E- Journal of Academic Innovation and Research in Intellectual Property Assets (E-JAIRIPA)

Vol. II (II), July-Dec 2021, pp. 1-12

ANALYSIS OF MYRIAD GENETIC CASE

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ABSTRACT

Recently, due to outbreak of Coronavirus, research in genetic science has elevated to its next level. The evolving genetic science demands updated laws to meet its challenges. Research on genes is important for drug innovation and development. Isolating and modifying the sequence of genetic material is the common phenomenon in genetic engineering but this phenomenon raises various concerns. The Human gene is the common heritage of all and merely identifying the precise location of specific genes in the whole genome and its isolation by breaking the covalent bond does not qualify the test of patent law however if the gene is altered or modified in such a way that its expression can be changed then it would come under the purview of Patent Act. This paper will look into the question whether a gene can be patented or not and try to identify the conditions on which a patent can be granted to the gene. This paper will also focus on the different ethical or moral objections of gene patenting in the international arena and how it violated the principle of self-ownership.

INDEX OF AUTHORITIES

Cases

Other Authorities

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INTRODUCTION

Biotechnology is not a new term, from time immemorial farmers have been using this technique to obtain the desired crop but this term today is used in a very restricted sense including genetic engineering. For instance, the transformation of milk into curd by using lactic acid and the traditional method of cross-breeding which includes selectively breeding is not a new technique. It will also come under the ambit of biotechnology.

One of the branches of biotechnology is genetic engineering that has emerged in 1970 and involves interspecies genes transfer it means it can allow "genes to be transferred between distant species that would never interbreed in nature. There are various techniques for transferring genes; one of the first and still central techniques involves the use of bacteria and" viruses.[2] This new form of biotechnology raises new issues, questions and problems in both the national and

[2] Sean D. Murphy, ' *Biotechnology and International Law*', (Vol.42 Harv. Int'l L. J. 47 2001), <http://heinonline.org/HOL/License > accessed 15 February 2019.
William H Francis, Robert C. Collins, James D. Stevens, '*Cases and Materials on Patent Law*' (sixth edition)

transnational sphere. Now pertinent question raised here is whether a patent can be granted to the processes of extracting genes or creating any new recombinant DNA or identification of genes and their functions. To answer these questions, we have to look into the history of Patents.

The English term 'Patent' is based on the Latin patens which is present participle of patere, which means "to be open". The term "letters Patent" comes from the practice in Great Britain of royal grants being sealed in closed condition or open condition. A royal grant sealed in open condition was generally termed as "litterae Patentis" which means open letters which could be read without breaking the royal seal. These "litterae patentis" were used for pardons, Title of Honor, official appointments and grants to inventors. Thus, Patents given to the inventors today in the United States and Great Britain are called Letters Patent[2]. Halsbury's Laws of England[3] defines Patent as "the truth is that letters patent do not give any right to use the invention- they do not confer upon him a right to manufacture according to his invention. That is a right which he would have equally effectually if there were no letter patent at all only in that case, all the world equally have the right 'what the letter patent confers is the right to exclude others from manufacturing a particular way and using a particular invention." The whole purpose of "patent law is to encourage the development of new technology and industry in the state".

"A patent is an exclusive right granted to a person who has invented a new and useful article or an improvement of an existing article or a new process of making" a thing or product and this right can be granted for a limited period. A patent is a manifestation of industrial property the holder of that "right can sell the whole or part of this property or can also grant licenses to others to use or exploit it. Since patent is a creation of statute and is therefore territorial in extent thus a patent granted in one country cannot be enforced in another country".[4]

In Great Britain, there was a practice of issuing royal grants prior to the first formal statute establishing patents. These were in the form of special grants and monopolies by the Royal to promote the public interest.
"Clause 8 of section 8 of Article 1 of the constitution of the United States":
"The Congress shall have the power to promote the progress of science and useful arts by securing for limited time to authors and inventors the exclusive right to their respective writings and discoveries".

