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DISSERTATION ON - PATENT ON GENETIC INVENTIONS

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Abbreviations

1. ABS - Access and Benefit sharing Clearing House
2. BiOS - Biological Innovation for Open Society
3. Bt - Bacillus Truancies
4. CBD - Convention on Biological
5. CRISPR cas9 - Clustered regularly interspaced short palindromic repeats
6. EU - European Union
7. DNA - Deoxyribonucleic Acid
8. IPR - Intellectual Property Rights
9. NBA - National Biodiversity Authority
10. Pvt. - Private
11. RNA - Ribonucleic Acid
12. rRNA - Ribosomal ribonucleic acid
13. tRNA - Transfer Ribonucleic acid
14. Ltd. - Limited
15. TALEN - Transcription Activator-Like Effector Nucleases
16. TRIPS - Trade Related Aspects of Intellectual Property Rights
17. WIPO - World Intellectual Property Organisation
18. WTO - World Trade Organisation
19. USPTO - US Patent Office
20. v. - Versus

List of Cases

1. Association for Molecular Pathology v. Myriad Genetics
2. Dimminaco A.G. v. Controller general of Patents & Designs (2002)
3. Monssanto Technology LLC v. Nuziveedu seeds (2019)
4. UC Berkley v. Broad institute & beyond
5. Novartis AG v. Union of India (2018)
6. Graham v. John Deere.Co

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7. Brustle v. Greeneace
8. Dimond v. Chkarabarthy
9. Mayo Collobarative Services v. Promethiseues Laboratories.INC
10. Parke – Davis v. Mulford

Abstract

The current landscape of intellectual property rights concerning patents on genetic inventions is characterized by a complex interplay of legal, ethical, and scientific considerations. As advancements in biotechnology and genomics continue to accelerate, the question of patentability has become increasingly contentious. The exploration of patents related to genetic inventions within the realm of intellectual property is a critical area of research that addresses the intersection of innovation, ethics, and legal frameworks. This investigation seeks to understand how genetic inventions, which encompass a wide range of biotechnological advancements, are protected under existing patent laws and how these protections influence both scientific progress and public access to genetic resources. By analysing the implications of patenting genetic materials and processes, researchers aim to uncover the potential benefits and drawbacks of such intellectual property rights, particularly in terms of fostering innovation while ensuring equitable access to genetic technologies. This study is based on doctrinal research methodology for data collection and interpreting legal texts, statutes, and case law. This methodology emphasizes the examination of existing legal principles and doctrines to derive insights and establish a coherent understanding of the law. Ultimately, the findings from this research could inform policymakers, legal experts, and the scientific community about the need for a balanced approach that promotes innovation while safeguarding public interests and ethical standards in the rapidly evolving field of genetics. And suggest, need for new legal awareness programmes to address the unique challenges posed by Patent on genetic inventions.

CHAPTER - 1

INTRODUCTION

The interplay between patents on genetic inventions and the broader intellectual property landscape presents a complex and evolving scenario. As advancements in biotechnology and genetic research continue to accelerate, the legal frameworks governing these innovations must adapt to address the unique challenges they pose. The intersection of genetic patents with intellectual property rights raises critical questions about ownership, ethical considerations, and the implications for innovation and public health. This dynamic environment necessitates a thorough examination of how existing intellectual property laws can accommodate the rapid pace of scientific discovery while ensuring equitable access to genetic resources.

In recent years, the debate surrounding the patentability of genetic inventions has intensified, particularly in light of landmark legal cases and shifting public perceptions. The tension between protecting the rights of inventors and fostering an open environment for research and development is at the forefront of discussions among policymakers, legal experts, and scientists. As genetic inventions often involve naturally occurring sequences and biological processes, the criteria for patent eligibility become increasingly contentious. This situation underscores the need for a nuanced understanding of intellectual property principles as they apply to the life sciences, balancing the interests of innovation with societal needs.

Furthermore, the implications of genetic patents extend beyond legal considerations, influencing ethical discussions and access to medical advancements. The commercialization of

genetic technologies can lead to disparities in healthcare access, particularly in low-income populations or developing countries. As such, the intersection of genetic invention patents and intellectual property rights not only shapes the landscape of innovation but also raises important ethical questions about the ownership of life itself. Addressing these multifaceted issues requires a collaborative approach that includes stakeholders from various sectors, ensuring that the benefits of genetic research are shared equitably while still incentivizing innovation in this critical field.

Research Questions:

1) CRISPR Cas 9 technique – Human genetic invention?

2) Patent on GMO?

3) Commercialising Biodiversity?

4) Intersection of Public Health & Patent on genetic inventions?

5) How genetic inventions, prevent us from diseases?

6) Challenges faced by inventor on inventions? Research Hypothesis:

By enforcing a strong legislation on 'Patent on Genetic Inventions' in India, it will incentivize the inventor's work and benefit for the public at large.

CHAPTER – 2

CONCEPT OF THE RESEARCH

The concept of the 'intersection of intellectual property and patent on genetic inventions' refers to the complex and evolving relationship between legal frameworks designed to protect innovative ideas (intellectual property) and their specific application to discoveries and creations in the field of genetics. Patents, a key form of intellectual property, grant inventors' exclusive rights for a limited period to prevent others from making, using, selling, or importing their inventions. When these rights are applied to genetic inventions, a unique set of scientific, ethical, and societal considerations arise.

1. Subject Matter of Genetic Inventions:

- Patents in this area can cover a wide range of biological materials and processes, including:
  - Isolated and purified gene sequences (DNA, RNA, cDNA).
  - Genetically modified organisms (GMOs) like bacteria, plants, and animals.
  - Diagnostic tests based on genetic markers.
  - Therapeutic methods involving gene therapy or gene editing.
  - Proteins and enzymes produced through genetic engineering.
  - Vectors and other tools used in genetic manipulation.

2. Patentability Criteria Applied to Genetic Inventions:

To be patentable, a genetic invention must generally meet the standard criteria of patent law:

Novelty: The invention must be new and not previously disclosed.

Non-obviousness (Inventive Step): The invention should not be obvious to someone skilled in the relevant field.

Utility (Industrial Applicability): The invention must have a specific, substantial, and credible use.

Enablement and Sufficiency of Disclosure: The patent application must describe the invention in enough detail for others to understand and reproduce it.

3. Unique Challenges and Considerations:

Product of Nature vs. Invention: A central debate revolves around whether genes as they exist in nature can be patented. Landmark legal cases (like *Association for Molecular Pathology v. Myriad Genetics*[1]) have clarified that isolated but otherwise unmodified natural gene sequences are not patentable in some

jurisdictions (e.g., the US), as they are considered products of nature. However, manipulated or synthetic DNA constructs (like cDNA) may be patentable.

Utility: Establishing a specific and substantial utility for gene sequences has been a challenge. Early patents on gene fragments with unknown functions faced scrutiny. Guidelines now often require a well-defined and credible utility.

Scope of Claims: The breadth of patent claims on genetic inventions can be controversial. Overly broad patents might hinder further research and development.

Ethical Implications: Patenting genes raises ethical concerns about the ownership of fundamental building blocks of life, access to healthcare (especially genetic testing and therapies), the potential for monopolies, and the impact on scientific research.

4. Impact on Innovation and Access:

Incentive for Innovation: Proponents of gene patents argue that they incentivize investment in research and development by providing a return on investment for costly and time-consuming genetic research.

Potential Barrier to Research and Access: Critics argue that gene patents can stifle innovation by limiting access to essential genetic information and tools needed for further research. They can also lead to higher costs for genetic testing and therapies, limiting patient access.

Balancing Competing Interests: The intersection of IP and genetic inventions requires a careful balancing act between encouraging innovation and ensuring public access to healthcare and the benefits of scientific progress.

5. International Variations:

Patent laws regarding genetic inventions vary significantly across different countries and regions, leading to complexities in global research and commercialization.

Note: The intersection of intellectual property and patent on genetic inventions is a dynamic field shaped by scientific advancements, legal interpretations, ethical debates, and societal needs. It involves determining the appropriate scope and limitations of patent rights on biological materials and processes to foster innovation while ensuring equitable access and ethical considerations are addressed.

CHAPTER – 3

Understanding Intellectual Property intersection with patent on genetic inventions

3.1 The Dawn of Genetic Inventions:

The impact of genetic inventions is not confined to a single sector; rather, it permeates diverse fields simultaneously. In medicine, they hold the key to potential cures for genetic disorders and the development of personalized therapies. In agriculture, they offer the promise of enhanced crop yields and resilience to environmental stresses. In biotechnology, they drive the creation of new biological processes and materials with industrial and environmental applications. This interdisciplinary nature underscores the broad implications of patenting these inventions, necessitating a comprehensive understanding of the various perspectives and potential consequences.

3.2 The Role of Intellectual Property:

In this era of rapid genetic innovation, intellectual property rights play a crucial role in protecting these novel creations and discoveries. Intellectual property encompasses a range of legal mechanisms designed to safeguard the creations of the mind, granting creators certain exclusive rights over their inventions, designs, or artistic works. Among these mechanisms, patents stand out as a particularly relevant tool for genetic inventions. Patents provide inventors with a government-granted right to exclude others from making, using, selling, or importing their invention for a limited period, typically 20 years. This system aims to encourage public disclosure of inventions, as the details of the invention are

made public in the patent document, thereby stimulating both follow-on research and, in some cases, public benefit. By enabling patent holders to control the commercial exploitation of their inventions, patents also offer an opportunity to recoup the often-substantial investments required for research and development, creating an incentive for licensees to invest in further development and market introduction.

However, the application of patents to genetic inventions presents a complex scenario. While patents are intended to incentivize innovation through the grant of exclusivity, they can also potentially restrict access to essential technologies and hinder further research. This creates a fundamental tension: balancing the reward for the inventor, which is crucial for driving investment and innovation, with the broader societal benefit of the invention, particularly in areas as critical as healthcare and food security. The exclusivity granted by patents can lead to the development of valuable new products and processes, but it might also impede the dissemination and application of crucial genetic knowledge if licensing terms are restrictive or costs are prohibitive. Therefore, a careful and nuanced approach is required when considering the intersection of intellectual property and patents on genetic inventions.

3.3 Defining Genetic Inventions:

Core Definitions:

A genetic invention refers to a novel and innovative creation or discovery related to genetics. It encompasses the identification, development, or manipulation of genes, DNA sequences, or genetic materials that hold the potential to significantly impact various fields, including biotechnology, medicine, and agriculture. These inventions often lead to the development of groundbreaking technologies such as new therapies, diagnostic tools, and genetically modified organisms, which can positively influence human health and the environment. Another perspective defines a genetic invention as a creation involving the manipulation or alteration of genetic material using biotechnology to produce new, useful genetic sequences, organisms, or biological processes that do not occur naturally. This type of invention is at the forefront of biomedical research and agricultural development, employing techniques like gene editing, synthetic biology, and recombinant DNA technology. Essentially, genetic inventions represent human-engineered modifications or applications of genetic material that result in something new and useful. The key element across these definitions is the notion of human intervention in altering or utilizing genetic material in a way that produces a novel outcome or application. This distinction from naturally occurring genes and genetic processes is fundamental when considering the applicability of patent law. Terms often used synonymously with genetic invention include genetic discovery, genetic breakthrough, and genetic innovation.

Key Technologies Involved:

Several key technologies underpin the creation and development of genetic inventions. **Gene editing technologies**, such as CRISPR-Cas9, are at the forefront, allowing scientists to precisely add, remove, or alter genetic material at specific locations within the genome. These modifications can lead to the creation of organisms with desirable traits or the correction of genetic defects in humans, animals, and plants. **Synthetic biology** involves designing and constructing new biological parts, devices, and systems that do not exist naturally, as well as redesigning existing biological systems for useful purposes. This can include the creation of synthetic organisms capable of producing pharmaceuticals or biofuels. **Recombinant DNA technology** is another crucial technique that combines DNA molecules from different sources into a single molecule, forming a new set of genes. This modified DNA is then transferred into an organism, giving it altered or novel genes to produce the desired traits. These technologies, along with others in the realm of genetic

engineering and biotechnology, enable the manipulation of genetic material to achieve specific goals, driving the creation of a wide array of genetic inventions. Understanding these underlying technologies is essential for appreciating the scope and potential of genetic inventions and for navigating the complexities of their patenting. Each technology presents unique considerations regarding the inventive step involved and the potential industrial applications.

Examples of Genetic Inventions:

The field of genetic inventions has yielded numerous examples with significant impact across various sectors:

Medicine: Gene therapies designed to target and correct the underlying genetic causes of diseases like sickle cell anaemia or cystic fibrosis are prime examples. Diagnostic tools that can detect genetic predispositions to diseases such as certain types of cancer, allowing for early intervention and personalized treatment strategies, also fall under this category. The production of synthetic insulin using genetically modified bacteria to treat diabetes was a landmark achievement. Similarly, recombinant vaccines, such as the hepatitis B vaccine produced by genetically modified baker's yeast, represent crucial medical advancements. The development of genetically modified animal models of human genetic diseases has enabled researchers to test novel therapies and explore disease mechanisms. Furthermore, genome editing techniques are being explored for treating various diseases, including cancer, HIV, and muscular dystrophy.

Agriculture: Genetically modified crops engineered for pest resistance, such as Bt corn which contains a gene from *Bacillus thuringiensis* that produces a natural insecticide, have significantly reduced the need for chemical pesticides. Herbicide-tolerant crops allow farmers to use specific herbicides for weed control without harming the crops themselves. Genetic engineering has also led to the development of crops with enhanced nutritional value, such as Vitamin D tomatoes and bio-fortified rice with increased levels of vitamin A or iron. Efforts are also underway to create livestock with improved disease resistance through genetic modification.

Biotechnology: Genetically modified microorganisms are being utilized for the production of biofuels, offering a sustainable alternative to fossil fuels. Bioremediation, the process of using genetically engineered organisms to clean up pollutants from the environment, is another significant application. The development of new enzymes with enhanced properties for industrial processes, such as in the production of detergents or pharmaceuticals, is also a result of genetic invention. Synthetic biology is enabling the creation of entirely new biological systems for various applications, ranging from producing novel biomaterials to developing new diagnostic tools.

These examples illustrate the broad spectrum of genetic inventions and their potential to address critical challenges in human health, food security, and environmental sustainability. The diverse applications across these sectors underscore the significant economic and social value associated with these inventions, making the debate surrounding their patenting all the more pertinent.

3.4 The Importance and Applications of Genetic Inventions: Advancements in Medicine and Healthcare:

Genetic inventions hold immense importance in the realm of medicine and healthcare, offering a multitude of applications and potential benefits. One of the most promising applications lies in the **development of gene therapies**, which aim to potentially cure genetic disorders by addressing the root cause – the defective genes responsible for the disease. Technologies like CRISPR-Cas9 have significantly advanced the field of **gene editing**, enabling scientists to precisely modify genetic material at specific locations in the genome, offering the possibility

of correcting genetic defects in humans. Furthermore, genetic inventions have revolutionized the **production of life-saving pharmaceuticals**. For instance, synthetic insulin, crucial for managing diabetes, is now produced using genetically modified organisms. Similarly, recombinant versions of growth hormone, clotting factors for haemophiliacs, and vaccines like the hepatitis B vaccine are manufactured through genetic engineering.

Genetic inventions are also pivotal in the development of **new diagnostic tools** for the early detection and personalized treatment of diseases. Genetic testing can identify inherited gene variants, aiding in the diagnosis of rare diseases and providing individuals with valuable medical information and family history insights. The ability to analyse large-scale DNA data helps researchers understand the impact of genes on health, potentially leading to treatments tailored to an individual's specific genetic makeup – the cornerstone of personalized medicine. Novel approaches like **edible vaccines**, where antigenic proteins are produced in the consumable parts of plants, and **DNA vaccines** may offer safer, cheaper, and more accessible ways to prevent diseases like HIV/AIDS, tuberculosis, and cancer. Moreover, genetically modified animal models of human genetic diseases are invaluable tools for researchers to test novel therapies and explore the roles of candidate risk factors. The rapid advancements in genetic technologies, moving from theoretical concepts to practical applications, offer a beacon of hope for preventing and curing diseases, managing chronic conditions, and ultimately improving human health.

3.5 Improvements in Agriculture and Food Security:

Genetic inventions have brought about significant improvements in agriculture, playing a vital role in enhancing food security and promoting sustainable practices. One of the most impactful applications is the development of **crop varieties with enhanced traits**. These include increased yield, making more food available from the same land; improved tolerance to environmental stresses like drought, heat, and salinity, allowing for cultivation in challenging conditions; and enhanced resistance to pests and diseases, reducing the need for harmful chemical pesticides. A notable example is **insect-resistant crops** like Bt corn, which contains a gene from the soil bacterium *Bacillus thuringiensis* that produces a natural insecticide, effectively protecting the crop from specific pests and reducing the reliance on synthetic pesticides. Similarly, **herbicide-tolerant crops** have been engineered to withstand the application of specific herbicides, facilitating weed management and promoting conservation tillage practices.

Genetic modification has also been employed to **enhance the nutritional content of crops**, a strategy known as bio-fortification. Examples include the development of rice, maize, and wheat varieties with increased levels of essential vitamins, minerals, and micronutrients like vitamin A, iron, and zinc, offering potential health benefits for millions facing malnutrition. Furthermore, genetic inventions are contributing to the development of **climate-resilient crop varieties** that can better withstand changing environmental conditions such as prolonged droughts and extreme temperatures. Techniques like CRISPR are being used to optimize crop architecture for more efficient harvesting and to extend the shelf life of produce, reducing food waste. In livestock agriculture, gene discovery has led to advancements in breeding for desirable traits such as disease resistance and improved production efficiency. Overall, genetic inventions are crucial for ensuring a sustainable and secure food supply for a growing global population while minimizing environmental impact.

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3.6 Advances in Biotechnology and Industrial Applications:

Beyond medicine and agriculture, genetic inventions are driving significant advances in biotechnology and various industrial applications. One important application is **bioremediation**, where genetically modified microorganisms are used to break down and clean up pollutants from the environment, offering a more efficient and sustainable approach to environmental cleanup compared to traditional methods. In **industrial biotechnology**, genetic engineering is employed to develop more efficient and sustainable processes for producing a wide range of chemicals, enzymes, and other materials. For example, genetically modified microorganisms can be used in fermentation processes to produce chemicals that were previously derived from petroleum, offering a more environmentally friendly alternative.

Genetic inventions are also playing a key role in the development of **biofuels and other renewable energy sources**. Scientists have created several liquid biofuels, such as ethanol and biodiesel, from plant material and other natural substances using genetically engineered organisms or enzymes. Furthermore, the power of bacterial anaerobic decomposition, a process that can be enhanced through genetic modification, is being leveraged to create and capture methane gas from waste materials. This not only provides a renewable energy source but also helps mitigate greenhouse gas emissions. The field of synthetic biology is further expanding the possibilities by enabling the design and construction of new biological parts, devices, and systems with novel functionalities for industrial and environmental applications. For instance, researchers are exploring the use of synthetic organisms to produce biodegradable plastics and other sustainable materials. Overall, genetic inventions are proving to be powerful tools for refining industrial processes, addressing environmental challenges, and fostering a more sustainable future.

3.7 Arguments in Favor of Patenting Genetic Inventions:

Incentivizing Innovation and Research:

A primary argument in favour of patenting genetic inventions centres on the premise that patents serve as a crucial incentive for innovation and research. The process of discovering and developing genetic inventions often requires substantial financial investment, time, and resources. Patents, by granting exclusive rights to the inventors for a limited period, provide a mechanism for them and their affiliated companies to potentially recoup these investments. This prospect of financial return acts as a powerful motivator, encouraging researchers and companies to undertake the often risky and expensive endeavours associated with genetic research and development. Without the assurance of patent protection, there is a concern that companies might be less inclined to invest in such long-term and high-risk projects, potentially slowing down the overall pace of discovery and the development of new genetic technologies.

Furthermore, the patent system encourages researchers to think more creatively and work diligently to achieve breakthroughs that can be protected by patents. The lure of obtaining a patent for a novel gene sequence, a new gene editing technique, or a genetically modified organism can drive researchers to push the boundaries of scientific knowledge and explore innovative approaches. In addition to incentivizing the initial invention, patents also play a role in promoting the public disclosure of these advancements. In exchange for the exclusive rights, inventors are required to disclose the details of their invention in the patent application. This disclosure serves a vital function by adding to the body of scientific knowledge, inspiring follow-on research by other scientists, and potentially leading to further innovations and improvements in the field. The information contained within patents can provide a foundation upon which future research can build, fostering a cycle of

continuous innovation.

3.8 Attracting Investment and Facilitating Commercialization:

Patents on genetic inventions are also instrumental in attracting the necessary investment for their further development and eventual commercialization. The development of a genetic invention from a laboratory discovery to a marketable product, such as a new gene therapy or a genetically modified crop, often requires significant capital investment. This includes funding for clinical trials, regulatory approvals, scaling up production, and marketing efforts. Patents provide a degree of exclusivity that makes these inventions more attractive to investors, who are more likely to provide financial support when there is a potential for a protected market and a return on their investment. The exclusive rights granted by a patent reduce the risk of immediate imitation by competitors, offering a window of opportunity for the patent holder to establish a market presence and generate revenue.

Moreover, patents facilitate the transfer of technology from research institutions to companies that have the resources and expertise to bring these inventions to the market. Through licensing agreements, patent holders can grant others the right to use, manufacture, or sell their patented invention in exchange for royalties or other forms of compensation. This process allows for the broader application of genetic inventions, ensuring that they reach the individuals and industries that can benefit from them. Patents also play a crucial role in helping companies establish markets for new discoveries. For example, companies like Myriad Genetics invested in educating patients and doctors about their BRCA gene tests and worked to facilitate insurance reimbursement for the cost of testing, actions that were incentivized by their patent protection. In essence, patents serve as a bridge between the initial discovery of a genetic invention and its widespread availability and utilization, fostering the translation of scientific breakthroughs into tangible benefits for society.

3.9 Promoting Economic Growth and Market Competition:

The patenting of genetic material has also been credited with fostering economic growth and promoting a dynamic innovation ecosystem within the biotechnology sector. The ability to secure patent protection has created a substantial market for private investment capital in biotechnology, supporting the growth of numerous companies and contributing to job creation. The biotechnology industry, fuelled in part by the patent system, has witnessed tremendous advancements and product development, boosting economies worldwide. While patents grant temporary exclusive rights, the information disclosed within patent documents can also inspire other companies and researchers to develop their own unique innovations, potentially leading to alternative or improved technologies. This process fosters a healthy market competition, as companies strive to create novel solutions that can also be protected by intellectual property rights.

