NATIONAL UNIVERSITY OF ADVANCED LEGAL STUDIES, KOCHI

DISSERTATION SUBMITTED IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTERS OF LAWS (2019-20)
ON THE TOPIC

PATENTABILITY OF GENES: AN ANALYSIS

Under The Guidance and Supervision Of

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CERTIFICATE

This is to certify that Ms. Arathy Nair, Reg. no. **LM0219004** has submitted her dissertation titled, **"*Patentability of Genes: An Analysis*"**, in partial fulfillment of the requirement for the award of Degree of Master of Laws in International Trade Law to the National University of Advanced Legal Studies, Kochi under my guidance and supervision. It is also affirmed that the dissertation submitted by her is original, bonafide and genuine.

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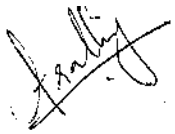

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ACKNOWLEDGEMENT

I take this opportunity to express my profound respect and deep sense of gratitude to **Dr. Athira P.S,** my guide and supervisor, for her support, guidance and encouragement throughout the course of my research work. She was always approachable, respected my ideas and gave me clear, cogent and meaningful suggestions, which has aided me profusely in completing this dissertation.

I would like to extend my gratitude to the Vice-Chancellor **Prof. (Dr.) K.C Sunny** for his constant encouragement and support. I express my sincere thanks to **Prof. (Dr.) Mini. S**, Director of Centre for Post Graduate Legal Studies for her support and encouragement extended during the course.

I would further extend my deep felt gratitude to the faculty of NUALS for their constant encouragement. I convey my thanks to **Mrs. Jeeja V**., Assistant librarian, **Mr. Anil Kumar C., Miss Neenu** and **Mr. Unnikrishnan K.K.,** Library Assistants for their timely assistance to carry out the work.

Words fall short of expressing love, appreciation and gratitude to my dear family and friends for their constant encouragement.

With genuine humility, I am thankful to The Almighty for all his uncountable bounties and blessings.

ARATHY NAIR

LIST OF ABBREVATIONS

BRCA gene	Breast Cancer gene
cDNA	Complementary deoxyribonucleic Acid
CRISPR	Clustered regularly interspaced short palindromic repeats
DNA	Deoxyribonucleic Acid
e.g.	Example ribonucleic acid
EPC	European Patent Convention
EPO	European Patent Office
EU	European Union
EST	Expression Sequence Tag
HGP	Human Genome Project
ICESCHR	International Covenant on Economic, Social and Cultural Rights
i.e.,	id est (that is)
IP	Intellectual Property
IPO	Indian Patent Office
JEV	Japanese encephalitis virus
mRNA	Messenger ribonucleic acid
NAFTA	North American Free Trade Agreement
NGO	Non-Governmental Organization
PCR	Polymerase chain reaction
R&D	Research and Development
RNA	Ribonucleic acid
TRIPS	The Agreement on Trade-Related Aspects of Intellectual Property Rights
UDHR	Universal Declaration of Human Rights

UK	United Kingdom
UPSTO	The United States Patent and Trademark Office
US	United States of America
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

JOURNALS

Acad Med	Academic Medicine
Am U Int'l L Rev	American University International Law Review
Annu. Rev. Genom. Hum. Genet	Annual Review of Genomics and Human Genetics
Ariz J Int'l & Comp L	Arizona Journal of International and Comparative Law
Asian Biotech & Dev. Rev	The Asian Biotechnology and Development Review
B.U. J. Sci. & Tech. L.	Boston University Journal of Science and Technology Law
Canterbury L. Rev	Canterbury Law Review
Chi.-Kent L. Rev-	Chicago-Kent Law Review
Harv JL & Tech	Harvard Journal of Law & Technology
Hous. J. Int'l L.	Houston Journal of International Law
Int.J. Curr. Microbiol. App. Sci -	International Journal of Current Microbiology and Applied Sciences
Inte'l J Envtl Stud	International Journal of Environmental Studies
Indian JL & Tech	Indian Journal of Law and Technology
Int J Genomics	International Journal of Genomics

Intell Prop Rts	Indian Institute of Patent and Trademark
IPCB	Indigenous Peoples Council on Biocolonialism
J. Health Care L. & Pol'y	Journal of Health Care Law and Policy
J. High Tech.L	The Journal of High Technology Law
J Vis Exp	The Journal of Visualized Experiments
Melb U Law Rw	Melbourne University Law Review
Minn. J.L. Sci. & Tech	The Minnesota Journal of Law, Science & Technology
Nt'l L Sch India Rev	National Law School of India Review
NUJS L. Rev	National University of Juridical Sciences
N.Y.U. L. Rev	New York University Law Review
Pac. Rim L. & Pol'y J	Pacific Rim Law & Policy Journal
PLoS	Public Library of Science
Queen Mary J. Intell. Prop	Queen Mary Journal of Intellectual Property
Sask L Rev	Saskatchewan law review
UMKC L. REV	University of Missouri-Kansas City Law Review
Wash. U. Global Stud. L. Rev	Washington University Global Studies Law Review
Willamette L. Rev.	Willamette Law Review

TABLE OF CASES

- Paschim Banga Khet Mazdoor Samity & Ors v State of West Bengal & Anor.: (1996) AIR SC 2426/ (1996) 4 SCC 37
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- Red dove case, BGH, 1 IIC 136 (1970)

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CHAPTER 1

INTRODUCTION

Life sciences, along with biotechnology, is widely regarded as the most promising cutting edge technologies for the coming decades.[1] Biotechnology makes use of biological systems found in organisms or the use of the living organisms themselves to make technological advances. It is increasingly recognized as the next wave in the knowledge-based economy, after information technology. It plays a crucial role in developing of many sectors like health, agriculture, food, and the environment.[2] Biotechnology is hugely multidisciplinary, spanning almost over every branch of science such as genetics, molecular biology, biochemistry, embryology, and cell biology, is related to specific fields such as chemical engineering, information technology, and robotics.[3] Since it is an area with endless opportunities for innovations, it becomes imperative to protect the knowledge and ideas evolved. This is where intellectual property rights step in. Intellectual property rights try to provide the necessary shield and protection to biotechnology.[4]

For the success of any technological innovation, ownership and exploitation of intellectual property rights play an important role. IPR plays a vital role in developing strategies to disseminate and transfer technology which would provide maximum benefit to society.[5] The intellectual property created in biotechnology takes different forms and most often one asset may attract more than one type of IP protection. Different types of IP protection available in biotechnology include patents, copyrights, trademarks, designs, and domain names. Among these IPs, patents are the most important ones.

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[1] *Life Sciences and Biotechnology – A Strategy for Europe*, European Commission (2002) http://priede.bf.lu.lv/grozs/Mikrobiologijas/BiotehIII/Life_sci_and_biotech.pdf

[2] *Fact Sheet Intellectual property in Biotechnology*, European IPR Helpdesk (June 2014) www.iprhelpdesk.eu

[3] K.K. Tripathi, *Biotechnology and IPR Regime: In the Context of India and Developing Countries*, Asian Biotech & Dev. Rev 1 (2004)

[4] K. Jeyaprakash, *Intellectual Property Rights –Role in Biotechnology*, Int.J. Curr. Microbiol. App. Sci 39-41 (2016)

[5] Tripathi, supra, at 6

The rationale behind awarding patents is to encourage inventors to invent. Sans rewards to promote innovation; future developments will remain stagnant. Often due to such rewards, people are willing to invest in risky research which otherwise would have been left untouched. It is safe to say that without such incentives and rewards, the progress in the field of biotechnology would not have reached where it is today.[6] Disclosure of knowledge to the public is also an important purpose of the patent system as it would help other inventors to invent around the patented inventions or make any modifications to the existing invention.[7] A patent further encourages commercialization of the research i.e., the inventors can commercially produce products without facing any competition from others. Such incentives to commercialize comes with both positive and negative repercussions.[8]

The modern biotechnology industry is based on the discovery and exploitation of DNA properties. Rapid advances in identifying how protein DNA codes and is regulated have driven the evolution of the biotechnology industry.[9] The evolution of how the biotechnology industry uses DNA can be grouped into three generations. The first generation is focused around the idea that gene codes for a protein and attempts to identify a gene and then use it to generate a specific protein through recombinant DNA technologies.[10] The second generation is based on the concept that all gene sequence variants correlate with a specific disease and using this association, that disease could be diagnosed.[11] Finally, the third generation makes use of automated sequencing to regulate or manipulate DNA or genetic material which are beneficial for medical and scientific purposes.[12]

Gene patents can be considered to be an important foundation of the modern biotechnology industry.[13] Over a few decades, the concept of genes has undergone

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[6] Amanda S. Pitcher, *Contrary to First Impression, Genes are Patentable: Should There be Limitations?*, 6 J. Health Care L. & Pol'y 284, 285 (2003).

[7] James Bradshaw, *Gene Patent Policy: Does Issuing Gene Patents Accord With The Purposes of the U.S. Patent System?*, 37 Willamette L. Rev.(2001)

[9]Suliman Khan et al., *Role of Recombinant DNA Technology to Improve Life*, 2016 Int J Genomics (2016) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5178364/ (last visited May 16, 2020)

[10] Rebecca S Eisenberg, *Why the Gene Patenting Controversy Persist?* 77 Acad Med 1381 (2002).

[11] Id

[12] Id

[13] John Raidat, *Patents and Biotechnology*, US Chamber of Commerce Foundation (2014) https://www.uschamberfoundation.org/patents-and-biotechnology (last visited Oct 12, 2019)

tremendous changes. It began as a simple unit of heredity, transferring characters from one generation to another.[14] With the discovery of the structure of the DNA and the 'genetic code', gene fragments became the source of information. A gene can thus be defined as a discrete unit of DNA containing information necessary to produce a particular protein. Proteins operate as building blocks for cellular structures and perform most cellular functions.[15] Thus, genes can be called the building blocks of life.[16] Most human traits like hair color, eye color, blood type, susceptibility to disease, and how an individual reacts to drugs are all controlled by genes.[17] Owing to the advanced technology and the rapid pace of research in the area of genetics, genetic materials can be isolated and manipulated in ways that were not possible a few years ago. Patented genetic inventions have different applications like producing therapeutic proteins, diagnosing diseases, gene therapy, and research tools. The list is non-exhaustive and the applications will continue to increase with rapid advances in the biotechnology sector.[18]

Despite its contribution to the medical field and other research, gene patents are often amidst controversies. The most argued point when it comes to gene patents is that patenting genetic materials, especially human genes are morally wrong. Some believe that when human genes are patented, they are treated as mere commodities, and thus calling it 'modern slavery'.[19] It's also argued that gene patents hamper research along with restricting access to medical diagnosis and treatment.[20] A patent is a powerful tool in the hands of the patent holder, which if left unchecked can cause more harm than good. Also, patents involving genes potentially have the most varied and unclear laws across different jurisdictions when compared to other areas of technology.[21]

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[14]Andrew W. Torrance, *Gene Concepts, Gene Talk, and Gene Patents*, 11 Minn. J.L. Sci. & Tech. 157-60 (2010).

[15] Bruce Alberts et al, Molecular Biology of the Cell 200 (4th ed, 2002)

[16] Alison Heath, *Preparing for the Genetic Revolution - The Effect of Gene Patents on Healthcare and Research and the Need for Reform*, 11 Canterbury L. Rev. 59, 60 (2005).

[17] Allen Nunnally, *Commercialized Genetic Testing: the Role of Corporate Biotechnology in the New Genetic Age*, 8 B.U. J. Sci. & Tech. L. 300, 306 (2002)

[18] Timothy Caulfield, *Sustainability and the Balancing of the Health Care and Innovation Agendas: The Commercialization of Genetic Research*, 66 Sask L Rev 629, 631(2003)

[19] Abhijeet Kumar, *Gene Patenting vis-a-vis Notion of Patentability*, 20J Intell Prop Rts 349 (2015)

[20] Lisa Campo-Engelstein et al, *How Gene Patents May Inhibit Scientific Research*, 4 BioéthiqueOnline 1 (2015)

[21] Jessica C. Lai, *Gene-Related Inventions in Europe: Purpose - vs Function-Bound Protection*, 5 Queen Mary J. Intell. Prop. 449 (2015).

With the recent trends in technology and research, it can be easily said that humanity is facing the dawn of a genetic revolution[22]. The scope of innovation in the area is unlimited and with a better understanding of genes, more applications of gene patents can be expected in the coming years.

And because of this very reason, it is important to timely consider the patentability of genetic inventions.[23] The whole concept of gene patents has both supporters as well as critiques. On the one hand, when moral, social and, legal arguments are lined up against gene patents, there is an equally supportive group for gene patents who consider gene patents inevitable from the point of view of research and medical advancements.[24] Denying patents to genetic invention seems unfair as patents are available to most inventions in other fields of science. Thus, it is often a perplexing challenge to strike a balance between preserving the integrity of our genetic heritage and providing a just reward for human efforts put into the innovation.[25]

STATEMENT OF PROBLEM

After the 1980 Chakrabarty case,[26] granting patents to inventions involving microorganisms, biotechnology has made major break-through in inventions involving living beings. Stem cell technology, somatic cell hybridization, genome technology, gene therapy, and cloning are some of these new trends. However, across jurisdictions, the lack of a uniform legal framework relating to the patentability of genes is found to be problematic. Further, the ethical, moral, and social implications of such patenting demand in-depth scrutiny as well as analysis.

SCOPE OF THE STUDY

The study aims to analyze the laws relating to patents for genes. It will focus on the position of granting patents for genes internationally, along with ascertaining the Indian position on the same, with a particular comparative focus on Australia, the US, and the

[22] Caulfield, supra, at 632
[23] Heath, supra at 61
[24] Campo-Engelstein, supra, at 2
[25] Patricia A. Lacy, *Gene Patenting: Universal Heritage vs. Reward for Human Effort*, 77 Or. L. Rev. 783, 784 (1998).
[26] Diamond v. Chakrabarty, 447 U.S. 303 (1980)

EU. The study will also analyze the arguments against patenting of genes including ethical, moral, and legal issues and attempt at arriving at an international standard applicable to the same.

RESEARCH OBJECTIVES

The research objectives are as follows-

1) To provide a scientific overview of genes and gene patents.
2) To analyze the various laws, policies, and judicial approaches related to the patentability of genes in India and other jurisdictions.
3) To ascertain the various social, legal, ethical and moral implications relating to gene patents.
4) To provide solutions or remedies to the problems existing in the patenting of genes.

RESEARCH PROBLEMS

The research problems are as follows-

1) What are the criteria for the patentability of genes?
2) What are the social, ethical, and moral issues related to gene patents?
3) What is the position of courts in questions relating to the patentability of genes in different jurisdictions?
4) Does gene patent in any way hamper research and innovation?
5) To what extent regulations should be exercised while granting patents to genes?

HYPOTHESIS

The hypothesis of the study is as follows-

1) India needs a specific lucid policy on patents involving genes.
2) Indiscriminate grant of patents to genes impedes research and innovation.

CHAPTERIZATION

CHAPTER 1: Introduction

The first chapter is a general introduction of the dissertation which includes the scope of the study research problems, research questions, hypothesis, and chapterization.

CHAPTER 2: A scientific overview of Genes

The second chapter provides for a general understanding of the concept of genes with a detailed description as to its characteristics, origin, composition, functions along with diagrams. The chapter also includes genetic engineering and its different applications.

CHAPTER 3: Social, moral, ethical implications of gene patents

The third chapter analyses the social, moral, and ethical problems related to the patenting of genes. Such analyses would be helpful in understanding whether the good outweighs the bad in the context of gene patents.

CHAPTER 4: Patentability of genes in India

The fourth chapter deals with the history of the Indian patent system and patentability requirements especially in the case of genetic inventions. A special reference to the Patents Act, its amendments in compliance with the TRIPS Agreement, Patent Rules, and Biotechnology Guidelines are made.

CHAPTER 5: Comparative study of standards relating to patentability of genes

The fifth chapter analyses the patentability standards for gene patents at the international level. For better understanding, patentability requirements in Australia, the US, and the EU are dealt with along with important case laws. The minimum flexibility to set standards of patentability provided by TRIPS to its member countries is also discussed.

CHAPTER 6: Conclusions and suggestions

The final chapter concludes the whole study after analyzing each chapter. Further the chapter also makes suggestions and recommendations in the context of gene patents at both national and international levels.

CHAPTER 2

A SCIENTIFIC OVERVIEW OF GENES

For many years, people have known that all living organisms inherit characteristics or traits from their parents. However, scientists were unable to find out how exactly this happened until the 20th century. Johann Gregor Mendel (1822–1884), 'father of genetics,' conducted a decade long research to find patterns of inheritance. He experimented on pea plants and came up with the law of segregation and the law of independent assortment. All his experiments were published under the title *Experiments in Plant Hybridization*. Mendel, through his experiments, deduced that biological variations are inherited from parent organisms.[27]. Though his work was published in 1865, it was not until 1900 that his findings were recognized and understood In 1900, three scientists Hugo de Vires, Carl Correns, and Erich von Tschermak, came with the same conclusions as that of Mendel through independent research.[28] Mendel hypothesized a factor that conveys traits from parents to offspring, "the genes".[29] But Mendel never used the term 'gene' in his observations. Charles Darwin used the term 'gemmule' for units of inheritance, which was later called chromosomes. Wilhelm Johannsen, a Danish botanist, coined the term 'gene' in the year 1909.[30]A gene is the fundamental physical and biological construct of heredity. Human cells contain a nucleus, within which are tightly coiled structures called chromosomes. Humans have 23 pairs of chromosomes, one from each parent. Each chromosome has thousands of genes. Genes are what carries our traits through generations and are made of deoxyribonucleic acid (DNA). They operate as a guide for the development of functional molecules such as ribonucleic acid (RNA) and proteins that conduct chemical reactions in our bodies. The DNA of each gene is characterized by a sequence of bases known as the genetic code. Genes, the working subunits of DNA, is the chemical information database carrying the complete set of information for the cells

[27] *History of Genetics*, News Medical Life Sciences https://www.news-medical.net/life-sciences/History-of-Genetics.aspx (Last Updated: May 3, 2019)

[28] Id.

[29] *1909:The Word Gene Coined*, National Human Genome Research Institute https://www.genome.gov/25520244/online-education-kit-1909-the-word-gene-coined (Last updated: April 22, 2013)

[30] Id.

as the nature of the proteins produced by it.[31] A gene can be defined as a hereditary determinant of a trait.

STRUCTURE AND FUNCTION OF GENES

The gene is the basic unit of genetic activity, for which the DNA molecule is the chemical foundation. All information necessary to build and maintain an organism is contained in the DNA. Whenever organisms reproduce, a portion of their DNA is passed along to their offspring. This transmission of all or part of an organism's DNA helps ensure a certain level of continuity from one generation to the next, while still allowing for slight changes that contribute to the diversity of life.[32] Nearly all living cells contain DNA. The exact location of a DNA within a cell, though, depends on whether the cell has a specific membrane-bound organelle called a nucleus. Organisms are often classified as eukaryotes and prokaryotes. Eukaryotes are composed of cells that contain nuclei, and the DNA is present within the nuclei. On the other hand, since prokaryotic organisms are composed of cells that lack nuclei, the DNA is located directly within the cellular cytoplasm.

Except for some viruses in which genes consist of a closely related compound called RNA, every other living organism contains DNA.[33]

Until the 1950s, scientists were clueless about the structure of DNA. For better understanding, experiments using X- rays as a form of molecular photography were conducted.[34] It was zoologist James Watson and physicist Francis Crick[35] who found out that DNA exists as a double helix, which was then considered to be the most profound discovery of the 20th century. The structure of DNA proved quite helpful in

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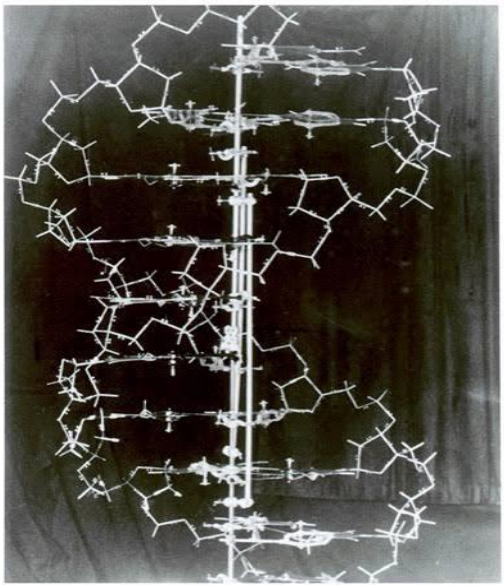
[31] Gurbachan S Miglani, Basic Genetics, 78 (1st ed, 2000)
[32] Heidi Chial et al., Essentials of Genetics 1 (Ilona Miko et al eds, 2009)
[33] See, PK Gupta, Genetics, (3 rd ed, 1999)
[34] Rosalind Franklin, a physical chemist, working with Maurice Wilkins at Kingston College in London, was among the first to use this method to analyze genetic material. See, *The History Of DNA Timeline*, DNA Worldwide, https://www.dna-worldwide.com/resource/160/history-dna-timeline (Last visited: Oct 18, 2019)
[35] Watson and Crick both worked at Cambridge University in the United Kingdom, where they tried to determine the shape of DNA. Their efforts were successful in 1953 when they discovered the 'double helix' shape of the DNA. In 1962, the Nobel Prize in physiology or medicine was awarded to Watson, Crick, and Wilkins for this work. Due to her untimely death, Franklin did not earn a share in the Nobel Prize. See, *Deciphering Life's Enigma Code, The Nobel Prize* https://www.nobelprize.org/prizes/medicine/1962/speedread/ (Last Updated: May 2020)

understanding the fundamentals of genetics. Scientists were finally able to solve the mystery of how genetic information is stored, transferred, and copied.