"From the standpoint of scientific and intellectual attainments", Thomas Jefferson was the best

[3] William H Francis, Robert C. Collins, James D. Stevens, '*Cases and Materials on Patent Law*' (sixth edition)

[4] P. Narayanan, '*Patent Law*' Eastern Law House (4th ed, 2006)

person in the United States who is suited to administer the patent law. He invented a number of useful and ingenious devices. Jefferson initially became an ally of the patent system but he was strongly opposed to monopolies of all kinds. His opposition to monopolies and about the full knowledge of their abuse lead to the belief that the government should not intervene in matters of the invention.[5] He explicitly expressed his dissatisfaction toward the monopolies and absence of the bill of rights.[6] The term of grants should be limited in time and not be perpetual. A perpetual monopoly would hamper the society "embarrass society with monopolies for every utensil existing and in all the details of life."[7] He also did not approve the idea of "granting patents for small details, obvious improvements, or frivolous devices". He totally believes in the standardisation of invention and it should be high for the application of patent law.[8] The "three tests of Patent Law" is 'novelty' test, the 'genius' test and the 'non-obviousness' test but after the decision given in the case of "*Graham v. John Deree Co*." only the last test survives.[9]

"The non-obviousness test shares the economic framework of both the novelty and genius tests. With the novelty test, it shares the premise that innovation should be encouraged and by the genius test which shares the premise that patent monopolies represent a substantial cost to the consumer".

Objective

To determine whether a gene can be patented or not?

- To identify the conditions on which a patent can be granted to the gene.
- To analyze whether the gene is intellectual property or not.
- To point out the different ethical or moral objections of gene patenting in the international arena and how it violated the principle of self-ownership.

Research Methodology

In order to understand how a gene is a unique and universal material that exists in every human being and granting patents to this common heritage, material will affect the community at large and international law and legal position towards each other, the methodology used here is doctrinal which is based on primary and secondary data collected from different sources such as books, statutes, and online databases.

[5] Letters to M. Hommade, Washington Edition, vol. II, page 236 (1787), Joseph Scott Miller, '*Patents*' Critical Concepts in Intellectual Property Law.
[6] Letters to Madison. Writings of Thomas Jefferson , Ed by P.L Ford, vol IV , page 476 (Dec. 1787)
[7] Letters to Oliver Evans. Washington Edition, vol V, page 75 (1807)
[8] Letters to Thomas Cooper, Washington Edition, Vol VI , page 180 (1814)
[9] Joseph Scott Miller, '*Patents*' Critical Concepts in Intellectual Property Law.

Research Question

1. Is the genetic material or "genome part of some common human heritage"?
2. Can the human beings "exert property rights over their individual genomes"?
3. Do patents on modified human genes and "other forms of intellectual property protection lead to economic efficiencies and innovation"?
4. Whether patents on Human genes violate the principle of self-ownership?
5. To what extent human gene can be altered or modified to come under the purview of Patent law?

CHAPTER I: WHAT IS GENE?

Before delving into the question of whether a gene can be patented or not, the question triggered in our head is 'what is a gene?' As per the definition given in the U.S. National Library of Medicine, "a gene is the basic physical and functional unit of heredity.[10] "DNA is composed of genes and each gene performs a specific function particularly, encoding the instructions for the production of cells which is mainly "responsible for cell differentiation, development and reproduction".

DNA is the most complex compound found in nature and to understand this complex compound first, we have to understand what is cell because without understanding the cell we would be unable to understand DNA. The cell is the most fundamental and functional unit of life. Every living thing is made up of billions/trillions of cells.[11] Cells provide structure to the body, take in nutrients from and transformed them into energy and perform specific functions. Cells are composed of different types of organelles and these organelles perform different functions within the cell. To understand the genes these two organelles are important for us namely, Mitochondria and Nucleus. Mitochondria play a very significant role in performing the major functions of the cell. It is considered to be the 'Power House of the cell' as it converts energy from food into a form the cell can use. It also contains genetic material but it is totally separate from the DNA in the Nucleus and has the ability to replicate (make copies of itself). Now coming to the most complex organelles of all, that is 'Nucleus'.

In layman's term we can call Nucleus the brain of the cell because its sole purpose is to command the cell and it sends signals to cells to grow, divide or die. Nucleus is the home of DNA which is the hereditary material of cells. The full name of DNA is Deoxyribonucleic acid. This is a

[10] Genetic Home Reference, '*What is a gene*', U.S. National Library of Medicine, http://ghr.nlm.nih.gov accessed on 17 Feb 2019
[11] Genetic Home Reference. 'What is DNA,' U.S. National Library of Medicine, http://ghr.nlm.nih.gov accessed on 17 Feb 2019

molecule which presents in every living being on the earth and it is a common heritage of all beings. It consists of four base pairs Adenine, Thymine, Cytosine, and Guanine. These base pairs basically "encode the data that directs in synchronization with the environment".[12]

