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PATENTABILITY OF GENETIC ENGINEERING: SCOPE IN INDIA

Yasha Sinha[*]

ABSTRACT

Genetic engineering is a quickly developing area of innovation that can possibly reform the manner in which we live, work, and connect with our general surroundings. At the heart of this field lies the ability to manipulate the genetic code of living organisms, allowing us to create new and improved products, medicines, and crops. The patentability of genetic engineering has been a topic of significant interest in the legal community. In India, the patentability of genetic engineering has been a topic of debate for several years. This research paper provides an overview of the patentability of genetic engineering in India and explores the scope of this field in the country. The paper begins with an introduction to genetic engineering and what all genes or parts of genes can be patented. It then discusses the scope of genetic engineering in India following to this the legal framework for patentability in India further with regards to TRIPS agreement and the criticism of TRIPS agreement for the patentability of genetic engineering. The paper then discusses about Protection of Plant Varieties and Farmers' Rights Act and it's relation with Patent Act 1970 and TRIPS agreement and following this includes the relevant statutes and landmark case laws. Finally, the paper explores the scope of genetic engineering in India, including its potential benefits and challenges.

KEYWORDS: *Genetic engineering, Patent, Plant variety, Gene, Biotechnology, Innovation, TRIPS, Micro-organism, Living organism, Technology, Invention*

1. INTRODUCTION

A development, which may be an item or an interaction that for the most part offers another strategy for following through with something or another innovative answer for an issue, is given a selective right via a patent[1]. An invention is patentable in the sense of a national or international body of law if it satisfies the necessary legal requirements for a patent to be issued. The term "patentability" is also used to describe the requirements that must be completed in order for a patent to be considered legitimate. Even though patents have been around for a while, many people are perplexed by their recent appearance in the field of genetics. The study and development of genes is a key component of

[*] 5th Year BBA LLB(Hons.), MIT-World Peace University, School of Law.

[1] What Is a Patent, *available at* https://www.wipo.int/patents/en/#:~:text=A%20patent%20is%20an%20exclusive,public%20in%20a%20patent%20application (last visited March 22, 2023)

biotechnology and is becoming more and more important. The genetic researcher has the ability to access an array of information and understanding attributable to gene sequence. Although the patentability requirements outlined in patent laws apply to innovations in all disciplines of technology in the same way, the application of patent law to biotechnological inventions must deal with several particularities that might not exist in the same way in other areas of technology[2].

A review of the literature on the Patentability of Genetic Engineering in India reveals a range of views on the subject. Some authors argue that patents are essential for promoting innovation in the field of genetic engineering, as they provide an incentive for researchers and companies to invest in the development of new technologies. One example of an author who argues that patents are essential for promoting innovation in genetic engineering is *S. Suresh Kumar*, in his article *"Patentability of Biological Inventions: A Review of Indian and International Perspectives"* (2014)[3]. Kumar contends that licenses give a significant motivation to organizations and specialists to put resources into the improvement of new hereditary advances, which can prompt critical advances in fields like medication and horticulture. He also says that patents can help inventors protect their rights and make sure they can get back what they spent on research and development.

Another example of an author who makes a similar argument is *K.S. Jayaraman*, in his article *"Gene Patents and Biotechnology Innovation in India"* (2012)[4]. Jayaraman notes that the patent system provides an important mechanism for protecting the intellectual property rights of inventors, which can help to encourage investment in research and development. He argues that without the ability to obtain patents, companies and researchers may be less willing to invest in genetic engineering technologies, which could slow down the pace of innovation in this field.

