# PATENTING OF LIFE FORMS

*by*

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**ABSTRACT**

*This research highlights various processes adopted under the patent law regime for patenting of life forms in India and the globe. The author has adopted doctrinal legal research as research methodology. The research examines statues under Indian, European and American legal system along with the relevant case laws. The author has categorised research into three parts, namely:*

1. *Patenting of plants*
2. *Patenting of animals*
3. *Patenting of microorganisms*

*In order to understand the concept of patenting of life forms it is essential to define an invention. Invention can be termed as manufacturing of any product or process which is novel and vendible. The term life form means any living creature. The main issue in this research is whether a life form can be granted patent protection?*

Journal of Multi-Disciplinary Legal Research

**Key Words:** Patent, life forms, plants, animals, microorganisms, transgenic, licensing and registration.

*"Inventions cannot be judged on the basis of Patent parameters, but patents have the ability to take inventions quite far"- Kalyan C Kankanala*

## HISTORY

The word Patent has originated from the expression "Letters Patent". The term "Letter Patent" meant open letters which were discern from closed letters. These were instruments under the Great Seal of the King of England addressed by the crown to all the subjects at large, in which the crown conferred certain rights and privileges on one or more individuals in the kingdom. In late nineteenth century novel inventions in the area of art, process, method or manner of manufacture, machinery, apparatuses and other substances, produced by manufactures were on the rise and the inventors became very much interested in the fact that their inventions should not be infringed by means of copying or by implementing methods which were employed by them in the first place. In order to protect the interests of such inventors the then British regime enacted the Indian Patents and Designs Act, 1911.[1]

Before 1911, The Act VI of 1856 on Protection of Inventions based on British Patent Law of 1852 was enacted under the British regime in India. The act gave certain exclusive privileges to the inventors or the manufacturers for period of fourteen years. In 1859 the act was renamed to act XV Patent Monopolies Act. Then in 1872 Patterns and Design Protection act came up followed by The Protection inventions Act in 1883 and in 1888 both the acts were consolidated as one under the name Inventions and Design Act.[2]

It was in 1911 when India officially got a legislation which was protecting patent rights of the inventors. Though with changing economy and political scenario of the country, there was a need of more detailed and comprehensive legislation which could more effectively protect the rights and interests of the inventors. In 1948 Government of India appointed a Patent Inquiry Committee to look into the working of Patent law in India. Since most of our law are derived from the common law regime of the United Kingdom, likewise in 1953 The Patents Bill, 1953 was introduced which had its fair share of similarities with the United Kingdom Patents Act 1949, though the Bill was dissolved. The Government of India wanted to start afresh, so in 1957 they appointed Ayyangar Committee under Justice N. Rajagopala Ayyangar and the committee submitted a detailed 368 page report in 1959. The report by Justice Ayyangar Committee laid down the foundation for Patent Law in India. Patents Bill of 1965 had largely incorporated in itself recommendations given by the comprehensive Justice Ayyangar Committee report. Finally it was in 1970 when the Patent Bill, 1965 was passed in both Houses of the Parliament and on 19th September, 1970 a bill became law by the approval of the President of India under the name of 'The Patent Act, 1970', act came into force in 1972.[3] The main aim of India was to lay down a robust patent law regime and

[1] B.L Wadhera 'Law relating to intellectual property rights' (fifth edition, Universal/LexisNexis) 3
[2] Department for Promotion of Industry and Internal Trade< https://ipindia.gov.in/history-of-indian-patent-system.htm> accessed on 8 October 2021
[3] B.L Wadhera 'Law relating to intellectual property rights' (fifth edition, Universal/LexisNexis) 3

became a member state of World Intellectual Property Rights Organisation (WIPO) in 1975 and signatory to Trade Related Intellectual Property Rights (TRIPS) treaty in 1995 which brought the country one step closer to its aim. Consequently India also became a signatory to following treaties under World Intellectual Property Rights (WIPO), WIPO Convention (1975), Phonograms Convention (1975) ,Patent Cooperation Treaty and Paris Convention in 1998, Berne Convention(1928)and the Budapest Treaty in 2001.[4] In 2005 the Patent Act 1970 was amended under the (Amendment) Act 2005 in which pharmaceutical drugs, foods, microorganisms were also included in product patents. Under (Amendment) Act 2005 one major development was the insertion of legislations relating to grant of Compulsory Licensing. Legislations relating to opposition of pre and post grant of patents were added. Also, legislations related to exclusive marketing rights have been omitted under the (Amendment) Act 2005. [5]