Figure 2.1- Watson and Crick's original 3-D demonstration model of DNA[36]

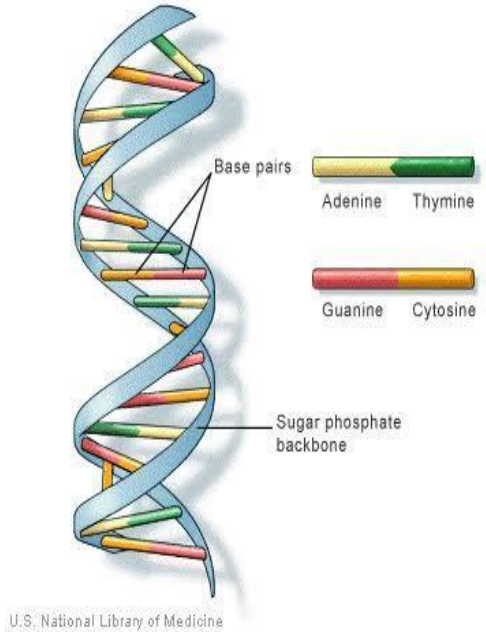


All DNA is made up of a series of smaller molecules called nucleotides at the most basic level. Each nucleotide consists of three main components: a nitrogen-containing region known as a nitrogen base, a carbon-based sugar molecule known as deoxyribose, and a phosphorus-containing region known as a phosphate group attached to the sugar molecule. There are four different nucleotides, and each of them is defined by a specific nitrogenous base. They are adenine (A), thymine (T), guanine (G), and cytosine (C). A DNA molecule is composed of two chains of nucleotides that are winded together as parallel handrails or a twisted ladder. The two sides of the ladder consist of sugar and phosphate. The bonded pairs of nitrogen bases form the rungs of the ladder. The two strands are complementary to each other i.e., A always matches with T and C with G. The sequence of bases in DNA provides the code that regulates the structure of proteins. Proteins are made up of a chain of amino acids. The unique characteristic of each protein

[36] Scientific Figure on ResearchGate.
https://www.researchgate.net/figure/Watson-and-Cricks-original-3-D-demonstration-model-of-DNA_fig2_317743119 (last visited Apr 23, 2020)

is determined by the ordering of the amino acid.[37]

Figure 2.2 – Structure of DNA[38]



Chromosomes

There are approximately 100 trillion cells in one human being. The process of fitting DNA into a compact form within the cell is called DNA packaging. During the process, the long double-stranded DNA is tightly looped, coiled, and folded so that they can fit in easily inside the cell. In order to fit inside the nucleus, eukaryotes wrap their DNA around a particular protein called histones. The eukaryotic DNA, along with the histone proteins that hold it together in a coiled form, is called chromatin.[39]

Further, DNA is compressed by a twisting process called supercoiling. Such tightly compacted DNA is then organized in both eukaryotes and prokaryotes, into structures

[37] Hans-Dieter Belitz et al., *Food Chemistry* 8 (2008). https://www.researchgate.net/publication/227032307_Amino_Acids_Peptides_Proteins (last visited Oct 20, 2019)
[38] *What is DNA?* US National Library of Medicine, https://ghr.nlm.nih.gov/primer/basics/dna (last visited Oct 20, 2019)
[39] Chial, supra, at 4

called chromosomes.[40] Except for eggs, sperms, and red cells, every cell in our body contains a full set of chromosomes in its nucleus. Chromosomes are different in shape in different organisms. In eukaryotes, chromosomes often appear as an X- shaped structure. In humans, there are 23 pairs of chromosomes. Humans contain two types of sex chromosomes, including X and Y. While a male has XY chromosomes, a female possesses XX chromosomes. The X chromosome is much larger than the Y chromosome. The X chromosome has about 2,000 genes, whereas the Y chromosome has fewer than 100, none of which are essential. Out of this, 22 pairs are identical in males and females. The 23rd pair is the sex chromosome that determines gender in humans. All the 22 pairs of chromosomes are numbered based on their size.[41] Other than the genes carried on by sex chromosomes, an individual inherits two copies of every gene, one from each parent. The location of a particular gene in a chromosome is called locus. The copies of a particular gene are called alleles. Alleles play an important role in shaping each human's individual features.[42]

Figure 2.3- DNA packaging and chromosomes[43]

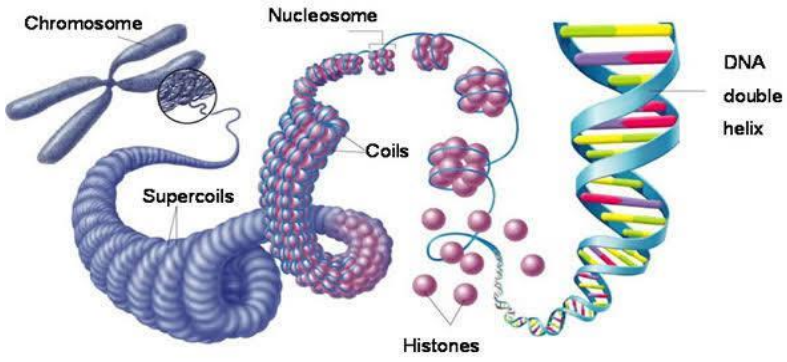
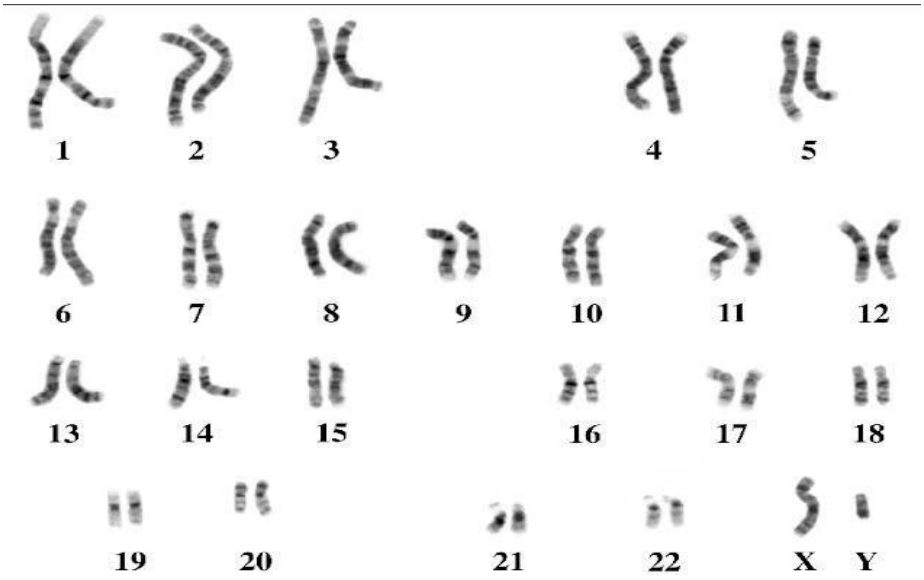


Figure 2.4- Chromosomes in humans numbered according to size[44]

[40] Chial, supra, at 5
[41] Miglani, supra, at 83
[42] Alberts, supra, at 202

[43] *The DNA packaging problem* https://steemit.com/science/@ovij/the-dna-packaging-problem (last updated Mar 2018)
[44] *Chromosome changes*, EuroGentest (2007) http://www.eurogentest.org/index.php?id=611 (last visited Oct 23, 2019)



Each chromosome contains thousands of genes that play a massive role in the body's development, growth and chemical reactions. Nevertheless, sometimes there can be some chromosomal abnormalities which can either be numerical or structural. When a whole chromosome is missing, or there is an extra chromosome in the usual pair, it is called numerical abnormality. Down syndrome is one of the most common numerical abnormalities in humans. An extra copy of chromosome 21 causes Down syndrome (trisomy 21). Such a genetic disorder often results in stunted physical growth, characteristic facial features, and mild intellectual capacity.[45] In some organisms, the arrangement of the genes in the genome is altered by a chromosome with a particular segment missing, reversed in orientation, or attached to a different chromosome.[46] Such variations result in abnormalities in the chromosome structure.[47]

DNA Replication

Our bodies are made of trillions of cells, but what is interesting is that it all started from a single cell. DNA replication is the process through which a double-stranded DNA

[45]See, *Down Syndrome*, U.S National Library of Medicine https://ghr.nlm.nih.gov/condition/down-syndrome (last updated June 2020)
[46] See, Daniel L. Hartl et al., Genetics: Principles and Analysis, 470 (4th ed, 1997)
[47]*Understanding Genetics: A New York, Mid-Atlantic Guide for Patients and Health Professionals* (2009) https://www.ncbi.nlm.nih.gov/books/NBK115563/pdf/Bookshelf_NBK115563.pdf

molecule is copied, resulting in two identical DNA molecules. Every time a cell divides, the resulting copied cells will contain the same amount of DNA (genetic information) as that of its parent cell. In order to make a copy of itself, the twisted DNA separates. To make a new strand, each strand becomes a blueprint or prototype, so the two new DNA molecules have one new strand and one old strand. A special cellular protein called DNA polymerase reads the template DNA strand and assembles the complementary new strand. Several other enzymes, like DNA helicases, topoisomerases, primases, and ligases, are also needed during the replication process.[48] This process of replication is speedy and mostly accurate. Sometimes some mistakes like duplication or deletion may occur during replication. Fortunately, most of these errors are fixed through different processes of DNA repair. Repair enzymes recognize structural imperfections between improperly pgeaired nucleotides, eliminate incorrect ones and replace them with the correct ones.[49] However, sometimes replication errors are not corrected through these repair mechanisms. Errors during replication that go past the repair mechanism become permanent mutations. A mutation can cause a gene to encode a protein that either works incorrectly or does not work at all. The mistake sometimes means no protein is produced. Mistakes during the replication process may lead to cancer and other genetic disorders. Three human genetic disorders associated with defects in DNA replication are xeroderma pigmentosum (XP), cockayne syndrome (CS) and trichothiodystrophy (TTD).[50] However, this does not mean that all mutations are harmful. Many mutations have no impact, while others produce new forms of proteins, which can give the species a survival advantage. Over time, mutation provides the raw material from which different forms of life evolve.[51]

Gene expression and gene regulation

All the instruction necessary to sustain a cell is contained with the genes. To implement

[48]See, 2 Ross C. Hardison, Working with Molecular Genetics, 231 (2008)
[49] Leslie A. Pray, *DNA Replication and Causes of Mutation*, Nature Education https://www.nature.com/scitable/topicpage/dna-replication-and-causes-of-mutation-409/ (last visited Oct 23, 2019)
[50] Carlos R. Machado et al, *Human DNA repair diseases: From genome instability to cancer*, 20 Brazilian J. Gent. 14(1997)
[51]Mark Johnston, *Mutations and New Variation: Overview* (2003) https://onlinelibrary.wiley.com/doi/abs/10.1038/npg.els.0001723 (last visited Oct 29, 2019)

such orders, it is essential to copy or express the instructions inside the gene in such a way that the cells can produce proteins needed to support life. Gene expression is the mechanism through which the genetic code of genes is used to guide protein synthesis and to create the cell structures. A cell reads and processes the instructions stored inside DNA in two steps: transcription and translation. During transcription, the information stored inside the DNA is copied into RNA. RNA polymerase, a protein reads the DNA and then makes RNA copy. Since it delivers the gene's message to the protein-producing machinery, it is called messenger RNA or mRNA. The newly created RNA molecule is itself a finished product in some situations and serves a vital role within the cell. Three out of four nitrogen bases, i.e., adenine (A), cytosine (C), and guanine (G), are similar in both RNA and DNA. A base called uracil (U) replaces thymine (T) in RNA. Unlike DNA, RNA is made in a single-stranded, non-helical form. Once a cell transfers information necessary to produce proteins from DNA to mRNA, the process of transcription is complete. The next step is translation, where the mRNA is used as a template for protein assembly.[52]

Translation involves a series of complex mechanisms. The flow of information from DNA to RNA and then into proteins is considered to be the central dogma[53] of genetics.[54] Translation takes place in specialized structures called ribosomes. Ribosomes contain vast amounts of RNA and different proteins. During translation, ribosomes move along the mRNA strand and assemble the amino acid sequence indicated by the mRNA with the help of proteins called initiation factors, elongation factors, and release factors, thus forming a protein. During translation, the second type of RNA called transfer RNA (tRNA) matches up to the nucleotides on mRNA with a specific amino acid. A set of three nucleotides codes for an amino acid. When a series of amino acids are built according to the sequence of nucleotides, a polypeptide chain is formed. All proteins are made of one or more linked polypeptide chains. A cell uses a set of rules called the genetic code to interpret a series of nucleotides inside the mRNA molecule. The mRNA

[52]Suzanne Clancy et al., *Translation: DNA to mRNA to Protein*, Nature Education (2008) https://www.nature.com/scitable/topicpage/translation-dna-to-mrna-to-protein-393/ (last visited Oct 29, 2019)
[53] Subhash Lakhotia, *What is a gene?*, 2 Resonance 44, 46 (1997)
[54] Chial, supra, at 8

molecule is translated into groups of three bases called codons.[55] The four nucleotides found in mRNA (A, U, G, and C) can produce a total of 64 different combinations. Moreover, out of these combinations, 61 combinations are amino acids, while the remaining three trigger the end of protein synthesis and are hence called stop signals.

All cells depend on a regulatory mechanism to control gene expression. The purpose of gene regulation is to make sure the gene is expressed only when a product is needed.[56] All nucleotide sequences in a strand of DNA do not code for the production of proteins. Some of these non-coding sequences act as binding sites for the different protein molecules needed to activate or control the transcription process. Additionally, specific other non-coding sequences near to the promoter sequence serve as protein binding sites that can either induce or block transcription. Gene regulation takes place in both prokaryotes and eukaryotes but in different ways.[57] Because of different factors like a higher number of genes and the presence of a nuclear membrane that separates the transcription and translation sites, the process of gene regulation in eukaryotes is much more complicated than that in prokaryotes.[58]

Gene isolation

Methods to isolate genes were not developed until the 1960s. However, by the 1970s, with the development of recombinant DNA technology, researchers were able to isolate any gene from an organism.[59] Gene isolation can be done either through copy DNA sequencing or genetic sequencing. The method of cDNA starts with the assumption that a person's exact genetic sequence does not directly code for a gene that later is translated into a protein. At first, the DNA molecule is first translated into an RNA (ribonucleic acid) molecule, and later it is transcribed into a messenger RNA (mRNA) sequence. The molecule of mRNA converts into the components that make up the protein, which is a

[55] Patricio Jeraldo, *The Genetic Code* (2006) http://guava.physics.uiuc.edu/~nigel/courses/569/Essays_Spring2006/files/jeraldo.pdf (last visited Oct 29, 2019)
[56] Akif Uzman, Molecular Biology of the cell 17 (Johnson B Alberts et al., 4th ed., 2003)
[57] Kevin Struhl, *Fundamentally Different Logic of Gene Regulation in Eukaryotes and Prokaryotes*, 98 Minireview 2 (1999)
[58] Chial, supra, at 8
[59] Alberts, supra, at 207

clone of DNA without introns. Reverse transcriptase enables the mRNA to be converted back into DNA. Once the DNA molecule is produced it does not contain the already spliced out introns.[60] In order to obtain the exact nucleic acid sequence, gel electrophoresis is performed on the DNA sequence.[61] Since it does not allow the sequencing of the introns, the overall sequence of a chromosome or gene is difficult to determine. Nevertheless, the exons provide valuable information about the expression of the genes themselves.[62]

Genetic sequencing is a slower process as compared to other methods of gene isolation. The process starts with the identification of a large genetic fragment which is later cut into smaller sequences using a restriction endonuclease. The pieces of DNA then go through gel electrophoresis. The nucleic acid sequence is identified through electrophoresis. This process is repeated and the results are compared until the genomic DNA sequence is determined.[63]

All genes, regulatory sequences, and non-coding information within an organism's DNA make up the genome.[64] The genome size increases proportionately with the organism's morphological complexity. Hence prokaryotic genomes are smaller as they contain lesser genes. Genomics focuses on the structure, function, evolution, mapping, and editing of genomes. For the purpose of identifying the influence of genes on the growth and development of an organism, genomics tries to address all genes and their interrelationships. The first genome to be sequenced was of a small bacteriophage in 1975. Gradually sequencing was considered to be a primary way to analyze macromolecules. Protein sequencing was an essential tool before genes could be cloned or sequenced. However, with the advent of technology like recombinant DNA

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[60] Pitcher, supra, at 285

[61] Lee Pei Yun et al., *Agarose gel electrophoresis for the separation of DNA fragments*, 20 J Vis Exp 62 (2012) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4846332/ (last visited Oct 30, 2019)

[62] Pitcher, supra, at 287

[63] James M Heather et al., *The sequence of sequencers: The history of sequencing DNA*, 107 Genomics 1 (2016) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4727787/ (last visited Oct 30, 2019)

[64] Aaron David Goldman et al, *What Is a Genome?* 21 PLoS Genetics, 12(2016)

technology, more efficient methods of DNA sequencing have been deduced.[65]

The Human Genome Project[66], which aimed to sequence all 3 billion letters in the human genome, is the result of such advanced technology. The project was launched in 1990, and its final draft was submitted in 2003. The project has revealed that around 20,500 genes exist in the human body. HGP has furnished the world with a database with in-depth information on the composition, organization, and function of the whole human gene pool.[67] Determination of genes that make us prone to diseases is one of the most important purposes of the human genome project. Genome projects are aiming to sequence the fruit fly, mouse, rat, and chimpanzee genomes. Comparison of human-sequenced genomes and fruit flies has found hundreds of genes that are so close between them that scientists can use fruit flies to study genes involved in human genetic diseases.[68]

GENETIC ENGINEERING

Genetic engineering is the manipulation of the genotype of an organism through recombinant DNA technology to change the DNA of an organism to achieve desirable traits. This is also known as gene manipulation, gene modification or gene transfer. Apart from recombinant DNA technology, the microinjection method, bio ballistics, electro, and chemical poration methods are also employed in genetic engineering.[69] DNA for all living organisms is made up of the same nucleotide building blocks which makes it possible for genes of one organism to be read by another organism.[70]

In most simple terms, genetic engineering is accomplished through the following basic

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[65] *Human Genomics in Global Health*, World Health Organization https://www.who.int/genomics/geneticsVSgenomics/en/ (last visited Jan 11, 2020)

[66] 2, Hub Zwart, *Human Genome Project: History and Assessment*, International Encyclopedia of the Social & Behavioral Sciences 311 (2015)

[67] *What is the Human Genome Project?* National Human Genome Research Institution https://www.genome.gov/human-genome-project/What (last visited Oct 30, 2019)

[68] Uzman, supra, at 28

[69] Jabar Zaman Khan Khattak, *Recent Advances in Genetic Engineering-A Review,* 4 Curr Research J. Biological Sci 82(2012)

[70] *What Is Genetic Modification?* Life science (2019) https://www.livescience.com/64662-genetic-modification.html (last visited Oct 30, 2019)

steps;[71]

(a) Gene identification and isolation
(b) Modification of gene so they can be transferred into another organism
(c) Gene removal
(d) Insertion of the isolated gene into host organism through a vector
(e) Evaluating the success of the resultant gene combination
(f) The successful completion of gene cloning results in a specific DNA sequence, which can be used commercially for a number of purposes, such as recombinant protein production, genetically modified microorganisms, transgenic plants, and transgenic animals.[72]

Applications of genetic engineering

With the rapid advancement in technology, more information about genomes of different organisms is known today. Owing to such information, the number of applications of genetic engineering is also increasing. The applications of genetic engineering can be seen in almost all fields including medicine, medicine, food, agriculture, and the environment.

i. Food industry – Due to genetic modification, many genetically modified food and ingredients are available today. Transgenic plants show a variety of improved traits due to genetic alterations like production of extra nutrients in the food, increased growth rate, disease resistance, better taste, increased shelf life and lesser requirement for water.[73]
ii. Medicine pharmaceutical industry and – A number of drugs and medicines are developed with the help of genetic engineering. Insulin, Growth hormones, Taxol, Interferon are some examples of genetically engineered medicines. Transgenic animals also play a vital role in the production of pharmaceutical products. The process is called pharming. Gene therapy has also gained a lot of importance in the medical field as it

[71] P. J. Greenaway, *Basic steps in genetic engineering*, 15 Inte'l J Envtl Stud 24 (2008)

[72] See, *Application of Genetic Engineering*, MHRD Govt. of India (last visited Feb 9, 2020)
[73] Id. at 14

can treat and prevent genetic disorders. More and more developments are made in this field every single day.[74]

iii. Environment- The enormous ability of microorganisms, plants and animals for the regeneration of the ecosystem is exploited by genetic engineering. Genetic engineering is actively involved in the development of microorganisms and biocatalysts to restore polluted habitats and in the development of eco-friendly methods, such as the development of recombinant strains for the production of biofuels. Genetically engineered microorganisms are developed to decrease the concentration of carbon dioxide in the atmosphere, help in the biodegradation of waste, quicken the process of photosynthesis etc.[75]

CONCLUSION

Genes are the functional unit of a genome. Genes determine the characteristics of all life forms and are passed from parents to progeny. With the advancement of technology, genetics has become one of the greatest adventures in science. Genetic engineering i.e., the genetic modification or genetic manipulation of an organisms' gene using biotechnology, has found its applications in fields like agriculture, pharmaceuticals, health, environment, and industry. The application of genetic engineering in medicine has paved the way for the development of vaccines, growth hormones, proteins, etc. Diagnosis and treatment for many diseases and genetic disorders have become easier due to such technology. Genetic engineering has made transgenic plants and animals with desirable traits a reality. Genetically modified crops are one of the significant contributions to the field of agriculture. The scope of research and innovation in genetics and related fields is unlimited and very promising.

[74] Id. at 17
[75] Id. at 23

CHAPTER 3

SOCIAL, LEGAL AND ETHICAL ISSUES IN PATENTING GENES

Genes are considered to be the building blocks of an organism. With the rapid level of advancement in biotechnological research and allied areas, the number of gene patent applications continues to increase. Humanity is said to be facing the dawn of a genetic revolution.[76] However, there is increasing fear that gene patents just profit a handful while dearly crippling larger society.[77] Patents are generally granted as a social contract between the inventor and society.[78] The patent system is intended to stimulate innovation. First, it encourages innovation by allowing individual inventors to recover research and development costs and profit from their technological progress. Second, it usually supports and promotes researchers by providing them direct access to the details of patented innovations. Given that inventions typically help society by offering better quality products or production methods, it has traditionally been believed that patent protection is a beneficial advantage to society as an incentive for innovation.[79]

The most prominent opponents of the current patent framework are not, in theory, against intellectual property rights, technological change, or scientific developments, but they have a certain resistance towards genetic inventions. For others, the problem is more ethical which arises from the fear of associating property rights with biological products, particularly in case of humans.[80] There are concerns that DNA does not satisfy the legal requirements for patentability. There are others who believe that the unusual character of the genes merits special attention.[81] Although gene patents play a major role in biotechnological innovations, issues relating to scientific research, health care access,

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[76] Caulfield, supra, at 635

[77] Campo-Engelstein, supra, at 2

[78] Andrew Allen, *Biotechnology, Research and Intellectual Property Law* 8 Canterbury L. Rev. 376 (2002)

[79] Heath, supra at 63

[80] *Genetic Inventions, Intellectual Property Rights and Licensing Practices -Evidence and Policies*, OECD (2002) https://www.oecd.org/health/biotech/2491084.pdf (last visited Nov 26, 2019)

[81] Id.

ethical and moral concerns must be taken into account.[82]

GENE PATENTS AND ISSUES RELATING TO RESEARCH

The breakthroughs in the field of medicine and healthcare over the past several decades have been outstanding.[83] Biomedical research and advancement in treatments both require several steps, each of which will produce patentable inventions and discoveries. Several of these developments and findings are useful in further research, such as newly identified genes that produce a specific protein or a novel chemical entity that may potentially be sold as drugs. Some innovations are useful both in their present state and in the future, for example, genetic markers for breast and ovarian cancer can be useful in ongoing studies and in screening prospective patients.[84] The research is often funded by individuals, governments, international charitable organizations, private foundations, and other organizations.[85]

It's indisputable that patents on genes provide a financial incentive for scientists to pursue further research works. However, there is an increasing concern that these patents can at the same time stifle subsequent research into the functions and probable application of patented genes.[86] Although all patents impede research to an extent, the stifling impact of gene patents are undoubtedly considered more serious. This is due to the fact that gene patents cannot be invented around unlike most other types of patents.[87]

In certain instances, where a patent limits the right of a researcher to make use of a specific invention, it would be possible to create another invention which carries out a

[82] Chester S. Chuang et al., *The Pros and Cons of Gene Patents* (2010) https://digitalcommons.law.ggu.edu/cgi/viewcontent.cgi?article=1171&context=pubs (last visited Dec 12, 2019)

[83] Thomas Sullivan, *The Difficulties and Challenges of Biomedical Research and Health Advances,* Policy and Medicine (2018) https://www.policymed.com/2011/02/the-difficulties-and-challenges-of-biomedical-research-and-health-advances.html (last visited Dec 12, 2019)

[84]Josephine Johnston et al, *Patents, Biomedical Research, and Treatments: Examining Concerns, Canvassing Solutions*, 37 Hastings Center Rep, 2 (2007)

[85] Id.

[86] Anna Harrington, *Gene Patents Stifle Basic Research: An Economic Analysis,* Harv Health Pol'y Rev 62(2002)

[87] Heath, supra, at 66.

similar purpose to the original but does not infringe the patent. Gene patents penetrate the diagnostic, therapeutic and biomedical research markets as the gatekeeper patents as they constitute an indispensable input for gene-based technology.[88] The reach of gene patents is exceedingly broad, as the patent holder claims as its invention the isolated gene sequence. Consequently, the rights of the patent owner are not confined to the product produced by the method or process specified in the patent application.[89]

So, if a researcher wants to investigate further on a patented gene and wishes to make use of that gene in some therapeutic or diagnostic tests, he must pay a license fee as required by the patent holder. Such licensing creates a tollbooth through which researchers must pass.[90] Patents are unlikely to affect research when it comes to research tools like chemical reagents, as such products are readily available in the market and can be purchased from the patent owner at a reasonable price. However, patents pose a threat to researchers when the patented inventions are made available to them at burdensome license conditions by the patent holder.[91] If the license is expensive, then pursuing research will be too costly. Sometimes, more than one license is required which makes the whole process more time consuming and costly.[92] There is always a possibility of patent holders refusing to grant a license which puts a stop to the research process altogether.[93]

The notion of cumulative innovation i.e., each finding based on previous results is fundamental to scientific research. And perhaps, more so in biotechnology research.[94] A patent thicket emerges where a multitude of patents are owned by multiple owners

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[88] Jolene S. Fernandes, *Duty to Deal: The Antitrust Antidote to the Gene Patent Dilemma,* 3 UC Irvine L. Rev 432 (2013)

[89] Id. at 433

[90] *The ethics of patenting DNA*, Nuffield Council on Bioethics (2002) https://www.nuffieldbioethics.org/assets/pdfs/The-ethics-of-patenting-DNA-a-discussion-paper.pdf (last visited Dec 16, 2019)

[91] Zakir Thomas, *Patenting of Research Tools — Issues and Some Pointers*, 20 Nat'l L Sch of India Rev 181, 184 (2008)

[92] Johnston, supra, at 5

[93] Cydney A. Fowler, *Ending Genetic Monopolies: How the TRIPS Agreement's Failure to Exclude Gene Patents Thwarts Innovation and Hurts Consumers Worldwide*, 25 Am. U. Int'l L. Rev. 1073, 1076 (2010).

