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PATENT ANALYSIS OF GENETICALLY MODIFIED PLANTS

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ABSTRACT

Today's agriculture marketing has seen a great shift from traditional agriculture methods, as it relies on modern techniques, the most important being genetically modified (GM) plants. In order to have a commercially successful invention on GM plants, the existing patents in this area must be studied. Through this paper, the author has done a thorough patent analysis of GM plants, which can not only be adopted by businesses to invent a GM plant, but also by those providing advices on patents to businesses. The author provides the details of legal provisions applicable in India, United States and European Union, regarding the patentability of GM plants and aspects of enjoyment of patent rights. This paper provides a clear-cut understanding of the position of patented GM plants in the market, substantiated with a table of classification of the number of patents on GM plants. For an in-depth comprehension, the need and challenges on patenting of Gm plants have been laid down and practical examples of patents which have been granted and rejected have also been given. The author has concluded the paper by presenting an evaluation of patenting of GM plants.

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I. <u>INTRODUCTION</u>

Until few decades ago, cross breeding was the major method resorted to by farmers and cultivators across the globe, in order to obtain desired produce from plants, using certain desirable traits. But using this method can be undertaken only in instances where the plants involved belong either to the same species or species that are very closely related not to mention the time the whole process takes. It was to do away with this hindrance that genetically modified plants were introduced. A genetically modified (GM) organism is "an organism whose DNA has been modified in the laboratory in order to favour the expression of desired physiological traits or the production of desired biological products."¹ This method of modification done to plants are termed as genetically modified plants. The first GM crop or plant that was commercially sold was a GM tomato called Flavr Savr that was produced by Calgene, a Californian company. It was submitted before the United States Food and Drug Administration in 1992 and was later approved for safe human consumption in 1994.

By engineering the DNA of plants, scientists can and have transferred certain desirable properties of one plant to another despite the fact that the two plants may be of two entirely different species. Essentially, the genes in a GM Crop are artificially inserted as opposed to the plant having possessed said gene through the process of pollination. GM plants are advantageous in many ways, including greater yield, lower cost of farming as compared to ordinary crops, increased profit, greater resistance to insects, greater tolerance to herbicides and more nutritious as compared to ordinary crops.

A GM organism which is neither found in nature nor is its activity exhibited in any naturally occurring organism, satisfies the pre-requisites for patentability, as it is a product of human ingenuity having a distinctive name, character and use.² Patent analysis is done so as to understand the complete information of the patented product, including the technological and competitive aspects of information. Through analyzing patents on GM plants, details of the applicant and inventor, information on the citations to prior art, claims and geographical location, can be obtained. Business professionals, scientists and researchers make use of patent information in order to analyze patenting activity in a geographical area, technology or company, for determination of the direction of technological transformation and the relative technological

¹ Julia M. Diaz, *Genetically Modified Organism*, BRITANNICA, <u>https://www.britannica.com/science/genetically-modified-organism</u>, (last visited on 17th June 2020).

² Diamond v. Chakrabarty, 447 US 303 (1980).

scenario of the GM plant in a marketplace. Moreover, the inventive output of the organizations using the patented GM plants can be measured and the impact of these GM plants can be studied.

II. <u>REQUIREMENTS FOR GRANTING PATENTS ON GENETICALLY</u> <u>MODIFIED PLANTS</u>

A. INDIA

In India, the Patents Act, 1970 is the legislation dealing with provisions relating to granting of patents. Through an amended, the word "plants" had been omitted from the list of non-patentable subject matter.³ An invention relating to GM plants can be patented on the following criteria:

- 1. Patentable subject matter: The Act contains provisions⁴ listing out non-patentable subject matter, as long as the invention does not fall under this, it means it possesses patentable subject matter.
- Novelty: Novelty/ new invention is defined under Section 2(1) of the Act. Novelty of an invention exists, if it is neither in the public domain nor is same/ similar to prior arts. 'Anticipation' is lack of novelty, which is determined by various factors like prior publication, public knowledge, etc.⁵
- 3. Inventive step or non-obviousness: Inventive step is defined under Section 2(ja) of the Act as a feature of an invention involving technical advancement and economic significance, which is not an existing knowledge and the invention is not obvious to a person skilled in the art.⁶
- 4. Capable of industrial application: It means that the invention is capable of being made/ used in an industry.⁷ Hence, the invention cannot exist in abstract and must have practical utility.
- 5. The invention related to the gene has required substantial human intervention and the gene is recombinant: As recombinant DNA constructs modified DNA and modified protein molecules are not discovered, but are developed in the laboratory and involves substantial human intervention, it will qualify as a patentable subject matter.⁸