## INTRODUCTION

### ❖ What is a Patent?

Patents are a form intellectual property rights which are exclusive rights granted for a novel "**invention"** to an inventor, where the person who is the proprietor of a patent has an exclusive right to exercise, vend or make use of his invention. By getting patent over a novel invention, the proprietor of a patent automatically excludes others from using or vending a patent. The main objective of having a patent law regime is to promote the notion of inventions by protecting the rights of the proprietor of a patent. Patent is a territorial right, which essentially means that a patent is only applicable the country where it has been registered. In order to obtain a patent in different country, the proprietor of the patent or the patentee has to go through the patent registration process of the said country. Patent rights are quite similar to property rights which ensure legal title over an invention. Though a right over a patent is not considered as positive right for its proprietor, it eliminates others to exercise any kind of right over the patent or utilize the patent in any form, hence making it a negative right. A patent can also be defined as a contractual agreement between the inventor and the state, wherein the consideration under this contract is full public disclosure. The person to whom a patent is granted or proprietor of a patent is known as **"Patentee"**.

[4] Jaya Bhatnagar and Vidisha Garg 'Patent Law in India' (Anand & Anand, 13 December 2007) < https://www.mondaq.com/india/patent/54494/patent-law-in-india> accessed on 12 October 2021

[5] Adv. Vijay Pal Dalmia Patent Law in India- Everything you must Know (Vaish Associates Advocates, 11 June 2015) < https://www.mondaq.com/india/patent/403564/patent-law-in-india--everything-you-must-know> accessed on 12 October 2021

## ❖ Applicability Criteria

The term Patentee is defined under section 2(1) (p) of the Patents Act, 1970 as the person for the time being entered on the register as the grantee or proprietor of the patent.[6] Likewise the term invention also finds its place in Patent Act, 1970 under section 2(1) (j) of the act, according to which "invention" means a new product or process involving an inventive step and capable of industrial application[7]. This definition was inserted in the act through the amendment act of 2002.[8] The act under section 2 (1) (l) also defines the term 'new invention' as any invention or technology which has not been anticipated by publication in any document or used in the country or complete specification, *i.e.*, the subject matter has not fallen in the public domain or that it does not form part of the state of the art".[9] The meaning of the term 'inventive step' is given under the Patents Act 1970, under section 2(1) (j) (a) as a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art'[10]. If the invention lacks an 'inventive step', then it can be a ground for opposition to the patent under section 25 (1) (e) and section 25 (2) (e) of the act. Section 25(1) (e) states that if the invention so far claimed in any claim of the complete specification is obvious and clearly does not involve any inventive step, having regard to the matter mentioned in clause (b) of section 25 (1) or having regard to what is used in India before the priority date of the applicant claim. [11]Section 25 (2) (e) says that the invention so far as claimed in any claim of the complete specification is obvious and clearly does not involve any inventive step, having regard to the matter published as mentioned in clause (b) of section 25 (2) or having regard to what was used in India before the priority date of claim.[12] Absence of an 'inventive step' in an invention is ground for revocation of patent under section 64 (1) (f) of the act. The section states that the invention so far claimed in any claim of the complete specification is obvious or does not involve any inventive step, having regard to what was publicly known or publicly used in India or what was published in India or elsewhere before the priority date of the claim.[13] The invention to be patentable must be technical in nature and should fulfil following criteria:-

1. Novelty – The specifications of the invention must be new and novel. This essentially means should not be already present in the public domain.
2. Utility - The invention should have an industrial application. It should be capable of being vended in the market. The inventor should have the leverage to use the invention without any disruption and fear of competition.

[6] Patent Act 1970, section 2(1)(p)
[7] Patent Act 1970, section 2 (1) (j)
[8] *See* Patent Amendment Act (2002)
[9] Patent Act, 1970 section 2(1)(l)
[10] *Id at section 2(1) (j)( a)*
[11] *Id at section 25*
[12] *Id*
[13] *Id* at section 64

3. Inventive Step / Non Obviousness – The invention should not be obvious to a person skilled in the art in the light of the prior knowledge, publication and document. Application of mind of the inventor should be apparent. An evidence of creative input of the inventor is an essential requirement.