After George Mendel's (Father of Genetics) experimentation on peas resulted in the discovery that there is something hereditary material that passes from parents to their offspring and his discovery proved to be a milestone for scientists across the world to find out that specific material. In the year 1953, two scientists namely, "James Watson and Francis Crick discovered the famous double helix structure of deoxyribonucleic acid. This discovery leads to the foundation of Modern Molecular Biology. Molecular Biology mainly deals with understanding how genes control the chemical processes within the cells. This knowledge of DNA yielded ground breaking insights into the genetic code and protein synthesis. During the 1970s and 1980s, it play an important part in producing new and powerful scientific techniques specifically recombinant DNA, Genetic engineering and gene sequencing and monoclonal antibodies these are the innovative techniques on which today's multi-billion dollar biotechnology industry is founded".[13]

To understand the role of each gene many big corporations introduced a concept called the Human Genome Project. It mainly involves mapping the genome. This "project was started in the early 1990s as a publicly funded multinational project" to develop the essential map. The Human Genome has been mapped and more of its territory becomes known and understood. The human genome project expected to find out about "100,000 distinct human genes but at its conclusion, the number came was less than a third of that". A human contains nearly 25,000 distinct genes. There is another belief about the different ways that DNA stores and Uses information. The HGP was introduced to meet the certain object such as decoding the "relation of the string of the whole genome to the information it encodes, the environment and finally the phenotype or the physical instances of each and every individual human". Phenotype is the "structure of our body and all its parts such as organs, tissues, metabolism etc. and genotype is the string of base pairs of our DNA, its complete structure that contributes significantly to our phenotype". The main purpose of producing of all these is a "full understanding of all the means by which information is encoded in our genome and how that information is encoded in our genome and how that information directs and regulates development" and metabolism.[14] Full knowledge of the "genome and its relationship to the environment and the organism will give us finally powerful new means of

[12] Regina Bailey, '*The Cell Nucleus: Definition, Structure, and Function*', (Jan 23, 2013) https://www.thoughtco.com accessed on Feb 21, 2019

[13] The Francis Crick Papers, '*The Discovery of the Double Helix*, 1951-1953, U.S National Library of Medicine.

[14] David Koepsell, '*Who Owns You?'The Corporate Gold Rush to Patent Your Genes*',(Blackwell Public Philosphy)

treatment of a variety of diseases both inherited and environmental".[15]

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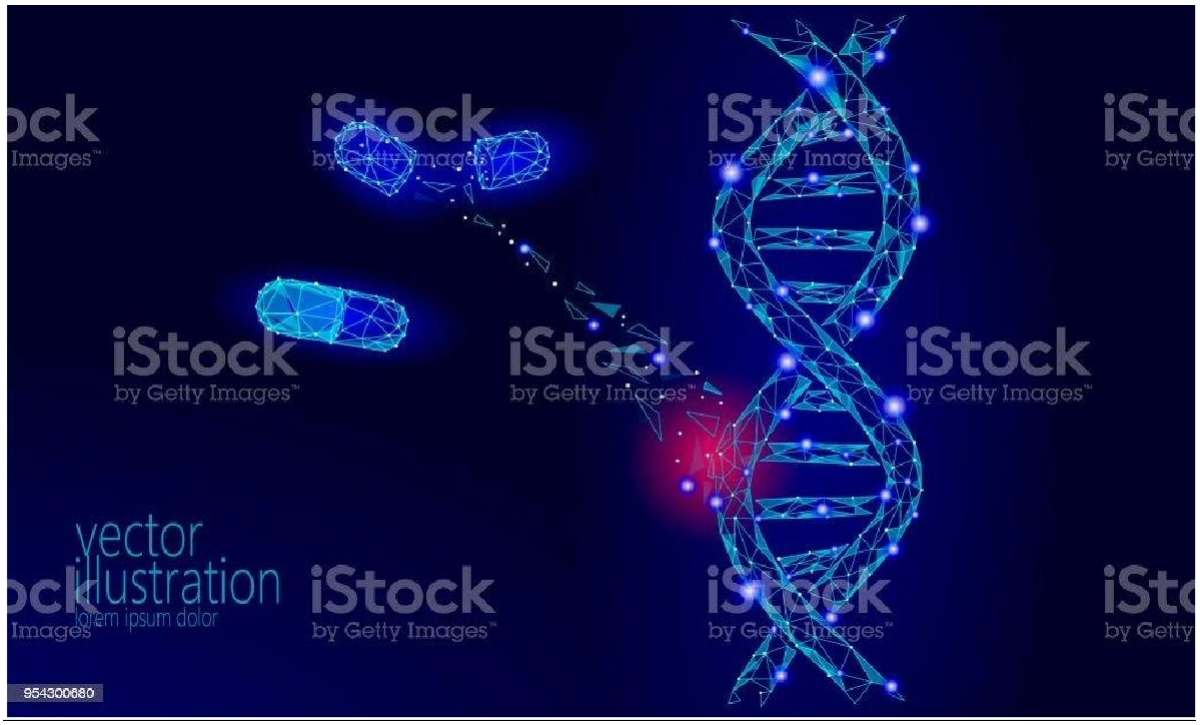