³ Patents (Amendment) Act, 2002, S.4(d)(ii), No. 38, Acts of Parliament, 2002 (India).

⁴ Patents Act, 1970, S. 3 and 4, No. 37, Acts of Parliament, 1970 (India).

⁵ Patents Act, 1970, S.29 to 34, No. 37, Acts of Parliament, 1970 (India).

⁶ Patents Act, 1970, S. 2(ja), No. 37, Acts of Parliament, 1970 (India).

⁷ Patents Act, 1970, S. 2(ac), No. 37, Acts of Parliament, 1970 (India).

⁸ Patents (Amendment) Act, 2002, S.4(b), No. 38, Acts of Parliament, 2002 (India).

6. The gene has been isolated by a human: A biotechnology product is considered patentable when there is substantial human intervention or human ingenuity in the invention, thus making a genetically modified gene or nucleic acid sequence patentable.⁹

The Protection of Plant Variety and Farmers Right Act, 2001 protects the creation of new plant varieties by a seed, biotech research company or an individual farmer. A transgenic plant variety is a plant variety that has one or more genes from a foreign organism incorporated in it by a biotechnology process. Plant varieties and seeds, including transgenic varieties and GM seeds that were excluded from the Patents Act stand protected under this Act.

Supreme Court held that genetically modified cotton seeds are patentable. Genetically modified seeds and plants should be patentable because the genetic method is man-made and does not exist in nature. These cannot be excluded under Section 3(j) of Patents Act as being essentially biological processes, since there exists significant human intervention."¹⁰

B. UNITED STATES

In the United States, the Title 35 of the United States Code is the legislation dealing with provisions relating to granting of patents. An invention relating to GM plants can be patented on the following criteria:

- Useful: The utility requirement demands that the invention be useful at the time the patent is issued. An invention or discovery which is new and a useful process or machine or manufacture or composition of matter, or any new and useful improvement can be patented.¹¹
- 2. Novelty: The invention should not have been published or in public use or publicly be available to the public before the effective filing date of the claimed invention. But, a disclosure made one year or less before the effective filing date of a claimed invention shall not be prior art or was disclosed by the inventor or joint inventor or someone connected directly or indirectly to them.¹²
- 3. Non-obvious subject matter: A patent may not be obtained if the subject matter to be patented and the prior art have only few differences, that the subject matter as a whole would

⁹ Patents (Amendment) Act, 2002, S.4(b), No. 38, Acts of Parliament, 2002 (India).

¹⁰ Monsanto Technology LLC v. Nuziveedu Seeds Ltd., AIR 2019 SC 559.

¹¹ United States Code Title 35, 1953, S. 101 (United States).

¹² United States Code Title 35, 1953, S. 102 (United States).

have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.¹³

4. Best mode: The patentee should specify the description of the invention, manner and process of making and using it, and mention the best mode contemplated by the inventor for carrying out his invention.¹⁴

Companies often obtain utility patents on their GM plants as compared to plant patents, as utility patents cover inventions beyond plants, to include integration of novel, foreign DNA into the plant genome and the uniquely designed DNA and they have a stronger protection against infringement.