## ❖ What is a life form?

Life form is defined as any living thing such as pant or an animal[14] or any living thing.[15] A life form can be any living organism which derives its survival from the nature.

## PATENTING OF LIFE FORMS

### ❖ Statutory Interpretations

A contentious question can be raised whether or not life forms can be patented?

Article 27 of the agreement on trade related aspects of intellectual property rights (TRIPS) talks about subject matter which is patentable and part (b) of clause 3 *i.e.* (27.3.b) states members may also exclude from patentability plants and animals other than microorganisms, and essentially biological processes for the production of plants and animals other than non-biological process and microbial processes. However, members shall provide for the protection of plant variety either by patents or by an effective *sui generis* system or by any combination thereof.[16] It prohibits the patenting of plants, animals and biologically produced plants and animals though microorganism and plant and animals produced through non-biological process can be patented. However, pants varieties can be patented under patent protection regime or through a system particularly created for the purpose (*sui generis)* or through a combination of both. The meaning of '*Sui generis*' is interpreted in numerous ways. There are two school of thought, one school of thought is of the opinion that plants and animals should be excluded from the patenting and plant varieties should be made eligible for patent protection. Others believe that plant varieties are given enough protection under the patent law regime and the missing element is absence of farmer's and plant breeder's right.[17]

[14] Oxford's Learned Dictionary, <https://www.oxfordlearnersdictionaries.com/definition/english/life-form> accessed on 17th November, 2021

[15] Cambridge Dictionary, < https://dictionary.cambridge.org/dictionary/english/life-form> accessed on 17th November, 2021

[16] Trips Agreement, Article 27

[17] Beatrix Tappeser and Alexandra Baier 'Who own biodiversity' (2000) https://doi.org/10.16997/eslj.228 accessed on 1st December, 2021

The year 2002 saw a remarkable change in the intellectual property law regime and especially patent law regime in India. It was the introduction patent amendment act 2002, prior to 2002 there was a blanket ban on patent protection for inventions pertaining to natural or artificial living entities. These changes were brought by introduction of section 3(j).

The meaning of Section 3(j) has been derived from Article 27.3 (b) of the TRIPS agreement. The section states that invention which are not patentable include plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals.[18] This section was inserted in the act through 2002 amendment act.[19] The section alike the Article 27.3 (b) of TRIPS, prohibits patenting of plants and animals in whole or parts thereof but allows patenting of seeds, microorganisms, varieties and species and essential biological processes for production and propagation of plants and animals. The term "essentially biological process" is not defined in the act, hence making the interpretation of it a subjective issue.

The Convention on the Grant of European Patents (European Patent Convention) in its Article 53 (b) state that patent shall not be granted on plant and animal varieties or essentially biological processes for the production of plants and animals; this provision shall not apply to microbiological process or the products thereof.[20] It imposes prohibition on grant of patents to plant and animal varieties or essentially biological process but allows patenting of microbiological process or the products thereof. The meaning of "essential biological process" is given in rule 25 (b) (5) of European Patent Convention which states "process for the production of plants animals is essentially biological if it consists entirely of natural phenomena such as crossing or section.[21]"

Now from the above statues it can be deduced that life forms can be divided into three major categories

1. Plants
2. Animals
3. Microorganisms

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## ❖ Patenting of Plants

This can also be viewed as patenting of agricultural activities. In India development of new plant varieties has been an issue for the authorities. India became a signatory to TRIPS agreement in 1994 and automatically had to comply with Article 27.3 of the agreement which says that protection of

[18] Patent Act 1970, section 3(j)
[19] *See* Patent Amendment act (2002)
[20] Convention on the Grant of European Patents (European Patent Convention) of 5th October 1973 as revised by the Act revising the EPC of 29 November 2000, Article 53 (b)
[21] Krishna & Saurastri, Analysis of section 3(j0 of the Patents Act, 1970 (2012) < https://www.asiaiplaw.com/article/analysis-of-section-3j-of-the-patents-act-1970> accessed on 1st December, 2021

plant variety is either by patent or by *sui generis* system or by combination of both.[22] It was the responsibility of the member countries to draft their own legislations. India mounted its own legislation known as Protection of Plant Varieties and Farmer's Rights Act 2001. All categories of plants except microorganism are covered in the act. The act contains specific provisions relating to registration of newly developed plant varieties. It also prevents the unauthorised use of registered plant varieties. Chapter 3 of the act provides for application of registration. Section 14 of the act states

