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PATENTS FOR GENETICALLY MODIFIED ORGANISMS IN INDIA: CHANGE IN THE VIEWPOINT OF THE INDIAN COURTS

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1. INTRODUCTION

Genetically Modified Organisms, which are popularly referred to as GMO, are the organisms that have its DNA altered or modified through genetic engineering. Usually the DNA is taken from any bacterium, virus, a plant or an animal. It sometimes also referred to as 'transgenic organisms'. These are more comparatively wild examples, but GMOs are already very common in the farming industry. The most common genetic modifications are designed to create higher yield crops, more consistent products, and resist pests, pesticides and fertilizer.

In early 2019, Indian Supreme Court had set aside the order given by the division bench of the Delhi High Court against the patent claims for the Bt cotton in the case of Monsanto Technology LLC v Nuziveedu Seeds Ltd[1] .In 2004, both parties entered into a 10-year agreement of the development of Genetically Modified Cotton seeds by the usage of the technology provided by the plaintiffs after the payment of the license fees for the same by the defendants. But in 2015, the agreement had to end due to the dispute arose between the parties over the matter of the price scheme initiated by the government.

The defendants in the suit argued that their rights were statutorily protected under the Protection of Plant Varieties and Farmers' Rights Act, 2001.It was argued that the patent was bad as unlike the "complex biological processes" adopted by the defendants, "claims 1-24 were "process claims" concerning genetic engineering or biotechnology method to insert "Nucleic Acid Sequence" (NAS) into a plant cell as in claim 25-27" were practiced in laboratory conditions. In short, it was contented that insertion of the NAS sequence couldn't reproduce on its own and would only impart insect resistance through the Bt trait which has to be injected into another organism and thus declaring this process to be non-biological hence to be eligible for the patent claims. The revocation of the patents was under Section 64 of the Patents Act, 1970.

[1] AIR 2019 SC 559

The Division Bench of the Delhi High Court upheld the defendants' counterclaim. The patent was excluded under Section 3(j) of the Patent Act, 1970 and was asked to register for their patent under the PPVFR Act, 2001.Under the appeal of the plaintiffs, in the Supreme Court, the plaintiffs argued that their plea was not with the issue of the patentability of their seeds but the actual issue was with regard to the patent infringement conducted by the defendants. It was also brought to the attention of the court that this patented technology had the highest number of seeds sold, and that the plaintiffs never intended to sue any Indian farmer individually. It was argued that the PPVFR Act and the Act were not complementary but were mutually exclusive in nature. Thus, it was argued that the DNA gene was not part of the plant variety as well it doesn't come under the preview of the 'plant grouping' i.e. the lowest ranking of the plant-species.

The plaintiffs also contended that it doesn't lie under the PPVFR Act either as this includes human intervention and not purely biological process. The defendants contended that genetically modified plant breeds can't be grant patents under the PPVFR Act as it goes against the scheme initiated in this Act. The donor seeds have to be registered under the said statue and its constructive benefits have to be listed under Section 26 of the Act. It was argued a proper construction of asserted claims and a determination of how the product infringes this claim, has to be proved in cases of patent infringement. They further contented that it is an improvement in the prior, existing form and it follows onto its progeny plants and infiltrates into every cell of the plant even though in its subcellular level and it is irreversible biological process to improve the characteristics of the plant. The insertion of the NAS sequence into Indian varieties would lead to a new variety of the breed. Section 2(j) and Section 3(c) of the Act didn't allow the biological process to be patented. Such patents claims can't deprive the farmers from using the infringement as the Section 48 of the Act only restricts the biotechnological companies who seek to exploit it.

The Supreme Court finally upholds the decision of the Single Bench and set asides the order passed by the Division Bench by stating that:

"The Division Bench ought not to have examined the counter claim itself usurping the jurisdiction of the Single Judge to decide unpatentability of the process claims 1-24 also in the summary manner done. Summary adjudication of a technically complex suit requiring expert

evidence also, at the stage of injunction in the manner done, was certainly neither desirable nor permissible in law. The suit involved complicated mixed questions of law and facts with regard to patentability and exclusion of patent which could be examined in the suit on the basis of evidence."[2]

