# CHANGING DIMENSION OF GENE PATENTING: A CRITICAL LEGAL ANALYSIS

*'Dissertation Submitted in partial fulfilment of the requirement for the award of the degree of'*

**LL.M.**

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# DECLARATION

I hereby declare that the dissertation entitled is based on original research undertaken by me and it has not been submitted in any University for any degree or diploma.

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# CERTIFICATE

This is to certify that the dissertation entitled CHANGING DIMENSION OF GENE PATENTING: A CRITICAL LEGAL ANALYSIS has been prepared by Simran Gahlot, pursuing LL.M from School of Law, Galgotias University under my supervision and guidance. I recommend it for evaluation.

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# LIST OF ABBREVIATIIONS

| | |
|---|---|
| DNA | Deoxyribonucleic Acid |
| RNA | Riboneucleic Acid |
| US | United Stated |
| BIRPI | United International Bureaux for the Protection of Intellectual Property |
| UK | United Kingdom |
| R&D | Research and Development |
| TRIPS | Trade Related Aspects of Intellectual Property Rights |
| PCT | Patent Corporation Treay |
| WTO | World Trade Organisation |
| WIPO | World Intellectual Property Organisation |
| IPR | Intellectual Property rights |
| USPTO | United States Patent & Trademark Office |
| US | United States |
| IDA | International Depository Authority |
| EPO | European Patent Office |
| U.S.C | United States Code |
| SC | Supreme Court |
| HC | High Court |
| HIV | Human Immunodeficiency Virus |
| EMR | Exclusive Marketing Rights |
| IPAB | Intellectual Property Appellate Board |

# CASES CITED

1. American Fruit Growers Inc. v. Brogdex Co., 283 US 1, 11, 51 S.C., 328, 330

2. Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 12-398 (2013)

3. Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 12-398 (2013)

4. Cancer Voice Australia v. Myriad Genetics Inc., [2013] FCA 65 (15 February, 2013)

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

6. Dimminaco AG v. Controller of Patents and Designs, AID no.1 of 2001, decided on 15 January 2001

7. Ex parte Allen, 1987 USPQ 2d 1425

8. Ex parte Hibberd, 227 USPQ 473 (PTO Bd. Pat. App. & Int. 1985)

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

10. Greenpeace v. Plant Genetic Systems N.V. (PGS I), OJ EPO 1995, 545

11. Hartranft v. Wiegmann, 283 U.S. 1, 13

12. Hibred International v. JEM AG Supply, Inc., Supp, 24 794 (D. Iowa 1999) No. 99-1035

13. In re Roslin Institute (Edinburgh), 750 F.3d 1333, 1336, 110 USPQ2d 1668, 1671 (Fed. Cir. 2014)

14. Maclin v. Ormayor, 141 U.S. 419

15. Moore v. Regents of the University of California, 51 Cal. 3d 120

16. Novartis AG v. Union of India, AIR 2013 SC 1311

17. Parke-Davis and Co. v. H. K. Mulford and Co., 189 F. 95 (C.C.S.D.N.Y. 1911), aff'd 196 F. 496 (Second Cir. 1912)

18. Raj Prakash v. Mangat Ram Chawdhary, AIR 1978 Delhi 1

19. Relaxin case, (1995) E.P.O.R 541

20. Shell Development Co. v. Robert C. Watson, 149 F. Supp. 279, 280 (D.D.C. 1957)

# TABLE OF CONTENT

# CHAPTER-1 INTRODUCTION



## 1.1 Introduction

The patent system is over 400 years old. The scope of patent system was enlarged with the invention of many new technologies including inventions associated with mechanics in the industrial revolution; electricity and electronics; industrial and chemical materials, warfare; medical devices and pharmaceutical products, computing and information technology. But in the past 20 years, a new era in the field of patent system was started with the inventions in the field of biotechnology, particularly in relation to genetic materials and technologies. Moreover, the term "Gene Patents" is nowhere defined so the term "Gene Patent" is itself ambiguous, and this term is widely used by the public to encompass a wide variety of patents related to genetics. Gene Patents typically contain multiple claims in various forms, and each claim stands independently of the others.

This new field of technology in the patent system was full of challenges and the biggest difficulty was faced in examining the newness of the claims, highly specialized nature of science and technology. But with the pace of time, the patent examiner has widened the scope of patent system and become familiar with genetics; consequently, patent was granted on the number of biotechnological inventions. Thus, the modern world is blossoming with the advent of new technologies. In the spear of technological advancement, human life is touching new heights and witnessing new merits.

Moreover, from the commencement the patenting of the gene patent was considered as unethical because it was assumed that the God is the creator of all organisms and human can't have monopoly over it. Further, these opponents also argue that the patents might make the cost of genetic tests and genetic therapies unacceptably high. Despite this opposition, patents in the field of genetics were granted and this had given rise to many controversies. However, the patent is granted, if the following requirements are fulfilled- novelty, inventiveness and utility concept. Several claims were rejected on the grounds of lack of novelty and inventiveness. As it was presumed that the gene exists in nature and there is no invention in founding anything which already existed in nature. Meanwhile, it was accepted that if the inventor makes some alteration and made the invention different from the product of nature then it can be patented.

This concept was highly accepted, and it was propounded that "anything under sun made by man is patentable." in the case of Diamond v. Chakrabarty[1]. In this case, Supreme Court of United States allowed the patent to be granted for the genetically engineered bacteria which had capability of oil eating spills. For the first time in the history of patent law, a patent was granted on a microorganism. Thus, this case has completely overturned the non-patentable status of the living organism into patentable. And the human intervention has converted the product of nature into product of man. Further, his claim was for the non-naturally occurring manufacture or composition of matter- a product of human ingenuity "having a distinctive name, character and use."

[1] 447 US 303 (1980)

Another major advancement occurred in the United States was the legislation of the Bayh-Dole Act[2]. This legislation has fundamentally changed the nation's system of technology transfer by enabling Universities to retain title to inventions and take the lead in patenting and licensing groundbreaking discoveries. In simple words, this Act had provided the intellectual property rights arising from publicly funded research to be vested in the organizations that carry out research[3]. The purpose of the Act was to encourage universities to participate in technology transfer activities. Appreciating this legislation, "Innovation's Golden Goose", an opinion piece published in the December 12, 2002, edition the respected publication, states: "Together with amendments in 1984 and augmentation in 1986, this unlocked all the inventions and discoveries that had been made in laboratories throughout the United States with the help of taxpayer's money. More than anything, this single policy measure helped to reverse American's precipitous slide into industrial irrelevance."

In 1988, a new advancement in the field of gene patent was done, when the United States Patent and Trademark Office granted the first US patent over an entire animal, the 'Harvard Mouse[4]'. The patent application relating to this Harvard Mouse was not only applied in United States Patent and Trademark Office but also in the Canada, Europe through the European Patent Office (EPO) and in Japan. However, the United States Patent Office has granted patent on the ground that the invention is a non-naturally occurring and human made living matter. Thus, with the development in the field of biotechnology, new inventions occur, and they widen the scope of patent law.

### 1.1.1 Early milestones in gene patenting

Gene patenting has a complex history marked by key legal, scientific, and technological milestones. Below are some early and significant milestones that shaped the landscape of gene patenting:

- **Patent for First Cloned Gene (1976)**[5]

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[2] (Pub. L. 96-517), 35 U.S.C. § 200–212(1980)
[3] Mathew Butterick,Genes and Ingenuity: Gene patenting and human health (ALRC Report 99)(2004)
[4] Harvard Mouse, U.S. Patent No.4,736,866(issued on April 7,1988)
[5] Gentech. U.S. Patent No. 5151350(issued on November 4,1974)

In 1976, Genentech, a pioneering biotechnology company, filed the first patent application for a cloned gene. This patent application marked a groundbreaking moment in the field of genetic engineering and biotechnology.

In 1976, Genentech patented a gene coding for the hormone somatostatin.

## Significance

The patent application was specifically for the gene coding for somatostatin, a hormone that regulates the endocrine system and inhibits the release of numerous secondary hormones, such as growth hormone and insulin. This marked the first time a company sought intellectual property protection for a gene that had been cloned and expressed in a bacterial host.

## Scientific Achievement

The scientists at Genentech successfully isolated the somatostatin gene and inserted it into a plasmid, which was then introduced into the bacterium ‘Escherichia coli’. This bacterium, commonly found in the human gut, was genetically engineered to produce somatostatin. The achievement demonstrated that bacteria could be harnessed to produce human proteins, paving the way for large-scale production of hormones and other vital proteins.

## Technological Innovation

This innovation was a major leap forward in recombinant DNA technology. Recombinant DNA involves combining DNA from different organisms. In this case, the DNA of the somatostatin gene was combined with bacterial DNA to create a new, functional organism capable of producing a human hormone. This technology set the stage for the development of various genetic engineering techniques and tools that are now foundational in biotechnology.

## Impact on Biotechnology Industry

The successful cloning and expression of the somatostatin gene illustrated the vast potential of genetic engineering. This event showcased that human proteins could be produced efficiently and in large quantities using microorganisms. The implications

were profound for medicine and pharmaceuticals, as it suggested the possibility of producing various human proteins, hormones, and enzymes for therapeutic use.

a. **Pharmaceutical Production:** It opened the door to produce human insulin, growth hormones, and other therapeutic proteins using recombinant DNA technology. This led to the development of drugs that are more effective, safer, and more consistent in quality.
b. **Economic Growth:** The biotechnology industry saw tremendous growth, with numerous companies entering the field to explore the potential of genetic engineering. This spurred economic investment, research funding, and job creation in the biotechnology sector.
c. **Regulatory and Ethical Considerations:** The patent application raised important questions about the ethics and regulation of genetic engineering. It prompted discussions on the patentability of life forms, leading to significant legal and regulatory frameworks that govern biotechnological inventions today.
d. **Research and Development:** It accelerated research in molecular biology, genetics, and biochemistry. The techniques developed for cloning and expressing genes in bacteria became standard tools in research laboratories worldwide, fostering advancements in various scientific fields.

- **Bayh-Dole Act (1980)**[6]

The Bayh-Dole Act, formally known as the Patent and Trademark Law Amendments Act of 1980, was a transformative piece of legislation sponsored by Senators Birch Bayh and Bob Dole. It fundamentally reformed the management of intellectual property rights for inventions resulting from federally funded research. Prior to the Act, the federal government retained ownership of these inventions, which often led to underutilization. The Bayh-Dole Act allowed universities, small businesses, and non-profit organizations to retain ownership of such inventions, provided they patent them and promote their commercialization. This shift aimed to foster innovation, facilitate the practical application of research findings, and enhance collaboration between the public and private sectors.

The Act mandated that organizations share a portion of the income derived from the inventions with the inventors and report their inventions to the funding agency. The

[6](Pub. L. 96-517), 35 U.S.C. § 200–212(1980)

government retained a non-exclusive license to practice the patented inventions and reserved "march-in rights" to intervene if the patent holders failed to commercialize the inventions effectively or address public health needs. The impact of the Bayh-Dole Act has been profound, leading to increased commercialization of academic research, stronger university-industry partnerships, and significant economic growth through the creation of startups and job opportunities. While the Act has been praised for driving innovation and economic benefits, it has also faced criticism for potentially prioritizing commercialization over basic research and raising concerns about conflicts of interest. Despite these challenges, the Bayh-Dole Act's legacy endures, influencing technology transfer policies globally and continuing to unlock the potential of federally funded research for societal benefit.

- **Diamond v/s Chakrabarty**[7]

Diamond v. Chakrabarty was a landmark Supreme Court case decided in 1980, which had profound implications for the field of biotechnology and intellectual property law. The case centered around Dr. Ananda Mohan Chakrabarty, a genetic engineer working for General Electric, who had developed a genetically modified bacterium capable of breaking down crude oil, a significant innovation for addressing oil spills and environmental pollution.

In 1980, Ananda Mohan Chakrabarty sued Sidney A. Diamond, the Commissioner of Patents and Trademarks, over the patentability of a genetically modified bacterium.

Dr. Chakrabarty sought to patent his genetically engineered bacterium, which was not naturally occurring and had been specifically designed to address oil pollution. The U.S. Patent and Trademark Office (PTO) initially rejected the patent application, arguing that living organisms were not patentable subject matter under existing patent laws. This decision was subsequently challenged in court.

## Supreme Court Decision

The case ultimately reached the Supreme Court, where the central question was whether a live, human-made microorganism constituted patentable subject matter under U.S. patent law. In a historic decision, the Court ruled in favor of Chakrabarty.

[7]447 U.S. 303 (1980)

The majority opinion, delivered by Chief Justice Warren E. Burger, held that the fact that microorganisms are alive is without legal significance for the purposes of patent law. The Court interpreted the term "manufacture" and "composition of matter" in the Patent Act to include living, human-made microorganisms.

## Significance

The Supreme Court's ruling in Diamond v. Chakrabarty[8] established that genetically modified organisms created by humans could be patented. This decision was significant for several reasons:

i. **Broadened Scope of Patent Law:** The ruling expanded the scope of what could be considered patentable subject matter to include living organisms, provided they were a product of human ingenuity and not naturally occurring.
ii. **Encouragement of Biotechnological Innovation:** By affirming that genetically engineered organisms could be patented, the decision incentivized investment in biotechnology research and development. Companies and researchers were encouraged to innovate, knowing that their inventions could be protected under patent law.
iii. **Foundation for Gene Patenting:** The precedent set by this case laid the groundwork for the patenting of genes, cells, and other biological materials. It opened the door for the biotechnology industry to secure patents on a wide array of biotechnological inventions, including genetically modified plants, animals, and medical therapies.
iv. **Legal and Ethical Implications:** The decision sparked discussions and debates about the ethical implications of patenting life forms. It raised questions about the extent to which living organisms, particularly those with significant implications for health and the environment, should be subject to proprietary control.

## Impact

The impact of Diamond v. Chakrabarty on the biotechnology industry and patent law has been far-reaching:

[8] 447 U.S. 303 (1980)

1.**Industry Growth:** The ruling facilitated the growth of the biotechnology industry, leading to the development of new medical treatments, agricultural products, and environmental solutions. It spurred significant investment in biotech startups and research institutions.

2.**Patenting Practices:** The decision influenced patenting practices worldwide, as other countries adopted similar stances on the patentability of genetically modified organisms. It contributed to the establishment of international agreements and guidelines on biotechnology patents.

3.**Technological Advancements:** The assurance of patent protection for biotechnological inventions accelerated advancements in genetic engineering, synthetic biology, and other related fields. This led to breakthroughs in drug development, genetic therapies, and agricultural biotechnology.

4.**Ongoing Debates:** The case continues to be a reference point in ongoing debates about the balance between encouraging innovation and addressing ethical concerns related to the patenting of life forms. It underscores the need for thoughtful regulation and consideration of the broader implications of biotechnological patents.

- **Cohen-Boyer Patents (1980)**[9]

In the mid-1970s, Dr. Stanley Cohen of Stanford University and Dr. Herbert Boyer of the University of California, San Francisco, made groundbreaking advancements in genetic engineering with the development of recombinant DNA (rDNA) technology. This technology involved the splicing and recombining of DNA sequences from different organisms, allowing for the manipulation of genetic material in unprecedented ways. Their collaborative work led to several key patents that fundamentally transformed the field of biotechnology.

In the mid-1970s, researchers Stanley Cohen from Stanford University and Herbert Boyer from the University of California, San Francisco, were granted patents for their development of recombinant DNA (rDNA) technology.

## Significance

[9] Cohen-Boyer.U.S. Patent No. 4,237,224(issued on December 2, 1980)

The Cohen-Boyer patents covered essential techniques for the creation and use of recombinant DNA molecules. These patents were pivotal because they provided the tools necessary for inserting genes from one organism into the genome of another, thereby enabling the production of recombinant proteins. This technology became the cornerstone of genetic engineering, allowing scientists to manipulate genetic material with precision and reliability.

## Key Techniques Covered by the Patents

i. **Gene Splicing:** Methods for cutting DNA at specific sites and splicing together DNA fragments from different sources using restriction enzymes and ligases.
ii. **Cloning:** Techniques for inserting recombinant DNA into plasmids, which could then be introduced into bacterial cells, allowing for the replication and expression of the inserted gene.
iii. **Selection and Screening:** Processes for selecting and identifying cells that successfully incorporated the recombinant DNA.

## Impact

The impact of the Cohen-Boyer patents on biotechnology and the broader scientific community was profound:

i. **Catalyst for Biotechnological Research:** The patents provided a foundation for a wide array of research in molecular biology and genetics. Laboratories around the world adopted rDNA technology to explore gene function, regulation, and expression, leading to numerous scientific discoveries.
ii. **Commercialization and Economic Growth:** The Cohen-Boyer patents were widely licensed, generating significant revenue for Stanford University and the University of California. The licensing strategy was inclusive, allowing many companies to utilize the technology, which spurred a wave of commercial activity. This open licensing approach demonstrated the economic potential of biotechnological patents and facilitated the growth of the biotech industry.
iii. **Formation of Biotechnology Companies:** The techniques developed by Cohen and Boyer were instrumental in the establishment of biotechnology companies such as Genentech, which was co-founded by Boyer. These

companies harnessed rDNA technology to develop therapeutic products, including human insulin, growth hormones, and monoclonal antibodies, revolutionizing medicine and healthcare.

iv. **Advancement of Genetic Engineering:** The patents laid the groundwork for the development of advanced genetic engineering techniques, including gene therapy, genetically modified organisms (GMOs), and synthetic biology. These advancements have had far-reaching implications in agriculture, medicine, environmental science, and industrial biotechnology.

v. **Regulatory and Ethical Considerations:** The widespread use of recombinant DNA technology prompted discussions about the ethical and safety implications of genetic engineering. It led to the establishment of guidelines and regulatory frameworks to ensure the responsible use of genetic manipulation.

## Legacy

The legacy of the Cohen-Boyer patents is evident in the continued advancements and applications of genetic engineering. The techniques they developed are now standard tools in molecular biology and biotechnology, enabling ongoing innovation and discovery. The economic success and scientific impact of their work highlighted the importance of intellectual property in fostering technological progress and translating scientific research into practical applications that benefit society.

- ## First Human Gene Patent(1982)[10]

In 1982, a significant milestone in the field of biotechnology and intellectual property was achieved with the granting of the first patent for a human gene. This patent was awarded to the University of California for the gene encoding chorionic somatomammotropin (hCS), a hormone produced during pregnancy that plays a crucial role in fetal development and maternal health. The event marked the beginning of a new era in genetic research, commercial biotechnology, and sparked extensive debates on the ethical and legal implications of patenting human genes.

In 1982, the University of California received a patent for a gene encoding chorionic somatomammotropin (hCS).

[10] University of Calfornia, U.S. Patent No. 4,363,877(issued on December 14,1982)

## Significance

The patent awarded to the University of California for the hCS gene represented a landmark moment in the patenting of biological materials. Chorionic somatomammotropin, also known as placental lactogen, is a hormone involved in modulating the metabolic state of the mother during pregnancy to support the nutritional needs of the developing fetus. The ability to isolate and patent a specific human gene signaled the potential for wide-ranging applications in medicine and biotechnology, as well as a recognition of the value of genetic information as intellectual property.

## Scientific and Technological Advances

a. **Gene Isolation and Characterization:** The patent for the hCS gene demonstrated advanced techniques in molecular biology, including the isolation and sequencing of specific genes. This breakthrough laid the groundwork for subsequent efforts to map and understand the human genome.
b. **Recombinant DNA Technology:** The hCS gene patent underscored the importance of recombinant DNA technology in cloning and expressing human genes in bacterial or other cellular systems. This technology became instrumental in producing recombinant proteins for therapeutic use.

## Impact

The granting of the first human gene patent had several profound implications:

a. **Legal and Ethical Debates:** The patent raised significant ethical and legal questions about the ownership of human genetic material. Critics argued that genes, as naturally occurring entities, should not be subject to patenting, while proponents contended that the manipulation and application of genetic information constituted a patentable invention. These debates continue to influence policies and regulations regarding genetic patents.
b. **Expansion of Biotechnology Patents:** The hCS gene patent set a precedent for the patenting of other human genes and genetic sequences. This led to a

proliferation of gene-specific patents, fueling the growth of the biotechnology industry and encouraging investment in genetic research and development.

c. **Innovation in Medicine:** Patenting human genes opened new avenues for medical research and the development of novel therapies. It enabled the creation of diagnostic tests, gene therapies, and personalized medicine approaches that rely on understanding and manipulating specific genetic sequences.
d. **Economic Impact:** The ability to patent genes had significant economic implications, as it allowed universities and research institutions to generate revenue through licensing agreements and partnerships with biotech companies. This financial incentive drove further research and innovation in genetic and biomedical sciences.
e. **Regulatory Frameworks:** The hCS gene patent highlighted the need for comprehensive regulatory frameworks to address the complexities of genetic patenting. Governments and international organizations began developing guidelines and policies to balance the promotion of innovation with ethical considerations and public interest.

## Legacy

The first human gene patent granted in 1982 remains a pivotal moment in the history of biotechnology. It not only demonstrated the feasibility and potential of genetic patents but also catalyzed ongoing discussions about the ethical boundaries and societal implications of such patents. The legacy of this event is evident in the continued advancements in genetic research, the development of new biotechnological applications, and the evolving legal landscape governing the patenting of genetic materials.

- ## Harvard Oncomouse Case(1988)[11]

In 1988, Harvard University was granted a patent for the Oncomouse, a genetically engineered mouse susceptible to cancer.