*any person specified in section 16 may make an application to the Registrar for registration of any variety—*

*(a) of such genera and species as specified under sub-section (2) of section 29 (the Central Government shall, by notification in the Official Gazette, specify the genera or species for the purposes of registration of varieties other than extant varieties and farmers' varieties under this Act); or*

*(b) which is an extant variety; or*

*(c) which is a farmers' variety*.[23]

It means that any person who is allowed to make an application under section 16 of the act for registration can make an application to the registrar of any species or genera mention under section 29 (2) of the act or for an extant variety which means a variety available in India[24] or a farmer's variety which means any variety which has been cultivated or developed by the farmers in their fields, or varieties that are wild or relative or land race of any variety about which farmer possesses common knowledge[25].

Section 15 of the act extensively explains varieties which can be registered

*(1) A new variety shall be registered under this Act if it conforms to the criteria of novelty, distinctiveness, uniformity and stability.*

*(2) Notwithstanding anything contained in sub-section (1), an extant variety shall be registered under this Act within a specified period if it conforms to such criteria of distinctiveness, uniformity and stability as shall be specified under the regulations.*

*(3) For the purposes of sub-sections (1) and (2), as the case may be, a new variety shall be deemed to be— (a) novel, if, at the date of filing of the application for registration for protection, the propagating or harvested material of such variety has not been sold or otherwise disposed of by or with the consent of its breeder or his successor for the purposes of exploitation of such variety— (i) in India, earlier than one year; or (ii) outside India, in the*

[22] Rekha Mittal and Gian Singh, Patenting Agricultural Activities from India (2005) < http://www.nbpgr.ernet.in/pgs-503/020_agril_patenting_india.pdf> accessed on 1st December 2021
[23] Protection of Plant Variety and Farmer's rights Act 2002, Section 14
[24] Seeds Act, 1966, section 5
[25] Kaye Lushington, The registration of plant varieties by farmers in India: A Status Report, < http://www.ras.org.in/print/the_registration_of_plant_varieties_by_farmers_in_india>

*case of trees or vines earlier than six years, or in any other case, earlier than four years, before the date of filing such application: Provided that a trial of a new variety which has not been sold or otherwise disposed of shall not affect the right to protection: Provided further that the fact that on the date of filing the application for registration, the propagating or harvested material of such variety has become a matter of common knowledge other than through the aforesaid manner shall not affect the criteria of novelty for such variety; (b) distinct, if it is clearly distinguishable by at least one essential characteristic from any another variety whose existence is a matter of common knowledge in any country at the time of filing of the application. Explanation.—For the removal of doubts, it is hereby declared that the filing of an application for the granting of a breeder's right to a new variety or for entering such variety in the official register of varieties in any convention country shall be deemed to render that variety a matter of common knowledge from the date of the application in case the application leads to the granting of the breeder's right or to the entry of such variety in such official register, as the case may be; (c) uniform, if subject to the variation that may be expected from the particular features of its propagation it is sufficiently uniform in its essential characteristics; (d) stable, if its essential characteristics remain unchanged after repeated propagation or, in the case a particular cycle of propagation, at the end of each such cycle.*

*(4) A new variety shall not be registered under this Act if the denomination given to such variety— (i) is not capable of identifying such variety; or (ii) consists solely of figures; or (iii) is liable to mislead or to cause confusion concerning the characteristics, value identity of such variety or the identity of breeder of such variety; or (iv) is not different from every denomination which designates a variety of the same botanical species or of a closely related species registered under this Act; or (v) is likely to deceive the public or cause confusion in the public regarding the identity of such variety; or (vi) is likely to hurt the religious sentiments respectively of any class or section of the citizens of India; or (vii) is prohibited for use as a name or emblem for any of the purposes mentioned in section 3 of the Emblems and Names (Prevention of Improper Use) Act, 1950 (12 of 1950); or (viii) is comprised of solely or partly of geographical name:*

*Provided that the registrar may register a variety, the denomination of which comprises solely or partly of a geographical name, if he considers that the use of such denomination in respect of such variety is an honest use under the circumstances of the case.*[26]

Under Protection of Plant Varieties and Farmer's Rights Act only plant varieties can be granted patent protection. If they are found in distinct, stable and uniform form. Seed Varieties cannot be patented in India. By doing this India has also ensured farmer's rights are protected and not allowing any person to control the food supply.

