



Genetically Modified Plants: The IP and Regulatory Concerns in India

Malathi Lakshmikumar

Abstract

The status of patent protection for genetically modified plants is presently uncertain in India and is a debate rife with economic and ethical considerations. The need for consistent public policy and robust frameworks for regulatory control poses significant challenges for the introduction of genetically engineered/modified crop plants in India. This is especially vital considering India's desire to foster an innovation-based economy. The research questions of this chapter include the following: How is the insertion of different traits, such as insect resistance in plants by methods such as transformation different from introgression/hybridization? Can genetic modification of plants by methods such as transformation be termed as "an essentially biological process"? If not, how can the said process be classified for the purpose of Section 3(j) of the Indian Patents Act, 1970?

Keywords

rDNA technology · Genetically modified plants · Transformation · Plant variety · Patents

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M. Lakshmikumar (✉)
Lakshmikumar & Sridharan, New Delhi, India
e-mail: malathi.l@lakshmisri.com

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K.-C. Liu, U. S. Racherla (eds.), *Innovation, Economic Development, and Intellectual Property in India and China*, ARCIALA Series on Intellectual Assets and Law in Asia, https://doi.org/10.1007/978-981-13-8102-7_16

1 Introduction

Although the diaspora of plant variation and biodiversity has been enriched by natural processes since time unknown, it was back in the mid-1960s that the first new high-yielding varieties of wheat were developed by Dr. Norman Borlaug of Mexico, followed by adaptation of this technology world over. It was in 1966, spearheaded by Dr. M. S. Swaminathan, often addressed as the “Father of Indian Green Revolution,” that India introduced and further developed the high-yielding varieties of wheat under the High-Yielding Varieties Program (HYVP). India started as a country largely based on agriculture following its independence in 1947, and even today, about 55% of its population makes its living on farming, either directly or indirectly.¹ Adoption of the HYVP in India overcame the life-threatening food crisis faced by Indians in the 1960s. With the rise in agricultural productivity, the “Green Revolution” made the Indian economy, self-sustainable. As India enters the new millennium, with increasing costs of living accompanied by increasing population and widening gaps in terms of access to resources, there has arisen a need and demand to revitalize Indian agriculture by “Gene Revolution.” Two technologies are at the forefront of shaping the next revolution in agriculture and plant-related technologies in India. One of them pertains to the recombinant DNA technology (rDNA) that was pioneered by Herbert Boyer and Stanley Cohen, who kick-started the field of biotechnology with the fundamental phenomenon of transferring genetic material from one organism and artificially introducing it into the genome of another organism, where the genetic material so transferred gets replicated and expressed by that other organism. The rDNA technology-based genetically modified organisms (GMOs) differ from traditional methods in nature and prior conventional plant breeding programs in that they do not involve overall mixing of genome between the plant species. Rather, GMOs involve very selective and precise movement of DNA fragment from one organism carrying a desired stretch/stretchches of genetic material that can confer desired traits to the receiving organism by employing tissue culture techniques. The rDNA technology has been extensively recognized as providing valuable tools, in agriculture and plant-related biotechnology, and products using these same tools have been extensively employed to produce GMOs and genetically modified (GM) plants (Commission 2010). Another path-breaking technique that has the potential to change the agriculture and biotechnology fields, both economically and technologically is clustered regularly interspaced short palindromic repeats (CRISPR) technology, which is a characteristic of the bacterial defense system and has been adapted and modified to become the foundation for CRISPR-Cas9 genome editing technology² along with other alternate systems. Using such technologies can bring about a change in the technological and economic landscape of Indian agriculture (Lakshmikumaran and Malhotra 2018).

¹<https://www.weforum.org/agenda/2017/10/more-than-55-of-indians-make-a-living-from-farming-heres-how-we-can-double-their-income/>

²The new frontier of genome engineering with CRISPR-Cas9, Jennifer A. Doudna, Emmanuelle Charpentier,

SCIENCE, Vol. 346, Issue 6213, 1258096, November 28, 2014

Much like the green revolution of the 1960s, which was a landmark adoption of innovative yet incentivized technology that enabled India to achieve a food surplus and feed its masses, the adoption of technologies such as rDNA technology and GM plants – Gene Revolution – may have a big impact on India's agricultural needs (Herring 2008).

The first genetically modified crop to be commercialized in India was *Bt* cotton, which is a nonfood plant product. The *Bt* cotton plant has been created by incorporating endotoxin-producing *Cry* genes (*CryIAc* and *Cry2Ab*) from the bacteria *Bacillus thuringiensis* into the genome of the cotton plant. India first approved the Bollgard® technology directed to *CryIAc* and then approved Bollgard II® (Bg II) technology directed to two genes, *CryIAc* and *Cry2Ab*. Both these genes have been identified in *Bacillus thuringiensis* and inserted into plants, such as cotton using recombinant DNA technology. The incorporation of these genes into the cotton genome by using synthetic recombinant DNA constructs enables the plant to produce δ -endotoxins, hence making it resistant to infestation from pests like bollworm. This reduced the need for foliar insecticides that targeted these pests and reduced outbreaks of secondary pests, thereby improving crop quality and yield and increasing the economic value of the crop. By 2011 over 95% of cotton in India was produced by using Bg II technology (Herring 2014). With the incorporation of this technology, India has evolved from an importer to an exporter of cotton, and at present, India's average yield is around 500 kg of lint per hectare. The monthly report released on March 9, 2018, by the Cotton Association of India (CAI) gauges the cotton production in India for the season 2017–2018 (October–September) to be around 362 lakh bales (one bale = 170 kg cotton) and exports to be between 65 and 70 lakh bales (Vyavhare and Kerns 2017).³ The United States Department of Agriculture (USDA) corroborates India as the largest producer of cotton in the world with 365 lakh bales in the year 2017–2018.⁴ However, due to demand and consumption by local mills, India stands as the fourth largest exporter of cotton, behind the USA, Australia, and Brazil (James n.d.). It took India several years to grant regulatory approval of *Bt* cotton for commercialization. While *Bt* cotton has been successfully grown since, recent developments mar this success, posing challenges to the future of such crops/plants in India (Jamiepighin 2003). However, as it stands, there are no food crops approved for use in India using GM technology. The Indian regulatory authority, the Genetic Engineering Approval Committee (GEAC), had approved *Bt* brinjal (eggplant) as being biosafe; however, its commercialization was not approved by the Ministry of Environment, Forest and Climate Change more on the basis of the precautionary principle.