The primary reason for not adopting the GM organisms was because as per Article 27.2 of the TRIPS agreement which is read that the members can exclude grant of patents to inventions that are commercially exploiting public policy and morality which also includes animal or plant or human life and cause serious deterrence to the environment. This reason was based on the protection of the consumers. Another reason is a coalition of international NGOs and Indian civil society action groups, including several farmers' organizations, has continuously opposed GM crops, as well as IP protection for such crops because both GM crops and IP protection would be detrimental for farmers.[3]

2. GENETICALLY MODIFIED ORGANISMS UNDER INDIAN LAWS.

The Patents Act, 1970 has been primarily in the field of the grant of patents to any inventions one but has given reasonable restrictions under Section 3(j) of the Act, for the inventions done under Section 2(m) that defines patent. Section 3(j) reads that*: plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals*[4] .This provision don't provides for any guidance for the grant of patents to genetically modified organisms or neither it has categories the above to be a subject matter of non-patentability. Section 3(j) was inserted through the Patent Amendment act, 2002 in the Act under India's ratification of the Marrakesh Agreement that aimed at establishing the World Trade Organization with respect to the Trade-Related Aspects of Intellectual Property Rights (TRIPS) while the TRIPS would encourage patents for all inventions in any fields of the technologies. Article 27 of the Agreement provides for the patentable subject matter along with certain exceptions. The

[2] Dushyant Kishan kaul, 'Patentability Of Genetically Modified Plant Breeds: The Monsanto Conclusion' (Mondaqcom, 28 January) <http://www.mondaq.com/india/x/775342/Patent/Patentability of Genetically Modified Plant Breeds The Monsanto Conclusion> accessed 5 July 2019

[3] Lodewijk Van Dycke and Dr Geertrui Van Overwalle, 'Genetically Modified Crops and Intellectual Property Law: Interpreting Indian Patents on Bt Cotton in View of the Socio-Political Background' (JIPITEC – Journal of Intellectual Property, Information Technology and E-Commerce Law, 8 February) <https://www.jipitec.eu/issues/jipitec-8-2-2017/4564/> accessed 7 June 2019

[4] The Patent Act 1970, s 3(j).

relevant one *is "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"*.[5] 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. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement. Article 27.3(b) of the Agreement excludes the grant of the patents to only naturally occurring organisms like plants and animals, on the other hand, it has three criteria that are qualified for patents (i) non-biological processes; (ii) micro-organisms and microbiological processes; (iii) plant varieties, where the agreements provides the power to its members to establish a sui generis system that protects the plant varieties or to protect them by grant of patents.

2.1. GENETICALLY MODIFIED ORGANSIMS AREN'T NATURALLY OCCURED

Indian laws hasn't defined or provided anything about genetically modified organisms. The U.S. patent laws recognizes 'product of nature' doctrine that categories the grant of patents only to those which doesn't lack in inventiveness or merely because of them being present in the nature. This doctrine was first recognized in *Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 US 127 [1948]* that states: *"He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end*.[6] Another case that strengthen the laws for the patents to the microorganisms, where it was interpreted for the first time, that these genetically modified organisms are not naturally occurring. The U.S. Supreme Court held that genetically modified bacterium capable of digesting multiple components of crude oil is patentable and the reason was very simple—*the claimed bacterium was not found in nature nor was its activity exhibited in any naturally occurring bacteria*. The Court also stated that the claimed bacterium satisfied the prerequisites for patentability, as it was a product of human ingenuity having a distinctive name, character and use.[7]

[5] Agreement on Trade Related Aspects of Intellectual Property Rights 1995, Article 27.3(b)
[6] Anmol Jain, 'The Future of Patents on Genetically Modified Organisms in India' (IPWatchdogcom, 27th April) <https://www.ipwatchdog.com/2019/04/27/future-patents-genetically-modified-organisms-india/id=108582/> accessed 12th June 2019
[7] Diamond v. Chakrabarty, 447 US 303 [1980]

This case was precedent of the grant of patents for many genetically modified animals like pigs, cows, chickens, monkeys, rabbits, sheep and salmon. Transgenic mouse from Harvard University which had an oncogene that increase susceptibility to cancer. The jurisdictions of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, the United Kingdom, and the United States have found it to be patentable subject matter. The Canadian Supreme Court held that "*The extraordinary scientific achievement of altering every single cell in the body of an animal which does not in this altered form exist in nature, by human modifications of the genetic material of which it is composed', is an inventive composition of matter.*"[8]

