PATENTING OF NATURALLY OCCURRING GENES

Author: Santhiya V, III year of BBA LLB (Hons.) from Alliance University

ABSTRACT

A patent is an exclusive right given to the inventor to exploit his invention subject to the provisions of the Patents Act, 1970 for a limited period. During this period, the inventor is entitled to exclude anyone from using his invention, therefore patents create a monopoly right over the invention in favour of the inventor[1]. A gene is the basic physical and functional unit of a person's heredity. Genes are composed of DNA. In humans, genes differ in size from a few hundred DNA bases to more than 2 million bases. An international research effort called the Human Genome Project, which attempted to find the sequence of the human genome and recognize the genes that it contains, assessed that people have between 20,000 and 25,000 genes[2]. This article will deal with the process of patenting a gene and its history and mainly about the issues and need for patenting a gene which is found naturally and will also discuss if a naturally occurring gene should be patented or not and on what grounds.

RESEARCH PROBLEM

According to the patenting of genes, the types of genes can be divided into two types. The first type, is the type gene that is genetically modified and it is not found in nature, on the other hand, the other type of the gene is which is found in nature and there is no inventive step is taken, for example, a gene that is found in humans. Out of these two, according to all the judicial precedents, the former is patentable, whereas the other is not patentable because of various reasons. The discovery of these genes has a lot of benefits, including, development in research and increasing the chances of finding medications for diseases that originate from these genes, for example, breast cancer. The patenting of such genes would promote such discoveries, by providing recognition to the one who discovered. But, the patenting of the same is not allowed

[1] V. K. AHUJA, LAW RELATING TO INTELLECTUAL PROPERTY RIGHTS 479 (LexisNexis, 2020)
[2] US NATIONAL LIBRARY OF MEDICINE,https://medlineplus.gov/genetics/understanding/basics/gene/#:~:text=A%20gene%20is%20the%20basic,more%20than%202%20million%20bases (last day visited 19 May 2021)

because of various ethical, legal and social reasons. So, should the patenting of naturally occurring genes be allowed?

RESEARCH QUESTIONS

Like the genetically modified genes, can the naturally occurring genes also be patented?

HYPOTHESIS

By the legal precedence and because of agreements, and due to various ethical, social and legal issues, such patenting of the naturally occurring genes is not possible.

SCOPE

The scope of this article is within the provisions and judgements regarding the patenting of genes in India and other countries.

METHODOLOGY

The present article uses the most recently available published secondary data. To achieve the objectives, secondary data was used.

INTRODUCTION

Gene patents, comprising genetic technologies, natural and isolated genetic material and genetic products. Genetic material and technologies are important in medical research and health care. As more people know about the biological function of genes and the proteins produced by genes, medical research and health care are likely to become more significant. The patenting system should constantly accommodate itself to new technologies. In the past 20 years, inventions regarding biotechnology have become a new focus of the patent system. Gene patenting also raises various social and ethical concerns. These concerns include the concerns about the social impact of gene patents on the conduct of research and the provision of healthcare; and ethical concerns about sharing the benefits of genetic research, consent to the use of genetic material in research that leads to commercial outcomes, and indigenous issues.

TRIPS AGREEMENT

Starting from the Paris Convention, the rights of a person regarding intellectual properties have been protected globally for more than 100 years. In 1994, the WTO enacted the agreement on Trade-Related Aspects of Intellectual Property (TRIPS), which created stronger rights related to Intellectual Properties, that is, to reward researchers and developers for their innovations and creative materials[3]. The major controversy is about the so-called 'life patents', which covers the gene sequences, microorganisms, plants, animals and human gene sequences. Though thousands of patents have been granted, on genetic resources and living matters, in various countries including, the United States, European Union, Japan and Australia, since the 1980s, the controversy is still going on[4].