In contrast, Bangladesh has approved four varieties of *Bt* brinjal for cultivation, based on India's biosafety analysis and data. Bangladesh's approved varieties have been advanced on the backbone technology developed in India for *Bt* brinjal, where

³ <http://www.smetimes.in/smetimes/news/indian-economy-news/2018/Mar/30/export-cotton37951.html>

⁴ <http://www.yarnsandfibers.com/news/textile-news/foreign-buyers-are-interested-sourcing-cotton-india#.W3K3iGwnY2w>

the brinjal plant has been transformed with a synthetic gene encoding the toxin protein *CryIAc*, which makes it resistant to pests and reduces the dependence on pesticides. Brinjal is second only to potato in terms of consumption in India; hence any decision on this issue of not accepting GM brinjal has far-reaching implications in the food crop industry.

In 2017, the GEAC had given approval to GM mustard, a genetically modified high-yielding variety developed in India by Delhi University's Centre for Genetic Manipulation of Crop Plants (CGMCP), called DMH 11 (Dhara Mustard Hybrid) for commercial release. DMH 11 carries three genes that have been isolated and transformed into mustard plants, including *bar*, *barnase*, and *barstar* genes. While in May 2018, the GEAC called for more tests, including field demonstrations of GM mustard, its commercial release has been put on hold by the Environment Ministry.

The need for consistent public policy and robust frameworks for regulatory control poses significant challenges for the introduction of genetically engineered crops in India. The intellectual property (IP) framework is prescriptive in its scope, and the recent judgments⁵ preclude protection for technologies for the development of genetically engineered plants under the existing provisions of the Patents Act, 1970 (the "Patents Act"). This would perhaps serve to disincentivize players who have developed proprietary technologies from bringing their latest inventions for use by farmers in India.

This chapter intends to, firstly, simplify and help the readers understand the science and technology involved in developing genetically modified plants and, having provided the readers with this background, move forward to discuss the eligibility of such genetically modified plants as patentable subject matter in light of relevant national, i.e., Indian, as well as international legal provisions. Thereafter, the chapter discusses the recent case of *Nuziveedu Seeds Ltd. & Ors. v. Monsanto Technology LLC & Ors*⁶ which is especially relevant in understanding the current legal position in India regarding patentability of genetically modified plants. The chapter also discusses the statutory regime available for protection of plant varieties in India and ends by drawing a distinction between intellectual property rights guaranteed under the Patents Act versus the plant variety protection regime in the context of genetically modified plants.

2 Transgenic Plants/GM Plants: Understanding the Technology

Understanding the science is critical for understanding the frameworks for genetically modified/transgenic plants. A transgenic plant is a GMO and indicates that genes from either an unrelated plant or a microbe have been transferred artificially, using rDNA technology into a plant of interest.

⁵ *Nuziveedu Seeds Ltd. & Ors. v. Monsanto Technology LLC & Ors.*, FAO (OS) (COMM) 86/2017, C.M. APPL. 14331, 14335, 15669, 17064/2017

Monsanto Technology LLC & Ors. v. Nuziveedu Seeds Ltd. & Ors., FAO (OS) (COMM) 76/2017, CAV. 328/2017, C.M. APPL. 133348-13352/2017

⁶ *Ibid.*

Selecting for plants during cultivation is not a new phenomenon. For many years plant breeding entailed the selection of the elite plants for higher yields and tolerance to biotic and abiotic stresses. Earlier, variation occurred through induced mutation or hybridization where two or more plants were crossed. Selection occurred through breeding process, and only the seeds with the best traits were selected. Even before the creation of a transgenic, the alteration of crops to improve their production had been performed through selection for thousands of years, becoming a science onto itself in recent centuries. However, to manipulate plants through selection takes many generations and does not always work due to randomness in the natural selection process. By using transgenic technology, which involves the use of genetic engineering techniques, one can control the process better and produce crops that are resistant to biotic and abiotic stresses. With recent developments in genetic engineering techniques, scientists can now identify, manipulate, and exploit genes responsible for specific traits.

Creating a transgenic plant involves modifying the plant genome for expressing the desired trait(s). The steps involved in developing a transgenic plant as illustrated in Fig. 1 include:

1. Step one. Synthesizing a DNA construct for a gene of interest under the control of a promoter (regulatory element) to express the gene and thus leading to the production of a desired protein in a host organism (recombinant host cell). In addition, the DNA construct could have DNA for selection markers for antibiotic or herbicide resistance, transit peptides that can localize its expression into organelles, and other transcription factors that function like an on/off switch.
2. Step two. Transformation of plant cells by insertion of the recombinant DNA construct using genetic engineering methods. However, this technique may lead