Hence, through the wider interpretation of the doctrine and the cases, the patents to these kinds of organisms can be granted if the human ingenuity led to the creation of the organism, which is not naturally occurring but the result of human intervention. Section 2(j) of the act defines about invention which is a new process without differentiating between 'product of nature' and 'man-made products'. The features of the doctrine are:

- Pure vs Impure-Webster's New International Dictionary also defines "pure" as "Separate from all heterogeneous or extraneous matter; free from mixture or combination and "Impure" is defined as "not pure; mixed or impregnated with something extraneous." It makes a clear distinction between the two for the purpose of novelty. As the pure material *per se* did not exist in nature the pure material so obtained was considered sufficiently new to cross the line of novelty. In plain words the novelty is not destroyed when the substance of nature is produced in pure or more useful form. Mostly such patents include claims for isolation and purification as well. However, where a patent is granted for product it is limited to the isolated and purified form only not for the form occurring in nature.[9]
- New form of known substance-Section 3(d) of the Act provides that mere discovery of a known substance which does not change the efficacy of that substance, or mere discovery of any new property or new use of the known substance or mere use of a known process, machine or apparatus unless such known process results in a new product or employs at

[8] Supra at 6

[9] DPS Parmar, ' Product Of Nature: Patentability Issues' (Mondaqcom, 14th July) <http://www.mondaq.com/india/x/822078/Patent/Product Of Nature Patentability Issues> accessed 9 June 2019

least one new reactant.[10]The difference between the efficacy of the known substance and the new form of the known substance may cross the lines of novelty but the improvement in the efficacy of the existing substance may amount to be patented under Section 3(d).

- Obviousness and substantially pure form- It is not true to admit that the substantially pure form of a natural product would not be granted patents. Patent act in India under section 3(d) has kept the obvious or substantial product to be non-patentable matter to put a check over its efficacy.

2.2. THE PROCESS INVOLVED IS MICROBIOLOGICAL PROCESS

Indian laws have prevented 'essentially biological processes' from being granted the patents but these laws are silent about micro-biological processes or has it been included in the Section 3(j). Article 27.3 of the TRIPS agreement has included the micro-biological processes and non-biological processes. Section 3(j) was incorporated into Patent Act, 1970 after the Patent Amendment Act, 2002. The relevant provision can be divided into two parts were the first part was amended under Section 3(j) of the Patent Act,1970 while the second part was in the form of 'explanation' to Section 5 of the act which read as: For the purpose of this section, "chemical processes" includes biochemical, biotechnological and microbiological processes". The Patent Amendment Act, 2002 was in compliance with the TRIPS agreement for which India is a signatory and to ensure that India was ready to grant patents to both microorganisms as well as micro-biological processes. Microbiological inventions include new products, processes, uses and compositions involving biological materials. These inventions cover methods to isolate and obtain new organisms, improve their character, modify them and find their new and improved uses.[11] As TRIPS or any patent law requires innovation or new products to be produced through human intervention. The patents are granted to the humans for bringing up something innovative in the biotechnological industry, this award has been granted to their idea or intelligence. The Indian patent laws prohibits essentially biological process to be patentable subject matter, but is silent in the matter of 'micro-biological process' which was earlier included in the explanation of Section 5 of the Patent Act,1970 that has been removed in the Patent(Amendment)Act, 2002. This distinction was discussed in the recent case on Monsanto's patent claims over its Bt cotton seeds in India. The Supreme Court of India, while setting aside the order of the Delhi high court,

[10] The Patent Act 1970, s 3(d)

[11] Department for Promotion for Industry and Internal Trade, Report of Technical Expert Group on Patent Law Issues, December 2008, para 5.20

noted that patent claims concern genetic engineering or biotechnology methods to insert nucleic acid sequences into a plant cell practiced in laboratory conditions, unlike the natural biological process.[12] The whole process of positioning of NAS into at a unique location in a genome in a cell is an event of separate, different and subsequent invention.

