to these products and its impact on farmer's & indigenous people legal and social rights. The researcher concludes that in order to utilize biotechnology to its greatest potential challenges associated with it should be closely examined and dealt with in future. Few countries globally analyzing these risk adopted precautionary approach of governance which resulted into banning of GM products in their respective jurisdiction. The possible solution to this problem is we need to come up with the system of governance which could probably accommodate existence of GE crops with non-genetically engineered crops. By this approach we could then be able to develop technologically with compromising the traditional values and interests of people involved in non-genetic method of cultivation i.e. farmers and indigenous groups.

List of References:

- Debra M. Strauss, the international regulation of genetically modified organisms: importing cautions into the U.S. food supply, 61 Food and Drug LJ 167, 167 (2006), available at <https://core.ac.uk/download/pdf/268549743.pdf> (last visited December 30, 2020)
- World Health Organization, 20 Questions on Genetically Modified (GM) Foods, <http://www.who.int/foodsafety/publications/biotech/20questions/en/index.html> (last visited on December 30, 2020)
- Stella G. Uzogara, The impact of genetic modification of human foods in the 21st century: A review, *Biotechnology Advances* 18 (2000) 179–206, available at <https://www.researchgate.net/publication/9057337> last visited February 8, 2021.
- Sudha Rani M, Satish Y, Rani C, Prasad NVVSD, Bharthi S, Sri Lakshmi B and Ratna Kumari S, “History, status and impact of genetically modified crops in India”, *International Journal of Chemical Studies* 2018; 6(5): 2735-2739, available at <https://www.chemijournal.com/archives/2018/vol6issue5/PartAV/6-5-6-713.pdf> last visited February 8, 2021.
- <https://www.centerforfoodsafety.org/issues/311/ge-foods/ge-food-and-your-health> last visited February 8, 2021
- The National Academy of Press members, *Genetically Engineered Crops: Experiences and Prospects*, 2016, available at <https://www.nap.edu> last visited February 9, 2021.

- Julie A nordlee, Steve Taylor, Jeffrey A. Townsend, Laurie A. Thomas & Robert K. Bush, “Identification of a Brazil-Nut Allergen in Transgenic Soybeans”, 1996, New England Journal of Medicine 334 (11):688-92, available at : <https://www.researchgate.net> last visited February 9, 2021.
- <https://www.britannica.com/science/gene-flow> last visited February 10, 2020.
- Conner, Glare and Nap, The State of Food and Agriculture, 2003-2004, available at <https://www.greenfacts.org/en/gmo/3-genetically-engineered-food/5-gene-flow.htm> last visited February 10, 2021.
- The State of Food and Agriculture, 2003-2004, available at <https://www.greenfacts.org/en/gmo/3-genetically-engineered-food/5-gene-flow.htm> last visited February 10, 2021.
- Reset Digital for Good, “The Privatisation of seeds”, available at <https://en.reset.org/knowledge/privatisation-seeds> last visited February 10, 2021.
- Anitha Ramanna, „Bt cotton and India’s policy on IPRs,” Asian Biotechnology and Development Rev., 2005.
- Anuradha Mittal, Harvest of suicides: how global trade rules are driving Indian farmers to despair, 2008, available at www.freelibrary.com last visited February 10, 2021.
- Anagh Mishra, “Intellectual Property Rights Regime Vis-A-Vis Food Security- Ironing Out The Creases”, International Journal of Law and Legal Jurisprudence Studies, Volume 4 Issue 3, available at: <http://ijlljs.in/> last visited February 10, 2021.
- Global Struggle, Native Americans Denounce Genetically Engineered Foods, Nw Resistance Against Genetic Engineering (2002), <http://nwrage.org/content/native-americans-denouncegenetically-engineered-foods> last visited February 10, 2021.
- Tauli-Corpuz, Genetic Engineering, Biosafety and Indigenous Peoples, in Biosafety First - Holistic Approaches To Risk And Uncertainty In Genetic Engineering And Genetically Modified Organisms 303, 304-06 (ed. 2007).
- Casandia Bellevue, GMOs, International Law and Indigenous Peoples, 30 Pace Int'l L. Rev. 1 (2017) Available at: <https://digitalcommons.pace.edu/pilr/vol30/iss1/1> last visited February 10, 2021.
- C. Niranjan Rao, Patents for Biotechnology Inventions in TRIPs, Economic and Political Weekly, Jun. 1-7, 2002, Vol. 37, No. 22 pp. 2126-2129, JSTOR, available at: <https://www.jstor.org> last visited February 10, 2021.

- Ramakrishna, “Globalisation and International Governance of Modern Biotechnology Development of IPR Regime In India with Reference To Agricultural Biotechnology”, (2003), Sussex UK.
- Suresh Kumar K, “The Current Indian Patent Regime and the Scope of Protection in Agricultural Biotechnology: Some Issues and Considerations”, Journal of Intellectual Property Rights Vol. 12, May 2007, pp. 341-348, Available at: <http://nopr.niscair.res.in/> last visited February 10, 2021.
- Monsanto Technology LLC v. Nuziveedu & Ors AIR 2019 SC 559.
- The Wire Staff, ‘What the Supreme Court Said in Its Bt. Cotton Judgment’, available at: <https://thewire.in/> last visited February 10, 2021.