Furthermore, the economic benefits of patenting extend across various sectors impacted by genetic inventions, including medicine, agriculture, and industrial biotechnology. The development of new pharmaceuticals, diagnostic tools, and gene therapies can lead to significant economic opportunities in the healthcare industry. In agriculture, the creation of improved crop varieties and more efficient farming practices can enhance productivity and profitability. Similarly, advancements in industrial biotechnology can drive the development of new materials, processes, and energy sources, contributing to economic growth and sustainability. While concerns exist about the potential for patents to create monopolies and restrict competition in certain instances, the overall effect of the patent system in the context of genetic inventions is often viewed as a positive driver of economic development and

technological advancement.

3.10 Intellectual Property Law and the Patenting of Genetic Inventions: Defining "Invention" and "Patentable Subject Matter" in the US:

In the United States, the foundation of patent law lies in 35 U.S.C. § 101, which defines

patentable subject matter as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof". This broad definition has been the subject of interpretation by the courts over time, particularly in the context of living organisms and biological materials. Historically, the United States Patent and Trademark Office (USPTO) had granted patents on natural biological substances, including isolated gene sequences, if they were considered sufficiently "isolated" from their naturally occurring state. This practice was based on the argument that the act of isolation and purification transformed the substance into a patentable "composition of matter."

A significant turning point in the patenting of living organisms came with the landmark Supreme Court case of **Diamond v. Chakrabarty** in 1980. The Court ruled that a genetically engineered bacterium capable of breaking down crude oil was indeed patentable subject matter, affirming that the question of whether an invention embraces living matter is irrelevant to patent eligibility. The Court famously stated that patentable subject matter includes "anything under the sun that is made by man". This decision paved the way for the patenting of various genetically modified organisms, including bacteria, viruses, seeds, plants, cells, and even non- human animals.

However, the landscape of gene patenting in the US underwent a major shift with the Supreme Court's 2013 decision in **Association for Molecular Pathology v. Myriad Genetics**. The case challenged the patentability of isolated DNA sequences for the BRCA1 and BRCA2 genes, mutations of which are linked to an increased risk of breast and ovarian cancer. The Supreme Court unanimously ruled that naturally occurring DNA segments are products of nature and are not patent eligible merely because they have been isolated from the human body. The Court reasoned that the process of isolating a gene does not alter its fundamental characteristics as they exist in nature and therefore does not constitute an invention. This decision invalidated Myriad's patents on the isolated BRCA1 and BRCA2 genes and effectively overturned the long-standing policy of the USPTO that allowed for the patenting of thousands of human genes based solely on their isolation. Importantly, the Court clarified that synthetically created complementary DNA (cDNA), which is produced by reverse transcribing messenger RNA and does not contain non-coding regions (introns), remains patent eligible because it is not a naturally occurring product. The *Myriad* decision marked a significant re-evaluation of the boundary between patentable human-made inventions and unpatentable products of nature in the realm of genetics.

Defining "Invention" and "Patentable Subject Matter" in Europe:

In Europe, the patenting of genetic inventions is primarily governed by the European Patent Convention (EPC) and the EU Biotechnology Directive (Directive 98/44/EC), which has been incorporated into the Implementing Regulations of the EPC. Article 52(1) of the EPC states that European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step, and are susceptible of industrial application.

While the simple discovery of an element of the human body, including the sequence or partial sequence of a gene, is not considered a patentable invention under Rule 29(1) of the EPC, Rule 29(2) provides an important exception. It states that an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a

patentable invention, even if the structure of that element is identical to that of a natural element. This provision reflects a broader view on the patentability of isolated gene sequences compared to the post-*Myriad* stance in the US. However, Rule 29(3) of the EPC emphasizes that the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application. This requirement ensures that a mere discovery of a gene sequence without any indication of its function or potential use is not patentable.

European patent law also takes ethical considerations into account. Article 53(a) of the EPC excludes inventions whose commercial exploitation would be contrary to "ordre public" or morality. This provision was central to the **Brustle v. Greenpeace** case, which involved a patent on neural progenitor cells derived from human embryonic stem cells. The Court of Justice of the European Union (CJEU) interpreted the concept of "human embryo" broadly and ruled that an invention requiring the destruction of a human embryo is unpatentable. This case highlights the significant role of ethical considerations in shaping the patentability of certain genetic inventions in Europe, particularly those involving human biological material.

3.11 Comparison of US and European Approaches:

The approaches to patenting genetic inventions in the US and Europe exhibit both similarities and key differences. While both jurisdictions adhere to the fundamental criteria of novelty, inventive step (non-obviousness), and industrial applicability (utility), their stances on the patentability of naturally occurring gene sequences have diverged, particularly after the *Myriad* decision in the US. In the US, the Supreme Court explicitly ruled that isolated naturally occurring DNA is not patentable as it is considered a product of nature. In contrast, European patent law, under the EPC and the Biotechnology Directive, continues to allow the patenting of isolated gene sequences derived from the human body or produced through a technical process, provided that their industrial application is disclosed. This reflects a more permissive stance on the patentability of isolated genetic material in Europe.

However, it is important to note that both the US and Europe generally permit the patenting of artificial DNA constructs, such as cDNA, and methods of manipulating genes, as these are considered to be human-made inventions. Additionally, both legal frameworks emphasize the need for a disclosed utility or industrial application for a genetic sequence to be patentable. The *Brustle v. Greenpeace* case underscores the greater emphasis on ethical considerations in European patent law, particularly concerning inventions involving human embryonic material, a factor that plays a less direct role in the US patentability criteria, although ethical arguments were raised in the *Myriad* case. These differing legal landscapes necessitate careful consideration for companies and researchers seeking global patent protection for their genetic inventions, as patenting strategies may need to be tailored to the specific requirements and interpretations in each jurisdiction.

3.12 Criteria for Patentability of Genetic Inventions:

Novelty:

In the United States, **novelty** is a fundamental requirement for patentability, codified in 35

U.S.C. § 102. An invention is considered novel if it has not been previously known, used, patented, or described in a printed publication anywhere in the world before the effective filing date of the patent application. This means the claimed invention must be new in relation to the "prior art," which encompasses all existing knowledge in the relevant field. The concept of **anticipation** dictates that a claimed invention is not novel if a single prior art reference discloses every element of the invention, either explicitly or inherently. Importantly, the discovery of a new property or use for a known substance or composition does not automatically render it

novel for patent purposes. For genetic inventions, this means that simply identifying a previously unrecognized DNA sequence that was inherently present in prior art would not meet the novelty requirement.

Similarly, in Europe, **novelty** is a prerequisite for obtaining a patent, as outlined in Article 54 of the European Patent Convention (EPC). An invention is considered novel if it does not form part of the state of the art, which comprises everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application. Interestingly, in the context of genetic inventions, European patent law considers that biological material isolated from its natural environment or produced by means of a technical process can be patentable, even if it previously occurred in nature. This implies that the act of isolating a gene sequence from its natural environment can confer novelty, even if the sequence itself is identical to the naturally occurring one. This contrasts with the US position post-*Myriad*, where mere isolation of a naturally occurring gene is not sufficient for patentability.

Non-obviousness (Inventive Step):

In the United States, an invention must also be **non-obvious** to be patentable, as stipulated in 35 U.S.C. § 103. This means that the invention, considering the prior art, would not have been obvious to a person having ordinary skill in the art (PHOSITA) at the time the invention was made. Determining non-obviousness involves a factual analysis, often guided by the factors outlined in the Supreme Court case *Graham v. John Deere Co.*, which include assessing the scope and content of the prior art, the differences between the claimed invention and the prior art, and the level of ordinary skill in the pertinent art. Secondary considerations, such as commercial success, long-felt but unresolved needs, and unexpected results, can also be relevant in determining non-obviousness[2]. Applying the non-obviousness standard to genetic inventions can be challenging due to the vast amount of genetic information and the rapid advancements in the field. For example, the mere identification of a gene or protein sequence might be considered obvious if the prior art suggested its existence or function.

In Europe, the requirement analogous to non-obviousness is the **inventive step**, as defined in Article 56 of the EPC. An invention is considered to involve an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art. The European Patent Office (EPO) employs a "problem-solution approach" to assess inventive step. This involves identifying the closest prior art, determining the objective technical problem solved by the invention, and then assessing whether the claimed solution would have been obvious to a skilled person. Generally, the standards for inventive step are considered to be higher in Europe compared to the non-obviousness standard in the US, making it comparatively more difficult to satisfy this requirement. In the context of genetic inventions, the inventive step might lie in identifying a gene with a previously unknown function or in developing a novel method for manipulating genetic material that yields unexpected results.

Industrial Applicability (Utility):

In the United States, an invention must have a **specific, substantial, and credible utility** to be patentable under 35 U.S.C. § 101. This **utility** requirement mandates that the invention must have a practical application and provide a tangible benefit. The USPTO guidelines specify that for genetic inventions, the patent application must disclose a "specific, substantial, and credible utility for the claimed isolated and purified gene". This means that a mere discovery of a gene sequence without a known function or a speculative utility is unlikely to be considered patentable. The claimed utility must be more than just an object of further research; it should offer a concrete benefit to the public.

Similarly, in Europe, an invention must be

susceptible of industrial application, as stated in Article 57 of the EPC. An invention is considered industrially applicable if it can be made or used in any kind of industry, including agriculture. For genetic inventions, Rule 29(3) of the EPC explicitly requires that the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application. This means that the patent application must indicate how the genetic sequence can be used in a practical or commercial sense. For instance, disclosing the function of a gene and its use in producing a specific protein or in gene therapy would typically satisfy the industrial applicability requirement.

3.13 Impact of Patenting Genetic Inventions:

On Scientific Progress:

The impact of patenting genetic inventions on scientific progress is a subject of ongoing debate, with compelling arguments on both sides. Proponents argue that patents incentivize research by offering a period of exclusivity that allows inventors to recoup their investments and potentially fund further research. The prospect of patent protection can drive researchers to pursue novel and innovative approaches, ultimately leading to scientific breakthroughs that might not otherwise occur. Additionally, the patent system encourages the public disclosure of inventions, which can stimulate follow-on research and the development of new technologies.

Conversely, critics contend that gene patents can impede scientific progress by limiting access to essential genetic information and creating a complex "patent thicket". The exclusive rights granted by patents may restrict other researchers from working with patented genes, potentially hindering the discovery of new diagnostic methods or therapeutic applications. The need to navigate licensing agreements and pay royalties can also add significant costs and administrative burdens to research, potentially diverting resources from actual scientific investigation. The impact of the *Myriad* case, which restricted the patentability of isolated human genes in the US, has been analysed for its effect on research, with some studies suggesting that it had a limited negative impact and may have even fostered innovation by opening up the field to more researchers. The overall effect of gene patenting on scientific progress appears to be nuanced and may vary depending on the specific context, the breadth of the patents granted, and the licensing practices of patent holders.

On Economic Development:

Patenting has played a significant role in the economic development of the biotechnology industry, which is heavily reliant on genetic inventions. The ability to obtain patent protection for genetic discoveries and inventions has attracted substantial private investment, leading to the growth of numerous biotechnology companies and the creation of a significant number of jobs. Patents facilitate the commercialization of genetic inventions by providing a period of market exclusivity, allowing companies to develop and market new products and services, such as pharmaceuticals, diagnostic tests, and genetically modified crops. This commercialization can lead to significant economic benefits across various sectors, including healthcare, agriculture, and industrial biotechnology.

The patent system also encourages technology transfer and the development of specialized expertise within the biotechnology sector. Companies often build their business models around patented technologies, leading to further investment in research and development to improve existing products or create new ones. While concerns exist about the potential for overly broad patents to stifle competition and create monopolies, the overall impact of patenting on economic development in the field of genetic inventions has generally been viewed as positive, driving innovation and fostering the growth of a vital industry.

On Public Health:

The patenting of genetic inventions has the potential to significantly impact public health, both positively and negatively. On the positive side, patents can incentivize the development of new diagnostics and therapeutics for a wide range of diseases, including genetic disorders, cancer, and infectious diseases. The exclusivity provided by patents can encourage companies to invest in the often lengthy and expensive process of bringing new medical treatments to market, ultimately benefiting public health by offering solutions for previously untreatable conditions.

However, concerns have been raised about how gene patents might limit access to essential genetic tests and treatments, potentially exacerbating health disparities. The monopolization of genetic testing due to patent protection can lead to higher costs, making these tests unaffordable for some individuals. The *Myriad* case highlighted these concerns, as the company's exclusive rights over BRCA1 and BRCA2 testing limited the availability of second opinions and potentially hindered the development of more comprehensive or affordable testing options. Ensuring equitable access to the benefits of genetic research, particularly in healthcare, remains a critical challenge in the context of patenting genetic inventions. Striking a balance between incentivizing innovation and ensuring that essential medical advancements are accessible to all segments of the population is crucial for maximizing the positive impact of genetic inventions on public health.

CHAPTER – 4

The Legal Framework for Patenting Genetic Inventions in India

4.1 The Indian Patents Act, 1970: The Cornerstone of Patent Law

The foundation of patent law in India is the Patents Act, 1970. This legislation, enacted to protect innovation, has undergone several amendments over the years, notably in 2002 and 2005, to align with international standards, particularly the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). These amendments reflect a gradual evolution in India's stance towards patenting biotechnological inventions. Initially, India held a strong reservation against patenting life forms. However, to meet its international obligations, the Act was modified to accommodate certain categories of biological inventions, such as microorganisms and genetically modified entities. This evolution indicates a reactive adaptation to global intellectual property norms, rather than a purely independent development of the legal framework.

A. Section 3: Defining What is Not Patentable

Section 3 of the Indian Patents Act, 1970, is crucial in delineating the subject matter that is not considered an invention and therefore not patentable. Several clauses within this section have significant implications for the patentability of genetic inventions.

B. Section 3(c): Discovery vs. Invention

Clause (c) of Section 3 explicitly prohibits the patenting of "the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature". This provision lies at the heart of the debate surrounding gene patenting in India. While naturally occurring genes are excluded from patentability under this clause, the Act does not explicitly define the boundary between a "discovery" and an "invention" when it comes to genes that have been isolated or modified through human intervention. The core challenge in this context is the interpretation of "discovery." Arguments exist that isolating a gene from its natural environment or manipulating its sequence requires significant human effort and ingenuity, thereby transforming it from a mere discovery into a patentable invention. This ambiguity presents a considerable hurdle for inventors seeking patent protection for genetic material.

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2. Section 3(j): Plants, Animals, and Biological Processes

Section 3(j) objects to the patentability of "plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals". This clause establishes a clear distinction regarding the patentability of different life forms. Microorganisms are explicitly excluded from this prohibition, making them potentially patentable subject matter. Furthermore, processes involving microorganisms are also generally considered patentable. However, the patentability of genetically modified organisms (GMOs) falling outside the definition of microorganisms is more nuanced. The prevailing understanding is that GMOs may be patentable if their development involves significant human intervention, distinguishing them from essentially biological processes. This creates a grey area where the degree of human intervention becomes a critical factor in determining patent eligibility.

3. Other Relevant Subsections of Section 3

Beyond the direct exclusions related to natural substances and life forms, other subsections of Section 3 indirectly influence the patenting of genetic inventions. Section 3(b) excludes inventions who's primary or intended use could be contrary to public order or morality. This can be relevant to certain genetic modifications that raise ethical concerns. Section 3(h) prohibits the patenting of "a method of agriculture or horticulture", which may impact the patentability of certain genetically modified crops or methods of plant breeding. Additionally, Section 3(i) excludes "any process for the medicinal, surgical, curative, prophylactic diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals". This clause can affect the patentability of certain gene-based diagnostic or therapeutic methods. These additional exclusions underscore the broader societal values and public interest considerations embedded within Indian patent law, which extend beyond the specific realm of genetic inventions.

C. Section 10: Disclosure Requirements for Biological Material

Section 10 of the Indian Patents Act, 1970, lays down the requirements for the specification of a patent application. It mandates that every complete specification must fully and particularly describe the invention. Recognizing the challenges in providing a detailed written description for biological materials, the Act allows for the deposit of such materials in a recognized depository institution as an alternative. Furthermore, Section 10 makes it obligatory to disclose the source and geographical origin of any biological material used in the invention, particularly if the material originates from India. In cases where the biological material is sourced from India, obtaining necessary permission from the competent authority is also a prerequisite before the grant of a patent. These disclosure requirements emphasize transparency and accountability in the patenting of genetic inventions, reflecting India's commitment to preventing the unauthorized exploitation of its biological resources and ensuring fair benefit sharing.

D. Patent Rules, 2003

The Patent Rules, 2003, provide the procedural framework for the implementation of the Patents Act, 1970. These rules offer detailed guidelines on various aspects of patent applications, including the examination process for biotechnological inventions. The rules also provide a definition for "biological material," encompassing any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.

4.2 Scope of Patentable Genetic Inventions in India

A. Categories of Patentable Genetic Inventions

Despite the restrictions outlined in Section 3, several categories of genetic inventions are considered patentable in India. Recombinant DNA and plasmids can be patented, provided their creation involves significant human intervention, demonstrating a departure from naturally occurring forms. Complementary DNA (cDNA), a synthetic form of DNA, is also generally patentable, particularly if it exhibits novelty and non-obviousness. Genetically modified microorganisms are explicitly patentable under the Act. Furthermore, processes for producing genetically modified organisms that involve substantial human intervention are also eligible for patent protection. While diagnostic methods are generally excluded under Section 3(i), diagnostic products such as kits and devices that utilize genetic principles can be patented.

The underlying principle is that inventions demonstrating a significant degree of human manipulation and exhibiting novelty are more likely to be considered patentable in the realm of genetics.

B. Criteria for Patentability Applied to Genetic Inventions

Genetic inventions, like all other inventions, must meet the standard patentability criteria of novelty, inventive step, and industrial applicability to be granted a patent in India.

1. Novelty

To be patentable, a genetic invention must be genuinely new and not have been disclosed to the public in any form before the date of filing the patent application. Establishing novelty for biological materials can be particularly challenging due to the inherent complexity and variability of biological systems. Subtle variations in gene sequences or the existence of similar biological entities in nature can complicate the assessment of whether an invention is truly new. Inventors must provide robust scientific evidence to demonstrate that their genetic invention is distinct from existing knowledge and prior art.

2. Inventive Step (Non-Obviousness)

A genetic invention must also involve a technical advance that would not be obvious to a person skilled in the relevant field. Determining what constitutes an inventive step in biotechnology can be problematic. The assessment often involves considering whether the invention offers unexpected properties or advantages compared to existing technologies. For instance, a minor modification to a known gene sequence might not be considered inventive unless it results in a significant and unpredictable improvement in function or efficacy.

3. Industrial Applicability (Utility)

The genetic invention must be capable of being made or used in an industry. The utility standards for genetic inventions can sometimes be higher than for other types of inventions. This means that the patent application must clearly disclose a specific, substantial, and credible utility for the claimed genetic invention. A mere theoretical application or a function that is not well-defined may not suffice to meet this criterion.

4.3 Rights Conferred by Patents on Genetic Inventions in India

A. Exclusive Rights of the Patent Holder

A patent granted for a genetic invention in India confers upon the patent holder certain exclusive rights for a period of 20 years from the date of filing the patent application. These rights include the authority to prevent others from making, using, selling, or importing the patented invention without the patent holder's permission. This exclusivity provides the patent holder with significant market power to commercially exploit their innovation and recoup their investment in research and development.

B. Licensing and Assignment

The patent holder also has the prerogative to license or assign their patent rights to other entities for commercial benefits. Licensing allows the patent holder to grant permission to others to use their invention under specific terms and conditions, often in exchange for royalties. Assignment involves the complete transfer of ownership of the patent rights to another party. These mechanisms enable broader utilization of the patented genetic invention and can generate revenue streams for the inventor.

C. Legal Recourse Against Infringement

In the event that others infringe upon their patent rights by making, using, selling, or importing the patented genetic invention without authorization, the patent holder has the right to initiate legal proceedings in court to seek remedies or damages. To effectively protect their rights, patent holders need to actively monitor the market for potential infringements. The legal framework provides avenues for seeking interim injunctions to prevent further infringement during the course of litigation.

4.4 Challenges Faced by Inventors in the Realm of Genetic Patenting in India

A. Demonstrating Novelty and Inventive Step

The inherent complexity and variability of biological systems present a significant challenge for inventors in demonstrating novelty and inventive step for their genetic inventions. The distinction between what exists naturally and what constitutes a novel human invention can be subtle and difficult to establish. Patent examiners often scrutinize claims related to genetic material to ensure they are not merely discoveries of naturally occurring substances or obvious modifications of existing knowledge.

B. Ethical and Moral Considerations

The patenting of life forms, including genetic material, raises profound ethical concerns regarding the ownership and control of fundamental biological resources. Critics argue that granting patents on genes can lead to the commodification of life and may have detrimental impacts on healthcare access and affordability. Balancing the incentives for innovation with broader societal values and preventing the patenting of inventions that could be harmful or contrary to public morality remains a significant challenge.

C. Biopiracy and Traditional Knowledge

India, being a biodiversity-rich country, places significant emphasis on safeguarding its biological resources and traditional knowledge from misappropriation. Inventors seeking patents on genetic inventions that utilize biological resources originating from India face the additional challenge of complying with the Biological Diversity Act, 2002, which mandates the disclosure of the source and origin of the biological material and requires obtaining prior approval from the National Biodiversity Authority (NBA). Navigating this regulatory landscape is crucial to avoid potential legal challenges and ensure ethical sourcing of biological materials.

D. Navigating the Regulatory Landscape

The Indian Patents Act and its associated rules constitute a complex regulatory framework that can be challenging for inventors, particularly those new to the field of patent law. The interpretation of specific provisions, especially those related to biotechnology, can evolve over time through judicial pronouncements and amendments. Inventors need to stay informed about these developments and ensure their patent applications align with the current legal understanding. The need for clear and consistent patent laws in the face of rapid advancements in biotechnology further underscores the ongoing challenges in this domain.