[94] Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools and Standard-Setting*, 1 Innovation Pol'y & The Economy 119, 121 (2001)

required for a single innovative product or method. It can be horizontal or vertical. Vertical thickets occur when licenses are issued on smaller and more common genes, for example, patents granted for individual causative mutations. Horizontal thickets may increase when genetic tests are developed for more complicated genetic diseases, in which several distinct variants of several specific genes may be tested.[95] These patent thickets have the potential to increase the cost of conducting research. Owing to the stacking of royalty, it could possibly increase the final cost of products.[96]

Apart from requiring researchers to obtain licenses and possibly surrender ownership of newly developed gene technology, gene patents also create practical and financial difficulties by slowing down the rate of dissemination of scientific information. Even if scientists negotiate the intellectual property rights that are needed to explore a patented gene, they may have considerable difficulty accessing others' relevant research findings.[97] Gene patents have been expected to impede the advancement of genetic technology because scientists are less willing to exchange knowledge if they can assert monopoly rights to genes and receive financial benefits.[98] The confidentiality around genetic innovations further raises the financial burden for all researchers employed in the field. Such risk emerges when a biotechnology company develops a genetic product only to discover later that during the process of production, new patents were issued which they were unaware of. This will contribute to unforeseen license expenses and potential punishments for infringement, depending on the mindset of the patent holder.[99] Hence, secrecy is also detrimental to research as sometimes scientists duplicate research already done by his peer which remains unknown owing to quiet patenting. Not only has such secretive nature of research causes financial burden but also wastes valuable time which

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[95] Naomi Hawkins, *The impact of human gene patents on genetic testing in the United Kingdom*, 13 Genet Med 320 (2011)

[96] Thomas, supra, at 188

[97] Lori B. Andrews, The Gene Patent Dilemma: Balancing Commerical Incentives with Health Needs, 2 Hous. J. Health L. & Pol'y 65, 67 (2002).

[98] Heath, supra, at 68

[99] Andrews, supra, at 68

could be used elsewhere.[100]

Since patents add to the storehouse of scientific knowledge by providing an incentive to disclose new findings, totally restricting gene patents may decrease the amount of socially valuable information available to the public. In the absence of gene patents, biotechnology corporations would try to protect the upstream innovations as trade secrets, to which the public will not have any access. This would make the exploitation of such information for more research impossible. Consequently, scientists who might have wanted to license the patented technology may not even realize that the technology exists.[101]

GENE PATENTS AND ACCESS TO HEALTHCARE

Gene patents have led to considerable concern in the area of healthcare than that of research. As more and more research is done in the biomedical field, many of those innovations will be subject to gene patents. There is a growing fear that gene patents would raise medical expenses, limit the resources public healthcare programs can afford to provide and exclude many people from receiving new and advanced medical technology.[102] Pharmaceutical and biotechnology companies spend a fortune in discovering proteins and other large molecules with the potential to treat human diseases. In the context of healthcare, gene patents cover three types of inventions. They are - diagnostics, compositions of matter, and functional uses.[103]

Disease gene patents typically cover all known methods of testing, including the use of hybridization, Southern blotting[104], PCR[105] and even DNA chips. There are some

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[100] Heath, supra, at 70

[101] Abigail Lauer, *The Disparate Effects Of Gene Patents On Different Categories OF Scientific Research*, 25 Harv JL & Tech 180, 185 (2011)

[102] Heath, supra, at 70

[103] Jon F Merz, et al., *"What are gene patents and why are people worried about them?"* 8 Community Genet. 203 (2005)

[104] See, Terence A Brown, *Southern Blotting and Related DNA DetectionTechniques*, Encyclopedia of Life Sciences (2001) https://www.alliot.fr/BIO/PDF/SouthernBlot-.pdf (last visited Dec 27, 2019)

[105] Karim Kadri, *Polymerase Chain Reaction (PCR): Principle and Applications*, IntechOpen (2019) https://www.intechopen.com/books/synthetic-biology-new-interdisciplinary-science/polymerase-chain-reaction-pcr-principle-and-applications (last visited Dec 27, 2019)

attributes of genes and disease gene patents that show how the genome is being broken up by small patent claims to overlapping genetic territories.[106] Patents for the disease gene differ greatly from these more prevalent patented tools which laboratories use to test for a variety of specific disease genes. Critically, there is no feasible way to get around such patents since a patent for a disease gene requires all means of testing for a particular gene, so patents can be used to monopolize a test.[107]

In some cases, patent owners refuse to grant licenses to perform certain tests to private laboratories. The patent owners themselves create a monopoly in the testing service by asking the samples to be directly sent to them or their specified licensees for testing.[108] Such compulsion has some serious implications in the healthcare system as there might be a failure in providing their patients with quality medical care, educating residents and fellows in hospitals, and inability to operate laboratories effectively. Due to the monopoly in such tests, hospitals are often compelled to charge high prices on testing, which most of the time is burdensome to the patients. In this context, these patents raise healthcare expenses and threaten the right of doctors to practice medicine.[109]

The second category of genetic inventions involves compositions of matter i.e. chemicals and materials. Isolated and purified gene (cDNA) and its derivative products like recombinant proteins, therapies for viral vectors and gene transfer, transfected cells, cell lines and animal models of higher-order all come under this category.[110]

The final category of gene patents claims the functional use of a gene. These patents are built on discovering the part genes play in disease or other bodily and cellular processes or mechanisms, and claiming methods and compositions of matter, typically named small molecule drugs used to up-or down-regulate the gene.[111]

One of the most major concerns regarding gene patents in the diagnostic testing domain

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[106] Merz, supra, at 208

[107] Jon F Merz, *Disease Gene Patents: Overcoming Unethical Constraints on Clinical*, 45 Clin Chem 324 (1999) https://academic.oup.com/clinchem/article/45/3/324/5643033 (last visited Dec 13, 2019)

[108] Id.

[109] Debra Leonard, *Medical Practice and Gene Patents: A Personal Perspective*,77 Acad Med. 1388 (2002)

[110] Merz, supra, at 208

[111] Merz, supra, at 209

is that such patents aggravate the tragedy of the anti-commons and thus impede progress in the prevention and treatment of diseases. The tragedy of the anti-commons defines a scenario in which the presence of multiple rights holders frustrates the pursuit of a socially desirable result.[112] The substantial number of patents on human genes and the diverse set of patent owners make the catastrophe of the anti-commons a real concern. With respect to diagnostics, the tragedy of the anti-commons may conflict with scientific and technological advances in the detection of genetic disease.[113] Many disorders can be triggered by defects in different genes, so a comprehensive analysis of a person's vulnerability to a particular disease sometimes involves a diagnostic test to investigate the potential sources of the disorder. A scientist must get permission to experiment with each genetic marker for the disorder, in order to create a suitably detailed diagnostic test.[114] If each gene has been patented by some other institution or company, the scientist might be discouraged to conduct his research because of the high transaction costs he would incur when negotiating licenses with multiple patent owners. Under these cases, gene patents hinder follow up invention which could have potentially benefited the medical field.[115]

Despite potentially reasonable fears regarding the impact of gene patents on information accessibility and future development, a discussion about the patenting of human genes in 2006 found that the issues anticipated by the catastrophe of the anti-commons hypothesis are not borne out in the available evidence. Researchers use a range of techniques to create effective alternatives to the access issue, including inventing around, going offshore, challenging patents, and utilizing non-licensed technologies.[116]

Also, the decision of the US Court in Myriad Genetics[117] case put rest to many controversies related to gene patents and healthcare. A patent held on genetic tests to diagnose breast and ovarian cancer was challenged in the US court. The patent granted

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[112] Michael A. Heller et al., *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 700 (1998).

[113] Id.

[114] Lauer, supra, at 189

[115] Id.

[116] Timothy Caulfield et al., Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies, 24 Nature Biotech 1092 (2006)

[117] Association for Molecular Pathology et al. v. Myriad Genetics, Inc., et al. 133 S. Ct. 2107 (June 13, 2013)

Myriad Genetics with a monopoly on genetic tests involving the separation of natural DNA strands and the development of cDNA mirroring the initial extracted strands with minimal alterations.[118] The Court found that the plaintiff had only discovered the already existing location of the two genes, BRCA1 and BRCA2 which is a mere discovery hence not patentable. The judgment made it clear that human genes cannot be patented as they are products of nature. The healthcare providers welcomed the decision with open hands as they believed the judgment would remove barriers to access to healthcare, reduce costs, and allow for innovation. The ruling of the Court could also eliminate obstacles to research into new genetic disorder testing and treatments, since patents on genes have been seen in the past to hinder genetic research, and researchers would be able to segment natural DNA without infringing a patent.[119]

GENE PATENTS AND ETHICAL DEBATE

Patenting genes, especially human genes have been highly controversial. There are numerous ethical issues which need to be answered depending on the existence of the genetic material. There are at least five non-consequential reasons why patenting human genes will affect human dignity:[120]

(1) It modifies our genetic integrity

(2) It is equal to human ownership

(3) It commercializes body parts that should not be turned into commodities

(4) Human genes should be regarded as collective property because they are part of a common human heritage and

(5) Distributive justice i.e., no group should be deprived of the benefits of genomic research.

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[118] Ryan Jaslow, *Supreme Court's gene patent ruling could boost patient care, experts say*, CBS News (June 13, 2013) https://www.cbsnews.com/news/supreme-courts-gene-patent-ruling-could-boost-patient-care-experts-say/ (last visited Jan 8, 2020)

[119] Lara Cartwright-Smith, "*Patenting genes: what does Association for Molecular Pathology v. Myriad Genetics mean for genetic testing and research?*."129 Public Health Rep. 289 (2014)

[120] Suzanne Ratcliffe, *The Ethics of Genetic Patenting and the Subsequent Implications on the Future of Health Care*, 27 Touro L. Rev. 435, 437 (2011).

Drastic modifications or alterations in genes may potentially prove detrimental to the collective genetic heritage and genetic integrity, resulting in injury or loss of human dignity. While modern biotechnology activities are based on beneficial scientific developments and improvements in disease prevention and diagnosis, the opportunity for eugenic exploitation resides in the enhancement and improvement of the human race.[121] Opponents of gene patents argue that modifying human genetic content to produce different and better human beings interfere with nature and natural processes and greatly affects them. This inappropriate alteration of our genetic material would ultimately threaten genetic integrity.[122]

Critics claim that patents cannot be granted on genes since the composition of human genomes is the very core of what it is to be human; thus no person or company can hold control or ownership over any genetic material. However, as opposed to ownership, patents confer intellectual property rights on patented materials, which relates to right to invention and not ownership.[123] However, even if a patent holder only holds intellectual property rights over the genetic sequence, such property rights could be interpreted as ownership of the genome. The right of an individual to exclude any other person from utilizing, producing, or researching the patented genetic sequence may be equated to ownership.[124]

Another argument claims that patenting genetic material commercializes genetic information that is part of nature and should not be commoditized. Human genome patenting may be regarded dehumanizing because it changes the conventional conception of human beings as dignified and respectful beings into items that can be bought, marketed or altered.[125] Patents have typically served an economic purpose, which

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[121] Melissa L. Sturges, *Who Should Hold Property Rights to the Human Genome? An Application of the Common Heritage of Humankind*, 13 Am U Int'l L Rev 34 (1999)
[122] Ratcliffe, supra, at 437

[123] Laurie L. Hill, *The Race to Patent the Genome: Free Riders, Hold Ups, and the Future of Medical Breakthroughs*, 11 Tex. Intel. Prop. L.J. 221, 233 (2003).

[124] Stephanie Constand, *Patently a Problem - Recent Developments in Human Gene Patenting and Their Wider Ethical and Practical Implications*, 13 QUT L. Rev. 100 (2013).

[125] Annabelle Lever, *Is It Ethical To Patent Human Genes?* Intellectual Property and Theories of Justice (2008)

presupposes the right to assess the patentable entity's commercial worth. Using economic theories to address human genetic content means that human beings and their parts are salable and may be reduced to commodities.[126]

Many also claim that because human genetic material is shared by all human beings, it should be considered collective property belonging to all human beings, as opposed to one person or company holding exclusive patent rights.[127] Moreover, unlike the production of drugs, which has predominantly been privately financed, genetic research and discovery is largely funded by public institutions. This point contributes to the contention that because the work is publicly endorsed, no private person or corporation can hold a certain kind of right to the discovered information, especially to the exclusion of all others.[128] Also in the context of distributive justice, it is often argued that genomic research mainly benefits the wealthier individuals and nations. Such a contention is against the basic notion of fairness and justice.[129]

Apart from these issues, patenting of human genes can have other negative impacts[130]

(1) The widespread use of genetic tests by employers, insurance companies, the government, and other organizations;

(2) Tampering with the human genome--i.e. mutations, and the like can possibly cause harm to the coming generations.

(3) In an attempt to eliminate genetic diseases or to improve the human genome, the human population will slowly lose its genetic diversity.

(4) Genetic discrimination and bias;

(5) A radical alteration of our conception of ourselves from persons with dignity to

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https://www.researchgate.net/publication/253074151_Is_It_Ethical_To_Patent_Human_Genes/ (last visited Jan 5, 2020)

[126] Ratcliffe, supra, at 439

[127] Constand, supra, at 101

[128] Timothy Caulfield, *Human Gene Patents: Proof of Problems?* 84 Chicago-Kent L Rev 133, 139 (2008)

[129] Ruth Macklin, The Ethics of Gene Patenting, in Genetic Information: Acquisition, Access and Control, 130 (Alison K. Thompson & Ruth F. Chadwick eds., 1999).

[130] David B. Resnik, *The Morality of Human Gene Patents*, 7.1 Kennedy I Ethics J 43 (1997)

commodities with a market-value;

(6) The exacerbation of existing social inequalities resulting from genetic engineering;

(7) Attack on one's privacy as outsiders can gain access to genetic information[131];

(8) The employment of genetics to develop biological weapons; and

(9) The exploitation of third world nations who provide the resources for gene harvesting.

Indigenous people and gene disputes are always a topic of debate in gene patent controversy. There has been a significant increase in genetic research projects over the past decade which placed Indigenous peoples at the frontline of the research process. The DNA of indigenous peoples is sought for medical, behavioral, large-scale human population studies, and ancient DNA genetic research.[132] In the past, many well-known instances of attempts to patent cell lines derived from indigenous populations were recorded as in the cases of Guyami of Panama, the Hagahai of Papua New Guinea, the Solomon Islands Melanese and many others.[133] Many researchers stress on the fact that it was important to collect the DNAs of the indigenous people before they are lost forever. The people of Guyami tribe carried a virus which was believed to be important for leukemia and AIDS treatment research. The US Government sought a patent for the cell line of a woman belonging to the tribe. Guyami General Congress along with many other indigenous communities and NGOs opposed the patent claim. Due to the global resistance, the US had to withdraw its patent claim in 1993.[134] The desire to harvest and preserve their DNA without any regard to their continued existence is an idea many Indigenous people deem offensive.[135]

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[131] See, Merilin Jacob, The New Age Eugenics Of DNA Patenting (2020) https://www.mondaq.com/india/patent/879710/the-new-age-eugenics-of-dna-patenting (last visited Feb 6, 2020)

[132] Debra Harry, Indigenous Peoples and Gene Disputes, 84 Chi.-Kent L. Rev. 147 (2009).

[133] Harry, supra, at 149

[134] Christie Jean, *Whose Property, Whose Rights?* Cultural Survival Quarterly Magazine (1996) https://www.culturalsurvival.org/publications/cultural-survival-quarterly/whose-property-whose-rights (last visited Feb 13, 2020)

[135] Maria Amparo Lasso, *Gene Study Puts Indians on Guard*, IPS News Agency (2005) http://www.ipsnews.net/2005/04/latin-america-gene-study-puts-indians-on-guard/ (last visited Feb 13,

Ultimately, the samples gathered from indigenous peoples end up in some sort of a gene bank, either in the private lab collection of a researcher or in some publicly accessible gene bank. These genetic collections or gene banks may be held by military, federal, academic, or private facilities for use in future medical or non-medical research. Moreover, many institutions maintain DNA collections specifically from identifiable populations, including indigenous peoples. Such collected samples are stored for indefinite time. Through cell transformation techniques, these samples are generated unlimited times and are used in research.[136] Most consent forms compel the donors to provide full consent to use his/her samples for future research. This scenario puts indigenous peoples in a position to trust the researchers to serve as guardians of their DNA and other related information.[137]

There is a growing trend to find human genetic material and information in the public domain. Any effort to arbitrarily put Indigenous peoples' DNA in the public domain will violate the internationally recognized right of Indigenous peoples to control any use of their DNA[138] and the right to free, prior, and informed consent[139]. Patents on genes of indigenous people have also been disputed on religious and spiritual grounds. Most tribes and indigenous populations see genetic resources as sacred gifts from their ancestors. So many times collecting blood, hair and tissue samples is an affront to the religious beliefs, cultural values, and sensitivities of many indigenous peoples.[140] The opponents of gene patents claim that in the research process, indigenous people are often exploited and just passive subjects whose interests are not adequately protected. At the end it is always the patent holder who benefits from all these.[141]

Screening one's genetic material may possibly lead to genetic discrimination. Sometimes, companies can seek genetic tests and refuse to employ individuals carrying those genes.

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[136] Gerald Dworkin, *Should There Be Property Rights in Genes?*, 352 Philosophical Transactions: Biological Sciences 1077 (1997)

[137] Harry, supra, at 149

[138] UN General Assembly, *United Nations Declaration on the Rights of Indigenous People,* 2 October 2007 A/RES/61/295, art. 31

[139] Id., art. 32 (2)

[140] Harry, supra, at 153

[141] Dennis Karjala, *Biotech Patents and Indigenous Peoples*, 7 MINN. J.L. SCI. & TECH 484 (2006).

Insurance providers may increase the premiums, or decline to insure individuals genetically identified as predisposed to certain diseases.[142] Though the intention behind such research projects are unclear, it is clear that in this area, like many other areas of life, indigenous people must face the real possibility of discrimination and stigmatization.[143]

Over the decades, international treaties, legislations of respective states, active involvement of NGOs and other organizations have helped the indigenous people to realize and exercise their rights to an extent. Initiatives such as Community-based concepts of participatory research would help in ensuring that genetic research and other related research addresses the priorities of the community and upholds their customary beliefs and practices.[144] Its application to genetic research, together with policy to protect the rights of indigenous peoples, like the work of the Indigenous People's Council on Bio colonialism will provide an improved groundwork that reflects and supports the interests of the indigenous community.[145]

The above raised issues and concerns regarding gene patents can be controlled to some extent. Some possible mechanisms that can be employed include:-

1. Compulsory licensing

Compulsory licenses can be considered as a means of addressing some of the gene patent issues. Under compulsory licensing, the government must issue licenses to doctors, academics, and others to use a patented gene sequence without the patent holder's consent at a reasonable fee payable to the patent holder.[146] For the fee to be reasonably determined, the market value of the drug produced as a consequence of the research must be calculated, as opposed to the fee fixed by the patent holder.[147] Labs may perform

[142] Debra Harry et al., *Indigenous Peoples, Genes and Genetics What Indigenous People Should Know About Bio colonialism*, IPCB (2000) http://www.ipcb.org/pdf_files/ipgg.pdf (last visited Feb 8, 2020)
[143] Id.
[144] Lorrieann Santos, *Genetic research in native communities*, 2 Prog Community Health Partnersh 321 (2008) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2862689/ (last visited Feb 8, 2020)
[145] Id.
[146] Sara M. Ford, *Compulsory Licensing Provisions Under the TRIPs Agreement: Balancing Pills And Patents*, 15 AM. U. INT'L L. Rev. 941, 945 (2000).

[147] Donna M. Gitter, *International Conflicts Over Patenting Human DNA Sequences in the US and the EU: An Argument for Compulsory Licensing and a Fair Use Exemption*, 76 N.Y.U. L. Rev. 1623, 1659 (2001).

genetic diagnostic testing and eventually allow diagnostic testing for new mutations to be identified. Pharmaceutical firms would not be in a position to prohibit pharmacogenomics tests related to their drugs and gene therapy research will be encouraged.[148]

The TRIPS Agreement permits compulsory licenses to be included. Compulsory licensing requires a competent governmental authority to authorize a third party or government entity to use a patented innovation without the patent-holder's permission. Article 31 of the Agreement sets out the requirements for the granting of compulsory licenses. In India, the provision for compulsory licensing can be found in Section 84 of the Patents Act.[149] Any person interested in or already a holder of a licence under a patent may, after three years from the date of grant of that patent, apply to the Controller for the grant of a compulsory patent licence subject to the conditions laid in Section 84. While reviewing the application for compulsory licence, the Controller will take into account nature of the invention, any measures already taken by the patentees or any licencee to make full use of the invention, ability of the applicant to work the invention to the public advantage and time elapsed since the grant of the patent.[150] The Controller will grant compulsory licence if the reasonable requirements of the public with respect to the patented invention have not been satisfied, the patented invention is not available to the public at a reasonably affordable price or the patented invention is not worked in the

[148] Andrews, supra, at 90

[149] The Patents Act, 1970, Sec.84 - Compulsory licences.—(1) At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory license on patent on any of the following grounds, namely:—(a)that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or (b)that the patented invention is not available to the public at a reasonably affordable price, or (c)that the patented invention is not worked in the territory of India.

[150] The Patents Act, 1970, Sec.84 (6) - In considering the application field under this section, the Controller shall take into account - (i) the nature of the invention, the time which has elapsed since the sealing of the patent and the measures already taken by the patentee or any licensee to make full use of the invention; (ii) the ability of the applicant to work the invention to the public advantage;(iii) the capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted; (iv) as to whether the applicant has made efforts to obtain a licence from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period as the Controller may deem fit.

territory of India.[151] Apart from Section 92 of the Act also deals with issuing of compulsory license suo motu by the Controller under the direction of the Central Government if there is a national emergency, extreme urgency or in case of public non-commercial use.[152] Since the procedure is lengthy, it might not be of immediate help to the researchers.[153]

In India, the first compulsory licence was granted in Bayer Corporation v. Natco Pharma Ltd.,[154] in 2012 where Natco was granted compulsory licence to manufacture the generic version of Bayer's Nexavar, an anti-cancer agent used in the treatment of liver and kidney cancer. Bayer charged an exorbitant amount of Rs.2.8 lakhs for the cancer drug which was easily accessible to only 2% of the cancer population. The Patent Office granted compulsory licence to Natco Pharma as they imported the drugs within India at a reasonable price of Rs.8800. Also, Natco Pharma was directed to pay 6% of its net selling price as royalties to Bayer.[155]

2. Research exceptions.

Some sort of research exception is permissible in almost all patent laws around the world. In Indian patent law, the research exception is limited to the purpose of research,

[151] The Patents Act, 1970, Sec.84 (4) - The Controller, if satisfied that the reasonable requirements of the public with respect to the patented invention have not been satisfied or that the patented invention is not worked in the territory of India or that the patented invention is not available to the public at a reasonably affordable price, may grant a licence upon such terms as he may deem fit.

[152] The Patents Act, 1970, Sec.92 (3) - (3) Notwithstanding anything contained in sub-section (2), where the Controller is satisfied on consideration of the application referred to in clause (i) of sub-section (1) that it is necessary in- (i) a circumstance of national emergency; or (ii) a circumstance of extreme urgency; or (iii) a case of public non-commercial use, which may arise or is required, as the case may be, including public health crises, relating to Acquired Immuno Deficiency Syndrome, Human Immuno Deficiency Virus, tuberculosis, malaria or other epidemics, he shall not apply any procedure specified in section 87 in relation to that application for grant of licence under this section: Provided that the Controller shall, as soon as may be practicable, inform the patentee of the patent relating to the application for such non-application of section 87.