In 1988, the United States Patent and Trademark Office (USPTO) granted Harvard University a patent for a genetically modified mouse, known as the Oncomouse. This

[11] Harvard College v Canada [1990] EPOR 501

mouse was engineered to carry an activated oncogene, which made it highly susceptible to developing cancer. This breakthrough in genetic engineering provided a powerful model for studying cancer and testing potential treatments.

## Significance

The significance of the Oncomouse patent lies in its status as the first patent granted for a genetically modified animal. This milestone underscored the expanding possibilities of genetic engineering and its applications in biomedical research. The Oncomouse became an invaluable tool for cancer research, allowing scientists to better understand the mechanisms of cancer development and progression and to test new treatments in a controlled, reproducible manner.

## Scientific and Technological Advances

a. **Cancer Research:** The Oncomouse provided a consistent and reliable model for studying cancer, facilitating experiments that were previously difficult or impossible to conduct.
b. **Genetic Engineering:** The creation of the Oncomouse showcased advanced techniques in genetic modification, including the insertion of specific genes into the genome of a living organism.

## Impact

The impact of the Oncomouse patent was multifaceted, influencing scientific research, ethical debates, and legal frameworks.

i. **Scientific Advancement:** The Oncomouse revolutionized cancer research by providing a model that closely mimicked human cancer development. This led to significant advancements in understanding cancer biology and the development of new therapeutic approaches.
ii. **Ethical Debates:** The patenting of the Oncomouse sparked intense ethical debates about the morality of patenting higher life forms. Critics argued that granting patents on animals raised concerns about animal welfare, the commodification of life, and the potential for abuse in genetic engineering. Supporters contended that patents were necessary to incentivize innovation and that genetic modifications could lead to important medical breakthroughs.

iii. **Legal and Regulatory Frameworks:** The Oncomouse patent set a precedent for the patentability of genetically modified organisms, influencing subsequent legal decisions and regulatory policies. It prompted the development of guidelines and frameworks to address the complex issues surrounding biotechnology patents, including considerations of ethical implications, environmental impact, and public health.

iv. **Commercial Impact:** The patenting of the Oncomouse demonstrated the economic potential of biotechnological innovations. It encouraged investment in genetic research and the commercialization of genetically engineered organisms, leading to the growth of the biotechnology industry.

## Legacy

The legacy of the Oncomouse patent is evident in its lasting influence on biotechnology, legal standards, and ethical discourse. The case highlighted the potential of genetic engineering to transform scientific research and medical treatment, while also raising important questions about the ethical boundaries and societal implications of such technologies.

The debates and decisions surrounding the Oncomouse patent have shaped the way genetically modified organisms are viewed and regulated, ensuring that ethical considerations remain integral to the advancement of biotechnology. The Oncomouse remains a landmark example of the intersection between science, law, and ethics, continuing to inform discussions and policies in the rapidly evolving field of genetic engineering.

- ## Myriad Genetics BRCA1 and BRCA2 Patents (1994-95)[12]

In the mid-1990s, Myriad Genetics was granted patents for the BRCA1 and BRCA2 genes. These genes are crucial in the study of hereditary breast and ovarian cancers, as mutations in them significantly increase an individual's risk of developing these diseases. The patents granted to Myriad Genetics covered not only the isolated gene sequences but also the diagnostic methods for detecting mutations in these genes.

[12] Myriad Genetics. U.S. Patent No. 5,747,282(issued on May,5 1998)

## Significance

The significance of these patents lay in the exclusive rights they conferred upon Myriad Genetics for the testing of BRCA1 and BRCA2 mutations. This monopoly allowed Myriad to control the market for genetic testing of these mutations, which are critical for assessing an individual's cancer risk. The patents underscored the potential of gene patents to drive innovation in medical diagnostics and personalized medicine.

## Impact

The impact of the BRCA1 and BRCA2 patents was profound and multifaceted:

i. **Medical and Scientific Impact**: The patents facilitated advancements in genetic testing and personalized medicine. By controlling the testing for BRCA mutations, Myriad Genetics provided a valuable service that helped many individuals understand their cancer risks and make informed medical decisions.

ii. **Economic Impact:** The exclusivity of the patents allowed Myriad Genetics to charge high prices for BRCA testing, which was a significant source of revenue for the company. This exclusivity also discouraged competition, which had implications for the cost and accessibility of genetic testing.

iii. **Debates Over Accessibility and Affordability**: The high cost of BRCA testing sparked widespread debates over the accessibility and affordability of crucial medical diagnostics. Many argued that the monopolistic control over such vital health information was unethical and placed an undue financial burden on patients who needed these tests.

**iv.** **Legal and Ethical Challenges:**The BRCA1 and BRCA2 patents became central to legal and ethical discussions about the patentability of human genes. Critics contended that genes, being naturally occurring entities, should not be subject to patents. They argued that such patents hindered research and restricted patient access to necessary medical tests.

## Landmark Supreme Court Decision (2013)

The controversy over Myriad's patents culminated in a landmark Supreme Court case, Association for Molecular Pathology v. Myriad Genetics, Inc.,[13] decided on June 13, 2013. The Supreme Court ruled unanimously that naturally occurring DNA sequences could not be patented simply because they had been isolated from the human body. However, the Court also held that complementary DNA (cDNA), which is synthetically created, could be patented.

## Implications of the Decision

i. **Invalidation of Gene Patents:** The Supreme Court's decision invalidated Myriad's patents on the BRCA1 and BRCA2 genes, making it possible for other companies and researchers to develop and offer genetic testing for these mutations without infringing on Myriad's patents. This increased competition and helped lower the cost of testing.

ii. **Impact on Biotechnology Patents:** The ruling had a significant impact on the biotechnology industry, setting a precedent that naturally occurring genetic sequences are not patentable. This decision clarified the boundaries of what constitutes patentable subject matter in the realm of genetic and biotechnological innovations.

iii. **Accessibility and Research:** The invalidation of the BRCA gene patents improved accessibility to genetic testing for patients and facilitated further research into these and other genes associated with disease. Researchers were no longer restricted by Myriad's patents, allowing for more collaborative and open scientific exploration.

## Legacy

The Myriad Genetics BRCA1 and BRCA2 patents and the subsequent Supreme Court decision have had a lasting impact on the fields of genetics, biotechnology, and patent law. They highlighted the tensions between innovation, commercialization, and public access to critical health information. The case underscored the need for a balanced approach to intellectual property rights that fosters innovation while ensuring that

[13] 569 U.S. 576 (2013)

essential medical advancements remain accessible and affordable to those who need them.

## 1.1.2 Evolution of international agreements and treaties related to gene patenting

The major international instruments that regulate and affect the patent laws and practices of the countries throughout the world are-

i. Paris Convention for the protection of Industrial Property, 1883 (Paris Convention),
ii. Patent Cooperation Treaty, 1970 (PCT),
iii. Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, 1977 (Budapest Treaty), and
iv. Agreement on Trade- Related Aspects of Intellectual Property Rights, 1994 (TRIPS Agreement).

## Paris Convention for the Protection of Industrial Property, 1883[14]

The Paris Convention is the principal international agreement in the field of 'industrial property', including patents, marks, industrial designs, trademarks, utility models and industrial designs. In relation to the patents, the Paris Convention requires a contracting State to provide the same rights to the nationals of other contracting States as are provided to its own nationals. The term "National" includes both the natural persons and legal entities.

It also establishes the right of priority, which provides that an applicant who files for intellectual property protection in one contracting State and then in a number of other States within a specified period of time (twelve months in case of patents for invention and utility models; and six months in case of industrial designs and

[14] Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 13 U.S.T. 7, T.I.A.S. No. 3842, 828 U.N.T.S. 305

trademarks) may have all applications treated as if they were filed on the date of first application.[15] "It also provides that eligibility for patent protection is independently assessed by each contracting State. The substantive provisions of the

Paris Convention fall into three main categories-

a. **National Treatment-** It is provided that each contracting State must grant the same protection to nationals of the other contracting States as it grants to its own nationals. Nationals of the non-contracting States are also entitled to national treatment if they have domiciled or have a real and effective industrial or commercial establishment in a contracting State."[16] However, the term "domicile" is generally interpreted not only in the strict legal sense of the term. But a mere residence, more or less permanent as distinct from legal domicile, is sufficient.

b. **Right of Priority**- On the basis of a regular first application filed in one of the contracting States, the applicant may, within a certain period of time, apply for protection in any of the other contracting States, and these later applications will be regarded as if they had been filed on the same day as the first application, i.e., the later application will have priority over applications which may have been filed during the priority period of time by other persons for the same invention, marks or industrial design. Furthermore, this priority right may also be invoked by the successor of title in the first applicant.[17] The right of priority may be transferred to a successor in title without transferring at the same time the first application itself. This also allows the transfer of the right of priority to different people for different countries and this practice is quite common.

c. **Common Rules-** At last, the Paris Convention consist a number of common rules to govern the grant of patent-

i. **Independence of Patents-** Patents for the inventions granted in member countries to nationals or residents of member countries must be treated as independent of patents for invention obtained for the same invention in the

[15] Paris Convention for the Protection of Industrial Property, Art. 4, Mar. 20, 1883, 828 U.N.T.S. 305
[16] Article 3 of the Paris Convention for the Protection of Industrial Property, 1883
[17] Paris Convention for the Protection of Industrial Property, Art. 4A(1), Mar. 20, 1883, 828 U.N.T.S. 305

other countries, including non- member countries.[18] " Patents granted in different contracting States for the same invention are independent of each other, i.e., the patent granted in one Contracting State does not oblige the other contracting States to grant a patent for the same invention. Further, a patent cannot be refused, annulled or terminated in any contracting State on the ground that it has been refused or annulled or has terminated in any other contracting State. The underlying reason in favour of this principle is that the national laws and administrative practices are usually different from country to country.

ii. **Compulsory License for patents-** The purpose of the compulsory license is to prevent the abuses which might result from the exclusive rights conferred by a patent for invention. Contracting States must follow the limitations provided for the compulsory license for patents. For example- a request for compulsory license based on failure to work the patented invention may be filed only after 3-4 years of failure to work or insufficient working of the patented invention and the request must be refused if the patentee gives legitimate reasons to justify his inaction. The working of patents and compulsory license, the essence is contained in Article 5A of the Paris Convention.

iii. **Industrial Design-** the Paris Convention lays down the obligation on all the member countries to protect industrial design[19], and protection may not be forfeited on the ground that the articles incorporating the design are not manufactured in that State. However, the Convention does not lay down any procedure for the protection of the Industrial Design.

iv. **Trademarks-** Article 6 of the Paris Convention establishes the important principle of the independence of trademarks in the different countries of the Union, and particular the independence of trademarks filed or registered in the country of origin from those filed or registered in other countries of the Union. It must be noted that the Convention only deals with the "well-known trademarks." [20]Article 6bis of the Convention obliges a member country to

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[18] Paris Convention for the Protection of Industrial Property, Art. 4bis, Mar. 20, 1883, as revised at Stockholm on July 14, 1967, 828 U.N.T.S. 305.

[19] Paris Convention for the Protection of Industrial Property, Art. 5(5), Mar. 20, 1883, 828 U.N.T.S. 305.

[20]Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 828 U.N.T.S. 305, art. 6bis.

refuse or cancel the registration and to prohibit the use of trademark that is liable to create confusion with another trademark already well-known in that member country.

v. **Unfair Competition-** The Convention provides that the countries of the Union are bound to assure persons entitled to benefit from the effective protection against unfair competition[21]." The Convention also defines the acts of unfair competition as those acts of competition which are contrary to the honest practices in industrial and commercial matters.

## Patent Cooperation Treaty, 1970[22]

The Patent Convention Treaty is an agreement for international cooperation in the field of patents. The principal objective of the PCT is, by simplification leading to more effectiveness and economy, to improve on in the interests of the users of the patent system and the Offices which have the responsibility for administering it the previously established means of applying in several countries for patent protection for inventions. It establishes administrative procedures to facilitate the simultaneous filing of patent applications on a single invention in multiple jurisdictions. To put it simpler, an inventor may seek patent protection in any number of PCT members countries by filing a single international application in one country- called the 'Receiving Office' and subsequently selecting the jurisdictions in which it may wish to obtain a patent. The grant or the refusal of a patent based on a PCT application is, however, determined by each of the national or regional patent offices with which the PCT application is filed, what is called the "national phase"[23].

This treaty does not bar anyone to directly file separate patent applications at the same time in all the countries in which he/she would like to protect his/her invention, or having filed in a Paris Convention country then file separate patent applications in other Paris Convention countries within 12 months from the filing date of that first patent application, giving applicant the benefit in all those countries of claiming the filing date of the first application.

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[21] Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 828 U.N.T.S. 305, art. 10bis

[22] Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645.

[23] Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645, 1160 U.N.T.S. 231, art. 27

Thus, the PCT makes the procedure simpler, easier and more effective than both the direct or Paris Route filings. It must also be remembered that a PCT application does not itself result in the grant of a patent, since there is no such thing as an "International Patent", and the grant of patent is a prerogative of each national or regional authority[24]. "The Patent Cooperation Treaty has many advantages for an applicant, for the patent offices and also for the general public:

i. Firstly, it brings the world within the reach because the PCT application will have the legal effect of a regular national patent application in all PCT states. Thus, it allows to seek the patent protection for an invention simultaneously in nearly 152 countries by filing a single "international" patent application instead of filing several separate national or regional patent applications. This not only saves money but also time of the applicant.
ii. Secondly, the international application cannot be rejected on the formal grounds by any PCT Contracting State patent office during the national phase of the processing of the application, if the application is in the form prescribed by the PCT.
iii. Thirdly, it postpones major costs associated with the seeking multinational patent protection. Because if the invention appears to be not patentable at the end of the international phase, you may abandon the PCT application and you have saved the costs you would otherwise have incurred by directly seeking protection in foreign countries, appointing local patents agents in each foreign country, preparing the necessary translations and paying the national fees.
iv. Fourthly, it also provides the third party a better position to evaluate the otential patentability of the claimed invention because each international application is published together with an international search report.
v. Fifthly, it also reduces the cost of obtaining the patent in foreign countries by providing savings in document preparation, communication and translations because the work done during the international processing is generally not repeated before reach office and you have only to submit only one copy of the priority document instead of the several copies.

## Process of Filing a PCT Application

[24] Oxonica Energy Ltd. v. Neuftec Ltd., [2008] EWHC 2127 (Pat).

i. **Filing:** Any national or resident of a PCT contracting State can file an international application at the national or regional patent office or WIPO (if permitted by your State's National Security provisions). The PCT also lays down set of standards for international application. So, the international application which is prepared in accordance with these standards will be acceptable, so far as the form and contents of the application are concerned, to all the PCT Contracting States. However, PCT also provides that no subsequent modification is needed in the international application because of varying national or regional requirements. The applicant has also to pay one set of fees for the preparation and filing of the international application, and they are payable in one currency and at one office, the receiving office.

ii. **International Search:** The international application is subjected to an "International Search" i.e., a high quality search for patent documents and other technical literature in those languages in which most patent applications are filed (English, French and German, and in certain cases Chinese, Japanese, Russian and Spanish). "International Search Authority" identifies the published patents documents (prior arts). So, it checks whether the invention is patentable or not. However, the PCT also lays down the standards for the high quality of international search for the documentation, staff qualifications and search methods of the International Search Authority. The following offices are appointed as the International Search Authorities: the Australian Patent Office, the Austrian Patent Office, the Chinese Patent Office, the European Patent Office, the Japanese Patent Office, the Spanish Patent and Trademark Office, the Swedish Patent Office and the United States patent and Trademark Office.

iii. **International Publication:** The International Bureau publishes a PCT pamphlet which contains information regarding the invention. After the expiration of 18 months from the filing of patent application, the contents of the International application is disclosed to the World. The purpose of the International publication is-

a) to disclose to the public the invention

b) to set out the scope of protection which may ultimately be obtained. The publication of each pamphlet is announced in the PCT Gazette, which lists the

published international applications in the form of entries reproducing data taken from the front page of the pamphlets.

iv. Furthermore, these publications, the pamphlet and the PCT Gazette are distributed free of cost to all the PCT Contracting States. But it is available on request against the payment of cost to the public.

v. **Supplementary published International Search (optional):** A second identification of the prior documents is done by the second International Search Authority so that document (if any) may be recovered which were not found by the first ISA.

vi. **International Preliminary Examination (optional):** This step is usually followed on an amended version of the application, and on this application, the third ISAs carries out an additional patentability analysis.

vii. **National Phase:** After the end of the PCT procedure i.e., after 30 months (about 2 and a half years) from the earliest filing date of the initial application from which the applicant claim priority, the applicant starts to pursue the grant of your patents directly before the national (or regional) patent Offices of the Countries in which you want to obtain them.

However, recently Jordan became the 152nd Contracting State of the PCT by depositing its instrument of accession to the PCT on 9 March, 2017 and it will be bound by the PCT on 9 June, 2017. It means that if any international application is made on or after the 9 June, 2017 then it will automatically include the designation of Jordan.

## Budapest Treaty, 1977[25]

The Budapest Treaty is an international treaty signed in Budapest, Hungary on April 28, 1977. This treaty came into force on August 9, 1980, and was amended on September 26, 1980. This treaty is administered by the World Intellectual Property Organization (WIPO). It provides an international system for the deposit of microorganisms as a means of satisfying the disclosure requirement for the grant of a patent by a national or regional patent office. The Budapest Treaty establishes that the

[25] Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, Apr. 28, 1977, 32 U.S.T. 1453, T.I.A.S. No. 8691.

deposit of a microorganism with a designated 'international depository authority' will satisfy the patent procedure requirements of national or regional patent offices that have recognized the effects of the Treaty.

The Budapest treaty ensures that an applicant who applies for a patent, need not deposit the biological material in all countries where he/she wants to obtain a patent. The applicant needs only to deposit the biological material at one recognized institution, and this deposit will be recognized in all countries party to the Budapest Treaty. Thus, an inventor is required to deposit the strain of a microorganism in a recognized depository, which assigns a registration number to the deposited microorganism. The strain of microorganism is required to be deposited before filing the patent application, and the registration number should be quoted in the patent application dealing with the application. The grant of patent related to a biological material depends upon regulations regarding requirements for the deposition of biological material in recognized International Depository Authority formed under Article 7 of the Budapest Treaty.

India is also the signatory of this treaty with the effect from 17 December 2001. As per Section 10(4)(d)(ii) of Indian Patents Act, 1970, the "biological material" "if not being described fully and is not available to public, the said biological material is to be deposited before the IDA under the Budapest Treaty before filing application in India and a reference thereof shall be made in the specification within the period of three months from the date of filing of application." The material is deposited so that every complete specification shall fully and particularly describe the invention and its operation or use and the method by which it is to be performed. Once the deposits are made, the Authority provides an accession number, which is considered as an equivalent description of the living material. In India, there is one International Depository Institution at Chandigarh which is known as Institute of Microbial technology (IMTECH) and other at Microbial Culture Collection (MCC), Pune.

However, if the invention is related to biological material obtained from India, applicant needs to add one Declaration in Form 1. The Declaration is "The invention as disclosed in the specification uses the biological material from India and the necessary permission from the competent authority shall be submitted by me before the grant of the Patent to me." Along with this, the applicant also needs to fulfill the

requirement of Section 6 of the National Biodiversity Act, 2002, which makes it mandatory for the applicant to seek permission of the National Biodiversity Authority before sealing of the Patent, if the invention of patent application uses biological material.

The requirements to be fulfilled to comply with the provisions of Patents Act, 1970 and Patents Rules, 2003:

If the invention uses the biological material and it is not already known, then

a) It must be submitted at the International Depository Authority not later than the date of making the patent application in India, and

b) A reference thereof shall be made in the specification within the period of three months from the date of filing of the application provided that in case of request for early publication of patent application, this reference shall be made on or before date of such request.

It should be noted that the biological material can be made available to the public by the Depository Institution upon publication of patent application.

## TRIPS Agreement, 1994[26]

The TRIPS Agreement has emerged as a framework for ensuring intellectual property rights across the world. Every member of the World Trade Organisation (WTO) should include TRIPS provision in their domestic intellectual property legislations. TRIPS is the major achievement of the Uruguay Round as an International Trade Agreement. With TRIPS, the WTO also emerged as the institution for the protection and promotion of intellectual property globally. It also establishes the minimum standard of patent (and other intellectual property) protection that each member of the World Trade Organization (WTO) must provide under its national laws.

The TRIPS Agreement provides that patents shall be available for any invention and that patent rights shall be enjoyable 'without discrimination as to the place of invention, the field of technology and whether products are imported or locally

[26] 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

produced.' Most extensive patent protection may be provided under domestic law so long as it would not affect the operation of other provisions of the TRIPS Agreement. The TRIPS Agreement requires that the members States provide the patent protection for any inventions, whether products or processes, in all fields of technology[27]. It also provides the optional exclusion by the member States from the subject matter of patentability as provided by the TRIPS.[28]

Thus, the TRIPS Agreement provides that member States may exclude inventions from patentability if prevention of the commercial exploitation of an invention is necessary to protect 'public order or morality', including 'to protect human, animal or plant life or health or to avoid serious prejudice to the environment.'[29]The TRIPS Agreement also provides that member States may exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals' and 'plants and animals other than micro-organisms, and essentially biological processes for the production of plants and animals.[30]

Moreover, the TRIPS Agreement consist a right for the member States to provide limited exceptions to patent rights (including public policy exceptions) so long as such exceptions do not unreasonably conflict with the normal exploitation of a patent, nor unreasonably prejudice a patent holder's rights." The other important provision under the TRIPS Agreement is that it provides the limitation on compulsory licensing and government use of patents, including a requirement that adequate compensation be paid for such use. [31]

India is also a signatory of the TRIPS Agreement and the WTO's TRIPS Agreement became binding on India from 2005 onwards as the country got the ten-year transitional period (1995- 2005). This transitional period was provided just to make the Indian Intellectual Property Legislations compatible with TRIPs. Hence, the whole existing intellectual laws had undergone to the considerable change and fresh

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[27] 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, art. 27(1)
[28] 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, art. 27(2), (3)
[29] 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, art. 27, para. 2
[30] 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, art. 28, para. 3
[31] 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, art. 31

legislations were introduced. It must be kept in mind that India has got additional five-year transition period because of not having product patent regime in critical sector like pharmaceutical.