The Indian Patent laws don't define what is neither 'an essentially biological process nor any definition on plant or animal or parts of plant and animal. Thus, the practitioners and patent jurists are relied on dictionary definitions or the international treaties that specifically defines the process like Article 2(2) of the Biotech Directive as well as Rule 26(5) of the EPC states that "a process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection".[13]Article 4(3) read with Article 4(1)(b) states that without prejudice, patentability of inventions concerning microbiological process or other technical process would be granted. Article 53(b) of the EPC reads the same. The division bench of the Delhi High Court stated that the process wouldn't amount to be 'essentially biological process' if it includes human intervention that amount to a remarkable alteration or introduction in the genetic composition of a plant cell. It is to interpret those essentially biological processes is different from the microbiological processes. It is to remark that patents for the microorganisms are valid.[14]

The other laws in India that govern over genetically modified organisms: As per Article 27.3 of the TRIPS agreement, India had its own sui generis model with respect of the plants and parts of the plants i.e. Protection of Plant Varieties and Farmers Rights Act, 2001.The special act promotes and protects farmers' rights in the usage of the unpatented plant varieties as well as helped them in production of cross-breed genetically modified plant varieties and increase the agricultural yield. Section 2(za) of the PPVFR Act, 2001 defines 'variety' which includes transgenic variety also. Under section 3 of the Food Safety and Standards (FSS) Act, 2006, *"food" means any substance, whether processed, partially processed or unprocessed, which is intended for human consumption and includes genetically modified or engineered food or food containing such ingredients…*" [15] This is to be proved that FSS Act is only responsible authority

[12] Supra at 6
[13] Pankhuri Agarwal, 'Excluding "Essentially Biological Processes": Implications for Monsanto vs Nuziveedu' (SpicyIP, 2nd January) <https://spicyip.com/2019/01/excluding-essentially-biological-processes-implications-for-monsanto-vs-nuziveedu.html> accessed 14 August 2019
[14] Dimminaco A G v. Controller of Patents Designs (2002) IPLR 255 (Cal)
[15] Food Safety and Standard Act 2006, s 3

to govern over genetically modified organisms in terms of food products in India. In 1989, under the guidelines of the Union Environment Ministry, Genetic Engineering Appraisal Committee (GEAC) that has been responsible for approving cultivation of genetically modified crops and the manufacture, import and selling of processed foods made from GM ingredients.[16] But in 2013, The Legal Metrology (Packaged Commodities) Rules, 2011, had mandated the food packaging industries to put a label of Genetically Modified (GM) on top of the packet for indicating in the usage of such products as GM products was not allowed in India , thus this rule was inconsistent. Transgenic animals are those animals whose DNA has been manipulated over a foreign gene. These kind of animals are ,mostly used in laboratories for research like mice, pigs, sheep, cows and fish. Such animals are governed under Genetic Engineering Appraisal Committee (GEAC) for their safety in public use. Earlier, FDA hadn't approved for human consumption of the transgenic animals due to its inedible quantities but on 19 November 2015, USFDA has given approval for the first genetically modified animal for human consumption i.e., transgenic mice.[17]

As we see, Indian laws have placed a room for genetically modified organisms in respect to the TRIPs agreement, but there are certain lacunae in the present law that has to be checked periodically and technologically too. Patent laws, in general, provide an opportunity of innovation, uniqueness and non-obviousness along with human intervention. Thus, these laws must be an expansion towards biotechnology for the country's progress and development. The move by the Indian supreme court towards industry research. The court's decision on the Monsanto cotton patent will set a precedent for the protection of other GM crops, which will have a profound effect on research and development in the field.

[16] Amit Khurana, Snigdha Das, Sonam Taneja, Bhavya Khullar, Vibha Varshney , Banjot Kaur, "Vacuum in governance on genetically modified foods in India" (DownToEarth , 9 August) < https://www.downtoearth.org.in/blog/food/vacuum-in-governance-on-genetically-modified-foods-in-india-61230> accessed 12 September 2019

[17] Anjali Gupta and Harikesh Maurya, 'FABRICATION TECHNIQUES AND UTILIZATION OF TRANSGENIC ANIMAL' [2018] 6(2) International Journal of Pharmaceutical and Medicinal Research <http://www.ijpmr.org/pdf/Fabrication-Techniques-and-Utilization-of-Transgenic-Animal.pdf> accessed 25 June 2019