Supreme Court has held that utility patents provide more extensive protection for GMO plants, as it prohibits the replanting of seeds harvested from a licensed plant. Whereas plant patents allow licensees to sexually reproduce indefinitely, with few exceptions.¹⁵

C. EUROPEAN UNION

In EU, the European Patent Convention is the legislation dealing with provisions relating to granting of patents. Directive 43 2001/18 / EC on deals with the cultivation, import and processing in industrial products of GMOs and Regulation44 of 1829/2003 deals with GM foods and feeds placed in the market. An invention relating to GM plants can be patented on the following criteria:

- Patentable subject matter: The EPC contains provisions listing out what does not constitute as an invention, as long as the invention does not fall under this, it possesses patentable subject matter.¹⁶
- 2. Novelty: Novelty means the invention should be new and not be published or made available to the public on a prior date; An invention is new if it does not form part of the state of the art.¹⁷
- 3. Non-prejudicial disclosures: A disclosure shall not be considered, if it occurred within six months prior to filing of application, due to an abuse in relation to applicant or was displayed at an official international exhibition.¹⁸

¹³ United States Code Title 35, 1953, S. 103 (United States).

¹⁴ United States Code Title 35, 1953, S. 112 (United States).

¹⁵ Bowman v. Monsanto Co., 569 U.S. 278 (2013).

¹⁶ European Patent Convention, Oct. 5, 1973, Art. 52.

¹⁷ European Patent Convention, Oct. 5, 1973, Art. 54.

4. Inventive step: An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art.¹⁹

Industrial application: An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.²⁰

III. ASPECTS OF ENJOYMENT OF PATENT RIGHTS

- <u>Enforceability</u>: Patent is treated as a property right in India and US, which is enforceable in their respective whole territory. Patents grant the holder the right to prevent anyone from making, using or selling the invention in the Country. Whereas the European Patent Office (EPO) grants patents for the member states of the European Patent Convention. On filing an application, EPO grants the applicant, same patent rights in countries designated by him²¹ and is hence referred to as a bundle of rights.
- <u>Publicly available invention</u>: Patent applications in European Union²² and India²³ are rejected, if the invention is made publicly available by the inventor or one of the inventors or an independent third party, prior to the filing of the application. Whereas in US, a one-year grace period is granted, i.e., the inventor has the right to make his/her invention publicly available a year prior to filing of application.²⁴
- <u>Granting of patent</u>: On fulfilling all criteria and removing objections to obtain patent, the controller will accept and advertise the invention in the official gazette. The patent granted will have seal of the Patent Office and the date of granting patent will be entered in the register.²⁵
- <u>Term</u>: The term of protection available for patents shall not end before the expiration of a period of twenty years counted from the filing date.²⁶ But countries are not forbidden from

¹⁸ European Patent Convention, Oct. 5, 1973, Art. 55.

¹⁹ European Patent Convention, Oct. 5, 1973, Art. 56.

²⁰ European Patent Convention, Oct. 5, 1973, Art. 57.

²¹ European Patent Convention, Oct. 5, 1973, Art. 88.

²² European Patent Convention, Oct. 5, 1973, Art. 54.

²³ Patents (Amendment) Act, 2005, S. 2(1), 29, 30 and 31), No. 38, Acts of Parliament, 2005 (India).

²⁴ United States Code Title 35, 1953, S. 102.

²⁵ European Patent Convention, Oct. 5, 1973, Art. 127; Patents Act, 1970, S. 2(ac), No. 67, Acts of Parliament, 1970 (India); United States Code Title 35, 1953, S. 261.

²⁶ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Art. 33.

providing patent-like rights with shorter terms, like utility models which are granted for six to ten years.

• <u>Patent term extension</u>: US and European Union have legislations granting PTE up to five years. This period is calculated by including Patent Term Adjustment in US.²⁷ In EU, the period is calculated from the end of lawful terms of the basic patent.²⁸ Whereas, India does not have any legislation granting PTE and till date there are no case laws awarding PTE to genetically modified plants.

IV. <u>POSITION OF PATENTED GENETICALLY MODIFIED PLANTS</u> <u>IN THE MARKET</u>

A wide range of claims are often admitted in relation to genetically modified plants, including genetic constructs and/or their components as well as modified cells and plants. The recent years have seen a change globally in the market position of patented genetically modified plants and seeds. The market three decades ago was constituted by thousands of players, whereas, now, two-thirds of the market is controlled by ten companies alone around the world.²⁹ These dominant companies are also the leaders in the pesticide and biotech market worldwide. The idea of patenting living materials was introduced by US in 1980s, which was followed by Western countries. The top 5 countries with the largest area of biotech crops planted (USA, Brazil, Argentina, Canada, and India) collectively occupied 91% of the global biotech crop area; Twenty-six countries planted 191.7 million hectares of biotech crops, which added 1.9 million hectares to the record of plantings in 2017.³⁰ The number of patents on plants worldwide has increased a hundredfold from just under 120 in 1990 to 12,000 today.³¹

In the United States, the investment on Research and Development in the agriculture industry has been as high as \$69 billion since 2013, which includes the technology on GM plants. But, due to

ISAAA,

²⁷ United States Code Title 35, 1953, S. 156.