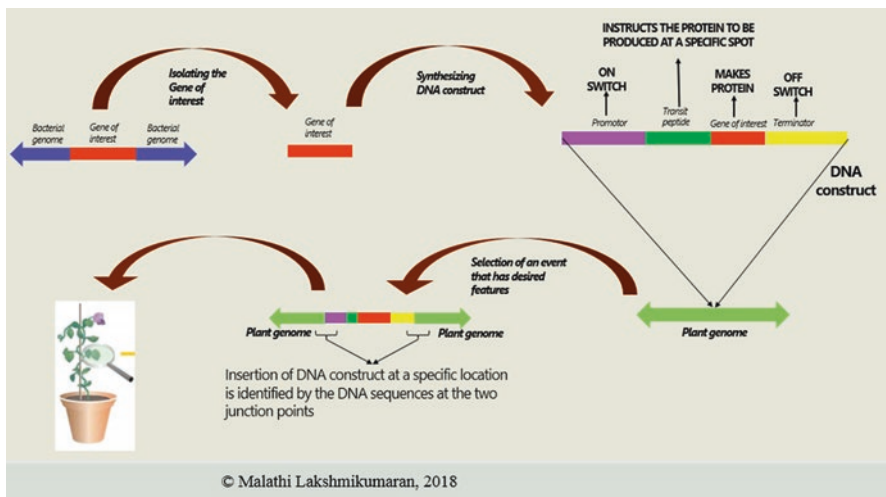


Fig. 1 Creating a transgenic plant involves modifying the plant genome for expressing the desired trait(s)

to the insertion of the gene of interest at any random location in the chromosome of the plant, leading to the production of several transgenic plants. It is possible that the transformation method can result in insertion of one copy to several copies of the recombinant DNA construct carrying the gene of interest.

3. Step three. It is possible that not all the insertions from the aforementioned transformation lead to the expression of the gene of interest. Therefore, the next step is to screen and select for the desired transformants expressing the gene of interest. Screening of these transformants involves identification of the most advantageous insertions, namely, the elite transformants, which are named as “events.” In other words, when the gene of interest is located at different locations in the plant genome, each constitutes a different “event.” Thus, this step entails selecting one or more elite event(s) with the desired expression of the gene of interest in the transgenic plant.

There are applications for patents that comprise of the first two steps as described above (e.g., Indian patent no. 214436, where claims 1–24 relate to the transformation process or step 2 and claims 25–27 relate to recombinant DNA construct carrying the modified bacterial gene of interest or step 1). There are also patent applications that pertain to specific events and their screening such as Indian patent no. 232681, for *Bt* gene associated with Bg II (more specifically the cotton event is named as MON 15985).

Finally, the elite transgenic event obtained from the transformation process is used to transfer the desired trait(s) (e.g., insect resistance) to different varieties of a plant. This can be done by using conventional crossing techniques like backcrossing, hybridization, etc. to produce new plant varieties expressing the desired gene of interest.

Usually, companies or research entities develop proprietary technologies for making the gene construct, transforming plant cells, and screening for the elite “events.” These events are licensed out as donor seeds in the exchange for licensing fees and royalties for the use of the GM technology in plants. The licensees (commercial seed growers/breeders) use the donor seeds for introgression of the desirable genetic trait developed by the licensor into their own specific varieties by backcrossing breeding.

3 Genetically Modified Plants: Patent Protection

The status of patent protection for GM plants is presently uncertain in India and is a debate rife with economic and ethical considerations. It is relevant to note the legislative intent of the Patents Act and follow the history of its revisions to become TRIPS (the Agreement on Trade-Related Aspects of Intellectual Property Rights) compliant to understand the issues surrounding the patentability of plant-related inventions in a broader context (Declaration on Patent Protection – Regulatory Sovereignty under TRIPS 2014).

3.1 Plants or Animals and Conventional Methods of Production and Propagation of Plants and Animals Are An Unpatentable Subject Matter

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

Article 27.3 of TRIPS states that "[m]embers may also exclude from patentability..."

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes."

Article 28.1(b) of TRIPS states that for process patents, the rights granted include the right "to prevent third parties not having the owner's consent ...from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process."

Section 48(b) of the Patents Act states that "where the subject matter of the patent is a process, the exclusive right to prevent third parties, who do not have his consent, from the act of using that process, and from the act of using, offering for sale, selling or importing for those purposes the product obtained directly by that process in India."

A combined reading of Article 27.3 with Article 27.1 of TRIPS would render biotechnological inventions in agriculture patentable and not excluded subject matter, provided they would otherwise qualify to be patentable. However, it is contended that plants, including GM plants are excluded under Section 3 of the Patents Act and hence constitute non-patentable subject matter.

The Ayyangar Committee Report of 1959, based on which the Patents Act was enacted, expressly clarified that the prohibition under Section 3(h)⁷ of the Patents Act, excluding "methods of agriculture or horticulture" from patentability, was intended to apply to "inventions in the field of plant propagation by asexual methods."⁸ Presently, the Indian Patent Office tends to consider every conventional practice that is carried out in an open field as a method of agriculture. Consequently, any claim in a patent application that refers to terms like germinate, seeds, hybrid, variety, etc. is objected to under Section 3(h) by the Indian Patent Office and deemed to be excluded from patentability.

Prior to being amended in 2002, Section 3(i) of the Patents Act read as:

"(i) any process for the medicinal, surgical, curative, prophylactic or other treatment of human beings or any process for similar treatment of animals or plants to render them free of disease or to increase their economic value or that of their products;"

⁷Section 3(h) of the Patents Act reads as: "3. What are not inventions.—The following are not inventions within the meaning of this Act,—(h) a method of agriculture or horticulture;...."

⁸Paragraph 331 of the Ayyangar Committee Report of 1959

Section 3(i) of the Patents Act was amended in 2002, and the words “or plants” were omitted by the Patents (Amendment) Act, 2002. Thus, the treatment of plants to render it free of disease or to increase its economic value no longer falls under the scope of the existing Section 3(i)⁹ nor under any of the other exclusions specified by Section 3 of the Patents Act.

Further, Section 3(c)¹⁰ of the Patents Act excludes the “discovery” of naturally occurring living things or nonliving substances from patentable subject matter. This means inventions such as isolated DNA or protein molecules are non-patentable subject matter. On the other hand, recombinant DNA constructs, modified DNA, and modified protein molecules developed in the laboratory and involving substantial human intervention qualify as patentable subject matter as these cannot be considered as discovery.

Furthermore, Section 3(j)¹¹ of the Patents Act excludes “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” from patentable subject matter. The Indian position on plants or animals and on conventional methods of production and propagation of plants and animals is that they do not fall under patentable subject matter.