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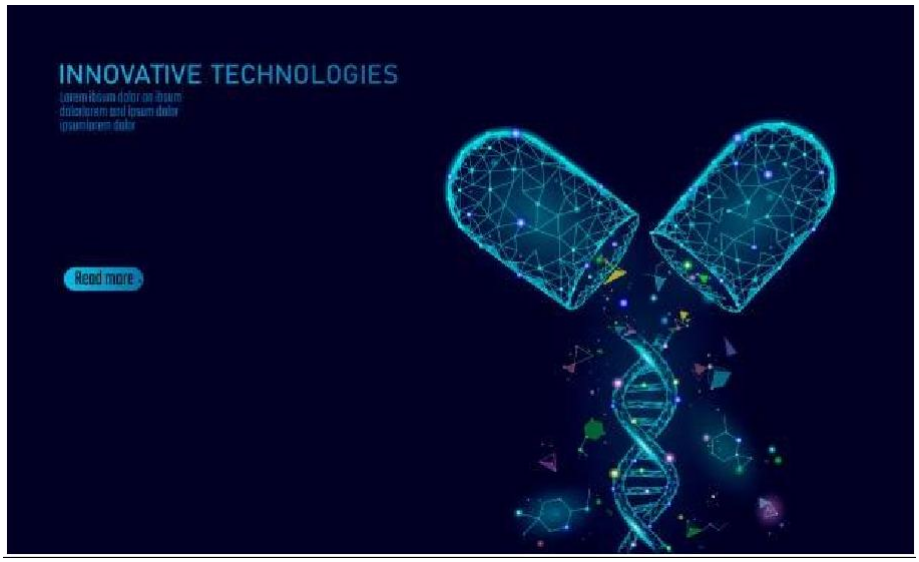

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CHAPTER II: LEGAL FACET OF GENE OWNERSHIP

The question raises here is how can we define human gene patents. "Human gene patents are

[15] Koepsell, David R. (David Richard), '*who owns you? : the corporate gold rush to patent your genes'*,

patents on human genes that have been extracted from the human bodies and scientifically isolated and modified in a laboratory". Thousands of patents are granted by the U.S Patent and Trademark office.[16] Legal and moral justification is not the same thing. "It can be a situation where the legal decisions will be immoral yet consistent with the legal precedent and procedure. So it leads to the conclusion that legal justification of human gene patents can remove the most unavoidable moral objections to them.[17] Though, those who are well equipped with patent law often believe that confusion over fundamental legal and scientific facts accounts for moral objections to such patents specifically for the belief that they justify ownership of one person by another".[18]

Human genes can only be patented if they can be isolated from the human body. To come under the purview of patent "an object or process must count as an invention not a discovery and has to meet further legal tests such as novelty, non-obviousness and usefulness. Therefore, legal facts about patents will not apply to naturally occurring objects unless and until they have been sufficiently modified by Human effort so as to count as "man-made" for legal purposes". Hence, "human genes can only pass the threshold test to qualify them as legally patentable only if they have been altered sufficiently" so that they can be legally differentiated from naturally occurring genes.[19] As we know human genes in our body are not patentable but the degree of manipulation and altercation that is essential to distinguish and identify a human gene scientifically equivalent to those genes that are so altered or modified can merit a legal patent. For instance, there are different methods of sequencing DNA and this all involves some basic processes such as "isolating DNA, purifying DNA, removing a small segment of the DNA from its place in the genome and connecting it to the bacterial DNA, chemically unwinding DNA", and radioactive florescent copies of the genomic DNA. Since the nature of DNA and genes to propagate its containment is entirely impossible. For instance air, water and radio frequencies cannot be exclusively controlled by one individual, country or corporation. This molecule would fit in the category of commons by necessity. However, genes can be regulated but they serve as a useful guiding factor for the determination of ethical and moral issues.[20]