Out of all these provisions, Article 27 of the TRIPS agreement has the most relevance in regard to the prohibition of gene patents. Patentability of a product depends on three independent criteria, that is, while no subject matter is explicitly excluded, the TRIPS agreement permits, but does not need, the Member States to prohibit the patentability of (1) inventions – provided the exclusion is necessary for public order or health, the protection of life, or the environment; (2) diagnostic, therapeutic and surgical methods; and (3) plants and animals—other than micro-organisms. The TRIPS Agreement intended to create a norm, a minimum level of protection for the intellectual property that would obligate the Member States to make the patent protection for all inventions. But the TRIPS Agreement does not provide a uniform definition of what comprises an 'invention'. This absence of a uniform definition of 'invention' has prompted the Member States to Carve out their distinct definitions, which need to adhere to the basic structure provided in Article 27(1). Article 5 of the TRIPS Agreement is quiet regarding the naturally occurring material and does not list genetic material as an exception to patentability. The WTO has not addressed any patentable subject-matter challenges under the TRIPS Agreement and it is unclear how it would rule. Individual Member States of differing economic and social

[3] Cydney A Fowler, '*Ending Genetic Monopolies: How the TRIPS Agreement's Failure to Exclude Gene Patents Thwarts Innovation and Hurts Consumers Worldwide'* (2010) 25 (5) AUILR 1073, 1093(2010)

[4] Christoph Then, '*Does TRIPS allow for the prohibition of gene patents? Do TRIPS allow for the prohibition of gene patents?'* (2011) Testbiotechhttp://thetarrytownmeetings.org/sites/default/files/TRIPS%20and%20gene%20patents.pdf(19 May, 2021, 10:34 PM)

development levels, therefore, struggle with addressing complex patentability issues on a case-by-case basis.

IN INDIA

The Patents Act of 1970was amended three times between 1999 and 2005. The first amendment in 1999, gave effect to the provisions of the TRIPS Agreement and thereby to meet the first deadline and some of the provisions were made retrospective from 1995. The second amendment, which was made in 2002, brought Indian law in substantial compliance with the TRIPS Agreement. The third amendment was made in December 2004, which came into force from 1 January 2005, to make the Patents Act fully TRIPS compliant. The removal of Section 56 of the Indian Patents Act was imperative to allow product patents in the area of biotechnology, chemicals and pharmaceuticals. Article 27 (1) of the TRIPS Agreement clearly states that patents should be granted for inventions in any field without any segregation, subject to certain clauses. This suggests that biotechnological inventions are patentable subject matter. The patenting of genes and DNA sequences are very popular in the United States, the European Union and Japan. But patenting of genes and DNA sequences per se was not allowed in India until January 2005, but processes involving recombinant DNA technology to produce proteins involving a gene or DNA sequence was the patentable subject matter. Product patents for DNA, RNA or genetic inventions are a patentable subject matter from January 2005 following the third amendment[5].

The Patents Act under section 3(c) specifies that the mere discovery of a scientific principle or the formulation of an abstract theory, the discovery of any living thing or non-living substance occurring in nature would not be patentable. Another relevant section is section 3 (i) which states that plants and animals, in whole or any part thereof, other than microorganisms but including seed, varieties and species and essentially biological processes for production or propagation of plants and animals – cannot be patented. A gene that occurs in nature is, therefore, not patentable as per section 3 (c). While it is true, it must be noted that there is considerable skill involved in identifying its function, location and isolation. The exclusion of parts of animals or plants ought to be taken seriously as the exclusion is phrased differently from the TRIPS provision which allows for the exclusion of plants and animals and does not make a specific provision for parts.

[5] MalathiLakshmikumaran, '*Patenting of Genetic Inventions'* (2007) 12 JIPR 45, 48 (2007) http://docs.manupatra.in/newsline/articles/Upload/28657BF6-ADAE-43AD-A87F-0DBB440B8D75.pdf

That is, therefore, a need to examine the Manual of Patent Practice and Procedure issued by the IPO over some time to understand their approach[6].

WHAT IS A GENE?