²⁸ Regulation (EC) No 1610/96, SPCs for Plant Protection Products, Art.13.

²⁹ Stephen Greenberg, *Biotechnology, Seed and Agrochemicals: Global and South African Industry Structure and Trends*, 6 (2009), <u>file:///C:/Users/Admin/Downloads/ACB09-Biotechseedagrochemicals.pdf</u>.

http://isaaa.org/resources/publications/briefs/54/#:~:text=A%20total%20of%2070%20countries,Acquisition%20of%20Agri%2Dbiotech%20Applications (last visited Aug.18, 2020).

³¹ DW, <u>https://www.dw.com/en/patents-on-plants-is-the-sellout-of-genes-a-threat-to-farmers-and-global-food-security/a-49906072 (last visited Aug.18, 2020).</u>

vast patent claims and scope for high research, the innovations have remained within the big five. This has been proved by the fact that in 2009, the top three seed companies controlled 85% transgenic and 70% non-transgenic corn patents.³² While Monsanto holds a notable fraction of seed patents, DuPont Pioneer holds more than half of active patents on GM plants and seeds. Other companies include Dow, Syngenta and Bayer. These companies spend around \$135 million and take more than seven years to produce a new GM plant. The influence of these companies have led GM corn and soybean to constitute more than 90% of the market. They also hold 75% of the world's pesticides market.

Out of the 12000 patents on plants worldwide, 3500 are registered in Europe, which includes genetically engineered plants.³³ Biotechnology is an important industrial sector in the EU economy and it is one of the ten most active fields for applications, which constitutes around 4.9% of all applications filed in 2010. Around three hundred applications are filed annually on GM plants, as compared to only seventy applications annually on non-GM plants. But, GM plants constitutes only about 0.2%, out of all patent applications filed with the EPO.³⁴

In India, the governments fund most of the agricultural research, as it is an emerging economy. The public sector Research and Development spending in agriculture has tripled in India from less than USD 1 billion to almost USD 3 billion. Though, India has progressed tremendously in GM crops research, evaluation and monitoring in last two decades, the regulatory system has impeded gravely as there exists lack of coordination and common stand between different governments, ministries and departments, when it comes to GM technology.³⁵ Despite lack of patenting, transnational companies have sought to commercialize agricultural biotechnology products in India.

³² Ruchir Raman, *The impact of Genetically Modified (GM) crops in modern agriculture: A review*, ISSN: 2164-5698 GM Crops & Food: Biotechnology in Agriculture and the Food Chain 195, 203 (2017), https://www.tandfonline.com/doi/pdf/10.1080/21645698.2017.1413522?needAccess=true.

 ³³ No patents on seeds, <u>https://www.no-patents-on-seeds.org/en/background/problem</u> (last visited on Aug. 18, 2020).
³⁴ EPO, <u>https://www.epo.org/news-events/in-focus/biotechnology-patents.html</u> (last visited on Aug. 18, 2020).

³⁵ Manish Shukla, Khair Tuwair Al-Busaidi, Mala Trivedi, and Rajesh K. Tiwari, *Status of research, regulations and challenges for genetically modified crops in India*, ISSN: 2164-5698 GM Crops & Food: Biotechnology in Agriculture and the Food Chain 173, 173 (2018), https://www.tandfonline.com/doi/abs/10.1080/21645698.2018.1529518?needAccess=true#aHR0cHM6Ly93d3cudG FuZGZvbmxpbmUuY29tL2RvaS9wZGYvMTAuMTA4MC8yMTY0NTY5OC4yMDE4LjE1Mjk1MTg/bmVlZEFj Y2Vzcz10cnVlQEBAMA==.