The act provides an extensive mechanism regarding grant of compulsory licence. According to section 47 (1) of the act any person interested may make an application to the authority stating the reasonable requirements of the public for seed or other propagating material of the

[26] Protection of Plant Variety and Farmer's rights Act 2002, Section 15

variety have not been satisfied of that the seed or other propagating material of the variety is available to the public at an exorbitant price. In such a scenario, any person after the expiry of three years can apply for a compulsory licence to undertake production, distribution or sale of the seed or other propagating material of that variety.

Even though legislations are present still Indian market cannot sustain the monopoly created by big corporates who acquire patent protection on a plant variety. This comes at cost where traditional farmers of India are to suffer. This also seen in the case of ***Pepsi Co v. Farmers***[27]

In 2019 Pepsi Co sued nine farmers from Gujarat seeking a whooping amount of Rs. 1.05 crore as compensation for infringement on variety of the potato from each farmer. It was alleged by the multinational company that the accused had used FC5 (commercial name) potato variety over which the company held patent protection since 2016. One the other hand the accused claimed that they had bought these potato seeds locally in a market known as grey market. The case stirred up a lot controversy and the time general elections were on the outset. Pepsi Co. withdrew the case. On 3rd December 2021, a new development took place where Pepsi Co. patent over F5 potato variety was revoked by the Protection of Plant Variety and Farmer's Right Authority.[28]

❖ **European Scenario on Registration of Plant variety**

One such plant variety which has been granted patent protect is 'golden rice'. It is a genetically modified form of rice which is viewed as more nutritious than normal rice. A group of European scientists spear headed by Dr Ingo Potrykus and Peter Byer brought into existence genetically engineered rice which contains components of beta- carotene, by injecting bacteria and daffodil along with maize genes into it. On transfusion of the same the grains of the rice turn golden, hence the name 'golden rice' is given to it. It is believed that this special variety of rice can curb Vitamin- A and other kind of nutrient deficiencies.[29] It is a known fact that deficiency of vitamin -A has caused millions of deaths and majority of them are children and it has also a major factor for blindness.[30] This technology was patented

[27] Vidushi Trehan, 'Pepsi Co. v. Farmers' (2019), < https://www.mondaq.com/india/corporate-and-company-law/829552/pepsico-vs-farmers-a-case-of-misplaced-priorities-or-possibility-of-laying-down-a-news-precedent> accessed on 3rd December 2021

[28] https://www.reuters.com/article/us-india-pepsi-farmers-idUSKCN1S21E accessed on 4th December 2021

[29] Grain and MASIPAG, 'Don't get fooled again! Unmasking two decades of lies about Golden rIce' (2018) https://grain.org/en/article/entries/6067-don-t-get-fooled-again-unmasking-two-decades-of-lies-about-golden-rice accessed on 1st December 2021

[30] Ed Regis, The True Story of Genetically Modified Superfood that all most saved Millions (2019) < https://foreignpolicy.com/2019/10/17/golden-rice-genetically-modified-superfood-almost-saved-millions/> accessed on 1st December

Ingo Potrykus and Peter Byer and they licenced the rights over the technology to Syngenta. In order to make their technology workable, Syngenta licensed it to Monsanto and after some time they licenced it back to inventors for humanitarian use.[31]