A gene is a structural unit of inheritance in living organisms. It is a segment of DNA that has a specific purpose, i.e., its codes for a protein or a specific enzyme. The strands of DNA on which the genes occur are organized into chromosomes. Each gene of an organism provides a blueprint for the synthesis (via RNA) of enzymes and other proteins at a specific time. Genes oversee both the structure and metabolic functions of the cells, and hence of the entire organism. Genes located in the reproductive cells pass their information to the next generation. A gene is DNA that encodes the essential sequence of some final gene product, which can be either a polypeptide or an RNA with a structural or catalytic function. The genetic materials that can be patented include genes, DNA sequences, cDNA, ESTs (Expressed Sequence Tags) and SNPs (Single Nucleotide Polymorphs). The DNA related inventions may be incorporated one of the following:

- mRNA (messenger RNA) which is encoded by the DNA to express a protein;
- 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;
- isolated and purified DNA sequence such as genomic DNA coding for a gene, or a fragment thereof;
- oligonucleotides;
- Proteins or polypeptides;
- DNA markers;
- Recombinant (genetically modified) DNA including recombinant plasmids or recombinant vectors; and
- Genetically modified organisms such as genetically[7].

ESSENTIALS OF A PATENT

To get a patent for a product, there are a few essentials that need to be fulfilled. These essentials are as follows:

[6] CYDNEY *Supra* note 3 at 1077
[7] MALATHI*Supra* note 5, at 49

- **Invention:** Invention means a new product or process involving an inventive step and is capable of industrial application. Even a process involving an inventive step is an invention, within the meaning of the Patents Act. Hence, the product doesn't need to be a new product, even if the product is substantially improved by an inventive step, it would be termed as an inventive step[8].
- **New or novel:** An invention that is to be patented, should be new. For it to be patentable, the invention should not be found in any matter whether a product, a process, information about either or anything else, which has been made available to the public anywhere in the world by written or oral description by use, or in any other way. New manufacture does not only mean a new article of manufacture but also means a new process or method of manufacturing something new. The novelty will be lost, where an inventor uses the invention secretly till the time it becomes a success and then applies for the patent at the most advantageous moment, the invention will be no more new[9].
- **Inventive step:** This implies a feature of the product that includes technical advances as compared with the existing knowledge or having economic significance or both and makes the development non-obvious to an individual skilled in the art. If the invention was obvious, then there could be no inventive step, whatsoever. The person skilled in the art means that the said person would have the knowledge and the skill in the said field of art and won't be known to a specific field of art and it is from that angle one needs to see that if the said document which is earlier patent if placed in the hands of the said person skilled in art whether he will the option to work upon the same in the workshop and accomplish the desired result leading to the patent which is under the challenge[10].
- **Non-obviousness:** The essential element of novelty and inventive step would depend on the given facts of each case. If the particular manner of manufacture is the same, then there cannot be any novelty in the subject matter. If there is no inventive step, it implies that it is obvious. Though the term 'obvious' has not been defined under the Patents Act, it can be safely stated to be a circumstance where a person of skill in the field, ongoing through the specification would complete the product[11].

[8] V. K. AHUJASupra note 1, at 482
[9] Id
[10] Id
[11] Id

- **Capable of industrial application:** capable of industrial application means that the invention is capable of being made or used in an industry, that is an invention should have commercial use or manifestation. Even though an invention may not be the final product, it will be patentable only if it has some commercial viability. Thus, it is not the product that is the focus of attention but the actual physical substance created which has the potential of a commercial manifestation[12].

Regarding the patenting of DNA and genes sequences, it is a broad term that refers to the patenting of a process that involves identification, isolation of DNA or associated materials like RNA as well as chemical substances related to DNA such as proteins, and peptides[13]. A DNA or a gene sequence can be considered to be new or novel, feature an inventive step, non-obvious and capable of industrial application. But there is a conflict in considering a DNA or gene sequence as an invention, it is considered as a discovery since they are naturally occurring.

INVENTION VERSUS DISCOVERY

Generally speaking, invention is the process of creating something new from one's ideas and thoughts, whereas discovery is recognizing something that already exists, for the first time. Something, that is just discovery, for example, the identification of a new gene, cannot be patented. However, if you have studied further what the gene's function is if it can be used as a medical product or diagnostic tool, then the same can be patented. The protection is often characterized as "isolated DNA molecules with (a certain) nucleotide sequence". The current patent law considers that material already exists in nature not as an adequate contention to exclude it from being patentable. If a substance found in nature has to be isolated from its surroundings to make it accessible and so it is necessary to apply technical processes for obtaining it, then such substance can be considered as an invention. It can be patented if the substance shows some new technical features that could not be predicted from its known properties. But, if the process for obtaining it cannot be considered as a significant technical problem and the substance does not reveal any new and unexpected features, then it is a