[153] Andrews, supra, at 94.

[154] Bayer Corporation v. Natco Pharma Ltd., Order No. 45/2013 (Intellectual Property Appellate Board, Chennai)

[155] Mansi Sood, *NATCO PHARMA LTD. V. BAYER CORPORATION AND THE COMPULSORY LICENSING REGIME IN INDIA*, 6 NUJS L. Rev. 99, 104 (2013)

experimentation or for imparting instruction to students.[156] The development of new products for commercial purposes will not come under the exception. Any other use of the invention beyond the scope of exception will result in the infringement of the patentee's right.[157] The legal framework applicable in India does not offer sufficient protection from infringement proceedings when the research object is the development of a marketable product. Since there has been no litigation on research exceptions, the approach of the court remains unknown.[158]

3. *Ordre public* and commercial exploitation

In order to prevent commercial exploitation and to protect *ordre public*, morality, and human life or health, exceptions can be made in the patent law.[159] As there is no definite definition of *ordre public*, countries are free to interpret the exception keeping in mind their social and cultural values. The *ordre public* exception, however, is not limited to national security, but also includes the safety of life or health of humans, animals or plants and can be extended to inventions that can cause significant environmental damage.[160] If the *ordre public* and morality exclusion was broadly interpreted, it could mitigate some of the concerns relating to healthcare and research.[161]

4. Patent pools

No individual organization or company would have enough sources to develop all the necessary information they need, especially in terms of genetic information. Researchers will be prevented from using protected gene sequences for developing new therapies and diagnostics if the information is not freely accessible or licensed in an affordable way.[162]

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[156] The Patents Act 1970, Sec.47 - Grant of patents to be subject to certain conditions- (3) any machine, apparatus or other article in respect of which the patent is granted or any article made by the use of the process in respect of which the patent is granted, may be made or used, and any process in respect of which the patent is granted may be used, by any person, for the purpose merely of experiment or research including the imparting of instructions to pupils;

[157] Thomas, supra, at 188

[158] Thomas, supra, at 189

[159] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

[160] Johnston, supra, at 7

[161] Heath, supra, at 76

[162] Ratcliffe, supra, at 440

In situations where compulsory licensing fails owing to its time consuming procedures, patent pool can be of great help. A patent pool allows for an arrangement between two or more patent owners to license one or more of their patents to each other, and together to third parties.[163]

Patent pools are beneficial as they foster research and innovation by preventing one or a few patent holders from declining to license their inventions and by preventing other scientists from utilizing vital genetic information to develop tests, drugs and treatments. Also, patent pools eliminate a substantial portion of the costs involved with several licenses. Lastly, patent pools provide their stakeholders with financial security by risk allocation. Since each member of the pool receives a certain proportion of the group's total royalties, individual patent holders are more likely to recover their investment on research and development.[164]

Patent pools are especially necessary where the usage of patent exclusivity is detrimental to the public interest, although the establishment of a pool can entail governmental pressure. Gene patent holders may have fewer chances of investing in voluntary patent pools than in other sectors.[165] Within the biotechnology and pharmaceuticals sectors, patents are more significant than in other sectors. Furthermore, the absence of alternatives for such biomedical developments such as patented genes may increase the leverage of certain patent holders and thus worsen holdout problems.[166]

5. Strengthening the role of gene sources.

Multiple initiatives are under way to encourage gene sources, such as patients, family members and other research participants, to have a greater say about whether or not their genes should be licensed and what uses are made of such patented genes. According to the American Medical Association's Code of Ethics in the U.S, a patient's consent must be obtained before the doctors decide to commercialize products developed from the

[163] See, Gene Patents and Collaborative Licensing Models- Patent Pools, Clearinghouses, Open Source Models and Liability Regimes (Geertrui Van Overwalle ed. 2009)

[164] Michele Westhoff, *Gene Patents: Ethical Dilemmas and Possible Solutions*, 20 Health Law 1 (2008).

[165] Shapiro, supra, at 125

[166] Andrews, supra, at 99.

patient's genetic material.[167] Also, the European Parliament's Directive on the Legal Protection of Biotechnological Inventions mandates that the source must have had the opportunity of expressing a free and informed consent if a patent application uses material of human origin. Hence, they can even refuse to patent their genes. Though enabling people to have an interest in their genes is not a comprehensive response to issues posed by gene patents, it is still a small step towards making the present scenario better.[168]

The area of gene patents inevitably poses many complicated legal, ethical and practical issues. Patenting in the field of biotechnology can provide an encouragement mechanism for innovation and the dissemination of research studies, which are core pillars of scientific endeavor.[169] A thorough analysis of patenting from an ethical viewpoint further shows that patenting biological products do not automatically precipitate human being's total commodification, nor will it derogate from individuals' inherent worth and individuality. Nevertheless, it is of great concern that monopolistic market dominance facilitated by patents will detract attention from fair access to healthcare services including genetic testing.[170]

CONCLUSION

Patents are justified on the basis of their positive outcomes. However, once the overall results generate more harm than good, it becomes a cause of concern.[171] In the present context, there are substantial arguments in favor of and against patenting genetic content, it is doubtful that any resistance would prove sufficiently successful to prevent gene patenting entirely. Research in this area is critical to encourage beneficial medical discoveries and advancements in disease prevention and diagnosis, but these advancements should not come at the risk of endangering the integrity and dignity of the

[167] Constand, supra, 104

[168] Id.

[169] Id.

[170] Heath, supra, at 77

[171] Johnston, supra, at 9

individual being.[172] Lawmakers should consider various alternatives, both from inside and outside of the conventional patent laws to make sure that the gene patents are used in a socially valuable way.[173] The ultimate goal of patent law, public benefit, will only be accomplished if the innovations are properly rewarded and the progress is fully shared.[174]

[172] Ratcliffe, supra, at 442

[173] Andrews, supra, at 102.

[174] Lacy, supra, 790

CHAPTER 4

PATENTABILITY OF GENES IN INDIA

The patent law encourages scientific and technological advancement by providing incentives for inventors and investors by granting them exclusive rights. The inventor provides the public with an invention and assumes exclusive rights over it for a period of time. The economic benefit resulting from the enjoyment of exclusive rights inspires inventors to invent and shareholders to invest. From the perspective of developed countries, intellectual property is a private right that should be protected as any other tangible property, but for developing nations, intellectual property is a public good that should be used to promote economic development.[175]

In India, the grant of patents is governed by the Patents Act, 1970. India's first patent law can be traced back to 1856, which was in line with the provisions of the English Patent Act, 1852. In 1859, the Act was re-enacted due to various defects. Later the Patents and Designs Protection Act, 1872, was passed, followed by the Protection of Inventions Act of 1883. Both these Acts were consolidated by the Inventions and Designs Act, 1888. Subsequently, the Indian Patents and Designs Act, 1911, replaced all the previous Acts. However, after independence, a need for more comprehensive patent law to cater the changing social and economic conditions of independent India was felt. With this view, the Indian government appointed a committee to review the patent system in India. The committee report opined that the current Indian patent system did not encourage development or inventions. A Bill was introduced in the Parliament based on this report, which was not preceded, resulting in subsequent lapse of the Bill. Nevertheless, another committee headed by Justice N. Rajagopal Ayyangar was appointed by the government to revise the patent law. The report was submitted in 1959, which contained the shortcomings of the patent laws along with its solutions. Based on the report, a Patent Bill was introduced in the Lok Sabha in 1965. Since the Bill of 1965 also lapsed, again, an amendment Bill was introduced in the Parliament. After much deliberations and discussions, the Patents Act, 1970, was passed. Later a draft of Patent Rules was also

[175] Terence P. Stewart, ed., *the GATT Uruguay Round: A Negotiating History 1986-1992*, 2 Commentary 2255 (1993).

published. Most of the provisions of the Act along with the Patent Rules came into force on 20th April 1972. The remaining provisions came into force on April 1, 1978.[176]

The Patents Act, 1970, remained untouched until an ordinance affecting some changes was issued in 1994. After 1994, the Act was amended a few times. The Uruguay Round which led to the creation of the World Trade Organization, paved the way for drastic changes in the area of law. India became a member the WTO in 1995 and was thus obligated to comply with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The obligations under TRIPS related to all forms of Intellectual Property but in India, it was the patent laws which required most changes.[177]

THE PATENTS ACT, 1970

The fundamental philosophy of the Act is that patents are granted to encourage inventions which will accelerate indigenous industrial growth by securing their working in India on a commercial scale. India's patent policy essentially concentrated on striking a balance between development and innovation. Patents were viewed as a tool to boost economic development and restricted the term of patents. However post-TRIPS, the term of every patent granted after the amendment in 2002 was 20 years from the date of filing patent application. However, for any application filed to Patent Cooperation Treaty, the term will be 20 years from the international date of filing the application. Patent protection in India is territorial i.e., it is only effective inside the Indian Territory. In India, an invention to be patentable must fulfill the criteria of being new, non-obvious and useful. The element of newness or novelty means that the invention should not be similar to any other known or existing inventions. An invention, if it does not form part of the state of the art, can be regarded to be new. It is important for an invention to be non-obvious to obtain a patent. The invention must be non-obvious to a person skilled in the field to which the invention belongs to. Along with being non-obvious and novel, the invention must also be useful. An invention which is of no use to mankind cannot be patented. The term 'invention' itself needs to be interpreted properly for the better

[176] *History of Indian Patent System*, Office of the Controller General of Patents, Designs & Trademarks http://www.ipindia.nic.in/history-of-indian-patent-system.htm (last visited Marc 7, 2020)

[177] Kalyan C Kankanala, Genetic Patent Law and Strategy, 29 (1st ed., 2007).

understanding of patentability criteria. The Patents Act, 1970, defined invention in section 2(j) as "*any new and useful- (i) art, process, method or manner of manufacture (ii) machine, apparatus or other article (iii) substance produced by manufacture, and includes any new and useful improvement of any of them, and an alleged invention*." This definition is no more dependable as the present definition of invention includes 'inventive step' and 'capable of industrial application'. The Patents Amendment Act, 2002 modified the definition of 'invention' to align it with Article 27 of the TRIPS. Article 27 of the TRIPS Agreement states that patents should be granted to any invention for both product and process if such an invention satisfies the requirements of being new, involves an inventive step and is capable of industrial application. This applies to inventions in all fields of technology.[178]

The Indian patent law does not directly spell out those inventions which are patentable. However, the Act provides for the list of subject matter which is not patentable under sections 3 and 4 of the Patents Act, 1970. Out of the list of subject matter which is not provided with patent protection, there are certain provisions of specific relevance.

An invention which is contrary to public order or morality or is injurious to human, animals or plants, health or to the environment is not patentable. Section 3 (b) before the amendment declared inventions "*contrary to law or morality or injurious to public health*" as not patentable. The present provision was brought into the Act through the 2002 amendment to accommodate the TRIPS regulations.[179] The TRIPS Agreement recognizes *ordre public* as a ground for exception from patentability.[180] Such exceptions should not be only because it is contrary to the laws of a particular nation.

A mere scientific principle, an abstract theory or discovery of any living or non-living

[178] TRIPS, art 27 (1) Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.
[179] The Patents Act, 1970, sec. 3 (b) an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment;
[180] TRIPS, art. 27 (2) Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

thing in nature is not patentable.[181] The terms 'invention' and 'discovery' often leads to confusion. The act of discovery and act of invention are closely connected, but are not similar. Discovery, essentially discloses a hidden fact or unknown property of an already known product or article. In invention, an act is done which either results in a new product, new process or a combination of both. Section 3(c) of the Act covers discoveries relating to products directly isolated from nature. Those modified products which do not constitute discovery of things occurring in nature are subjected to patent protection. On further reading into the provision, it could be understood that the provision is silent on the stipulated degree of modification required for it to be patentable. The finding of a new substance or microorganism occurring freely in nature is discovery and not an invention. However, in order to isolate and extract such substance, a process is developed that process could be patented if it satisfies the requirements of patentability under the Act.[182]

The mere discovery of a new form of an already known substance not resulting in an increased level of efficiency of that substance is not patentable.[183] The basic idea behind the provision is that patents should be only granted when the invention is new in all its elements as well as in the combination, if it is a combination. The provision seeks to prevent ever-greening of patents wherein the pharmaceutical companies bring a small modification to their already patented product to extend its patent life.

Any substance obtained by the mere mixture of known ingredients and showing the aggregate properties of the components is not patentable.[184] Both the ingredients as well as its properties must be known. If the resulting admixture shows an unknown property which was not expected, then such inventions can be patented. The patentee is required to prove that the combination of the known substances has resulted in a synergism wherein

[181] The Patents Act, 1970, sec. 3 (c) 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

[182] *An overview of patentability in India*, Lexology (2018) https://www.lexology.com/library/ (last visited Dec 19, 2019)

[183] The Patents Act, 1970, sec. 3 (d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

[184] The Patents Act, 1970, sec. 3 (e) a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance

the combination displays properties that are not displayed individually by each component.[185]

If any medical treatment method of human beings or animals renders them free of any disease or in some way increases their economic value, then such method is not patentable. The method of treatment could be medicinal, surgical, curative, prophylactic diagnostic, therapeutic or any other treatment. Section 3 (i) of the Act deals with this provision.[186]

Plants and animals along with seeds, varieties, species and essentially biological processes for production and propagation of plants and animals are excluded from patentability. However, micro-organisms and microbiological processes are not covered under this provision.[187]

In Dimminaco A.G v. Controller General of Patents, Designs and Trademark[188],the appellant filed an application for an invention relating to a process for preparation of the bursitis vaccine which contained a living virus as an end product. The Patent Officer Examiner examined the application and said that the said invention is not invention under Section 2(j) (i) of the Act. Dimminaco A.G filed an appeal against the rejection of the application to the Controller of Patents. The Assistant Controller, who acted under the delegated authority of the Controller, also rejected the patent application stating that the vaccine contained a gene sequence and it further involved processing of certain microbial substances. The process was considered to be only to be a natural one and lacked any manufacturing activity. Moreover the end product contained a living material. All these reasons led to the rejection of the claim. The appellants approached the Calcutta High Court with their appeal. The Court set aside the decision of the Controller and found that the Patents Act did not prohibit the patenting of biotechnological inventions. The Court applied the vendibility test. If the invention results in the manufacture of certain

[185] Shamnad Basheer et al., *The "Efficacy" of Indian Patent Law: Ironing out the Creases in Section 3(d)*, 5 Scripted 234 (2008)

[186]The Patents Act, 1970, Sec.3 (i) "Any process for the medicinal surgical curative, prophylactic diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products."

[187]The Indian Patents Act, 1970, sec.3

[188] Dimminaco A.G v. Controller General of Patents, Designs and Trademark, (2002) I.P.L.R 255 (Cal)

commercially viable item or it improves the conditions of the former vendible item or it resulted in the preservation of the vendible item from deterioration, then the vendible test is satisfied. The Court held that the term 'manufacture' then used in the Act did not exclude a vendible product containing living organisms. The court then directed the Patent Office to re-examine the application. Eventually, the Patent Office granted patent protection to the process. This decision opened the doors for the grant of patents to inventions where the final product of the claimed process contained a living microorganism.[189]

THE PATENT RULES, 2003

In India, the non-substantive procedural issues relating to the procurement and granting of patents is governed by the Patents Rules. The Patents Rule, 1972 came into force on 20th April 1972, along with Patents Act, 1970. After the TRIPS amendments, a lot of changes were made to the Act which called for the need of corresponding changes in the Rules. The Patents Rules, 1972 was repealed and the new Patents Rule, 2003 was enacted in May 2003. The Rules after being published were circulated over for six months to receive public comments. The Rules were again amended several times in 2005, 2006, 2012, 2014, 2016, 2017 and 2019.[190] The amendments aimed at reducing the processing time of the patent application along with simplifying the procedures. At present the Rules contain 15 chapters containing detailed procedure for the grant of patents along with 4 schedules which state the prescribed fees and form for different applications.[191]

Rule 9 (2) of the Patents Rule, 2003 requires the patent application to be filed in electronic form if it discloses any sequence listing of nucleotides or amino acids or both. The fee payable in case of sequence is provided in the Rules. The total page count determines the fee for filing a complete specification. In case of sequence listing, the fee

[189] Ramkumar Balachandra Nair et al., *Patenting of microorganisms: Systems and concerns*, 16 J Comm Biotech, 337 (2010)
[190] The Patents (Amendment) Rules 2005, 28-12-2004, SO No. 1418 (E), The Patents (Amendment) Rules 2006, 05-05-2006 SO No. 657 (E), The Patent (Amendment) Rules, 2012, Patents (Amendment) Rules, 2014, Patents (Amendment) Rules 2016, Patents (Amendment) Rules 2017, Patents Amendment Rules, 2019 http://www.ipindia.nic.in/rules-patents.htm (last updated Oct 25, 2019)
[191] Manoj Pillai et al., *Patent Procurement in India*, IPO Asian Practice Committee (2007) https://ipo.org/wp-content/uploads/2013/03/Whitepaper-PatentprocurementinIndia.pdf (last visited Dec 23, 2019)

is generally high due to the increased number of pages. Any patent application which relates to biological matter is subjected to the provision under section 10 (4) (ii) of the Act and Rule 13(8) of the Patents Rules, 2003. The rule states that patent applications relating to the reference of deposition of biological material should be made within three months from the date of filing of such application. The applicants should ensure that the deposition of the biological material to the International Depositary Authority is made prior to the date of filing of patent application in India.[192]

GUIDELINES FOR EXAMINATION OF BIOTECHNOLOGY APPLICATIONS FOR PATENT, 2013

Biotechnology inventions, both classical and modern have been of great importance to human life. Be it a simple fermentation process or complex procedure like genetic engineering, biotechnology has played a vital role in the development of different spheres of life. However, when it comes to patentability of biotechnology inventions there arises some issues or concerns. Apart from the patentability criteria like novelty, non-obviousness, industrial application and extent of disclosure, social and moral concerns along with environmental safety should be looked into. This paves way for formulating certain guidelines that will establish a consistent and uniform practice while examination patent application in the field of biotechnology. These guidelines are meant to help the patentee, examiners and controllers of the Patent Office by reducing confusions and bringing uniformity to the procedures. It is important to understand that these guidelines are not in any way above the Patents Act or the Patents Rules, 2003. Based on interpretations by a Court of Law, statutory amendments and valuable inputs from the stakeholders the guidelines are subject to revision from time to time.[193]

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[192] Guidelines for Examination of Biotechnology Applications for Patents, 2013, cl. 20- Deposit of biological materials- 'If the invention relates to a biological material which is not possible to be described in a sufficient manner and which is not available to the public, the application shall be completed by depositing the material to an International Depository Authority (IDA) under the Budapest Treaty. The deposit of the material shall be made not later than the date of filing of the application in India and a reference of the deposit shall be given in the specification within three months from the date of filing of the patent application in India. All the available characteristics of the material required for it to be correctly identified or indicated are to be included in the specification including the name, address of the depository institute and the date and number of the deposit.' http://www.ipindia.nic.in/writereaddata/Portal/IPOGuidelinesManuals/1_38_1_4-biotech-guidelines.pdf (last visited Dec 23, 2019)

[193] Chesta Sharma, *Legal Guidelines for filing patent for biotechnology in India*, IIPTA (2017) https://www.iipta.com/legal-guidelines-filing-patent-biotechnology-india/ (last visited Dec 23, 2019)

Generally, the below mentioned subject matter forms a part of biotechnology applications;[194]

(a) Gene sequences

(b) Protein sequences (product and/or process),

(c) Vectors

(d) Gene constructs or cassettes and gene libraries,

(e) Host cells, microorganisms and stem cells, transgenic cells,

(f) Plants and animals tissue culture

(g) Pharmaceutical or vaccine compositions comprising microorganisms, proteins, etc.

Some of the important guidelines in relation to patentability of biotechnology and allied subject are:

1. When a patent application which contains sequence listing of nucleotide or amino acid is to be filed, such sequence listing should be filed in an electronic form. The examiner should carry out the sequence search in patented and unpatented databases making use of diverse search tools.[195]
2. The expression 'capable of industrial application' is very important when it comes to patentability of invention. An invention to be patentable must have some use and industrial applicability either in implicit or explicit manner. In matters relating to genes, no matter how inventive or original step was involved in discovering a gene sequence, it cannot be patented unless it has a useful purpose. The specification must disclose a practical way of making use of such invention.[196]

[194]Guidelines for Examination of Biotechnology Applications for Patents 2013, cl.5- Claims of Biotechnology Industry, http://www.ipindia.nic.in/writereaddata/Portal/IPOGuidelinesManuals/1_38_1_4-biotech-guidelines.pdf (last visited Dec 23, 2019)

[195] Kankanala, supra, at 38

[196] Prabhu Ram, *India's New TRIPS-Complaint Patent Regime between Drug Patents and the Right to Health*, 5 Chi.-Kent J. Intell. Prop. 195, 199 (2005-2006).

3. Certain processes like cloning of humans and animals, use of human embryos, modification of germ lines in human beings etc. involve living subject matter. Hence it becomes imperative that adequate care be taken while examining such inventions. The subject-matter must not be contrary to public order, morality and should not cause any serious prejudice to human, animal or plant life or health or to the environment.[197]
4. Products that are directly isolated from nature are not patentable, which includes micro-organisms, proteins, enzymes etc. However, the processes of isolation of these products can be considered to be patentable subject matter if it fulfills the requirements of Section 2 (1) (j) of the Act. This guideline is an interpretation of Section 3(c) of the Act.
5. In the context of 'methods of treatment' under Section 3 (i) of the Act, medicinal, surgical, curative, prophylactic, diagnostic and therapeutic methods are not patentable. A diagnostic method using drug response markers or detection of a gene signature is also completely barred under this section.[198] Any claims relating to biological processes of growing plants, germination of seeds or development stages of plants and animals, which are very natural, will not be patented. The Act grants patents to modified microorganisms, which do not constitute discovery of living things occurring in nature.[199]
6. Section 10 of the Act specifically lays down the requirements or contents of specifications. The specification must fully and clearly describe the invention and its use, the best method to perform the invention along with a set of claims defining the scope of invention for which protection is sought. The claim should be clearly and briefly explained. In case of specifications containing a wide range of unrelated diseases, if a gene plays an important role in treatment of one or more listed diseases it may not mean that the same gene will have a vital role to play in the treatment of all other diseases. If there is no evidence showing that the gene

[197] Id.
[198] Harikesh Bahadur Singh, Intellectual Property Issues in Biotechnology 35 (1st ed. 2016)
[199] Id.

can be used for therapeutic or diagnostic purposes for every disease listed, the specification will be insufficient.[200]

7. An application for any invention relating to a biological material which is impossible to describe in definite terms and which is unavailable to the public, should be completed by depositing such material to an International Depository Authority (IDA). The name, address of the depository institute, date and number of the deposit should be clearly indicated in the specification as given in the guidelines.

GENE PATENTS UNDER THE PATENTS ACT, 1970

The debate as to whether biotechnological inventions are inventions in the right sense or just mere discovery has been going on for a long time, which applies to patentability of genes too. There is no clear norm for determining patentability of genes. In order to address the question of patentability effectively, a set of criteria is put forward by the patent law. The patentability of the subject matter will be decided based on its novelty, utility/ industrial application and inventive step or non-obviousness.

Novelty

Regardless of the nature of the subject matter to be patented, novelty is an essential requirement under the patent law. In the Patents Act 1970, novelty is replaced by the term 'new invention'[201] which means that the subject matter has not fallen in the public domain or has not formed part of the state of art. The Supreme Court of India tried to explain the importance of novelty while granting patents in the case of Bishwanath Prasad Radhey Shyam vs. Hindustan Metal Industries[202]. The Court held that it is essential for the validity of a patent that it must be the inventor's own discovery as opposed to mere verification of what was already known before the date of the patent. The information can be said to be in public domain if it has reached the public knowledge

[200] Aayush Sharma, *India: Patent Specification - Where The Rubber Meets The Road* (2016) https://www.mondaq.com/india/patent/550572/patent-specification--where-the-rubber-meets-the-road (last visited Dec 30, 2019)
[201] The Patents Act, 1970, Sec. 2 (l)
[202] Bishwanath Prasad Radhey Shyam vs. Hindustan Metal Industries (1979) 2 S.C.C 511

either through oral exchange of information or through publication in any books, journals, online portals or any other source of media.