E. Challenges Specific to Gene Editing Technologies (e.g., CRISPR)

The emergence of gene editing technologies like CRISPR has introduced new and complex

challenges to the existing patent framework. Determining the original inventor of GMOs developed using these technologies can be difficult, especially given the collaborative nature of scientific research. Assessing the industrial applicability of gene-edited organisms and addressing the ethical dilemmas related to their commercial exploitation, particularly in the context of human rights, are also significant hurdles. Furthermore, the ongoing patent disputes over CRISPR technology in other parts of the world have implications for the Indian patenting system, creating uncertainty and potentially slowing down the development and commercialization of CRISPR-based products in India.

4.5 Ethical and Societal Implications of Gene Patenting in India

A. Commodification of Genetic Material

A central ethical debate surrounding gene patenting revolves around the question of whether genes and other fundamental components of life should be treated as private property. Opponents argue that patenting life forms amounts to a violation of their inherent dignity and could have far-reaching moral and philosophical consequences. Conversely, proponents contend that the process of isolating, characterizing, and modifying genes involves significant human innovation deserving of patent protection to incentivize further research and development.

B. Impact on Healthcare Access and Affordability

A significant societal concern associated with gene patenting is its potential impact on healthcare access and affordability. Granting exclusive rights over genes involved in genetic testing or therapeutic development can lead to monopolies, potentially increasing the costs of these essential services and limiting access for patients who need them most. Striking a balance between incentivizing innovation in the healthcare sector and ensuring affordable access to medical technologies is a critical ethical and societal imperative.

C. Environmental Concerns

The patenting of genetically modified organisms, particularly in the agricultural sector, raises environmental concerns. Potential hazards to the environment due to the release of GMOs, their impact on ecological balance, and the potential for unintended consequences on biodiversity are important ethical considerations that need to be carefully evaluated. Regulatory frameworks and rigorous risk assessments are crucial to mitigate these potential environmental impacts.

D. Intersection with Traditional Knowledge and Biodiversity Rights

India's rich biodiversity and the traditional knowledge associated with it necessitate careful consideration in the context of genetic patenting. Ensuring fair and equitable sharing of benefits arising from the use of genetic resources and protecting the rights of indigenous communities who have traditionally conserved and utilized these resources are paramount ethical considerations. The role of the National Biodiversity Authority in regulating access to biological resources and ensuring benefit sharing is crucial in this regard.

4.6 Illustrative Case Studies

A. *Dimminaco A.G. v. Controller of Patents & Designs* (2002)

This landmark case in the Calcutta High Court played a pivotal role in shaping the understanding of patentability for inventions involving living organisms in India. The court ruled that a process for preparing a live vaccine against bursitis was patentable, establishing that the presence of a living organism in the final product does not automatically disqualify the process from being considered an invention under the Indian Patents Act, 1970. This decision was significant in clarifying that methods involving microbiological processes could be patentable, even if the resulting product contained a living entity.

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B. *Monsanto Technology LLC v. Nuziveedu Seeds Ltd* (2019)

The legal battle between Monsanto and Nuziveedu Seeds over patent rights related to genetically modified cotton seeds is a significant case illustrating the complexities of genetic patenting in India. The Division Bench of the Delhi High Court initially held that genetically modified plants, seeds, and gene sequences providing traits to plants were not patentable subject matter in India. However, the Supreme Court later set aside this decision and re- examined the case. While the Supreme Court has not yet given a final ruling on the patentability of isolated DNA and cDNA in plants, the case highlights the ongoing legal uncertainty and debate surrounding the patentability of genetically modified crops and related genetic material in India.

C. *Novartis Ag v. Union of India* (2013)

Although primarily focused on pharmaceutical patents, the Supreme Court's decision in the *Novartis* case has broader implications for the patentability of biotechnological inventions, including those related to genetics. The court emphasized the stringent criteria for novelty and inventive step required under the Indian Patents Act, particularly concerning the patenting of modified forms of known substances. This ruling underscore the principle that minor modifications to existing biological entities or sequences, without a significant enhancement in efficacy or a demonstrable inventive step, are unlikely to be granted patent protection in India.

D. *Association for Molecular Pathology v. Myriad Genetics, Inc.* (US Supreme Court, 2013)

This landmark case in the United States Supreme Court addressed the patentability of human genes. The court ruled that naturally occurring human genes are products of nature and therefore not patentable. However, it also held that complementary DNA (cDNA), a synthetic form of DNA, is eligible for patenting because it is not naturally occurring. While this decision is not binding in India, it has significantly influenced the international debate on gene patenting and provides a comparative perspective on how other jurisdictions grapple with similar issues.

4.7. Recent Trends and Ongoing Debates in Genetic Patenting in India

A. Judicial Interpretations of Section 3

Recent judicial pronouncements in India indicate a trend towards a more nuanced interpretation of Section 3 of the Patents Act, 1970, particularly in the context of biotechnological inventions. Courts have clarified that while naturally occurring substances are excluded from patentability under Section 3(c), engineered or synthetic substances or molecules that are products of human intervention can be patented, provided they meet the criteria of novelty and inventive step. This distinction emphasizes the role of human ingenuity in transforming a natural substance into a patentable invention. Furthermore, courts have acknowledged that significant human intervention in biological processes can distinguish them from "essentially biological processes" excluded under Section 3(j), potentially opening avenues for patenting certain biotechnological methods.

B. Patentability of Gene Editing Technologies

The patentability of gene editing technologies, such as CRISPR, remains a subject of ongoing debate in India, mirroring discussions taking place globally. The complexity of these technologies and the ethical considerations surrounding their use, particularly in human germline editing, add layers of intricacy to the patenting process. The outcomes of patent disputes related to CRISPR in other jurisdictions are likely to influence the approach taken by the Indian Patent Office and courts in determining the patentability of such inventions in India.

C. International Harmonization Efforts

India's patent law framework for genetic inventions is influenced by its obligations under international agreements like TRIPS and the

Convention on Biological Diversity. There is a growing global recognition of the need for greater harmonization of patent laws across different jurisdictions to facilitate international collaboration in genetic research and development and to streamline the patenting process for inventions with global applications. However, achieving complete harmonization remains a challenge due to differing national interests and ethical considerations.

4.8. Resources for Inventors Seeking Patents on Genetic Inventions in India

A. Guidelines and Practices of the Indian Patent Office

The Indian Patent Office provides guidelines for the examination of biotechnology applications for patents, which serve as a valuable resource for inventors. These guidelines offer insights into the Patent Office's interpretation of the relevant sections of the Patents Act, particularly Section 3 and Section 10, in the context of genetic inventions. Inventors should pay close attention to the requirements related to the written description of the invention and the process for depositing biological material. The guidelines also emphasize the importance of accurately disclosing the source and geographical origin of any biological resources used in the invention. Understanding and adhering to these guidelines can significantly enhance the chances of a successful patent application.

B. Interacting with the National Biodiversity Authority (NBA)

Inventors whose genetic inventions are based on biological resources obtained from India must be aware of the mandatory requirement to obtain prior approval from the National Biodiversity Authority (NBA) before applying for a patent, whether in India or abroad. The NBA has prescribed specific application forms and procedures for seeking this approval. Providing detailed information about the biological resource, its source, and its intended use in the invention is crucial for the NBA's review process. Initiating the NBA approval process early in the patent application timeline is highly recommended to avoid potential delays.

C. Intellectual Property Organizations and Legal Firms

Intellectual property organizations and legal firms specializing in biotechnology patents in India can provide invaluable assistance to inventors navigating the complexities of genetic patenting. These experts possess in-depth knowledge of the Indian Patents Act, relevant case laws, and the practices of the Indian Patent Office and the NBA. Seeking advice from patent attorneys specializing in this field can help inventors understand the specific requirements for their inventions, draft comprehensive patent applications, and navigate potential legal challenges.

CHAPTER - 5

Patenting Human Genetic Inventions and Gene Editing Technologies

The rapid advancements in the field of human genetics, coupled with the emergence of powerful gene editing technologies such as Clustered Regularly Interspaced Short Palindromic Repeats-associated protein 9 (CRISPR-Cas9) and Transcription Activator-Like Effector Nucleases (TALEN), have ushered in a new era of biological research with profound implications for human health. These technologies provide unprecedented capabilities to manipulate the fundamental building blocks of life, offering potential therapeutic solutions for a wide range of diseases previously considered untreatable. The ability to precisely alter the genetic code holds immense promise for correcting genetic defects, developing novel treatments for cancer, and combating infectious diseases.

Securing patent protection for these groundbreaking inventions is a critical step in incentivizing innovation and attracting the substantial investment required for their further development and eventual commercialization. Patents grant inventors a temporary period of exclusivity, allowing them to recoup the

significant research and development costs associated with bringing these complex technologies to market. This is particularly vital in the biotechnology sector, which is characterized by high investment risks and lengthy development timelines.

However, the patenting of human genetic material raises a multitude of complex legal, ethical, and societal questions, leading to significant debates and diverse patent laws across different jurisdictions. The very idea of claiming proprietary rights over aspects of the human genome sparks ethical concerns about the ownership of life and the potential for hindering research and limiting access to essential healthcare.

This report aims to provide a comprehensive analysis of the current landscape of patenting for human genetic inventions and related technologies. It will focus on key jurisdictions, including the United States, Europe, and India, and highlight the major trends and challenges that define this dynamic field. By examining the legal frameworks, the patent landscapes of prominent gene editing technologies, and the associated ethical implications, this report seeks to offer a nuanced understanding of the intricate relationship between human genetics, gene editing, and patent law.

5.1. Defining the Foundational Concepts Gene Editing: Mechanisms and Applications

Gene editing, also known as genome editing, refers to a collection of technologies that provide scientists with the ability to precisely alter an organism's DNA. These technologies enable the addition, removal, or alteration of genetic material at specific, targeted locations within the genome. While several approaches to gene editing have been developed, the CRISPR-Cas9 system has emerged as a particularly impactful tool due to its advantages in speed, cost- effectiveness, accuracy, and efficiency compared to earlier methods such as Zinc Finger Nucleases (ZFNs) and TALENs.

The CRISPR-Cas9 system is derived from a natural immune defence mechanism used by bacteria to protect themselves against viral infections. When a bacterium is infected by a virus, it captures small fragments of the viral DNA and integrates them into its own genome in specific patterns known as CRISPR arrays. These arrays allow the bacterium to "remember" the virus. Upon subsequent viral attacks, the bacterium produces RNA segments from the CRISPR arrays that recognize and bind to specific regions of the invading virus's DNA. The bacterium then employs a Cas enzyme, most commonly Cas9, to cut the viral DNA, thereby disabling the virus.

Scientists have ingeniously adapted this bacterial defence system for genome editing in various organisms, including humans. They design a small piece of RNA, known as a guide RNA, with a short sequence that is complementary to a specific target sequence in the cell's DNA. This guide RNA then directs the Cas9 enzyme to the precise location in the genome. Once the guide RNA binds to the target DNA sequence, the Cas9 enzyme acts as a molecular scissor and cuts the DNA at that specific site.

Following the DNA cut, the cell's natural DNA repair mechanisms are activated. Researchers can then leverage these repair pathways to introduce desired changes to the genome. This can involve deleting or inserting specific DNA sequences, correcting disease-causing mutations, or even replacing an existing segment of DNA with a customized sequence.

Gene editing technologies hold immense potential for the prevention and treatment of a wide array of human diseases. This includes inherited genetic disorders such as cystic fibrosis and sickle cell disease, as well as more complex conditions like cancer, heart disease, mental illness, and human immunodeficiency virus (HIV) infection. Beyond therapeutic applications, gene editing is also a powerful tool in research laboratories for understanding gene function through the creation of animal models of disease and in drug discovery. Furthermore,

these technologies have applications in agriculture for improving crop yields and disease resistance, as well as in the production of biofuels.

The application of gene editing technologies, particularly CRISPR-Cas9, to human genomes raises significant ethical concerns. A key distinction is made between somatic cell editing, which involves modifying genes in non-reproductive cells and affects only the individual being treated, and germline editing, which targets the DNA of egg and sperm cells or embryos, leading to heritable changes that can be passed on to future generations. While somatic cell editing generally faces fewer ethical objections, germline editing raises profound ethical challenges related to the potential for unintended consequences for offspring and the broader societal implications of altering the human gene pool. Questions also exist regarding the ethical permissibility of using gene editing for human enhancement purposes beyond treating disease.

Gene Silencing: Methods and Biological Significance

Gene silencing refers to the regulation of gene expression in a cell to prevent or reduce the production of a specific gene product, typically a protein. This can occur at the transcriptional level, by preventing the gene from being transcribed into RNA, or at the translational level, by preventing the RNA from being translated into protein. The term gene silencing is often used interchangeably with gene knockdown, which describes a significant reduction in gene expression, typically by at least 70%, but not a complete elimination, as seen in gene knockout.

Various methods are employed to achieve gene silencing, including the use of antisense oligonucleotides (ODNs), ribozymes, and RNA interference (RNAi). Antisense ODNs are short, single-stranded DNA or RNA molecules designed to bind to specific messenger RNA (mRNA) molecules, thereby blocking their translation into proteins. Ribozymes are catalytic RNA molecules that can cleave specific mRNA molecules, leading to their degradation and subsequent gene silencing.

RNA interference (RNAi) is a naturally occurring post-transcriptional gene silencing mechanism found in many eukaryotic organisms. This process is triggered by the presence of double-stranded RNA (dsRNA) in the cell. An enzyme called Dicer processes the dsRNA into smaller fragments, including small interfering RNAs (siRNAs) and microRNAs (miRNAs), which are typically 21-23 nucleotides in length. These small RNA fragments are then incorporated into a protein complex known as the RNA-induced silencing complex (RISC). RISC uses one strand of the siRNA or miRNA, the guide strand, to target and degrade complementary mRNA molecules or to suppress their translation into proteins.

Gene silencing plays a fundamental role in normal biological processes, including development, cell differentiation, and the regulation of metabolism and gene expression throughout the life of an organism. In plants, gene silencing is a key defence mechanism against pathogens and also regulates developmental processes.

The ability to artificially induce gene silencing has significant applications in therapeutics. By specifically targeting and silencing genes that contribute to disease, such as those involved in cancer, infectious diseases, and neurodegenerative disorders, researchers are developing novel treatment strategies. Gene silencing offers a potentially controllable and reversible approach to treating genetic conditions by targeting the underlying disease mechanism. This reversibility can be advantageous compared to gene therapy, which often involves permanent genetic modifications.

5.2. The Legal Landscape of Human Genetic Invention Patenting Patenting in the United States: Key Legislation and Landmark Cases

In the United States, patent law is primarily governed by Title 35 of the United States Code.

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Section 101 of this title defines patentable subject matter broadly as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof". However, this broad definition is subject to judicial interpretation, which has established exclusions for laws of nature, physical phenomena, and abstract ideas. This principle is crucial in the context of patenting human genetic inventions, as it directly relates to whether naturally occurring genetic material can be considered patentable.

The landmark Supreme Court case of *Association for Molecular Pathology v. Myriad Genetics, Inc.* (2013) significantly reshaped the legal landscape for patenting human genetic material in the United States. The case involved patents held by Myriad Genetics on the BRCA1 and BRCA2 genes, which are associated with an increased risk of breast and ovarian cancer. The Court unanimously ruled that isolated naturally occurring human genes are products of nature and are therefore not patentable simply because they have been isolated from the human body. The Court's reasoning emphasized that the sequence and order of nucleotides in a gene are dictated by nature, not by human invention. The act of merely isolating a gene, even if it requires significant effort, does not transform it into a patentable invention.

However, the *Myriad* decision also clarified that complementary DNA (cDNA) is patentable. cDNA is a synthetic DNA molecule created in the laboratory from messenger RNA (mRNA) and lacks the non-coding regions (introns) present in genomic DNA. The Court reasoned that cDNA is not naturally occurring because humans create it through a technical process. This distinction is critical, as many diagnostic tests and therapeutic proteins are based on cDNA sequences.

Prior to the *Myriad* ruling, the United States Patent and Trademark Office (USPTO) had generally granted patents on isolated gene sequences with known functions. The rationale was that isolating and purifying a gene sequence from its natural state differentiated it sufficiently to be considered patentable. The first patent on an entire human gene was awarded in 1982. This practice fuelled significant investment and innovation in the biotechnology sector.

The USPTO has also granted patents on biological materials derived from humans, including isolated and manipulated cells such as human embryonic stem cells (hESCs). However, the patentability of human-related inventions has faced legal and ethical scrutiny.

The patenting of human genetic inventions in the US has been a subject of considerable debate, with concerns raised about its potential to impede scientific research and limit access to genetic testing and therapies. Critics argued that patents on genes could lead to monopolies, increase the cost of healthcare, and hinder further innovation. The *Myriad* decision aimed to address some of these concerns by clarifying that naturally occurring genes are not patentable.

Patenting in Europe: The European Patent Convention and Biotechnology Directive

In Europe, the patentability of inventions is governed by the European Patent Convention (EPC). Article 52(1) of the EPC states that European patents shall be granted for any inventions which are susceptible of industrial application, which are new, and which involve an inventive step. This framework differs from the US approach in its treatment of naturally occurring substances.

The European Union's Biotechnology Directive (Directive 98/44/EC) provides specific rules concerning the patenting of biotechnological inventions, including those related to human genetic material. Article 5(2) of the Directive clarifies that while the simple discovery of a gene sequence or a partial gene sequence is not patentable, an element isolated from the human body or produced by a technical process, including a gene sequence or partial gene

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sequence, can be patentable even if its structure is identical to that of a natural element. This provision allows for the patenting of isolated gene sequences provided that their industrial application is disclosed in the patent application. The disclosed industrial application must be specific and substantial, going beyond mere scientific interest.

The European Patent Office (EPO) examines patent applications for biotechnological inventions based on the criteria of novelty, inventive step (non-obviousness), and industrial applicability (utility). For gene patents, the function of the gene sequence or the protein it encodes must be clearly disclosed in the patent application to demonstrate industrial applicability. The EPO also assesses whether the claimed invention involves an inventive step, meaning it would not have been obvious to a person skilled in the art.

While the Biotechnology Directive aims to harmonize patent law across EU member states, some national laws may impose additional limitations. For example, France has banned the patenting of whole or partial human gene sequences per se. Similarly, Germany and Italy allow for purpose-bound patent protection for gene sequences, limiting the scope of the patent to the specific industrial application disclosed. However, the validity of national laws that significantly deviate from the Directive is questionable, and applicants often file directly with the EPO.

The European Court of Justice (ECJ) has addressed the ethical dimensions of gene patenting, ruling in 2001 that patenting genetic material isolated from the human body does not violate principles of human dignity. This ruling affirmed the legality of the Biotechnology Directive.

Patenting in India: The Indian Patents Act and Evolving Jurisprudence

The Indian Patents Act, 1970, governs patent law in India and includes specific provisions relevant to the patenting of human genetic inventions. Section 3 of the Act outlines categories of inventions that are not patentable. Section 3(c) explicitly prohibits the patenting of "the discovery of any living thing or non-living substance occurring in nature". This provision serves as a primary barrier to patenting naturally occurring genes or their mere isolation.

Furthermore, Section 3(j) of the Act excludes from patentability "plants and animals in whole or any part thereof including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals". This section, added through a 2002 amendment, has been interpreted to restrict the patenting of genes that are considered part of plants or animals.

Initially, the Indian Patents Office (IPO) had a more permissive stance on patenting isolated genomic DNA. However, the Indian Biotechnology Guidelines of 2013 brought a change, classifying such isolated material as a "mere discovery" and therefore not patentable under Section 3(c). Additionally, Section 3(d), which prohibits patenting "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance," can also be used to argue against the patentability of isolated DNA.

Despite these restrictions, the Indian patent law offers some flexibility for patenting modified genetic material. Isolated and purified gene sequences, particularly complementary DNA (cDNA), may be patentable if they meet the criteria of novelty under Section 2(1)(j) of the Act, involve an inventive step (non-obviousness), and demonstrate industrial applicability, especially when significant human intervention is involved in their creation. The Manual of Patent Practice and Procedure in India has seen changes over time regarding the requirement of "substantial human interaction," with the 2011 version removing this specific criterion.

Several judicial decisions have influenced the understanding of gene patentability in India. The Calcutta High Court's ruling in *Dimminaco A.G.*

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v. Controller of Patents & Designs (2001) was a significant case that upheld the patentability of a process for manufacturing a vaccine containing a live virus, stating that there was no legal bar to patenting a method of manufacture even if the final product is living. However, the Supreme Court has not yet provided a definitive judgment on the patenting of isolated DNA and cDNA, although a patent was granted for the Japanese Encephalitis Virus cDNA, as it was deemed "new and novel" under Section 2 of the Patents Act, 1970. The case of *Monsanto Technology LLC v. Nuziveedu Seeds Ltd* (2019) saw the Division Bench stating that genetically modified plants, seeds, and gene sequences providing genetic traits to plants are not patentable in India. The Supreme Court re-examined this case, but a final decision on the patenting of isolated DNA and cDNA is still pending.

The implementation of the TRIPS agreement by the WTO has also influenced India's patent regime. While Article 27(3) of TRIPS allows member states to exclude plants, animals, and essentially biological processes from patentability, it remains silent on the patenting of genetic material like DNA sequences. However, Article 8 of TRIPS allows member states to take measures to protect public health and nutrition, which could be used to justify restrictions on gene patenting. The Indian Patents Act was amended in 2005 to align with TRIPS, including the removal of Section 5, which previously restricted patentability to methods or processes of manufacture, thus allowing product patents in biotechnology. The Indian patent system has also been influenced by the US legal framework in this area, and the *Myriad* decision has had an impact on the interpretation of gene patentability in India.

5.3. The CRISPR-Cas9 Patent Arena Key Patent Holders and Their Claims

The patent landscape for CRISPR-Cas9 technology is intensely competitive and characterized by a complex web of intellectual property rights, primarily held by the University of California, Berkeley (UC Berkeley), and the Broad Institute of MIT and Harvard (Broad Institute).

UC Berkeley, led by Jennifer Doudna and Emmanuelle Charpentier, filed its initial patent application in May 2012, broadly covering the fundamental mechanism of the CRISPR-Cas9 system and its potential for genome editing in vitro. Their claims were not initially limited to specific cell types, encompassing the general application of the technology. UC Berkeley has subsequently been granted multiple patents in the US for CRISPR technologies across various cellular and non-cellular settings and holds over 50 CRISPR patents globally.