2. WHAT IS GENE?

A gene is a segment of DNA or Deoxyribonucleic acid that contains the genetic

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2 Patent Expert Issues: Biotechnology, *available at* https://www.wipo.int/patents/en/topics /biotechnology.html (last visited March 22, 2023)

3 Kumar, S. Suresh. "Patentability of Biological Inventions: A Review of Indian and International Perspectives." Journal of Intellectual Property Rights, (JIPR) vol. 19, no. 5, 2014, pp. 221-230

4 Jayaraman, K.S. "Gene Patents and Biotechnology Innovation in India.", *Journal of Intellectual Property Rights*, (JIPR) vol. 17, no. 5, 417-427 (2012)

code for a specific protein or trait [5]. It is the fundamental unit of heredity that is inherited from one set of parents by another. The form of the two twisted DNA strands, known as a helix, resembles that of a spiral ladder. The four nucleotides that cosmetics DNA are adenine (A), thymine (T), guanine (G), and cytosine (C). Base pairs join the two DNA strands together when the nucleotides A with T and G with C bind to one another[6]. Genes are compact DNA molecules that contain particular genetic information. The growth, development, and operation of all living things are governed by genes, which are found on chromosomes inside the cell nucleus. The study of genes and their functions is known as genetics, which is a key field in biology and biotechnology. The discovery of the DNA molecule's structure led to a significant development in technology. Since then, researchers have worked to identify these molecules' molecular sequences, as well as their functions, and have even experimented with modifying them to get certain outcomes.

3. GENETIC ENGINEERING

Genetic engineering is the process of manipulating the genetic material (DNA or RNA) of an organism to alter its characteristics, often by inserting or deleting specific genes or DNA sequences. This innovation permits researchers to change the hereditary code of a living being in an exact and designated way, which can prompt the creation of new items or the improvement of existing ones. The creation of new medicines, the investigation of genetic disorders, and the creation of genetically modified organisms (GMOs) for agricultural and industrial purposes are just a few of the many uses for genetic engineering. It includes different procedures, like recombinant DNA innovation, CRISPR-Cas9 genome altering, and quality treatment. Genetic engineering has a large number of utilizations in different fields, including farming, medication, and biotechnology. A few models incorporate making crops that are impervious to bugs or sicknesses, creating immunizations and therapies for hereditary issues, and delivering new medications or biofuels.

New technologies and products, many of which are the subject of patents, have been developed as a result of genetic engineering. It very well may be protected in specific situations, for example, when it prompts the making of a novel and non-clear item or cycle that is helpful, new, and not recently known. Licenses are lawful instruments that furnish the proprietor with select freedoms to

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5 National Human Genome Research Institute, Gene, *available at* https://www.genome.gov/genetics-glossary/Gene (last visited on March 21, 2023)

6 U.S. Department of Health and Human Services, National Institutes of Health, *available at* https://www.cancer.gov/publications/dictionaries/genetics-dictionary/def/gene (last visited on March 21, 2023)

utilize, sell, or permit the innovation for a restricted timeframe, normally a long time from the date of recording. In addition, the patentability of genetic engineering is governed by various national legal frameworks. For instance, the European Association has stricter guidelines on the protection of hereditarily altered living beings (GMOs) contrasted with the United States[7]. In general, patent offices around the world require a thorough examination of the novelty, inventiveness, and usefulness of the genetic engineering invention before granting a patent.

4. WHAT ALL GENES OR PART OF IT CAN BE PATENTED?

Overall, the patentability of genetic engineering remains a complex issue that requires a careful balance between promoting innovation and protecting the public interest. The phrase "patenting of DNA and genetic sequences" is an overall one that covers the most common way of distinguishing, confining, and safeguarding DNA or its related materials, like RNA, as well as substance compounds connected to DNA, like proteins and peptides. Genes, DNA sequences, cDNA, expressed sequence tags (ESTs), and single nucleotide polymorphs (SNPs) are among the genetic components that can be patentable.

Any of the following DNA-related innovations might exist when to comes to the patentability of genes:

1. mRNA (messenger RNA) which is encoded by the DNA to express a protein;
2. cDNA (complementary DNA), that is a DNA without introns matching the sequence of the mRNA, which provides the exact DNA sequence of the expressed protein;
3. isolated and purified DNA sequence such as genomic DNA coding for a gene, or a fragment thereof;
4. oligonucleotides;
5. Proteins or polypeptides;
6. DNA markers
7. Recombinant (genetically modified) DNA including recombinant plasmids or recombinant vectors;
8. Genetically modified organisms such as genetically modified bacteria, fungi, plants and animals[8]