For a claim to be novel, it is to be proved that it did not exist in the public knowledge. This is why natural phenomena, abstract ideas, laws of nature etc. are beyond the scope of patentability.[203] In the case of DNA, they are naturally occurring matters whose properties and composition are already known. So, isolating the DNA from its natural state without any human intervention in regard to the functioning of the said gene or gene sequence cannot claim patentability.[204] The Indian Patent Office's Manual of Patent Process and Procedure clarifies that biological materials such as rDNA, plasmids and their production processes are patentable because they are produced through significant human interference. Several patents were issued in India for isolated gene sequences, and those sequences were deemed novel by the patent office in the light of their natural counterparts.[205]

Inventive step or non- obviousness

Under the Indian patent law inventive step is a pre-requisite to grant patent to an invention, which has been defined as; "*a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art*".[206] In determining the non- obviousness of the invention, it is not only important to ascertain that the invention was not known earlier but also that a person of ordinary skill in the art was unable to figure out the invention. Considering that there are issues, particularly with regard to chemical compounds, several sub-rules have been suggested to assess the non-obviousness of every chemical product, and DNA as a chemical substance is only tested on this standard. For example, a similar composition of the alleged chemical invention as to the current state of the art causes obviousness on the face of it, and then the

[203] The Patents Act 1970, sec.3

[204] *US Supreme Court Strikes Down Gene Patents but Allows Patenting of Synthetic DNA*, GenomeWe (2013) https://www.genomeweb.com/diagnostics/us-supreme-court-strikes-down-gene-patents-allows-patenting-synthetic-dna (last visited March 29, 2020)

[205] Himatej Reddy, *Patenting Biotechnology Based Inventions - In India* (2012) http://dx.doi.org/10.2139/ssrn.2198744 (last visited on March 30, 2020)

[206] The Patents Act 1970, Sec. 2 (ja)

responsibility of justifying the claim transfers to the patent claimant and he must prove that his innovation has qualities that are superior to that of the existing prior art.[207] the notion of obviousness at the initial stage itself does not negate the possibility of patentability, it merely shifts the burden of showing the unexpected properties of the claimed inventions are not present or suggested in the prior art on the applicant.

The patentability of isolated genes can be recognized because, irrespective of the knowledge of the functioning of the gene by a person with ordinary expertise in the art, working in the same field of study, the exact sequence responsible for that specific reason may not have been identified and therefore it may not become evident. Thus, a claim that an individual gene, not being part of a prior art, will easily pass the check of obviousness. According to the Patent Practice and Procedure Manual, the isolated gene sequences and protein sequences shall be considered as possessing an inventive step in the light of their natural counterparts. As the biotechnology innovations have different applications in the medicines and diagnostics field, the criterion for economic significance is simple to prove. The law does not prescribe any special requirements for biotechnology inventions in comparison to other inventions in India.

Industrial application or utility

The patent law in India mandates the invention to be capable of industrial application[208] i.e., the invention is capable of being made or used in an industry. The test of utility over the DNA stays in the grey area where on one hand, the economic need or financial return of the investors should be considered but on the other hand the medical care of the general population will be in jeopardy. When such patents are granted, it is often commercialized resulting in absolute monopoly and high- priced medicines that are unaffordable to the common man.[209]

As the Indian Patent Act, 1970, does not specifically mention anything about the industrial applicability of biotechnology patents, it is appropriate to extend the general industrial applicability criteria to biotechnology inventions. It would be easy to satisfy the

[207] Kumar, supra, at 350

[208] The Patents Act 1970, Sec. 2 (ac)

[209] Pitcher, supra, at 288

condition of industrial applicability in India as inventions in biotechnology can be created and used in an industry and can be replicated numerous times. The instructions in the Manual of Patent Procedure for the review of biotechnology inventions specify that gene sequences and DNA sequences whose functions are not disclosed do not meet the criterion of industrial applicability.[210] The 2013 Guidelines further provides that Fragments/ESTs (Expression Sequence Tag) are allowable if they in addition to other conditions satisfy the question of usefulness and industrial application. The mere disclosure of the use of an EST as a gene probe or chromosome marker would not be considered sufficient to show its industrial application. A credible, specific and substantial use of the EST should be disclosed, for example use as a probe to diagnose a specific disease.[211]

Disclosure

According to Indian law, any patent application must be accompanied by complete specifications which must explain the invention in detail and in particular, specify the scope of the invention and also include the best possible way of implementing or utilizing the invention.[212] In order to reduce the occurrence of doubts, the enabling disclosure made must be full and careful details. One of the main problems with the disclosure process for biological materials is that enabling disclosure requires certain extra criteria such as the source of the biological material used. It's because of this complexity that patenting of genes is particularly opaque. The DNA sequences are made of different combinations and chemical properties and so the researcher will need a computer-based search and analysis method to analyze the invention. Subsequently, if the application fails to provide the examiner with access to a computer readable database, the conditions for public disclosure of the patent scheme will not be fulfilled.[213]

In the case of gene patenting, the inventor must clearly differentiate between sequence

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[210] Officer of Comptroller General of Design & Trademarks, Manual of Patent Office Practice & Procedure, 14 (March 9, 2004).

[211]Guidelines for Examination of Biotechnology Applications for Patents 2013, cl 9.1

[212] The Indian Patents Act, 1970, Sec.10 (4),

[213] Osmat A Jefferson, *Exploring the Scope of Gene Patents Through New Levels Of Transparency*, World Intellectual Property Organization (2004)

disclosure and claiming of sequence in the patent application.[214] The inventor is expected to render all practicable disclosures of the sequences protected by the "sequence lists" section and may also explain the role of any of the sequences concerned and whether they vary from the previously disclosed sequence.[215] However, most of the applications fail to mention all the sequences disclosed and prevent the inventor from claiming monopoly over the use of that particular sequence. The Budapest Treaty of 1977 has tried to overcome this difficulty to some extent in case of microorganisms, wherein it is required to submit a sample of the biological material which is being used in depositories so that it can be used by people of ordinary skill in order to follow the instructions provided in the enabling disclosure. However, most inventors are unwilling to disclose all the information relating to their invention, which defeats the purpose of enabling disclosure. In the absence of such detailed disclosure, the patent examiners conduct the tests, trial-&-error again, in order to derive at the patented material which is often time consuming.

Along with satisfying all these criteria, an invention to be patentable must not come under the scope of Section 3 of the Act which specifically lists out those subject matters which are not patentable. There are provisions in the section which are significant for the better understanding of patentability of genes.

Section 3(b) of the Indian Patent Act provides that "*an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment*" is not patentable. According to the section, an invention which is immoral or against public order, harmful to human, animal or plant life or harmful to the environment should not be patentable. The Indian Patent Law has strong prohibitions against patenting of biotechnology inventions based on morality and public order.[216] Section 3 (c) of the Act excludes patenting of a living or non- living thing occurring in nature. Patentability of any microorganism found in nature is rejected unless it satisfies the requirement of human intervention. Since genetically modified or genetically

[214] Kumar, supra, at 351

[215] Kumar, supra, at 354

[216] Reddy, supra, at 3

engineered organisms fulfil the criteria for substantial human intervention they can be patented. Also, plants and animals in "whole" or "any part thereof" is not patentable under section 3 (j) of the Act. Therefore, a merely isolated natural gene is also not patentable. Nonetheless, a genetically modified sequence that is new, inventive and has industrial application is patentable. In principle, under the present patent system, naturally occurring genes cannot be patented per se, but when modified with considerable human interference resulting in the disclosure of their distinct roles, combined with their industrial feasibility, they constitute patentable subject-matter. Furthermore, 3(i) forbids the patenting of diagnostic methods. Accordingly, the Manual of Patent Office Practice and Procedure prohibits medical procedures that are performed on the human or animal body.[217] However, it does not preclude diagnostic techniques that have been conducted on substances or fluids that have been completely extracted from the body. Diagnostic methods employing DNA are patentable to that extent.[218] Also, when a genetically modified gene sequence or amino acid sequence is novel, involves an inventive step, and has an industrial application, patents on the following can be claimed:[219]

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[217] MANUAL OF PATENT OFFICE PRACTICE AND PROCEDURE, Nov 26, 2019, cl 08.03.05.08 - *Any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products is not an invention***.** This provision excludes from patentability, the following: (a) Medicinal methods: As for example a process of administering medicines orally, or through injectables, or topically or through a dermal patch. (b) Surgical methods: As for example a stitch-free incision for cataract removal. (c) Curative methods: As for example a method of cleaning plaque from teeth. (d) Prophylactic methods: As for example a method of vaccination. (e) Diagnostic methods: Diagnosis is the identification of the nature of a medical illness, usually by investigating its history and symptoms and by applying tests. Determination of the general physical state of an individual (e.g. a fitness test) is considered to be diagnostic. (f) Therapeutic methods: The term ―therapy includes prevention as well as treatment or cure of disease. Therefore, the process relating to therapy may be considered as a method of treatment and as such not patentable. (g) Any method of treatment of animal to render them free of disease or to increase their economic value or that of their products. As for example, a method of treating sheep for increasing wool yield or a method of artificially inducing the body mass of poultry. (h) Further examples of subject matters excluded under this provision are: any operation on the body, which requires the skill and knowledge of a surgeon and includes treatments such as cosmetic treatment, the termination of pregnancy, castration, sterilization, artificial insemination, embryo transplants, treatments for experimental and research purposes and the removal of organs, skin or bone marrow from a living donor, any therapy or diagnosis practiced on the human or animal body and further includes methods of abortion, induction of labour, control of estrus or menstrual regulation. (i) Application of substances to the body for purely cosmetic purposes is not therapy. (j) Patent may however be obtained for surgical, therapeutic or diagnostic instrument or apparatus. Also the manufacture of prostheses or artificial limbs and taking measurements thereof on the human body are patentable.

[218] Id.

[219] Bhavishyavani Ravi, *Gene Patents in India: Gauging Policy by an Analysis of the Grants made by the Indian Patent Office* 18 J Intel Prop Rts. 323, 324 (2013)

(1) A gene sequence or amino acid sequence,

(2) A method of expressing the above sequence,

(3) An antibody against the protein or sequence,

(4) A kit made from the antibody or sequence.

But, the Manual of Patent Office Practice and Procedure do not define what "genetically modified gene sequence" constitutes which can be considered to be an ambiguity in the law.

PATENT ELIGIBILITY OF HUMAN GENES

The Indian jurisprudence on patenting human genes is quite unsettled as compared to that of U.S or European laws. The only guidelines presently available are the Indian Guidelines for the Examination of Patent Applications for Biotechnology (Indian Guidelines) and the Indian Patent Practice and Procedure Manual (IMPPP). The main question that needs to be answered is whether the term 'animal' used in section 3 (j) of the Act includes humans. A careful reading of section 3 (b) which talks about "human", "animal" and "plant life" would support the claim that humans are excluded from the scope of 'animals'.[220] Analyzing sections 3(c), 3(d), 3(e) and 3(j) and their effects on human genes naturally occurring DNA, isolated genomic DNA and cDNA will make it easier to understand the patent eligibility of human genes.

i. Naturally occurring DNA

The Indian patent law does not recognize naturally occurring DNA as patentable subject matter.[221] If the location of a human gene is identified or part of a gene as it exists in the chromosome, it would amount only to 'discovery' of a naturally occurring living thing and not an invention. It would also be excluded as "*part of a [human] animal*" under

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[220] Elizabeth Siew-Kuan NG, Patenting Human Genes: Wherein Lies the Balance between Private Rights and Public Access? 11 The Indian JL & Tech 2 (2015)

[221] Bhattacharyasayan, *Patenting of Human Genes: Intellectual Property vs Access to Healthcare & Research* (2017) https://patenting-of-human-genes-intellectual-property-vs-access-to-healthcare-research/ (last visited Apr 3, 2020)

section 3(j), if the clause is applicable to human genes. [222]

ii. Isolated genomic DNA

Until the year 2103, the Indian Patent Office granted patents to isolated genomic DNA. However, once the Indian Biotechnology Guidelines of 2103 came into force, the isolation of such materials was mere discovery rendering them unpatentable under Section 3 (c) of the Act. Sequences of nucleic acids, proteins, enzymes, compounds, etc. that have been directly extracted from nature will be regarded as a discovery rather than an invention that prevents them from patentability. If the term 'substance' under section 3(d) includes human genes then, the isolated genomic DNA will only be considered to be a mere discovery. Unless such isolated sequence results in the "*enhancement of the known efficacy of that substance*", it will not come under the scope of patentability. As the arrangement of the nucleotide sequence is similar in both the isolated genomic DNA as well as that occurring in nature, it becomes difficult to prove that the mere act of isolating the genomic DNA is sufficient to result in the "enhanced efficacy" of the genetic sequence.[223] Similarly, if the provision under section 3 (j) applies to human genes, then a modified element isolated from the human body would still constitute a part of an animal, which would make the claim unpatentable. Hence, the simple act of isolating the substance from nature would not be sufficient to convert the unaltered isolated element into a non-human component.

iii. cDNA

Sections 3(c) and 3(j) excludes a naturally occurring short exon- only DNA sequences existing in nature from scope of patentability. Similarly, a broad reading of section 3 (c) shows that an artificially created exon-only sequence, even with a human excision of introns, is considered to be a discovery. Another claim may be raised on a narrower interpretation of the term "discovery" in section 3(c) that a strand of artificial cDNA which is not "directly extracted" from nature cannot be called a discovery per se instead it is a man-made product created artificially from experiments conducted on a naturally occurring substance. In addition, cDNA may be more properly referred to as a product

[222] Siew-Kuan NG, supra, at 4

[223] Singh, supra, 42

derived indirectly from a substance which is directly extracted from nature. Based on this definition, it can be assumed that the excision of the introns transformed the product of the "discovery" into an invention. It shows that human intervention can serve to exclude cDNA from the reach of section 3(c).[224] However, no guidance is provided on the extent of modification required. The Indian Biotechnology guidelines and the patents manual does not provide proper guidance in this subject matter.

Section 3 (d) is also relevant when it comes to the patentability of cDNA. CDNA may be excluded from patentability if it constitutes a "*mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance*", if the provision applies to human genes.[225] Even if the cDNA constitutes a new form of a known genomic DNA sequence, its patentability will be dependent on whether it results in enhanced efficacy. Now what constitutes enhanced efficacy in the context of human genes is largely uncertain.

The most challenging issue is to decide whether cDNA comes under the exclusion under section 3 (j), if the provision applies to human genes. Two arguments are put forward in relation to the provision. First is the broader interpretation of the section, which excludes cDNA from patentability as it still forms part of an animal even though it has been artificially constructed by a man. In other words, human interference from the genomic DNA strand is not sufficient to transform it into a "non-human" component.[226] Secondly, a narrow reading of the section will result in the conclusion that to be a 'part of an animal' it should exist in nature as it is in an unaltered state. So, an artificially created cDNA will no longer be a part of an animal, as it does not exist in nature.[227]

Indian patent case law does not have enough precedential value to determine the amount of alteration/deletion/moderation by human intervention needed to make modifications on objects of nature patent eligible.[228]

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[224] Siew-Kuan NG, supra, at 20
[225] Siew-Kuan NG, supra, at 20
[226] Robert Cook-Deegan et al., *Patents in genomics and human genetics*, 11 Annu Rev Genomics Hum Genet. 383 (2010) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2935940/ (last visited Apr 7, 2020)
[227] Siew-Kuan NG, supra, at 22

[228] Bhattacharyasayan, supra, note at 208

In India, case laws relating to this subject matter is difficult to come across but there are two major cases to be looked into which are J. Mitra v Kesar Medicaments[229] and Emergent Genetics India v Shailendra Shivam[230].

In J. Mitra v Kesar Medicaments, the case involved a patent infringement claim for a diagnostic kit to diagnose Hepatitis C virus (HCV) antibodies in human serum and plasma. The patent dispute was on the grounds that it lacks novelty, inventive step, patent eligibility and patent specification sufficiency. The Court decided that the complainant had set up a prima facie infringement argument and issued a temporary injunction founded on the principle of balance of convenience.[231] Although the full merits of the issues like the question of patent protection have not been thoroughly discussed, the argument concerning diagnostic devices has not been challenged. The patent-eligibility of medical products in India will seem to be less contentious.

Emergent Genetics India v Shailendra Shivam, dealt with copyright questions related to information about genetic sequencing in hybrid seeds. While the patenting of genetic variants was not discussed explicitly, the decision of the High Court of Delhi applied to gene patents and can be instructive in its general approach to genetic IP concerns.[232] Justice Bhat denied the argument put forward by the appellant for patent infringement and held that the gene sequence lacked originality. The learned judge was of the view that the genetic code was "not a true" transmission of ideas but simply a replication of something in nature.[233]

SOME PATENTS GRANTED BY THE INDIAN PATENT OFFICE

1. GENETICALLY STABLE JEV CDNA BASED ON JAPANESE ENCEPHALITIS VIRUS[234]

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[229] J. Mitra v Kesar Medicaments (2008), CS(OS) No. 2020/2006
[230] Emergent Genetics India v Shailendra Shivam (2011) (47) PTC 494 (Del)
[231] Siew-Kuan NG, supra, at 16
[232] Id.at 17

[233] Shan Kohli, *The debate on copyright for DNA sequences finally put to rest? The Delhi High Court's Verdict*, De-Coding Indian Intellectual Property Law (2011) https://spicyip.com/2011/12/debate-on-copyright-for-dna-sequences.html (last visited Apr 12, 2020)
[234] Young-Min Lee, Genetically stable Jev cDNA based on Japanese Encephalitis Virus (JEV), Indian Patent No. 243799 (8 November 2010)

The present invention involves the identification of an authentic RNA sequence of the Japanese encephalitis virus (JEV) genome, the creation of infectious JEV cDNA clones and the utility of the clones or their variants for medical, vaccine and diagnostic purposes. Furthermore, the discovery often applies to JEV vectors, e.g. for systems of heterologous gene expression, genetic immunization, and transient gene therapy.[235] The nucleotide length and the actual non-translating regions and the regions coding for a peptide are further described in detail. The original title of the invention during filing of the patent application related to 'novel genomic RNA' of the JEV and an infectious cDNA from it. Since the final title is different it can be believed that there were amendments made to the claims, the title, and the abstract to cover the cDNA instead of the RNA. Even though the sequence was a mere derivative of the existing one and not recombinant, the IPO granted protection to the cDNA sequence. Hence cDNA sequences can claim patent protection in India.[236]

2. AN EXPRESSION VECTOR OR CLONING VECTOR ENCODING A FILARIAL PARASITE POLYPEPTIDE[237]

The invention relates to the prevention and treatment of filarial parasite infections where polypeptide is used as a therapeutic agent.[238] At first, many claims made by the applicant were objected by the IPO on the grounds of sections 3(c), 3(j) and 3(n). A claim for cDNA sequence was objected because it was obtained from an already existing component in nature. Other claims based on polypeptides and RNA were objected under section 3 (c). Later on, all these claims were withdrawn and the patent was granted. However, still doubts arose in determining if these sequences are completely non-obvious since the particular nucleotide sequence is put inside a vector which is known recombinant DNA technology and has no new or enhanced utility.[239]

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[235] See, Indian Patents http://www.allindianpatents.com/patents/243799-genetically-stable-jev-cdna-based-on-japanese-encephalitis-virus-jev (last visited Apr 14, 2020)
[236] Ravi, supra, at 327
[237] Abdullah K A Noordin R, An expression vector or cloning vector encoding a filarial parasite polypeptide, Indian Patent No. 246865 (Universiti Sains Malaysia) (18 March 2011).

[238] See, Indian Patents at http://www.allindianpatents.com/patents/246865-an-expression-vector-or-cloning-vector-encoding-a-filarial-parasite-polypeptide (last visited Apr 14, 2020)
[239] Ravi, supra, at 329

3. AN ISOLATED NUCLEIC ACID (NA) MOLECULE COMPRISING AN ALLELE OF A GENETIC POLYMORPHISM LINKED TO RESISTANCE TO ENTEROTOXIGENIC ESCHERICHIA COLI (ETEC)[240]

The present invention relates to an isolated nucietc acid (NA) molecule, comprising an allele of a genetic polymorphism linked to resistance to enterotoxigenic E. coli (ETEC). It further relates to a kit for determining if a pig is homozygous, heterozygous or non-carrier of an allele of a genetic polymorphism being linked to resistance to ETEC.[241] The patent covers both the original sequence and the other man-made probes/primers for character trait identification. No objection is raised in the first review report either to the gene's animal source or for a claim involving an isolated gene sequence.[242] This also points to the fact this in India, animal genes are patentable.

4. AN ISOLATED NUCLEIC ACID MOLECULE CODING FOR HUMANS Akt3

The patent here applies to an individual nucleic acid coding in mammalian cells for a human Akt3 protein, relevant to the cycle of cell death, the protein sequence and a process to produce it and express the sequence. The protein's expression stops apoptopic death in cells. The claim relates to an *'isolated nucleic acid encoding a human Akt3 protein*' possessing a particular amino acid series, *'or a significantly close sequence*.'[243] Here, instead of simply having the gene ID for the nucleotide sequence, the protein sequence is used. It is uncertain since there are several different nucleotide sequences that can code for one amino acid, so the exact protein encoding sequence in particular is not pinned down. The major problem with this is that the patent only protects single, naturally occurring human Akt3 material, and the coding sequences among the other claims that envisage it being added, developed etc. The first evaluation study would not respond to such arguments and it is also important to notice that the IPO did not respond

[240] Cirera S et al., An isolated nucleic acid (na) molecule comprising an allele of a genetic polymorphism linked to resistance to enterotoxigenic Escherichia Coli (ETEC), Indian Patent No. 244118 (University of Copenhagen) (18 November 2010).

[241] See, Indian Patents at http://www.allindianpatents.com/patents/244118-an-isolated-nucleic-acid-na-molecule-comprising-an-allele-of-a-genetic-polymorphism-linked-to-resistance-to-enterotoxigenic-escherichia-coli-etec (last visited Apr 14, 2020)

[242] Noordin, supra,

[243] Noordin, supra,

to the argument that it actually has a human source.[244] It points to the inference that human genes may also be patented in India.

It is quite evident that the IPO is moderately vague when it comes to granting patents to gene sequences that have also been patented. Since a lot of human illness can be diagnosed by gene markers based on human genes, it is very important to have a clear patentability criterion for human genes and related diagnostic methods. In this context, it is important for the IPO to review the Guidelines for Review of Biotechnology Applications for Patent, 2013. The Guidelines are a positive leap in the right direction because they acknowledge and state that consistent and clear practices are essential at the IPO. However, at the same time, it is often mentioned that these are not laws and that the instructions should be superseded by the Patents Act, 1970 and Patent Law, 2003. Ensuring consistency in granting patents is very important as expansive patents can result in hindrance in development and innovation.[245]

GENE PATENTS AND RIGHT TO HEALTH

In India, the challenge of developing patent policy is subject to one important limitation - the Constitution of India. The values in the Constitution obligate to balance economic values with social needs. Health is one of the most basic fundamental rights of every human being. Article 21 of the Constitution which guarantees right to life and liberty also encompasses with it 'right to health'.[246] The Supreme Court held the right to health and medical care as a fundamental right which has to be read along with Articles 39(e), 41 and 43.[247] Article 25 of the Universal Declaration of Human Rights also speaks about the right to health.[248] Similarly, Article 12 of the International Covenant on Economic, Social and Cultural Rights requires parties to the Covenant to recognize the right of

[244] Noordin, supra,
[245] P.A. Andanda, *Human-Tissue-Related Inventions: Ownership and Intellectual Property Rights in International Collaborative Research in Developing Countries*, 34 J Med Ethics 171(2008)
[246] 'Right to life, if given a broad interpretation incorporates right to livelihood and right to health' M.K. Sharma v. Bharat Electronics Ltd, AIR 1987 SC 1792.
[247] Bandhua Mukti Morcha v. Union of India (1984) 3 SCC 161; Consumer Education and Research Centre v. Union of India (995) 3 SCC, 42.
[248] UN General Assembly, *Universal Declaration of Human Rights*, 10 December 1948, 217 A (III) [hereinafter referred as UDHR], Art 25(1)- "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services."

everyone to the enjoyment of the highest attainable standard of physical and mental health.[249] As India is a signatory to both these treaties, India is obligated to follow the provisions and facilitate the enjoyment of 'right to health' by its citizens. In a welfare state, it is the obligation of the state to ensure the creation and the sustenance of conditions congenial to good health.[250] The concept of right to health has four important dimensions to it. They are availability, accessibility, quality and acceptability of better healthcare.[251] Every society needs an adequate healthcare system that can cater to the needs of its population. It is not only important to have such facilities available, but also to be able to accessible to all sections in the society without discrimination of any kind. Accessibility should be both in terms of physical and economic accessibility. However, more than often, gene patents infringe these conditions of right to health.[252]

The fundamental information about genetic behavior which is useful in the field of research is often claimed by gene patents. All applications of gene including gene therapy and pharmacological modulation of the gene have to go through the original gene patent or the 'gatekeeper patents' before they could be made use in an invention.[253] Such patents have an 'anti common effect' in the society and can be referred to as 'blocking patents' since it's the patentee who has the whole control of all the research and allied activities related to the gene.[254] When essential features of a patent are covered so as to restrict others from inventing around it, it is called a blocking patent which later leads to restrictive licensing.[255] Even those products which have no relation to the gene in

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[249] UN General Assembly, *International Covenant on Economic, Social and Cultural Rights*, 16 December 1966, United Nations, Treaty Series, vol. 993[hereinafter referred as ICESCR], Art. 12 - "The right of everyone to the enjoyment of the highest attainable standard of physical and mental health."