The Broad Institute, spearheaded by Feng Zhang, filed its first patent application in December 2012, specifically describing and enabling the use of CRISPR-Cas9 for genome editing in eukaryotic cells, including plant and animal cells, which are crucial for human therapeutic applications. The Broad Institute demonstrated the successful adaptation of CRISPR-Cas9 for genome editing in these more complex cell types. The Broad Institute received its first US patent for this specific application in April 2014. By late 2020, the Broad Institute had been granted 26 patents specifically for CRISPR-Cas9 in the United States and 29 in Europe.

In addition to these two primary entities, other biotechnology companies such as Editas Medicine, CRISPR Therapeutics, and Intellia Therapeutics have also established significant patent portfolios focusing on specific applications and enhancements of CRISPR-Cas9 technology. These companies often license foundational patents from either UC Berkeley or the Broad Institute to support their research and development efforts.

5.4. The Protracted Patent Disputes: UC Berkeley vs. Broad Institute and Beyond

The groundbreaking nature and immense commercial potential of CRISPR-Cas9 technology ignited an intense and long-running

patent dispute, primarily between UC Berkeley and the Broad Institute, which unfolded in patent offices and courts in the United States and Europe.

In the United States, the USPTO initiated several interference proceedings to determine which party was the first to invent the use of CRISPR-Cas9 in eukaryotic cells. The first interference, commencing in 2016, concluded in 2017 with the PTAB ruling that there was no "interference- in-fact" because the Broad Institute's claims, specific to eukaryotic cells, were deemed patentably distinct from UC Berkeley's broader claims[3].

However, UC Berkeley subsequently filed new patent applications with claims specifically directed to eukaryotic cells, leading to a second interference proceeding initiated in 2019. In a significant ruling in February 2022, the PTAB sided with the Broad Institute, concluding that UC Berkeley had not provided sufficient evidence of successfully using CRISPR-Cas9 in animal and plant cells before the Broad Institute's demonstration of such use. This decision represented a major setback for UC Berkeley, potentially resulting in the loss of significant licensing revenue related to human therapeutics. UC Berkeley has expressed its disagreement with the ruling and is exploring options for further legal challenges.

The patent dispute has also unfolded in Europe with differing outcomes. The European Patent Office (EPO) initially granted a broad patent to Jennifer Doudna and Emmanuelle Charpentier. However, the EPO also revoked a key patent held by the Broad Institute due to a technicality concerning priority claims. These divergent rulings in major jurisdictions underscore the complexities of patent law and its application to groundbreaking scientific discoveries.

The CRISPR-Cas9 patent landscape is further complicated by the involvement of other entities, such as ToolGen in South Korea, which also holds patents related to the technology.

5.5. Scope and Implications of Granted CRISPR-Cas9 Patents

The granted CRISPR-Cas9 patents, held by UC Berkeley, the Broad Institute, and other entities, encompass a wide range of claims related to the technology. These claims cover the fundamental CRISPR-Cas9 system itself, its individual components such as the Cas9 enzyme and guide RNAs, methods for using the system to edit genes in various cell types and organisms (including eukaryotic cells), and specific applications in diverse fields including human therapeutics, agriculture, and diagnostics.

Ownership of these foundational patents grants the patent holders significant control over the use and commercialization of CRISPR-Cas9 technology. This control can influence who can utilize the technology, for what purposes, and under what terms, potentially impacting the pace and direction of innovation within the field.

The ongoing patent disputes and the resulting fragmented ownership of CRISPR-Cas9 patents have created a complex licensing landscape that can be challenging for researchers and companies to navigate. Securing the necessary licenses to conduct research or develop commercial products may necessitate engaging with multiple patent holders, potentially leading to delays and increased costs.

To address these challenges and promote broader access to CRISPR-Cas9 technology, efforts have been made to establish patent pools or joint licensing strategies involving the key patent holders. The Broad Institute has been a proponent of such approaches, aiming to create a more streamlined and equitable licensing framework. However, achieving a comprehensive agreement among all relevant parties has proven to be difficult.

The broad scope of some CRISPR-Cas9 patents has also raised ethical concerns regarding potential limitations on research and the accessibility of future therapeutic applications,

particularly if exclusive licenses result in high treatment prices.

5.6. TALEN Technology: Patent History and Current Status Evolution of TALEN Patents and Key Players

Transcription Activator-Like Effector Nucleases (TALENs) emerged as a significant genome editing tool in the years preceding the widespread adoption of CRISPR-Cas9. TALENs are engineered proteins created by fusing DNA-binding domains known as TAL effectors to the catalytic domain of the FokI nuclease. The DNA-binding specificity of TAL effectors is determined by a series of repeated amino acid sequences that can be designed to recognize and bind to specific DNA sequences.

Key patent holders in the TALEN technology space include Cellectis, a genome engineering company, as well as academic institutions such as the University of Minnesota and Iowa State University.

Cellectis was a pioneer in the development and commercialization of TALEN technology, establishing a strong partnership with the University of Minnesota and Iowa State University in 2011. Cellectis holds exclusive rights to a portfolio of patents owned by these universities related to TAL-effector nucleases, covering various aspects of the technology, including the nucleases themselves and the polynucleotides encoding them.

The University of Minnesota System also holds patents related to TALEN-mediated DNA editing for the treatment of disease-causing mutations in the human genome and human cells. These patents cover methods for personalized gene therapy using TALENs to correct mutations while preserving the integrity of the rest of the genome.

Cellectis was the first company to bring TAL-effector nucleases to the market in 2011, commercializing them under the trademark TALEN™. The company provides its customers with TALEN™ products under license of these patents, enabling researchers to undertake a wide range of genome engineering projects.

While TALENs represented a significant advancement in DNA targeting and genome editing, the emergence of CRISPR-Cas9, with its relative ease of implementation and lower cost, has led to its more widespread adoption in research laboratories. However, TALENs continue to be utilized and offer certain advantages in specific applications.

5.7. Comparative Analysis of TALEN and CRISPR-Cas9 Patent Landscapes

CRISPR-Cas9 has rapidly become the dominant genome editing technique due to its exceptional ease of design and use compared to earlier methods like TALENs. Designing guide RNAs for CRISPR-Cas9 is significantly simpler and less expensive than engineering TALEN arrays to target specific DNA sequences.

Both TALENs and CRISPR-Cas9 offer high target site specificity, enabling precise genetic alterations. However, TALENs are generally considered to have less off-target activity compared to early CRISPR-Cas9 systems, although advancements in CRISPR specificity have narrowed this gap. TALENs require a pair of nucleases to bind on opposite sides of the target site for cleavage, resulting in a longer recognition sequence (approximately 36 base pairs), which is less likely to be found elsewhere in the genome, thus enhancing specificity. In contrast, CRISPR-Cas9 relies on a 20-nucleotide guide RNA sequence followed by a PAM motif.

A key advantage of TALENs over CRISPR is their flexibility in targeting virtually any specific locus in the genome without the constraint of a nearby PAM sequence, which is required by the commonly used Cas9 enzyme. This allows researchers to access a broader range of genomic sites for editing using TALENs. For instance, TALENs have been the primary tool for targeting and manipulating mitochondrial genomes, as early CRISPR systems were less efficient in this cellular compartment. The patent landscape for CRISPR-Cas9 is significantly more complex and contentious

than that of TALENs. The ongoing high-profile patent disputes between UC Berkeley and the Broad Institute over CRISPR-Cas9 contrast with the more settled IP situation for TALENs, where Cellectis has a strong licensing position.

While CRISPR-Cas9 is generally less expensive to use than TALENs, the potential licensing costs associated with the complex CRISPR patent landscape could offset this advantage in some cases. Researchers and companies need to carefully consider the IP implications when choosing between these technologies for their specific applications.

5.8. Patenting Other Significant Genetic Techniques

RNA Interference (RNAi): Patent Holders and Therapeutic Potential

RNA interference (RNAi) is a naturally occurring gene silencing mechanism that has been harnessed for therapeutic applications, leading to a significant body of patents in this area.

Key patent holders in the RNAi field include Alnylam Pharmaceuticals, Thermo Fisher Scientific (which acquired Dharmacon), and Sirnaomics. Alnylam Pharmaceuticals has established a dominant patent position in RNAi therapeutics, with a vast portfolio of patents covering various aspects of the technology.

The foundational patents for siRNA technology, often referred to as the "Tuschl II" patents, are exclusively licensed to Alnylam from their originators at the Max Planck Institute, MIT, Whitehead Institute, and the University of Massachusetts. These patents cover the structural characteristics of siRNA molecules crucial for their gene silencing activity.

Recent patent analysis indicates a growing trend in RNAi innovation, particularly in the development of treatments for metabolic, infectious, neurological, and cardiovascular diseases. The majority of patent activity in this area is driven by universities and research institutions, with an increasing number of filings from companies in Southeast Asia.

The first FDA-approved RNAi therapeutic, ONPATTRO™ (patisiran) developed by Alnylam, targets a protein involved in hereditary transthyretin-mediated amyloidosis. This approval validated the therapeutic potential of RNAi and the importance of patent protection in this field.

Zinc-Finger Nucleases (ZFNs): Key Patents and Applications

Zinc-Finger Nucleases (ZFNs) were among the first programmable gene editing tools, enabling targeted modifications to the genome. ZFNs consist of engineered zinc finger proteins that bind to specific DNA sequences and a nuclease domain that cuts the DNA.

Sangamo Therapeutics holds a dominant patent position in the ZFN technology field, with a significant portfolio of patents covering various aspects of ZFN design and application. Sangamo has actively acquired and licensed ZFN-related intellectual property from academic institutions.

ZFNs have been used in various applications, including creating HIV-resistant human cells and in clinical trials for genetic disorders. They also have applications in plant genetic engineering and the production of biopharmaceuticals.

Antisense Technology: Patent Strategies and Market Players

Antisense technology utilizes antisense oligonucleotides (ODNs) to silence gene expression by binding to specific mRNA sequences and preventing their translation into proteins.

Patenting strategies in antisense technology often involve developing comprehensive patent portfolios covering the oligonucleotide sequence, chemical modifications, manufacturing processes, and therapeutic applications.

Ionis Pharmaceuticals is a key player in the antisense technology field, holding numerous patents and having successfully developed and

commercialized several antisense drugs.

5.9. Ethical and Societal Ramifications of Patenting Human Genetic Inventions and Gene Editing Technologies

Moral and Philosophical Considerations of Gene Ownership

The patenting of human genetic inventions raises fundamental moral and philosophical questions about the ownership of life's building blocks. Many argue that genes, as naturally occurring components of the human body, should not be subject to proprietary rights. This perspective views the patenting of genes as a form of commodification of human life, potentially undermining human dignity.

Conversely, proponents argue that patents on genetic inventions do not confer ownership of the gene itself but rather a limited right to exclude others from using the specific invention as claimed in the patent. This exclusivity is seen as a necessary incentive to encourage investment in the costly and time-consuming research and development required to translate genetic discoveries into useful diagnostic tools and therapeutic treatments.

A crucial ethical distinction is often drawn between naturally occurring genes and human- altered genetic sequences, such as cDNA. Many believe that while naturally occurring genes might be considered discoveries, human-engineered sequences involve an element of invention and are therefore more ethically justifiable for patenting. The *Myriad* case in the US reflected this distinction by invalidating patents on isolated natural genes but upholding the patentability of cDNA.

Concerns also exist that gene patents could lead to monopolies that restrict access to vital genetic information and technologies, potentially hindering medical progress and creating inequities in healthcare. The balance between commercial interests and the public good remains a central ethical consideration in this debate.

5.10. Impact on Scientific Research and Innovation

The patenting of human genetic inventions and gene editing technologies has a complex and sometimes conflicting impact on scientific research and innovation.

On one hand, patents are intended to incentivize innovation by providing a period of exclusivity that allows inventors to recoup their investment and potentially profit from their discoveries. This can be particularly important in the biotechnology industry, where research and development costs can be substantial. Furthermore, the patent application process requires inventors to disclose the details of their inventions, which can contribute to the broader scientific knowledge base.

However, concerns have been raised that gene patents can sometimes hinder rather than promote scientific progress. Patent holders may restrict the use of patented genes or technologies by other researchers, potentially impeding further investigation and the development of new applications. The existence of "patent thickets," where multiple overlapping patents cover different aspects of a particular technology, can also create barriers to research and innovation by requiring researchers to navigate a complex web of intellectual property rights and potentially obtain licenses from multiple parties. The *Myriad* case highlighted concerns that patents on the BRCA genes might have limited research on these important cancer-related genes.

5.11. Accessibility and Affordability of Genetic Diagnostics and Therapies

A significant societal concern related to the patenting of human genetic inventions and gene editing technologies is their potential impact on the accessibility and affordability of genetic diagnostics and therapies.

Patents can grant exclusive rights to patent holders, allowing them to control the market for specific genetic tests or therapies. This monopoly power can lead to higher prices,

making these essential healthcare tools unaffordable for many patients. The case of Myriad Genetics' BRCA tests, which were priced at a premium due to patent exclusivity, is a prime example of this issue.

The high costs of patented genetic tests and therapies can also exacerbate existing healthcare disparities, particularly in low- and middle-income countries where access to advanced medical technologies is already limited.

There is a growing recognition of the need to balance intellectual property rights with the public interest in ensuring access to essential healthcare. Policy measures such as compulsory licensing have been suggested as potential tools to address situations where patents may be hindering access to critical genetic tests or treatments.

Broader Societal Implications and Public Perception

The patenting of human genetic inventions and gene editing technologies has broader societal implications that extend beyond the realms of research and healthcare.

The prospect of using gene editing to alter the human germline raises profound ethical questions about the potential long-term consequences for the human gene pool and future generations. Concerns about unintended genetic mutations and the potential for misuse of these powerful technologies are also prominent in public discourse.

The use of gene editing for human enhancement purposes, beyond treating or preventing disease, raises further ethical dilemmas related to the definition of normalcy, the potential for creating social inequalities, and the concept of "playing God".

Public perception of gene patenting and gene editing technologies is often influenced by a complex interplay of hope for medical advancements and apprehension about the ethical and societal ramifications of manipulating the fundamental building blocks of life.

The high-profile patent disputes surrounding CRISPR-Cas9 have also contributed to public awareness and discussion about the implications of intellectual property rights in this rapidly evolving field.

5.12. Illustrative Case Studies in Human Genetic Invention Patenting Examples of Successful Patent Applications and Their Impact

Despite the limitations set by the *Myriad* decision on patenting isolated naturally occurring genes in the US, successful patent applications related to human genetic inventions continue to be granted, particularly for complementary DNA (cDNA). Patents covering cDNA-based diagnostic tests and therapeutic proteins have been successfully obtained and have significantly contributed to advancements in personalized medicine and biopharmaceuticals.

Patents on specific therapeutic applications of gene editing technologies, such as CRISPR-Cas9 modified hematopoietic stem cells for treating sickle cell disease and beta-thalassemia, as described in patent application WO2019113149A1, exemplify successful patenting strategies focused on utility and human intervention. The FDA approval of Casgevy, the first CRISPR-based therapy, highlights the value of patents in this area.

Historically, the Cohen/Boyer patents on recombinant DNA technology and the Axel patents on co-transformation were foundational to the biotechnology industry. These patents, while not directly on natural human genes, enabled the manipulation of genetic material and the production of recombinant proteins, generating significant revenue through broad licensing.

Patents covering methods of using genetic sequences for diagnostic testing, provided they meet the criteria of novelty, non-obviousness, and utility, have also been successfully patented. The key is often to claim a specific

method or process that involves more than just observing a natural phenomenon.

Analysis of Unsuccessful Patent Applications and Key Reasons for Rejection

The *Association for Molecular Pathology v. Myriad Genetics, Inc.* case serves as a prime example of unsuccessful patent applications for isolated naturally occurring human genes. The Supreme Court invalidated Myriad's patents on the BRCA1 and BRCA2 genes, concluding that these DNA sequences were products of nature and not patent-eligible merely by virtue of their isolation.

The initial NIH application to patent expressed sequence tags (ESTs) also faced challenges and was largely abandoned due to concerns about the lack of a specific and substantial utility for these gene fragments.

In Europe, the rejection of European patent No. 1 407 044 related to RNA interference illustrates how insufficient disclosure can lead to the failure of a patent application. The EPO found that the application did not adequately describe the structural requirements for the claimed dsRNA molecules to mediate RNAi.

CHAPTER - 6

Patenting Genetic Inventions in GMOs and the Monarch Butterfly Issue

6.1. Understanding Patent Law and GMOs

A. Types of Intellectual Property Protection for GMOs

Patents serve as a fundamental mechanism for protecting intellectual property, granting inventors exclusive rights to their creations for a defined period. This exclusivity aims to encourage innovation by allowing inventors to potentially recoup their investment in research and development. In the realm of biotechnology, particularly concerning Genetically Modified Organisms (GMOs), several types of patents and intellectual property protections are relevant, including utility patents, plant patents, and Plant Variety Protection Certificates (PVPCs).

1. Utility Patents

Utility patents represent a broad category of intellectual property protection, covering novel inventions that possess practical uses. These patents can encompass a wide array of innovations, such as new technologies, processes, machines, and compositions of matter. When applied to GMOs, utility patents are frequently used to safeguard the underlying technology and methods employed in their creation. The scope of protection offered by utility patents for GMOs can be quite extensive, potentially covering the genetically modified plants themselves, new plant strains derived from various breeding methods, and specific genetic modifications that confer desirable traits. For instance, utility patents can protect GMO plants, new plants discovered or invented in a cultivated state that can be asexually reproduced, new plant strains resulting from crossbreeding, and even plants that are sexually reproduced by licensees, with restrictions on the licensees' ability to further distribute the seeds.

Compared to other forms of intellectual property protection available for GMOs, utility patents generally offer stronger safeguards, particularly concerning the saving of seeds by farmers and the use of patented material in breeding programs. Unlike PVPCs, utility patents do not typically include exemptions for farmers to save seeds or for breeders to use the patented invention for further breeding without a license from the patent owner. This robust protection can grant patent holders significant control over the utilization of their GMO technology. Obtaining a utility patent requires meeting stringent criteria, including providing a detailed description of the invention. For GMOs, the availability of comprehensive molecular information often facilitates meeting these demanding requirements.

2. Plant Patents

Plant patents constitute a specific type of patent designed to protect new varieties of plants that are asexually reproduced. To be eligible for a

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plant patent, a genetically modified plant variety must be new and distinct, possessing characteristics that differentiate it from existing plants. Additionally, the plant must be capable of asexual reproduction, meaning that plants reproduced through natural methods like seeds are generally not eligible for plant patents. While plant patents grant exclusive rights to the inventor, their scope has certain limitations Notably, a plant patent does not prevent others from using the patented plant for research or breeding purposes, as long as such use does not involve commercial propagation. This limitation aims to foster further innovation and scientific advancement in plant breeding. Furthermore, plant patents protect the specific new plant variety itself and do not necessarily cover the broader genetic modification technology or methods used to create the GMO; for more comprehensive protection of these aspects, utility patents are often preferred. Consequently, GMO companies typically Favor utility patents over plant patents due to the broader protection offered by the former.

3. Plant Variety Protection Certificates (PVPCs)

In the United States, Plant Variety Protection Certificates (PVPCs), established by the Plant Variety Protection Act (PVPA) of 1970, provide another form of intellectual property protection for new plant varieties. PVPCs are administered by the U.S. Department of Agriculture (USDA) and protect sexually reproduced crops and tubers. Unlike utility patents, PVPCs include exemptions that allow breeders to use protected varieties for breeding other varieties and permit farmers to save seeds of protected varieties for their own subsequent plantings. This approach represents a different balance between protecting the rights of plant breeders and ensuring access for researchers and farmers. However, utility patents offer stronger intellectual property protection compared to PVPCs because they do not have these breeder or farmer-use exemptions, granting a greater degree of control to the patentholder. This difference in the strength of protection has contributed to the preference for utility patents in the context of GMOs.

B. Criteria for Patenting Genetic Inventions

To secure patent protection for an invention, including genetic inventions in GMOs, the invention must generally meet three fundamental criteria: novelty, non-obviousness, and utility. These criteria are designed to ensure that patents are granted for genuine advancements that represent a significant contribution to the field.

1. Novelty

The criterion of novelty dictates that an invention must be new and not previously disclosed to the public in any form. In the context of GMOs, this means that the specific genetic modification or the resulting genetically modified organism must be unique and not already existing in nature. The introduction of foreign DNA or the alteration of existing genetic material in a way that does not occur naturally can satisfy the novelty requirement for patenting a GMO.

2. Non-Obviousness

Non-obviousness requires that the invention is not an evident or obvious improvement over existing technologies to someone with ordinary skill in the relevant field. For GMOs, this implies that the genetic modification must involve an inventive step and should not be a routine or straightforward alteration of the organism's genome. The process of genetically engineering an organism to express a new trait or to enhance an existing one often involves complex techniques and specialized knowledge, thus typically meeting the non-obviousness standard.

3. Utility

The criterion of utility mandates that the invention must have a practical application and provide a tangible benefit. In the case of GMOs, this means that the genetically modified organism must have a demonstrated use or purpose. This could include traits such as

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increased crop yield, resistance to pests or diseases, tolerance to herbicides, enhanced nutritional value, or other beneficial characteristics that offer a practical advantage in agriculture or other fields. A mere discovery of a gene or genetic sequence without a demonstrated use is generally not sufficient for patentability; a specific and practical application must be disclosed.

C. Scope of Patent Protection for GMOs

Utility patents can provide a broad scope of protection for GMOs, potentially encompassing not only the genetically modified plant itself but also the specific genetic traits introduced and the processes used to create the organism. This multi-layered protection allows patent holders to control various aspects of their GMO innovations. For example, patents have been granted for GMOs exhibiting herbicide resistance, such as Monsanto's Roundup Ready soybeans, which are engineered to tolerate the herbicide glyphosate. Similarly, insect resistance, as seen in Bt corn which produces a toxin harmful to certain insect pests, is another aspect of GMOs commonly protected by utility patents. Modifications for enhanced traits, such as faster maturation in the case of AquAdvantage salmon, have also been subject to utility patent protection. Furthermore, patent protection extends to the gene targeting technologies themselves, such as CRISPR/Cas9, which are used to create GMOs, as well as to the specific methods applied to genetically modified organisms to achieve desired outcomes. While naturally occurring DNA sequences are generally excluded from patentability in some jurisdictions like the United States, engineered genes or complementary DNA (cDNA), which is a variation of the original gene, can be patented, offering protection for the specific genetic modifications introduced.