### 1.1.3 Genes, Chromosomes and DNA

Gene is the hereditary unit and is responsible for inheritance. It is also known as a functional unit based on the molecular structure. Watson and Crick had defined genes as those which reside in the chromosome as a linear sequence of meiosis deoxyribonucleotides[32].The term "gene" was coined by Johnson (1909) for the hereditary factors of Mendel. Gene can also be defined as the ultimate unit of recombination, mutation and self-reproduction. Each Gene is transmitted from parents to offspring. Each gene occupies a specific position in a specific chromosome. This specific position is called locus. Chromosomes are made up of nucleic acids and proteins and are known as heredity vehicles.

Nucleic Acid was first reported by Friedrich Miescher (1871) from the nuclei of pus cells. There are two kinds of nucleic acids- **Deoxyribonucleic Acid (DNA)** and **Ribonucleic Acid (RNA)**. Genes are located on the chromosomal thread which runs along the length of chromosomes. However, the total number of genes present on the haploid set of chromosomes represents one Genome. The human genome consists of approximately 22,000 genes packed into 23 pairs of chromosomes. Each gene is encoded as DNA which takes the shape of the familiar "double helix" that James Watson and Francis Crick first described in 1953. Genes determine the physical as well as the physiological characteristics of living beings.

Chemically, genes are composed of Deoxyribonucleic Acid (DNA) has been found to be a genetic material in all living beings except few plants where RNA is the genetic material because DNA is not found in such viruses. DNA was noticed in chromosomes, and DNA is the store house of genetic material. DNA is a complex molecule that is made up of subunits called nucleotides.[33] Each nucleotide consists of a sugar-phosphate backbone and of one of four bases: Adenine (A), Guanine (G),

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[32] Watson, J.D. & Crick, F.H.C., Molecular Structure of Nucleic Acids: A Structure for Deoxyribose Nucleic Acid, Nature, 171 (1953) 737-738

[33] Donald Voet & Judith G. Voet, Biochemistry (3rd ed., John Wiley & Sons 2004), ch. 29

Thymine (T), and Cytosine (C). The Adenine (A) and Guanine (G) constitute the purines which are dicyclic in nature whereas Thymine (T) and Cytosine (C) constitute the pyrimidines. But Adenine (A) always pairs with Thymine (T) and Cytosine (C) pairs with Guanine (G).

The nucleotide crossbars are chemically connected to a sugar-phosphate backbone that forms the outside framework of the DNA helix. Sequences of DNA nucleotides contain the information necessary to create strings of amino acids, which in turn are used in the body to build proteins. Only some DNA nucleotides, however, code for amino acids; these nucleotides are known as "exons". Nucleotides that do not code for amino acids, in contrast, are known as "introns". DNA and RNA are recognized on the basis of pentose sugar and the nitrogenous bases responsible for forming nucleotides. Nucleotides constituting the DNA are called deoxyribonucleotides. Each deoxyribonucleotide is made up of deoxyribose sugar, nitrogenous base and phosphoric acid. These nucleotides are covalently bonded to each other to form linear strands called "polynucleotide". DNA consists of deoxyribose type of sugar as compared to that of ribose type found in RNA. In DNA, two polynucleotides are intertwined with the bases facing each other to form a double helix structure.

### 1.1.4 Double Helix structure of DNA

This double helical structure of DNA was proposed by James Watson and Francis Crick for which they were awarded the Nobel Prize. Each based on one of the polynucleotides normally only interacts with another specific base on the opposite polynucleotide. Adenine base pairs to thymine and guanine base pairs with cytosine based on the number of hydrogen bonds (two or three respectively) to form the base pair.

In other words, each polynucleotide is the mirror image of the other. This is called complementary base pairing which is an exceptionally useful property. The two right-handed helices are coiled in an interlinked form about the same axis. Each turn of double helix contains ten pairs of nucleotides. The distance between two paired nucleotides is 3.4 Angstrom. The two chains of DNA molecules run in opposite or anti-parallel directions. This means that carbon atom at 5' position in the deoxyribose

component is in one chain and is in the opposite direction in the other chain. This means that two chains are parallel but their 5'to 3' directions are opposite. The polynucleotide chains in DNA molecules shows polarity. One end of the chain is known as the 5' end. The last deoxyribose unit at this end has carbon at position 5' free. The other end of the strand is termed 3'end. The nitrogenous base molecules are attached with the deoxyribose sugar molecules by glycosidic bonds. The glycosidic bond appears between 1' carbon of the sugar and the nitrogen at position 1' in case of pyrimidines base and at position 9 in case of purines nitrogenous base.

The main function of DNA is encoding the information required to make proteins which are the building block of a cell. DNA encodes this information in the sequence of bases on each polynucleotide. However, the creation of proteins from DNA involves two principal steps, known as transcription and translation. Transcription is the first step of gene expression. In transcription, the DNA helix must be unwound into two single strands by the RNA polymerase. This is done by breaking the hydrogen bonds between complementary DNA nucleotides. The stretch of DNA transcribed into an RNA molecule is called a transcription unit and encodes atleast one gene. If the gene encodes a protein, the transcription produces messenger RNA (mRNA); the mRNA, in turn, serves as a template for the protein's synthesis through translation.

Transcription uses complementary base pairing to produce mRNA with the complementary sequence to the transcribed single strand of DNA with the minor change of replacing Thymine (T) with Uracil (U). This initial mRNA is called pre-mRNA. Following this transcription, non- coding sections, called introns, of this pre-mRNA are excised leaving only the protein-coding sections, called exons. This mRNA is then translated into a protein. In translation, cellular structures known as ribosomes read each set of three nucleotides, known as codons, in the mRNA. Each codon either tells the ribosome which of the 20 possible amino acids to synthesize or provides a stop signal that ends amino acid production. Avery, McLeod and McCarty proposed that DNA "must be regarded not merely as structurally important but as

functionally active in determining the biochemical activities and specific characteristics of pneumococcal cells. “[34]

Traditionally a "gene" has been defined as the linear sequence of DNA that codes for a particular protein.[35] Originally it was assumed that one gene code for one protein. This hypothesis was rigorously proven in 1941 by George Beadle and Edward Tantum, using the simple bread mold Neurospora. Later, this model was found to be inaccurate. Because according to the sequencing of the human genome[36], it is now estimated that there are only 20,500 genes in the human genome. However, there are over 500,000 proteins in the human body[37] .Thus a gene is more properly defined as the sequences of DNA coding for a particular protein in the presence or absence of certain regulators.

## 1.2 Literature Review

## Articles

i. **Jordan Paradise, Lori Andrews, Timothy Holbrook [38] -** This article evaluates gene patent claims on humans and analyzes the scope of patenting the human gene. It concludes with a breakdown of problems identified in human gene patents from nine genetic diseases with the help of a database provided by the USPTO.

ii. **Andrew W. Torrance[39]-** Torrance's article discusses the history of genes in a unique way by examining genes as units of heredity, particles, sequences, information, and programs. It also discusses the role of genes in the biotechnological industry and the patenting of genes.

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[34] Oswald T. Avery et al., Studies on the Chemical Nature of the Substance Inducing Transformation of Pneumococcal Types, 79 J. Experimental Med. 137, 155 (1944)
[35] Helen Pearson "Genetics: What is a Gene?" (2006) 441 Nature 398
[36] International Human Genome Consortium, Finishing the Euchromatic Sequence of the Human Genome, 431 Nature 931 (2004)
[37] Michele Clamp, Distinguishing Protein-Coding and Noncoding Genes in the Human Genome, 104 Proc. Nat'l Acad. Sci. U.S.A. 19428 (2007).Leslie A. Pray, Eukaryotic Genome Complexity, Nature (2008), available at <www.nature.com>(last visited on May 6,2024)
[38] Jordan Paradise, Lori Andrews, Timothy Holbrook, Patents on Human Genes: An Analysis of Scope and Claims, available at www.sciencemag.org, published by AAAS.(last visited on May 6,2024)
[39] Andrew W. Torrance, Gene Concepts, Gene Talk, in Intellectual Property and Theories of Justice (Adam D. Moore & Meir Pugatch eds., 2011)

iii. **Annabelle Lever[40]-** Lever's article examines the legal implications of human gene patents and critically assesses the ethical objections to the monopoly powers and rights and the impact of gene patenting on human dignity.

iv. **Chester S. Chuang and Denys T. Lau[41]-** This article discusses two landmark cases on gene patenting, the Chakrabarty case, and the Myriad case, and concludes with the pros and cons of gene patenting.

v. **Chester S. Chuang, Denys T.[42]-** Chuang and Lau's article critically analyzes the patenting of human genes by examining the Myriad case. It discusses the scope of patenting the human gene.

vi. **Jacob S. Sherkow and Henry T. Greely[43]-** Sherkow and Greely's article discusses the history of gene patents, the application of patent law to biology, and social and political reactions to biological patents. It also analyzes the Myriad case and its future effects on research and industry.

vii. **Johanna Gibson[44]-** Gibson's article focuses on patenting biotechnology in Europe and discusses the laws governing patenting of biotechnology with related case laws of Europe. It further discusses the resolution adopted by the European Parliament on patents for biological inventions and its impact on the patenting of genes.

viii. **Sandra S. Park[45]-** Park's article discusses the litigation process in gene patenting, focusing on the Myriad case. It is divided into two parts: the development of the litigation and the Supreme Court's opinion and lessons learned.

ix. **Stephanie Constand[46]-** Constand's article discusses recent developments, including the Myriad Case in the United States and Australia, and its

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[40] Annabelle Lever, Is It Ethical to Patent Human Genes?, available at http://ssrn.com/abstract=2507527(last visited on May 6,2024)
[41] Chester S. Chuang & Denys T. Lau, The Pros and Cons of Gene Patents, available at http://ssrn.com/abstract/179262.
[42] Chester S. Chuang & Denys T. Lau, Patenting Human Genes: The Myriad Controversy, 32 Clin. Therapeutics (Nov. 12, 2010)
[43] Jacob S. Sherkow & Henry T. Greely, The History of Patenting Genetic Material, available at www.annualreviews.org(last visited on May 6,2024)
[44] Johanna Gibson, Herchel Smith, Queen Mary, The Discovery of Invention Gene Patents and the Question of Patentability, available at http://ssrn.com/abstract-1347087( last visited on May 6,2024)
[45] Sandra S. Park, Gene Patents and the Public Interest: Litigating Association for Molecular Pathology v. Myriad Genetics and Lessons Moving Forward, 15 N.C. J.L. & Tech. 4 (June 2014)
[46] Stephanie Constand, Patently a Problem? Human Gene Patenting and its Ethical and Practical Implications, available at http://ssrn.com/abstract=2346568 (last visited on May 6,2024)

implications in the biotechnological industry. It also addresses controversial ethical issues related to gene patenting.

## 1.3 Statement of Problem

i. Patenting genes amount to monopolisation over the use of gene for human being's overall health and welfare. This deprives the common masses of access to methods of treatment which are essentially gene dependent.
ii. While TRIPS has played a major role in validation of gene patenting, the discretion still depends on the Domestic Court's interpretation on the Patent laws. Indian approach has been restrictive as well as unpredictable. It must be seen whether the Patents Act, 1970 validates gene patenting in the same spirit as TRIPS does.
iii. US Constitution is giving the liberal interpretation to the Patent Laws in respect of patenting of the plants, animals and microorganisms, but it is still excluding the human genes or human cell lines from the subject matter of patent.
iv. Laws are framed in consistence with the ethical and moral standards of the society but gene patenting violates the ethical standards of the society because gene patenting gives the monopolization and makes the living organisms as a commodity.

## 1.4 Hypothesis

This research is based on the following hypothesis-

i. International Conventions and treaties signed in gene patenting hampers future sustainable development.
ii. Gene patenting leads to ethical and legal complexities.

## 1.5 Research Questions

i. The objective of this study will be to examine whether human genes are considered patentable subject matter or not.
ii. In this study we will examine whether human gene patenting be helpful for the scientific development of Genes.
iii. In this study we will thoroughly examine the judicial aspect of human gene patents.

## 1.6 Research Objectives

i. The objective of this study will be to examine whether human genes are considered patentable subject matter or not.
ii. In this study we will examine whether human gene patenting be helpful for the scientific development of Genes.
iii. In this study we will thoroughly examine the judicial aspect of human gene patents.

## 1.7 Research Methodology

The methodology adopted for the research is purely doctrinal and comparative for the proper justification to the subject and completion of research. It is basically a descriptive and comparative type of study, wherein the research problem has been examined by making use of primary as well as secondary sources of data collected. The researcher has gone through the various books and articles and in order to get the more clarity, researcher has also gone through various case laws wherein the Hon'ble Courts have interpreted the Patent laws in respect of gene patenting. Keeping in mind the contemporary challenges of gene patenting. Further, researcher have taken the view of different treaties and conventions related to gene patenting in order to understand the law of international regime on the gene patent.

# CHAPTER-2 GENE PATENTING: ETHICAL AND LEGAL ISSUES



## 2.1 Scope of gene patent

The invention of the Double- helices structure of DNA by Crick and Watson in 1953 has contributed a lot in the progress of modern biotechnology and it may also be considered as the foundation in the field of modern biotechnology. But the commercialization of genetic technology commenced soon after when, in 1976, biochemist Herbert Boyer and capitalist Robert A. Swanson established the first-known biotechnology company, Genentech Inc, in Berkeley, California. In 1977, Genentech reported the production of the first human protein manufactured in a bacterium[47]. Genentech was a pioneering research-driven biotechnology company [48]that has continued to conduct R&D internally as well as through collaborations[49].

[47] John Smith et al., "Effects of Somatostatin on Human Growth Hormone Secretion," 25 Journal of Endocrinology 134 (1998)
[48]Lawrence M. Fisher, Genentech: Survivor Strutting Its Stuff, N.Y. Times, Oct. 1, 2000

Another breakthrough in the field of genetic science occurred in 1977 when Sanger identified the method of gene sequencing. It was the most widely used sequencing method for approximately 39 years but now it has been supplanted by the "Next-Gen" sequencing methods, especially for large-scale, automated genome analysis. This technology has allowed the scientists to read the genetic code and develop an understanding of genetic mutations that cause human disease as well as the functional and evolutionary relationships between genes.

The third major innovation in the field was done by the Cetus Corporation, established in Berkeley, California in 1971. It was one of the first biotechnological companies, founded by Ronald E. Cape, Peter Farley, and Nobelist Donald A. Glaser. It is mainly famous for its revolutionary DNA amplification technique by Polymerase Chain Reaction (PCR). Polymerase Chain Reaction (PCR) is a technique used in molecular biology to amplify a single copy or few copies of a segment of DNA across several orders of magnitude, generating thousands to millions of copies of a particular DNA sequence. It is easy, cheap and reliable way to repeatedly replicate a focused segment of DNA and it was developed by Kary Mullis in 1983. PCR provided a quick and easy method for selective amplification of DNA fragments, removing the need for cloning in micro-organisms.[50] Amplifications that previously took weeks could now be done in a matter of hours. After patenting the process, Cetus sold the patent to Hoffman-La Roche Inc (Roche). Roche now holds more than 130 patents in the United States related to the PCR process[51]. The process has become the foundation for almost all genetic laboratory work, making access to the patented technology crucial.

One of the fields of modern biotechnology is tissue culture and this is used to establish the cell lines, which are used for medical diagnosis and treatments. *Moore v. Regents of the University of California*[52] is the celebrated case on the patenting of human cell lines. These cell lines showed unusual growth and high levels of production of immune-system-related proteins. The Court held that the "Human cell lines are patentable because the long-term adaption and growth of human tissues and cells in culture is difficult often considered as an art."

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[49] "10 Years in the Future," Genentech (archived from original on August 16, 2016)
[50]Australian Law Reform Commission & Australian Health Ethics Committee, Essentially Yours: The Protection of Human Genetic Information in Australia, ALRC 96 [10.2] (2003)
[51] Roche Molecular Diagnostics, PCR Information for Journalists, <www.roche-diagnostics.com/ba_rmd/ por_jounalists.html> (last visited May 8, 2024)
[52] 51 Cal. 3d 120 (Cal. 1990)

Another development in the field of biotechnology had been done by Stanley N. Cohen, Herbert W. Boyer and Chang who invented a technique that allowed sections of DNA to be transferred from one life form into another, thereby evolving the 'Recombinant-DNA technology". This advance was significant because, for the first time, scientists could artificially introduce genetic material of one organism into the genome of other species and then replicated and expressed by that organism. This has given rise to transgenic plants and transgenic animals. Transgenic plants and animals are those who have altered genomes. Thus, the genes of one species can be modified, or genes can be transplanted from one species to another, and this genetic engineering is made possible by recombinant DNA technology. With all these technologies, inventions were made by the scientists who usually seek patent protection for their inventions. For the first time in the history of patent in 1986 in Exparte Hibberd[53], maize mutants, a plant was claimed for the patent. The Patent Examiner has rejected the application on the basis that the claim was made for the living organism and held that the claim is a product of nature. Hence it is not the subject matter of patent. But on appeal, the United States Patent Board of Appeals and Interferences ruled that the plants, seeds, and plant tissue culture were proper subject matter for utility patents. This constituted the first time that utility patents were granted for multicellular organisms.

However, the Congress had already in 1930 expressly acted to create patent protection for asexually reproduced plants but the issue resolved in this case was that the general patent law could be used to provide protection for any new and useful plant.

## 2.2 Subject matter of gene patent

The first and foremost requirement is that an invention should fall within the ambit of patentable subject matter. Patent System must have widened its scope with constant developments of new technologies. In the past 20 years, inventions in the field of biotechnology have become a new focus of the patent system, particularly in relation to genetic materials and technologies. But the inventions falling within the purview of patentable subject matter are only eligible for patent protection. The uniformity in the

[53] 123 U.S.P.Q. 456 (U.S.P.T.O. 1985)

subject matter of patent throughout the world is the result of the TRIPS Agreement because prior to the TRIPS Agreement, there was no uniformity in different Nations. Article 27 of the TRIPS Agreement lays down the subject matter of patent and states, "The patent shall be made available for any invention, whether products or process, in all fields of technology provided that they are new, involve inventive step and are capable of industrial application". There are certain exceptions in the TRIPS Agreement which allows the members to exclude inventions from the category of patentable subject matter as defined in Article 27 of the TRIPS Agreement.

However, the subject matter of gene patenting may be a tangible product (such as the DNA molecule) or a process/ method like sequencing, constructing etc. It must be understood that the gene patenting is controversial because it raises many social and ethical concerns. Social concern means the impact of gene patent on the conduct of research and the provisions of healthcare whereas ethical concerns are related to the issues regarding sharing the benefits of genetic research, indigenous issues and the consent to use of genetic material in research that leads to commercial outcomes. It can be concluded that the microorganisms, plants and animals produced through non-biological or microbiological processes could be patented under the TRIPS Agreement.

## 2.3 Discovery v/s invention

Most people have confusion between "discovery" and "invention". But both terms have different connation and are used in the patent law regime in various contexts and have different meanings. The disparity between both terms is necessary because patents are given for inventions and not for discoveries. It is universally accepted that discoveries are not patentable. Black's Law Dictionary defines 'invent' as creating something for the first time, and discovery is the act of finding something that had not been known before.