[16] The Nuffield Council on Bioethics, 2002 ch. 2
[17] Meister, Mertens, Emmot and Alexander, '*Biotechnology, Patent and Morality*' (1997) [pp. 185-201]
[18] Ossorio p 411, Crespi p 225
[19] Dr. Annabelle Lever, '*Is It Ethical To Patent Human Genes*?,' Intellectual Property and Theories of Justice (Palgrave MacMilln, UK 2008)
[20] Zhang, '*Proposing resolutions to the insufficient gene Patent system,*' Santa clara Computer and High Technology Law Journal & High Tech Law Institute Publications, (vol. 20, pp. 1139-50)

A. Confusion of patenting with owning

The main ethical objection to human gene patents is the confusion with legally patentable genes with naturally occurring genes and there is also confusion about patenting with owning. A patent does not confer legal ownership of anything. One can have the legal patent on a pen without owning any pen. "One can have the legal patent on an invention but is devoid of any legal right to use that invention let alone to license others to use or manufacture it". The obvious reason is that the only legal right conferred by a patent is the right to prevent others from using or possessing one's invention. Hence we can say that human gene patents confer no right over naturally occurring genes but patent rights confer none of the positive rights to possess and use in which ownership consists. Now question raise will human gene patents directly pose a threat to our self-ownership? The "right to exclude others from using certain things is a very powerful right in itself".[21] It can be tantamount to absolute property rights. Patents are basically alienable rights which means it can be transferred to someone like tickets you can have a monopoly over it yet you can give it to someone else to use it and it is totally different from the unalienable right which cannot be transferred in any condition such as the right to life, liberty and to some extent property as argued by John Locke.

"The main problem of a patent system is to distinguish between which is patentable that which is not. The primary legal issue has been the standard of the invention. The principal test of the invention in the American system is that subject matter must be new", suppose does a change in colour or shape something new enough to be patentable? The court answered negatively and held that the invention must be substantially new to be patentable. The application of a substantial novelty test presents difficulties, but it is always clear what question is being asked. To qualify the test, it must be something more than the substantial novelty but it has not been explicitly mentioned what new question is being asked? The court stated invention must reveal a "flash of creative genius"[22] and standard should be "non –obviousness".

In an American case, the Supreme Court granted a "patent on oil-eating bacteria" giving the reason "that such a patent was perfectly consistent with legal objections to patenting natural objects that have not been significantly" modified by Human effort. In the case of "Parke-Davis and Co. v. H.K. Mulford and Co." the court gave patent on purified human adrenaline were patentable because by purification it became a new substance which can be used for a practical purposes like commercial and therapeutics and therefore if work involves "scientifically isolating and identifying a gene" which is resulted into changing of the properties of the gene then that would come under the umbrella of Patent law.

[21] *Dr. Annabelle Lever, 'Is It Ethical To Patent Human Genes?, (eds A. Gosseries, A Marciano and A. Strowel)*
[22] *Edmund W. Kitch,, Graham v. John Decree Co, New Standard for Patents, (1996 Sup. Ct. Rev 293)*

B. Do genes fit any recent concept of Intellectual property?

The law treated "genes as a form of intellectual property". The Patent can be granted to the processes, methods, manufacturers, and composition of matter. Patents do not "protect ideas but rather exclude the use of those ideas by others". Patent protection has been extended to genetic material as well as to the products and processes. Each segment of the "un-engineered human genome" is a naturally occurring object. "Its existence as" an intangible ideal that is inherent in every human being has no element of the type expressed above. The term "expression" we understand as applying legal terminology and its meaning in the field of biotechnology is totally different. The word "expression" in biotechnology means genotype is expressed through phenotype and hence unaltered genetic material that is the product of nature is not expressive but they can be made into expressions through some intentional modification. The genes are always expressed in some manner. It is expressed "in sequence with the letters that indicate its base pairs (CATTCCGG....) and the string representing the gene sequence cannot be granted protection". This limitation is acknowledged in "intellectual property law and precedent". The obvious reason is that granting a monopoly over those things precludes their application by others for useful purposes and it is not just to reward someone with a monopoly for finding something rather than creating it but this constraints also necessarily excludes protection of certain expressions where those expressions are the standard means representing that law of nature or abstract ideas.