3. IMPACT OF PATENTS OF GENETICALLY MODIFIED ORGANISMS IN INDIA

Research in India has been improving and advancing in itself for so long, which has been appreciated and also achieved the goals to the next level. India is currently among the top 12 biotech destinations in the world and ranks third in the Asia-Pacific region.[18] Since 2005, India has followed the product patent regime. Biotechnology involves the use of living organisms or biological materials in the preparation of pharmaceutical products. [19] But, According to the TRIPs agreement, patentability of living organisms was treated to be invalid unless it suits in the criteria of patenting as per Indian patent Act, 1970. Creation of genetically modified organisms through biotechnology was sidelined due to lack of protection as patents laws of India were stringent towards them thus it affected its growth. The patents were granted only to very few categories of such organisms such as plants and parts of the plants under Protection of Plant Varieties and Farmers' Rights Act, 2001.Through the recent judgement; it has laid down a permissive way to conduct biotech research in India. The judgement provides for the patents to all organisms including microorganisms. In India, the improvement and protection of genetically modified organisms are governed under the department of biotechnology, regulated by the Ministry of Science and Technology, Government of India. Under Biosafety Research programme main emphasis is given to facilitate the implementation of biosafety procedures, rules and guidelines under Environment (Protection) Act 1986 and Rules 1989 to ensure safety from the use of Genetically Modified Organisms (GMOs) and products thereof in research and application to the users as well as to the environment.[20] Genetically modified organisms have many benefits in various fields where it has been used.

- Food agriculture- Genetically modified organisms or GM crops in the food agriculture have always been on the heated topic since its development. On one hand, the usage of these crops has benefits for the farmers as well as consumers, but on the other hand,

[18] Ciipharmain, 'CII Pharma- History/Introduction' (*Ciipharmain*, 1st January 1992) <http://ciipharma.in/history-introduction.php> accessed 3 September 2019

[19] Vipin Mathur "Patenting of Pharmaceuticals: AnIndian Perspective", Int. J. Drug Dev. & Res., 11 July 2012, <http://www.ijddr.in/drug-development/patenting-of-pharmaceuticals-an-indian-perspective.php?aid=4994> accessed 7 August 2019

[20] Make in India, 'Biotechnology-Make in India' (*Make in India*, September 2014) <http://www.makeinindia.com/sector/biotechnology> accessed 24 September 2019

increase in the use of such crops affects the human health and environment. Human health issues with respect to genetically modified organisms is in two folds: firstly, direct source which is through GM plant , animal or fish , and secondly indirectly source, which were prominent form of livestock feed to animals and food processing that has commercial backing. Environmental issues are where the transfer of GM matter into non-GM matter may arise to genetic abnormalities like mutation. The regulation of the same was a huge burden on the policy makers across the world. The FAO report dated 18th March 2003 said that *"the presence of GM products has affected trade, both in commercial transactions and in food aid deliveries. Segregated markets are developing for non-GM products to accommodate consumer preferences, with some countries focusing on supplying the markets for non-GM commodities and some major importers sourcing part of their products in countries known to be free of GM varieties"*. At international spectrum, Cartagena Protocol on Biosafety to the Convention on Biological Diversity was adopted in 2000-01 and enforced in the year 2003 to which 103 countries are signatories including India. It is the first among the international framework on Genetically Modified organisms. This agreement opens an FAO Biotechnology Forum where the outcome was to form The State of Food and Agriculture (SOFA) 2003, an important publication of the FAO that deals with world agriculture. The SOFA 2003 was entitled as "Agricultural biotechnologies: Meeting the needs of the poor?" The following publication specified in Section 2 provides a brief overview of the current status regarding GMOs in food and agriculture. In Section 3 the areas that might be regulated are covered while Section 4 considers some key factors concerning regulation of GMOs. Section 5 lists some specific questions that should be addressed in the conference.[21] The forum had opened doors for conference where the discussions concerning biotechnology in food and agriculture in developing countries.

India had to fight a long battle backing Bt Brinjal, a GM Crop that was developed by Mahyco using a fusion/ hybrid Bt toxin gene (from Monsanto) which produces a hybrid Cry1Ac / Cry1Ab protein. As per the company, this gene was 99.4% similar with

[21] Food and Agriculture Organization of the United Nations, *"Regulating GMOs in developing and transition countries"*, 28 April 2003 < http://www.fao.org/biotech/C9doc.htm> accessed 10 July 2019