3.2 Differing Interpretations of What Is Covered Under “Any Part of a Plant” of Section 3(j) of the Patents Act: To Consider an Artificial DNA Construct as a Part of a Plant Is Scientifically Incorrect

The gray area lies in the interpretation and implication of what is covered under “any part of a plant” – is it limited to organs such as leaves, roots, stems, and flowers, or can this term “any part thereof” extend to plant cells as well? The Indian Patent Office’s position at present does not allow claims directed to eukaryotic cells that include plant cells and animal cells as these are objected to under Section 3(j) of the Patents Act. The Indian Patent Office considers cell as a part of a plant even though it uses transgenic technology to produce transformed, recombinant plant cells. In contrast, all microbial cells (prokaryotic) are patentable under Section 3(j)

⁹Section 3(i) of the Patents Act reads as: “3. What are not inventions.—The following are not inventions within the meaning of this Act,—(i) 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 to render them free of disease or to increase their economic value or that of their products.....”

¹⁰Section 3(c) of the Patents Act reads as: “3. What are not inventions.—The following are not inventions within the meaning of this Act,—....(c) the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature;.....”

¹¹Section 3(j) of the Patents Act reads as: “3. What are not inventions.—The following are not inventions within the meaning of this Act,—....(j) 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;.....”

of the Patents Act, as long as these do not fall under discovery and meet the criteria of novelty and inventive step.

While many patent applications for method of transforming plants have been allowed by the Indian Patent Office, interestingly, the Indian Patent Office has also found Section 3(j) of the Patents Act to be applicable in case of transgenic plants in the case of *Monsanto Technology LLC. v. Controller General of Patents*.¹² In this case, the Controller of Patents refused Monsanto's patent application claiming an invention titled "A method for producing a transgenic plant with increased heat tolerance" as non-patentable subject matter falling under the scope of Section 3(j) of the Patents Act, among others. Monsanto challenged the Controller's order before the Intellectual Property Appellate Board (IPAB). The IPAB accepted Monsanto's argument that since the production of the transgenic variety being claimed involved substantial human intervention, it could not be considered as an "essentially biological process" and, thus, was not hit by Section 3(j) of the Patents Act. The IPAB held as follows:

"29.The plant is modified by the introduction of known recombinant DNA into its genome, thereby causing the said predisposition. The specification also teaches how the known regeneration and screening technique can be used to screen the transformed plant with heat, salt or drought tolerance. The appellant has given up all claims relating to recombinant DNA, plant cell, progeny, plant, crop plant, propagule, seed etc. [claims 1-15] and also claims 17 [transgenic plant], 19 [Isolated protein] and 20 [a field crop].

30. Let us see amended Claim 1 [claim16 amended]. It relates to a method that requires several steps that together provide claimed solution. The method here is best considered as a series of individual steps. It is a method that includes an act of human intervention on a plant cell and producing in that plant cell some change. Therefore, the respondent erred in finding this method as essentially biological process and excluded under section 3(j). We set aside his findings to that extent."

Following the above interpretation of the IPAB, there have been many decisions by the Indian Patent Office, wherein the objection under Section 3(j) of the Patents Act has been set aside on account of the inventions having a substantial human intervention and tissue culture steps such that they no longer constituted essentially biological processes for the production or propagation of plants and animals, thereby allowing the patent grant. This has been especially true and applicable to method of transformation in plants involving recombinant DNA constructs. While the IPAB ultimately rejected Monsanto's application on grounds of lack of inventive step and non-patentability under Section 3(d),¹³ it set aside the Controller's order on the issue of non-patentability under Section 3(j) of the Patents Act.

¹²IPAB Order No. 146 of 2013 dated 5 July 2013

¹³Section 3(d) of the Patents Act reads: "(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. **Explanation.**—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy."

In a differing interpretation of Section 3(j) of the Patents Act, the Division Bench of the Delhi High Court in the case of *Nuziveedu v. Monsanto*¹⁴ *vide* judgment dated April 11, 2018 invalidated Monsanto's patent no. 214436, holding that the subject matter of the patent was non-patentable under Section 3(j) of the Patents Act.¹⁵ First, the judgment does not address the question of whether DNA should be considered as a part of a plant or not and is further unclear with regard to the interpretation and applicability of Section 3(j) of the Patents Act. This is especially relevant to an otherwise patentable subject matter concerning isolated, modified genes, i.e., modified DNA molecules, to create DNA constructs for transformation of plants.

Claims 25–27 of the Monsanto's impugned patent no. 214436 pertain to a DNA construct where the gene of interest encodes for *Bacillus thuringiensis* (*Bt.*) toxin. Claim 25 of the said patent is reproduced below:

"25. A nucleic acid sequence comprising a promoter operably linked to a first polynucleotide sequence encoding a plastid transit peptide, which is linked in frame to a second polynucleotide sequence encoding a Cry2Ab Bacillus thuringiensis δ -endotoxin protein, wherein expression of said nucleic acid sequence by a plant cell produces a fusion protein comprising an amino-terminal plastid transit peptide covalently linked to said δ -endotoxin protein, and wherein said fusion protein functions to localize said δ -endotoxin protein to a subcellular organelle or compartment.

Such a DNA construct comprising a promoter sequence, transit peptide, and a gene of interest expressing the *Cry2Ab* protein is a synthetic molecule called as recombinant DNA construct and considered a patentable product under the Patents Act in India. Such a DNA construct was never a part of a plant and further did not occur in nature. Therefore, the product claims for the recombinant DNA construct cannot be considered a plant or part thereof and thus should be excluded from falling under the purview of Section 3(j) of the Patents Act. This is the view taken by the Indian research institutes and the scientists' community.

The question to be asked is can and should DNA, proteins, RNA, cDNA, etc., which are chemical molecules, and although may be present in the plant cells, fall under the scope of the term "any part thereof" or the expression "parts of a plant"?