6.2. Global Perspectives on GMO Patent Regulations

A. United States

The United States has been a pioneer in offering patent protection for GMOs, including both genetically modified plants and animals. This approach stems from landmark legal precedents that affirmed the patentability of living organisms created through human intervention. Utility patents serve as the primary mechanism for protecting GMO innovations in the US, providing comprehensive coverage for the genetically modified organisms, their specific traits, and the methods of their production. The regulatory landscape in the US for GMOs is governed by the Coordinated Framework for Regulation of Biotechnology, which involves the USDA, FDA, and EPA, focusing on ensuring the safety of GMO products rather than the process by which they are developed. Key legal decisions, such as *Diamond v. Chakrabarty* in 1980, which established the patentability of genetically engineered microorganisms, and *JEM Ag Supply v. Pioneer Hi-Bred* in 2001, which extended utility patent protection to include plants, have significantly shaped the patenting of GMOs in the US. Despite the robust patent protection offered, there remains an ongoing debate in the US regarding the appropriate level of protection for GMO companies and the balance of rights with farmers, particularly concerning issues like seed saving and the potential for corporate control over the food supply.

B. Europe

In Europe, the patenting of genetically engineered plants is permitted, although the regulatory environment tends to be more stringent compared to the United States. A significant recent development in Europe is the proposed ban on patenting plants engineered using new genomic techniques (NGTs) like CRISPR/Cas. This initiative aims to prevent legal uncertainties and reduce the dependence of farmers and breeders on large aggrotech companies. The European Parliament has voted in Favor of this ban, which would apply to NGT plants, plant parts, and the genetic information they contain. The current legal framework in Europe includes the Biotech Directive (98/44/EC) and the European Patent

Convention (EPC), which provide the basis for the patentability of biological inventions. However, concerns have been raised in Europe that the patenting of plants, including those derived from conventional breeding, could hinder innovation in plant breeding and increase the market power of a few major agribusiness corporations. Additionally, there is a strong emphasis in Europe on the labelling of GMOs and ensuring traceability throughout the food supply chain to protect consumer rights and allow for the withdrawal of GMOs from the market if safety concerns arise.

C. India

India's patent law takes a distinct approach to the patenting of GMOs. Section 3(j) of the Patents Act, 1970, explicitly excludes plants in whole or any part thereof, seeds, and essentially biological processes for the production and propagation of plants from being patentable. This provision reflects India's commitment to protecting farmers' rights and preserving biodiversity. While direct patenting of plants and seeds is prohibited, there is a possibility of obtaining patents on recombinant genes if they demonstrate an inventive step, industrial application, and significant human intervention. Furthermore, India has the Protection of Plant Variety and Farmer's Rights Act, 2001 (PPVFR Act), which provides a framework for protecting plant varieties and the rights of farmers, including those related to transgenic varieties. In India, there is an ongoing debate regarding the potential impact of GMOs on farmers' dependence on multinational corporations and concerns about maintaining seed sovereignty, with legal provisions aiming to balance intellectual property rights with the interests of farmers and local companies.

6.3. Ethical and Societal Debates Surrounding GMO Patents

A. Arguments for Patenting Living Organisms

The patenting of living organisms, including GMOs, is supported by several arguments. A primary justification is that patents serve as a crucial incentive for innovation in the biotechnology sector. The development of GMOs requires substantial investment in research, development, and navigating complex regulatory approval processes.[1] By granting inventors exclusive rights for a limited period, patents provide a mechanism for them to potentially recoup these investments and generate profits, thereby encouraging further advancements in the field. Furthermore, patents are seen as facilitating the commercialization and wider dissemination of GMOs. Patent holders can control the production and distribution of their GMOs, which proponents argue helps ensure that they are produced according to high standards of quality and safety. The patent system also promotes transparency and the sharing of knowledge, as inventors are required to publicly disclose the details of their inventions in exchange for exclusive rights. The landmark US Supreme Court decision in *Diamond v. Chakrabarty* (1980) played a pivotal role in establishing the patentability of genetically engineered microorganisms, significantly stimulating patent activity within the genetic engineering sector.

B. Arguments Against Patenting Living Organisms

Despite the arguments in favour, the patenting of living organisms, particularly GMOs, raises significant ethical and societal concerns. A central ethical objection revolves around the idea of ownership of life itself. Critics argue that life forms are products of nature or creation and should not be subject to private ownership and commercial exploitation. There are also significant concerns about the potential for GMO patents to lead to monopolies within the agriculture sector. Patents can limit farmers' access to certain seeds, potentially impacting agricultural diversity and undermining farmer autonomy. Furthermore, the patenting of GMOs creates a tension with the traditional practice of farmers saving and replanting seeds from their harvest, a practice often prohibited by patent agreements. The issue of biopiracy also arises,

where corporations may patent genetic resources or traditional knowledge originating from indigenous communities without providing fair compensation or obtaining proper consent. Environmental concerns are another key aspect of the debate, with critics arguing that GMOs could lead to unintended ecological consequences, such as the loss of biodiversity and cross- contamination with non-GMO species. Additionally, some argue that the patenting of genes can hinder scientific research by restricting access to and use of genetic information, potentially slowing down medical and agricultural advancements.

C. Societal Perceptions and Controversies

GMOs and their associated patents are a subject of considerable public debate and controversy. These controversies often stem from concerns about the safety of GMO foods, their potential environmental impacts, and the increasing control that large corporations exert over the global food supply through patent rights. There is a notable divergence in views between scientists, who generally agree on the safety of currently available GMOs, and the general public, where scepticism and distrust are more prevalent. The significant role of large agribusiness companies in the GMO sector, holding numerous patents and wielding considerable market power, fuels concerns about corporate dominance over food production. Moreover, there are worries that the patenting and commercialization of GMOs could exacerbate existing socio-economic disparities, potentially limiting access to food and agricultural technologies in developing countries.

6.4. The Impact of GMO Patents on Agricultural Innovation and Food Systems

A. Driving Agricultural Innovation

Patent protection plays a significant role in driving agricultural innovation by providing incentives for seed companies and biotechnology firms to invest in the research and development of new GMO traits. These innovations can include traits such as increased crop yield, enhanced resistance to pests and diseases, tolerance to herbicides, and improved nutritional content. The prospect of obtaining patents and the associated market exclusivity encourages companies to undertake the often costly and time-consuming process of developing new GMOs. Following the expansion of intellectual property rights protections for crop seeds, including utility patents for GMOs, there has been a notable increase in research and development spending by seed companies. This investment has led to the commercialization of a variety of innovative GMOs that have transformed agricultural practices. Examples of such innovations include herbicide-tolerant crops like Roundup Ready soybeans, insect-resistant crops such as Bt corn, and crops with modifications aimed at improving nutritional value. Furthermore, patents are expected to play a crucial role in the ongoing development and commercialization of gene-editing technologies like CRISPR, which are opening up new possibilities for creating crops with desirable traits. The ability to patent these advanced gene- editing tools and the resulting genetically modified crops is likely to further accelerate the pace of innovation in the agricultural biotechnology sector.

B. Implications for Food Security

GMOs hold the potential to contribute to global food security by increasing crop yields and enhancing the resilience of crops to various environmental stresses, particularly in the context of a growing global population and the challenges posed by climate change. Traits like drought tolerance, pest resistance, and improved nutritional content, often introduced through genetic modification, could play a role in ensuring a more stable and sufficient food supply. However, concerns have been raised that the patenting of GMOs could lead to increased corporate control over the food system, potentially limiting access to essential agricultural resources, especially for small-scale farmers in developing countries.

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Dependence on patented seeds and technologies, coupled with restrictions on the traditional practice of saving seeds, could undermine the livelihoods and autonomy of farmers, particularly in regions where affordability and access are significant issues. The necessity of GMOs to feed the world is also a subject of debate, with some arguing that other factors, such as political instability, conflict, and food waste, are more significant drivers of global hunger. Additionally, the focus on profit-driven innovation through the patent system may not always prioritize research and development efforts that could benefit smaller markets or address the specific needs of poorer populations.

C. Accessibility of Seeds for Farmers

GMO patents, particularly utility patents, often impose restrictions on farmers regarding the saving and replanting of seeds harvested from patented crops. Unlike conventional seeds, where farmers have a long-standing tradition of saving and reusing seeds, GMO patents typically require farmers to purchase new seeds for each planting season. This can lead to increased costs for farmers and create a dependence on seed companies that hold the patent rights. Furthermore, farmers often enter into contractual agreements with seed companies when purchasing GMO seeds, which can further limit their rights concerning seed use and may even grant seed companies the right to inspect farmers' fields to ensure compliance with the patent terms. Concerns have also been raised about the consolidation of the seed industry, where a few large companies control a significant portion of the market for patented GMO seeds, leading to increased seed prices and potentially impacting farmers' profitability. The enforcement of GMO patents has also resulted in patent infringement lawsuits against farmers who have unknowingly grown patented GMO crops due to unintentional contamination from neighbouring fields, adding another layer of complexity to the issue of seed accessibility. In contrast, some forms of intellectual property protection for plants, such as Plant Variety Protection certificates, include exemptions that allow farmers to save seeds for their own use, offering a different model that seeks to balance the rights of breeders with the needs of farmers.

6.5. The Monarch Butterfly Decline: Causes and Concerns

A. Factors Contributing to Population Decline

Monarch Butterfly populations have experienced a significant decline in recent decades, affecting both the eastern and western migratory populations. The eastern monarch population, which overwinters in central Mexico, saw a concerning 59% decrease in its wintering grounds in 2023-2024 compared to the previous year. Similarly, the western monarch population, which overwinters along the California coast, has plummeted by more than 90% since the ^1980s. Several factors contribute to this decline. A major cause is habitat loss, particularly the loss of milkweed, which is essential for monarch breeding. Agricultural practices, including the widespread use of herbicides on herbicide-resistant crops, have significantly reduced milkweed availability in agricultural landscapes, which were once important breeding grounds for monarchs. Pesticide and herbicide use also directly harm monarchs and degrade their habitat by killing non-target insects and reducing the availability of nectar plants for adult butterflies. Climate change is another significant factor, affecting monarch populations through erratic weather patterns, changes in the timing of milkweed emergence, and harsher conditions at their overwintering sites. Other contributing factors include logging and development in the oyamel fir forests of Mexico, where eastern monarchs overwinter, and the loss of overwintering sites in California due to development.

B. The Importance of Milkweed

Milkweed is the sole host plant for Monarch Butterfly caterpillars, meaning that monarch larvae feed exclusively on milkweed leaves. This obligate relationship underscores the critical importance of milkweed for the survival and

reproduction of Monarch Butterflies. Adult female monarchs lay their eggs exclusively on milkweed plants, ensuring that the newly hatched caterpillars have an immediate and essential food source. The significant decline in milkweed abundance, particularly within agricultural landscapes across the United States, is strongly correlated with the observed decline in Monarch Butterfly populations. The loss of this crucial breeding habitat has had a profound negative impact on the Monarch's life cycle and overall population numbers.

6.6. Investigating the Link Between GMOs and Monarch Butterfly Decline

A. Herbicide-Resistant GMO Crops and Milkweed Loss

The widespread adoption of herbicide-resistant Genetically Modified Organisms (GMOs), such as corn and soybeans engineered to tolerate broad-spectrum herbicides like glyphosate (the active ingredient in Roundup), has been identified as a major contributor to the decline in milkweed availability. These GMO crops allow farmers to spray their fields with herbicides to control weeds without harming the crop itself. However, this practice has also led to the indiscriminate killing of milkweed plants that once grew abundantly in and around agricultural fields, which were significant breeding habitats for Monarch Butterflies. Several studies have highlighted the strong correlation between the increased use of herbicides in conjunction with herbicide-resistant GMOs and the subsequent decline in milkweed populations, which in turn has negatively impacted Monarch Butterfly numbers. Research indicates that a substantial percentage of the milkweed plants utilized by Monarch Butterflies were found in agricultural landscapes, making the loss of this habitat due to herbicide use particularly detrimental to their populations.

B. Scientific Studies and Findings

Initial scientific investigations in the late 1990s raised concerns about the potential harm of pollen from genetically modified *Bacillus thuringiensis* (Bt) corn to Monarch Butterfly larvae. A 1999 study reported that Monarch larvae in laboratory settings died after consuming milkweed plants dusted with Bt corn pollen. This finding sparked significant public debate about the safety of GMOs and their potential impact on non-target organisms like the Monarch Butterfly. However, subsequent field studies conducted by various research groups indicated that the actual risk to Monarch larvae from Bt corn pollen under real-world agricultural conditions is relatively low. These studies found that the levels of Bt corn pollen typically deposited on milkweed plants in and around cornfields were generally not high enough to cause significant mortality in Monarch larvae. While some early Bt corn varieties were found to have higher pollen toxicity, they were quickly replaced by other types with lower risk.

More recent research has suggested that the decline in both Monarch Butterfly and milkweed populations began several decades before the widespread introduction of herbicide-resistant GMO crops in the mid-1990s. These studies, utilizing long-term datasets from museum records and herbaria, indicate that the decline started around 1950, suggesting that factors other than herbicide use associated with GMOs have also played a significant role. Variables such as a decline in the number of farms, changes in farming practices predating GMOs, and weather patterns have also been identified as potentially important contributors to the trends in milkweed and monarch abundance. These findings highlight the complexity of the issue and suggest that while the use of herbicides with GMOs has likely exacerbated the decline in milkweed, it may not be the sole or primary driver of the long-term trends in Monarch Butterfly populations.

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CHAPTER – 7

Commercializing Biodiversity on Patent on Genetic Inventions

7.1. The International Legal and Policy Landscape Governing Patents and Biodiversity

The commercialization of biodiversity related to genetic inventions is significantly shaped by a complex web of international legal and policy frameworks, primarily cantered around the Convention on Biological Diversity (CBD) and its supplementary agreements.

The Convention on Biological Diversity (CBD), adopted in 1992, serves as a comprehensive global framework for biodiversity conservation and sustainable use. Its primary objectives are the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of benefits arising from the utilization of genetic resources. A cornerstone of the CBD is the recognition of the sovereign rights of states over their natural resources, including genetic resources within their borders. This principle grants national governments the authority to determine access to these resources and is subject to national legislation. The CBD also establishes the requirement for prior informed consent (PIC) from the contracting state providing the resources before access is granted. Furthermore, the convention mandates the fair and equitable sharing of benefits arising from the use of genetic resources with the contracting party providing them. This framework marked a significant shift from the historical perspective of genetic resources as freely available, establishing national ownership and the necessity for benefit-sharing, which has fundamentally altered the landscape for research and commercialization endeavours.

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, adopted in 2010 and entering into force in 2014, is a supplementary agreement to the CBD specifically focused on implementing the third objective of fair and equitable benefit-sharing. The protocol sets out obligations for its contracting parties related to access to genetic resources, benefit-sharing (which can be monetary, such as royalties, or non-monetary, such as sharing research results or technology transfer), and compliance with the access and benefit-sharing legislation of provider countries. It also includes provisions addressing traditional knowledge associated with genetic resources, recognizing the rights of indigenous and local communities to grant access to this knowledge and to a fair and equitable share of the benefits arising from its utilization. To facilitate the implementation of the Nagoya Protocol, the Access and Benefit-sharing Clearing-House (ABS Clearing-House) was established as a platform for exchanging information on access and benefit-sharing procedures and for monitoring the utilization of genetic resources. While the Nagoya Protocol aims to create legal certainty and transparency for both providers and users of genetic resources, its implementation at the national level has been uneven and faces challenges due to varying national interpretations and enforcement capacities.

A significant development in the international landscape is the recent adoption of the WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge on May 24, 2024. This treaty, the first WIPO treaty in over a decade, specifically addresses patent rights in the context of genetic resources and associated traditional knowledge. A key provision of the treaty is the establishment of a mandatory patent disclosure requirement, obligating patent applicants to disclose the country of origin or source of any genetic resources and the Indigenous Peoples or local community who provided any associated traditional knowledge if the claimed inventions are based on these resources or knowledge. This measure aims to enhance transparency in the patent system and facilitate the objectives of ABS legislation.

While patent offices will provide guidance on

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this requirement, they will not be obligated to verify the authenticity of the disclosed information. Failure to disclose may be subject to appropriate measures, but the treaty includes a non-retroactivity clause, meaning its obligations will not apply to patent applications filed before it comes into force, subject to existing national laws on disclosure. The WIPO Treaty signifies a growing international recognition of the need for transparency regarding the origin of genetic resources and traditional knowledge within the patent system, potentially supporting the enforcement of ABS principles.

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), under the World Trade Organization (WTO), also plays a role in governing the patent protection of genetic inventions. The TRIPS Agreement mandates that members shall provide patent protection for inventions in all fields of technology, allowing for limited exceptions, such as for the protection of public order or morality, including the protection of health or the environment. It also requires the protection of plant varieties either by patents or by an effective *sui generis* system or a combination thereof. The patentability of life forms, particularly genes, has been a subject of intense debate, with potential conflicts arising between the objectives of the TRIPS Agreement, which focuses on promoting innovation and trade, and the CBD's goals of biodiversity conservation and equitable benefit-sharing. However, the TRIPS Agreement does offer flexibilities that allow member countries to exclude certain inventions from patentability, providing space for national policies that balance intellectual property rights with biodiversity concerns.

7.2. National Regulatory Frameworks: Implementing International Commitments

Countries around the world have adopted diverse approaches to implement the principles of the CBD and the Nagoya Protocol into their national legal frameworks. These national approaches vary significantly based on their specific biodiversity resources, economic priorities, and legal traditions.

India's Biological Diversity Act of 2002 provides a detailed example of national implementation. The Act mandates that foreign companies seeking to access biological resources in India for research or survey purposes, as well as anyone intending to provide the results of research obtained on Indian biological resources to foreign entities, must obtain approval from the National Biodiversity Authority (NBA). Furthermore, for inventions based on information or research results derived from biological resources acquired in India, all applicants, regardless of their nationality, are required to secure approval from the NBA before filing for any intellectual property rights, whether within or outside India. Violation of this disclosure requirement can lead to the rejection of the patent application or the invalidation of the granted patent, with opposition to a patent or revocation being possible based on these regulations.

Several countries and regions have also implemented disclosure requirements directly within their patent laws for inventions concerning genetic resources or traditional knowledge. For instance, the Andean Community, India, Brazil, the EU, and certain of its member states have introduced such legislation. These measures typically require patent applicants to disclose specific information about the genetic resources or traditional knowledge used in their invention, such as the country of origin or source. The primary objectives of these disclosure requirements are to prevent the erroneous granting of patents on inventions that are not novel or inventive in light of existing genetic resources or traditional knowledge, and to facilitate the fair and equitable sharing of benefits arising from their utilization. However, the effectiveness of these national disclosure requirements has been limited, partly because they generally apply only to patent applications filed nationally.

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National laws are instrumental in translating the broad principles of international agreements into concrete actions at the domestic level. However, the significant divergence in the scope and enforcement of these national regulations creates a complex and often challenging landscape for companies engaged in cross-border commercialization of biodiversity-related genetic inventions.

7.3. Strategies and Models for Commercializing Biodiversity-Related Genetic Inventions

Several strategies and models are employed for the commercialization of biodiversity-related genetic inventions, each with its own implications for access, benefit-sharing, and biodiversity conservation.

Licensing agreements represent a key mechanism for commercialization, allowing patent holders to grant permission to others to use their patented genetic inventions under specific terms and conditions. These agreements can be exclusive, granting rights to only one licensee, or non-exclusive, allowing multiple licensees. Cross-licensing, where two or more patent owners grant licenses to each other, can be particularly useful in fields with overlapping patent rights. In the context of genetic inventions, various models exist to facilitate access. Patent pools, for example, involve agreements where multiple patent owners license their patents to each other or to third parties willing to pay royalties, which can help overcome issues of stacking licenses and reduce transaction costs. The Golden Rice Pool, aimed at providing royalty-free licenses for humanitarian purposes in developing countries, and the SARS Corona Virus Pool, intended to facilitate access to technologies relevant to the pandemic, illustrate the potential of this model. Clearing-house mechanisms, such as information exchanges, technology-exchange platforms, and royalty-collection systems, also serve to connect providers and users of patented genetic technologies. The BiOS (Biological Innovation for Open Society) license, promoting cooperative invention and sharing of improvements, and the SNP Consortium, aiming to create a public map of human genome SNPs without proprietary rights, represent examples of such mechanisms. Careful management of intellectual property issues during the negotiation and drafting of access and benefit-sharing agreements is crucial to ensure equitable outcomes that respect the interests of resource providers.

Product development across various sectors heavily relies on biodiversity and genetic inventions. In the pharmaceutical industry, natural compounds derived from diverse organisms continue to be a vital source for drug discovery and development. Examples include the development of Calanolides, with potential for treating HIV and cancer, derived from a Malaysian rainforest tree. Agricultural biotechnology utilizes genetic resources to develop genetically modified crops with enhanced traits such as increased yield, drought tolerance, and pest resistance, contributing to food security. Industrial biotechnology leverages genetic resources for the development of specialty enzymes and molecules used in various industrial processes, including the production of specialized chemicals and bioremediation. The use of genetic resources in product development is rarely a simple process, often involving multiple research steps from accessing the resource to the final commercial product.

Research collaborations play a critical role in advancing genetic inventions related to biodiversity. These collaborations, spanning public and private sectors and often involving international partnerships, are essential for leveraging diverse expertise and resources. Indigenous knowledge, held by communities with generations of experience in managing and utilizing biodiversity, can provide valuable insights for research and development. Numerous collaborative projects focused on genomics and biodiversity are underway, such as the Darwin Tree of Life Project aiming to sequence the genomes of all known species in

Britain and Ireland, and the Vertebrate Genomes Project. These initiatives underscore the importance of equitable partnerships and benefit-sharing in research collaborations, particularly when they involve genetic resources and traditional knowledge from specific regions or communities.