Item	India		European Union		United States			
	Since '70	Since '10	Since '98	Since '10	Since 2001			
GM plants	3944	2611	4409	3490	4103			
GM mustard	21	10	4	2	6			
GM cotton/ Bt cotton	286	181	50	42	86			
Soybean	90	59	1034	874	155			
Corn	109	73	964	777	172			
Canola	10	8	92	68	37			
Papaya	24	20	37	32	7			
Flowering plants	79	49	9	6	1			
Database from which	https://ipindiaservices		https://worldwide.esp		http://patft.uspto.gov/			
information was	.gov.in/publicsearch		<u>acenet.com/</u> ,		netahtml/PTO/search			
collected.			https://register.epo.or		<u>-adv.htm</u>			

TABLE CLASSIFYING THE NUMBER OF PUBLISHED PATENTS ON GENETICALLY MODIFIED PLANTS IN INDIA, EU AND US.

V. NEED TO PATENT GENETICALLY MODIFIED PLANTS

<u>Recoup expenses</u>: On an average, a genetically modified plant costs \$136 million, due to its discovery, development, and authorization.³⁶ Such exceptionally high costs are covered by the profitability granted during the period of exclusivity, where the patent holder does not have to worry about unfair competition. As improving agriculture leads to high costs, the same is often avoided. But by giving patent rights, companies and individuals are willing to invest time and money in the same.

g=en

g/advancedSearch?ln

• <u>Spur innovation</u>: Patent protection to GM plants is significant to the development of grainproducing nations as farmers rely on it. In the U.S., for example, more than 90 percent of

³⁶ Wen Zhou, *The Patent Landscape of Genetically Modified Organisms*, SITN HARVARD UNIVERSITY (Aug.12, 2020, 5:51 PM), <u>http://sitn.hms.harvard.edu/</u>.

corn and soybeans are GMO.³⁷ Most companies enter into a race to bring out the best useful GM plant.

- <u>Beneficial to public</u>: These GM plants are an effective and cheap solution to feed the world. As they are resistant to diseases, it specially benefits low-socioeconomic regions like Africa which are dependent on crops like bananas to survive. On patenting, companies can innovate more and bring more of these products to market.³⁸ Upon the expiry of the patent granted to GM plants, the same becomes a public knowledge and companies, farmers, etc. can develop improved versions of the GM plant and be mass-reproduced, thereby making it beneficial to the public.
- <u>Novelty</u>: Genetically modified plants undergo sufficient alteration of the base organism and thus turn into a form of manufacturing for a novel use. They are altered in such way so as to be resistant to disease and climate change.
- <u>Reduced pollution</u>: By using the Bt corn and soy which have in-built pesticides, the farmers can avoid the excess usage of herbicides and pesticides.
- <u>Patents are finite</u>: On expiry of the patent, the invention enters the public domain which can be accessed for further research and development by anyone. For instance, Okanagan Specialty Fruits used Monsanto's expired patent to develop a non-browning apple.³⁹

VI. <u>CHALLENGES ON PATENTING GENETICALLY MODIFIED</u> <u>PLANTS</u>

• <u>Bio-piracy</u>: It is the private appropriation of public biological resources. The original seed required to develop a genetically modified crop technically comes from farmers. The patenting of such plants causes monopoly, which in turn undermines farmers' choice. These patents are used to prohibit outside scientific research into the plants.⁴⁰ Before patents, there

³⁷ Jorge Fernandez-Cornejo, Seth Wechsler, Mike Livingston, and Lorraine Mitchell, *Genetically Engineered Crops in the United States*, 162 USDA Economic Research Report, 9, https://www.ers.usda.gov/webdocs/publications/45179/43668_err162.pdf.

³⁸ Malathi Lakshmikumaran, *Genetically Modified Plants: The IP and Regulatory Concerns in India*, SPRINGER LINK (Sept. 07, 2019), <u>https://link.springer.com/chapter/10.1007/978-981-13-8102-7_16#citeas</u>.