Bacillus thuringiensis kurstaki.[22] The gene was derived from cauliflower mosaic virus promoter. This gene was resistant to BFSB, lepidopteran pest, i.e., a moth. When this gene is inserted into plant, thus produces Bt toxin, which destroy the pest at its larvae stage. The main contention of the environmentalists, civil societies, public at large against cultivation of Bt brinjal was of health concerns. There were allergic reactions and immunological deficiencies in the gut region of the humans. Mahyco conducted Multi-location Research Trials (MLRTs) in various locations across the country. They violated biosafety guidelines provided by the GEAC like not informing neighboring farmers about the trials and allowing the family of the farmer in question to consume and sell the Bt brinjal.[23] The various concerns arose are Bt toxin, inadequacy in the summary data and testing provided by the company to the GEAC for sought permission to conduct large-scale trials. In 2006, Ms Aruna Rodrigues and others filed a Public Interest Litigation in the Supreme Court with respect to the 10- year moratorium for the Bt Brinjal. On 22nd September 2006, the Supreme Court passed an interim injunction by directing GEAC for stoppage of the new approvals for fresh trials of any GM crops. But in 2008, this injunction was lapsed in spite of the recommendations by Dr. M S Swaninathan, who was appointed by the committee on the directions of the Court. Later in 2009, GEAC approved for the LSTs of the Bt Brinjal, eventually led to the outrage amongst the public on the ban of Bt Brinjal. Due to the public decision and national interest, state governments step forward to look upon this matter. Orissa agriculture ministry was the first to ban Bt Brinjal by reasoning that it does no good to small farmers and protection of biological diversity and it was followed by Chhattisgarh and Kerala. In February 2010, after hearing the people consultations across India, Mr.Shri Jairam Ramesh, the then Minister of Environment & Forests, on 9 February 2010, announced his decision to declare a moratorium on Bt brinjal, which he stated as "It is my duty to adopt a cautious, precautionary principle-based approach and impose a moratorium on the release of Bt

[22] GEAC, Expert Committee (EC-II). (2009, October). Report of the Expert Committee (EC-II) on Bt Brinjal Event EE-1. MoEF (Ministry of Environment and Forests). New Delhi. India. < http://moef.nic.in/downloads/public-information/Report%20on%20Bt%20brinjal.pdf> accessed 5 September 2019

[23] Centre for Sustainable Agriculture (2006, March 3). Field Trials of [Mahyco's] Bt Rice and Bt Brinjal in Farmers' Fields in Andhra Pradesh- A CSA report from the field <http://www.global-sisterhood-network.org/content/view/782/76/).> accessed 22 September 2019

brinjal till such time independent scientific studies establish, to the satisfaction of both the public and professionals, the safety of the product from the point of view of its long-term impact on human health and environment, including the rich genetic wealth existing in brinjal in our country."[24] Hence, this is how the fate of the Bt Brinjal on Indian soil was.

The National Library of Medicine defines about Genetically Modified Organisms which are meant to make a plant more resistant towards pests drought and diseases. At Least 90% of soy, cotton, canola, cane and sugar in the United States are pest resistance created through genetic engineering. According to the World Trade Organization, the most incorporated gene used for the plants in this process is *Bacillus thuringiensis* (BT) genetics, a bacterium that produces proteins that repel insects. The safety of Genetically Modified organisms was always in question. The Centre for Food Safety termed genetically modified organisms to be "one of the greatest and most intractable environmental challenges of the 21st century." Institute for Responsible Technology has coined genetically modified food to have link with allergic reactions with toxicity. According to the Non-GMO Project, most developed countries do not consider GMO as safe. In 2012, American Association for the Advancement of Science (AAAS) stated that the use of biotechnology in food products is more emotional issues than factual and said that "crop improvement through molecular techniques of biotechnology is safe". The reference by the AAAS, "The World Health Organization, the American Medical Association, the U.S.National Academy of Sciences, the British Royal Society, and every other respected organization that has examined the evidence has come to the same conclusion: Consuming foods containing ingredients derived from GM (genetically modified) crops is no riskier than consuming the same foods containing ingredients from crop plants modified by conventional plant improvement techniques."[25]

- Pharmaceutical Industry-As the process of the creation of Genetically Modified microorganisms was largely in food industry and followed by the pharmaceutical

[24] MoEF (Ministry of Environment and Forests). (2010, February 9). Decision on commercialization of Bt brinjal. MoEF. New Delhi. India < http://moef.nic.in/downloads/public-information/ minister_REPORT. > accessed 8 June 2019