## ❖ Patenting of Animals

Animals developed as a result of recombinant DNA technology also known as genetic engineering are called patentable animals. In world of science they are referred to as transgenic animals. It is DNA (deoxyribonucleic acid) in living creatures which contains information and is essential for cells to grow into a living creature.[32] A number of smaller units known as genes are joined together to form a DNA. Genes are the building blocks which determine characteristics of a creature. [33] The practice of intertwining and manipulation of genes in several ways is known as Recombinant DNA (rDNA) technology. Apart from rDNA technique there are several other slow and unpredictable breeding techniques which are used to produce animals with specific traits. In traditional breeding techniques the breeds selects the animal to be bred with specific traits and mating is done in order to acquire an offspring with specific traits. The results of this technique are unpredictable, because desired gene is not identified and transferred by itself.[34] One the other hand, classic breeding techniques or genetic engineering involves altercation of animals through inserting DNA from other species or animals or from a human being.[35] The method which most frequently used is known as 'microinjection' and there are various steps to it.[36] The process includes separation of a desired gene from the original creature. The gene is then microinjected by way of a glass tube into a fertilized embryo of the done species while it still at the single stage cell.[37] There is a possibility that foreign gene is passed to the offspring as it will be part of the sperm cell or egg cell as well.[38] These transgenic animals are used for research purposes by many research institutions. The development of a transgenic animal is a capital intensive and time

[31] Grain and MASIPAG, 'Don't get fooled again! Unmasking two decades of lies about Golden rIce' (2018) https://grain.org/en/article/entries/6067-don-t-get-fooled-again-unmasking-two-decades-of-lies-about-golden-rice accessed on 1st December 2021

[32] Elizabeth Joy Hecht, Beyond Animal Legal Defense Fund v. Quigg: The Controversy Over Transgenic Animal Patents Continues, 41 Am. U. L. RPv. 1023, 1026 (1992)

[33] *Id*

[34] *Id*. at 1028 n. 21. The term 'selected' here means the random sampling that occurs when one item is chosen out of many.

[35] *Id* at 1207

[36] Rebecca Dresser, Ethical and Legal Issues in Patenting New Animal Life, 28 JUiME-mcs J. 399, 405 (1988)

[37] *Id*

[38] *Id*

consuming process.[39] The only practical way is to recoup investment is through patent protection.[40] The inventors may recoup their investment through royalties.[41] One such method of creating transgenic animals is known as cloning.

❖ **Oncomouse**

In 1988 first transgenic animal known as oncomouse was granted patent protection in the United States. Oncomouse was created using a fine needle to inject cancer in the embryo of the mouse just after fertilization. This change in the genetic composition of the mouse made the mouse cancer prone and it was ensured that these cancer genes are passed onto the progeny. Oncomouse was developed by Philip Ledger and Timothy Stewart from Harvard for the purpose cancer research specifically breast cancer.[42]

❖ **Cloning**

Cloning involves producing identical copies of an organism or cell. In animals the term clone is used to refer the offspring produced by the process of nuclear transfer, wherein an intact genome is transferred to the recipient cell from the donor cell. The offspring is the genomic copy of the nuclear donor. [43] Cloning can be broadly classified into three types:-

- Gene Cloning
- Therapeutic Cloning
- Reproductive Cloning

- Gene Cloning - The process in which the required gene is cloned out from the DNA molecule of an organism. The method is used create copies of specific genes for process like sequencing, mutagenesis, genotyping and heterologous expression of a protein. It involves shifting of the DNA fragment of interest from one organism to a self - replicating genetic element like bacteria plasmid. [44] This type of cloning is also known as molecular cloning.[45]

[39] Louis A. Schapiro,' The Role of Intellectual Property Protection and International Competitiveness', 58 ANTITRUST 569, 572 (1989).
[40] *Id*
[41] *Id*
[42] Wipo Magazine, Bioethics and patent law: The case of oncomouse https://www.wipo.int/wipo_magazine/en/2006/03/article_0006.html accessed on 5th December, 2021
[43] K.H.S Campell, Brenner's Encyclopedia of Genetics (second edition), 2013
[44] *See https://www.bio-rad.com/en-in/applications-technologies/introduction-gene-cloning-analysis?ID=LUSNKO4EH>* accessed on 4th December 2021
[45] Michael Rugnetta, 'Cloning' https://www.britannica.com/science/cloning/Ethical-controversy accessed on 4th December, 2021

- Therapeutic Cloning – It is used for extracting stem cells from the cloned embryos, without embryo implantation in the womb. Under therapeutic cloning the stem cells that are genetically identical are cultured and then differentiated. These differentiate cells are then transplanted into the patient's body in order to cure the disease. According to research, many diseases like Alzheimers, Parkinson's, diabetes mellitus, stroke and spinal cord can be treated using therapeutic cloning. [46]