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7 Smita Srivastava, "Gene Patenting In Plants: Indian Scenario", *Journal of the Indian Law Institute*, ILI Law Review Vol. II, 239 ,241-242 (2019)

8 Malathi Lakshmikumaran, "Patenting of Genetic Inventions", *Journal of Intellectual Property Rights*, (ILI), Vol 12, January, pp 45, 46, (2007)

5. PATENTABILITY OF GENETIC ENGINEERING:

The patentability of genetic engineering has been a topic of significant interest in the legal community. Recent advances in biotechnology have opened up the historically unprecedented potential for both people and industrial growth. It is now the technology that is advancing the quickest worldwide. There are now several research institutes operating in the field of contemporary biotechnology, both governmental and private, with a robust national scientific research infrastructure[9]. However, the development of contemporary biotechnology has brought up a number of crucial challenges, one of which is Intellectual Property Protection (IPP). In India, the Patents Act, of 1970 governs the patentability of genetic engineering.

Genetic engineering, microbiology, medical inventions, and biotechnological inventions are examples of inventions that may be eligible for patent protection under Indian patent law as of the year 1970 can be categorised as:

1. Animals, plants, and other living things of a natural origin that are whole or in part cannot be patented.
2. Microorganisms and technologies based on terminator genes are not patentable.
3. It is not possible to patent biological components like tissues, organs, viruses, etc. or the methods used to create them. Recombinant DNA, plasmids, and their production processes, however, are patentable examples of biotechnological materials.
4. Without a functional explanation, gene and DNA sequences are not patentable. The creation of chemical compounds utilizing such microbes or processes pertaining to microorganisms are, nonetheless, patentable[10].
5. The act of cloning a human being or an animal is not patentable[11].

India's patent framework is constrained by two bits of regulation: the Licenses Act, 1970 (No. 39 of 1970), as amended by the Patents (Amendment) Act of 2005 and the Patents Regulations of 2003, as amended by the Patents (Amendment) Rules of 2006, both of which came into effect on May 5, 2006. In general, patentability requirements include novelty, inventive steps, and industrial applicability. The first prerequisite that must be met is novelty. The innovation

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9 Griliches Z, "Patent statistics as economic indicators: A survey", *Journal of Economic Literature*, 28(4), 1661-1707, (1990)

10 Eisenberg R, "Genes, patents and product development*", Science*, 257(5072), 903-908, (1992)

11 Hellar AM, Eisenberg SR, "Can patents deter innovation, The anticommons in biomedical research.", *Science*, 280(5364), 698-701, (1998)

must be original, that is, distinct from "prior art," according to *Section 2(1)(j)* of the Indian Patents Act. In other words, it shouldn't have been made public before the application's filing date anyplace in the globe. According to *Section 2(1)(ja)* definition, a "inventive step" is a component of an invention that includes technical advancement relative to the state of the art, has economic importance, or both, and prevents the invention from being apparent to a person versed in the art. As qualities and quality items are viewed as substance elements and can be protected in most patent workplaces on the off chance that they are purged and secluded from the structure wherein they happen in nature, the necessity of creativity as to qualities and quality items is promptly satisfied.

According to *Section 3(c) of the Patents Act 1970*, no living entity or non-living substance found in nature would be allowed to be patented. The same goes for the discovery of a scientific concept or the formulation of an abstract theory. A gene that naturally occurs and is not patentable in accordance with Section 3 (c). Nonetheless, it should be highlighted that determining the purpose, location, and isolation of a gene requires a great deal of talent. Section 3(j) of the Act excludes patents for “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”. However, the Act allows the patenting of genetically modified microorganisms, as they are not considered to be naturally occurring. The prohibition under section 3(h) of the Patent Act, barring "strategies for farming or cultivation" from patentability, was explicitly expressed to apply to "developments in the field of plant proliferation by agamic techniques in the *Ayyangar Committee Report of 1959*, on the basis of which the Patents Act was enacted.