³⁹ Allison Baker, *Artic Apples: A fresh new take on genetic engineering*, SITN HARVARD UNIVERSITY, (Aug.10, 2020, 7:37 AM), <u>http://sitn.hms.harvard.edu/</u>.

⁴⁰ RESET.ORG: DIGITAL FOR GOOD, <u>https://en.reset.org/knowledge/privatisation-seeds</u> (last visited Aug.15, 2020).

was a lot of innovation that came out of trading germplasm and now the invention by many leads to lack of access to each other's programs.

- <u>Stifles innovations</u>: Patent holders are given the right to restrict other individuals, companies and farmers from researching on their GM plants. Some companies allow academic researchers access to their GM plants through licenses.
- <u>Restricts breeding</u>: Most companies require farmers to sign a contract which prohibits them from breeding the plant.
- <u>Consolidation of seeds</u>: The top 10 seed companies made nearly 200 acquisitions between 1996 and 2013, as the easiest way for large companies to enter into the market was to buy seed companies and attach their GM traits to those seeds.⁴¹ The top three being Monsanto, DuPont and Syngenta are now in control of over half the industry.
- <u>Restricts choice</u>: Farmers' choices are restricted and they are forced to buy either GM plants at high prices, when they require conventional plants or plants with more than one GM trait, when they require only one. Eg: In North Dakota, farmers who grew soybeans were unable to access conventional soybean after the availability of GM soy. They were only able to access some old varieties which lacked disease resistance. Though North Dakota State University bred soybeans which adapted to local conditions, it stopped developing new varieties, as it could not compete with the big companies.⁴²
- <u>Does not cater to needs of the farmers</u>: Patent holders gain piles of money by forcing farmers to buy the seeds and plants developed by them. Companies would have focused on crops that the farmers cannot save seed for, had patent not existed. Roundup-Ready corn and soy, which can be sprayed with the herbicide glyphosate (used to kill weeds) and show no ill effects, are widely planted because farmers want them. For instance, farmers can grow roundup-ready corn and soy with the help of herbicides and saving seeds. But, Monsanto, through its patented GM plants force vast majority of farmers to buy it.⁴³
- <u>Risk of being sued</u>: Companies like Monsanto, Syngenta, BASF and DuPont, often sue farmers for illegally growing their patented plants. But in reality, their fields would have

⁴¹ QRIS, <u>https://qrius.com/seed-wars-and-monopolization-the-case-of-monsanto/</u> (last visited Aug.15, 2020).

⁴² IAPT, <u>https://www.iatp.org/news/monsanto-sues-nelson-farm-a-north-dakota-familys-frustrations-with-genetically-engineered-soybe</u> (last visited Aug.18, 2020).

⁴³ Jordan Wilkerson, *Why Roundup Ready Crops Have Lost Their Allure*, SITN HARVARD UNIVERSITY, (Aug.17, 2020, 3:15 PM), <u>http://sitn.hms.harvard.edu/</u>.

been accidentally contaminated with patented GM crops due to wind, insects, etc., thereby putting farmers at risk of being sued.

• <u>Imbalance in economic power</u>: The food chain has been controlled by big corporates with their patented GM plants and its restrictions. They also control production of herbicides and fertilizers. Such patenting of genetic material by these companies have shifted the balance of economic power to themselves alone.

VII. <u>EXAMPLES OF PATENTS ON GENETICALLY MODIFIED</u> <u>PLANTS:</u>

1. PATENTS GRANTED

• Patent number: 1055714644

Inventors: Caixia Gao, Yanpeng Wang, Jin-Long Qiu

Current assignee: Institute of Genetics and Developmental Biology CAS

Genetically modified plant: Wheat resistant to powdery mildew

Number of claims made: 27

Number of patent citations: 9

Number of priority and related applications: 4

Patent abstract: Powdery mildew (Pm) is an important cereal disease and is caused by Blumeria graminis f. sp. tritici (Bgt) in wheat. The resistance responses towards Pm pathogen are genetically well characterized. The invention in hand is a genetically modified, mutant wheat plant which is resistant to Pm. A method to determine presence or absence of a mutant TaMLO-A1, TaMLO-B1 and TaMLO-D1 nucleic acid or polypeptide in a wheat plant is also invented. The TALEN-induced mutations in all three TaMLO homoeologs which are inherited and the simultaneous mutation of all three TaMLO homoeologs confers broad spectrum resistance to powdery mildew.