- Reproductive Cloning – The implantation of a cloned embryo into an actual or an artificial uterus is referred to as reproductive cloning.[47]

❖ ***Dolly the Sheep***

On 5th July 1996 the first ever clone of an adult mammal was produced by British development biologist Ian Wilmut, Kieth Henry and Stockman Cambell through nuclear transfer from a cell taken from the mammary gland of the donor. The nucleus fused with an oocyte and an embryo develops. The developed embryo is implanted into a surrogate mammal. This is also known as somatic method of cloning and was patented at United States Patent and Trademark Office (USPTO) and assigned Roslin Institute, Edinburgh.[48] They also had submitted another application on Dolly sheep as a product. USPTO rejected that application stating subject matter of patent excludes "laws of nature, natural phenomenon and abstract ideas".[49] The Roslin Institute later appealed the decision of USPTO but Patent Trial and Appeal Board upheld the decision. The matter went to the U.S Court of Appeals in Federal Circuit at Washington and a three judge panel opined that since the DNA extracted to develop Dolly is found in animals which exist naturally, her similar genetic identity to her donor is the reason patent protection cannot be provided.

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❖ ***Ass'n for Molecular Pathology v. Myraid Genetics, Inc***

The U.S Supreme Court held that a naturally occurring DNA segment was a product of nature and patent protection under 35 U.S.C.S & 101 just because it isolated from entire segment. Although, cDNA was eligible for patent protection as it was artificially developed. In isolating the genes, the laboratory found important and useful genes but did not create or alter either the genetic information encoded in the genes or the genetic structure of the DNA, and the location and order of the genetic sequences existed in

[46] *Id*
[47] *Id*
[48] Gilat Bareket and Co., Reinhold Cohn Group, 'The Saga Of Patenting Dolly' https://www.lexology.com/library/detail.aspx?g=0dcc72d6-7535-480c-9eef-39c98eb5fc67 accesed on 4th December 2021
[49] Kelly Servick, No Patent for Dolly The Cloned Sheep, Court Rules, Adding to industry jitters https://www.science.org/content/article/no-patent-dolly-cloned-sheep-court-rules-adding-industry-jitters accessed on 4th December, 2021

nature before the laboratory isolated them. However, cDNA which removed codes for anything other than amino acids was not a product of nature and was patent eligible since the removal of the unwanted codes unquestionably created something new.[50]

## ❖ Patenting of Microorganisms

A microorganism can be essentially defined as which can only be view under a microscope. Under the umbrella of the term microorganism many microscopic organism are included bacteria, fungi, viruses, algae and protozoa are few among them. The Directive of The European Parliament and The Council defines microorganisms as "any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including viruses, viroids, and animal and plant cells in culture."[51] There has always been a question mark on the patentability of genetically modified microorganisms. The Directive of The European Parliament and The Council has also defined genetically modified microorganisms as "a micro-organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination; within the terms of this definition:

(i) genetic modification occurs at least through the use of the techniques listed in Annex I, Part A;

(ii) the techniques listed in Annex I, Part B, are not considered to result in genetic modification"[52]

The question was first answered by the United States of America in the case of ***Diamond v. Chakrabarty*** [53]

Anand Chakrabarty a microbiologist and research of the General Electric Company filed a patent application with respect to bacteria from the genus pseudomonas which was genetically modified bacteria. The man- made bacteria had the ability to break down the components of crude oil, it was affirmed that the invention could treat oil spills.

There claims were made in the patent applications:-

- The claim over the method of producing bacteria.
- The claim over immunization which consisted of a carrier material floating on water such as straw and the new bacteria.
- The claim over the bacteria itself.

[50] Ass'n for Molecular Pathology v. Myraid Genetics , Inc- 569 U.S 576, 133S.Ct. 2107 (2013)
[51] Directive of The European Parliament and The Council, Article 2 (a)
[52] *Id*, Article 2(b)
[53] Diamond v. Chakrabarty 447 US 303 (1980)

The patent examiner held that only first two claims were eligible and rejected the third claim on the grounds that

- The microorganism are the products of nature
- These products of nature are classified as living organisms hence they are not patentable subject matter.

