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## Human Gene Patenting in India: An Analysis

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*Traditionally, promoting innovation and research for the advancement of beneficial results was the fundamental purpose of the patent institution. This promoted the objective of promoting time-limited exclusivity to eliminate others from using the invention. Though patents have been in existence for the longest time their contention with regard to the patentability of genes has been perplexing. This article analyzes the eligibility for patenting of genes by understanding various cases both nationally and internationally. This has been achieved by understanding what a patent is and what is the legal framework provided for patenting in India. This article has been concluded by providing the implications of granting gene patents followed by recent developments along with some concluding remarks.*

**Keywords:** *patent, exclusivity, invention, innovation, genes.*

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### INTRODUCTION

Biotechnology has proved to be a major contributing factor to the growth of the economy in the current years. There have been monumental advancements that have resulted in modern innovations and discoveries. One such discovery would be the discovery of genes formed of deoxyribonucleic acid (DNA) which is considered to be the functional and physical unit of heredity. Scientists can now proficiently exact DNA from cells to segregate segments for

research. They can also extract particular strands of DNA from the cells for synthetically creating DNA. Such a proficient discovery in the field of science is through and through an invention. With this, there arises a question that can someone take ownership of these genes and that are these inventions patentable. Gene patenting, in essence, refers to the patenting of the process in which the DNA and chemical structure is manipulated that otherwise do not exist in their original state. In this article, we shall discuss the various aspects of gene patenting rights along with some cases.

### WHAT IS A PATENT?

A patent is a right granted to the inventor by the government to prevent others from making and selling the same invention for a period of time. A patent can also be granted for improvising the previous invention. The main intention behind enacting the patent law is to encourage the inventors to keep contributing in the field and award them patenting rights for their work and inventions for the public good. In fundamental terms, a patent means a right that is granted to an inventor for the invention of any non-obvious, new, machine, useful article of manufacture, or composition of matter. The word patent is derived from the Latin term “patere” which translates as “to lay open” or in other words- to make available for public inspection.

There are three tests for checking the eligibility of granting a patent license:

*The invention must be novel (it must not already be in existence)*

In the context of patentability of genes, novelty addresses the question that whether the genes that occur naturally can be said to be newly found. An animal, a plant, a microbe, a chemical, a mineral, or any part thereof, newly discovered are excluded from being patentable on the observation that these are naturally occurring and lack invention. The discoveries are free to all men, reserved exclusively to none, and are manifestations of nature. In the case of *Diamond v Chakrabarty*,<sup>1</sup> the Supreme Court of the United States made a useful distinction between living organisms being discovered in nature or being invented as a result of human

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<sup>1</sup> *Diamond v Chakrabarty* [1980] 447 U.S. 303

intervention. If it is a product of human intervention it would rightly qualify as a novel product.

*The invention must be non-obvious (it must be a significant improvement to a previous one)*

Article 27.1<sup>2</sup> of the TRIPS (Trade-Related Aspects of Intellectual Property Rights) agreement which addresses the requirements states that to qualify as an invention, following an inventive process is a must. The comparison of anything which is already known or is obvious would not qualify as an invention. The legal protection is denied ignoring the fact that a significant effort was made. It cannot be denied that the advancing computer technology has significantly improved the gene identification process. However, even in the United States the requirement focuses on the invention rather than considering the technique for invention as well. In the case of *Re Bell*<sup>3</sup>, “human insulin-like growth factors” for DNA and RNA sequences were claimed. It was held that the “degeneracy of the genetic code meant that there are vast numbers of DNA sequences that might code for a specific protein and concluded that prior disclosure of amino acid sequences and general sequencing methods did not render the claimed sequences obvious”.