According to the examination guidelines for patent applications relating to inventions in the fields of chemicals, pharmaceuticals, and biotechnology, [Annexure 1, Manual of Patent Practice and Procedure, Patent Office (2005), India][12] gene and DNA sequences are not patentable if functions (utility for the genetic inventions) are not disclosed. The Microbial Type Culture Collection and Gene Bank (MTCC) in India was named an International Depository Authority (IDA) by the WIPO on October 4, 2002. Subsequently, it turned into the first IDA in Quite a while, the 6th in Asia, and the third-most noteworthy on the planet.

[12] Malathi Lakshmikumaran, “Patenting of Genetic Inventions”, *Journal of Intellectual Property Rights*, (ILI), Vol 12, January,45, 51, (2007)

6. SCOPE OF GENETIC ENGINEERING PATENTS IN INDIA

The scope of genetic engineering patents in India is vast, and the field has seen numerous advancements in recent years. One example of the scope of genetic engineering patents in India is in the field of agriculture. In 2016, the Indian Council of Agricultural Research filed a patent application for a genetically modified variety of cotton that is resistant to bollworm infestations. This patent application was granted in 2020, and it is an example of the scope of genetic engineering patents in India.

In the field of medicine, genetic engineering has also shown significant promise. Chemicals and pharmaceuticals were the two main industries in which Indian businesses received patents between 1990 and 2002, according to data on patents awarded to them in various sectors. A review of Indian patent applications during 2003–2004 reveals that the chemical and pharmaceutical industries continued to be the main focus of this country's patent applications during this time. Over these two years, the pharmaceutical industry had 213 patents (46 percent of all patents), whereas the chemical industry had 125 patents (27 percent of total patents). With 48 patents awarded during this time, the biotechnology industry received good attention as well[13]. Genetic engineering in India has been used to develop new treatments for diseases such as cancer and hemophilia. The development of these treatments has led to numerous patent applications, and many of these applications have been granted. For example, in 2018, an Indian pharmaceutical company was granted a patent for a genetically engineered drug that treats a form of lung cancer.

7. TRIPS AND PATENT LAWS:

Alongside 116 different countries, India consented to the *General Agreement on Trade and Tariffs* (GATT) on April 16, 1994. The *Uruguay Round* of global exchange talks directed under the sponsorship of the GATT was started with the Punta del Este articulation in September 1986[14]. They are also referred to as the Trade-Related system. The negotiating mission included provisions related to intellectual property rights (TRIPS). Somewhere in the range of 1987 and 1989, emerging nations were fruitful in slowing down conversations on standards and guidelines of Licensed innovation Freedoms (IPRS). The most combative of the

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[13] Rishabha Malviya, Vineet Bhardwaj, Pranati Srivastava, Mayank Bansal, Pramod Kumar Sharma, "Biotechnological Innovations Patent: A Review*"*, *International Journal of Pharmaceutical Sciences Review and Research ISSN* 0976 – 044X, Volume 3, Issue 2, July – August Article 024, (2010)

[14] C. Niranjan Rao, "Patents for Biotechnology Inventions in TRIPs", *Economic and Political Weekly*, Vol. 37, No. 22, pp. 2126, 2129, (2002)

issues in the Excursions Arrangement was that connecting with licenses. Inside this, Article 27 pulled in the most consideration since it specifies the innovation fields to be covered and exemptions for patentability. Article 27 (3) (b), which manages biotechnology licenses, is fundamental.

However, Article 27(1) of TRIPS, which mandates that all inventions of goods and processes, with the exception of plants and animals, be protected, has not been completely complied with by India. Only techniques or procedures for chemical processes have received complete patent protection in India, leaving the finished product unprotected. Furthermore, while the actual item isn't patentable, strategies planned for or equipped for being utilized as food, medication, or drug are. The precarious subject is in how "any piece of a plant" is perceived and deciphered. Does it only mean plant organs like leaves, roots, stems, and flowers, or does "any portion thereof" include plant cells as well? Claims directed at eukaryotic cells, which include plant and animal cells, are prohibited by the Indian Patent Office's current policy because they violate Section 3(j) of the Patents Act[15].