Thus, the invention relates to a genetically modified wheat plant comprising of a triple loss of TaMLO-A1, TaMLO-B1 and a TaMLO-D1 gene using targeted genome modification, having increased resistance to powdery mildew as compared to a wild type plant.

- Publication number: 20090307801⁴⁵
 - Inventor: Lilli Sander Jensen

Current assignee: Kobenhavens Universitet

Genetically modified plant: Novel phenotypes upon plants incorporating the SHI family gene Number of claims made: 52

Number of patent citations: 5

Number of priority and related applications: 8

Patent abstract: Improvement in plant quality and yield used to be attained through retardation. But, the increasing use of chemical retardants lead to potential health risks and hence have been banned. The present invention is an alternate to retarding plants. It is regarding novel genetically modified plant cells wherein short internodes (SHI) family gene is integrated into the nuclear genome. This is beneficial in ornamental plants or certain crop plants, as it reduces the height and improves the branching and flower set in plants. A foreign nucleic acid molecule encoding a SHI family gene is integrated into the nuclear genome of the genetically modified plant cells from wild type plants. Also, a foreign nucleic acid molecule encoding an antisense SHI gene, which is complementary to a SHI family gene, is integrated into the nuclear genome of the genetically modified plant cells of the nuclear genome of the genetically modified plant the nuclear genome of the genetically modified plant the nuclear genome of the genetically modified plant cells from wild type plants. Also, a foreign nucleic acid molecule encoding an antisense SHI gene, which is complementary to a SHI family gene, is integrated into the nuclear genome of the genetically modified plant cell. The invention also has a propagation material of genetically modified plants with at least one phenotypic trait among reduced height, increased branching, increased flower set, narrow leafs, reduced lateral root formation, and reduced fertility.

Thus, through genetically modifying plants, alteration to plants are done without use of any growth retardants. The plant cells are genetically modified to confer novel phenotypes incorporating the SHI family gene. The invention discloses transgenic plants and methods for plant production, where the plants are dwarfed, but exhibit normal or increased flower set.

Publication number: 20130060016⁴⁶
Inventors: Claus Frohberg, Ralf-Christian Schmidt
Current assignee: Bayer Crop Science AG

⁴⁵ Google Patents, <u>https://patents.google.com/patent/US20090307801A1/en?oq=publication+20090307801</u> (last visited Aug. 21, 2020).

⁴⁶ Google Patents, <u>https://patents.google.com/patent/US20130060016A1/en?oq=20130060016</u> (last visited Aug. 21, 2020).

Genetically modified plant: Plants that synthesize low amylose starch with increased swelling power.

Number of claims made: 24

Number of patent citations: 18

Number of priority and related applications: 9

Patent abstract: Starch is a nutritionally essential component for both humans and animals. Starch is an important storage material in plants and is closely related to polysaccharides and cellulose. Thus, the characteristics of food depends largely on the starch present in the plant tissue. This invention is an alternate to plant breeding methods of modifying starch producing plants by recombinant methods. It causes a genetic modification by introducing at least one foreign nucleic acid molecule into the genome of the plant, to encode a protein with glucan, water dikinase and enzymatic activity of starch synthase II. Monocotyledonous plant cells are genetically modified, due to which the modified starch is synthesized, rather than being isolated in a wild-type plant cell. The genetic modification of plant cell leads to regeneration of plants. Swelling power is important in processing starch in the food industry. A physically modified starch can swell even in cold water, as compared to negligible swelling power of natural starch in cold water. It is obtained by undergoing various processes including warming starch granules in the presence of excess water and obtaining a quotient from weight of resulting residue and amount of starch weighed. A swelling power of about 30 g/g is measured for acetylated waxy-rice starch and about 15 g/g for cross-linked waxy-rice starch.

Thus, the invention produces and provides methods and means for a modified waxy-starch with a change in functional characteristics and novel plant cells. The change of which is due to modified starch having an increased hydrothermal expansion power.