*The invention must have a substantial utility (it must be used for the fulfillment of specific objectives)*

This requirement states that the applicability of the gene patent should be disclosed. In the case of *Brenner v Manson*<sup>4</sup>, it was observed that the inventions must have a “specific benefit” and “substantial utility” rather than merely capable of beneficial use. In the case of *Parke-Davis & Co. v H.K. Mulford & Co.*<sup>5</sup>, it was stated that mere claiming the products of nature does not promise patentability. The court also said that “if there is sufficient reason for granting a patent, then the subject-matter requirement will be satisfied even if the subject matter claims product of nature. It has been said that the difference between a discovery and invention is a difference in degree rather than its kind”.

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<sup>2</sup> Trade-Related Aspects of Intellectual Property Rights, 1995, art. 27.1

<sup>3</sup> *Re Bell* [1993] 26 U.S.P.Q. 2d 1529

<sup>4</sup> *Brenner v Manson* [1966] 383 U.S. 519

<sup>5</sup> *Parke-Davis & Co. v H.K. Mulford & Co.*, [1911] 189 F. 95

## THE ACT GOVERNING PATENTS IN INDIA

The Indian Patent Act, 1970 governs the law relating to patents in India. To understand the contention of law with regard to gene patenting, we shall look into Section 3(c)<sup>6</sup> of the Act which throws light on what is not patentable, one of them being- “the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature.” This means to state that substances ordinarily occurring in nature are not patentable. Accordingly, it can be concluded that genes, which exist naturally are not eligible to be patented under the Indian Patent Act. This raises the question of the patentability of synthesized DNA sequences. Unfortunately, there is a deficit of judicial decisions when it comes to manipulated DNA and its patentability. However, we can analyze some of the patents granted by the Indian Patent Office, such as:

- Genetically Stable JEV cDNA based on Japanese Encephalitis Virus (Patent No. 243799). The patent was granted in this application to a cDNA sequence that was not synthesized or recombined and was merely an outcome of the already existing natural sequence.
- An Expression Vector or Cloning Vector Encoding Filarial Parasite Polypeptide (Patent No. 246865)

Here, the Patent Office took a different opinion mentioning that the cDNA sequence already exists in nature but concluded to grant the patent in this application. The lack of guidance in the act and the manual have caused a hiatus when it comes to the eligibility of granting patents while considering the various sequences and combinations. Though, it can also be observed that patents have been granted in various cases where the judiciary is of the opinion that the DNA is not merely a derivative of natural sequence.

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<sup>6</sup> Indian Patent Act, 1970, s 3(c)

## IMPLICATIONS OF GRANTING GENE PATENTS

Ethics proposes we vocalize our intentions and explain our actions while advancing in technologies. Article 53(a)<sup>7</sup> of the European Patent Convention states “inventions, the publication, or exploitation of which would be contrary to ‘ordre public’ or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the contracting states” are not accepted.<sup>8</sup> In conclusion, it states that a patent can upfront be refused if it is contrary to public policy or hinders morality. There are certain implications that cannot be ignored when it comes to the patenting of genes. These can be understood in brief as follows:

### *Moral Implications*

- Humans shall not be treated as a commodity and be owned with regard to their genetic structure.
- Causing unethical actions and crossing genetic borders raises a question on ethics as seen in the case of “Dolly sheep” wherein animal genes were manipulated with human genes.
- What is the driving force- innovation or personal gain? The incentives may also result in over-patenting of genes which could contribute to greater global injustice.

### *Legal implications*

What constitutes to be a synthetically isolated sequence of DNA as well as an understanding of the transformed or natural criterion?

If the gene is allowed the patentability then what constitutes a valid use of the gene sequence as well as the specificity of the use.

If the patent is granted what will its implication be on the previous foundational patents?

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<sup>7</sup> European Patent Convention, 1973, art. 53(a)

<sup>8</sup> Thambisetty, Sivaramjani, ‘Understanding Morality as a Ground for Exclusion from Patentability Under European Law’ (2002) 12 (2) Eubios Journal of Asian and International Bioethics, 48-53

## CASES RELATING TO GENE PATENTS

### Association for *Molecular Pathology v Myriad Genetics, Inc.*<sup>9</sup>

The Supreme Court of the United States held that DNA is a “product of nature” and therefore, human genes cannot be patented. The court also mentioned that there was no intellectual property to protect as nothing new was discovered and the gene already existed naturally. 4300 human genes were patented prior to this judgement which got invalidated because of this ruling. The removal of patent rights from these genes enabled them to be used for the purpose of research and further developments. The Court in this ruling specifically mentioned the eligibility for patenting a type of DNA known as complementary DNA (cDNA). cDNA is synthetically manipulated in the lab and is not merely a derivative of natural existence hence, it can be patented.