Bioprospecting, the systematic exploration of biodiversity for new biological resources of social and economic value, is a key strategy for discovering genetic resources with commercial potential. This activity is undertaken across various industries, including pharmaceuticals, agriculture, and biotechnology, in search of new chemical compounds, genes, and organisms with potential applications. However, bioprospecting has also been associated with ethical concerns related to biopiracy, where genetic resources and traditional knowledge are exploited without prior informed consent and fair benefit-sharing with the originating countries and communities. Models for sustainable and ethical bioprospecting emphasize the importance of obtaining PIC, establishing mutually agreed terms for benefit-sharing, and ensuring that bioprospecting activities contribute to biodiversity conservation and the socio-economic development of the resource-providing countries.

7.4. Economic Valuation and Market Dynamics in the Commercialization of Biodiversity

The economic landscape surrounding the commercialization of biodiversity in the context of genetic patents is characterized by significant market opportunities, diverse revenue streams, and complex valuation challenges.

The global market for genome editing technologies, a key area related to genetic inventions and biodiversity, was estimated at USD 7.96 billion in 2023 and is projected to grow to USD

25.00 billion by 2030, with a significant adoption in agricultural biotechnology and a substantial share held by biotechnology and pharmaceutical companies. The market for marine biotechnology is also substantial, expected to reach $6.4 billion by 2025, spanning pharmaceuticals, biofuels, and chemicals. Bioprospecting activities and the resulting biodiversity-based products constitute a booming business across various sectors, including cosmetics and pharmaceuticals. These market analyses indicate the significant economic potential associated with the commercialization of biodiversity through genetic inventions.

Commercializing biodiversity-related genetic inventions can generate revenue through various streams. Royalties derived from licensing agreements for patented genetic technologies represent a direct revenue source for patent holders. The sale of products developed using these inventions, such as genetically modified crops or novel pharmaceuticals, forms another primary revenue stream. Furthermore, revenue-sharing models are increasingly being explored, particularly in the context of access and benefit-sharing agreements, where a portion of the profits generated from commercialized products is shared with the providers of the genetic resources or associated traditional knowledge. The concept of a multilateral fund, financed by contributions from companies benefiting from the use of digital sequence information (DSI) derived from genetic resources, is also gaining traction as a potential mechanism for revenue sharing and supporting biodiversity conservation.

Investment in the commercialization of biodiversity related to genetic patents is influenced by several considerations. Intellectual property rights, particularly patents, play a crucial role in attracting investment by providing a degree of exclusivity and the potential for a return on the often-substantial costs incurred during research and development. The return on investment in human genetics and genomics research has been shown to be significant, with substantial

contributions to the US economy and job creation. However, balancing the incentives for innovation provided by patents with ensuring public access to essential technologies remains a critical consideration for sustainable investment in this field.

The valuation of genetic resources presents a complex challenge, particularly given their historical status as public goods. Traditional market mechanisms are often inadequate for determining the true value of these resources, which can have both direct use value in research and product development, and indirect use value in supporting ecosystem functions. Various methods are being explored to assess the economic value of genetic resources, including stated preference methods and analysis of their contribution to agricultural productivity and pharmaceutical development. Accurate valuation is crucial for informing conservation efforts and for establishing fair and equitable benefit-sharing agreements between providers and users of these resources.

7.5. Ethical Dilemmas in Patenting and Commercialization of Genetic Resources

The patenting and commercialization of genetic resources raise several profound ethical dilemmas that necessitate careful consideration.

At the heart of these dilemmas lies the principle of access and benefit-sharing, which calls for the fair and equitable sharing of benefits arising from the utilization of genetic resources.[6] While widely endorsed, the practical implementation of this principle faces numerous challenges. These include the complexity of establishing mutually agreed terms between diverse stakeholders, the difficulty in tracing the origin and use of genetic resources, and the varying interpretations of "fair and equitable" across different national contexts. Ensuring that benefits, both monetary and non-monetary, flow back to the providers of genetic resources, particularly developing countries and indigenous communities, remains a significant ethical and practical hurdle.

The issue of biopiracy, defined as the misappropriation of genetic resources or traditional knowledge for commercial gain without proper consent or compensation, represents a major ethical concern. This can take various forms, including the patenting of traditional knowledge or genetic resources that are already in the public domain, or accessing these resources from developing countries or indigenous communities without obtaining prior informed consent or establishing benefit-sharing agreements. Alleged cases of biopiracy, such as the patenting of neem extracts and turmeric's medicinal uses, highlight the ongoing power imbalances between developed and developing nations and the urgent need for stronger mechanisms to protect the rights of traditional knowledge holders and resource-rich countries.

The patenting of genes themselves is a particularly contentious ethical issue. Arguments against gene patenting often centre on the idea that genes are naturally occurring and part of the common heritage of humanity, thus should not be owned or controlled by private entities. Concerns also exist that gene patents can hinder scientific research and limit access to essential diagnostic tests and treatments, potentially leading to monopolies and higher healthcare costs. The landmark case of *Association for Molecular Pathology v. Myriad Genetics*, which challenged the patentability of human genes, underscores the ongoing ethical and legal debates in this area. Conversely, proponents argue that gene patents incentivize innovation by providing a mechanism for companies and researchers to recoup the substantial investments required for genetic research and development.

7.6. Case Studies: Successes and Failures in Commercializing Biodiversity

Numerous case studies illustrate both the successes and failures in the commercialization of biodiversity associated with patented genetic inventions across various sectors.

Successful commercialization attempts can be

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found in pharmaceuticals, agriculture, and biotechnology. In the pharmaceutical sector, the development of Captopril, an ACE inhibitor derived from the venom of the Brazilian pit viper, stands as a significant success, demonstrating how studying biodiversity can lead to major medical breakthroughs. The potential of Calanolides, compounds derived from a tree in the Malaysian rainforest, for treating HIV and certain cancers also highlights the value of natural resources in drug discovery. Trabectedin, an anti-cancer drug developed from a marine organism, represents another successful example of commercializing marine biodiversity through patented inventions. In agriculture, the soybean breeding industry in countries like Brazil, Canada, and the US has seen significant success through advances in crop technology. The development of gene-edited crops with enhanced traits like increased yield and resilience also holds promise for successful commercialization. The biotechnology sector boasts successes such as the discovery and commercialization of Pfu polymerase, an enzyme from a hyperthermophilic archaeon used in genetic engineering. Additionally, the development of Luminase, an enzyme used in the pulp and paper industry for bio bleaching, demonstrates the potential for environmentally beneficial products derived from biodiversity. These successes often involve substantial research and development, effective intellectual property protection, and increasingly, a consideration for ethical sourcing and benefit-sharing.

Conversely, several attempts to commercialize biodiversity have faced failures and challenges. In pharmaceuticals, Myriad Genetics encountered significant controversies and legal challenges regarding its patents on the BRCA genes associated with breast and ovarian cancer, highlighting issues related to restricted access and high costs. The commercialization of Hoodia, a cactus with appetite-suppressing properties, also faced setbacks. Agriculture has seen its share of unsuccessful attempts, such as the failure of a virus-resistant GM sweet potato project in Kenya. Controversies surrounding GM crops like Golden Rice and Bt cotton in various regions also underscore the challenges in gaining widespread acceptance and realizing the intended benefits. Numerous cases of alleged biopiracy, including W.R. Grace's patent on neem tree seed extract and attempts to patent the uses of turmeric and Basmati rice, illustrate the ethical and legal hurdles in commercializing biodiversity without proper consent and compensation. These unsuccessful attempts often highlight issues related to biopiracy, overly broad patent claims, lack of novelty, ethical concerns, technical limitations, and market acceptance challenges.

The case study of Dr. Paul Cox and the Falealupo community in Samoa provides an example of an ongoing effort to commercialize biodiversity with a strong focus on benefit-sharing. Research on the Mamala tree (Homalanthus nutans) led to the discovery of prostratin, a molecule with potential anti-viral properties. Agreements were established to ensure that the Falealupo community would benefit from any commercial success, including debt repayment, a rainforest preserve, and potential royalties. While the research has faced challenges in reaching commercialization, this case demonstrates a model for engaging local communities in bioprospecting research and emphasizing equitable benefit-sharing from the outset, highlighting both the potential and the complexities involved in such endeavours.

7.7. Navigating the Key Challenges in the Commercialization Process

The commercialization of biodiversity related to patented genetic inventions is fraught with several key challenges that stakeholders must navigate.

Regulatory hurdles represent a significant obstacle, as the landscape governing genetic inventions is complex, constantly evolving, and often fragmented across different jurisdictions. Navigating diverse national regulations for areas like gene editing and genetic testing can be particularly challenging for companies

seeking to commercialize products internationally. In the US, for example, gene-edited plants face oversight from the USDA, FDA, and EPA, each with specific regulatory requirements. The lack of harmonization across national regulatory frameworks can lead to delays and increased costs for commercialization.

Technological limitations also pose challenges in the development and application of genetic inventions related to biodiversity. While genetic engineering technologies have made remarkable progress, limitations persist in areas such as data analysis, scalability for industrial applications, and the potential for unintended consequences, including harm to non-target organisms or ecosystems. Specific technologies like synthetic biology and gene drives, while holding great promise, still face technical hurdles related to precise genetic manipulation, delivery methods, and potential ecological impacts. Continued research and development are necessary to overcome these limitations and ensure the safe and effective application of genetic inventions.

Market acceptance and public perception can significantly influence the success of commercializing biodiversity-related genetic inventions. Genetically modified organisms (GMOs), in particular, have faced challenges related to public perception and ethical concerns, impacting their market uptake in some regions. Societal concerns about the safety of genetically modified foods, the potential environmental impacts, and the ethical implications of altering living organisms can affect consumer preferences and regulatory decisions. Building public trust through transparent communication, addressing ethical considerations proactively, and demonstrating the benefits of these technologies are crucial for gaining market acceptance.

7.8. The Dual Role of Intellectual Property Rights (Patents) in Biodiversity Commercialization

Intellectual property rights, particularly patents, play a dual role in the commercialization of biodiversity related to genetic inventions, acting as both facilitators and potential hindrances.

Patents serve as crucial facilitators of commercialization by providing inventors with exclusive rights to their inventions for a determined period, typically 20 years. This exclusivity incentivizes innovation by allowing inventors to recoup the often-substantial investments made in research and development. Patents can also attract investment by providing legal security to companies that their intellectual property will be protected, fostering an environment where research and development can flourish. For small agrochemical businesses or startups, the strength of their patents can be particularly vital, as it can deter larger companies from simply copying their products. By establishing a proprietary leadership position in the market, patents can provide a commercial advantage and generate financial rewards through royalty-bearing licenses.

However, patents can also act as potential hindrances to the commercialization of biodiversity and can restrict access to genetic resources and related technologies. The increasing number of patents on genetic inventions has raised concerns about restricted access to research and healthcare, potentially leading to the creation of "patent thickets" where a dense web of overlapping patents held by different owners can stifle innovation and commercialization. Overly broad patent claims can also hinder the use of biodiversity for further research and development, potentially monopolizing genetic resources and limiting the development of new varieties or products. In agriculture, for instance, patents on specific gene variants can exclude other breeders from using them, potentially hindering conventional breeding practices. Furthermore,

patents on genetic technologies can limit domestic production of generic versions, impacting access to life-saving diagnostics and therapeutics, particularly in developing countries. The granting of patents on inventions derived from genetic resources or traditional knowledge without adequate compensation or permission from the original holders has also led to accusations of biopiracy, further highlighting the potential negative impacts of patents on equitable commercialization.

7.9. Impact of Commercialization on Biodiversity Conservation and Sustainable Use

The commercialization of biodiversity in the context of genetic patents holds the potential to both incentivize and negatively impact biodiversity conservation and sustainable use, depending on how it is approached and regulated.

Commercialization can potentially incentivize biodiversity conservation by assigning economic value to genetic resources and the ecosystems that harbor them. Market-based approaches, such as biodiversity credits that allow businesses to invest in ecosystem restoration, and sustainable bioprospecting models that ensure benefits flow back to conservation efforts, can help bridge the funding gap for biodiversity protection. Access and benefit-sharing mechanisms, as outlined in the Nagoya Protocol, can provide economic incentives for countries and communities to conserve their genetic resources, knowing that they will receive a fair share of any benefits arising from their use.

However, unsustainable commercialization practices can have significant negative impacts on biodiversity. Overexploitation of certain species for commercial purposes, such as in commercial fishing and the wildlife trade, can lead to drastic declines in populations and even extinctions. Habitat destruction, often driven by the expansion of agriculture and infrastructure to support commercial activities, is a leading cause of biodiversity loss. The promotion of monoculture in agriculture, often associated with the commercialization of patented seeds, can reduce genetic diversity and increase the vulnerability of crops to pests and diseases. If commercialization efforts prioritize short-term economic gains without considering the long-term ecological consequences, they can ultimately lead to the degradation and loss of the very biodiversity resources upon which future innovation and economic benefits depend.

7.10. The Crucial Role of Local and Indigenous Communities

Local and indigenous communities play an indispensable role in biodiversity conservation and the sustainable commercialization of genetic resources. Their traditional knowledge, accumulated over generations through a deep connection with their local environments, provides invaluable insights into the sustainable use and conservation of biodiversity. Recognizing, respecting, and integrating this knowledge into both conservation efforts and commercialization initiatives is crucial for ensuring their long-term success and sustainability.

Ethical and legal frameworks, such as the CBD and the Nagoya Protocol, emphasize the requirement for obtaining prior informed consent from local and indigenous communities before accessing their genetic resources or traditional knowledge. Furthermore, establishing fair and equitable benefit-sharing mechanisms with these communities is essential, ensuring that they receive a just return for their contributions to the commercialization process. When commercialization initiatives are designed to include local and indigenous communities as active partners and ensure they benefit directly, it can contribute to their well-being, support their economic development, and foster a sense of stewardship towards biodiversity conservation. Meaningful consultation, respect for traditional practices, and equitable distribution of benefits are therefore not just ethical imperatives but also critical factors for

the sustainable commercialization of biodiversity.

CHAPTER – 8

Intersection of Patent Law and Public Health: The Case of Genetic Inventions

8.1. Defining Genetic Inventions in Patent Law

Within the realm of patent law, "genetic inventions" encompass a range of innovations related to genetic material. In the United States, these can include patents on specific isolated gene sequences, their chemical composition, the processes for obtaining or utilizing them, or a combination of such claims. Biological patents, a broader category that includes genetic inventions, grant the patent holder the exclusive right to prevent others from making, using, selling, or importing the protected invention for a limited time. Historically, in the U.S., isolated natural biological substances, including genes, were patentable if sufficiently "isolated" from their natural state. However, a landmark Supreme Court ruling in 2013 in the case of *Association for Molecular Pathology v. Myriad Genetics* established that mere isolation of naturally occurring DNA sequences is not sufficient for patent eligibility, though synthesized DNA sequences not found in nature can still be patented.

Several examples illustrate the scope of genetic inventions that can be patented. **Gene sequences** themselves, such as isolated DNA, cDNA (complementary DNA), RNA, expressed sequence tags (ESTs), and single nucleotide polymorphisms (SNPs), have been subjects of patent claims. Early patents were granted on isolated natural substances like adrenaline and insulin. The *Myriad Genetics* case, however, significantly altered the landscape for patenting naturally occurring DNA. **Diagnostic tests** that detect genetic variations associated with diseases are another category of genetic inventions covered by patents. A prominent example is the BRCA1/2 test for assessing the risk of breast and ovarian cancers, which was previously under patent by Myriad Genetics. Patents in this area can cover specific mutations or methods of testing. **Gene therapies**, which involve altering genes to treat or prevent diseases, also fall under the umbrella of genetic inventions. Recombinant insulin, one of the first gene-based therapeutics, was also patented. **Genetically Modified Organisms (GMOs)**, including genetically engineered bacteria, plants, and animals, can also be patented. The *Diamond v. Chakrabarty* case in 1980 was a pivotal moment, establishing that genetically modified bacteria could be patented as a "man-made" invention. Finally, **research tools** used in genetic research, such as the polymerase chain reaction (PCR) and recombinant DNA technology, have also been patented. The Cohen/Boyer patents, which covered fundamental techniques for splicing genes, are a key example.

To be eligible for patent protection, genetic inventions must generally meet the criteria of novelty, non-obviousness (inventive step), and utility. For genetic inventions, the utility standards have often been higher. Additionally, the patent application must adequately describe the invention to enable someone skilled in the field to reproduce it, a requirement known as enablement and sufficiency of disclosure. A central debate in the patenting of genetic inventions revolves around whether a DNA sequence is a discovery of nature or a human invention. While discoveries of naturally occurring, phenomena are generally not patentable, isolated and purified genes with a demonstrated technical effect have often been considered inventions, although this view has been challenged and refined over time, as evidenced by the *Myriad* ruling.

The definition of a genetic invention under patent law is not static; it has undergone significant evolution, particularly shaped by landmark legal decisions such as *Diamond v. Chakrabarty* and *Association for Molecular Pathology v. Myriad Genetics*. The core distinction between a naturally occurring "product of nature" and a "man-made invention" remains a critical point of contention. Initially,

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the patenting of isolated genes as "compositions of matter" was predicated on the argument that the act of isolation itself constituted sufficient human intervention to render them patentable. However, the *Myriad* case directly challenged this premise, leading to the prevailing understanding that naturally occurring gene sequences are not patentable solely by virtue of their isolation. This shift reflects a growing appreciation for the informational content inherent in DNA and its fundamental role within the natural world. Nevertheless, the continued patentability of cDNA and other forms of modified genetic material underscores that the boundary between discovery and invention in the field of genetics remains a subject of ongoing interpretation and legal development[4].

8.2. The Rationale Behind Granting Patents for Genetic Inventions

The primary rationale for granting patents on genetic inventions centres on the idea of **incentivizing innovation**. Patents provide a temporary period of market exclusivity, allowing companies and researchers to potentially recoup the substantial costs and time invested in the research and development of genetic technologies. It is argued that without the prospect of patent protection, there would be significantly less incentive for private entities to invest in the often high-risk and long-term endeavour of genetic research.

Patents are also believed to play a crucial role in **promoting research and development (R&D)** within the biotechnology and pharmaceutical industries. Bringing new drugs and diagnostic tools to market can involve hundreds of millions of dollars in investment. Patents can attract investment from both companies and individuals by offering the potential for a return on that investment through the exclusive rights granted.

Furthermore, the patent system encourages **disclosure and transparency**. In exchange for the grant of exclusive rights, inventors are required to publicly disclose the details of their invention. This disclosure can prevent the duplication of research efforts and can facilitate further innovation by allowing other scientists to build upon the disclosed knowledge.

Finally, patents can be instrumental in **facilitating technology transfer and commercialization** of basic research findings into products and services that can benefit public health. By providing a degree of market exclusivity, patents can attract venture capital and foster the development of public-private partnerships necessary to bring genetic technologies from the laboratory to the patient.

The fundamental justification for patenting genetic inventions rests on the idea that it provides necessary incentives for innovation and investment in a field characterized by high risk and potentially high reward. However, the empirical evidence regarding the direct impact of gene patents on innovation is a subject of ongoing debate, with some studies suggesting a limited or even negative effect in certain contexts. The traditional economic argument supporting patents as a driver of innovation is frequently invoked in the context of genetic inventions, particularly given the substantial financial resources required for research and development. The underlying principle is that the exclusive rights granted by patents enable companies to recoup their investments and subsequently reinvest profits into further research endeavours. Nevertheless, research indicates that the influence of gene patents on subsequent innovation may not always be beneficial. For instance, the National Centre for Human Genome Research (NCHGR) previously advised against patenting raw genomic sequence data, expressing concerns about a potential "chilling effect" on the development of future useful products. This suggests a more complex relationship where patents might incentivize initial discoveries but could potentially hinder downstream research and development by creating intricate webs of patent rights and restricting access to foundational genetic information.[5]

8.3. Potential Negative Impacts of Patents on Genetic Inventions on Public Health

While patents on genetic inventions aim to foster innovation, they also carry potential negative impacts on public health. One significant concern is **limited access to essential medicines and diagnostic tools**. Patents can create monopolies, allowing patent holders to set high prices for life-saving medicines and crucial diagnostic tests, making them unaffordable or inaccessible to many patients. The case of Myriad Genetics, which held patents on the BRCA1/2 genes, exemplifies this issue, with the cost of testing reaching several thousand dollars. Exclusive licensing practices can further restrict access by limiting the number of laboratories or providers authorized to offer a particular test or therapy. Moreover, royalties and licensing fees associated with patented genetic inventions can contribute to increased healthcare costs.

Another significant concern is that patents on genes or genetic sequences can **hinder research and development**. The existence of "patent thickets," where numerous patents cover related genes or technologies, can create a complex and costly landscape for researchers seeking to advance scientific understanding and develop new applications. Researchers might choose to avoid working on patented genes altogether to circumvent potential legal issues and licensing negotiations, thereby slowing down the pace of scientific discovery. Furthermore, when a single entity holds a patent on a gene, it can lead to delays in obtaining medical results due to the centralized nature of testing.

The **monopolization of genetic information** is another critical issue associated with gene patents. Granting exclusive rights to fundamental genetic information raises ethical concerns about treating genes, which are essential to human biology, as mere commodities. Patent holders may also exert control over the use and interpretation of genetic data, potentially hindering the broader scientific understanding of these complex biological systems.

Finally, limited access and the absence of competition resulting from gene patents can negatively impact the **quality of healthcare**. When a single entity holds exclusive rights to a genetic test, patients may be unable to obtain confirmatory testing from another laboratory, which is a crucial aspect of quality assurance in medical diagnostics. Furthermore, patent holders may effectively dictate the standard of care by controlling which tests are available and how they are performed.

The intended benefits of patents on genetic inventions to stimulate innovation are juxtaposed with significant risks to public health, including restricted access, increased costs, impeded research, and the monopolization of fundamental biological information. The case of Myriad Genetics serves as a stark illustration of these potential negative consequences.

8.4. Specific Examples or Case Studies of Patents on Genetic Inventions Affecting Public Health Outcomes

While the primary aim of genetic patents is to incentivize innovation, their impact on public health has been a subject of considerable scrutiny, with both potential benefits and significant drawbacks.

On the positive side, it is argued that patents can indeed incentivize the development of novel diagnostic and therapeutic inventions that might not otherwise be pursued due to the high costs and risks involved. A notable example is the development of recombinant human insulin, which was facilitated by early patents in biotechnology. Patent protection in the biotechnology sector has also been credited with attracting substantial private investment, which has fuelled further innovation. In some instances, patent holders have argued that their patented technologies have led to improvements in the accuracy and efficiency of testing compared to earlier methods.