Recombinant DNA constructs cannot fall under Section 3(j) of the Patents Act, even if these constructs function, or express genes in plant species. Since, recombinant DNA technology used in the construction and synthesis of such recombinant DNA constructs has been singularly practiced in the laboratories requiring human intervention and manipulation, these cannot fall under Section 3(j) of the Patents Act. It is to be emphasized that "plant" under the meaning of Section 3(j) of the

¹⁴*Nuziveedu Seeds Ltd. & Ors. v. Monsanto Technology LLC & Ors.*, FAO (OS) (COMM) 86/2017, C.M. APPL. 14331, 14335, 15669, 17064/2017, *Monsanto Technology LLC & Ors. v. Nuziveedu Seeds Ltd. & Ors.*, FAO (OS) (COMM) 76/2017, CAV. 328/2017, C.M. APPL. 133348-13352/2017

¹⁵This judgment has been set aside by the Supreme Court *vide* judgment dated 08 January 2019 in C.A. Nos.4616 – 4617/2018, *Monsanto Technology LLC & Ors. v. Nuziveedu Seeds Ltd. & Ors.*

Patents Act is a “living organism,” while “DNA” or a gene or a DNA construct are inanimate molecules, not a living entity, which merely code for production of a protein in a living organism. Hence, it is erroneous to focus on the “application” or “use” of such an inanimate product, when used in a plant to conclude it as a part of a plant. Thus, to consider an artificial DNA construct as a part of a plant is scientifically incorrect. In fact, Section 3(j) of the Patents Act nowhere mentions “use” of a product as a basis for non-patentability of inventions; it only covers product (plant or parts thereof) or process (essentially biological process). DNA constructs inserted into a plant using recombinant DNA technology cannot be interpreted as falling under the definition of plants or parts thereof.

3.3 Transformation Is Neither a Conventional Breeding Method nor an “Essentially Biological Process” for Production of Plants

However, in contrast to the aforementioned IPAB order for the process of generating transgenic plants by transformation, in *Nuziveedu v. Monsanto*,¹⁶ the Delhi High Court inferred that claims 1–24 of the patent no. 214436 that are directed to a method of transformation of plants fall under Section 3(j) of the Patents Act. Claim 1 of the said patent is reproduced below:

“1. A method for producing a transgenic plant comprising incorporating into its genome a nucleic acid sequence comprising a plant functional promoter sequence operably linked to a first polynucleotide sequence encoding a plastid transit peptide, which is linked in frame to a second polynucleotide sequence encoding a Cry2Ab Bacillus thuringiensis δ -endotoxin protein, wherein said plastid transit peptide functions to localize said δ -endotoxin protein to a subcellular organelle or compartment.”

Transformation is the method by which a recombinant DNA construct is inserted into a plant system, which has been equated to a microbiological process and, thus, is patentable. Transformation creates hundreds or thousands of possibilities, i.e., gene insertion can take place at any location in the plant genome, and there can be multiple insertions as well. Thousands of plants having the DNA construct at various locations in the plant genome can be produced by transformation methods. The recombinant DNA constructs, such as the construct of claims 25–27 of the patent no. 214436, has a gene of interest encoding for *Cry2Ab* protein. Similarly, any gene of interest can be introduced into a plant species. Importantly, the gene of interest expressed by such a recombinant DNA construct (as claimed in patent no. 214436) is a protein of bacterial origin, which cannot be considered as a part of a plant. This process is carried out in a laboratory under strictly controlled tissue culture

¹⁶This judgment has been set aside by the Supreme Court *vide* judgment dated 08 January 2019 in C.A. Nos.4616 – 4617/2018, *Monsanto Technology LLC & Ors. v. Nuziveedu Seeds Ltd. & Ors.*

conditions and thus, under no stretch of imagination, can be said to be either a “conventional method of breeding” or an “essentially biological process” for the production of plants.

In fact, it is to be considered as a microbiological process, where the transformation occurs, which is an insertion of a recombinant, synthetic DNA construct into a plant species mediated by *Agrobacterium tumefaciens*, microprojectile bombardment, etc., and cannot be equated to an essentially biological process. The Delhi High Court has overlooked the claims directed to the process of transformation of plants (using the recombinant DNA construct) to express the *Bt* toxin and rather focused on post-invention, conventional breeding methods for introgression of desired traits into plants and not on the claimed transformation method, which does not involve any conventional method of breeding. Transformation can neither be considered a conventional breeding method nor an “essentially biological process” for the production of plants as it is carried out in the laboratory, involving tissue culture techniques in the laboratory which are results of human ingenuity, and, therefore, cannot fall under Section 3(j) of the Patents Act.

It must be understood that transformation is in no way even similar, to any conventional means of breeding such as hybridization or introgression. While transformation is not considered as an “essentially biological process” (since it is performed using DNA constructs in the laboratory), hybridization/introgression, on the other hand, falls under essentially biological process involving crossing, backcrossing, selfing, etc. of plant varieties to transfer the genes or genetic material conferring the traits from one plant to another; and these are carried out in the fields or greenhouses and constitute conventional methods of breeding.

The European Enlarged Board of Appeals, in its decision of *Plant Bioscience Limited v. Syngenta Participations AG Groupe Limagrain Holding*¹⁷ while expanding the definition of an “essentially biological process,” has held that:

1. *A non-microbiological process for the production of plants which contains or consists of the steps of sexually crossing the whole genomes of plants and of subsequently selecting plants is in principle excluded from patentability as being “essentially biological” within the meaning of Article 53(b) EPC.*¹⁸

2. *Such a process does not escape the exclusion of Article 53(b) EPC merely because it contains, as a further step or as part of any of the steps of crossing and selection, a step of a technical nature which serves to enable or assist the performance of the steps of sexually crossing the whole genomes of plants or of subsequently selecting plants.*

3. *If, however, such a process contains within the steps of sexually crossing and selecting an additional step of a technical nature, which step by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced, so that the introduction or*

¹⁷*Plant Bioscience Limited v. Syngenta Participations AG Groupe Limagrain Holding*, G2/07 dated 9 December 2010, page 71

¹⁸Article 53(b) EPC reads as: “53. Exceptions to patentability – European patents shall not be granted in respect of: ... (b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof.”

modification of that trait is not the result of the mixing of the genes of the plants chosen for sexual crossing, then the process is not excluded from patentability under Article 53(b) EPC.