Previously, the patenting of microorganisms was believed to be equivalent to that of an item, and the protection lasted for five years and an honor date or seven years after the date of the patent application's submission. The current conceding time frame for microbiological advancement licenses is 20 years from the documenting date. India or other emerging countries don't allow the protection of microorganisms that as of now exist in nature since such organic entities are viewed as revelations under the terms of segment 3(d) of the Patent Act, which is the main contrast between lawful practices in India and industrialized nations. Nonetheless, a patent can be obtained for the same microorganisms that have undergone genetic modification in order to increase their proven efficacies. The criteria governing the prerequisites for depositing microorganisms under the Budapest Treaty, of which India is now a member, as well as the availability of that microbe from the depositories, are what determine whether a patent is granted with regard to microorganisms[16]. As per provision (ii) section 10(d), in the event that a microorganism isn't totally and particularly characterized and isn't open to the overall population, it should be saved with the International Depositary Authority in accordance with the Budapest Treaty of 2002.

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15 "Patentability of transgenic & genetically modified plants in India, *available at* https://www.lexology.com/library/detail.aspx?g=2aecaf10-9631-4758-a83c-a04eadcce49f (last visited on March 22, 2023)

16 Suja Senan, M. G. Haridas, J. B. Prajapati, "Patenting of microorganisms in India: a point to ponder", *Current Science*, Vol. 100, No. 2,159-162, (2011)

The TRIPS agreement has drawn criticism for two reasons. It puts at risk the ability to develop nations to produce or import affordable generic copies of proprietary medicines. At a time when the AIDS pandemic and other illnesses are so prevalent, this is especially wicked. Furthermore, TRIPS compels all members to adopt a variety of new biotech patents that cover genes, cell lines, organisms, and living things by forcing them to accept these "patents on life" through indirect means[17].

The *Protection of Plant Varieties and Farmers' Rights Act, 2001 (PPVFR Act)* is a regulation enacted in India to safeguard the freedoms of plant reproducers and ranchers. The act accommodates the foundation of an arrangement of insurance for new plant assortments and perceives the privileges of ranchers to save, use, sow, resow, trade, offer or sell their homestead produce, including seed of a safeguarded assortment. Concerning the patentability of hereditary designing, the PPVFR Act gives that any assortment which is basically gotten from an assortment enrolled under the Demonstration will likewise be enlisted, given that it is particular, uniform and stable. This intends that in the event that another assortment is made utilizing hereditary designing methods, it very well might be qualified for enlistment under the Demonstration, given that it meets the models of peculiarity, consistency, and soundness. Nonetheless, it is critical to take note of that the PPVFR Act doesn't accommodate patent security for plant assortments. All things being equal, the Demonstration accommodates the award of a "plant reproducer's right", which is a sui generis type of security that is like a patent however has a few significant contrasts. For instance, a plant raiser's right just gives insurance to the proliferating material of a safeguarded assortment, though a patent can cover a more extensive scope of developments.

The PPVFR Act also includes provisions aimed at protecting the rights of farmers, such as the recognition of their traditional knowledge and the establishment of a system of compulsory licensing. These provisions are in line with the TRIPS Agreement, which recognizes the importance of protecting intellectual property rights while also promoting public health and socio-economic development.

8. POTENTIAL BENEFITS AND CHALLENGES

The patentability of genetic engineering in India presents both opportunities and challenges, and it is important to strike a balance between incentivizing innovation and ensuring access to technology, while also addressing

[17] Mae-Wan Ho, “Why Biotech Patent are Patently Absurd- Scientific Briefing on TRIPS and Related Issues”, *Journal Intellect Property Rights*, Vol7, 151,156-160, (2002)

environmental and ethical concerns. Here are some potential benefits and challenges:

Benefits:

a) **Innovation:** Patent protection can incentivize researchers and companies to invest in genetic engineering research and development, leading to the creation of new and innovative products and technologies.

b) **Economic growth:** The development and commercialization of genetic engineering products can lead to job creation and economic growth, especially in the biotech industry.

c) **Increased food security:** Genetic engineering can possibly foster yields that are impervious to nuisances, sicknesses, and ecological anxieties, prompting expanded food security and rural efficiency.