The Patent Office of Board of Appeals upheld the decision of the examiner on the ground that microorganisms are living creatures hence they do not fall under the ambit of patentable subject matter. The matter went to Court of Customs and Patent Appeal and for the first time it was held that the bacteria wasn't part of nature rather a human invention which deserves patent protection. The court stated that the main issue was whether the bacterium constituted an invention made by human intervention. The U.S Supreme Court critically analysed the matter and read the term manufacture base don it's dictionary definition as production of articles for the use from raw or prepared material by giving these materials a new form, qualities, properties or combinations whether by hand labour or by machinery. The court examined the intention of legislators while drafting the legislation and use of broad terminology such as "any composition of matter" or "manufacture". The court deduced a rationale that the drafters used broad language while drafting because they wanted to encourage innovation in a wide range and observed that according to the legislative history of patent law regime patentable subject matter includes "anything under the sun made by a man." As a result for the first time patent protection to microorganism was granted.

❖ **Indian Context**

In the case of ***Dimminaco AG v. Controller of Patents***[54]an appeal was filed against the Assistant Controller of Patents and Designs as infectious Bursitis vaccine was denied patent protection on the ground that the term 'manufacture' does not include process of preparation of virus and as virus is considered a living creature hence it cannot be categorised as inanimate substance. The Calcutta High Court held that the word 'manufacture' includes process of preparing a vendible commodity. Court added that the end product is eligible for patent protection as it fulfils the criteria of novelty and is capable of industrial application. As a result petitioner's patent application was allowed.

***Monsanto Technologies Pvt. Ltd v. Nuziveedu Seeds***[55]

Monsanto Technologies contended that there no patent infringement under section 3(j) of the Patents Act, 1970 and their patent is a man-made chemical product called Nucleotide Acid Sequence (NAS) which was inserted with *Bacillus thuringiensis* (Bt gene). The genetically modified form of NAS was capable of killing ballworms when inserted in cotton. Nuziveedu claimed that NAS wasn't a man-made invention and lacked the patent

[54] (2002) I.P.L.R 255 (Cal)
[55] AIR (2019) SC 559

criteria of industrial application.[56] The division bench of Delhi High Court overturned the decision of the trial court and held that invention was patentable subject matter under section 3(j) of the Patents Act, 1970. The Supreme Court set aside the order of the division bench and restored the order of the trail court. The suit was remanded back to the trail court for disposal in accordance with law.

**Suggestions and Conclusions**

In today's world scientific advances are happening every other day. New inventions are appearing every day. In these times there is a need of a robust patent law regime. It is a fact that increase in inventions leads to increase in filing of patent applications. It is really important to understand that the subject matter covered under biotechnological invention is extremely complex. The outset of Patent Amendment Act, 2002 has brought many changes in the patent protection with respect to biotechnological inventions. Introduction of section 3(j) of the Patents Act, 1970 has proved that India is also evolving with dynamism of science and technology field. Introduction Protection of Plant Variety and Farmer's Rights Act 2001 has provided opportunities to farmers, breeders and researchers and ensures that their rights are protected at all times. The act has also provided a *sui generis* system with respect to registration of new plant varieties. In the author's opinion it is unfair to compare India with nations such United States of America and England or for that matter other developed nations on the basis of patenting of life forms. We need to consider factors like economic disparity, poverty and availability of resources between India and other developed nations. Agriculture is the backbone of the Indian economy therefore patenting of certain agriculture products can have an unpleasant impact on the financial situation of the poor farmers of the country. The revocation of patent license of Pepsi Co. over its F5 potato variety by the office of protection plant variety shows that the system has not turned a blind eye towards the indigent of the country. On the other hand the decision of Calcutta High Court in case of ***Dimminaco AG v. Controller of Patents*** shows that Indian patent regime is matching with the patent regime of other developed countries where it's possible.

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[56] Nidhisha Garg, Monsanto v. Nuziveedu : A missed opportunity by the Supreme Court? (2020) < http://patentblog.kluweriplaw.com/2020/01/27/monsanto-v-nuziveedu-a-missed-opportunity-by-the-supreme-court/> accessed on 5th December, 2021