### *O'Reilly v Morse*<sup>10</sup>

In this case, it was observed that a natural phenomenon or a scientific principle, such as human DNA, which is ordinarily found in nature, should be free for all to use. Hence, in this case, electromagnetism, being a scientific principle, cannot be patented.

### *Diamond v Chakrabarty*<sup>11</sup>

In this case, it was observed that a living micro-organism can be patented under 35 U.S.C. Section 101, the condition is that it is made by man. It was observed that a naturally existing bacterium was genetically manipulated for breaking down oil in order to treat oil spills. This ruling cleared the air as to the eligibility of patenting micro-organisms. The court stated that anything is patentable provided that it is created by man. The court also provided further clarification that abstract ideas, physical phenomena, and laws of nature cannot be patented.

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<sup>9</sup> *Association for Molecular Pathology v Myriad Genetics, Inc.*, [2013] 569 U.S. 576

<sup>10</sup> *O'Reilly v Morse* [1853] 56 U.S. 62, 133

<sup>11</sup> *Diamond* (n 1)

## RECENT DEVELOPMENTS

There have been ceaseless developments in the fields of Science and Technology which have contributed and continue to contribute toward the greater social and economic advantage. One such remarkable accomplishment of Emmanuelle Charpentier and Jennifer A. Doudna who were awarded the Nobel Prize in 2021 has been in the talks for both its benefits and implications. The research represents "the development of a method for genome editing" also known as the discovery of "genetic scissors". CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats) is a molecular tool that allows scientists to make extremely precise changes to the genetic code of organisms that are still alive.<sup>12</sup> This method includes artificial editing of genes by breaking the genome sequence, editing the DNA by deletion, insertion, and integration of new DNA section. Though this is considered to be a significant advancement in the field of Science, its implications cannot be ignored and must be used with great caution. Also addressing the ethical aspect with regard to the discovery of genetic scissors, Claes Gustaffson, the chair of the Nobel Committee for Chemistry, warned that the technology must be "used with great care." A scientist was imprisoned for creating the "gene-edited babies" in China in 2019. He Jiankui announced that a woman had given birth to genetically manipulated twins by using the CRISPR-Cas9 technology to produce human embryos that were immune to HIV. There are a number of concerns that arise with the alteration in genetic sequence. Some researchers show significant mutations that go so far as to cause serious health risks.

## CONCLUSION

Patent rights can make or break the economy. While there are advantages that attribute to the overall growth, certain implications cannot be ignored. These implications do not freely allow the granting of patent licenses. It can also lead to over-patenting and monopolizing among other disadvantages. Also, the modification of genes and synthetic DNA sequences contributes greatly to the advancement of Science and should also be seen as a boon. Tracing through the

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<sup>12</sup> Gabriel Borrud, 'Nobel Prize in chemistry awarded for 'genetic scissors' discovery' (*DW*, 10 October 2020) <<https://www.dw.com/en/nobel-prize-in-chemistry-awarded-for-genetic-scissors-discovery/a-55182141>> accessed 07 October 2020

history of judicial decisions on gene patenting, the reasons involving inconsistency is evident. The litigations with regard to granting gene patents will continue with the recurring advancements in the field of genetic evolution. This inconsistency can be minimized with uniform practice and a comprehensive and unambiguous manual on gene patenting. Though gene patenting has its merits, it should include a comprehensive process so as to not grant patents without thoroughly analyzing the facts. If patents are granted without comprehending the facts it can hinder the overall innovation and development.