[12] Id
[13] MALATHI*Supra* note 12

discovery and as it cannot be patented. There is no clear difference between an inventive process and something that can be viewed to be obvious, this distinction can even be changed by the patent offices. For example, the European Patent Office follows a line for 'raising the bar' for inventiveness and so dismissing several patent applications. Regardless, the answer to the question, which technical features are considered to fulfil inventiveness is not fixed by the TRIPS Agreement, but by the national or regional laws of the countries. Even now, there are considerable differences between the member states of WTO regarding the question of what can be considered as a patentable invention. For example, in the US business methods and software developments are considered as inventions, while Europe refuses such patents[14].

THEORIES OF INTELLECTUAL PROPERTY

- **Utilitarian theory:** This theory is based on the idea of 'the greater good for the greatest number'. According to this theory, the law should guarantee maximum benefit for the maximum members of the society. Applying this theory to intellectual property rights, it is stated that by allowing a creator to profit from his work, monetary incentives are afforded for technological invention and artistic creation which typically benefit society and humankind at large. Further, the increase of intellectual property rights as a means to foster investments of temporal and financial resources in innovation in the hope that the invention increases the standard, quality of living and thereby the net welfare benefit among the general population[15].
- **Labour theory:** This theory is based on the idea that a person, who labours upon resources that are held in common, has a natural right to the fruits of his efforts and the State must respect and enforce that right. According to this theory, if a person applies mental labour on knowledge or information which is available in the public domain and produces knowledge goods, he would be entitled to the protection of such goods[16].
- **Personality theory:** This theory centres on an individual's personality and the external extensions thereof. According to this theory, a man acquires an absolute right to appropriation by putting his will into any and everything, thereby making it his. Under

[14] V. K. AHUJA*Supra* note 1, at 483
[15] DR. B. L. WADEHRA, 'LAW RELATING TO INTELLECTUAL PROPERTY RIGHTS'8 (Universal Law Publishing, 2016)
[16] Id

this theory, authors and creators should be allowed to earn respect, honour, administration and money from the public by selling or giving away copies of their work, but should not be allowed to surrender their rights to others. This theory signifies the intimate and emotional connection between the author or creator and his works or creations respectively[17].

- **Social planning theory:** This theory is rooted in the proposition that property rights in general and intellectual property rights, in particular, can and should be shaped to help foster the achievement of a just and attractive culture. It differs from the utilitarian theory as it seeks to go beyond the notion of social welfare to a much broader vision of society served by intellectual property[18].

When we compare all these theories to the concept of patenting a gene, that is naturally occurring, we can say that based on the utilitarian theory, labour theory and personality theory of intellectual property, the patent can be provided to naturally occurring genes. That is, under the utilitarian theory, if a gene is patented, then it promotes research of such gene by a particular person or company, this will lead to various inventions and cure to certain genetic diseases, thus profiting the society at large. Under the labour theory, the person or scientist, who has discovered the gene has put in his labour and so he the right to be recognised for the same and so, naturally occurring genes could be patented. Under personality theory, the person who found and isolated the gene should get the recognition, respect and honour that he deserves for his acts, and so he is entitled to get the gene patented.

ETHICAL AND OTHER ISSUES

The main issue related to the patenting of genes is that it may hurt the cost and quality of healthcare services. A patent holder might have the option to set a higher price than what would apply because the patent holder has monopoly rights over the patented product or process. A patent holder who adopts the restrictive licensing practices may restrict the admittance to a specific test, treatment or meditation[19].

[17] Id
[18] Id
[19] Australian Law commission, *Genes and Ingenuity: Gene Patenting and Human Health* (Aus Law Com no 99, 2010)

Ethical concerns about gene patenting can be divided into two:

- Ethical objections in granting patents over genetic material; and
- Ethical concerns about the abuse of the gene patents[20].