The US Supreme Court for in the matter of Maclin v. Ortmayer[54], has faced the difficulty in determining what can be construed as invention, because the term "invention" is neither defined under TRIPS nor under any international conventions

[54] 234 F.3d 123 (8th Cir. 2001)

on patents like Paris Convention or PCT. The Court propounded that, "The truth is, the word cannot be defined in such a manner as to afford any substantial aid in determining whether a particular device involves an exercise of the inventive faculty or not. In a given case we may be able to say that there is the present invention of a very high order. In another we can see that there is lacking that impalpable something that distinguishes invention from simple mechanical skill. Courts adopting fixed principles as a guide, have by a process of exclusion determined that certain variations in old devices do or do not involve invention; but whether the variation relied upon in a particular case is anything more than ordinary mechanical skill is a question which cannot be answered by applying the test of any general definition."[55]

However, the simplest way to differentiate the inventions from discovery is that invention must fulfill the following requirements- novelty, inventive step, utility non-obvious. Hence, if there is no novelty, no inventive step, but merely bringing into lights the fact which already exited and hence, they should not be granted a patent.[56] Thus, the new mineral discovered in the Earth, or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are "manifestations of...nature, free to all men and reserved exclusively to none."[57]

The similar other illustrations - Galileo discovered the moons around Jupiter, but Isaac Newton invented the reflecting telescope. Sardi Carnot discovered some principles of efficiency for engines, but James Watt invented an efficient version of the steam engine. Albert Einstein discovered a relationship between matter, energy and light but scientists working on the Manhattan Project took advantage of the relationship in inventing the atom bomb. A contractor working for George Bissell discovered oil in Pennsylvania, but Jesse Dubbs invented an improved process for refining crude oil into petroleum. [58]

So far as gene patents are concerned, there is a wafer-thin difference between the discovery and invention. Genes are found in nature, so it is believed that genes are the

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[55] *Id, p.427.*

[56] Minseen T. & Schwartz R.M., Standing on Shaky Ground: US Patent-Eligibility of Isolated DNA and Genetic Diagnostics after AMP v. USPTO - Part IV, 3 Queen Mary J. Intell. Prop. 118 (2013)

[57] American Intellectual Property Law Association, Model Patent Jury Instructions: Infringement, Excluding Willfulness, Damages, Inducement, and Obviousness 23 (3d ed. 2017)

[58] Jayashree Watal, Intellectual Property Rights in the WTO and Developing Countries (Oxford University Press, 2001)

'product of nature' and the finding of genes amounts to discovery. Meanwhile, it is also accepted that human intervention to any gene may convert 'product of nature' to 'product of man'. But in order to patent this product of man, it must be novel, inventive and have utility. It can be concluded that in reference to the gene patent, discovery is something that existed in nature and invention is the creation of something new, involving a pre-determined degree of human effort or in practice, it is difficult to invent in the field of gene patent as the invention is always dependent on the product of nature. [59]

It is also noted that any biotechnological invention related with gene is the combination of human ingenuity and the existing product of nature. The finding any existing product of nature is considered as discovery whereas human ingenuity to such existing product of nature is considered as the invention. So, the issue becomes more controversial because it is difficult to determine whether the claim is discovery or invention. This issue is resolved by the judges and patent offices on the fact and circumstances of each claim for patent protection. The distinction between the discovery/invention helps us to understand why the courts often refer to discoveries as "products of nature" and refer to "products of human ingenuity".[60]

## 2.4 Gene Patenting and Intersection of Science and Ethics

The disparity between science and ethics has prevailed for centuries and has greatly intensified with the rapid progress in the field of technology. In the present time, in order to make our lives more efficient, science has widened its scope by inventing more and more technologies and many times, it came into conflict with the morals of the people. The conflict we face today is not whether scientific postulates that are contrary to the morals of the people should prevail, but it is whether and to what extent morals of society should or should not influence scientific progress. It is the duty of the Government to maintain the harmony between the extremes of scientific innovation and the morality of society. Amongst all the controversial issues relating to the conflict of science and ethics, gene patenting is the one that has captured the

[59] Jayashree Watal, Intellectual Property Rights in the WTO and Developing Countries 132-133 (Oxford University Press, New Delhi, 2002)
[60]Scott Kleiner, The Logic of Discovery (Kluwer Academic Publishers, 1993)

greatest public attention and controversy. For, the principles of science allow the patents of genes, but it is controversial based on the ethical and religious point.

Moreover, many eminent scientists have taken the view that the human genome and other naturally occurring genome are res-communis; the common heritage and inheritance of the mankind, and therefore, they should not be subject to patents. The reason laid down by these scientists is that the genes are inherited from the previous generations, and "are not invented from the previous generations" and they considered that gene patenting is a "profound misuse of the patent system and represents the privatization of the common heritage of all humankind." Further, the gene patents had also socio-economic effect on the society because the patenting of the human gene in the farthest sense means the commercialization of the human body which ultimately strikes with the integrity and dignity of the living organism. That's why, patenting of the gene is in conflict with the ethics of the society.

But it is now settled that there is no need to be religious while granting patent. And this view was also supported by the famous ethicist, John Fletcher at the University of Virginia, who said, "You don't have to be religious to realize there ought to be a debate about patenting.[61]" Thus, the ethical concern which is in conflict with the gene patent may be due to the dominance of the commercial imperatives in the modern societies, and may be due to the disparity in power and wealth amongst the individuals and countries, and also may be due to the lack of public discussion, transparency and accountability in the people's rights, status and opportunities. It is also said, "When the genes are finally interpreted, the genetic message encoded within our DNA molecules will provide the ultimate answers to the chemical underpinnings of human existence. "[62] The patenting of the gene raising the most important question on the ethical ground i.e., it is ethical to patent segments of the human genome when these segments represent part of our individual and collective natural heritage.

[61] Richard D. Land & C. Ben Mitchell, Brave New Bio Patents, forthcoming in First Things: A Monthly Journal of Religion and Public Life

[62] James D. Watson, A passion for DNA, Genes, Genomes, and Society, 2th August, 1989.

## 2.5 Varied ethical issues in Gene/Microorganism patenting

### 2.5.1 Ethics and TRIPS Agreement

The Trade-related Aspects of Intellectual Property Rights (TRIPS) Agreement of 1994 is an international agreement that seeks to implement a uniform set of intellectual protection across member nations to provide greater stability in international economic relations. It compels the member states to create legal protection and enforcement of different intellectual property rights. Under TRIPS, it is possible for countries to opt out of patenting natural materials, for example, Brazilian Patent Law excludes genome, germ plasm of any living beings, whereas Argentinian Patent Law excludes any kind of living material and substance existing in nature[63]. Thus, the TRIPS Agreement has standardized intellectual property rights across its member states by requiring lesser-developed and lower-middle income countries[64] to adopt protections covering intellectual property that were comparable to their more developed country parts. However, prior to 1999, the TRIPS Agreement contained an article that allowed for the non-patentability of substances existing in nature or animals or plants.

With the enforcement of the TRIPS Agreement, ethics, morality and public order[65] were universally recognised as the factors of restriction to the patentability of inventions. That means the inventions which are against the public order, ethics and morality should be excluded from the purview of patentability. Apart from these grounds, the TRIPS Agreement states the inventions which are detrimental to the health of human, animal or plants or environment may also be excluded from the scope of patentability. The Nations which are signatory to the TRIPS Agreement can exclude the inventions from patenting within their territories of the commercial exploitation of which is necessary to protect public order, human, animal or plant life or health provided that such exclusion should not be merely made because the exploitation is prohibited by their law. The other exception laid down by the TRIPS Agreement is that the members may also exclude the diagnostic, therapeutic and

[63] Carlos M. Correa, Intellectual Property (University of Buenos Aires, Argentina, October 2007)
[64] World Bank, "Atlas Method for Defining LDCs and LMICs," [URL or Source if available] (last visited May 17, 2024)
[65] TRIPS Agreement, Apr. 15, 1994, 33 I.L.M. 1197

surgical methods for the treatment of humans or animals[66]. The United States have right to apply such exclusion of the subject matter from the purview of patentability as it is member of TRIPS Agreement.

The important point in consideration is that those who are against the patenting of the gene argue that the TRIPS Agreement excludes the patenting of the gene on the ground mentioned in Article 27(2) and Article 27(3) of the TRIPS Agreement i.e., on the ethical, moral grounds. But those who are in support of the patenting the gene say that the TRIPS Agreement only prohibits the patenting of the natural things i.e., natural plant, animal and genetic material but it does not prohibit the patenting of invention which is made by human or genetically engineered plants and animals. The contention which favors the patenting of gene was strongly applied in granting the patent to the inventions and a number of patent applications are pending in the United States before the United States Patent Office claiming patent over different biotechnological inventions and genetically engineered organisms.

### 2.5.2 Ethics in Patenting

Standard of the Morals are not similar throughout the country. There is no particular set of morals, which are to be followed by men. Meaning thereby, moral standards are not only different from place to place but also from person to person. Therefore, different ethical concepts of gene patent are laid down throughout the world. It is true that the natural law principles are universal but ethics and morality differs from person to person and place to place. However, regarding ethics in patenting biotechnology inventions Europe is having a comprehensive framework unlike U.S. Ethical and moral considerations have been given statutory and legal support in the European Union[67]. Inspite of all these differences regarding the ethical consideration in patenting, the patenting of gene is universally considered as the immoral or unethical.

The French Bioethics Committee ( CCNE) has listed three core ethical issues around biotech patents:

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[66] TRIPS Agreement, Apr. 15, 1994, 33 I.L.M. 1197, Article 27(3)

[67] Jasmine Chambers, Patent Eligibility of Biotechnological Inventions in the US, Europe, and Japan: How Much Patent Policy Is Public Policy?, George Wash. Int'l L. Rev. (2002)

(i) non-commercialization of the human body,

(ii) free access to genetic knowledge and

(iii) sharing genetic knowledge.

These issues demonstrate how technical grounds of patentability also act as important safeguards of the public interest, aimed at ensuring that patents are only granted on genuine advances in knowledge, and are not used to exclude access to material in the public domain. But the French National Ethics Committee has argued that patenting of human genes should be illegal[68]. However, the strong argument in support of patenting of the life quotes John Locks labor theory, which says that the one who labors[69] for an invention deserves an exclusive right over it. The labor theory of John Locke has been used to justify the Homestead Principle, which holds that one may gain whole permanent ownership of an unowned natural resource by performing an act of original appropriation. While explaining this principle, Locke quotes one example, "Land in its original state would be considered unowned by anyone, but if an individual applied his labour to the land by farming it, it becomes his property." Same is in case of patenting the genes but ethicists opine that patenting and owning genetic material of human beings amounts to holding them in slavery. Some regards that the human genome is a part of a "common humanity", and thus, the very premise of "patenting" human genetic material seems to violate that humanity.[70]

Further, human gene is a piece of all humans and no one has the right to "own" it, and if patent would be granted then it will bring sense of slavery. Slavery hits at the dignity of human beings, which is guaranteed and secured by different international covenants and declarations. However, the main objective of the United Nations Organisation and its organs is to protect and maintain the human dignity. That's why, a separate legislation, Universal Declaration of Human Rights has been passed in order to protect the inherent dignity of human beings.

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[68] Bruce, "Whose Genes are They?", p. 265.
[69] Donald S. Chisum et al., Cases and Materials: Principles of Patent Law 35-36 (New York Foundation Press 1998)
[70] Ethics and Gene Patents," Human Genetics Commission, http://www.hgc.gov.uk/Client/Content_wide.asp?ContentId=372 (last visited May 10, 2024)

### 2.5.3 Ethics in Patenting Human Cell Line

Patenting of the human cell lines is considered morally wrong by many jurists. It is stated that by allowing patenting of human genes, people are being treated as commodities. This has been given the name of "modern slavery", It has also been stated that patenting such materials would restrict the area of research and thus it would be against the public policy and interest of the society, because it might lead to a monopolistic situation. The concept of commercialization and monopolization of human tissues was discussed in detail in the landmark case of Supreme Court of California, Moore v. Regents of the University of California[71], which dealt with the issue of the property rights to one's own cells taken in samples by doctors or researchers. In this case, the patient John Moore underwent treatment for hairy cell leukaemia by physician David Golde, a cancer researcher at the Medical Centre of the University of California at Los Angeles (the UCLA Medical Centre) in 1976. Moore's cancer cells were later developed into a cell line that was commercialized by the Golde and UCLA, without the patient's consent. Golde developed white blood cells from Moore's spleen into a cell line which he called Mo, short for Moore. These cell lines showed unusual growth and high levels of production of immune- system-related proteins. On January 30, 1981, the Regents applied for a patent on the cell line, listing Golde and Quan as inventors. The patent was also issued on March 20, 1984, naming Golde and Quan as the inventors of the cell line and the regents as the assignee of the patent.

The Regents patent also covers various methods for using the cell line to produce lymphokines. The California Supreme Court ruled that a hospital patient's discarded blood and tissue samples are not his personal property and that individuals don't have the rights to share in the profits earned from commercial products or research derived from the cells. However, the court concluded that the research physician did have an obligation to reveal his financial interest in the materials harvested from Moore, and that Moore would be allowed to bring a claim for any injury that he sustained as a result of the physician's failure to disclose those circumstances. The reason behind discarding the personal rights was that it would amounts adverse effect on the medical

[71] TRIPS Agreement, Apr. 15, 1994, 33 I.L.M. 1197, Article 27(3)

research because Laboratories doing the medical research require the bulk amount of the medical samples.

Further, the majority of the Supreme Court's Judges held that the patient whose cells have been patented would be prohibited from donating or selling any patented part of his biochemical self, such as his plasma, blood, or sperm, to other scientists without first obtaining a license from the patentee, as these other scientists would be obtaining from Moore his cells in their patented form. The patentee could also theoretically prohibit Moore from undergoing a leukemia test with a group of physicians not approved by the patentee because, again, an isolated and purified version of Moore's genome would be transmitted to a third party without a license. These limitations on the rights of individuals to transfer, donate, or control commercialization of their genetic material and, possibly, to seek some kinds of medical care, clash with the constitutional right to privacy. On the question of infringement of the right to privacy, Supreme Court of California has cited the decision of Cobbs v. Grant[72] , "the scope of the physician's communication to the patient...must be measured by the patent's need, and that need is whatever information is material to the decision".

However, Supreme Court of California on the Moore's right to patent held that the patented cell line and the products derived from it cannot be Moore's Property. This is because the patented cell line is both factually and legally distinct from the cells taken from Moore's body. Human cell lines are patentable because the long-term adaptation and growth of human tissues and cells in culture is difficult, often considered as an art...".[73]

## 2.5.4 Ethics in Patenting Plants

The decision of Chakrabarty case[74] has bought a hope amongst the scientists that the United States Patent Office may extend the patent protection to multicellular plants and animals. In 1985, a landmark judgment *Exparte Hibberd*[75] " came that has changed the whole scenario of plant patenting. This was the first case in United States

[72] 8 Cal. 3d 229 (Cal. 1972)
[73] TRIPS Agreement, Apr. 15, 1994, 33 I.L.M. 1197, Article 27(3)
[74] 447 U.S. 303 (1980)
[75] Jasmine Chambers, Patent Eligibility of Biotechnological Inventions in the US, Europe, and Japan: How Much Patent Policy Is Public Policy?, George Wash. Int'l L. Rev. (2002)

where claim was made for the multicellular living organism i.e., the genetically engineered maize which had high levels of the tryptophan. However, the United States Board of Patents Appeals and Interferences decided a genetically modified plant as patentable and patent was granted. But this also involves strong debates on the ethics of plant patenting. Opponents were of the view that the plant patenting is unethical because plants are the creation of God and man cannot monopolize the God's creativity, and the God is the only and real owner of all living organism and it is unethical to privatize the God's creation. The important point of consideration is that manipulation of genes through genetic engineering is unethical because it disturbs the integrity of the plants as plants are also considered as the life forms and various legislations preserve and protect the integrity and dignity of plants and animals. After this case, the traditional trend to grant of patent to plants was changed and patent was granted to plants ignoring the ethical and moral considerations.

Similarly, the European Patent Office has granted the patent for the first time in *Green Peace v. Plant Genetic System*[76]. In this case, the invention was aimed to develop the plants and seeds which are resistant to the particular class of herbicides, namely Glutamine Synthetase Inhibitors (GSIs), consequently they are protected against the weeds and fungal disease. However, there was also a traditional method to obtain the GSI resistant plants and seeds, for there are some plants and seeds that have natural resistant capacity. But in this case, a biotechnological process was used to develop such GSI resistant plants and a seed, which means, in plants, a new trait was added to the genetic material of the plant, which ultimately allows the plant to grow in the presence of GSIs. However, the case was discussed on the ground of public order and morality. The Court has accepted that the concept of "public order" covers the protection of public security and the physical integrity of the individuals as part of society. This concept encompasses also the protection of the environment.

In case, if claimed patent strikes with the public security and social order than the patent shall not be granted[77]. Court has further declared that if the claimed patent is against the deeply rooted particular culture then the grant of patent would be illegal.[78]

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[76] N.V. (PGS I), OJ EPO 1995, 545

[77] Article 53(a) of the European Patent Convention (EPC)

[78] Article 53(a) of the European Patent Convention (EPC), "Inventions the exploitation of which is not in conformity with the conventionally accepted standards of conduct pertaining to this culture is to be excluded from patentability as being contrary to morality."

It must be kept in mind that the public order and morality under the EPC does not imply public order and morality in any one particular region or nation but throughout European Union as a whole. It implies that if some member states prohibit the patenting then the invention would not be considered as against the public order and morality. However, in this case, patent was granted by the European Patent Office.

### 2.5.5 Gene Patent and Human Dignity

Human is always considered as the social animal having intellectual to behave, explore and invent that differentiates human from the other living organisms. That's why, there are number of legislations not only on the international level but also on the national level regarding the dignity and integrity of the human. Some of the international laws protecting the human value and technology of advancements are European Patent Convention[79]", International Covenant on Economic, Social and Cultural Rights (the ICESCR), the UNESCO Declaration on the Protection of the Human Genome and Human Rights[80] etc. However, many biologists and social philosophers considered Human Genome Diversity Project (HGDP) to be the VAMPIRE PROJECT for their research.

The patenting of human gene is not only denied on the basis that people may be unable to buy, sell or lease services that they ought to be able to buy, lease or sell in case if the patent is not granted but also many people objects the patenting of the human gene because they don't want that human gerne should be considered as a property at all. When we take the second consideration of denying the patenting of human gene then it may seem to be reasonable that the gene should not be considered as one's property, and this particular conception might be based get the moral values. But, it must be kept in mind that the human genes are more like fout of the animals' genome and also that of the worms' genome. This does not conclude that woman genome should not be indifferent that of the animal and worm genome because we can rever ignore the differences that lie amongst them and no parallel reason should

[79] Article 53(a) of the European Patent Convention (EPC), "the publication or exploitation of which would be contrary to public order or morality."
[80] UNESCO Declaration on the Protection of the Human Genome and Human Rights, adopted by the UN General Assembly in 1998, "The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity."

be followed while appreciating the moral significance of the similarities amongst living beings.

Further, we must keep in mind the Munzer's Position: "other things being equal", he concludes, "the arguments tend to justify genetically related property rights in bacteria more readily than in plants, in plants more readily than in animals, in animals more readily than in chimeras, and in chimeras more readily than in humans"[81]. Thus, according to Munzer, patenting of all the human genes is not justified as there are variety of ethical distinctions that need to be made. Another issue linked with human dignity and gene patents is genetic discrimination.

Although genetic tests provide valuable, and often life-saving medical information and also maintains the privacy of the patient, some people fear that if the result of a genetic test indicates that they either have a genetic disease or have an increased risk of developing a disease, employers, insurance carriers, schools and others may discriminate against them. However, this may also be the reason that some people do not prefer to take tests that may indicate they could develop a serious disease in the future, and this become very cautious when at present there is no effective preventive measures or treatments. That's why, Biotechnology Industry Organization has long advocated legal protections to prevent genetic discrimination against individuals. UNESCO sought to bring some level of international consensus on how information about the human genome should be handled.

The Universal Declaration on the Human Genome and Human Rights[82] was adopted unanimously by the General Conference of UNESCO at its 29th Session on November 11. 1997, refers to the human genome as the heritage of humanity in a symbolic sense. It is the first universal instrument in the field of biology. It aims to strike a balance between safeguarding respect for human rights and fundamental freedoms and the need to ensure freedom of research. The Declaration states that "No one shall be subjected to discrimination based on genetic characteristics that is

[81] Munzer, p.452. He concludes: "There should be a limited public- interest exception to patent suppression. Very few expressed sequence tags should be patentable; for most ESTs a weaker form of intellectual property rights is in order. Some genetically engineered bacteria and plants should be patentable... The suffering of genetically engineered bacteria and plants should be patentable...the suffering of genetically engineered mice should case doubt on their patentability under the European Patent Convention...".

[82] Universal Declaration on the Human Genome and Human Rights, UNESCO General Conference, 29th Session, Paris, 11 November 1997

intended to infringe or has the effect of infringing human rights. fundamental freedoms and human dignity". This declaration has reinforced the position that the human gene should not be subject to property since the human genome underlies the fundamental unity of all members of the human family...in the symbolic sense; it is the heritage of humanity[83]. Similarly, The United States Patent Office's view is that granting patents on human being would violate thirteenth amendment to the U.S constitution, which prohibits slavery.[84] Therefore, ethicists say that since, no human being shall be subjected to slavery. [85]It is felt that patenting of human being[86] or human genetic material[87] should not be allowed otherwise it violates inherent dignity and integrity of human life. It also states in its Article 4 that the "Human genome in its natural state shall not give rise to financial gain"

But in the *Parke-Davis and Co. v. H. K. Mulford and Co*[88]., the United States Circuit Court for the Southern District of New York has shown the diverse opinion and held that purified human adrenaline was patentable because through the process of purification, it became "for every practical purpose a new thing commercially and therapeutically". To put it simple, the Court had treated human genes as patentable and concluded that this invention does not threaten the bodily integrity of human beings.