4. In the context of examining whether such a process is excluded from patentability as being “essentially biological” within the meaning of Article 53(b) EPC, it is not relevant whether a step of a technical nature is a new or known measure, whether it is trivial or a fundamental alteration of a known process, whether it does or could occur in nature or whether the essence of the invention lies in it.

Since, transformation has introduced a recombinant DNA construct conferring a trait in the genome of the plant species; and this introduction of the trait is not the result of the mixing of the genes of the plants, but rather a process carried out in the laboratory under strict supervision and with ample human interference; it is not an “essentially biological process” for production of plants and thus ought not to fall under the ambit of Section 3(j) of the Patents Act. The confusion arises due to the use of the terms, transformation and hybridization, but it is pertinent to distinguish them and to emphasize that the initial transformation process forms part of the patentable subject matter in India, which cannot be equated to an “essentially biological process” for the production of plants.

Further, in the case of *Plant Genetic Systems v Greenpeace*,¹⁹ the European Enlarged Board of Appeals has held that insertion of the relevant DNA sequence into the genome of a plant could not occur without human intervention, and consequently, this step is an important technical step which has a decisive impact on the desired final result. Such a process is not “essentially biological” by any definition and thus not excluded from patentability. Moreover, the first plant directly obtained by such a transformation process is to be considered as a product of a microbiological process. In contrast, the subsequent generations obtained using the first transformed plants by conventional breeding them to other plants to obtain subsequent transgenic plants would constitute an essentially biological process.

Claims 25–27 of the patent no. 214436 pertain to a recombinant synthetic DNA construct where the gene of interest encodes a bacterial protein, *Bt* toxin, while claims 1–24 pertain to a transformation method for insertion of the recombinant DNA construct into the plant species. Clearly, the said patent is directed at a method of transformation. Therefore, neither the product claimed in claims 25–27 can be considered as a plant or part thereof, nor can the transformation method of claims 1–24 be considered an “essentially biological process” under Section 3(j) of the Patents Act. Therefore, in our view, neither the product, nor the process claimed in the patent no. 214436 falls under the scope of Section 3(j) of the Patents Act.

¹⁹ *Plant Genetic Systems v Greenpeace*, T0356/93, dated 21 February 1995, paragraph 40.1

4 Genetically Modified Plants: Plant Variety Protection

4.1 Difference Between Patent Law and PPV&FR Act

4.1.1 Transformation Method Cannot Get Protection Under PPV&FR Act

The Protection of Plant Varieties and Farmers' Rights Act (PPV&FR Act), 2001, is a *sui generis* legislation formulated by India to fulfill its obligation under TRIPS²⁰ for providing effective intellectual property right protection for plant varieties. However, one is to note here that the PPV&FR Act awards protection to the commercial growers/breeders/seed companies for specific varieties in terms of Distinctness, Uniformity and Stability (DUS) testing to distinguish and identify a new, extant,²¹ essentially derived variety²² and farmer's variety.²³

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

- (i) *defined by the expression of the characteristics resulting from a given genotype of that plant grouping;*
- (ii) *distinguished from any other plant grouping by expression of at least one of the said characteristics; and*

²⁰Article 27.2 of the TRIPS Agreement reads as follows: "3. Members may also exclude from patentability: (a)diagnostic, therapeutic and surgical methods for the treatment of humans or animals;(b)plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. 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 4 years after the date of entry into force of the WTO Agreement."

²¹Section 2(j) of the PPV&FR Act defines "Extant Variety" as "a variety available in India which is— (i) notified under section 5 of the Seeds Act, 1966 (54 of 1966); or (ii) farmers' variety; or (iii) a variety about which there is common knowledge; or (iv) any other variety which is in public domain."

²²Section 2(i) of the PPV&FR Act states that an "Essentially Derived Variety" in respect of a variety (the initial variety) "shall be said to be essentially derived from such initial variety when it— (i) is predominantly derived from such initial variety, or from a variety that itself is predominantly derived from such initial variety, while retaining the expression of the essential characteristics that results from the genotype or combination of genotype of such initial variety; (ii) is clearly distinguishable from such initial variety; and (iii) conforms (except for the differences which result from the act of derivation) to such initial variety in the expression of the essential characteristics that result from the genotype or combination of genotype of such initial variety."

²³Section 2(l) of the PPV&FR Act defines a "Farmers' Variety" as "a variety which— (i) has been traditionally cultivated and evolved by the farmers in their fields; or (ii) is a wild relative or land race of a variety about which the farmers possess the common knowledge."

- (iii) *considered as a unit with regard to its suitability for being propagated, which remains unchanged after such propagation, and includes propagating material of such variety, extant variety, transgenic variety, farmers' variety and essentially derived variety.*"

Considering the aforesaid, a gene can never be equated to be a variety, wherein a trait is determined by the expression of one or more genes. Thus, a gene made of nucleic acids is a chemical compound within a plant which may confer a specific trait or characteristic to a plant but cannot be considered a variety under PPV&FR Act. Moreover, when a gene or DNA molecule is inserted into a plant species through the transformation method, such method cannot get protection under PPV&FR Act. Such methods can only be protected under the patent regime, since there is no provision of protecting a method of transforming a plant or regeneration of plant using tissue culture methods under PPV&FR Act.