[250] Mathews P. George et al., *Gene Patents and Right to Health*, 3 NUJS L. Rev. 323, 326 (2010).

[251] CESCR, General Comment No. 14 (2000), The Right to the Highest Attainable Standard of Health (Article 12 of the International Covenant on Economic, Social and Cultural Rights, 22nd Session) E/C. 12/2000/4, August 11, 2000, cl 12.

[252] George et al., supra 326

[253]John Barton, *Patents and Antitrust: A Rethinking in Light of Patent Breadth and Sequential Innovation*, 65 Antitrust L J 449 (1997).

[254] George et al., supra 327

[255] Overwalle, supra, at 154

question may require the permission from the patentee to do an independent research.[256] Patent thickets[257], are always a threat to the diagnostic sector and increases the cost of R&D. Thus, it is evident that gene patenting can impede healthcare and related R&D that can be of immense benefit to the public. It can scuttle progress toward better [258]and more efficient healthcare. It can also increase healthcare expenses and streamline exposure to the Indian population's affluent areas. It can thus infringe availability and accessibility to better healthcare.[259]

India is bound by various international treaties like the ICESCR and UDHR and its own Constitution[260] to facilitate the fundamental right of right to health to all its citizens. Since gene patents impede research and restrict the right to health to a larger section of the population, it becomes inevitable to have a vigilant approach in the matter. The Indian Patents Act, 1970 and the Competition Act, 2002 may be relevant here. Compulsory licensing is one such clause of patent law that provides for the issuance of a compulsory license when the reasonable requirements of the public with regard to the patented invention have not been met or the public has no access to the patented invention at a reasonably affordable price.[261] The cause of concern is often felt in the time period of issuing a compulsory license as an application for the same can only be made after a period of three years once the patent has been issued.[262] The Act also provides exception to the patent protection for the purposes of research, experiments or education.[263] Thus, third parties would be able to experiment with patented products and make new manufacturing processes. Such products cannot however be used commercially without the patent holder's prior approval.[264]

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[256] OECD, supra, at 77

[257] Hawkins, supra, at 3250
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3319650/ (last visited Apr 15, 2020)
[258] Ram, supra, at 203

[259] George, supra, at 329

[260] Right to health is a guaranteed fundamental right under Article 21: Paschim Banga Khet Mazdoor Samity & Ors v State of West Bengal & Anor.: (1996) AIR SC 2426/ (1996) 4 SCC 37
[261] The Patents Act, 1970, Sec. 84
[262] The Patents Act 1970, Sec 84 (2)
[263] The Patents Act 1970, Sec 47(3)
[264] Ram, supra, at 204

When an enterprise abuses its power or position in the market, section 4 of the Competition Act[265] can be invoked. The abuse of dominant position which results in denial of market access in any manner can trigger essential facilities doctrine.[266] This theory may be used in the case of certain patent owners whose authorization is necessary for the production or manufacture of downstream gene products. For example, the theory should be applied on reasonably fair terms for mandatory licensing. The prudential application of such laws can help protect 'right to health' from being violated. This will not, however, be a panacea for solving disputes regarding gene patents and right to health.[267]

CONCLUSION

The applications of gene technology can be seen in almost all fields today including health, food, agriculture and environment. Genes are essential for the practice of all downstream inventions relating to such technologies. Therefore, patenting a gene can theoretically decide all downstream innovations and thereby protect the entrance into a field. Hence, they are known as gatekeeper patents. Even if one rejects the basic terms of

[265] The Competition Act, 2002, Sec 4. Abuse of dominant position— (1) No enterprise shall abuse its dominant position (2) There shall be an abuse of dominant position under sub-section (1), if an enterprise, —(a) directly or indirectly, imposes unfair or discriminatory—(i) condition in purchase or sale of goods or services; or(ii) price in purchase or sale (including predatory price) of goods or service; or Explanation.— For the purposes of this clause, the unfair or discriminatory condition in purchase or sale of goods or services referred to in sub-clause (i) and unfair or discriminatory price in purchase or sale of goods (including predatory price) or service referred to in sub-clause (ii) shall not include such discriminatory conditions or prices which may be adopted to meet the competition; or (b) limits or restricts—(i) production of goods or provision of services or market therefor; or(ii) technical or scientific development relating to goods or services to the prejudice of consumers; or (c) indulges in practice or practices resulting in denial of market access; or (d) makes conclusion of contracts subject to acceptance by other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts; or (e) uses its dominant position in one relevant market to enter into, or protect, other relevant market. Explanation.—For the purposes of this section, the expression—(a) "dominant position" means a position of strength, enjoyed by an enterprise, in the relevant market, in India, which enables it to—(i) operate independently of competitive forces prevailing in the relevant market; or(ii) affect its competitors or consumers or the relevant market in its favour; (b) "predatory price" means the sale of goods or provision of services, at a price which is below the cost, as may be determined by regulations, of production of the goods or provision of services, with a view to reduce competition or eliminate the competitors.

[266] Apporva Vijh, *Position of Essential Facilities Doctrine in India*, Society of International Trade and Competition Law (2018) https://nujssitc.wordpress.com/2018/04/07/position-of-essential-facilities-doctrine-in-india/(last visited Apr 19,2020)

[267] Mathews, supra, at 339

this claim, it cannot be disputed that it is impossible to "invent around" proprietary genes or find replacements for them, unlike other proprietary inventions. A clear definition of micro-organism can clear ambiguity regarding the position of Indian law in patenting of genes to an extent. On the other hand, lenient rules for biological innovations vis-a-vis chemical innovations, can lead to evergreening of inventions and frivolous patents. Thus, India needs guidelines specifically for genetic patenting. The basic requirements for patentability, i.e. innovation, non-obviousness and usefulness, have to be precisely tailored for genetic patenting. India is a country with a strong biotechnological base. So rather than a defensive approach, a more positive approach should be adapted to the question of intellectual property rights, keeping in mind the long-term contributions biotechnology can make to the economic development of the country.

CHAPTER 5

COMPARATIVE STUDY OF STANDARDS RELATING TO PATENTABILITY OF GENES

The human mind has always been motivated by the desire to innovate in order to improve the human condition. Patent system was created and developed as an attempt to encourage such innovations through private incentives.[268] With the advancement in science and technology the subject matter for patent eligibility has also evolved. Patents are the pillars of modern biotechnology which requires protection for its success. Patents by their very definition restrict what others can do, by giving the patent holder a term of exclusive control over the innovation in exchange for public disclosure of information on the patented invention so that other inventors may build on it.[269] In general patents are granted for inventions and not discoveries. It is often difficult to distinguish between the two. Discovery is what exists in nature whereas invention has a certain level of human intervention. Patenting in biotechnology presents challenges to this distinction, because the subject matter in question consists of "natural" entities.[270]

With the arrival of genomics, the ambit of biotechnology has widened. In order to decipher the genetic information, progress in the field of molecular biology is made through cloning, sequencing and other techniques which makes the issue relating to patents significant.[271] Each new technology brings in with itself new challenges to the patent regime. In case of gene patents difficulty is felt in the area of newness of the claims, increasing pace of technological change, the global nature of scientific inquiry and the highly specialized nature of genetic science and technology along with the

[268] Philippe Baechtoldet et al., International Intellectual Property A Handbook to Contemporary Research, International Patent Law: Principles, Major Instruments and Institutional Aspects, 37 (ed. Daniel J Geravis, 2015)

[269] Jordan Paradise et al., *Patents on Human Genes: An Analysis of Scope and Claims*, 307 Science 1566 (2005)

[270] *Genetics, genomics and the patenting of DNA- Review of potential implications for health in developing countries*, World Health Organization 10 (2005)

[271] Bergel, supra, 327

increased number of patent applications.[272] Also, the patentability criteria for genes are different across various jurisdictions. Effective harmonization of law as regards to patentability standards is required to adequately protect innovations. The difference in patentability criteria may be due to the different social, cultural, legal and economic conditions of a country. However, every member nation must follow certain minimum standards while determining patentability criteria as a result of international agreements like TRIPS.[273]

TRIPS AGREEMENT

The Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS) is a comprehensive international agreement between member countries aimed to reduce distortions and impediments to international trade by effectively and adequately protecting intellectual property rights. Under the agreement, Members shall be free to determine the appropriate way of applying the terms of this Agreement in their own legal system and procedure. The TRIPS Agreement only lays down certain minimum standards to be followed by the member nations. Members may adopt measures necessary to protect public health and nutrition, and to promote public interest in sectors of vital importance to their socio-economic and technological development. However, formulating or amending such laws should not be inconsistent with the provisions of the Agreement.[274] The provisions relating to patents are envisaged in section 5 of the Agreement. Both process and product patents are available to inventions in all fields of technology if it satisfies three main criteria:[275]

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[272]*Genes and Ingenuity: Gene patenting and human health*, ALRC Report 99 (2004) https://www.alrc.gov.au/publication/genes-and-ingenuity-gene-patenting-and-human-health-alrc-report-99/ (last visited Apr 20, 2010)

[273] Advice on Flexibilities under the TRIPS Agreement, WIPO https://www.wipo.int/ip-development/en/policy_legislative_assistance/advice_trips.html (last visited Apr 20, 2020)

[274]TRIPS Agreement, Art 8

[275] TRIPS Agreement, Art 27(1)- Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

(i) It must be new

(ii) Involves an inventive step (non-obvious)

(iii) Capable of industrial application (useful).

Further the patents will be made available without any discrimination as to field of technology, place of invention or whether the products are imported and locally produced.[276] This ensures that all TRIPS member states will grant patents for biotechnology at some point and cannot explicitly forbid them as a technological area. Also, the participating countries can regulate and monitor patents granted by patent offices and law courts based on national legislation and decisions. The Agreement does not expressly exclude any subject matter from patentability. However, member countries can exclude inventions from the scope of patentability to protect *ordre public*, health, animal and plant life, and environment.[277] Furthermore, member states can exclude from patentability:

i) diagnostic, therapeutic and surgical methods for the treatment of humans or animals,

ii) plants and animals not including micro-organisms,

iii) biological processes for the production of plants or animals other than non-biological and microbiological processes.[278]

TRIPS Agreement fails to give a definition to the term 'invention'. Because of such failure, Member nations often carve out distinct definitions of their own which needs to be in resonance with the basic framework provided in Article 27. The agreement is essentially silent regarding naturally occurring substances and nowhere excludes genetic

[276] Id.

[277] TRIPS Agreement, Art 27(2) - Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

[278] TRIPS Agreement, Art. 27(3) - Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

materials from patentability. Though it specifically excludes patents to 'biological processes', it is still confusing as to whether patents should be granted to genes or not. However, after interpreting the relevant Articles the TRIPS, many jurists have concluded that genes in isolation can be granted patents.[279] The broad language used in the TRIPS Agreement makes it easier for the member states to interpret the provisions, but it often leads to disparities in national legislations creating legal conflict between member the country and the patent holder and their respective governments.[280]

The question as to whether genes are patentable or not raises serious doubts and the lack of any specific provision on the subject matter increases the uncertainty. The TRIPS Agreement's failure to protect research needed to promote innovation, monitor anti-competitive behavior, regulate the convergence of various national laws, and require safeguards against license and transaction costs demonstrates that the inadequacies of the Agreement ought to be resolved.[281]

AUSTRALIA

Australia has always developed a system that promotes both fundamental and applied scientific research, contributing to the growth of a research community that ranks consistently high across foreign jurisdictions and creates a benchmark for efficiency and quality.[282] Australian patent laws have been comparatively generous towards subject matters that can be patented. The decisions taken by both the Australian Patent Office and Australian courts reflect their intention of promoting research, development and commercialization of technology which are the incentives of a strong patent system.[283]

Australia's patent obligations are laid down in both its national patent laws and international agreements. The origins of Australian patent law are traceable to English

[279] Kumar, supra, at 355

[280] Laura C. Whitworth, *Comparison of the Implementation of Statutory Patent Eligibility Requirements Applied to Gene Patents in the European Union, the United States, and Australia*, 56 IDEA 449, 450 (2016)

[281] Fowler, supra, at 1080

[282] Adam Denley et al., *Decoding gene patents in Australia,* 5,1 Cold Spring Harb perspect med 2 (2014) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4292076/#FN1 (last visited Apr 25, 2020)

[283] Whitworth, supra, at 468

patent law. As an English colony, early Australian inventors filed for patents in England until the Australian colonies established their own independent legislatures.[284] In June 1904, the various patent systems in each colony were combined into a single Australian commonwealth agency to administer all patents in Australia. This agency is known as IP Australia and administers the patent system currently.[285] In 1925, Australia entered into the Paris Convention and is a member of the World Intellectual Property Organization. Also, it is signatory to the Trade-Related Aspects of Intellectual Property Rights agreement ("TRIPS") owing to the membership in the World Trade Organization.[286]

The patent law in Australia grants two types of patents- standard patent and innovation patents. The term of protection is twenty years and eight years respectively for standard patent and innovation patent.[287] Like most other jurisdictions, for an invention to be granted patent it must fulfil the following requirements[288]-

(i) It is a is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies

(ii) It must be novel and involve an inventive step and

(iii) It must be useful

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[284] Patents History, Australia State Victoria Library https://guides.slv.vic.gov.au/patents/history (last visited Apr 23 2020)

[285] Kate M. Mead, Gene Patents in Australia: A Game Theory Approach, 22 Pac. Rim L. & Pol'y J. 751, 754 (2013).

[286] Id. at 755

[287] Patent Basics, IP Australia https://www.ipaustralia.gov.au/patents/understanding-patents/patent-basics (last updated June 2018)

[288] The Australian Patents Act 1990, Sec.18 - Patentable inventions for the purposes of a standard patent (1) Subject to subsection (2), an invention is a patentable invention for the purposes of a standard patent if the invention, so far as claimed in any claim:(a) is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies; and(b) when compared with the prior art base as it existed before the priority date of that claim: (i) is novel; and (ii) involves an inventive step; and (c) is useful; and (d) was not secretly used in the patent area before the priority date of that claim by, or on behalf of, or with the authority of, the patentee or nominated person or the patentee's or nominated person's predecessor in title to the invention.

Patentable inventions for the purposes of an innovation patent (1A) Subject to subsections (2) and (3), an invention is a patentable invention for the purposes of an innovation patent if the invention, so far as claimed in any claim: (a) is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies; and (b) when compared with the prior art base as it existed before the priority date of that claim: (i) is novel; and (ii) involves an innovative step; and (c) is useful; and (d) was not secretly used in the patent area before the priority date of that claim by, or on behalf of, or with the authority of, the patentee or nominated person or the patentee's or nominated person's predecessor in title to the invention.

(iv) It should not have been secretly used in the patent area before the priority date of that claim.

The Act specifically excludes human beings and biological processes for their generation from the scope of patentability.[289] Also, plants and animals along with biological processes for their generation are not patentable for the purpose of innovation patent.[290] However, if the invention relates to a microbiological process or a product of such a process it cannot be excluded from patentability.[291] Isolated bacteria, cell lines, hybridomas, some related biological materials and their use, and genetically manipulated organisms are eligible for standard patent protection. Some examples for such patentable inventions include isolated bacteria and other prokaryotes, fungi, algae, protozoa, plasmids, cell lines, cell organelles, hybridomas, genetic vectors and expression systems, apparatus or processes for enzymology or microbiology, compositions of micro-organisms or enzymes, propagating, preserving or maintaining micro-organisms, mutagenesis or genetic engineering, fermentation or enzyme using processes to synthesize a desired compound or composition etc.[292] Gene sequences, RNA, DNA or nucleic acid sequences replicating the genetic information existing in the genome of any human or other organism is not eligible for patent protection. It is irrelevant whether the genetic material was man made or isolated from nature.[293]

Inventions involving genotypically or phenotypically modified living organisms, like genetically modified bacteria, plants and non-human organisms and isolated polypeptides and proteins form a subject matter eligible for patent protection. As a result, an isolated protein expressed by a gene, vectors containing a transgene, methods of transformation using a gene, host cells carrying a transgene, higher plants or animals carrying a transgene, organisms for expression of a protein from a transgene and general

[289] Patent Act 1990, Sec.18 (2)
[290] Patent Act 1990, Sec. 18 (3)
[291] Patent Act 1990, Sec.18 (4)

[292] *Patents for biological inventions*, IP Australia (2016) https://www.ipaustralia.gov.au/patents/understanding-patents/types-patents/what-can-be-patented/patents-biological-inventions (last visited Apr 23 2020)

[293] Luigi Palombi, *The Patenting of Biological Materials In The Context of The Agreement on Trade-Related Aspects of Intellectual Property Right,* UNSW 65 (2004)

recombinant DNA methods such as PCR and expression systems can be patented under the Australian patent law.[294] Though biological materials like microorganisms, peptides and organelles are eligible for patent protection, it can only be patented if it has been isolated from its natural environment or has been recombinant produced.[295]

The patent laws were not as flexible as it is today. In Rank Hovis McDougall Ltd.'s Application[296]the Assistant Commissioner for Patents awarded a patent for a new strain of micro-organism that could be used in the production of an edible protein production. The method itself was patentable but the actual micro-organism was denied a patent since it occurred naturally.[297]

The jurisprudence in Australia relating the patenting of biological materials was changed through the landmark judgment in National Research Development Corporation v Commissioner of Patents.[298] The High Court held that the invention claiming patent must achieve an artificial state of affairs with economic utility. Also, the inventiveness should be more than a mere new use of an old substance. This decision has given a very broad and flexible scope for patentable subject matter, maintaining the law with the constant evolving technology.[299]

Australia's stance on gene patentability is primarily based on the decision of the Australian Patent Office in Kirin-Amgen Inc. v Board of Regents of University of Washington[300] in 1995. The APO made it clear that an isolated gene is not a mere discovery but constitutes an 'artificially created state of affairs'. Hence such claims can be patented as they satisfy the requirement of "manner of manufacture" under the patent law.[301] On appeal[302], the Federal Court of Australia upheld the Patent Office's decision

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[294] Id.

[295] Id. at 66

[296] Rank Hovis McDougall Ltd's Application (1976) 46 AOJP 3915

[297] Dianne Nicol, *On the Legality of Gene Patents*, 29(3) Melb ULaw Rw 25 (2005)

[298] National Research Development Corporation v Commissioner of Patents (1959) 102 CLR 25.

[299] Kumar, supra, at 357

[300] Kirin-Amgen Inc. v Board of Regents of University of Washington (1995) 33 IPR 557.

[301] David P Simmons et al., *Gene Patents in Australia: Where Do We Stand?*, 30 Nature Biotechnology 323(2012)

and held that isolated genes and any other biological or genetic material derived from it will not be excluded from the scope of patentability.[303]

As in most countries' debates relating to patenting of biological inventions, genes in particular started gaining momentum. There have been two notable attempts in Australia which tried to ban patentability of isolated genes and gene sequences. The amendment to the Patents Act was rejected in 1990, stating that restrictions on patents will hinder research and development in the area of medicine.[304] Again in 1996, the attempt to amend the Act was postponed so many times that it relapsed without any discussion on the matter.[305]

Again in 2010, the Patent Amendment (Human Genes and Biological Materials) Bill 2010, a private member's Bill was introduced in the Senate. The object of the Bill was to exclude or prevent human genes and other biological materials from the scope of patentability. Because of the ongoing debate, the Australian government decided to appoint a Law Commission to look into the current patent system and to review the position of patents over biological materials which included human and microbial genes and non-coding sequences, proteins and their derivatives, and those materials in isolated forms. The Commission undertook a substantial range of studies into the relationship between gene patenting and human health[306], gene patents[307] and patentable subject-matter in general[308] with a view to evaluate the legal situation on gene patentability and considering a potential restriction on the related provision.[309] The main issue in hand for

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[302] Genetics Institute Inc. v Kirin-Amgen Inc. (1996) 34 IPR 513.

[303] Id.

[304] Dipika Jain, Gene-Patenting and Access to Healthcare: Achieving Precision, 36 Hous. J. Int'l L. 101, 116 (2014).

[305] Id.

[306] ALRC, supra, at 249

[307] *Senate Standing Committee on Community Affairs Inquiry into Gene Patents*, AUSTL. LAW REFORM COMM'N (2009) http://www.alrc.gov.aulsenate-standingcommitteecommunity-affairs-inquiry-gene-patents (last visited Apr 23, 2020)

[308] Patentable Subject matter Final Report, ADVISORY COUNCIL ON INTEL. PROP., (Dec. 2010) http://www.acip.gov.aulpdfs/ACIPFinal-ReportPatentableSubjectMatterArchived.pdf (last visited Apr 23, 2020)

[309] Jain, supra, at 116

the government was to decide whether the current patent system needed any reformation by disallowing patent claims relating to such materials or should it continue to stand as it is.[310]

In 2011, after receiving the recommendations from the Commission reports, the government took a firm stand rejecting the notion of absolute ban on the patenting of genes and other biological materials.[311] Along with stressing on the importance of gene patents in scientific research and the medical industry, the government also attempted to address ethical concerns relating to gene patents. The Government proposed that the legislature shall enact certain ethical exclusions on patents whenever patenting such genes runs against the sentiments and values of society.[312]

Apart from the legislative and administrative bodies, the Australian judiciary also became a part of the debate with its judgment in Cancer Voices Australia v Myriad Genetics Inc.[313] The suit was to decide whether a naturally occurring nucleic acid, either DNA or RNA that has been isolated can claim a valid patent protection. The case centered on the susceptibility gene for breast and ovarian cancer, BRCA1, which was extracted from the human body and thereby deemed an isolated gene. The patent for the isolated BRCA1 gene had been given to Myriad Genetics Inc., a US biotechnology company. The plaintiff challenged Myriad's patent stating that isolated genes are products of nature which could not be patented. Myriad Genetics argued that the process of extracting the gene from the body fulfilled all the requirements under the Patents Act and hence was an invention patentable under the Act.[314] The court had to decide whether the isolated genes constitute an artificial state of affairs. The court stated three factors for their conclusion that such isolated genes (BRCA) constitute an artificial state of affairs for the purpose of gene patenting. First, the court states that the concept of "an artificial state of affairs" should be

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[310] Simmons, supra, at 323

[311] Sally Dalton-Brown, *Healthcare in Australia Gene Patenting and the Dr. Death Issue*, 25 Cambridge Q. Healthcare Ethics 414, 417 (2016).