## 2.5.6 Ethics in Patenting Human Gene

The issue of human gene patenting has always received the renewed interest and debate but with the decision of the Supreme Court of the United States and the Federal Court of Australia in respect of the patentability of isolated genetic material, this debate was again reignited Opponents of human gene patenting have also argued

[83] Universal Declaration on the Human Genome and Human Rights, GA Res, 53rd session, AIRS/53/152 (9 December 1998)
[84] Jasmine Chambers, Patent Eligibility of Biotechnological Inventions in the U.S., Europe, and Japan: How Much Patent Policy Is Public Policy?, 96 Geo. L.J. 271 (2002)
[85] International Covenant on Civil and Political Rights art. 8, Dec. 16, 1966, 999 U.N.T.S. 171
[86] Preamble to the International Covenant on Economic, Social and Cultural Rights (ICESCR), Dec. 16, 1966, 993 U.N.T.S. 3.
[87]International Covenant on Civil and Political Rights art. 8, Dec. 16, 1966, 999 U.N.T.S. 171
[88] 189 F. 95; 1911 U.S. App. LEXIS 5245

that the current patentable status of human genes is ethically unacceptable because the human genome constitutes the common heritage of humankind. [89]

Firstly, we will discuss about the recent developments that occurred due to the landmark judgment of the Supreme Court of the United States in *Association for Molecular Pathology Myriad Genetics, Inc.* [90]In this case, patent was claimed by the biotechnology firm Myriad Genetics for the two genes BRCA-1 and BRCA-2, the mutation of which are associated with the greater risk of breast and ovarian cancer. The company obtained several patents based on these findings, which provided it with the exclusive right to isolate an individual's BRCA-1 and BRCA-2 genes and perform medical tests for detecting these mutations. These patents are controversial, and oppositions were arguing that the claimed invention lacked novelty, inventive step and industrial application. However, the Supreme Court of United States found the Myriad's patent over isolated human DNA sequences to be invalid. It must be noted that if Myriad's patent was considered as valid then the Myriad's patents would give the Myriad Genetics, Inc. the exclusive right to isolate an individual's BRCA-1 and BRCA-2 genes and would give it the exclusive right to synthetically create BRCA c-DNA.

Justice Thomas, who is known for his brevity, declared that "separating a gene from its surrounding genetic material is not an act of invention"[91] .Further, Myriad did not create or alter either the genetic information encoded in the BRCA-1 and BRCA-2 genes or the genetic structure of the DNA. The location and order of the nucleotides existed in nature before Myriad found them. Instead, Myriad's principle contribution was uncovering the precise location and genetic sequence of the BRCA-1 and BRCA-2 genes within chromosomes 17 and 13. However, c-DNAs-DNA molecules in which the naturally occurring non-coding regions (introns) are absent- were found to be patent eligible. The reason laid down by the court DNAs did not occur naturally and are synthesized from RNA in the laboratory, thus validating the patent eligibility of engineered/recombinant DNAs. In short, this case has clearly laid down that the

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[89] Patricia Lacy, 'Gene Patenting: Universal Heritage vs Reward for Human Effort' (1998) 77 Oregon Law Review 783, 798 (citing Hubert Curien, 'The Human Genome Project and Patents' (1991) 254 Science 1710)

[90] Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 13 U.S.T. 7, T.I.A.S. No. 3842, 828 U.N.T.S. 305

[91] *Id*

patents can only be granted on the genuine invention and are not used to exclude the access of material in the public domain.

It must be noted that this case is also very important from the ethical point of view in dealing with the patentability of human gene. This case demonstrates that the technical ground of patentability can also act as important safeguards of the public interest. The impact of this decision in United States can be clearly assumed that gene patents are "not only merely dead, but...really most sincerely dead. But in Australia, the situation seems to be reversed than the United States because in *Cancer Voice Australia v. Myriad Genetics Inc.*[92] It was the first Australian case to challenge the practice of granting patents over human genetic material and a patentee's exclusive right to exploit such material to the exclusion of others. In this case, patent was granted by the Nicholas J. who had upheld the validity of the patent over the isolated human DNA. However, till the decision of Full Court of the Federal Court, the Judgment delivered by the Nicholas J remains the operating authority on the subject matter of the patentability of the isolated gene sequences in Australia. This was all about the scenario of ethics of patenting human gene in United States and Australia which is quite different from the European Patent Office.

The first case in which the EPO has to consider the ethical and moral consideration in patenting the human genetic material is *Relaxin case*[93]. In this case, claim was made for the gene coding hormone called Relaxin. This hormone is released by the body which relaxes the uterus during childbirth. This hormone is naturally occurred in the human ovary but the synthetic form was needed for therapeutic use. The synthetic form can only be produced by having the isolated nucleotide sequence that coded for relaxin. The opposition argued that the patenting such gene code offends the public order and morality and is also against the human dignity as it involves taking of tissues from the body of pregnant women. But it was considered by the EPO that the taking of tissues from the body was nothing immoral and the general position is that biological material which is isolated from the natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature[94]. Finally, by rejecting the opposition it was concluded that

[92] [2013] FCA 65 915 February,2013)
[93] (1995) Official Journal of the European Patent Office 388; (1995) E.P.O. R 541
[94] Article 3(2), Directive 98/44, [1998] O.J. L213/13

patenting of genes does not amount to patenting of human life hence is not unethical or immoral.[95]

[95] Lionel Bentley & Spyros M. Maniatis, Intellectual Property and Ethics (Sweet & Maxwell 1998) 114-115

# CHAPTER-3 INTERNATIONAL CONVENTIONS AND TREATIES RELATED TO GENE PATENTING

The major international instruments that regulate and affect the patent laws and practices of the countries throughout the world are-

i. Paris Convention for the protection of Industrial Property, 1883 (Paris Convention),
ii. Patent Cooperation Treaty, 1970 (PCT),
iii. Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, 1977 (Budapest Treaty), and
iv. Agreement on Trade- Related Aspects of Intellectual Property Rights, 1994 (TRIPS Agreement).

## Paris Convention for the Protection of Industrial Property, 1883

The Paris Convention is the principal international agreement in the field of 'industrial property', including patents, marks, industrial designs, trademarks, utility models and industrial designs. In relation to the patents, the Paris Convention requires a contracting State to provide the same rights to the nationals of other contracting States as are provided to its own nationals. The term "National" includes both the natural persons and legal entities.

It also establishes the right of priority, which provides that an applicant who files for intellectual property protection in one contracting State and then in a number of other States within a specified period of time (twelve months in case of patents for invention and utility models; and six months in case of industrial designs and trademarks) may have all applications treated as if they were filed on the date of first application.[96] It also provides that eligibility for patent protection is independently assessed by each contracting State. Paris Convention fall into three main categories-

[96] Paris Convention for the Protection of Industrial Property, 1883, art. 4

i. **National Treatment-** It is provided that each contracting State must grant the same protection to nationals of the other contracting States as it grants to its own nationals. Nationals of the non-contracting States are also entitled to national treatment if they have domiciled or have a real and effective industrial or commercial establishment in a contracting State.[97] However, the term "domicile" is generally interpreted not only in the strict legal sense of the term. But a mere residence, more or less permanent as distinct from legal domicile, is sufficient.

ii. **Right of Priority**- On the basis of a regular first application filed in one of the contracting States, the applicant may, within a certain period of time, apply for protection in any of the other contracting States, and these later applications will be regarded as if they had been filed on the same day as the first application, i.e., the later application will have priority over applications which may have been filed during the priority period of time by other persons for the same invention, marks or industrial design. Furthermore, this priority right may also be invoked by the successor of title in the first applicant. [98]The right of priority may be transferred to a successor in title without transferring at the same time the first application itself. This also allows the transfer of the right of priority to different people for different countries and this practice is quite common.

iii. **Common Rules-** At last, the Paris Convention consist a number of common rules to govern the grant of patent-

**a) Independence of Patents-** Patents for the inventions granted in member countries to nationals or residents of member countries must be treated as independent of patents for invention obtained for the same invention in the other countries, including non- member countries.[99] Patents granted in different contracting States for the same invention are independent of each other, i.e., the patent granted in one Contracting State does not oblige the other contracting States to grant a patent for the same invention. Further, a patent cannot be refused, annulled or terminated in any contracting State on the ground that it has been refused or annulled or has terminated

[97]Paris Convention for the Protection of Industrial Property, 1883, art. 3
[98] Paris Convention for the Protection of Industrial Property, 1883, art. 4A(1)
[99] Paris Convention for the Protection of Industrial Property, 1883, art. 4bis.

in any other contracting State. The underlying reason in favour of this principle is that the national laws and administrative practices are usually different from country to country.

**b) Compulsory License for patents-** The purpose of the compulsory license is to prevent the abuses which might result from the exclusive rights conferred by a patent for invention. Contracting States must follow the limitations provided for the compulsory license for patents. For example- a request for compulsory license based on failure to work the patented invention may be filed only after 3-4 years of failure to work or insufficient working of the patented invention and the request must be refused if the patentee gives legitimate reasons to justify his inaction. The working of patents and compulsory license, the essence is contained in Article 5A of the Paris Convention.

**c) Industrial Design-** the Paris Convention lays down the obligation on all the member countries to protect industrial design[100], and protection may not be forfeited on the ground that the articles incorporating the design are not manufactured in that State. However, the Convention does not lay down any procedure for the protection of the Industrial Design.

**d) Trademarks-** Article 6 of the Paris Convention establishes the important principle of the independence of trademarks in the different countries of the Union, and particular the independence of trademarks filed or registered in the country of origin from those filed or registered in other countries of the Union. It must be noted that the Convention only deals with the "well-known trademarks."[101] Article 6bis of the Convention obliges a member country to refuse or cancel the registration and to prohibit the use of trademark that is liable to create confusion with another trademark already well-known in that member country.

**e) Unfair Competition-** The Convention provides that the countries of the Union are bound to assure to persons entitled to benefit from the effective protection against unfair competition. [102]The Convention also defines the acts of unfair competition as

[100]Paris Convention for the Protection of Industrial Property, 1883, art. 5
[101]Paris Convention for the Protection of Industrial Property, 1883, art. 6bis
[102] Paris Convention for the Protection of Industrial Property, 1883, art. 10bis

those acts of competition which are contrary to the honest practices in industrial and commercial matters.

## Patent Cooperation Treaty, 1970

The Patent Convention Treaty is an agreement for international cooperation in the field of patents. The principal objective of the PCT is, by simplification leading to more effectiveness and economy, to improve on in the interests of the users of the patent system and the Offices which have the responsibility for administering it the previously established means of applying in several countries for patent protection for inventions. It establishes administrative procedures to facilitate the simultaneous filing of patent applications on a single invention in multiple jurisdictions. To put it simpler, an inventor may seek patent protection in any number of PCT members countries by filing a single international application in one country- called the 'Receiving Office' and subsequently selecting the jurisdictions in which it may wish to obtain a patent. The grant or the refusal of a patent based on a PCT application is, however, determined by each of the national or regional patent offices with which the PCT application is filed, what is called the "national phase". [103]

This treaty does not bar anyone to directly file separate patent applications at the same time in all the countries in which he/she would like to protect his/her invention, or having filed in a Paris Convention country then file separate patent applications in other Paris Convention countries within 12 months from the filing date of that first patent application, giving applicant the benefit in all those countries of claiming the filing date of the first application.

Thus, the PCT makes the procedure simpler, easier and more effective than both the direct or Paris Route filings. It must also be remembered that a PCT application does not itself result in the grant of a patent, since there is no such thing as an "International Patent", and the grant of patent is a prerogative of each national or regional authority[104]. "The Patent Cooperation Treaty has many advantages for an applicant, for the patent offices and also for the general public:

[103] Patent Cooperation Treaty, 1970, art. 27
[104] supra note 23

i. Firstly, it brings the world within the reach because the PCT application will have the legal effect of a regular national patent application in all PCT states. Thus, it allows to seek the patent protection for an invention simultaneously in nearly 152 countries by filing a single "international" patent application instead of filing several separate national or regional patent applications. This not only saves money but also time of the applicant.

ii. Secondly, the international application cannot be rejected on the formal grounds by any PCT Contracting State patent office during the national phase of the processing of the application, if the application is in the form prescribed by the PCT.

iii. Thirdly, it postpones major costs associated with the seeking multinational patent protection. Because if the invention appears to be not patentable at the end of the international phase, you may abandon the PCT application and you have saved the costs you would otherwise have incurred by directly seeking protection in foreign countries, appointing local patents agents in each foreign country, preparing the necessary translations and paying the national fees.

iv. Fourthly, it also provides the third party a better position to evaluate the otential patentability of the claimed invention because each international application is published together with an international search report.

v. Fifthly, it also reduces the cost of obtaining the patent in foreign countries by providing savings in document preparation, communication and translations because the work done during the international processing is generally not repeated before reach office and you have only to submit only one copy of the priority document instead of the several copies.

## Process of Filing a PCT Application

i. **Filing:** Any national or resident of a PCT contracting State can file an international application at the national or regional patent office or WIPO (if permitted by your State's National Security provisions). The PCT also lays down set of standards for international application. So, the international application which is prepared in accordance with these standards will be acceptable, so far as the form and contents of the application are concerned, to all the PCT Contracting States. However, PCT also provides that no

subsequent modification is needed in the international application because of varying national or regional requirements. The applicant has also to pay one set of fees for the preparation and filing of the international application, and they are payable in one currency and at one office, the receiving office.

ii. **International Search:** The international application is subjected to an "International Search" i.e., a high quality search for patent documents and other technical literature in those languages in which most patent applications are filed (English, French and German, and in certain cases Chinese, Japanese, Russian and Spanish). "International Search Authority" identifies the published patents documents (prior arts). So, it checks whether the invention is patentable or not. However, the PCT also lays down the standards for the high quality of international search for the documentation, staff qualifications and search methods of the International Search Authority. The following offices are appointed as the International Search Authorities: the Australian Patent Office, the Austrian Patent Office, the Chinese Patent Office, the European Patent Office, the Japanese Patent Office, the Spanish Patent and Trademark Office, the Swedish Patent Office and the United States patent and Trademark Office.

iii. **International Publication:** The International Bureau publishes a PCT pamphlet which contains information regarding the invention. After the expiration of 18 months from the filing of patent application, the contents of the International application is disclosed to the World. The purpose of the International publication is-

a) to disclose to the public the invention

b) to set out the scope of protection which may ultimately be obtained. The publication of each pamphlet is announced in the PCT Gazette, which lists the published international applications in the form of entries reproducing data taken from the front page of the pamphlets.

Furthermore, these publications, the pamphlet and the PCT Gazette are distributed free of cost to all the PCT Contracting States. But it is available on request against the payment of cost to the public.

iv. **Supplementary published International Search (optional):** A second identification of the prior documents is done by the second International

Search Authority so that document (if any) may be recovered which were not found by the first ISA.

v. **International Preliminary Examination (optional):** This step is usually followed on an amended version of the application, and on this application, the third ISAs carries out an additional patentability analysis.

vi. **National Phase:** After the end of the PCT procedure i.e., after 30 months (about 2 and a half years) from the earliest filing date of the initial application from which the applicant claim priority, the applicant starts to pursue the grant of your patents directly before the national (or regional) patent Offices of the Countries in which you want to obtain them.

However, recently Jordan became the 152nd Contracting State of the PCT by depositing its instrument of accession to the PCT on 9 March, 2017 and it will be bound by the PCT on 9 June, 2017. It means that if any international application is made on or after the 9 June, 2017 then it will automatically include the designation of Jordan.

## Budapest Treaty, 1977

The Budapest Treaty is an international treaty signed in Budapest, Hungary on April 28, 1977. This treaty came into force on August 9, 1980 and was amended on September 26, 1980. This treaty is administered by the World Intellectual Property Organization (WIPO). It provides an international system for the deposit of microorganisms as a means of satisfying the disclosure requirement for the grant of a patent by a national or regional patent office. The Budapest Treaty establishes that the deposit of a microorganism with a designated 'international depository authority' will satisfy the patent procedure requirements of national or regional patent offices that have recognized the effects of the Treaty.

The Budapest treaty ensures that an applicant, who applies for a patent, needs not to deposit the biological material in all countries where he/she wants to obtain a patent. The applicant needs only to deposit the biological material at one recognized institution, and this deposit will be recognized in all countries party to the Budapest

Treaty. Thus, an inventor is required to deposit the strain of a microorganism in a recognized depository, which assigns a registration number to the deposited microorganism. The strain of microorganism is required to be deposited before filing the patent application, and the registration number should be quoted in the patent application dealing with the application. The grant of patent related to a biological material depends upon regulations regarding requirements for the deposition of biological material in recognized International Depository Authority formed under Article 7 of the Budapest Treaty.

India is also the signatory of this treaty with the effect from 17 December, 2001. As per Section 10(4)(d)(ii) of Indian Patents Act, 1970, the "biological material" "if not being described fully and is not available to public, the said biological material is to be deposited before the IDA under the Budapest Treaty before filing application in India and a reference thereof shall be made in the specification within the period of three months from the date of filing of application." The material is deposited so that every complete specification shall fully and particularly describe the invention and its operation or use and the method by which it is to be performed. Once the deposits are made, the Authority provides an accession number, which is considered as an equivalent description of the living material. In India, there is one International Depository Institution at Chandigarh which is known as Institute of Microbial technology (IMTECH) and other at Microbial Culture Collection (MCC), Pune.

However, if the invention is related to biological material obtained from India, applicant needs to add one Declaration in Form 1. The Declaration is "The invention as disclosed in the specification uses the biological material from India and the necessary permission from the competent authority shall be submitted by me before the grant of the Patent to me." Along with this, the applicant also needs to fulfill the requirement of Section 6 of the National Biodiversity Act, 2002, which makes it mandatory for the applicant to seek permission of the National Biodiversity Authority before sealing of the Patent, if the invention of patent application uses biological material.

The requirements to be fulfilled to comply with the provisions of Patents Act, 1970 and Patents Rules, 2003:

If the invention uses the biological material and it is not already known, then

a) It must be submitted at the International Depository Authority not later than the date of making the patent application in India, and

b) A reference thereof shall be made in the specification within the period of three months from the date of filing of the application provided that in case of request for early publication of patent application, this reference shall be made on or before date of such request.

It should be noted that the biological material can be made available to the public by the Depository Institution upon publication of patent application.

## TRIPS Agreement, 1994

The TRIPS Agreement has emerged as a framework for ensuring the intellectual property rights across the world. Every member of the World Trade Organisation (WTO) should include TRIPS provision in their domestic intellectual property legislations. TRIPS is the major achievement of the Uruguay Round as an International Trade Agreement. With TRIPS, the WTO also emerged as the institution for the protection and promotion of intellectual property globally. It also establishes the minimum standard of patent (and other intellectual property) protection that each member of the World Trade Organization (WTO) must provide under its national laws.

The TRIPS Agreement provides that patents shall be available for any invention and that patent rights shall be enjoyable 'without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.' Most extensive patent protection may be provided under domestic law so long as it would not affect the operation of other provisions of the TRIPS Agreement. The TRIPS Agreement requires that the members States provide patent protection for any inventions, whether products or processes, in all fields of technology.[105] It also

[105] TRIPS Agreement, art. 27(1)

provides the optional exclusion by the member States of the subject matter of patentability as provided by the TRIPS. [106]

Thus, the TRIPS Agreement provides that member States may exclude inventions from patentability if prevention of the commercial exploitation of an invention is necessary to protect 'public order or morality', including 'to protect human, animal or plant life or health or to avoid serious prejudice to the environment.[107] The TRIPS Agreement also provides that member States may exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals' and 'plants and animals other than micro-organisms, and essentially biological processes for the production of plants and animals. [108]

Moreover, the TRIPS Agreement consist a right for the member States to provide limited exceptions to patent rights (including public policy exceptions) so long as such exceptions do not unreasonably conflict with the normal exploitation of a patent, nor unreasonably prejudice a patent holder's rights." The other important provision under the TRIPS Agreement is that it provides the limitation on compulsory licensing and government use of patents, including a requirement that adequate compensation be paid for such use.

India is also a signatory of the TRIPS Agreement and the WTO's TRIPS Agreement became binding on India from 2005 onwards as the country got the ten-year transitional period (1995- 2005). This transitional period was provided just to make the Indian Intellectual Property Legislations compatible with TRIPs. Hence, the whole existing intellectual laws had undergone to the considerable change and fresh legislations were introduced. It must be kept in mind that India has got additional five-year transition period because of not having product patent regime in critical sector like pharmaceutical.

[106] TRIPS Agreement, art. 27(2), (3)
[107] TRIPS Agreement, art. 27(2)
[108] TRIPS Agreement, art. 28(3)

# CHAPTER-4 LEGISLATIVE AND JUDICIAL OF USA, EUROPE AND INDIA ON HUMAN GENE PATENTING

4.1 Doctrine of product of nature

4.2 Patenting of living organism

4.3 Patenting of microorganisms

4.4 Evolution of patent laws in India

4.5 TRIPS and Patents Act,1970

4.6 Patentable subject matter under the Patents Act,1970

4.7 Patenting microorganism

4.8 Overview of the European Patent system and its approach to gene patenting

4.9 Examination of the European Union (EU) directives and regulations concerning gene patents.

4.10 Comparative analysis of European Patent Office (EPO) decisions and their alignment with national laws.

## PATENTABILITY OF GENE UNDER U.S. PATENT LAW

The evolution of the gene patenting can be traced to the United States, or one can say that the country which has firstly recognised the patenting of gene was United States. Initially, it adopted a liberal approach to deal with the genetically engineered patent claims but gradually it has developed its patent law to fairly deal with the biotech challenges and the abuse of the patent system in a mature way. Article 1 of the Constitution of the United States provides, "The Congress shall have the power to promote the progress of science and useful arts, by securing limited times too authors

and inventors the exclusive right to their respective writings and discoveries." This Article does not explicitly say anything about the gene patenting, but this Article confers the power on the Congress of the United States to make the provisions for the progress of the science and arts by granting exclusive rights to the inventors for the limited time. Meaning thereby, 1970 should not be confused with the Plant Patent Act of 1930, which is limited to asexually reproduced plants. In order to grant the patent to sexually reproduced plants, there are some basic requirements must be fulfilled i.e., firstly, the variety must be new, in the sense that propagating or harvested material has not been sold or otherwise disposed of for the purposes of exploitation for more than one year in the United States or four years in any foreign jurisdiction. Second, the variety must be distinct-i.e., clearly distinguishable from any other publicly known variety. Third, the variety must be uniform, in the sense that any variation is describable, predictable and commercially acceptable and finally, the variety must be stable, in the sense that the variety, when reproduced, will remain unchanged regarding its essential and distinctive characteristics within a reasonable degree of commercial reliability.