2. <u>PATENT REJECTED</u>

• Application number: 2245/DELNP/2009⁴⁷

Inventor: Plant Advanced Technologies PAT SAS

Genetically modified plant: Process for the production of recombinant proteins using carnivorous plants

⁴⁷ INPASS, <u>https://ipindiaservices.gov.in/PublicSearch/PublicationSearch/PatentDetails</u> (last visited on Aug.22, 2020).

Reason for refusal of patent: The claim was that the carnivorous plant can be used as a medium for production of the protein of interest. A process to genetically modify the plant by transformation and to express protein in the digestive secretion of the genetically modified plant, was the claim proposed by the applicant. The patent application was thus refused on the ground of S.3(j) and S.3(h), Indian Patent Act, 1970, as cultivation/ growing of the plant and harvesting of fluid from the trap is considered as a method of agriculture, which is not a patentable invention.

Application number: EPO-T 1165/03⁴⁸
Inventor: Monsanto Company

Genetically modified plant: Particle-mediated transformation of soybean plants and lines Reason for refusal of patent: European Patent Office revoked the patent owned by Monsanto for the genetic modification of soybeans, on the ground that the technique lacked novelty. The first application for soybean patent was submitted in 1988 by US biotech company Agracetus. Monsanto acquired Agracetus in 1996, thus becoming the owner of the patent, which was due to expire in 2008. The idea of this patent was actively researched by several teams during the 1980s, one of which was Agracetus. Moreover, this technique was also used on onions in 1987. The patent was opposed on grounds of exclusions or exceptions to patentability as under Art. 52(2)(a) and 53(a)(b) of EPC, lack of novelty and inventive step as under Art. 54 and 56 EPC and insufficiency of disclosure as under Art. 83. It was concluded by the Board that the term "foreign gene" will not be interpreted by a skilled person as exclusively depicting genes from other species than soybean. Thus, the soybean cultivar/seeds which are disclosed as being resistant to cyst nematodes by having acquired the corresponding genetic determinant from another line of soybean is novelty-destroying to the subject-matter of the claim.

VIII. <u>EVALUATION AND CONCLUSION OF ANALYSIS ON</u> <u>PATENTING OF GENETICALLY MODIFIED PLANTS</u>

Today's agriculture marketing has seen a great shift from traditional agriculture methods, as it relies on modern techniques, the most important being genetically modified plants. The initial

⁴⁸EPO, <u>https://www.epo.org/law-practice/case-law-appeals/recent/t031165eu1.html</u> (last visited on Aug. 22, 2020).

years of GM plants had least or no market position in most countries, unlike today, where manufactures of GM plants have occupied a dominant position in the market.

In order to attain a place in the market, the manufacturer must study what the population of the market in which he desires to release his GM plant, mostly relies on. In India, the main crop is rice, while in US it is corn and EU it is sugar beet. Considering Indian markets, the demands vary from state to state, due to the diverse population. Apart from this, the manufacturer should also identify the issues faced by a particular plant and methods required to rectify the drawback by genetically modifying it. The issues may either be at the stage of growing it or those which arise only in the end product. The best instances being introduction of Bt corn with in-built pesticides, which prevented the excessive use of chemicals during farming and the introduction of GM apple, which prevents the browning of an apple.

The market in the recent times have been favourable for GM plants and patenting of the same has brought in great advantages to the inventors, which help them to exclusively produce and fix high prices. Though, farmers and cultivators are now depending on GM plants, due its convenient usage and bounteous defect-free end products; to another group, the GM plants remain unaffordable, due to its high prices and restrictions on re-using. There is also a negative impact upon researchers, as patented GM plants prevent them from the freedom to conduct further research. If the inventor willingly adopts terms to curb the negative impact of these patents, like reducing prices, permitting licenses for further research, reducing the number of exclusive rights for production, etc., the patented GM plant can be beneficial to the entire society.

Thus, from the above data on patenting of GM plants, it is right to conclude that a patented GM plant can acquire a good market position at present, provided the inventor studies the market well and is ready incorporate the requirements of the society.