[25] Marc Lallanilla, 'What Are GMOs and GM Foods?' (*LiveScience*, 8 July 2019) <https://www.livescience.com/40895-gmo-facts.html> accessed 25 September 2019

industry. Various organisms are engineered in order to be a factory for the production of drug product. Most used organism is a bacterium, because it is easiest in the multiplicity and scale-up for production. This field requires uniqueness and human intervention to create drugs or medicines that holds resistance towards any kind of pathogens or diseases that are omnipresent. Many pharmaceutical drugs have 3D structures that boost their efficiency and this can only be possible through introduction of animal cells that has a unique feature to produce such structures. Hence, the genetically animals were serving the purpose of 'bioreactor' which could produces such drugs at an industrial scale. The first drug produced by GMO animals, antithrombin III from the milk of transgenic goats, prevents the formation of small blood clots that could break loose and plug other vessels. The first bacteria produced drug, Humulin (human insulin) from Eli Lilly has been used by millions if not billions since 1982.[26] The patents to life forms and international campaign on the right to drugs for the AIDS patients have violated the rules provided by the Trade Related Aspects of Intellectual Property Rights (TRIPs) which was discussed at the Fourth WTO Ministerial Meeting in Doha in November 2001 where it was held that developing countries the right to override TRIPS rules where they are convinced this needs to be done to protect public health. This would be under the emphasis of human rights overriding a property right.[27] There are two procedures where biotechnology involved in biopharmaceuticals in the form of plants. One being modification of plants so that they can produce vaccines that make a plant resistant of the external conditions like drought, pests or anything else. The other being where the modified plants produce substances that can be extracted by the harvested plants and eventually processed into refined compounds. The advantages of having edible vaccines are like injected vaccines are too expensive; need of trained staff for its proper care and maintenance which creates a difficult in developing countries. The use of needles causes severe infections. There are various crops/ animals that are experimented to impact the disease resistance or help build human health. At the Cornell University, tomatoes are modified to produce vaccine against Norwalk virus, that are responsible for the severe diarrhea. The studies on mice

[26] Xiuchun Tian, 'Pharmaceutical use of GMOs' (*Uconnedu*) <https://gmo.uconn.edu/topics/pharmaceutical-use-of-gmos/> accessed 27 June 2019

[27] Jagjit Kaur plahe and Chris Nyland, 'The WTO and Patenting of Life Forms: Policy Options for Developing Countries' [2003] 24(1) Third World Quarterly 29-45

show an increased immune response. The genetically modified bananas have produced vaccine against hepatitis. GM potatoes shown to be resistant against rotavirus and the bacterium *E. coli* that causes diarrhea. Genetically modified mosquitoes are preventives for the parasitic diseases that block the entry of malaria parasite, Plasmodium, into the mosquito's gut. In European Union, when there was a debate on labelling of Genetically Modified products arose in the 1990s, many consumer groups and health federations disapproved for the consumption of Genetically Modified products. However, despite this, in Europe, including US Food and Drug Administration has declared that consumption of Genetically Modified products is safer even in cases where Genetically Modified products contain genetic material that derived from very distantly organisms. Likewise U.S and European Union, many countries such as Canada, China, Argentina and Australia had openly made the policies for the regulation of Genetically Modified organisms.[28]

4. CONCLUSION

Genetically modified organisms has built a negative image in the minds of the public because of its alter and deviant behaviour from nature. The use of chemicals and artificial products like pesticides and certain pest controlling substances in turn harmful to humans, thus these organisms are alternatives to such chemicals. India, being a signatory to the TRIPs agreement has incompletely formulated its patent laws by not including microorganisms and microbiological process with respect to Section 3(k) of the Act. Hence, this paper has explained the importance of Genetically Modified Organisms in India. The paper has provided evidence based on the theories, doctrines and conventions to provide patents for such organisms. In recent judgement, Indian courts have positively reacted towards genetically modified organisms. Such organisms do follow the criteria recommended by the law-makers. The Indian climate is getting worse day by day, where there are heavy rains in places with moderate humidity and on the other hand droughts are increasing. Hence, to curb this issue, genetically modified products in Indian research is essential to ensure the food and nutrition security in India.[29]

[28] Judith L Fridovich-Keil and Julia M Diaz, 'Genetically modified organism' (*Encyclopedia Britannica*, 7 July 2019) <https://www.britannica.com/science/genetically-modified-organism> accessed 25 September 2019

[29] S Datta and others, 'India needs genetic modification technology in agriculture ' [2019] 117(3) CURRENT SCIENCE 390-394