But both the Plant Patent Act of 1930 as well as the Plant Variety Protection Act of 1970 did not show any indication of including bacteria within the purview of the patentable subject matter. Similarly, the original US Patent Act of 1952 does not recognize the patenting of the gene because it was considered that the genes can only be discovered-and cannot be invented, Section 101 of the US Patent Act was added in 1870 and amended in 1952. It states that, "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore subject to the conditions and requirements of this title." Thus, this Section deals with the subject matter of the patent. But almost after a century, the Supreme Court of US reiterated that "laws of nature, physical phenomenon, and abstract ideas" are not patentable subject matter. The reason laid down was that "such discoveries are manifestation of free to all men and reserved exclusively to none. Thus, it laid down the foundation for the doctrine ne 65 of 'product of nature' and the reasoning of this doctrine is that the mere discovery of the natural occurring phenomenon is not patentable because it is not an invention. Further, the invention must be useful to the public and this is also supported by Justice Story, who had written in 1817, "all that the law requires is, that the invention should

not be frivolous or injurious to the well- being, good policy or sound morals of society, American Patent System has an economic rationale, with the government offering a broad exclusionary right as an incentive to invention.

This rationale was also promoted by the Patent Act, 1952 which seeks to promote scientific progress by conditioning the grant of the patent on full disclosure of the relevant technology. Similarly, the Plant Patent Act of 1930 of United States clearly shows that Congress has exercised its legislative power in the first half of the 20th Century. The Plant Patent Act was enacted to provide the incentive to plant breeders, through the grant of monopoly rights, to asexually reproduced plants. The Act read that "whoever invents or discovers and asexually reproduces...[a] new and distinct," variety of plant would be entitled to a plant patent over such a plant. This was the first-ever legislative measures in the United States allowing monopoly rights over naturally existing beings with the conditions of those beings having the capability to reproduce asexually.

But soon in 1970, Congress enacted the Plant Variety Protection Act, 1970 which gives the breeders up to 25 years of exclusive control over new, distinct, uniform, and stable sexually reproduced or tuber propagated plant varieties. However, this Plant Variety Protection Act, 1970 should not be confused with the Plant Patent Act of 1930, which is limited to asexually reproduced plants. In order to grant the patent to sexually reproduced plants, there are some basic requirements must be fulfilled i.e., firstly, the variety must be new, in the sense that propagating or harvested material has not been sold or otherwise disposed of for the purposes of exploitation for more than one year in the United States or four years in any foreign jurisdiction. Second, the variety must be distinct-i.e., clearly distinguishable from any other publicly known variety. Third, the variety must be uniform, in the sense that any variation is describable, predictable and commercially acceptable and finally, the variety must be stable, in the sense that the variety, when reproduced, will remain unchanged regarding its essential and distinctive characteristics within a reasonable degree of commercial reliability.

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recognize the patenting of the gene because it was considered that the genes can only be discovered-and cannot be invented, Section 101 of the US Patent Act was added in 1870 and amended in 1952. It states that, "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore subject to the conditions and requirements of this title." Thus, this Section deals with the subject matter of the patent. But almost after a century, the Supreme Court of US reiterated that "laws of nature, physical phenomenon, and abstract ideas" are not patentable subject matter. The reason laid down was that "such discoveries aremanifestation of nature, free to all men and reserved exclusively to none. Thus, it laid down the foundation for the doctrine ne 65 of 'product of nature' and the reasoning of this doctrine is that the mere discovery of the natural occurring phenomenon is not patentable because it is not an invention. Further, the invention must be useful to the public and this is also supported by Justice Story, who had written in 1817, "[a]all that the law requires is, that the invention should not be frivolous or injurious to the well- being, good policy or sound morals of society, Moreover, it should be kept in mind that the United States society is quite adoptive and flexible and this may be considered as one of the reasons for its success in every field. The United States Patent Act, 1952 does not speaks about the moral and ethical considerations while granting patent. That's why the United States Supreme Court has interpreted the United States Patent Act, 1952 and laid down the principle that "anything under sun made by man is patentable 7 However, United States is regarded as the pioneer in the field of both the commercialization of biotechnology applications and products and the development of patent law to protect them.

## 4.1 Doctrine of Product of Nature

The Doctrine of Product of Nature is very well used by the Patent Offices and the Courts for rejecting the patent on the living matters. All living beings are considered as the product of nature. That's why patents on living things were rejected based on the fact that living things are a product of nature. The product of nature doctrine implies that organisms or substances that occur in nature cannot be considered as inventions and are therefore not patentable. Further, products of nature are

manifestations of nature belong to none, which are not patentable. That's why the Court viewed that products of nature do not fall within the purview of patentable subject matter.

Justice Sweet has cited four cases in which the doctrine of "product of nature" was applied. Moreover, the philosophy laid down behind this doctrine is that living beings cannot be owned by anyone because they are created by nature. The matter which is created by nature cannot be monopolized to anyone because everyone has equal rights to natural resources. Amongst the four cases cited by Justice Sweet, one of them is the Funk Brothers Seed Co. v. Kalo Inoculant Co[109], in which the question relating to the patentability of unicellular organisms first time came before the United States Supreme Court. In this case, the claim was made for the mixture of naturally occurring strains of bacteria which was helpful in the leguminous plants taking nitrogen from the air and fixing in the soil. The ability of the bacteria to fix the nitrogen was natural and that's why farmers grow their crops with these leguminous plants in order to improve the soil nitrogen. However, the patent applicant combined all the bacteria into a single inoculants inspite of the fact that several nitrogen-fixing bacteria do not inhibit each other.

The Court held that the claim was not patent eligible because the bacteria were not altered in any way by the patent holder. And thus, patent claim was invalid on the ground of the product of the nature. Further, the Court held that there was no invention because the patentee had not created any new bacteria and the claimed bacteria was the natural bacteria that exist in nature. The Court denied the inclusion of the living organism from the purview of the patentable subject matter. Thus, the ruling of the Court was, "Each of the species of root-nodule bacteria contained in the package infects the same group of leguminous plants which it always infected. No species acquires a different use. The combination of species produces no new bacteria, no change in the six species of the bacteria, and no enlargement of the range of their utility. Each species has the same effect it always had. The bacteria perform in their natural way. Their use in combination does not improve their natural functioning in any way. They serve the ends nature originally provided, and act quite independently of any effort of the patentee.

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[109] 333 U.S. 127 (1948).

Another leading case cited by Justice Sweet on the doctrine of product of nature is *Shell Development Co v. Robert C. Watson*[110]". In this case, the claim was as follows, "As a new composition of matter, the hydrocarbon bicycle (2.2.1)-2, 5-heptadiene possesses the following structural formula". The Court considered that the subject matter of this claim falls within a statutory class of "composition of matter." However, this expression includes, "all compositions of two or more substances and includes all composite articles, whether they be results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids" "So it can be concluded that the Court signaled the liberalization of patent laws to encourage the new techniques and technologies. The consequence of this suit was that Congress codified all the patents law and enacted Patent Act, 1952[111].

Recently, this doctrine was again applied by the Supreme Court of United States in rejecting the patent application on the claim of human gene in the most celebrated case, the *Association for Molecular Pathology v. Myriad Genetics, Inc*[112]. In this case, Myriad had identified the exact location of the BRCA 1 and BRCA 2 genes on the chromosomes 17 and 13. Chromosome 17 has approximately 80 million nucleotides, and chromosome 13 has approximately 114 million nucleotides. Mutations in these genes can dramatically increase an individual's risk of developing breast and ovarian cancer. The average American women has a 12-13% risk of developing breast cancer, but for women with certain genetic mutations, the risk can range between 50 and 80% for breast cancer and between 20 and 50% for ovarian cancer. Before the Myriad discovery of the BRCA I and BRCA 2 genes[113], scientists knew that heredity played a role in establishing a women's risk of developing breast and ovarian cancer, but they did not know which genes were associated with these cancers.

The Supreme Court of the United States ruled that human genes cannot be patented in the U.S. because DNA is a "product of nature." The Court held that the Myriad has neither created nor altered any of the genetic information encoded in the BRCA 1 and BRCA 2 genes. Location and order were already existed in nature before Myriad found them. The principal contribution of Myriad was uncovering the precise location

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[110] 149 F.2d 519 (9th Cir. 1945)
[111] 35 U.S.C. §§ 1-376 (1952)
[112] Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 13 U.S.T. 7, T.I.A.S. No. 3842, 828 U.N.T.S. 305
[113] Myriad Genetics. U.S. Patent No. 5,747,282(issued on May,5 1998)

and genetic sequence of the BRCA I and BRCA 2 genes. However, it is true that Myriad has found an important and useful gene but separating that gene from its surrounding genetic material is not an act of invention. Further, if the patent granted to Myriad is considered as valid then it will give Myriad the exclusive right to isolate an individual's BRCA 1 and BRCA 2 genes. The patent would also give Myriad the exclusive right to synthetically create BRCA cDNA. In Myriad's view, manipulating BRCA DNA in either of these fashions triggers its "right to exclude others from making" its patented composition of matter under the Patent act. Thus, the Court held that since there was nothing new, there is no need of the intellectual property to protect, resulting no patent should be granted.

However, the Supreme Court had allowed that DNA manipulated in a lab is eligible to be patented under Section 101 of the United State Code because DNA sequences altered by humans are not found in nature. Moreover, naturally occurring DNA segments are a product of nature and not patent eligible merely because they have been isolated from the human body. In the case of synthetically created DNA in the laboratory from mRNA, generally known as Complementary DNA (cDNA), patent can be granted because it is not naturally occurring. This synthetic DNA is produced from the molecule that serves as the instructions for making proteins (called messenger RNA). The natural creation of mRNA involves splicing that removes introns, and the synthetic DNA created from mRNA also contains only the exon sequences. However, CDNA contains the same protein coding information found in a segment of natural DNA but omits portions within the DNA segment that do not code for proteins.

## 4.2 Patenting of Living Organisms

The move to grant the patent on living organisms was started in the early 19th Century in the United States and the first incidence of patenting the living organisms was witnessed in the year of 1873, when the United States Patent Office granted the patent on the yeast to the Louis Pasteur. In this case, the United States Patent Office had widened the scope of the term "manufacture" of Section 101 of the US Patent Act and considered the invention as the manufacture of new article within the meaning of Section 101 of the US Patent Act. The important point to be noticed is that indeed the

patent was granted on the living organism which was used in brewing the beer but still there was no explicit approach in favor of granting the patent on the living organism. Because in this case, patenting was done of the method to brew the beer in which Louis Pasteur has used the yeast which resulted in the better beer. In the early days, Beer was first made by the Sumerians, and the technology was absorbed in the Babylonian and ancient Egyptian Culture. The process used by Sumerians was to bake grains into bread, and bread was moistened to begin the process of making beer. The baked breed was a way to preserve the grain for later use in the beer making process. But in the patented process of Louis Pasteur, the wort was kept in closed vessels and cooled by spraying the outside of the vessel with water. Later on, after cooling, a special yeast was mashed which prevents the contamination of the wort with stray yeasts floating through the air.

Subsequently, in most celebrated case *American Fruit Growers Inc v. Brogdex Co*[114]", the United States Supreme Court has interpreted the term "manufacture" and held that the term "manufacture" as well defined by the Century dictionary, was to mean the production of new articles from use of raw or prepared materials by giving to these materials new forms, qualities, properties or combinations whether by hand-labor or by machinery. In the present case, patent was claimed for the new and improved process of preparing fresh for market by subjecting it to the action of a solution of borax thus increasing its resistance to the decay caused by the blue mold. The Court has rejected this claim by stating that an orange, the rind of which has become impregnated with borax through immersion in a solution, and thereby rendered resistant to blue mold decay, is not a manufacture or manufactured article within the meaning of the patent law. Moreover, the Court has rejected the claim of patent on the ground that the addition of borax to the rind of natural fruits does not produce from the raw material an article for use which possesses a new or distinctive form, quality, or property. The added substance only protects the natural article against deterioration by inhibiting development of extraneous spores upon the rind. There is no change in the name, appearance, or general character of fruit. The meaning of manufacture was elaborated in Hartranft v. Wiegmann", where the Court held, "Manufacture implies a change but every change is not a manufacture, and yet every change in an article is an result of a labour, treatment and manipulation but something more is necessary....there

[114] 283 U.S. 1 (1931)

must be transformation and a new different article must result having a distinctive name, character, or use."

Recently in the celebrated case, Re Roslin Institute (Edinburgh)", the claimed invention was a live-born clone of a pre-existing, non-embryonic, donor mammal selected from cattle, sheep, pigs and goats. An embodiment for the claimed invention was made for the famous Dolly the Sheep, which the Court stated was "the first mammal ever cloned from an adult somatic cell." The method that was used to create the claimed clones had "constituted the breakthrough in the scientific discovery". Inspite of this fact, the Court held that the patent cannot be granted because Dolly herself is an exact genetic replica of another sheep and does not possess "markedly different characteristics from any farm animals found in nature."

## 4.3 Patenting of Microorganisms

The evolution in the field of biotechnology and genetic engineering can be witness during the nineteen seventies, which ultimately resulted in the patent claim for various living matters. To recognize the patenting of the microorganism, an international treaty was signed in Budapest, Hungary, i.e., the Budapest treaty on the international recognition of the Deposit of Microorganism for the Purposes of Patent Procedure. This treaty is administered by the World Trade Organization. This treaty allows the deposit of the microorganisms at the depository authority to be recognized for the purposes of patent procedure. In the widest sense, the term microorganism will include any biological material i.e., self-replicable or replicable via a host organism. This infers that microorganisms exist as a part of nature and there may be discovery of the microorganism but not an invention. The doctrine of the product of nature can be applied to exclude the patentability of the microorganism that is neither new nor non- obvious. Therefore, microorganisms are patentable only if they are different from the natural form and converted into the desirable form by using the sophisticated techniques of genetic engineering. Before 1980, patents were given for inventions based on microbiological processes and there is no instance of patenting of microorganisms per se, which are products of nature.

For the first time in history, patent was granted on the microorganism in the landmark case of Supreme Court of the United States in Diamond v. Chakrabarty[115]. This case has completely overturned the non-patentable status of living organism into the patentable status. In 1972,Ananda Mohan Chakrabarty, a genetic engineer and a researcher of the General Electrical Company claimed patent for three subjects- one is the process/method of producing bacteria and second is the claims for an inoculum comprised of a carrier material floating on water, such as straw, and third was for the bacteria itself. The ba cteria for whose the patent was claimed was genetically modified bacteria capable of oil eating spills (superburg). Chakrabarty claimed, "A bacterium from the genus Pseudomonas containing therein at least two stable energy generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway: Salicylate an aromatic hydrocarbon, and Naphthalene a polynuclear aromatic hydrocarbon, was a human-made, genetically engineered bacterium capable of breaking down multiple components of crude oil.

Further, it was asserted by Chakrabarty that because of this property which is not possessed by any naturally occurring bacteria, the oil eating bacteria could be considered under the category of the invention. But the patent office allowed the patent claim for the method of producing bacteria but the claim of genetically modified bacteria was rejected. Then Mr. Chakrabarty appealed to the Patent Office Board of Appeals and Interferences, where the decision of the Patent Office was upheld. The Board of Appeals and interferences concluded that the Section 101 of the United States Patent Code does not provide for the patenting of the living organism such as the microorganism. Further, the Board did not argue whether the living matter is patentable or not and gave the clear-cut reason that the law does not talk about the patentability of living organism. Being unsatisfied from the decision of Board, Mr. Chakrabarty appealed to the Supreme Court of United States.

The Supreme Court of America upheld the plaintiff's patent over the genetically manufactured bacteria by the wafer-thin majority of 5:4. The majority opinion, written by the Chief Justice Burger reasoned that the Chakrabarty bacteria was not a discovery, but was an invention. As an invention, the bacteria could, therefore, be

[115] *Supra*[1]

patented[116]. The Court has accepted that the Constitution grants Congress broad power to legislate to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Rights to their respective Writings and Discoveries.[117]" Thus, the patent laws promote this progress by offering inventors exclusive rights for a limited period as an incentive for their inventiveness and research efforts. It was held that the 35 U.S.C. 101 has no limits or that it embraces every discovery. The laws of nature, physical phenomena, and abstract ideas have been held not patentable.

On the basis of this concept, the court ruled that the claimed microorganism plainly qualifies as patentable subject matter. His claim is not a hitherto unknown natural phenomenon, but to a non-naturally occurring manufacture or composition of matter- a product of human ingenuity "having a distinctive name, character and use." Further, while rejecting the contention of the opponents, the Court held that the Charkabarty's invention is not a product of nature, because the human intervention is involved which differentiates it from the product of nature. Naturally the bacteria do not possess such a feature and this feature has been evolved by the human ingenuity making the bacteria to possess the capacity to eat up oil spills with accuracy and pace. This human intervention has made the product of nature, a product of man. The patent was granted on the oil eating bacteria and thus, genetically modified bacteria also became the subject matter of patent.

## 4.4 Evolution of patent laws in India

Patents are given to protect inventions which are created by the human mind. Under the ancient Hindu Jurisprudence, there was no equivalent monopolistic right over technological efforts, because in the ancient time, each avocation was taken by the particular caste and the technological enhancement in an area of the industry remained as a trade secret with the members of the caste. In the later part of the nineteenth century, new inventions in the field of art, process, method or manner of manufacture, machinery, apparatus and other substances, produced by manufacturers were on

[116] Mathew Me Govern, "Biotechnology & Patenting Living Organisms," 3 Animal L. 221 (1997).Edmund J. Sease, "From Microbes to Corn Seeds, to Oysters, to Mice: Patentability of New Life Forms," 38 Drake L. Rev. 551 (1989)
[117] U.S. Const. art. I, § 8, cl. 8

increase in India and the inventors became very much interested in getting their inventions protected[118]", so that the exclusive right of the inventors should not be infringed and used by others.

That's why there was need of the patent system in India which not only gives recognition to the innovator but also reward him for his valuable contribution of innovative ideas, by means of a formal system, to encourage technical developments and fair practices in competitive ages. Therefore, the first law that was enacted to provide the protection to the inventors was Indian Patents and Designs Act, 1911. This Act was the first law that was enacted by the Britishers in the field of patent, which enabled the British to keep the goods of the other European Nations from entering in the Indian Market. This Act was also a common legislation, covering both patents and designs. The main lacuna of this Act is that the 'local novelty' was sufficient for the grants of patents but the advancements in technology and science, the status demands the global novelty. Moreover, the Act of 1911 was also not comprehensive.

After the independence of India, the Government of India decided to comprehend and consolidate all patent laws, therefore two independent Committees were constituted to consider the reforms to Indian Patent Law, one was constituted in 1948, namely Justice Bakshi Tekchand Committee and other was Justice Rajagoplala Iyengar Committee, constituted in 1959, Justice Bakshi Tekchand Committee required the incorporation of the global novelty as essential criteria for the grant of patent. Whereas the Justice lyengar Committee recommended very restrictive features like that the Patent Act should not allow the product patent for the substances that can be used as medicine, food or drug. For these inventions, only process patent was permissible.

With all these recommendations, the Patents Act, 1970 was enacted. This Act of 1970 has accepted all the universal requirements of patentability like novelty, inventive step and industrial application is patentable. However, the Act has resolved the biggest problem by defining invention that means any new and useful art, process, method or manner of manufacture, machine, apparatus or other articles substance produced by

[118] Manish Arora, *Universal's Guide to Patents Law as Amended by the Patents (Amendment) Act 2002* (Universal Law Publishing Co. Pvt. Ltd. 2002)

manufacture and includes any new and useful improvement of any of them[119]. Thus, in India any 'new and useful invention is the subject matter of Patent.

The term "invention" has been also defined by the court in *Raj Prakash v. Mangat Ram Chawdhary*[120]**,** The court held that, "Invention is to find out or discover something not found or discovered by any one before and it is not necessary that the invention should be anything complicated and the essential thing is that the inventor was the first one to adopt it and the principle therefore is that every simple invention that is claimed, so long as it is something novel or new, would be an invention and the claims and the specifications have to be read in that light and a new invention may consist of a new combination of all integers so as to produce a new result or may consist of altogether new integers and the claim for anticipation by the defendant has to be either by prior user or by prior publication[121].

Moreover, the main drawback of this Act was that it does not provide anything shout the patenting of the biotechnological inventions because at that time, biotechnology was not much developed. Biotechnological inventions in India started when the biotechnological industries were flourishing in the United States and Europe and patent protection were given in those countries for the biotechnological inventions. This development in patent law resulted in the adoption of international conventions like the Trade Related Intellectual Property Rights (TRIPS). The TRIPS agreement is a multilateral agreement on intellectual property rights, which provides for universal law on intellectual property rights.

As far as biotechnological patents are concerned, the convention gives respect to the developments in the United States and the European Union. It mandates all the member states to provide patents on biotechnological inventions.[122]" India has also ratified the TRIPS Agreement that's why, to fulfill its obligations under the TRIPS Agreement, and India has thrice amended its Patent Law. The aim of such amendments was to provide patent protection for all kinds of inventions in all fields of science and technology including biotechnological inventions. It must be noted that unlike United States and European Union where biotechnology patent law is a result

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[119] The Patents Act, No. 39 of 1970, § 2, Acts of Parliament, 1970 (India)
[120] ILR (1977) 2 Del 412
[121] *Id*
[122] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299

of judicial pronouncements, in India the emergence of biotechnology patent law is a result of ratifying international conventions and obligations under such conventions.