Challenges:

a) **Access to technology:** Patent protection may limit access to genetically engineered technologies for farmers and small-scale breeders, leading to potential issues of inequality and lack of access.

b) **Monopoly power:** The grant of patents can confer monopoly power to patent holders, leading to higher prices and restricted access to genetic engineering products.

c) **Environmental concerns:** The development and use of genetically engineered crops and organisms can raise environmental concerns and risks, such as gene flow, pest resistance, and ecological impacts.

d) **Ethical concerns:** Patenting life forms raises ethical concerns related to the ownership of living organisms and the potential misuse of biotechnology.

Overall, The patenting of genetic engineering has been controversial, with some arguing that it creates monopolies on natural resources and can stifle research and development in certain fields. Additionally, there are concerns that patents on genes or genetic sequences may limit access to genetic testing and medical treatments. As such, the granting of patents in the field of genetic engineering is a complex issue that requires careful consideration of both the benefits and potential drawbacks of patent protection.

9. CASE LAWS

The case of *Diamond v. Chakrabarty (1980)*[18] is a landmark case in the field of patent law, particularly with respect to the patentability of genetically engineered organisms. The case involved a scientist named Ananda Chakrabarty who had developed a new strain of bacteria using genetic engineering techniques. Chakrabarty had applied for a patent on the bacteria, but the patent office had rejected the application on the grounds that living organisms were not patentable subject matter. The case went the whole way to the US High Court, which held that Chakrabarty's bacteria were patentable because they were a *"manufacture"* or "*composition of matter*" under the patent laws. The Court held that the fact that the bacteria were living organisms did not make them ineligible for patent protection.

The decision in Diamond v. Chakrabarty has had important implications for the patentability of genetically engineered organisms and other biotechnological inventions. It laid out that such creations are qualified for patent security assuming they meet the rules of novelty, non-obviousness, and utility. In India, the case of *Monsanto Technology LLC v. Nuziveedu Seeds Ltd. (2018*[19]*)*, discussed earlier, involved similar issues with respect to the patentability of genetically modified plant varieties. However, the Indian Supreme Court ultimately held that plant varieties were not patentable subject matter under Indian law, in contrast to the decision in Diamond v. Chakrabarty.

The case *F. Hoffmann-La Roche Ltd. v. Cipla Ltd. (2008)*[20] is again a landmark judgement given by the Honourable Delhi High Court. This case involved a dispute between two pharmaceutical companies over the patentability of a drug used in the treatment of lung cancer. The drug was a variant of the protein *"erythropoietin"*, which is naturally produced by the body to stimulate the production of red blood cells. The patent office had at first conceded a patent for the medication to Roche, yet it was subsequently tested by Cipla in light of the fact that the creation needed curiosity and imaginative step. The case went to the Delhi High Court, which held that the patent was legitimate and enforceable. This case laid out a significant point of reference for the patentability of hereditary designing developments in India, especially concerning the models of curiosity and creative step.

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18 *Diamond v. Chakrabarty*, 447 U.S. 303 (1980)

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

20 *F. Hoffmann-La Roche Ltd. v. Cipla Ltd.* (2008) 37 PTC 71 (Del)

10. CONCLUSION

The patentability of genetic engineering in India is a complex and evolving area of law. As of 2021, the Indian Patent Act allows for the patenting of genetically engineered products and processes, including those related to biotechnology and genetic engineering. However, there are certain restrictions and exclusions that apply to the patentability of such inventions, particularly with respect to the use of living organisms. Office and the Indian courts, evaluate whether a creation meets the necessities of novelty, non-obviousness, and industrial applicability. Furthermore, the Indian Patent Act likewise forces specific moral and moral limitations on the licensing of specific innovations, like those connected with human cloning and genetically modifying human microorganism cells.

The scope of genetic engineering patents in India is vast and has led to numerous advancements in fields such as agriculture and medicine. As the field of genetic engineering continues to grow, it is likely that the patentability of genetic engineering will continue to be an area of interest for legal scholars and practitioners alike.