C. DNA as a common heritage of all mankind

Different theories of intellectual property justify patent protection over such a thing which is novel and non-obvious in nature and created through human labour. Though possession of anything creates the presumption of ownership and this is acknowledged in society and legal norms from time immemorial. The brute facts of possession and of generally recognised determinants give rise to valid claims over property rights. On contrary to this "physical ability to exclude others from possession which is absent from the realm of ideas" and place intellectual property regimes in the realm of positive law. "Genes are not expressions of the sort that have been afforded intellectual property protection" and hence genes "are not the products of human intention and thus should not be given intellectual property protection". Genes are "natural products, resulting from evolutionary forces but connected with our individuality", uniqueness and "identity" like password or PIN of the ATM Card. Only 1 % of Human DNA exists differently in every human being which gives rise to variation in each organism and makes us uniquely who we are. And if the single base pair of SNP is changed or mutated then it will lead to disease. Genes are very much similar to expression except for one distinction that they are not product of human intention however expression is not the last

determining factor that decides something is copyrightable or patentable. The indices are generally "its usefulness and utilitarian or aesthetic". "Machines are expressive" of ideas and so are books. "There are" kinds and "tokens for each". "The blueprint of a machine is a representation of the type while the individual machine is a token". Thus, we have to take a pragmatic approach to grant more latitude for potential overlap of aesthetic expression than for primarily utilitarian expression.

CHAPTER III: AFTERMATH OF MYRIAD GENETIC CASE

Myriad genetic Inc. was the company engaged in scientific research and after conducting research "this company obtained patents for discovering the precise location and sequence of the BRCA1 AND BRCA2 Genes". These "genes are responsible" for cancer in the breast. Slight mutation in "these genes can increase the risk of ovarian and breast cancer and this knowledge" of genes give rise to early detection of these diseases and hence led to the development of advanced medical tests. This right give Myriad Genetics the "exclusive right to isolate BRCA1 and BRCA2 genes and also the exclusive right to produce BRCA c DNA". The District Court held that the patent was invalid because they covered the product of nature "under section 101 of U.S.C".[23] The "Federal circuit however reversed the decision of the District Court and held that isolated and" c DNA is patent-eligible.[24]

"Section 101 of the Patent Act" states:

"Whoever invents or discovers any new and useful composition of matter, or any new and useful improvement thereof, may obtain, therefore, subject to the conditions and requirements of this title." "Law of nature, natural phenomena, and abstract ideas are not patentable."

Since "Myriad did not create or alter any of the genetic information" encrypted in the "BRCA1 and BRCA2 genes", these genes are already found in "nature before Myriad found them" however Myriad main contribution was to unravel "the precise location and genetic sequence of the BRCA1 and BRCA2 genes" inside chromosomes "17 and 13" but separating these two genes from "surrounding genetic material" is not an act of invention.[25] Even "ground breaking", "innovative" or "excellent discovery" does not qualify the "test of section 101".[26]

[23] Medlmmmune Inc. v. Genetech, Inc., 549 U.S. 118 (2007)
[24] Mayo Collaborative Services v. Prometheus Laboratories, Inc. 566 U.S
[25] Association for Molecular Pathology v. Mriad Genetics

[26] Funk Brothers Seed Co. v Kalo Inoculant Co., 333 U.S. 127 (1948)

As per the "Biotechnology Guidelines 2013" of India, any gene that is in form of recombinant and it has developed though inventive step then in that case it would be eligible for patent.

Due to recurrent problem of "Bio piracy" and "Cultural piracy", India has reformed its Patent laws. One important law that was passed by the parliament concerning this was Plant Variety and farmers Right (PPVR) Act, 2001, and Biological Diversity Act, 2002. The principle of "benefit sharing" is embodied in these Acts so that common people of the country shall be benefitted

Indian courts are granting patents to cDNA as per the provisions of the patent law. In *Monsanto Technology LLC v. Nuvizeedu Seeds Ltd* case, patent was granted to "BT" crops for instance patent was granted to "Genetically stable JEV cDNA which is related to "Japanese Encephalitis Virus" court considered it novel and non-obvious and hence eligible for patent.

CONCLUSION

The whole Myriad Genetic case revolved around the question of whether "naturally occurring genes" can be patented or not. Genes can only be patented when it is altered or modified in such a way that they can be easily distinguished from the natural genes. Merely finding the precise location does not satisfy the requirements of section 101 however c DNA is not the product of nature. C DNA leads to the creation of Exons only molecule without interruption of Introns and hence it is new and meets the eligibility criteria of section 101.

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