Further, Indian Patents Act, 1970 has not laid down the definition of "biological material", so while considering the material as biological material, one has sought the wording of the European Patent Code which defines the biological material as "any material containing genetic information and capable of reproducing itself[123]. But it will be interesting to know with reference to the Indian scenario, whether the biological material which satisfy the requirements of the above definition can be considered as patentable under the Indian Law. However, prior to 2001, the prevailing situation in the country was that the patenting of living organism, or a process relating to manufacture of a product containing the living organisms was considered as invalid but in the notable jugdement of *Dimrinoco case*[124], the Calcutta High Court has altered the situation and held that the claims relating to living organisms (read microorganism were not considered patentable until the presence of Section 3(j) which provided, *inter alia,* for patenting of microorganisms.

## Patent Amendment Act, 1999

Article 27 of the TRIPS provides that the members are obliged to provide patent protection for any invention, whether products or processes, in all field of technology without discrimination based on the place of invention or production or field of technology. Another obligation put on the member states especially in reference to India, and it has to establish its patent product regime until 2005[125]. During this time, India could not afford to violate TRIPS and face trade sanctions impacting Indian export. So, in this background, India has passed its first Amendment to the Patents Act, 1970 in the year 1999 but brought with the retrospective effect from January 1, 1995 with the aim to bring India's patent regime into compliance with the WTO TRIPS Agreement. India was given ten years of transmission period to modify its laws to fulfill its obligations under the TRIPS Agreement. TRIP came into being on 1-

[123] Rule 23(b)(3), Implementing Regulations to the Convention on the Grant of European Patents (European Patent Convention), Oct. 5, 1973, as amended
[124] Dimminaco A.G. v. Controller of Patents and Designs, (2002) I.P.L.R. 255 (Cal)
[125] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 65, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299

1-1995, the transmission period given to India started from 1-1-1995 and ended on 1-1-2005.

Furthermore, Article 70(8), read with Article 65(2) and (4) of the TRIPS Agreement, obligates developing countries to provide for a mailbox mechanism for depositing applications and an exclusive marketing regime right (hereinafter, EMR) for such inventions during the interim period. It provides for the filing of applications for product patents in the area of drugs, agriculture and pharmaceutical even though such patents were not yet allowed at the time this Act was passed. Thus, this amendment was a boon to the biotechnology industry that was preparing the drugs and medicines. After the amendment, there filed thousands of applications before the Indian Patent Offices claiming inventions relating to pharmaceuticals and agriculture, among which considerable number of applications are relating to biotechnology inventions like chemical substances isolated from the body of living beings. This amendment introduced Chapter IV dealing with exclusive marketing rights in the Patents Act, 1970.

## Patents (Amendment) Act, 2002

The second patent amendment to the 1970 Act was made through the Patents (Amendment) Act. 2002 (Act 38 of 2002). This Act came into force on 20th May 2003 with the introduction of the new Patent Rules, 2003 by replacing the earlier Patents Rules, 1972. This amendment has not only made the products patentable but also various processes were brought under the subject matter of patentability. However, prior to this Amendment Act of 2002, microorganisms and living beings such as plants and animals produced through non-biological or microbiological processes such as biotechnological processes do constitute patentable subject matter. India has amended her patent law in 2002, to bring life and living beings created through biotechnology within the purview of patentable subject matter.

The main changes brought by this Act are as follows: -

i. The definition of the term 'invention' was modified in consonance with the international practices and consistent with the TRIPS Agreement.

ii. The Uniform term of patent protection of 20 years for all categories of invention as per Article 33 of the TRIPS Agreement was prescribed by this Amendment Act. Further, the time for restoration of a ceased patent under Section 60 has now increased from 12 months to 18 months; as such an application for restoration of a patent ceased on or after 20th May, 2003 can be filed within 18 months from the date of ceasing.

iii. Until this amendment, there was no provision for the burden of proof in case of infringement. But this Amendment Act has added a provision for reversal of burden of proof in case of infringement, suit on process patent, in accordance with Article 34 of the TRIPS Agreement.

iv. The provision relating to compulsory licensing was modified to suit the requirements of the public interest and also to comply with the TRIPS Agreement.

v. A provision was incorporated for enabling parallel importation of patented products at the lowest international prices.

## The Patent Amendment Act, 2005

After the second amendment in the Patents Act, 1970, the third Amendment to the Parents Act, 1970 was introduced through the Patents (Amendment) Ordinance, 2004[126]. This Ordinance was later replaced by the Patents (Amendment) Act, 2005 (Act 15 of 2005) on 4th April,2005 which was brought into force from 1 Jan 2005. This amendment was made to recognize the obligations of the Budapest Treaty[127]. This treaty has mandated that if the invention involves microorganisms, a deposit of biological material must be made in a recognised institution. India is also a signatory of this treaty[128]. Thus according to this treaty, if the invention uses biological material and it is not already known, then it has to be submitted at the International Depository Authority not later than the date of making patent application in India and a reference

[126] The Patents (Amendment) Ordinance, 2004, Gazette of India, Extraordinary, Part II, Section 1, No. 7, Jan. 1, 2005

[127] Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, Apr. 28, 1977, 1015 U.N.T.S. 57

[128] India, Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, Apr. 28, 1977, 1015 U.N.T.S. 57

thereof shall be made in the specification within the time period of three months from the date of filing of the application.

The purpose of this deposition was that every complete specification shall fully and particularly describe the invention and its operation or use and the method by which it is to be performed and shall also disclose the best method of performing the invention. In India, there is one International Depository Authority (IDA) at Chandigarh which is known as the Institute of Microbial Technology (IMTECH) and other is at Microbial Culture Collection (MCC), Pune Access to the material is available in the depository institution only after the date of the application of patent in India or if a priority is claimed after the date of the priority[129]. The features of this Amendment Act are as follows-:

i. This amendment has again defined the term 'invention' and held that "mere new use for a known substance" is not an invention[130].
ii. The most important feature of this Act was that the provision which prohibits product patents for food, medicine, drug and chemical processes has been removed. Thus, after this amendment the product patent regime in respect of drug, medicine, food and chemical processes is implemented in India.
iii. Section 9 of the Patents Act, 1970 was amended and it provided that if the patent application is accompanied by a provisional specification, the complete specification should be filed within 12 months of filing of the application. Otherwise, the application shall be deemed to be abandoned.
iv. Provisions relating to the Exclusive Marketing Rights (EMRs) have been removed. EMR provision was introduced in India with the Amendment Act of 1999 in order to comply with the provision of TRIPS as a product patent for drug and medicine was not available in the Indian Patent Act. But this Amendment to the Patent Act has provided that the product patent for the Drugs, medicines, food, and chemical processes should be granted, thus EMR provision has become redundant and has been repealed.
v. Another important amendment was that the Act has provided the appeal provision from the decision of the Controller to the Intellectual Property

[129] Indian Patent Office, Guidelines for Examination of Biotechnology Applications, Form I, §3.2.1 (2020)
[130] Patent Act, 1970, §3(d), as amended by the Patent (Amendment) Act, 2005

Appellate Board (IPAB). Further, the power of revocation is conferred with IPAB.

Thus, India has complied with all the requirements of the TRIPS Agreement but still India is lagging behind the other countries in respect to patent on the gene.

## 4.5 TRIPS and Patents Act,1970

The TRIPS Agreement is an international treaty which introduced intellectual property law into the international trading system for the first time and remains the most comprehensive international agreement on intellectual property to day. This Agreement is administered by the World Trade Organization (WTO). The Agreement to TRIPS provides detail criteria of patentability in Article 27, which states: "...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". However, the basic principle which formulates the nature and scope of obligations under the Agreement on TRIPS mandatorily confers an obligation on the members to give effect to its provisions[131].

The TRIPS Agreement has not laid down any patentable subject master, but it has provided What is to be excluded from patentability. The TRIPS Agreement is also silent on the fact that whether naturally occurring materials are to be excluded or not from patentable subject matter[132]. Being the signatory to the TRIPS Agreement, India has to comply with the provisions of the TRIPS and it faced the major challenge in respect of patenting of ice Inventions. The Mashelkar Committee was constituted in order to deal with this situation. The Mashelkar Committe has interpreted the terms 'microorganisms" and "essentially biological process', referred in the TRIPS Agreement. Therefore, the Patents Act, 1979 was reviewed. With the amendments made in the Patents Act, 1970, there emerged the era of patenting the biotechnological inventions in India.

Thus, in the present scenario, merely discovering a gene in its natural environment will not attract any patent. In order to be eligible to be granted a patent, it is essential

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[131] Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations (Marrakesh, 1994), 33 I.L.M. 1125 (1994)

[132] Khor M, Intellectual Property, Biodiversity and Sustainable Development: Resolving the Difficult Issues (Zod Books, United Kingdom 2002) 70

that the gene should be isolated from its natural environment and it should be meet the requirements of patenting like novelty, utility and human intervention. Thus, the patenting of plants, animals, microorganisms and isolated human genetic material including the products of such genetic material such as proteins are patentable. However, research in the human genetics is not lagging behind. In order to regulate the human genetics, the Indian Council of Medical Research (ICMR) brought guidelines to regulate the research in human genetics. These guidelines are related to the ethical issues related to the human genetics and intended to safeguard the ethics and human rights in the human genetic research. However, it should be noted that there is no legislation in relation to the human genetics. Therefore, these guidelines work as a milestone in order to maintain the harmony in the society.

However, the tremendous capability of the scientists to manipulate the genetic material bas required the Government to think about the safety considerations, this resulted in the evolution of the Recombinant DNA Safety Guidelines by the Department of Biotechnology. The Department has also set up the Recombinant DNA Advisory Committee (RDAC) for this purpose. The guidelines are related to the research area involving-

i. Genetically engineered organisms,
ii. Genetic transformation of green plants, animals,
iii. rDNA technology in the vaccine development
iv. Large Scale production and deliberate/ accidental release of organisms, plants, animals and products derived by rDNA technology,

Thus, we can say that the DNA safety guidelines intends to ensure safety in using, storing of DNA and genes in research in biotechnology. So, it can be inferred that as far as biotechnology and its regulation is concerned India is not lagging behind too far as it has got considerable legal mechanism to patent, regulate and to monitor biotechnology inventions.

## 4.6 Patentable subject matter under the Patents Act,1970

It is globally accepted that only inventions are patentable but not discoveries. There is also a clear distinction between the invention and discovery as the invention involves

three requirements novelty, innovation and non-obviousness and also the presence of human intervention in case of biological matter. The Indian Patents Act, 1970 was enacted on the frame of the TRIPS Agreement, that's why Indian Patents Act, 1970 does not lay down any provision regarding the subject matter of patent, instead it does provide for the subjects that are not patentable. The Patents Act provides for an illustrative list which deals with the subject that is not patentable. Thus, in order to get the patent, an invention must meet two requirements laid down by the Patents Act, 1970. The first one is that it must not fall in any of the categories specifically excluded under Section 3 of the Patents Act and another is the globally followed test of novelty, inventive step and industrial applicability. Thus, Section 3 deals with the subject matter, which does not fall within the purview of the illustrated list, does constitute a patentable subject matter. After the ratification of the TRIPS Agreement, the contents of this list were updated and modified to comply with the provisions of the TRIPS Agreement.

## Section 3(b) - Inventions contrary to public morality

Section 3(b) of the Patents Act, 1970 provides that the inventions for which the primary or intended use or commercial exploitation is contrary to public order or morality or which cause serious prejudice to human, animal or plant life or health or to the environment are unpatentable. This section explicitly forbids the inventions which causes the adverse impact on the environment and also result in the suffering of the modification of animals which results in the suffering of the modified animal without any substantial medical or other benefit.

## Section 3(c)- Discoveries, things isolated from nature, plants and animals

Section 3(c) of the Patents Act, 1970 provides that the discoveries of the living things or non-living substances occurring in nature are not patentable subject matter. This section imbedded the concept of doctrine of product of nature, which concludes that the microorganism occurring in the nature, and DNA, RNA or proteins isolated from living organisms are unpatentable. should be kept in mind that the natural occurring

microorganisms are unpatentable, but the genetically modified microorganisms and vaccines are patentable, subject to other requirements. The Act of 1970 was amended in 2002 to include "biochemical, biotechnological and microbiological processes" within the definition of potentially patentable chemical process. So as per the modified definition of the chemical process, it is implied that biotechnological processes and products of such processes are unambiguously patentable. However, there is no decided case law in India on the patentability of the biotechnological inventions.

The Patents Act, 1970 is very restrictive in nature, the essential biological processes for the production of the plants or animals (namely, conventional methods of plant breeding and tissue culture techniques) are also unpatentable. However, the Act does not define the expression "essential biological processes" but in Monsanto (2013), the Intellectual Property Appellate Board (IPAB) provided some guidelines on what constitutes the essential biological processes. It held that, "Mere use of admittedly known substance is not permitted under Section 3(d). The argument of surprising result will not change the position as it will be still be a new use of known even if it produces better results."

## Section 3(d) - New Forms or Uses of known Substance

A new form of a known substance is unpatentable unless it differs significantly in properties with regard to the known efficacy. This is somewhat a prohibitory provision which restrict the inventors in getting patent just by making the trivial modifications in the existing one. The Supreme Court of India has provided some guidelines for the interpretation of the scope of this section in the landmark and most recent case, *Novartis AG v. Union of Indigos*[133]. This case began in the year 1997 with the patent application filed by the petitioner before Chennai Patent Office related to drug name GLIVEC which was slightly different version of their 1993 patent for ANTI LEUKAMIA drug. So, the Assistant Controller of Patent and Design, Chenai Patent Office rejected the application under Section 3(d) of the Patents Act, 1970. So, the applicant has appealed in the Madras High Court and challenged the

[133] (2013) 6 SCC 1

constitutionality of Section 3(d) of this Act. But the Madras High Court has upheld the constitutionality of Section 3(d) and confirmed the decision of the Assistant Controller of Patent and Design. Being unsatisfied, the applicant appealed to the Supreme Court where it was observed that the term "efficacy" has not been defined in the Act, but the term "efficacy" is used to mean "the ability to produce a desired or intended result." The efficacy test depends on the function, utility or purpose of the product under consideration. A mere change of form of a chemical substance with properties inherent to that form would not qualify as enhancement of "efficacy" of a known substance. Therefore, it was found that the Novartis' patent application for the beta-crystalline form of Imatinib Mesylate (polymorph B) did not pass the test of Section 3(d) as it did not have any therapeutic efficacy.

Thus, the Apex Court of India has also confirmed the decision of the Madras High Court and rejected the patent application of the petitioner. The Chennai High Court remarked: "As we stated earlier, due to the advanced technology in all fields of science, it is possible to show by giving necessary comparative details based on such that the discovery of a new form of known substance had resulted in the enhancement of the known efficacy of the original substance and the derivative so derived will not be same substance, sine the properties of the derivates differ significantly will regard to efficacy[134]. "In *Monsanto (2013)*[135], a claim for a method of producing heat, salt and drought-tolerant transgenic plant using cold shock protein was already known in the art. So, the patent claim was rejected by the Intellectual Property Appellate Board of India.

## Section 3(e) - mere admixture

The mere admixture of two or more previously known substances is unpatentable, unless it is shown that the combinative effect of such substances is more than the sum of the individual effect, Similarly, Section 3(i) of the Patents Act, 1970 precludes from patentability- any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings; or any treatment of animals which tender them free of disease or increase their economic value. Methods

[134] *Id*
[135] 569 U.S. 278 (2013)

of agriculture or horticulture are also considered unpatentable under the Patents Act, 1970,

Thus, the main object of these amendments was to bring under the Act the regulations of the TRIPS and to extend the scope of the Act to protect plants, animals and human beings. It is important to note that all the above-mentioned sections have a direct impact on the protection of biodiversity. Therefore, a check on the use of the technology must be done from time to time.

## 4.7 Patenting microorganism

It is accepted in almost all countries that naturally microorganisms are not patentable but with the intervention of humans, microorganisms are also patentable. Section 3(j) of the Patents Act allows for patents for microorganisms. For the first time in Indian history, the permissibility of patenting microorganisms was considered in *Dimminaco AG v. Controller of Patents and Design*[136]*s*, a case involved an invention relating to a process for preparation of infectious Bursitis vaccine for protecting poultry. The Assistant Controller of Patents and Designs rejected the application on the ground that it did not constitute an invention under Section 2(1)(1) of the Patents Act, holding that the process of preparing the vaccine which contains a living virus cannot be considered as 'manufacture' under the old definition of invention The Assistant Controller further held that the vaccine with living organisms cannot be considered a substance. An intimate object can be described as a thing or item but not as a living one. Further, it was held that a living micro-organism cannot be considered as an intimate aspect as it cannot convert physically or chemically to any other product.

On appeal, the Calcutta High Court has reversed the decision of the Assistant Controller and said that the Controller erred himself by holding that merely because the end product contains a live virus, the process involved in bringing out the end product is not an invention. It was held that there is no statutory bar to accept a manner of manufacture as a patentable even if the end product contains a living organism. The said vaccine is useful for protecting poultry against contagious Bursitis infection. Therefore, it is new process and such process is apparently patentable under

[136] 447 US 303 (1980)

Section 5 read with Section 2(i)(i) of Patents Act. Therefore, where the end product is a new article, the process leading to its manufacture is an invention. Thus, this case has paved way for the grant of patent on the living process in India.

Till date except the *Dimminaco case*[137], there is no a substantive case law or patent office report or records in India on the patenting of biotechnological inventions. Indian Patent practice and jurisprudence with respect to the patenting of biological material (mainly antibodies) are relatively new and thus not so well-settled or uniform. But as the research projects are going on, it can be assumed that in future there may be judicial pronouncements and patent office reports on the patenting of biotechnology inventions that will turn India into a biotech hub in the near future. Since there is high level of research and development in India, so there will be definitely growth in the biotech industry. Moreover, the Indian Government has always supported and promoted by announcing special assistance and scholarships for studies and research in biotechnology to boost expertise and man power in this sector. Recognizing the significance of the upcoming sector of biotechnology in the present world, the Government of India has come out with certain strategic plans to boost the biotechnological industries.

## 4.8 Overview of the European Patent system and its approach to gene patenting

### European Patent System

The European Patent System is governed by the European Patent Convention (EPC), which established the European Patent Organisation(EPO) in 1973. The EPO provides a centralised procedure for patent applications, enablinng inventors to obtain patent protection in multiple European countries through a single application process.

### Key Features:

i. **European Patent Convention (EPC):** The legal framework for patent law in Europe, governing the granting of European patents.

[137] 447 US 303 (1980)

ii. **European patent Office (EPO):** The body responsible for examining and granting European patents.
iii. **Patent Cooperation Treaty (PCT):** Allows for an international phase of patent application, which can later enter the European phase.
iv. **Member States:** There are 39 member states of the EPO, covering almost all of Europe.
v. **Unitary Patent System (UPS):** An initiative to provide uniform patent protection across participating EU member states with a single patent.

## Gene Patenting in Europe:

Gene patenting involves the granting of patents for specific sequences of DNA, genes, or the methods of using them. The approach to gene patenting in Europe is guided by the EPC, biotechnology directives, and various case laws.

## Legal Framework:

i. **Directive 98/44/EC (Biotech Directive):** This directive specifically addresses the legal protection of biotechnological inventions.
ii. **Article 52 EPC:** Sets out the requirements for patentability, stating that inventions must be new, involve an inventive step, and be susceptible of industrial application.
iii. **Exclusions from Patentability (Article 53 EPC):** Certain inventions are excluded from patentability, including discoveries of natural substances as they exist in nature.

## 4.9 Examination of the European Union (EU) directives and regulations concerning gene patents.

The European Union (EU) has a comprehensive framework for regulating gene patents, balancing the protection of biotechnological inventions with ethical

considerations. The key legislative instruments governing gene patents in the EU are the Biotechnology Directive (Directive 98/44/EC) and various regulations from the European Patent Convention (EPC). Here is a detailed examination of these directives and regulations:

## Biotechnology Directive

### Overview:

Adopted on July 6, 1998, the Biotechnology Directive is the cornerstone of EU legislation on the patenting of biotechnological inventions, including gene patents. It aims to harmonize the laws of the Member States concerning the patentability of biotechnological inventions.

### Key Provisions:

- **Patentability:**
  - Article 3(1) states that biological material which is isolated from its natural environment or produced by means of a technical process may be patentable even if it previously occurred in nature.
  - Article 5(1) clarifies that the human body, at various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot be patented.
  - However, Article 5(2) allows for patents on elements isolated from the human body or otherwise produced by means of a technical process, including gene sequences, provided the industrial application of the sequence or its partial sequence is disclosed.
- **Ethical Considerations:**
  - Article 6(1) excludes from patentability inventions whose commercial exploitation would be contrary to ordre public or morality.
  - Article 6(2) specifically lists processes for cloning human beings, modifying the germ line genetic identity of human beings, uses of human embryos for industrial or commercial purposes, and processes for modifying the genetic

identity of animals which are likely to cause them suffering without substantial medical benefit to man or animal.

- **Scope and Protection:**

– Article 9 provides that the protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall extend to any biological material derived from that material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

– Article 10 extends this protection to products containing or consisting of genetic information, with the protection covering all material in which the product is incorporated and wherein the genetic information is contained and performs its function.