However, numerous case studies highlight the

negative impacts of genetic patents on public health. The case of **Myriad Genetics and its patents on the BRCA1 and BRCA2 genes** is perhaps the most well-known example. For many years, Myriad held exclusive control over testing for these genes, which are associated with an increased risk of breast and ovarian cancer. This monopoly led to high testing costs, limited the availability of second opinions, and was argued to have hindered further research on these critical genes. The American Civil Liberties Union (ACLU) filed a lawsuit challenging these patents, arguing that human genes are products of nature and should not be patentable. In 2013, the U.S. Supreme Court ruled against the patentability of naturally occurring DNA, a decision that significantly impacted the landscape of gene patenting.

Another case involved **hereditary hemochromatosis**, where the enforcement of a gene patent led to a reduction in the number of laboratories offering testing for this condition. Similarly, patents related to **Canavan disease**, a rare genetic disorder, sparked controversy due to concerns about restricted access to testing. The **COVID-19 pandemic** also highlighted potential negative impacts, with concerns raised about how patents on viral genetic material could impede the rapid development and widespread accessibility of diagnostics and vaccines. Furthermore, patents on innovative gene editing technologies like **CRISPR** have raised concerns about potential limitations on their use in research and therapy.

These case studies illustrate the complex and often contentious relationship between genetic patents and public health. While patents can provide incentives for innovation, their broad application and enforcement can lead to significant barriers in accessing essential healthcare technologies and hindering further scientific progress.

8.5. Analysing the Legal and Ethical Debates Surrounding the Patenting of Genetic Material

The patenting of genetic material has ignited significant legal and ethical debates. At the heart of the ethical arguments lies the question of **ownership of life**. Many argue that genes, as fundamental building blocks of life, should not be owned or treated as commodities. This perspective often draws a distinction between genetic identity and personal identity, suggesting that while a patent might cover a specific gene sequence, it does not confer ownership over an individual's genetic makeup. Furthermore, some argue that the human genome represents a common heritage of humanity and should not be subject to private ownership.

The patenting of genetic material also raises concerns related to **human rights**, particularly the right to health and access to healthcare. High costs and limited access to essential medicines and diagnostic tools resulting from gene patents can disproportionately affect vulnerable populations, thus undermining the principle of equitable access to healthcare. This can also place a significant burden on healthcare systems and public funding for genetic testing.

A central challenge lies in **balancing innovation and access**. While patents are intended to incentivize the costly and time-consuming research and development of genetic technologies, concerns exist about whether they are truly necessary for driving innovation in this field. The debate continues on how to best foster scientific progress in genetics while ensuring that the resulting technologies are accessible and affordable to those who need them.

The ethical considerations surrounding gene patenting are deeply intertwined with legal interpretations of patent law. The fundamental question of whether human genetic material should be patentable touches upon deeply held beliefs about the nature of life and the right to

health. The tension between the desire to incentivize innovation through patent protection and the imperative to ensure equitable access to healthcare advancements remains a central challenge for policymakers and legal scholars alike.

8.6. Examining Existing Legal Frameworks and Regulations in Different Countries

The legal frameworks and regulations concerning the patenting of genetic inventions vary significantly across different countries, reflecting diverse legal traditions, ethical considerations, and public policy priorities.

In the **United States**, the legal landscape has been significantly shaped by landmark Supreme Court cases. *Diamond v. Chakrabarty* established the principle that living organisms could be patentable if "made by man." However, the more recent case of *Association for Molecular Pathology v. Myriad Genetics* ruled that isolated naturally occurring DNA sequences are not patentable because they are products of nature. Conversely, the Court held that cDNA, a synthetic form of DNA, is patentable. The U.S. Patent and Trademark Office (USPTO) also has specific guidelines regarding the utility requirement for patenting genetic inventions.

In **Europe**, the legal framework is guided by the European Union's Biotech Directive, which allows for the patenting of natural biological products, including gene sequences, if they are isolated from their natural environment or produced through a technical process. The European Patent Office (EPO) examines patent applications based on criteria of novelty, inventive step, and industrial applicability. However, patents can be refused if the invention is deemed contrary to public order or morality.

Australia initially affirmed the patentability of isolated, naturally occurring DNA sequences, but the High Court of Australia later overturned this, ruling that naturally occurring genes cannot be patented. The Australian framework requires that patentable biological inventions must be isolated or synthetically produced and have a demonstrated use resulting from technical intervention.

In **Canada**, while the Canadian Intellectual Property Office (CIPO) grants patents for isolated gDNA and cDNA, the Supreme Court of Canada has not yet issued a definitive ruling on the patentability of genes. However, a settlement in 2016 concerning patents related to Long QT syndrome allowed Canadian health institutions to conduct testing on a non-profit basis, indicating a complex legal environment.

Japan examines patent applications for biological inventions, including those related to genetics, under general patent guidelines, with specific guidelines for biology-related inventions. Patented inventions must be industrially applicable, but methods of surgery, therapy, and diagnosis of human diseases are excluded.

The **TRIPS Agreement**, an international agreement administered by the World Trade Organization, requires member countries to have intellectual property protection for most biological innovations, including biotechnological inventions. However, it also allows for certain exceptions and flexibilities, which contribute to the variations observed in national legal frameworks.

8.7. Investigating Alternative Models or Mechanisms for Promoting Research and Development

Given the potential downsides of relying solely on the traditional patent system to incentivize research and development in genetic technologies, several alternative models and mechanisms have been proposed and, in some cases, implemented. **Open science initiatives** emphasize the free and unrestricted sharing of research data, materials, and findings to accelerate the pace of scientific discovery. The establishment of open access databases and collaborative research platforms can foster a more rapid dissemination of knowledge and potentially reduce redundancy in research

efforts.

Government funding and public research play a crucial role in supporting both basic and translational research in genetics and biotechnology. Increased public investment in these areas could potentially lessen the reliance on patent-driven innovation, particularly for research with significant public health implications.

Patent pools and clearinghouses offer mechanisms for pooling patents related to a specific technology, allowing broader access to these technologies for research and development, often under fair, reasonable, and non-discriminatory (FRAND) terms. This approach can help to overcome the challenges posed by patent thickets and facilitate innovation.

Compulsory licensing is another tool that can be used in certain circumstances, particularly in public health emergencies, to ensure access to essential medicines and diagnostics, even when they are under patent protection. This mechanism allows governments to authorize the use of a patented invention without the patent holder's consent, subject to certain conditions and the payment of reasonable royalties.

Research use exemptions in patent law aim to allow non-commercial research activities on patented inventions without infringing the patent. Strengthening and clarifying the scope of these exemptions could help to ensure that patents do not unduly hinder basic scientific inquiry.

Alternative incentive mechanisms such as **prizes and rewards** for significant breakthroughs in genetic research and development could also be explored. These approaches could provide recognition and financial support for innovation without granting exclusive rights that might limit access.

Finally, encouraging **socially responsible licensing practices** among companies and institutions that hold genetic patents could promote wider access to these technologies. This could include offering licenses on more affordable terms, particularly for applications that address critical public health needs, or granting non-exclusive licenses to allow for broader use.

Exploring these alternative models and mechanisms is crucial for finding a more balanced approach that fosters innovation in genetic technologies while ensuring that the resulting benefits are accessible to all and serve the broader public health needs.

8.8. Considering the Role of International Organizations and Initiatives

International organizations and initiatives play a vital role in addressing the complex intersection of genetic patents and global public health. The **World Health Organization (WHO)** has been actively involved in discussions and initiatives concerning intellectual property and public health, particularly in the context of access to medicines and promoting research for diseases that disproportionately affect developing countries.

The **World Intellectual Property Organization (WIPO)**, a specialized agency of the United Nations, works to develop a balanced and accessible international intellectual property system. Its work on international patent law has significant implications for the patenting of genetic inventions and their impact on public health.

The **United Nations (UN)** has various initiatives and declarations related to human rights, access to health, and the role of technology in development, which provide a broader ethical and policy context for considering the intersection of genetic patents and public health.

The **Human Genome Project (HGP)**, an international collaborative research program, aimed to map the entire human genome and made its data publicly available, significantly influencing the debate around gene patenting

and highlighting the importance of open access to fundamental genomic information.

Numerous **international research collaborations** focus on understanding and addressing genetic diseases and public health challenges on a global scale. These collaborations often involve the sharing of data and expertise across borders, which can be crucial for advancing scientific knowledge and developing effective interventions.

Furthermore, there are ongoing **efforts to promote access and equity** in the realm of genetic technologies and the benefits of genomic research, particularly for developing countries. These efforts aim to ensure that the advancements in genetic research translate into tangible benefits for all populations, regardless of their economic status or geographical location.

Through their various activities, these international organizations and initiatives contribute to shaping the global discourse and policy landscape surrounding genetic patents and public health, striving to find solutions that balance the need for innovation with the imperative of ensuring equitable access to healthcare for all.

CHAPTER – 9

Patenting Genetic Inventions in India: Legal Framework, International Conventions, and Ethical Considerations

9.1. Patentability Criteria for Genetic Inventions under the Indian Patents Act 1970

To be eligible for patent protection in India, a genetic invention must satisfy the general criteria of patentability as outlined in Section 2(1)(j) of the Patents Act 1970, which includes novelty, inventive step, and industrial applicability.

For a genetic invention to be considered **novel**, it must be new and not anticipated by prior art, meaning it has not been disclosed to the public in any form before the date of filing the patent application. Prior art encompasses any information that has been made publicly available through publication, public use, or prior patent filings. Determining novelty in the context of genetic sequences and biological materials can be particularly challenging, especially when dealing with substances that occur naturally. While a gene in its native state within an organism is not considered novel, the isolation and purification of a gene from its natural environment might meet the criteria for novelty if the process of isolation and the resulting purified form were previously unknown. However, Section 3(c) of the Patents Act explicitly excludes the "discovery of any living thing or non-living substance occurring in nature" from patentability, creating a complex interplay between the concept of novelty and the exclusion of discoveries.

The criterion of **inventive step** requires that the genetic invention involve a technical advance compared to existing knowledge or have economic significance, and it must not be obvious to a person skilled in the art. A person skilled in the art is defined as someone having ordinary technical knowledge and experience in the specific field of the invention. In the context of biotechnology and genetics, this would typically refer to a researcher or scientist with a standard level of expertise in the relevant area. Assessing non-obviousness for genetic inventions, such as isolated genes, modified sequences, and biotechnological processes, involves determining whether a person skilled in the art would have considered the invention an obvious development based on the existing state of knowledge. While the isolation of DNA sequences using well-known techniques might generally be considered obvious, the isolation of a specific gene with a previously unknown function or a significantly improved property might be deemed to involve an inventive step.

Finally, the genetic invention must possess **industrial applicability**, meaning it is capable of being made or used in some kind of industry, including manufacturing, agriculture, or healthcare. This criterion necessitates that the invention has practical utility and is not merely

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a theoretical or abstract concept. For genetic inventions, demonstrating industrial applicability often involves disclosing a specific and substantial use for the gene sequence, diagnostic method, or therapeutic application being claimed. A mere identification of a gene sequence without any known function or practical application would likely not satisfy this requirement. The utility standards for genetic inventions are often considered higher than for other types of inventions, requiring a credible and well-established real-world use.

The rapid advancements and evolving nature of biotechnology present ongoing challenges to the application of these traditional patentability criteria to genetic inventions. One significant hurdle lies in clearly distinguishing between a "discovery" of something that already exists in nature and a genuine "invention" that involves human ingenuity and a novel application.

Furthermore, the standard of a "person skilled in the art" can be difficult to apply in a field where knowledge and techniques are constantly advancing.

9.2. Key Provisions of the Indian Patents Act 1970 Relevant to Genetic Inventions

The Indian Patents Act 1970 contains several key provisions that are particularly relevant to the patenting of genetic inventions, most notably Section 3, which lists categories of inventions that are not patentable, and Section 10, which outlines the requirements for patent specifications.

Section 3 of the Act enumerates various exclusions to patentability, many of which have direct implications for genetic inventions. **Section 3(b)** excludes inventions that are contrary to public order or morality or which cause serious prejudice to human, animal, or plant life or health or to source 3, 22, 23, 24] This provision is particularly relevant to genetically modified organisms (GMOs) and processes that raise ethical concerns or have the potential for harmful consequences. The interpretation of the "morality clause" in the context of biotechnology is often debated, as seen in cases involving genetic modifications. **Section 3(c)** explicitly states that "the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature" is not patentable. This section is crucial for genetic material, as it necessitates a clear distinction between the mere identification of a naturally occurring gene or DNA sequence (considered a discovery) and an invention that involves a significant degree of human intervention, such as genetic modification or a novel application. While isolated and purified genes might be considered patentable under certain circumstances, the baseline exclusion of naturally occurring substances poses a significant hurdle. **Section 3(d)** further restricts patentability by stating that "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance" is not patentable. This provision has implications for patents on modified genetic sequences that do not demonstrate a significant improvement in efficacy compared to known sequences, as exemplified by the landmark *Novartis AG v. Union of India* case. **Section 3(j)** specifically excludes "plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties, and species and essentially biological processes for production or propagation of plants and animals" from patentability. This section allows for the patenting of microorganisms, including genetically modified microorganisms, but excludes plants and animals, impacting the landscape of agricultural biotechnology, as seen in the *Monsanto Technology LLC v. Nuziveedu Seeds Ltd.* case. Finally, **Section 3(k)** excludes "a mathematical or business method or a computer program per se or algorithms" from patentability, which is relevant to bioinformatics tools and software used in genetic analysis, although software with

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a demonstrable technical contribution may be patentable.

Section 10 of the Patents Act outlines the requirements for patent specifications, which are crucial for inventions involving biological material. It mandates a full and particular description of the invention, its operation, and the best method of performing it. For inventions involving biological material, specific requirements include the mandatory disclosure of the source and geographical origin of the biological material used in the invention. Furthermore, under certain conditions, such as when the biological material is not fully described in the specification and is not available to the public, the applicant may be required to deposit the biological material with a recognized depository. If a deposit is made, a reference to it, including the depository details and accession number, must be included in the patent specification within a specified timeline. For genetic inventions involving genes, nucleotide sequences, and polypeptide sequences, the patent application must also include a sequence listing in electronic form.

The numerous exclusions under Section 3 demonstrate a cautious approach to patenting genetic inventions in India, reflecting a policy aimed at safeguarding public health, morality, biodiversity, and traditional knowledge. The strict interpretation of Section 3(c) emphasizes the need for more than just the identification of naturally occurring substances to qualify for patentability. The requirements under Section 10 for disclosing biological material, particularly its source and origin, underscore the importance of aligning patent law with biodiversity conservation efforts and preventing the misappropriation of biological resources.

9.3. International Conventions and Treaties Pertaining to Genetic Patents

India's patent law framework for genetic inventions is significantly influenced by its membership in various international conventions and treaties.

The **TRIPS Agreement**, administered by the World Trade Organization (WTO), sets minimum standards for intellectual property protection among its member countries, including India.[1] Article 27 of the TRIPS Agreement mandates that patents should be available for inventions in all fields of technology, including biotechnology. However, it also allows for certain flexibilities, such as the exclusion from patentability of inventions that are contrary to public order or morality (Article 27.2) and plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals (Article 27.3(b)). India's Patents Act was amended several times between 1999 and 2005 to align with its obligations under the TRIPS Agreement, including the introduction of product patents in the pharmaceutical and biotechnology sectors. India has also strategically utilized the flexibilities within TRIPS, such as those related to compulsory licensing and the provisions of Section 3(d) of the Patents Act, to balance patent rights with public health concerns and ensure access to affordable medicines.

The **Convention on Biological Diversity (CBD)**, to which India is a signatory, aims to conserve biological diversity, promote the sustainable use of its components, and ensure the fair and equitable sharing of benefits arising from the utilization of genetic resources. Article 15 of the CBD recognizes the sovereign rights of states over their natural resources and emphasizes the importance of prior informed consent (PIC) and mutually agreed terms (MAT) for access to genetic resources. The principles of the CBD have significantly influenced India's approach to patenting genetic resources, leading to the enactment of the Biological Diversity Act 2002. This Act mandates the disclosure of the source and geographical origin of biological material in patent applications and requires prior approval from the National Biodiversity Authority (NBA) for certain entities seeking to access and utilize India's biological resources for research or commercial purposes, including patenting. The CBD also emphasizes the principle of benefit

sharing, ensuring that the benefits derived from the use of genetic resources are shared fairly and equitably with the providers, including local communities and conservers.

India is also a signatory to the **Paris Convention for the Protection of Industrial Property**, which provides for the principles of national treatment and the right of priority for patent applications. This convention allows Indian applicants to claim priority for a patent application filed in India when filing in other member countries within a 12-month period, and vice versa.

The **Patent Cooperation Treaty (PCT)** facilitates the filing of international patent applications, including those for genetic inventions, through a unified procedure. India is a member of the PCT, and the Indian Patent Office acts as a receiving office, as well as an International Searching Authority (ISA) and International Preliminary Examining Authority (IPEA) for PCT applications.

Finally, the **Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure** streamlines the process for depositing microorganisms required for patent applications. This is particularly relevant for patenting genetically modified microorganisms in India, as it provides a mechanism for fulfilling the disclosure requirements of patent law when the invention involves biological material that cannot be adequately described in writing.

India's patent law framework for genetic inventions is thus intricately linked with its international obligations and commitments. The TRIPS Agreement necessitates providing patent protection in biotechnology, while the CBD mandates the protection of biodiversity and the fair sharing of benefits. The Paris Convention and the PCT facilitate international patenting, and the Budapest Treaty addresses the specific requirements for biological inventions involving microorganisms.

9.4. Implementation and Interpretation of International Conventions in India

India has taken significant steps to align its patent law with its international obligations. The Patents Act 1970 has been amended to incorporate provisions of the TRIPS Agreement, most notably the introduction of product patents in the pharmaceutical and biotechnology sectors. Furthermore, the enactment of the Biological Diversity Act 2002 serves as a key mechanism for implementing the principles of the CBD within the Indian legal framework, particularly concerning access to genetic resources and benefit sharing. India also adheres to the procedures and requirements of the Paris Convention and the PCT, facilitating international patent applications for genetic inventions. The recognition of the Budapest Treaty further streamlines the patenting process for inventions involving microorganisms.

The Indian Patent Office (IPO) plays a crucial role in the implementation and interpretation of these international conventions within the domestic context. It issues guidelines and manuals for the examination of patent applications, including the "Guidelines for Examination of Biotechnology Applications for Patents," which provide specific guidance on assessing novelty, inventive step, and industrial applicability for genetic inventions. The IPO also functions as a receiving office and an International Searching Authority/International Preliminary Examining Authority under the PCT, ensuring that Indian patent practices align with global standards. Moreover, the IPO is responsible for ensuring compliance with the disclosure requirements for biological material, including the source and origin, and for requiring permission from the National Biodiversity Authority for inventions based on Indian biological resources.

The Indian judiciary also plays a vital role in interpreting the provisions of the Patents Act and international conventions through various case laws. Landmark cases have provided clarifications on the patentability criteria for genetic inventions and the application of Section 3 exclusions, such as the *Novartis* case concerning enhanced efficacy. The judiciary

also addresses disputes related to patent infringement and revocation in the context of biotechnology, further shaping the practical application of the law.

The Indian Patent Office's guidelines serve as a vital link between the broad principles of the Patents Act and the specific challenges posed by genetic inventions, offering a practical framework for examiners. The judiciary's role in interpreting the law, particularly in significant cases, provides crucial precedents that guide the application of patent law to this complex field. The implementation of the CBD through the BDA adds a unique dimension to the patenting of genetic inventions in India, ensuring that biodiversity protection and benefit sharing are integral considerations in the patenting process.

9.5. Key Doctrines and Legal Principles in the Examination of Genetic Patents

Several key doctrines and legal principles are applied by the Indian Patent Office and courts when examining patent applications for genetic inventions.

The **doctrine of novelty** requires a thorough examination of prior art to ascertain whether the genetic invention has been previously disclosed. This assessment considers novelty in the context of gene sequences, proteins, and other biological molecules, adhering to the principle of absolute novelty under Indian patent law.

The assessment of **inventive step** involves evaluating the technical advancement or economic significance of the genetic invention and determining whether it would have been obvious to a person skilled in the art of biotechnology. This requires considering the level of skill and common general knowledge prevalent in the relevant field at the time of the invention.

The **requirement of industrial applicability** necessitates demonstrating that the genetic invention can be made or used in an industry, with a specified practical utility for gene sequences, diagnostic methods, or therapeutic applications. Disclosing a specific and substantial utility is crucial for meeting this requirement.

The **public trust doctrine**, while not explicitly codified in the Patents Act, raises debates about whether fundamental genetic resources, such as the human genome, should be subject to private ownership through patents, as these resources are often considered to belong to the public.

Finally, the **principles of benefit sharing**, as mandated by the CBD and the Biological Diversity Act 2002, are increasingly relevant in the examination of genetic patents, particularly those involving biological resources sourced from India. These principles aim to ensure a fair and equitable distribution of benefits arising from the use of such resources, often through mechanisms involving monetary and non-monetary compensation to local communities and knowledge holders.

The specialized knowledge required to assess novelty and inventive step in the complex field of biotechnology underscores the need for examiners with expertise in genetics and related areas. The public trust doctrine introduces a philosophical debate about the boundaries of patentability concerning essential genetic resources. The principles of benefit sharing add an important ethical layer to the patenting of genetic resources, particularly those originating from India, reflecting a commitment to equity and the recognition of traditional knowledge.

9.6. Case Studies and Legal Precedents in India

Several case studies and legal precedents in India have significantly shaped the understanding and application of patent law to genetic inventions.

The Supreme Court's decision in **Novartis AG v. Union of India (2013)** remains a landmark case, emphasizing the strict interpretation of Section 3(d) of the Patents Act. The court rejected Novartis's patent application for the beta-

crystalline form of imatinib mesylate (Gleevec), a cancer drug, holding that the new form did not demonstrate a significant enhancement in therapeutic efficacy compared to the known alpha-crystalline form. This case has had a lasting impact on pharmaceutical patents in India, preventing the "evergreening" of patents through minor modifications without substantial improvement.

In **Monsanto Technology LLC v. Nuziveedu Seeds Ltd. (2018)** , the Delhi High Court addressed the patentability of genetically modified plants and seeds under Section 3(j) of the Patents Act. The court clarified that plants and seeds are excluded from patentability under this section, with the exception of microorganisms. This ruling has significant implications for the agricultural biotechnology industry in India, limiting the scope of patent protection for genetically modified crops.