A variety of ethical objections have been made to granting patents on human genetic materials. Some people are not convinced that the patent system adequately takes account of the ethical concerns. Critics of gene patents have said that these patents are ethically wrong because they are incompatible with: the view that the human genome is the common heritage of a human being; respect for human dignity; self-determination and self-ownership; and certain religious beliefs. The human genome is often described as the common heritage of humanity, which has been supported by the Human Genome Organisation's (HUGO) Ethics Committee and by the United Nations Educational, Scientific and Cultural Organization (UNESCO). Patents on human genetic materials are in some cases criticised the grounds that they are thought to grant exclusive rights over this common heritage to a limited number of entities. This objection rests partially on the concern for reasonable distribution of the advantages of genetic research. This view was communicated in various entries[21]. Another issue to patents on genetic materials is that they may induce a lack of regard for human life and dignity. On this view, to give a proprietary right over something suggests that it is an appropriate subject for such rights. Thus, patents on genetic materials are thought to commodify parts of human beings by regarding them as objects, or as something to be put in the stream of trade for monetary benefits. Others recommend that genetic materials have exceptional importance, which expects them to be treated with special respect. These objections rest on the rule of respect for persons and the advancement of individual independence. The commodification of parts of human beings is ethically problematic because it might affect how we value people[22].

JUDICIAL APPROACH

[20] Mark Sagoff, '*Patented Genes: An Ethical Appraisal'*SAGOFF(1998),https://issues.org/sagoff/
[21] Robert Cook-Deegan and Christopher Heaney, '*Patents in Genomics and Human Genetics'NCB* (22 September 2010),https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2935940/
[22] CHRISTOPHER*Supra* note 4

In the case of *Amgen Inc v Chugai Pharmaceuticals*[23], an 'isolated gene' was held to constitute patentable subject matter. In the EPO case of *Howard Florey/Relaxin*[24], it was held that purified copies of genes produced by technical processes outside the body are patentable. Here, the claims were toward a method for the synthesis of peptides with relaxin activity, which included synthesis of relaxin and certain analogues of relaxin. Relaxin is an ovarian hormone that softens and lengthens the inter-pubic ligaments during pregnancy. It also dilates the cervix and inhibits contractions of the uterus. The patent granted was for a process of producing relaxin from a cDNA fragment and a product such as the gene sequences coding for the relaxin molecule. The patent was opposed by the Green Party of the European Parliament because the subject matter of the patent was not patentable due to the lack of novelty and an inventive step, and that it offends the public and morality. The Opposition Division of the EPO did not agree with the opposition. The claimed DNA fragments encoding relaxin and its precursors were cDNAs and these cDNAs are not found in the human body. Thus, the sequences were considered novel.

Funk Brothers Seed Co v Kalo Inoculant Co[25], the patent involved a process for immunising leguminous plants with strains of naturally occurring bacteria to allow the plants to fix nitrogen from the air. Wherein the Court laid down that, claimed inventions are a 'discovery of the phenomena of nature,' and the court further said, 'these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none and so genes should not be patentable. A gene is not an 'invention' in the same sense that the machine is considered as an 'invention.'

In *Diamond v Chakrabarty*[26], the Court held that bacteria, which had been genetically modified to degrade oil, could be patented. The distinguishing factor in *Chakrabarty,* as compared to *Funk Brothers*, is that in *Chakrabarty*, the bacteria has been altered by human intervention, furthermore, the bacteria was considered to be an invention as it had two energy-generating plasmids which are quite different and uncommon for the existing bacteria. The Court of

[23] Amgen Inc v Chugai Pharmaceuticals**706 F. Supp. 94 (1989)**
[24] Howard Florey/Relaxin1995 EPOR 541
[25] Funk Brothers Seed Co v Kalo Inoculant Co,92 L. Ed. 588
[26] MALATHI*Supra* note 5, at 51

Appeals for the Federal Circuit, in In re Deuel[27], held that 'general motivation to search for some gene that exists does not necessarily make obvious a specifically-defined gene that is subsequently obtained as a result of that search'. Hence, it was possible to obtain a gene patent using an obvious method. In the case of Hybritech Incorporated v Monoclonal Antibodies Inc[28], wherein a suit was brought alleging infringement of US Pat No 4,376,110 for immunometric assays using monoclonal antibodies, the Court laid down that 'whether the claimed invention would have been obvious at the time the invention was made is reviewed free of the erroneous standard although the underlying factual inquiries--scope and content of the prior art, level of ordinary skill in the art, and differences between the prior art and the claimed invention-- integral parts of the subjective determination involved in Section 35 USC 103, are reviewed under that standard. Objective evidence such as commercial success, failure of others, long-felt need, and unexpected results must be considered before a conclusion on obviousness is reached and is not merely icing on the cake.'