It is further important to note that a trait for resistance to biotic and abiotic stress may be a distinct characteristic under the PPV&FR Act regime. However, the protection under this regime is for all the characteristics of a plant variety and not for a specific distinct trait which differentiates this variety from other closely related varieties. Therefore, genes, proteins, promoters, enhancers, and traits in plants cannot get specific protection under PPV&FR Act and need to be protected under the patent regime. Thus, a recombinant DNA construct, which is neither a plant or part thereof, nor a variety, can be protected under the patent regime and not under the PPV&FR Act regime.

4.1.2 PPV&FR Act Allows Breeders to Use Protected Varieties to Develop Newer Ones

Article 27.3(b) of the TRIPS Agreement gives the flexibility to member nations to exclude plants and animals from being patentable subject matter, provided that the members have an alternative provision for protecting plant varieties through a separate system such as the PPV&FR Act, or a combination thereof. In terms of the leeway provided under the Patents Act and PPV&FR Act in India, it is to be understood that the Patents Act only allows the use of a patented invention for merely "experimental use," while the PPV&FR Act allows breeders to use even protected varieties to develop newer varieties. The aforesaid exemption is described under Section 30²⁴ of the PPV&FR Act.

²⁴ Section 30 of the PPV&FR Act reads as: "30. Researcher's rights—Nothing contained in this Act shall prevent— (a) the use of any variety registered under this Act by any person using such variety for conducting experiment or research; or (b) the use of a variety by any person as an initial source of variety for the purpose of creating other varieties: Provided that the authorisation of the breeder of a registered variety is required where the repeated use of such variety as a parental line is necessary for commercial production of such other newly developed variety."

4.1.3 Benefit Sharing Under PPV&FR Act Offers No Benefits to IP Holders

Another difference between the PPV&FR Act and the Patents Act is the benefit sharing provisions under Section 26 of the PPV&FR Act.²⁵ But the system of benefit sharing, much like the limitation to “variety” under PPV&FR Act, is applicable only for varieties registered under the PPV&FR Act regime. Post registration of a variety, the authority invites claims of the public, and where it is established that the third party had played a role in contributing to the development of the registered variety, such third party is awarded the right to seek part of the benefits that a registered owner of a variety may derive. The overall scheme and object of PPV&FR Act suggests that the benefit sharing system has been created to benefit the farmers and communities who have helped conserve plant germplasm that may have contributed to the development of registered varieties.

To interpret the benefit sharing system as catering to IP holders will actually lead to an absurdity. This is because the benefit sharing system under Section 26 of PPV&FR Act only applies to registered varieties that are generated out of the research varieties that are in the true sense the varieties produced by the primary transformation event, also referred herein above as a microbiological process. Therefore, if a recombinant technology is used to develop subsequent transgenic varieties that are not ultimately registered under the PPV&FR Act, the benefit sharing system will not apply, and the IP holder would have no recourse for being rewarded for their valuable technology. This injustice would only become manifold

²⁵ Section 26 of the PPV&FR Act describes benefit sharing as: “Determination of benefit sharing by Authority — (1) On receipt of a copy of the certificate of registration under sub-section (8) of section 23 or subsection (2) of section 24, the Authority shall publish such contents of the certificate and invite claims of benefit sharing to the variety registered under such certificate in the manner as may be prescribed. (2) On invitation of the claims under sub-section (1), any person or group of persons or firm or governmental or non-governmental organisation shall submit its claim of benefit sharing to such variety in the prescribed form within such period, and accompanied with such fees, as may be prescribed: Provided that such claim shall only be submitted by any person or group of persons, if such person or every person constituting such group is a citizen of India; or firm or governmental or non-governmental organisation, if such firm or organisation is formed or established in India. (3) On receiving a claim under sub-section (2), the Authority shall send a copy of such claim to the breeder of the variety registered under such certificate and the breeder may, on receipt of such copy, submit his opposition to such claim within such period and in such manner as may be prescribed. (4) The Authority shall, after giving an opportunity of being heard to the parties, dispose of the claim received under subsection (2). While disposing of the claim under sub-section (4), the Authority shall explicitly indicate in its order the amount of the benefit sharing, if any, for which the claimant shall be entitled and shall take into consideration the following matters, namely the extent and nature of the use of genetic material of the claimant in the development of the variety relating to which the benefit sharing has been claimed; the commercial utility and demand in the market of the variety relating to which the benefit sharing has been claimed. (5) The amount of benefit sharing to a variety determined under this section shall be deposited by the breeder of such variety in the manner referred to in clause (a) of sub-section (1) of section 45 in the National Gene Fund. (6) The amount of benefit sharing determined under this section shall, on a reference made by the Authority in the prescribed manner, be recoverable as an arrear of land revenue by the District Magistrate within whose local limits of jurisdiction the breeder liable for such benefit sharing resides.”

if there is no patent protection for the technology in the first place. Thus, the interpretation that IP holders under the PPV&FR Act regime can take the advantage of the benefit sharing system is not a possible option.

4.2 Infringement Under PPV&FR Act

Section 64²⁶ of the PPV&FR Act states that the sale, import, and production of a variety registered under the PPV&FR Act by a person who is not the breeder of the said variety or the registered licensee of a registered breeder, without the permission of the registered breeder of the said variety, shall constitute as infringement of the registered variety. Further, the said section also states that the sale, import, and production of any other variety by giving it a denomination identical with or deceptively similar to the denomination of a variety registered under the PPV&FR Act, in a manner that causes confusion in the mind of general people, will also amount to infringement of the registered variety.

Section 65²⁷ of the PPV&FR Act states that a suit for infringement of a registered variety or any right relating to a registered variety shall not be instituted in a court inferior to a District Court.

Thus, it can be seen that the PPV&FR Act only provides for a legal recourse when either the variety registered under the PPV&FR Act or any right relating to such a registered variety is infringed by any person who is not authorized to use such a registered variety. The factum of infringement would have to be established by examining whether the allegedly infringing variety carries all characteristics of the registered variety or not, as infringement under Section 64 of the PPV&FR Act is with respect to a registered variety only and not for a trait.