[312] Jain, supra, at 109

[313] Cancer Voices Australia v Myriad Genetics Inc. [2013] FCA 65

[314] Tarishi Desai, *Cancer Voices Australia v Myriad Genetics Inc.: Reflections on a Patent Controversy*, McCabe Centre for Law and Cancer (2013) https://www.mccabecentre.org/news-and-updates/cancer-voices-australia.html (last visited Apr 23, 2020)

interpreted broadly. Secondly, the nucleic acid extraction cycle (DNA) involves human involvement and does not occur naturally. Third, isolating these genes also involves time-consuming research and effort, and may thus deserve patent protection. On such grounds the court decided that the genes (BRCA) are patentable.[315]

While deciding the case, the Court opined that the whole purpose of intellectual property rights will be defeated if individuals are not rewarded for their intellect and time spent on bringing such genes into isolation.[316] On appeal,[317] the decision was upheld, and it was declared that isolated nucleic acid, be it DNA or RNA, was an eligible subject matter for patentability under the Australian patent laws.[318] On further appeal to the High Court, the court disagreed with the findings of the Federal Court. The essential element of the invention was coding of the information, as observed by the High Court.[319] The information was read as it existed in the human body and there was nothing man- made in it. The Court concluded that the isolated genes were not patent eligible. Additionally, the Court also held that cDNA was unpatentable for the same reasons.[320]

Many people believed that after the decision in Myriad case, all claims relating to methods involving the practical application of genes would be invalidated. But the Federal Court's decision in Meat & Livestock Australia Limited v Cargill, Inc.[321] proved the assumptions wrong. The petitioners in the case argued that the patent claim related to known methods of using naturally occurring markers for gene sequences and bovine traits in cattle.[322] While deciding the case, the Court made a distinction between Myriad case and the present case as the later involved product claim and the later focused on process

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[315] Jain, supra, at 110

[316] Kumar, supra, at 359
[317] D'Arcy v Myriad Genetics Inc. [2014] FCAFC 115.
[318] Kumar, supra, at 359
[319] Whitworth, supra, at 463

[320] Trevor Davies, *High Court unanimously finds isolated genetic material not patentable*, Allens (2015) https://www.allens.com.au/insights-news/insights/2015/10/high-court-unanimously-finds-isolated-genetic-material-not/ (last visited Apr 24, 2020)
[321] Meat & Livestock Australia Limited v Cargill, Inc. [2018] FCA 51

[322] *Australia remains a gene-patent friendly jurisdiction*, Shelston Intellectual Property (2018) https://www.shelstonip.com/news/australia-remains-gene-patent-friendly-jurisdiction/ (last visited Apr 24, 2020)

claim. After considering the complex subject matter in detail, the Court held that the claims were directed to artificial subject matter resulting from human action, rather than something that exists in nature *per se* hence, patentable.[323] The decision provides clarity about the patentability of claims defining practical applications of gene sequences, including genetic screening methods along with the proof that Australia still remains to be patent friendly jurisdiction.[324]

Patents involving genetic material as subject matter have been granted regularly in Australia for a long time. Unless an explicit legislative change or amendment excluding genetic materials from the scope of patentability comes into force, this trend is likely to continue.[325]

UNITED STATES OF AMERICA

In the United States, the Constitution grants power to the Congress to promote art and science by granting the authors and inventors exclusive right over their work.[326] Under this power the Congress has drafted patent laws from time to time. The first legislation with respect to patent law was in 1790. The patent laws underwent a general reform which came into effect on January 1, 1953 which was passed on July 19, 1952. It is codified in the United States Code, Section 35. Furthermore, on 29 November 1999 Congress passed the 1999 American Inventors Protection Act (AIPA), which further revised the patent laws. At present the patent law in the US is governed by the Patent Act (35 U.S. Code) updated in April 2019.[327]

Patent laws in the US were developed to encourage creation and sharing of information. The idea was to promote more and more inventions which in turn would stimulate other

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[323] Dr. Victoria Longshaw et al., *The Doom and Gloom lifts: patentability of Gene Marker-Trait Correlation Methods in Australia* (2020) http://houlihan2.com/the-doom-and-gloom-lifts-patentability-of-gene-marker-trait-correlation-methods-in-australia/ (last visited Apr 24, 2020)

[324] Jain, supra, at 112

[325] Denley, supra, at 2

[326] U.S. CONST. art. 1, § 8, cl. 8- 'To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.

[327] Virginia Alexandria, *General information concerning patents*, UNITED STATES PATENT AND TRADEMARK OFFICE (2015) https://www.uspto.gov/patents-getting-started/general-information-concerning-patents (last visited Apr 24, 2020)

innovations based on that knowledge and benefit the public through dissemination of knowledge. The United States Patent and Trademark Office (USPTO) under the US Department of Commerce grants patents to inventions for a period of 20 years.[328] US patents are territorial in nature i.e., they are effective only within the US territories and US possessions. Extension to patent terms is made under certain special circumstances.[329]

The patent granted to the patent holder by the patent office is to exclude others from '*making, using, offering for sale or selling*' the invention in the US or importing the invention to the US.[330] The right is granted not in respect to make, use, sell or import the invention but to exclude others from doing so. The patentee must enforce the patent without any intervention from the UPSTO once the patent is granted. In US, three types of patents are granted by the UPSTO:

(i) Utility patents,
(ii) Design patents,
(iii) Plant patents.

For a claim to obtain a patent, certain statutory requirements are to be fulfilled as provided in patent laws. They are;[331]

(i) Subject matter eligibility
(ii) Novelty
(iii) Utility
(iv) Non- obviousness
(v) Written description and enablement

Under the US patent law, a patentable subject matter is determined as "*any new or useful process, machine, manufacture, or composition of matter, or any new useful improvement thereof.*"[332] The term invention includes both inventions and discovery under the US

[328] US CONST. 35 U.S.C. § 154 (2)
[329] James Bradshaw, *Gene Patent Policy: Does Issuing Gene Patents Accord with the Purpose of the U.S. Patent System*, 37 Willamette L. Rev. 637 (2001).

[330] US CONST. 35 U.S.C. § 154 (d) (1) (A) (i)
[331] Utility Examination Guidelines, 66 Fed. Reg. 1093 (Jan. 5, 2001).
[332] US CONST. 35 U.S.C. § 101

patents law. To be patentable, the invention must demonstrate utility, novelty and non-obviousness. The invention must be novel to afford patentability. It should not have been available to the general public or used or known to others for more than one year prior to the filing of the patent application.[333] Also, the essential components of the claimed invention should not have been contained in a prior invention. Unlike in other jurisdictions, the US does not require absolute novelty for granting a patent but allows for the information to be disclosed or known within only the one year prior to the filing of an application.[334] Therefore, laws of nature, a natural phenomenon, an abstract principle, etc. is viewed outside the scope of patentability.[335]

An invention is said to have utility when it is of significant use to the public along with being available to them. The utility standard requires to be specific, substantial, and credible.[336] The constitution mandates that patents should only be granted to those inventions coming under the ambit of useful arts. The patent application should contain a written description of the invention along with the manner and process of making or using the invention.[337]

The patent laws in the U.S are more flexible than any other legislation across the world. The U.S Supreme Court itself observed that the broad language used in the Patent Act of 1952, shows the intention of the Congress to "patent anything under the sun made by a man".[338] The UPSTO and the US Courts play a major role in shaping the jurisprudence relating to patents, especially patents on biological inventions.[339] The Court of Appeals for the Federal Circuit was created by the Congress in 1982 to address the subject of patenting and ensure consistency in decisions regarding patent cases. The decisions of both the Circuits and the Supreme Court have been instrumental in shaping the patent

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[333] US CONST. 35 U.S.C. § 102
[334] Pitcher, supra, at 289

[335] Nicholas C. Whitley, *An Examination Of the United States and European Union Patent System With Respect to Genetic Material*, 32 Ariz J Int'l & Comp L 463(2015)
[336] Utility Examination Guidelines, 2001
[337] Srividhya Ragavan, *Patent Judicial Wisdom*, 20 Nt'l L Sch India Rev. 165, 172 (2008)

[338] Diamond v. Chakrabarty, 447 *U.S.* 303 (1980)
[339] Whitworth, supra, at 466

laws regarding biological matters.[340]

Evolution of patent laws in relation to gene patents are better understood through the judicial decisions over the course of time. US courts did not allow patents to biological inventions in the early days. In 1948, when a patent claim came before the Supreme Court for a mixed culture of different strains of bacteria in Funk Brothers Seed Co. v. Kalo Inoculant Co.[341] the court invalidated the patent claim. The Court opined that patents cannot be granted for discovery of any natural phenomenon. Patenting of genes or proteins was seen with suspicion back then because they were not considered to be new, but merely as a part of the living organism. So, in the light of the Funk Brothers case, DNA sequences, proteins or human genome did not come under the scope of patentability in the U.S.[342]

The next major decision relating to gene patenting came in the case Merk & Co. v. Olin Mathieson Chemical Corp.,[343] where a purified vitamin was granted patent. The Court held that just because an element of an invention occurs in nature does not mean that the whole invention is unpatentable. Also, nothing in the prior art could anticipate the new vitamin invented.[344]

Later in 1980, in Diamond v. Chakrabarty[345], the U.S Supreme Court again came across a question relating to biotechnology invention. The patent claim related to a genetically engineered, "oil-digesting bacterium". Initially the developers sought patent under plant patent application stating that their invention did not come under the category of animal and their rights are similar to that of plant breeders' rights. The USPTO rejected their claim stating that bacteria did not come under the Plant Patent Act. When the matter comes before the Supreme Court for appeal, the Court agreed with UPSTO's decision of excluding bacteria from Plant Patent Act. However, the Court also held that the applicant's claim was valid as a live microorganism made with human intervention comes

[340] Pitcher, supra, at 289

[341] Funk Brothers Seed Co. v. Kalo Inoculant Co. 333 U.S. 127 (1948).
[342] Pitcher, supra, at 300.

[343] Merk & Co. v. Olin Mathieson Chemical Corp., 253 F.2d 156 (1958).
[344] Pitcher, supra, at 300

[345] Diamond v. Chakrabarty 447 U.S. 303 (1980).

under the scope of patentability. The developed process and product were different from the ones' already existing.[346] The researcher's product was innovative and valuable and hence eligible for patent protection. This decision opened gates for patent protection to anything that was man- made. Transgenic animals, plants and microorganisms now came under the preview of patentability. According to the decision, gene technical methods including diagnostic methods and treatment are patentable. Although it was very clear that the human body cannot be patented, DNA sequences, cell lines and genes which can be separated from the body may be eligible for patent protection.[347]

The decision in Diamond Case not only impacted the U.S patent laws but also influenced many other countries. After this decision the U.S started investing a huge amount of both public and private funds into genetic and biotechnology research by the 1990s. The goal was to develop a strong biotechnology industry with potential health benefits, economic growth and a knowledge-based economy.[348] Patent applications claiming patents for biological inventions and discoveries soon started piling up. The liberal interpretation of the U.S patent law along with patent harmonizing treaties like TRIPS and NAFTA has a major impact on the international gene patenting.[349]

Another important case came before the Court of Appeals in 1991, which was important in the evolution of laws relating to gene patents. In Amgen, Inc. v. Chugai Pharmaceutical[350], the patent claim related to the genetic sequence of a blood protein. Though the blood proteins' full DNA sequence was disclosed in the patent application, the Court failed to look at the obviousness of the protein itself. Despite it all, the patent was granted to the blood protein. However, two years later, in In re Bell[351], the court took a different view. The following case involved patenting of the DNA sequence of a protein. Unlike in previous cases, much importance was given to the obviousness factor. Even though the Patent Office rejected the claim stating it to be obvious, the Federal

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[346] Ryan M. T. Iwasaka, *From Chakrabarty to Chimeras: The Growing Need for Evolutionary Biology in Patent Law*, 109 Yale LJl, 1505 (2000)

[347] Id.

[348] Johnston, supra, at 13

[349] Siew-Kuan NG, supra, at 23

[350] Amgen, Inc. v. Chugai Pharmaceutical 927 F.2d 1200(1991).

[351] In re Bell 991 F.2d 781 (1993).

Court held that information about a polypeptide sequence and a general method to isolate a gene does not render the corresponding gene sequences obvious. Hence, the patent claim was allowed in this case.[352]

Again in 1995, in In re Deuel[353], a patent claim for an invention related to a protein called heparin-binding growth factor (HBGF), facilitating the repair of damaged tissue came into question. Initially, the claim was rejected by the UPSTO stating it to be obvious. But the Court held that in this case the prior art did not reveal any complementary DNA molecules that were relevant to the invention in question, which made the invention non-obvious. The Court reversed the decision of the Patent Office and granted the patent.[354]

The issue of applying the 'non-obviousness' test was discussed in length when the case, *KSR International Co. v. Teleflex Inc.*[355] came before the Supreme Court. The Court held that the decisions taken by the Federal Circuit were inconsistent with the patent laws and Supreme Court precedents. The Court shed light on the Federal Courts' practice of applying the TSM test i.e., 'teaching, suggestion or motivation' test,[356] which was strictly applied to invalidate the patent claims. The Supreme Court held that TSM test should only be secondary and act as mere helpful insights in each case. The Court also remarked that the lower courts conclusion as to patent claim cannot be proved obvious merely by showing that the combination of elements was obvious to try was wrong.[357] Finally the Court in its judgment held that while determining obviousness of a patent claim, the courts must consider the prior art, the differences between the prior art and the subject matter of the claim, and the level of ordinary skill a person must have in the subject matter of the claim before the TSM test is considered.[358]

Through the KSR case, the Court set up an 'obvious to try' rule which many considered

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[352] Joanne Kwan, *A Nail in the coffin for Gene Patents*, 25 Berkeley Tech LJ. 10 (2010)
[353] In re Deuel 51 F.3d 1552, 1559 (Fed. Cir. 1995)

[354] In re Deuel, Case Briefs https://www.casebriefs.com/blog/ /in-re-deuel/ (last visited Mar 16, 2020)
[355] KSR International Co. v. Teleflex Inc., 127 S.Ct. 1727 (2007)
[356] Graham v. John Deere Co., 383 U.S. 1 (1966)
[357] Alex Harding, *Shedding Light on the Obviousness of Gene Patents*, Jolt Digest (2018) https://jolt.law.harvard.edu/digest/obviousness-gene-patents
[358] Stephen J. Schanz, *KSR International Co. v. Teleflex Inc.: Patentability Clarity or Confusion?*, 6 Nw. J. Tech. & Intell. Prop. 192, 194 (2008).

to be as rigid as the TSM test.[359] Following suit, two years later In re Kubin,[360] the Court held that gene sequence is unpatentable as its cloning was obvious to try with a reasonable expectation of success.[361] Here an invention claiming a patent on the isolation and sequencing of DNA molecules encoding a protein known as the Natural Killer Cell Activation Inducing Ligand was denied by the Patent Office. The Court also affirmed the decision of the Patent Office in rejecting the patent claim.[362] Many thought that application of such stringent standards to test patentability criteria would retard investment in the area of research and development.[363]

Once again, the paradigm shifted when in 1997, the Myriad Genetics was granted the first patent on BRCA1 genes and associated diagnostic tests. The company was granted exclusive right over a functional gene sequence which did not have any substantial human intervention. Myriad Genetics also filed patent applications for the methods of detecting *BRCA1* mutations and the entire sequence of the *BRCA1* gene and tools used in their work. In 1998 they were granted a patent covering the whole gene and all its uses.[364] Similarly, Myriad gained patents for *BRCA2* DNA, mutations, and diagnosis along with a patent over the method of detecting *BRCA2* mutations and antibodies in 1998. This gave Myriad uncontrolled power in the area of diagnostic testing. Both the genes BRCA1 and BRCA2 were essential in detecting ovarian and breast cancer in women.

Soon the UPSTO was over flooded with applications for patenting genes. Many considered gene patents an integral component of a new and flourishing biotechnology industry. The following decision saw a lot of critiques, more than supporters. The patent visibly had a number of negative effects on both research as well as on the patients. Prior to the patent, diagnostic testing involving the patented genes was done either for free or at a low fee at many research institutes. However, the patent owned by Myriad Genetics

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[359] Id. at 196
[360] In re Kubin 561 F.3d 1351, 2009

[361] Kwan, supra, at 330
[362] In re Kubin, Case Briefs https://www.casebriefs.com/ in-re-kubin/ (last visited Mar 16, 2020)
[363] Kwan, supra, at 330
[364] E Richard Gold, "*Myriad Genetics: In the eye of the policy storm.*" 12 Genet Med. 39(2010). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3037261/ (last visited Mar 14, 2020)

made such practices impossible to continue.[365]

For a long time, the US was known for granting exclusive rights to isolated genes. However, the trend soon came to a halt when the validity of the patent granted to Myriad Genetics over BRCA1 and BRCA2 was challenged in 2009 in Association for Molecular Pathology v. Myriad Genetics, Inc.[366] the Court while deciding the case found that the scientists at Myriad have only uncovered the precise location and genetic sequence of BRCA1 and BRCA2. They have not created or altered the genetic information encoded in the genes or the genetic structure. Due to these reasons, the invention claimed will only fall under the law of natural exception. Mere isolation of genes was still considered to be products of nature and their isolation itself could not sufficiently fulfil all the requirements of patentability. The decision by the Court invalidated the patent held by Myriad Genetics over the genes.[367] Nevertheless, the Court ruled that the cDNA claims did not pose the same issues as the formation of a cDNA sequence culminating in an exon-only molecule that did not exist naturally and is, thus, patentable.[368]

Before the judgment in the Myriad case in 2103, another case with a deep influence in the area of gene patenting is Mayo Collaborative Services. v. Prometheus Labs., Inc.,[369] case. The dispute in the case relates to a conflict between the two companies for diagnostic tests concerning the use of thiopurine drugs used in the treatment of autoimmune diseases. The plaintiff was the licensee of the two patents concerned with the use of thiopurine drugs and hence sold diagnostic tests incorporating the patent to the defendant. When the defendant started selling its own diagnostic kit in the market, Prometheus sued them for patent infringement. On analyzing the case, the Court found that the steps involved in the patent claim are not invention but mere application of natural laws. The Court not only invalidated the patent held by the plaintiff but also led down an important principle for future patent claims that patent law should not inhibit future discovery by

[365] Id. at 42
[366] Association for Molecular Pathology v. Myriad Genetics, Inc. 569 U.S. 12-398 (2013).

[367] Kumar, supra, at 360
[368] Whitworth, supra, at 458

[369] Mayo Collaborative Servs. v Prometheus Labs., Inc., 566 U.S. 66 (2012)

"improperly tying up the future use of laws of nature."[370] Through the decision the Court held that, in order to be a patent-eligible subject-matter under § 101, a patent must do more than simply state the rule of its existence with the terms "apply it;" it must also limit the scope of the patent to a specific, inventive application of the law.[371]

After the decisions in Myriad and Mayo, thousands of patent claims relating to isolated DNA as well as diagnostic tests became invalid. However, non–naturally occurring nucleic acids, such as cDNA or synthetic DNAs with man-made variant sequences, are still patent eligible. The recent judgment in Ariosa Diagnostics, Inc. v. Sequenom, Inc.,[372] combines the principles put forth in Myriad and Mayo cases. The claims concerned methods of genetic testing by identifying and amplifying paternally derived fetal cell-free DNA (cffDNA) from maternal blood and plasma. The claim was found to be based on natural phenomenon and so the reasoning in the Mayo case was applied. The patent claims were thus rejected.[373]

The general rule of 'obvious to try' saw some exceptions when it came to emerging and unprecedented technologies.[374] If the standard of obviousness is applied to strictly, then it would be disadvantageous to innovations like gene therapy. Investors will be discouraged from investing new technology even if it has great potential in treatment or products due to the fear of invalid patent claims. Firms invest huge amounts of money in developing novel technology. If their invention is denied patent, then the whole investment is pointless. Slowly investors will stop investing in new technology and innovation will come to a halt.[375] Many believe that low levels of patentability for genetic tools increase research in the genetic sphere but at the same time it would lead to

[370] Whitworth, supra, at 457

[371] Whitworth, supra, at 461

[372] Ariosa Diagnostics, Inc. v. Sequenom, Inc. 788 F.3d 1371 (Fed. Cir. 2015)

[373] Michael J. Flibbert, *Ariosa Diagnostics v. Sequenom Among the Most Important Federal Circuit Decisions from 2015*, Federal Circuit IP Blog (2016) https://www.finnegan.com/en/insights/blogs/federal-circuit-ip/ariosa-diagnostics-v-sequenom-among-the-most-important-federal-circuit-decisions-from-2015.html (last visited Apr 1, 2020)

[374] Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd., *492 F.3d 1350 (Fed. Cir. 2007)*, Ortho-McNeil Pharmaceutical, Inc. v. Mylan Labs., Inc., *520 F.3d 1358 (Fed. Cir. 2008)*

[375] Harding, supra, at 8

commercialization of diagnostic products or treatments.[376]

At present, the eye of the storm in the area of gene patents is the CRISPR-Cas9, which stands for clustered regularly interspaced short palindromic repeats. It is a technology related to genome editing which can potentially change an organism's DNA. The CRISPR technology is considered to be a lot faster, cheaper, accurate and efficient than most other genome editing methods.[377] In the US, the University of California has the largest number of patents over CRISPR-Cas9. CRISPR also holds extraordinary potential as an antiviral therapy according to the latest studies. The development of a gene targeting antiviral agent against the COVID-19 using the PAC-MAN technology is under study. The researchers are trying to explore the molecular mechanism of the novel virus utilizing the CRISPR technology, which would assist in identifying potential drug combinations. [378] Though the potential and application of CRISPR technology is limitless, there still remains uncertainty as to what extent such technologies are regulated. Also, CRISPR has attracted severe criticisms on ethical grounds.[379]

In 2019, the Congress proposed a Bill that is likely to overturn the decisions in Myriad and Mayo cases. The draft Bill has attracted mixed reviews. Some scientific societies and patient advocates have criticized the proposal as it would overturn the earlier decision of barring the patenting of human genes and ease other restrictions on patenting biomedical inventions.[380] However, the biotechnology industry is looking forward to the Bill as the Supreme Court decisions have created confusing and overly stringent patent eligibility rules in its earlier judgments.[381] Given the present scenario, the greatest challenge before the legislators and the Courts is to balance patent protection without paralyzing academic

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[376] Id.

[377] *What are genome editing and CRISPR-Cas9*? NIH US National Library of Medicine (2017) https://ghr.nlm.nih.gov/primer/genomicresearch/genomeediting (last visited Apr 1, 2020)

[378] Dhanusha A Nalawansha et al., *Double-Barreled CRISPR Technology as a Novel Treatment Strategy For COVID-19*, ACS Pharmacol Transl Sci. (2020) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7469881/

[379] F Hirsch, *Ethics assessment in research proposals adopting CRISPR technology*. 29(2) Biochem Med (2019) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6559619/ (last visited Apr 1, 2020)

[380] Kelly Servick, Controversial U.S. bill would lift Supreme Court ban on patenting human genes, Science (Jun. 4, 2019) https://www.sciencemag.org//controversial-us-bill-would-lift-supreme-court-ban-patenting-human-genes (last visited Apr 3, 2020)

[381] Id.

research, provide incentives to the investors for their time and investment and cater the needs of the general public.

EUROPEAN UNION

The International Convention for the Protection of Industrial Property signed in Paris is seen as an international landmark in the area of intellectual property.[382] Following the Paris Convention, many new treaties were entered by nations which tried to give a wide variety of rights to the inventors. In order to harmonize the patent laws, the European States agreed to the Convention on the Unification of Certain Points of Substantive Law on Patents for Invention[383], which ultimately led to the European Patent Convention (EPC) in 1973. EPC[384] is a regional convention which grants patents in Europe called 'Europatents[385]' with the aim to strengthen cooperation between European states in terms of patent protection. The European Patent Office (EPO) is the patent granting authority and it mandates uniform patent eligibility criteria for member States.[386] Europatents are granted for a period of 20 years from the date of application.[387] The Convention requires that national legislation to be brought in line with Europatents. It does not displace individual nation patent regimes but rather exists as an alternative route to obtain patent protection.

Europatents are granted to inventions in every field of technology, if the invention is new,

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[382] Thomas R Nicolai, The European Patent Convention: A Theoretical and Practical Look at International Legislation, 5 (1) The International Lawyer 135 (1971)

[383] Convention on the Unification of Certain Points of Substantive Law on Patents for Invention, signed on Nov 11, 1963, ETS No. 047

[384] Convention on the Grant of European Patents (European Patent Convention) of 5 October 1973 as revised by the Act revising Article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000 [hereinafter referred as EPC].

[385] EPC, Art.2 European patent - (1) Patents granted under this Convention shall be called European patents. (2) The European patent shall, in each of the Contracting States for which it is granted, have the effect of and be subject to the same conditions as a national patent granted by that State, unless this Convention provides otherwise.

[386] EPC, Art. 4 European Patent Organisation (1) A European Patent Organisation, hereinafter referred to as the Organisation, is established by this Convention. It shall have administrative and financial autonomy. (2) The organs of the Organisation shall be: (a) the European Patent Office; (b) the Administrative Council. (3) The task of the Organisation shall be to grant European patents. This shall be carried out by the European Patent Office supervised by the Administrative Council.