MYRIAD GENETICS

Myriad Genetics, Inc. is a genomic research firm. One of the firm's mission was to learn what various sequences of DNA in the human genome do. During their research, Myriad's scientists, in 1994, discovered two genes, now known as BRCA1 and BRCA2. By the influence of these genes, they were able to evaluate the risk of women developing breast cancer at some point in their lives. Women with mutations in the BRCA1 and BRCA2 genes can take steps to reduce the risk of cancer, including enhanced screening, medications, and preventive surgery to remove breasts. This prophylactic surgery can significantly reduce the risk of death linked to BRCA mutations. The company began to offer screening tests to the public and then they patented these genes. Myriad claimed exclusivity over the tests and other items to these genes. This act of Myriad claiming the exclusivity of these genes was controversial and problematic. Because, by this act, it would mean that Myriad owned the genes for most practical purposes and applications. This ownership could affect the scientific process and health care efforts, including, academic research related to these genes, labs offering tests related to these genes and medical professionals offering treatments related to this gene. Several people came together to form

[27] re Deuel51 F. 3d 1552 (Fed Cir 1995)
[28] Hybritech Incorporated v Monoclonal Antibodies Inc, 802 F. 2d 1367

groups and to file a suit seeking to invalidate Myriad's patents so that research, tests and treatments related to these two genes could be pursued in an unrestricted manner. This is the case of *Association for Molecular Pathology v. Myriad Genetics, Inc.*[29]**]**,. The Supreme Court of the US agreed with the petitioners to a certain extent. The court said that mere isolation and identification of a gene sequence is not enough to get it patented, as nothing new was created. However, the methods related to the sequence and copies and derivations of the sequence were left to further review. Finally, the court invalidated the patent of the genes[30].

CONCLUSION AND SUGGESTIONS

In this article, we have discussed gene patenting, provisions in the TRIPS Agreement that are related to gene patenting, the position of gene patenting in India, essentials of patenting and in it the difference between discovery and invention, theories of intellectual property, application of patent law in different countries, social and ethical issues in gene patenting and finally about the judicial approach towards gene patenting. In light of the research question, legally, the patenting of naturally occurring is not possible, for various reasons. But according to me, this patenting of naturally occurring genes should be made valid. To support this statement, I would point out the aim of the theories of intellectual property. As mentioned earlier, in this paper, patenting of these genes, would provide the person who discovered the genes with recognition, which would act as a recognition for him and encourage him and others in the field to research and come up with different ideas. This is important because the naturally occurring genes would mostly help in the medical field and it may encourage the development of new products and processes with important healthcare applications and by this, a greater good can be achieved. The possibility of getting a patent over another or improved diagnostic test or therapeutic product gives the motivation to contribute the time and resources that are needed to build up the invention. But as we can see from the case of Myriad Genetics, there are situations where this can be misused. Hence, to prevent this, there should be strong guidelines, regarding the application of this idea. My suggestions for this problem are:

- Patents should be made available to naturally occurring genes too,
- This is to promote research among scientists,

[29] Association for Molecular Pathology v. Myriad Genetics, Inc, 106 U.S.P.Q.2d 1972

[30] *case study: Association for Molecular Pathology v. Myriad Genetics, Inc.',* WASHULAW,(20 May, 2021, 11:48 AM),https://onlinelaw.wustl.edu/blog/case-study-association-for-molecular-pathology-v-myriad-genetics-inc/

- But there should be strict guidelines in enforcing this to prevent misuse,
- The example of the guidelines are as follows:
- The patent holder can have the right to make a profit, but it should be limited or in reasonable terms,
- No or limited restrictions can be placed upon others, who use this product for research purposes,
- There should be transparency on part of the company in regard to what they are using the gene for, to prevent any misuse of the genes,
- There should be confidentiality between the company and the customer, etc.