Therefore, recourse in the manner of a suit for infringement under Section 65 of PPV&FR Act is no recourse to the developers having IP in the recombinant DNA technology by which the GM plants are created.

²⁶Section 64 of the PPV&FR Act reads: "Infringement.— Subject to the provisions of this Act, a right established under this Act is infringed by a person— (a) who, not being the breeder of a variety registered under this Act or a registered agent or registered licensee of that variety, sells, exports, imports or produces such variety without the permission of its breeder or within the scope of a registered licence or registered agency without permission of the registered licensee or registered agent, as the case may be; (b) who uses, sells, exports, imports or produces any other variety giving such variety, the denomination identical with or deceptively similar to the denomination of a variety registered under this Act in such manner as to cause confusion in the mind or general people in identifying such variety so registered."

²⁷Section 65 of the PPV&FR Act reads: "Suit for infringement, etc.—(1) No suit— (a) for the infringement of a variety registered under this Act; or (b) relating to any right in a variety registered under this Act, shall be instituted in any court inferior to a District Court having jurisdiction to try the suit. (2) For the purposes of clauses (a) and (b) of sub-section (1), 'District court having jurisdiction' shall mean the District Court within the local limit of whose jurisdiction the cause of action arises."

4.3 Researcher's Rights?

Nevertheless, even if one were to consider the PPV&FR Act as an alternative regime for protecting the transgenic plant variety containing the recombinant DNA construct conferring the specific trait to the plant, the third party infringes under the garb of researchers' rights provided under Section 30 of the PPV&FR Act can use such a variety as an initial source to create other varieties containing the recombinant DNA construct.

Section 30 of the PPV&FR Act reads:

Nothing contained in this Act shall prevent –

- (a) *the use of any variety registered under this Act by any person using such variety for conducting experiment or research; or*
- (b) *the use of a variety by any person as an initial source of variety for the purpose of creating other varieties:*

Provided that the authorisation of the breeder of a registered variety is required where the repeated use of such variety as a parental line is necessary for commercial production of such other newly developed variety.

It is clear from Section 30 of the PPV&FR Act that one can use the initial research variety to create other varieties, which in turn if not registered would lead to unauthorized and inappropriate use of research varieties. Such unauthorized and inappropriate use of research varieties cannot be brought into justice under any provision of Indian IP law. In other words, the PPV&FR Act regime does not offer any protection against the unauthorized use, sale, export, import, and production of the specific distinct trait, e.g., insect resistance, which may have been inserted into another plant variety by conventional breeding methods using the initial transgenic plant.

Accordingly, neither the benefit sharing under Section 26 nor infringement under Section 64 of the PPV&FR Act can come to the aid of an innovator when it comes to protecting a specific distinct trait in a plant variety. Thus, it is imperative to have protection under the patent regime for such inventors as a compensation for disclosing and sharing their technology for the public's benefit.

5 Conclusion

In case of transgenic plants developed using recombinant DNA technology, such as those having a trait for insect resistance, the flow of innovation, inter alia, requires the synthesis of a recombinant DNA construct, followed by the transformation of a plant cell by insertion of the recombinant DNA construct. Due to fundamental differences in biology, if the gene is obtained from a completely unrelated species (e.g., a bacterium), it cannot be successfully inserted into a plant with any success. Significant human intervention in the form modifying the gene for it to be suitable for a plant genome and adding several other components is required. Further, the

insertion of the DNA constructs into the plant can occur at different locations in the plant genome, but not all of them will result in a desired trait. Only through significant human intervention can one select one of these “events” that will result in the transgenic plant expressing the desired trait at the optimal level. The recombinant DNA constructs developed in vitro, the method for developing the genetically modified plants using that gene, and the integration of the DNA construct into the plant genome at a specific location in the plant genome cannot be termed as “essentially biological processes” and should be considered as patentable subject matter.

Such recombinant DNA constructs, recombinant DNA sequences, and methods of developing a transgenic plant are *per se* not a subject matter of protection under the PPV&FR Act because none of them can be considered as a “variety.” A variety as defined under the PPV&FR Act only refers to a plant grouping within a given species of plants and does not cover such recombinant DNA constructs. A plant variety being registered under the PPV&FR Act could also be a variety which was developed by backcrossing/breeding/hybridization of the transgenic plant – the “event.” The PPV&FR Act also does not deal with granting any form of intellectual property rights to plant breeding methods.

Effectively then, rights under the PPV&FR Act and the rights granted under the Patents Act operate in completely different spheres. What is protected under the Patents Act cannot be protected under the PPV&FR Act, and the vice versa holds true as well.²⁸

Recently, on January 8, 2019, the Hon’ble Supreme Court set aside the Delhi High Court, Division Bench judgment in *Nuziveedu Seeds Ltd. & Ors. (Supra)*, holding that the findings of the Division Bench were not based upon examining any technological or expert evidence, which was of critical value in the present case, the issue involved therein being complicated and relating to chemical, biochemical, biotechnological, and microbiological processes. The matter has been remanded back to the *Ld.* Single Judge of the Delhi High Court for proper adjudication and disposal in accordance with law. Even though the Supreme Court has not provided any observations or interpretation of Section 3(j), setting aside of the Division Bench’s order entails that the interpretation of Section 3(j) adopted by the Division Bench shall no longer be applicable. A trial will commence soon, and the outcome of this case will be of great significance and will have a deep impact on how plant-related biotechnological inventions are treated under the Indian patent regime.

Thus, the future of IP protection for agricultural biotechnologies in India needs (Statutory?/Regulatory?) clarification on the scope of protection for technologies involved in developing transgenic plants – the “events” – the scope of protection for “plant varieties” being made clear under the PPV&FR Act. This is especially vital considering India’s desire to foster an innovation-based economy.

²⁸ *Monsanto Technology LLC & Ors. v. Nuziveedu Seeds Ltd. & Ors.*, C.A. Nos.4616 – 4617 of 2018

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