## European Patent Convention (EPC)

## Overview:

- The EPC, established by the European Patent Organisation (EPO), is an international treaty providing a legal framework for the granting of European patents. It aligns closely with the Biotechnology Directive concerning biotechnological inventions.

## Key Provisions:

- **Patentable Inventions:**

- Article 52 EPC stipulates that European patents shall be granted for any inventions which are susceptible of industrial application, are new, and involve an inventive step.

- Rule 29(2) (now Rule 27 in the amended EPC) explicitly allows for the patenting of elements isolated from the human body or otherwise produced by means of a technical process, including sequences or partial sequences of genes.

- **Exclusions from Patentability:**

- Article 53(a) EPC excludes inventions from patentability if their commercial exploitation would be contrary to "ordre public" or morality. This includes the same ethical considerations outlined in the Biotechnology Directive.

- **Disclosure Requirements:**

- For gene patents, the industrial application of a gene sequence must be disclosed in the patent application, ensuring that the use of the sequence is clear and specific.

- **Case Law and Ethical Implications**

## Case Law:

- European case law has further clarified the application of these directives and regulations. Notable cases include the "Onco-mouse" and the "Harvard/Onco-mouse[138]" case[139]h, which dealt with ethical issues surrounding the patenting of genetically modified animals.

- The Brüstle v. Greenpeace[140] addressed the patentability of inventions involving human embryonic stem cells, emphasizing ethical boundaries.

- **Ethical Considerations:**

- The EU framework reflects a careful balance between promoting biotechnological innovation and addressing ethical concerns. This is evident in the explicit exclusions from patentability and the requirements for industrial applicability and specific disclosures for gene sequences.

## 4.10 Comparative analysis of European Patent Office (EPO) decisions and their alignment with national laws.

Conducting a comparative analysis of European Patent Office (EPO) decisions and their alignment with national laws involves examining how the EPO's rulings integrate with and influence patent law across various European countries.

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[138] supra note 10
[139] SCC Case Information - Docket 28155, Supreme Court of Canada
[140] Case C-34/10, [2011] ECR I-6013 (E.C.J.)

- ## Introduction to the EPO and National Patent Systems

The European Patent Office (EPO) serves as a centralized authority for granting patents that are recognized and valid across multiple European countries. Established to streamline the patent application process and ensure consistency in patent standards, the EPO operates under the framework of the European Patent Convention (EPC).

Under the EPC, uniform standards for patentability and procedural rules are established, providing a cohesive framework for patent applications and grants. This harmonization allows inventors and innovators to seek patent protection for their inventions across multiple European countries through a single application process.

In addition to the EPO, individual European countries maintain their own national patent systems, each governed by distinct sets of national laws. While these national laws must align with the principles and standards outlined in the EPC, they may also incorporate unique provisions tailored to the specific needs and legal traditions of each country. These national patent systems play a crucial role in the administration and enforcement of patents within their respective jurisdictions, working in conjunction with the overarching framework provided by the EPC and the EPO.

- ## Methodology for Comparative Analysis

In selecting cases for comparative analysis, it's important to choose a diverse yet representative sample of EPO decisions across various technical fields and legal issues. This ensures a comprehensive understanding of patent law and practice within the European patent system. Similarly, corresponding national court rulings should be identified for comparison, focusing on cases involving similar patentability criteria, procedural aspects, enforcement proceedings, and appeals processes.

**Criteria for Comparison:**

- **Patentability:** Assessing the patentability criteria of novelty, inventive step (non-obviousness), and industrial applicability across both EPO decisions and national court rulings. Analyzing how these criteria are interpreted and applied in each jurisdiction can highlight differences or similarities in legal standards.
- **Procedural Aspects:** Comparing procedural aspects such as filing requirements, examination procedures, and opposition proceedings between

the EPO and national courts. This includes examining differences in timelines, evidentiary requirements, and the role of stakeholders throughout the patent application and grant process.

- **Enforcement and Infringement Proceedings:** Evaluating the enforcement mechanisms and infringement proceedings in both the EPO and national courts. This involves analyzing the legal remedies available to patent holders, the burden of proof in infringement cases, and the remedies for patent infringement, including injunctive relief and damages.
- **Appeals and Revocation Processes:** Examining the appellate processes and mechanisms for patent revocation or invalidation at the EPO and national court levels. This includes reviewing the grounds for appeal, the standard of review applied by appellate bodies, and the impact of appellate decisions on patent rights and enforcement.

By systematically comparing EPO decisions with corresponding national court rulings based on these criteria, researchers can identify legal trends, disparities, and best practices within the European patent system. This comparative analysis facilitates a deeper understanding of the complexities and nuances of patent law and practice across different jurisdictions, ultimately contributing to more informed policymaking and legal decision-making processes.

- ## Patentability Criteria

In examining a case example related to biotechnology patentability, we can focus on a hypothetical scenario where the European Patent Office (EPO) grants a patent for a biotechnological invention based on its assessment of novelty and inventive step. The case involves a novel method for genetically modifying a particular plant species to enhance its resistance to common pests.

**EPO Decision:**

The EPO, applying uniform patentability criteria across its member states, grants the patent after a rigorous examination process. The decision highlights the innovative aspects of the invention, emphasizing its novelty and non-obviousness compared to existing techniques. The EPO's decision is based on thorough documentation and

evidence provided by the patent applicant, demonstrating the uniqueness and inventive merit of the claimed invention.

**National Interpretations:**

Following the EPO's decision to grant the patent, national courts in Germany, France, and the UK may encounter legal challenges or disputes related to the validity or infringement of the patent within their respective jurisdictions. While these countries align their patent laws with the European Patent Convention (EPC), they may have nuanced interpretations or case law specific to biotechnological inventions.

In Germany, for instance, the Federal Patent Court may review the EPO's decision and consider any relevant German patent law or case precedents that could impact the validity or enforcement of the patent. Similarly, French and UK courts may assess the patent's compliance with national laws and regulations, including any legal requirements or limitations specific to biotechnological patents.

**Comparative Analysis:**

By analyzing how Germany, France, and the UK interpret and enforce the EPO decision on the biotechnology patent, researchers can identify commonalities and differences in legal standards, procedural practices, and judicial interpretations across these jurisdictions. This comparative analysis provides insights into how national courts apply patentability criteria such as novelty and inventive step in the context of biotechnological inventions, contributing to a deeper understanding of patent law harmonization within Europe.

- ## Procedural Aspects

In exploring the procedural aspects of filing, examination, opposition, and appeals in the context of patent applications, we can delineate the key features of both the European Patent Office (EPO) and national patent systems within European countries.

**Filing and Examination:**

The EPO offers a centralized filing process, allowing applicants to submit their patent applications to a single authority for examination. This streamlines the initial filing process and ensures consistency in the evaluation of patent applications across member states. However, applicants also have the option to file patent applications directly with national patent offices in individual countries. While filing through the EPO is advantageous for obtaining patents valid in multiple countries, local offices may have additional procedural requirements or documentation specific to their jurisdiction.

**Opposition and Appeals:**

At the EPO, third parties have the opportunity to oppose a granted patent within nine months of its grant. This opposition process provides a mechanism for challenging the validity of a patent after it has been granted, allowing interested parties to raise objections based on grounds such as lack of novelty or inventive step. In contrast, national patent systems may have varying processes and timelines for filing oppositions and appeals. Each country's patent laws dictate the procedures for challenging granted patents, including the grounds for opposition, the timeframe for filing, and the appellate review process. As a result, the opposition and appeals procedures in national patent systems may differ in terms of their complexity, efficiency, and outcomes compared to those of the EPO.

By examining the filing, examination, opposition, and appeals procedures at both the EPO and national patent offices, researchers can gain insights into the differences and similarities in the patent prosecution process across European jurisdictions. This comparative analysis helps elucidate the advantages and challenges associated with navigating the patent system at both the regional and national levels, contributing to a broader understanding of patent law and practice in Europe.

- ## Enforcement and Infringement

In exploring the aspects of enforcement and infringement within the context of patent law, it's essential to understand how enforcement mechanisms operate at both the European Patent Office (EPO) and the national level in European countries.

**Enforcement:**

At the EPO, enforcement of patents is not within its purview; instead, it falls under the jurisdiction of national courts in each member state. National patent laws govern the procedures and remedies available for patent infringement, including the granting of preliminary injunctions, awards of damages, and other forms of relief. Each country's legal system may have its own set of rules and procedures for patent enforcement, reflecting the broader legal landscape and judicial practices of that jurisdiction.

**Infringement:**

Interpretation of patent claims, particularly regarding the scope of protection conferred by a patent, can vary between jurisdictions. While patent claims are construed according to established principles of patent law, differences in legal traditions, case law, and judicial interpretations may lead to divergent outcomes in infringement cases. Consequently, the same patent asserted in multiple countries may encounter differing interpretations and enforcement outcomes, highlighting the importance of understanding the nuances of patent law across different jurisdictions.

By examining enforcement mechanisms and infringement proceedings both at the EPO and within national courts, stakeholders can gain insights into the complexities of patent enforcement in Europe. Understanding the interplay between regional and national enforcement frameworks is crucial for effectively protecting intellectual property rights and navigating patent disputes in the European market.

- ## Appeals and Revocation

In examining the appeals and revocation processes within the European patent system, it's essential to understand the mechanisms available at both the European Patent Office (EPO) and the national level in various European countries.

**EPO Appeals:**

The EPO provides a centralized appeal process through its Boards of Appeal. Parties dissatisfied with decisions made by the EPO's Examining Division, Opposition Division, or other departments can appeal to the Boards of Appeal for a review of the decision. The Boards of Appeal operate independently and have the authority to overturn, uphold, or amend decisions made by the lower instances within the EPO.

**National Laws:**

In addition to the appeal process available at the EPO, national patent laws in European countries may provide separate mechanisms for revocation proceedings. These proceedings typically involve challenges to the validity of a granted patent and can be initiated before national courts or specialized patent offices. Unlike the centralized appeal process at the EPO, national revocation proceedings may lead to different outcomes depending on the legal standards, procedural rules, and judicial practices of each country.

By comparing EPO appeal procedures with national revocation proceedings, stakeholders can gain a comprehensive understanding of the mechanisms available for challenging patent validity and seeking redress in cases of dispute within the European patent system.

- ## Harmonization and Divergence

In the context of the European patent system, efforts towards harmonization are aimed at creating consistency and coherence in patent law and procedures across different jurisdictions within Europe. These efforts are particularly crucial for promoting legal certainty, reducing administrative burdens, and facilitating innovation and commerce in the region.

**Harmonization Efforts:**

**European Patent Convention (EPC):** The EPC serves as the primary instrument for harmonizing patent laws and procedures among its member states. By establishing uniform standards for patentability, examination, and enforcement, the EPC fosters a cohesive framework for patent protection across Europe.

**Unified Patent Court (UPC):** The establishment of the UPC represents a significant step towards further harmonization of patent litigation in Europe. The UPC is envisioned as a specialized court system with exclusive jurisdiction over European patents and Unitary Patents, providing a centralized forum for resolving patent disputes. By offering a single judicial authority and a uniform set of procedural rules, the UPC aims to streamline patent litigation and enhance legal certainty for patent holders and challengers alike.

**Divergence Issues:**

**National Legal Traditions:** Despite the harmonization efforts facilitated by the EPC and the UPC, differences in national legal traditions and practices persist among European countries. These variations can influence the interpretation and application of patent law, leading to divergent outcomes in patent disputes across different jurisdictions.

**Judicial Interpretations:** National courts retain significant autonomy in interpreting and applying patent law within their respective jurisdictions. Variations in judicial interpretations, case law, and procedural practices may contribute to divergent outcomes in patent litigation, even for patents granted by the EPO under the unified European patent system.

By acknowledging both the harmonization efforts and the persistent challenges of divergence, stakeholders in the European patent system can better navigate the complexities of patent law and litigation across Europe. Continued collaboration and dialogue among stakeholders, as well as ongoing efforts to enhance harmonization mechanisms, will be essential for promoting a cohesive and efficient patent system in the region.

# CHAPTER-5 CONCLUSION

5.1 Summary of key findings from the study.

5.2 Suggestions

## 5.1 Summary of key findings from the study.

The journey of patenting genes is always a fascinating one - a twisting tale of science, money, culture, and courts, where the advancement of new technology brings new problems. At the same time, it is globally accepted that human ingenuity should not only get liberal encouragement but also it should be identified and recognized through rewards. The inventions in the field of genes are the result of human ingenuity to biological processes. But this reward for human ingenuity comes in the form of monopoly. That's why, some economists argued that intellectual property rights,

including patent law, do not increase either innovation or creation and they are unnecessary evil.

However, the commencement of the law relating to patenting of living beings could be traced during the year of 1893, in which United States Patent Office had granted patent to Louis Pasture for the fermentation process of beer using the yeast. But it must be remembered that the patent was granted on the brewing of the beer using yeast and not distinctly on the yeast. So, in this case, patent was granted on the method involving living organism, but the patent was not granted on the living being. Indeed, this decision has encouraged scientists and research and given them hope for the wide interpretation of Patent law.

But the foundation of the patenting of the genes can be traced in the year 1980 in Chakrabarty case[141], where the Supreme Court of America had granted patent on the oil eating spills. The Court had found that the claim was the result of human ingenuity, having distinctive name, character and use. In this case, for the first time, human intervention was recognised as a ground for creating disparity between the product of nature and the product of man. Thus, for the first time, a patent was granted on genetically modified bacteria. This decision had opened the new era of patenting of the living organism and thus, completely turned out the traditional patent philosophy which is against the patenting of the living beings. This decision has attracted lot of public debate because the liberal interpretation to the Patent Law was given by the Supreme Court of America. Further, the Supreme Court of America also held that naturally occurring bacteria are outside the scope of patent but the genetically modified bacteria are subject matter of patent if they fulfill all the requirements of invention.

This decision had not only given new direction to interpretation of Patenting of living beings in US but also liberal approach in the interpretation of the Patent laws was followed in the European Union. So, the foundation was laid down with the patenting of microorganisms that had ended with the patenting of different living beings like transgenic animals, plants and the human cell lines and genes.

Another breakthrough was the TRIPS, an International Agreement which was negotiated as part of the eight round of multilateral trade negotiations in the period of

[141]447 U.S. 303 (1980)

1986-1994 under General Agreement on Tariffs and Trade (GATT), commonly referred as the Uruguay Round. The importance of this Agreement lies in the fact that this Agreement has brought the uniform patent law on the biotechnological inventions throughout the world. This Agreement has widened the scope of the patent law by providing that the patents shall be available for any invention and that patent rights shall be enjoyable 'without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced. Further, this Agreement has also mandated that all the member countries have to comply with the provisions of the TRIPS Agreement. The TRIPS Agreement also provides that the subject matter of patent must fulfill the traditional requirement of patentability such as novelty, inventive step and industrial application.

To put it simple, TRIPS Agreement has allowed the patenting of the transgenic plants and animals but not the wild plants and animals because they lack the industrial application. But it is globally accepted that the transgenic human beings would not be patentable. The philosophy behind rejecting the patent of transgenic human beings is that commercialization and monopolization over human beings can't be allowed. Further, according to Kant, human being is a rational being exist an end in itself and not merely as a means to an end. The claim of gene patents are not absolutely innovative because genes exist in nature and are considered as the product of nature, thus gene can be discovery and not the invention. In order to make gene as the subject matter of patent, it is accepted that there should be human intervention to the gene. However, it is difficult to invent in the field of gene patent as the invention is always dependent on the product of nature.

Earlier there was diversity on the subject matter of patent and also conflicts of the patent laws among the countries. Therefore, a number of international tries were signed Paris Convention, the Patent Cooperation Treaty, 1970; the Strasbourg Agreement Concerning the Cons Patent Classification, 1971; and the Budapest Treaty[142] on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, 1977. But one thing is common amongst these treaties that they had kept the living organisms beyond the subject of patentability. The reason was that the living organisms were considered to be the "common heritage of

[142] supra note 123

mankind and not considered to be patentable. Therefore, the major advancement has done by the TRIPS Agreement which allowed the patenting of all inventions, including the transgenic plants and animals.

However, courts had also favored the denial of patents on the living beings by applying the Doctrine of Product of Nature. This doctrine has rejected all the organisms and substances that occur in nature from the patentability criterion because they already occur in nature and could be considered as discovery and not invention. Another reason for applying this doctrine is that the living beings cannot be owned by anyone because they are created by the nature. The matter which is created by nature cannot be monopolized to anyone because everyone has equal right on the natural resources. But the United States Supreme Court was very liberal in interpreting its patent law, and therefore granted a number of patents on the living organisms including the microorganisms, transgenic plants and transgenic animals. The US Supreme Court has always focused on the inventive step and innovation of the patent claim.

In India, inventions in the field of biotechnology has commenced later than in United States and European Union. Apart from this, the Patents Act, 1970 provides no inclusive definition of patentable subject matter, but provides only a list of unpatentable subject matter. Unfortunately, these exceptions in respect of the biotechnological inventions are vague and lead to uncertainty, because the biotechnological inventions are the association of human ingenuity and the product of nature. The turning point in the history of patenting of living organism came in the year of 2001, in case Dimminaco AG v. Controller of Patents and Designs[143], where the Supreme Court of India has allowed the patenting of process for the preparation of infectious Bursitis Vaccine. It was found that the said vaccine is useful for protecting poultry contagious Bursitis infection and process involving the manufacture of vaccine is an invention, even though the end product contains the living organisms. Thus, this case has given the hope to the scientists and the researchers to get the patent protection involving human ingenuity and resulting in the biotechnological inventions. With the ongoing progress in research in the field of gene patents, there

[143] supra note 136

will be definitely growth in the biotech industry and India will have great hub of patents related to the biotechnological inventions.

Meanwhile the ethical and moral considerations influence the law of the society. Therefore, gone patenting has also to qualify the ethical standards of the society. Ethical standards provide that the patenting of gene amounts the privatizing and owing life as a property, therefore gene patenting is considered as morally wrong. Ethicists say that patenting of life amounts owing private property rights over life, making life as market commodity. But living beings are considered as the creation of the God and they can't be monopolized and commercialized by anyone. Patenting living beings amounts to slavery, and which is against the dignity of living beings. By granting patents, we are making the patent holder as the owner of the living beings and patent holder would have full right to exploit its patent claim for particular time period. Further, grant of patent means the exclusion of property from the public domain and the right over that property goes to the patent holder. Further, it also opined that patenting and owning genetic material of human beings amounts to holding them in slavery.

However, if we consider these ethical and moral considerations of the society then we will surely undermine the development in the field of biotechnology. Therefore, we have to ignore these obsolete moral standards of the society in order to enhance the development of the gene patenting. Meanwhile it must be remembered that we cannot complete ignore these moral and ethical considerations of the society, otherwise it will cause imbalance in the society. So, there must be a balance between the ethical standards of the society and the patenting of the biotechnological inventions. This infers that all the biotechnological inventions cannot be patented because we cannot absolutely ignore the ethical standards of the society. The best illustration on this point is that we cannot allow the patenting of the transgenic human beings or the patenting of the human genome. It is true that we have reached to that stage of development that we are capable to develop anything through the biotechnology but all cannot be patented by sacrificing or ignoring the ethical and moral standards of the society. So, we can say that the ethical and moral considerations of the society act as the check and balance for the patenting of the biotechnological inventions. Now, there can be question that why we put different ethical standards while patenting of the microorganisms, plants and animals from that of patenting of the transgenic human

beings. The reason is quite simple that in case of the intenting of transgenic animals and plants, the incurring profits to the society undermine the ethical standard, whereas in case of transgenic human beings and human embryos, ethics overweigh the incurring benefits.

## 5.2 Suggestions

Patenting of gene recognizes the efforts of the inventor and allows the patent holder in do the further research without any competition. The inventors have not to worry that others may get recognition on his claim. It encourages the research and development in the field of game patenting. The lure of the patent pushes the researchers and the scientists to think more creatively and work harder in order to obtain a patent for their work.

Moreover, gene patenting brings the financial support in order to carry out further research. because after the invention of the new drug, patent holder can take hundreds of millions of dollars to introduce that drug into market. Without gene patenting, it would be possible for a company to copy the potential research and develop the similar therapies without the same level of investment.

Despite the above advantages, there are some disadvantages like, gene patenting slows down the medical results, because if a company holds a gene patent, they own sole rights to research and testing on that gene. So, if a patient has a test done on that gene, the samples must be sent to the company owing the gene patent in order to be tested. This philosophy was applied by the judges in rejecting the patent claim in Myriad case. Moreover, it is also assumed that if we allow gene patenting with any restrictions then any high possibility of misusing the potential of genes in producing destructive biological weapons against social order.

Further, there is a possibility of producing a transgenic human being by abusing biotechnology in violation of public order and morality. There expected doubts that given the potential of the biotechnology there might have produced transgenic human being already. Gene patenting also gives monopoly to the patent holders over the claim that have the exclusive right to use it and exploit it. Thus, it gives the patent holder the right, to hinder the research and public access on his patented gene.

The important problem is that gene patenting hikes the prices of the medicines, and there would be one source of the manufacture of the medicines to meet out the needs of world population, which is highly impossible. Furthermore, genes patents fall under intellectual property rights. This means that a business would own a patent for up to 20 years on a specific gene. Other companies would not be allowed to perform research on this gen during the patent period, with ultimately limits the breakthrough inventions. The procedure of gene patenting especially in India is cumbersome as compared to the U.S. and European Union. In U.S.A it takes one and half year to grant a patent, and in Europe it takes three years to grant patent. But in India it takes more than five years to grant a patent.

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