[387] EPC, Art. 63

involves an inventive step and is susceptible to industrial application.[388] According to the European Patent Convention, to claim a patent;

(i) The invention should be novel[389],
(ii) Should not be disclosed earlier[390],
(iii) Involve an inventive step[391],
(iv) Should have an industrial application.[392]

An invention is novel if it differs from what is known in the prior art. The relevant date for the determination of the state of the art is the filing date of the European Patent application.[393] The European patent law requires absolute novelty as opposed to the American laws.

Discoveries, mathematical methods, scientific theories, rules or methods for games or business, aesthetic creations, etc. cannot claim patent protection.[394] The convention also lays down a list of subject matter which is explicitly excluded from patentability under Article 53. They are;

(i) Inventions contrary to *ordre public* or morality
(ii) plant or animal varieties or essentially biological processes for the production of plants or animals
(iii) therapeutical, surgical or diagnostic methods or methods of treatment for human or animal body.

However, microbiological processes or their products are not excluded from patentability.[395] For many years, inventions involving biological matters were not granted patented in the European countries stating them to be 'products of nature' and not

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[388] EPC, Art. 52 (1)

[389] EPC, Art. 54
[390] EPC, Art. 55
[391] EPC, Art 56
[392] EPC, Art 57
[393] EPC, Art 54(2)
[394] Id.
[395] EPC, Art 53 (b)

technical. German Court's decision in Red Dove[396] case brought in changes to this long-standing notion. The patent claim related to a method of breeding doves with red feathers. Though the Supreme Court denied the patentability of the invention by declaring that the method of breeding doves having red feathers lacked reproducibility, the Court clearly extended the scope of patentability to inventions involving living things.[397]

One of the major decisions by the EPO relating to the patenting of human genes came through its judgment in the Relaxin[398] case. It was held that relaxin which was isolated from the human gene could not be ignored as a mere discovery. The gene sequence was novel and did not exist in nature. Until the inventor isolated it for the first time, the form of relaxin that it coded for was unknown. Awarding a patent for the protein and the encoding genetic sequences was not contradictory to morals or ethics since patenting a single human gene has little to do with patenting human life.[399]

In the 1980s- 90s disputes arose as to what all inventions can be patented and what cannot be in the field of biotechnology. It was then a need to harmonize laws in all EU States was felt.[400] As a result, on July 6, 1998 the Directive 98/44/EC of the European Parliament and the Council was adopted by the European Union.[401] At present, the patenting of biological materials in the EU States is determined by the European Union Directive 98/44/EC and the EPO Guidelines. The process of adapting to the Directives was quite slow as only four countries- United Kingdom, Finland, Denmark and Ireland put the rule into practice initially. It was much later that other member States followed suit.[402] The Biotech Directive has been incorporated into EPO law through the EPC

[396] Red dove case, BGH, 1 IIC 136 (1970)
[397] Martina Schuster, Patentability and Scope of Protection of Three-Dimensional Protein Structure Claims under German, European and US law, 65 (1st ed. 2010)

[398] Howard Florey Institute's Application/Relaxin (OJ EPO 1995, 388) (V 0008/94).

[399] *Bioethics and Patent law: the Relaxin case*, WIPO (2006) https://www.wipo.int/wipo_magazine/en/2006/02/article_0009.html (last visited Apr 3, 2020)
[400] Schuster, supra at 61

[401] DIRECTIVE 98/44/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 July 1998 on the legal protection of biotechnological inventions July 30, 1998 [hereinafter referred as Directive98/44/EC].

[402] Schuster, supra, at 66

Implementing Regulations which was amended by a decision of the Administrative Council of the European Patent life Organization on June 16, 1999.[403]

In Kingdom of the Netherlands v. European Parliament & Council of the European Union[404], Netherlands, Norway and Italy brought an action for the annulment of the treaty under Article 230 of the EC Treaty. The court found that there existed a lot of differences between relevant provisions in the national legislation and the Directive in a way that tried to harmonize the laws relating to the protection of biotechnological inventions. The member states while deciding to unilaterally grant or refuse a patent to an invention can have adverse effects to the unity of the internal market.[405] While deciding the case, the Court also threw some light to the strict conditions for patentability set out in the Directive. Patent can be granted to the sequence or partial sequence of a human gene only when the patent application has a description of the original method of sequencing which led to the invention and an explanation as to the industrial applicability of the invention. If these two things are not provided in the application, then there is no invention but just mere discovery which is not patentable.[406]

The Directive defines biological material as '*any material containing genetic information and capable of reproducing itself or being reproduced in a biological system*.'[407] Nucleotide sequences, full length genes, complementary DNA (cDNA) and fragments come under this definition. The invention can be patented even if it involves a biological material or any related processes given such an invention is new, involves an inventive step and has some industrial application.[408] The industrial application of the gene sequence or partial sequence should be specifically mentioned in the patent application. Biological material extracted from its natural environment or created through a technical process may be the product of an invention, even if it existed in nature previously.[409]

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[403] EPC Implementing Regulations (n 8), Rule 26(1)
[404] Netherlands v. European Parliament & Council of the European Union, Case 377/98 2001 ECR I- 7079
[405] Case Law, 39 Common Market L. Rev. 1147 (2002)
[406] Id. at 1150

[407] Directive98/44/EC, Art. 2

[408] Directive98/44/EC, Art. 3
[409] Directive98/44/EC, Art. 3(2)

The Directive explicitly excludes plant and animal varieties along with biological processes for their production from patentability.[410] But if the technical feasibility of an invention is not confined to a plant or animal variety, then such inventions can claim patent.[411] Similarly, an invention involving any microbiological process or any other technical process or any of its product is eligible subject matter for patents.[412]

The provisions with respect to biological materials from the human body are a little different. Those inventions constituting mere discovery of the sequence or partial sequence of a gene cannot be patented.[413] The Directive also rules out the scope of patenting on the human body in all its developmental phases.[414] Naturally occurring genetic sequences from a human body can be patented under certain conditions. They are;[415]

(i) biological material isolated from its natural environment
(ii) discovered to exist in nature and its technical effect is known
(iii) biological material produced by means of some technical process like cDNA, genetically engineered proteins etc.

The Directive in Article 6 specifically lists the inventions which cannot be patented. Any invention which is contrary to *ordre public* or morality will be deemed to be unpatentable. Accordingly, the following are unpatentable in EU States;[416]

(i) Process involving cloning of human beings
(ii) Use of human embryos for any commercial or industrial purposes
(iii) Process for modifying the germ line genetic identity of human beings
(iv) Processes to modify the genetic makeup of any animal without any major medical benefit to animals or man or any animal as a result of such processes.

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[410] Directive98/44/EC, Art. 4 (1)
[411] Directive98/44/EC, Art. 4 (2)

[412] Directive98/44/EC, Art. 4 (3)

[413] Directive98/44/EC, Art. 5
[414] EPC Implementing Regulations (n 8), Rule 26(1)
[415]Directive98/44/EC, Art. 6

[416]Directive98/44/EC, Art. 6 (2)

The Directive also provides for a commitment to the significant value of the 'ethical clause,' as it specifies that all ethical dimensions of biotechnology will be viewed in the context of the specific principles of patent law and reviewed explicitly by the Commission's European Group on Ethics in Science and new Technologies.[417]

The European Patent Office relies heavily on the principles laid down in the Directives to decide if an invention should be patentable or not. Though the EPC and the Directives provide for a framework to regulate the patentability criteria, not all EU member States have an identical set of patent rules. Some countries follow a more liberal approach while others are more stringent in granting patents, especially patents over genes.

Germany is one such EU member worth mentioning. German patent laws are governed by both the German Patents Act as well as the directives issued by the EU. The implementation of the Biotech Directive into the national legislation of the German patent law led to a more restrictive legislation than the Directive itself, especially in the context of genes or DNA sequences.[418] The Germans believed that the absolute protection afforded to biotechnological inventions were too extensive. The laws were brought in line with the Directives though a more restrictive protection was given to human DNA sequences. However, in the case of plant and animal DNA sequences no major changes were done.[419]

The recent amendment made to the German patent law in 2017 has brought in changes to the laws relating to the patentability of genes.[420] Patents shall be granted to inventions in every field of technology given they are new, involve an inventive step and are susceptible of industrial application. Patents shall be granted even to those inventions

[417] Directive98/44/EC, Art. 7- The Commission's European Group on Ethics in Science and New Technologies evaluates all ethical aspects of biotechnology.

[418] Christoph Ann, *Patents on Human Gene Sequences in Germany: On Bad Lawmaking and Ways to Deal with It*, 7 German L.J. 279 (2006).

[419] Erin Bryan, *Gene Protection: How Much is too Much - Comparing the Scope of Patent Protection for Gene Sequences between the United States and Germany*, 9 J. High Tech.L. 52 (2009).

[420] Patent Act as published on 16 December 1980 (Federal Law Gazette 1981 I p. 1), as last amended by Article 4 of the Act of 8 October 2017 (Federal Law Gazette I p. 3546).

involving biological materials which are isolated from its natural environment.[421] However, the human body, including germ cells and any discovery of one of its elements still remains unpatentable. An element extracted from the human body or otherwise produced by means of a technical process, including a sequence or partial sequence of a gene, even if the structure of that element is similar to that of a natural element can be patentable.[422]

The German patent law requires the patent application to identify a definite function of the DNA sequence to grant absolute protection, and mandates the applicant to name a definite function for which the patent will be exclusively granted.[423] Such a restricted view was taken to avoid hampering of research into additional uses of DNA sequences and genes.[424] However, these changes are only applicable to the national patents and not to the Europatents granted by the EPO.[425] Similarly, countries like Switzerland being a non-member EU state has adopted the Directive into its patent legislation.

CONCLUSION

The patentability requirements relating to an invention in all three jurisdictions- the US, the European Union and Australia vary, though not greatly. Both the patent laws in the

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[421] The Patent Act, 1980, Sec. 1 (1) Patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application. (2) Patents shall be granted for inventions within the meaning of subsection (1) even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used. Biological material which is isolated from its natural environment or produced by means of a technical process can also be the subject of an invention even if it previously occurred in nature.

[422] The Patent Act, 1980, Sec. 1 (a) - (1) The human body, at the various stages of its formation and development, including germ cells, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions. (2) An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention even if the structure of that element is identical to the structure of a natural element. (3) The industrial application of a sequence or partial sequence of a gene shall be disclosed in the application specifying the function performed by the sequence or partial sequence. (4) If the invention concerns a sequence or partial sequence of a gene whose structure corresponds to that of a natural sequence or partial sequence of a human gene, the patent claim shall include its use for which industrial application is disclosed pursuant to subsection (3).

[423] Id.
[424] Ann, supra, at 281
[425] Jain, supra, at 114

US and Australia had its origin from the European laws. The European Union mainly relies on the EPC and the Directives to determine the patent eligibility of an invention i.e., heavily relies on the text of the legislation. However, unlike in the EU, the US and Australian courts played a major role in shaping the laws relating to patentability. So, it came as no surprise when the EU adopted TRIPS almost verbatim while Australia and the US made advancements in their patent rules through case laws.[426] Because of this reason, the U.S and Australia are more at liberty to change their patentability criteria without causing much disruption to the already existing legislation.[427]

The gene patent regime varies in different jurisdictions. From careful analysis of recent judgments, legislative changes and other policies, divergence in the area of gene patenting has increased like never. Currently in the US, isolated naturally occurring nucleotide sequences along with the methods of using them are not patentable if they are obvious and conventional. However, cDNA sequences still are patentable if they fulfil the patentability criteria.[428] But, in Europe, isolated sequences of naturally occurring nucleotides, equivalent cDNA sequences and methods of their use remain patent eligible.[429] Whereas in Australia, though isolated naturally occurring nucleotide sequences and equivalent cDNA sequences are not eligible for patent protection, methods of using them can claim patent.[430]

The modern biotechnology industry requires consistent and clear patent protection to foster innovation and investment in new products. Nevertheless, this need must be balanced with the ethical dilemmas that accompany the expansion of technology. Such goals would be better fostered by the harmonization of patent-eligible subject matter throughout jurisdictions.[431]

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[426] Whitworth, supra, at 470.

[427] Whitworth, supra, at 470

[428] Dianne Nicol et al., *International Divergence in Gene Patenting*, Annu. Rev. Genom. Hum. Genet. 520, 522 (2019)

[429] Id.

[430] Id.

[431] Whitworth, supra, at 475

CHAPTER 6

CONCLUSION AND SUGGESTIONS

Our interpretation of the idea behind genes started with the realization that genes act to produce protein, during the twentieth century. The concept of genes is continuously evolving. According to the classical view, a gene is an indivisible unit of inheritance, recombination, mutation and function. The neoclassical view of gene concept placed much importance on the structure of DNA.[432] Once the structure of DNA came into light various mechanisms and functions involving genes including gene expression and gene replication were studied. These studies helped in bringing new definitions of genes which was earlier unknown. By the last of the twentieth century with advancement in technology and rapid development in the scientific area, DNA sequencing was introduced which ultimately resulted in the sequencing of human genomes.[433] Genetic engineering, the process of modifying the genetic make-up of an organism, has changed the world we live in. It has touched upon almost every sphere of human life including health, medicine, food and agriculture, environment and energy applications.[434] Now that genes can be easily isolated and analyzed, the concept of genes has become concrete. Paradoxically, at the same time the concept is now more general, open and abstract.[435]

Patent is a form of intellectual property right which gives the patent owner the exclusive rights to make, use or sell the patented invention for a specific period of time. Patentability of genes have often raised many questions and controversies. Most people found it difficult to define gene patents, so the whole idea remains unclear.[436] A gene patent can apply to a sequence of a specific gene, a sequence of DNA, gene sequence

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[432] Petter Portin , *The Concept of the Gene: Short History and Present Status,* 68 The Quarterly Review of Biology, 173, 177 (1993)

[433] Bruce R. Korf, *Basic genetics*, 31 Prim Care Clin Office Pract. 461 (2004) http://www.sld.cu/galerias/pdf/sitios/genetica/genetica_basica.pdf (last visited May 16, 2020)

[434] Khan, supra, at 11

[435] Portin, supra, at 185

[436] Kyle Jensen et al., *Intellectual Property Landscape of the Human Genome,* 310 SCIENCE 239-40 (2005) https://www.researchgate.net/publication/7542356_Intellectual_Property_Landscape_of_the_Human_Genome (last visited May 16, 2020)

utilization, or its chemical composition thereof.[437] The debate over gene patents have been going on for more than two decades now. However, the most important thing to understand is the difference between personal property rights and the rights of a patent holder as people often get confused between the two. A gene patent simply gives rights to a patent holder to make, use and sell the physical molecule rather than violating the idea of an individual's right to his own genes.[438] The patent holder has no right over the dignity of a person's life in any way.[439]

The objections to gene patents are more or less based on social, ethical, moral, religious or legal grounds. One of the major allegations is that it hinders scientific research and development. Critics argue that this patenting mechanism limits development, inhibits scientific collaboration, and frustrates science activities since patenting genes can limit access to inexpensive genetic testing because patent holders can prohibit certain researchers from utilizing their cell line or technique.[440] There is also the risk that patent holders will demand whatever price they want, which amplifies the issue of offering affordable and efficient treatment and diagnostic tools for people with the particular disorder which is the discovery was meant to address.[441] Opponents often oppose the patenting of genes as religiously and morally repugnant as well as contradictory to public policy. Such concerns underline the stance that by converting it into a commodity, we are trivializing human integrity.[442] Validity gene patents are often questioned as it does not fulfil the requirement of alternativeness.[443]

The advocates of gene patents often argue on the ground of social benefit or utilitarian justification. Patenting of genetic sequences, its derivatives and allied methodologies are

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[437] Brian Zadorozny, *The Advent of Gene Patenting: Putting the Great Debate in Perspective*, 13 SMU Sci. & Tech. L. Rev. 89 (2010)
https://scholar.smu.edu/scitech/vol13/iss1/7 (last visited May 16, 2020)

[438] See, U.S CONSTI. 35 U.S.C. § 27 1(a) (2006).

[439] Rebecca S. Eisenberg, *Re-Examining the Role of Patents in Appropriating the Value of the DNA Sequences*, 49 EMORY L.J. 783, 788 (2000).

[440]Byron Williams-Jones, *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing*, 10 HEALTH L. J. 123 (2002)

[441] Zadorozny, supra, at 91

[442] Mark J. Hanson, *Religious Voices in Biotechnology: The Case of Gene Patenting*, 27 The Hastings Center Rep, 1 (1997)

[443] See, Nuno Pires de Carvalho, *The Problem of Gene Patents*, 3 Wash. U. Global Stud. L. Rev. 701 (2004).

believed to benefit the society more than any potential harmful effects.[444] Since research and development are notoriously expensive and time consuming, patents are a tool for the investors to recoup the money they initially invested. The whole purpose of a patent is to reward the time and intellect spent on the invention. Another common argument in favor of gene patents is that it promotes innovation by offering incentives. Through patent protection, individual researchers undertaking works are guaranteed a security and safety blanket.

Gene patents have forwarded a myriad of concerns but it goes without saying that gene patents are now a necessary evil. There is no evidence to show that patenting genes actually inhibits research.[445] Most arguments against gene patents are made due to limited knowledge, in ignorance of patent laws or as a result of negatively publicized news and comments.[446] Today the society has received ample benefits from the research done on the patent protected inventions.[447] Though the benefits of gene patents outweigh its negative does not mean that those arguments should be disregarded completely. Human integrity and values should be safeguarded under all circumstances.[448]

The door towards patentability of genes was opened by the US Court in the land mark judgment of Diamond v. Chakrabarty[449]. Following suit, many jurisdictions including Australia and the UK started granting patents to genes. Since patents are territorial in nature, there is no concept as to a global patent. The criteria for granting patents varies from country to country and patent applications are reviewed based on the laws of the domestic country. To make the divergence between patent laws less complicated TRIPS came into force which TRIPS establishes specific minimum requirements for the protection of intellectual property in Member States' domestic law but does not aim at completely harmonizing the substantive patent laws all across the globe.[450] TRIPS lists out the requirements to be fulfilled to be granted a valid patent along with 20-year term

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[444] Christopher M. Holman, *The Impact of Human Gene Patents on Innovation and Access: a Survey of Human Gene Patent Litigation*, 76 UMKC L. REV. 295, 359-60 (2007)
[445] See, Christopher M. Holman, *Will Gene Patents Derail the Next Generation of Genetic Technologies: A Reassessment of the Evidence Suggests Not*, 80 UMKC L. Rev. 563 (2012).
[446] Zadorozny, supra, at 92
[447] Zadorozny, supra, at 92
[448] Zadorozny, supra, at 94
[449] Diamond v. Chakrabarty, 447 U.S. 303 (1980)
[450]Trade-related aspects of intellectual property rights, World Trade Organization (2018) https://www.wto.org/english/tratop_e/trips_e/trips_e.htm (last visited May 17, 2020)

protection for inventions in all fields of technology. However, in case of patentability of genetic materials, TRIPS remain ambiguous. No specific definition as to genetic material is given in any of the provisions of TRIPS. This lack of clarity creates serious legal conflicts between the Member States as well as the patent holder and their respective governments.[451]

When it comes to patentability of genes, most jurisdictions rely on the courts rather than the legislation itself. Also, countries are often influenced by the decisions taken in foreign jurisdictions. An extensive study on the patent eligibility of genes shows that the US and Australia provide for a broader patent protection regime whereas European Union follows a rather restrictive view. However, some major changes were witnessed in the US patent system once the judgment in Association for Molecular Pathology v. Myriad Genetics, Inc.,[452] was delivered.

At the same time major countries like India and China who have an appropriate patent system in force along with specific guidelines to deal with genetic materials and other biotechnological inventions, have no significant case laws to discuss the patenting criteria of genes. In India the Patent Act, 190 and the Guidelines for the Examination of Biotechnology Application for Patents, 2013 along with the Patent Rules, 2003 governs the laws relating to patents and gives a clear view on what can be patented. 'Right to Health' under Article 21 of the Indian Constitution is often cited in the context of gene patents. Gene patents are often viewed as in violation of the right to health but that does not mean that all gene patents are bad. The violation is dependent on the approach of the patent holder towards the patented invention. To reduce the friction between rewarding the inventor and public benefits, provisions like compulsory licensing and patent pools are proved to be helpful.[453]

Even after four decades of granting patents on living forms, the confusion and debate surrounding it has not stopped yet. Due to varied economic, social and religious cultures it is impossible to give a uniform structure to patent laws all over the globe, especially a subject matter as sensitive as genes. The national governments as well as international bodies can come with alternatives to the patent system or make such policy

[451] Fowler, supra, at 1088

[452] Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013)

[453] Shapiro, supra, at 131

recommendations that would safeguard the rights and interests of the inventor along with keeping in mind the larger public interest.[454]

SUGGESTIONS

The whole rationale behind patenting genes should be dealt in a prudent and vigilant manner. So, some suggestions put forward are;

- There is a need to ensure that there is consistency in granting patents. Many at times it is seen that courts deliver different judgments on similar case laws. Acquiring a patent is a long and expensive process. Once the validity of such patents is questioned in court, it again increases the burden on the patent holder. A consistent pattern is granting in patents can, to an extent prepare the inventor to see what lies ahead of him.
- Though there is no empirical evidence showing that gene patents do not hinder research and development, the possibility of that happening cannot be ignored. Instead of monopolizing genetic research, an incentive alternative mechanism should be implemented which could facilitate further research and encourage academic collaborations.
- TRIPS have tried to bring in a consistency in the patent regime for its Member States by mandating certain minimum standards. However, the Agreement fails to define 'genetic material' as such. A detailed and separate provision regarding patenting of living forms i.e. genes in particular should be added to the Agreement.
- Patenting genes is controversial in nature, especially human genes. In today's world, gene patents have become a necessary evil. So, if patenting of such genes is deemed to be absolutely necessary, it must be stringent with regard to the scope of claims granted. It must be kept in mind that such monopoly does not extend beyond reasonable limits.
- While reviewing a patent application, the Constitution, International Treaties or Agreements, State Legislations etc. should be referred to instead of going deep

[454] Hope Shand, *New Enclosures: Why Civil Society and Governments Need to Look Beyond Life Patenting,* 3 The New Centennial Rev. 187, 196 (2003)

into trivial moral or ethical concerns. In many cases decisions of the Courts in various jurisdictions are quite helpful.

- Public health should be prioritized. Although patent is mostly a commercial venture, gene patents should in no way control the research but rather facilitate more R&D without affecting the availability accessibility and quality of the healthcare system.
- India is emerging as a hub for biotechnology research and commercial market. After the amendments made to the patent law, the number of patent applications has also increased. However, when it comes to gene patents, there is always some confusion in place. It may be advised to appoint a body or panel of subject matter experts since the Controller might not be well versed in the area. Appointing such an expert can reduce the time period required to make a decision and can decrease the number of claims challenging the validity of a patent in court.
- To restrict the abuse of powers in the hand of the patent holder, the provision for compulsory license[455] is quite useful. Application of compulsory license can only be filed after 3 years from the grant of patent. In the context of genetic research where new discoveries are made every day, this time period seems to be too long. A change in the time period for urgent matters or matters relating to public health can be recommended.
- Laws in biotechnology field are mostly evolved through courts. At present India has enough legislations and guidelines to guide the courts. However, unlike in other major countries like the US and UK, India has not witnessed that many cases in the field of gene patents. For now, strict enforcement of the patentability criteria is the need of the hour, and a fair balance should be preserved between the public and private interests, keeping in mind that the development of research and technology should not disrupt the environment we live in.

[455]The Patents Act, 1970, Sec. 84- Compulsory licenses.—(1) At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory license on patent on any of the following grounds, namely: —
(a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or
(b) that the patented invention is not available to the public at a reasonably affordable price, or
(c) that the patented invention is not worked in the territory of India.

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ANNEXURE 1

PLAGIARISM REPORT

Arathy Dissertation Final
By Athira P S

General metrics

77,393	11,886	668	47 min 32 sec	1hr 31 min
Characters	Words	Sentences	Reading time	Speaking time

Score

This text scores better than 71% of all texts checked by Grammarly

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923 Issues left	264 Critical	659 Advanced

Plagiarism

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