Dimminaco A.G. v. Controller of Patents & Designs (2002) is another important precedent, where the Calcutta High Court allowed the patenting of a process for manufacturing a product containing living organisms. This case was significant in establishing the patentability of certain biotechnological processes in India, marking a shift in the patent office's approach to inventions involving living entities.

Beyond these landmark cases, numerous other legal precedents have contributed to the interpretation of novelty, inventive step, and industrial applicability in the context of genetic inventions. Courts have also addressed disputes related to the disclosure of biological material and compliance with the Biological Diversity Act, as well as patent infringement cases involving genetic inventions. These cases collectively demonstrate the ongoing judicial engagement with the complex legal and scientific issues surrounding the patenting of genetic inventions in India. Recent cases like *University Health Network vs Adiuvo Diagnostics Private Limited* on jurisdictional aspects and *Microsoft Technology Licensing vs Assistant Controller of Patents and Designs* on the patentability of software related to biotechnology further illustrate the evolving legal landscape.

These case studies highlight the Indian judiciary's role in interpreting and applying the provisions of the Patents Act to the specific context of genetic inventions. The *Novartis* case underscores the strict standards for pharmaceutical patents, while the *Monsanto* case clarifies the exclusions for plants and seeds. The *Dimminaco* case represents an early recognition of the patentability of certain biotechnological processes. The broader body of case law reflects a continuous effort to balance the promotion of innovation with public interest concerns in this rapidly advancing field[5].

9.7. Guidelines and Clarifications from the Indian Patent Office

The Indian Patent Office (IPO) issues guidelines and clarifications to provide a framework for the examination of biotechnology patent applications, including those related to genetic inventions.

The "Guidelines for Examination of Biotechnology Applications for Patents" outline the IPO's approach to assessing the patentability criteria of novelty, inventive step, and industrial applicability for biotechnology inventions, including genetic material. These guidelines offer specific instructions on the patentability of gene sequences, proteins, and genetically modified organisms. Notably, they emphasize the requirement of "substantial human intervention" for patenting isolated biological material, suggesting a stricter standard than mere isolation. The guidelines also highlight the consideration of traditional knowledge during the patent examination process, aligning with India's commitment to protecting its cultural heritage.

The Manual of Patent Office Practice and Procedure provides detailed procedures for filing and prosecuting patent applications involving biological material. It includes specific

information on the requirements for disclosing the source and origin of biological material, as well as guidelines on the deposit of microorganisms under the Budapest Treaty.

The IPO may also issue other relevant notices and clarifications regarding the patenting of genetic inventions, providing updates on the examination process and timelines for biotechnology patent applications.

The IPO's guidelines serve as a crucial tool for ensuring consistency and clarity in the examination of biotechnology patents, offering a practical interpretation of the Patents Act in this specialized field. The emphasis on "substantial human intervention" reflects a cautious approach to patenting naturally occurring biological material. The consideration of traditional knowledge underscores India's commitment to preventing the misappropriation of its cultural and biological heritage through the patent system.

9.8. Ethical and Societal Considerations in Patenting Genetic Inventions in India

The patenting of genetic inventions in India is accompanied by significant ethical and societal considerations.

Ethical implications include concerns about the "commodification of life" and the patenting of genetic material that is naturally occurring. Opponents argue that patenting genes can diminish human dignity by treating fundamental components of life as mere commercial commodities. There are also concerns that gene patents could hinder scientific research and restrict access to essential genetic testing and therapies, potentially jeopardizing public health. Issues of privacy and consent related to genetic information further complicate the ethical landscape. The "morality clause" in Section 3(b) of the Indian Patents Act reflects some of these ethical concerns and can be invoked to refuse patents on inventions considered contrary to morality.

The societal impacts of patenting genetic inventions in India are far-reaching. In agriculture, the patenting of genetically modified crops and seeds raises concerns about farmers' rights, food security, and the potential for corporate control over essential agricultural resources. The patenting of genetic resources also has implications for biodiversity conservation and the potential for biopiracy, where traditional knowledge and biological resources are exploited without fair compensation. In the realm of public health, gene patents can affect access to affordable healthcare, including genetic diagnostics and treatments, by creating monopolies that drive up prices. Balancing commercial interests with the broader public good remains a central challenge in this context. Public opinion and ongoing debates in India reflect the complex and often conflicting perspectives on gene patenting.

These ethical and societal considerations are reflected in the restrictive provisions of Section 3 of the Indian Patents Act, which excludes certain categories of inventions from patentability. Judicial decisions, such as the *Novartis* case, demonstrate a cautious approach to patenting in areas with significant public health implications. The Biological Diversity Act further addresses concerns about biopiracy and benefit sharing, reflecting India's commitment to its rich biodiversity and traditional knowledge.

The ethical dilemmas surrounding gene patenting in India highlight the tension between incentivizing scientific advancement and protecting fundamental principles of human dignity and equitable access. The societal impacts, particularly in agriculture and healthcare, necessitate a careful regulatory approach that balances innovation with the broader public interest. Indian legislation and judicial interpretations reveal a tendency towards a more restrictive stance on gene patenting compared to some other jurisdictions, reflecting a prioritization of public health, biodiversity, and traditional knowledge.

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CHAPTER – 10

The Significance of Patent Protection for Genetic Inventions in Protecting Against Human Diseases

10.1. Defining the Landscape: Genetic Inventions in Patent Law

Understanding the scope of patent protection for genetic advancements requires a clear definition of what constitutes a "genetic invention" within the realm of patent law. Gene patents, a specific category of intellectual property rights, grant exclusive rights to individuals, organizations, or corporations over particular DNA sequences for a defined period, typically 20 years from the patent's filing date. This exclusive ownership often encompasses crucial genetic information, allowing the patent holder to control its utilization. This definition extends beyond mere gene sequences to include various forms of genetic material, such as DNA, RNA, complementary DNA (cDNA), expressed sequence tags (ESTs), single nucleotide polymorphisms (SNPs), and recombinant vectors, which are considered analogous to chemical inventions within the patent system. Patenting can also cover isolated natural gene sequences, their specific uses in diagnostic testing, or gene sequences that have been altered through human intervention to enhance their utility by adding promoters or other modifications. Furthermore, the scope of patentable genetic inventions includes not only the genetic material itself but also the processes and methodologies for obtaining or utilizing these sequences. The breadth of this definition underscores the potential reach of patent protection in the field of genetics.

A central point of contention in the patenting of genetic material revolves around the distinction between a discovery and an invention. This debate is particularly relevant when considering naturally occurring DNA sequences. Legal precedents, most notably the 2013 United States Supreme Court decision in *Association for Molecular Pathology v. Myriad Genetics*, have significantly impacted the patentability of such sequences in the US. The court ruled that naturally occurring isolated genes are considered "products of nature" and, therefore, are not eligible for patent protection simply by virtue of their isolation. In contrast, manipulated or synthetic forms of DNA, such as cDNA, which is created in the laboratory and does not occur naturally, can still be patented. This stance reflects a legal philosophy that favours patent protection for human-made innovations over naturally existing substances. Interestingly, the approach in the European Union (EU) differs in this regard. While both jurisdictions generally prohibit the patenting of native gene and protein sequences, the EU allows for exceptions, particularly for biological materials and identical gene or protein sequences found in nature when they have been isolated or technologically produced. This divergence highlights differing legal interpretations of what constitutes patentable subject matter in the context of genetic material.

Several landmark legal cases have played a crucial role in shaping the patentability landscape for genetic inventions. The 1980 Supreme Court case of *Diamond v. Chakrabarty* established a significant precedent by allowing the patenting of genetically modified organisms, recognizing that a "man-made" organism with markedly different characteristics from naturally occurring ones could be patentable. This decision paved the way for patents on various genetically engineered entities, including bacteria, viruses, seeds, plants, and even non-human animals, as well as isolated and manipulated cells, including human cells. Furthermore, the *Cohen/Boyer patents*, invented by Stanley Cohen and Herbert Boyer, covered fundamental techniques for splicing genes to create recombinant proteins, laying the groundwork for the entire biotechnology industry. However, the *Association for Molecular Pathology v. Myriad Genetics* case in the US stands out as particularly pivotal for gene patenting. The Supreme Court's ruling in this case invalidated

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Myriad's patents on the BRCA1 and BRCA2 genes, which are associated with increased risk of breast and ovarian cancer, on the grounds that the isolated gene sequences were products of nature. This decision marked a significant shift in US patent law concerning genetic material. In contrast, the European Patent Office (EPO) guidelines permit the patenting of isolated genes, even if their structure is identical to that of a natural element, provided that the patent application discloses the industrial application of the sequence. This contrast underscores the differing regulatory environments for genetic invention patents in the US and the EU.

10.2. Navigating the Process: Patenting Genetic Inventions

Securing patent protection for a genetic invention involves a well-defined process that requires meticulous attention to detail and adherence to specific legal criteria. To initiate this process, an inventor must file a patent application with the relevant patent office, such as the United States Patent and Trademark Office (USPTO) in the US or the European Patent Office (EPO) in Europe. This application must include a comprehensive description of the invention, providing sufficient detail to enable a person skilled in the relevant field to reproduce it. The application typically includes a detailed written description, drawings or diagrams where necessary, and specific claims that define the scope of the patent protection sought. For those seeking international protection, the Patent Cooperation Treaty (PCT) offers a mechanism to file a single international patent application that can then be pursued in multiple member countries. Once a patent is granted, research institutions may engage in technology transfer processes, often involving licensing the patented inventions to commercial entities to facilitate their development and market availability.

Patent offices around the world evaluate patent applications based on a set of fundamental criteria. **Novelty** is a primary requirement, meaning that the invention must be new and not previously disclosed to the public in any form before the date of the patent application. This ensures that patents are granted for truly new advancements rather than existing knowledge. Another crucial criterion is **non-obviousness**, also referred to as inventive step in some jurisdictions. This requires that the invention must involve an inventive step and should not be obvious to a person skilled in the relevant technical field at the time the invention was made. The invention must also possess **utility**, meaning it must have a practical application or be capable of industrial use. In the context of genetic inventions, the standards for utility can sometimes be more stringent, requiring a specific and substantial use to be disclosed. Finally, the patent application must provide a **sufficiency of disclosure**, also known as enablement. This means that the invention must be described clearly and comprehensively enough to allow a person skilled in the art to understand and reproduce it without undue experimentation. These core patentability criteria serve as the foundation for evaluating genetic inventions, although their specific application can be nuanced and subject to interpretation by patent offices and courts.

In addition to the general patentability criteria, there are specific considerations that apply to genetic material. In the United States, the *Myriad* decision established that the mere isolation of a naturally occurring gene is not sufficient for patentability. Generally, some form of human intervention that significantly alters the naturally occurring state, such as creating cDNA or genetically engineering an organism, is required for patent eligibility in the US. This reflects a legal stance against patenting products of nature. Conversely, in the European Union, isolated naturally occurring genetic sequences can still be eligible for patent protection, provided they meet other requirements such as industrial applicability and the disclosure of their function in the patent application. This difference highlights a key divergence in the legal frameworks of the US and the EU regarding the patentability of

genetic material. Similarly, in Australia, biological materials must be isolated from their natural environment or produced synthetically or recombinantly to be patentable. Furthermore, patents are not granted for gene sequences, DNA, or RNA that simply replicate the genetic information found in the blueprint of any human or other organism. These variations across jurisdictions underscore the importance of understanding the specific legal landscape when seeking patent protection for genetic inventions in different parts of the world.

10.3. Fuelling Innovation: Incentivizing Research and Development

The patent system serves as a powerful engine for driving research and development in the field of genetic inventions aimed at protecting against human diseases. By granting inventors and their assignees exclusive rights for a limited time, patents create a crucial financial incentive for investing in this often expensive and time-consuming area of research. The potential for market exclusivity allows companies to recoup the substantial investments made in the lengthy and risky process of discovering, developing, and bringing new genetic-based diagnostics and therapies to market. This prospect of a return on investment is particularly vital in the biotechnology and pharmaceutical industries, where research costs can be exceptionally high and the path to a marketable product can be arduous. Furthermore, patents enable the collection of fees through licensing agreements, offering inventors an opportunity to transfer their rights to others who may be better positioned to further develop and commercialize the invention, thus creating a secondary incentive for investment and innovation. Investors are also more inclined to support potentially groundbreaking genetic research when they have the assurance that their investments will be protected by exclusive patent rights, reducing the risk of competitors immediately copying successful innovations.

The promise of patent protection directly stimulates the development of novel diagnostic tools and therapeutic strategies for human diseases. By offering the potential for market exclusivity, patents encourage researchers and companies to pursue innovative approaches to disease prevention, diagnosis, and treatment that might otherwise be deemed too financially risky. Gene patents, in particular, have been credited with elevating genetic engineering beyond the realm of basic science, spurring significant advancements in therapeutic technologies. The patenting of genetic material has also fostered a substantial market for private investment capital in the biotechnology sector, leading to the emergence of numerous new diagnostic and therapeutic inventions based on genomics and proteomics. This cycle of patent protection leading to investment and then to the development of new healthcare solutions underscores the critical role of patents in driving progress in this field.

Interestingly, the patent system also fosters a degree of transparency and knowledge sharing within the scientific community. In exchange for the grant of exclusive rights, inventors are required to publicly disclose the details of their inventions in the patent application. This public disclosure can prevent the duplication of research efforts across different institutions, as researchers can learn from the patented findings of others. It also reduces the incentive for secrecy within the scientific community, allowing scientists access to each other's findings in a way that can potentially accelerate the overall pace of research. While the primary function of a patent is to grant exclusivity, the accompanying requirement for disclosure contributes to the broader dissemination of scientific knowledge, which can, in turn, catalyse further innovation.

However, it is important to acknowledge the counterarguments and potential hindrances associated with gene patents. Concerns have been raised that the exclusivity granted by patents can sometimes impede rather than stimulate research. Restricting access to patented genes or genetic technologies could

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potentially lead to monopolies, increased costs for diagnostic tests and treatments, and a slowdown in the translation of research findings into clinical applications. Some argue that gene patents can violate patients' rights to access potentially life-saving genetic information and treatment, without necessarily fulfilling the patent system's intended goal of promoting innovation. The debate surrounding the optimal balance between incentivizing innovation through patent protection and ensuring broad access to genetic healthcare innovations remains a critical one.

10.4. Pioneering Progress: Examples of Patented Genetic Inventions and their Impact

Several specific examples of patented genetic inventions illustrate their significant impact on preventing or treating human diseases. The *Cohen/Boyer patents*, for instance, were foundational to the entire biotechnology industry, providing the essential technology for splicing genes to produce recombinant proteins. This breakthrough paved the way for the development of numerous life-saving therapeutics, such as recombinant insulin for diabetes and human growth hormone (HGH) for growth disorders, which are often protected by composition of matter patents. Another notable example is the *Winter patent*, which covered key methods for manipulating DNA to create chimeric and humanized antibodies. This patented technology has been licensed to approximately fifty companies and has been instrumental in the development of a wide range of antibody-based therapies for various diseases, including cancer and autoimmune disorders. In the realm of diagnostics, Foundation Medicine has successfully obtained patents for its comprehensive genomic profiling methods. These patented techniques analyse multiple cancer-related genes to guide treatment decisions, representing a significant advancement in personalized medicine for cancer patients. These examples demonstrate how patent protection has facilitated the development and commercialization of crucial genetic inventions that have had a profound impact on human health.

10.5. Empowering Progress: Benefits of Patent Protection for Companies and Institutions

Patent protection offers numerous benefits to companies and institutions involved in developing genetic inventions for disease prevention and treatment. A primary advantage is the ability to attract investment and funding. In the highly competitive and capital-intensive field of biotechnology, patents serve as a crucial signal to investors that an innovation is protected and has the potential for commercial success. This assurance of intellectual property rights makes companies and research institutions more attractive to venture capitalists, pharmaceutical companies, and other funding sources, enabling them to secure the substantial financial resources required to conduct further research, development, and clinical trials. For early-stage biotech companies, having secured patents is often a prerequisite for attracting significant investment.

Furthermore, patent protection provides companies and institutions with vital market exclusivity and a significant competitive advantage. The exclusive rights granted by a patent allow the patent holder to prevent competitors from making, using, or selling the patented invention for a specified period, typically 20 years. This temporary monopoly enables the patent holder to establish a strong market position, recoup their R&D costs, and potentially generate significant revenue from their innovation. Owning a patent can also strengthen a company's brand and reputation, differentiating them from competitors and positioning them as leaders in specific technological areas.

Patents also play a crucial role in facilitating licensing agreements and collaborations. Companies and institutions that hold patents on genetic inventions can license these rights to other entities, allowing them to further develop or commercialize the technology in exchange for licensing fees or royalties. This can be

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particularly beneficial when the patent holder lacks the resources or expertise to fully exploit the invention themselves. Licensing can generate valuable revenue streams and foster collaborations that can accelerate the development and broader adoption of genetic-based healthcare innovations. Moreover, for biotechnology companies, a strong patent portfolio can significantly enhance their overall valuation, making them more attractive targets for strategic alliances, mergers, or acquisitions by larger pharmaceutical companies.

10.6. Bridging the Gap: Patents, Commercialization, and Accessibility

Patents are instrumental in bridging the gap between scientific discovery and the availability of genetic-based healthcare innovations to patients. By providing a framework for ownership and exclusivity, patents encourage the often complex and expensive process of translating research breakthroughs into commercially viable products and services. The protection afforded by patents incentivizes companies to invest in the necessary steps for commercialization, including scaling up production, conducting further clinical testing, navigating regulatory approvals, and establishing distribution channels. Furthermore, the requirement for public disclosure in patent applications can facilitate the dissemination of knowledge, allowing other researchers and companies to build upon patented inventions and potentially develop improved or complementary technologies. This interplay between protection and disclosure is a key mechanism through which the patent system aims to promote overall technological advancement.

However, the impact of patents on the accessibility and affordability of genetic-based healthcare innovations is a complex and often debated issue. While patents are intended to incentivize the development of new technologies, the market exclusivity they grant can also lead to increased prices for genetic tests and therapies, potentially limiting patient access. There have been instances where patents have been used to consolidate the market for genetic testing, resulting in sole providers and potentially higher costs for patients. For example, the patents held by Myriad Genetics on the BRCA1 and BRCA2 genes led to the company becoming the sole provider of testing for these genes in the US for a period, raising concerns about cost and access. Conversely, the Supreme Court's decision in the *Myriad* case, which invalidated patents on naturally occurring genes, has been credited with leading to a substantial drop in the prices of genetic testing for these genes and increased accessibility. This highlights the delicate balance between incentivizing innovation through patents and ensuring that essential healthcare technologies remain accessible and affordable. Policy mechanisms such as compulsory licensing have been suggested as potential tools to mitigate the adverse effects of gene patents on public health in certain circumstances.

Various commercialization strategies can be employed for patented genetic inventions. These include directly manufacturing and selling products based on the patented invention, licensing the patent to other companies for them to commercialize, identifying and pursuing infringers, forming patent pools with other patent holders to cross-license technologies, and outright selling the patent. In the biotechnology industry, licensing is a particularly common strategy, allowing research institutions and smaller companies to partner with larger pharmaceutical or diagnostic companies that have the resources and infrastructure to bring genetic innovations to market. While the prospect theory of patents suggests that broad patent rights can streamline commercialization by reducing rivalry, concerns remain about the potential for such broad protection to lead to supercompetitive pricing and limited access, particularly in the context of essential healthcare technologies.

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10.7. Ethical Crossroads: Considerations and Potential Drawbacks

The patenting of genetic inventions raises several profound ethical considerations and potential drawbacks that warrant careful examination. One of the most fundamental ethical debates centres on the ownership of genetic information. Critics argue that genes are products of nature, intrinsic to human life, and should not be owned or controlled by private entities. Patenting human genetic material is seen by some as setting a troubling precedent for the commodification of human life and potentially granting undue control over information that is essential for understanding and treating human health. The question of whether a private company should have the right to own or control information about our bodies is a central point of contention in this ethical debate.

Another significant ethical concern revolves around the potential for gene patents to limit research and innovation. By granting exclusive rights, patents can restrict the ability of other researchers to use patented genes or genetic sequences in their work, potentially increasing research costs and slowing down the pace of scientific discovery and medical advancement. While the patent system is designed to incentivize innovation, there is a valid concern that in the realm of fundamental genetic information, overly broad patent protection could inadvertently stifle further research and the development of new and improved diagnostic and therapeutic tools.

The impact of gene patents on patient access and healthcare disparities also raises serious ethical issues. The potential for patent-driven monopolies to lead to increased prices for genetic tests and treatments raises concerns about justice and equity in healthcare. Limited access to essential genetic testing and therapies due to patent restrictions could disproportionately affect underserved populations and exacerbate existing healthcare disparities between wealthier and poorer nations. The case of Myriad's patents on BRCA1 and BRCA2, which for a time gave the company exclusive rights to testing for these genes, exemplifies these concerns.

Finally, the patenting of gene editing technologies introduces a new set of ethical considerations. While these technologies hold great promise for treating genetic diseases, they also raise ethical questions about their potential impact on the human genome and the implications of altering the fundamental building blocks of life. The fact that patents are routinely granted for gene editing technologies like CRISPR-Cas9, even as ethical guidelines and societal debates surrounding their use continue to evolve, highlights the complex interplay between innovation, patent law, and ethical responsibility in this rapidly advancing field.

10.7. Global Perspectives: Legal Frameworks and Regulations Worldwide

The legal frameworks and regulations governing the patenting of genetic inventions vary significantly across different countries and regions, reflecting diverse legal traditions, economic priorities, and ethical considerations.

In the **United States**, the legal landscape has been significantly shaped by the Supreme Court's 2013 decision in *Association for Molecular Pathology v. Myriad Genetics*. This landmark ruling established that naturally occurring isolated human genes are not patentable as they are considered products of nature. However, the Court clarified that manipulated or synthetic forms of DNA, such as cDNA, which are created through human intervention, remain eligible for patent protection. The US patent law framework, as outlined in Title 35 of the US Code, defines patentable subject matter broadly as "any new and useful process, machine, manufacture, or composition of matter". To be patentable, an invention must also meet the criteria of novelty, non-obviousness, and utility. Notably, there is ongoing discussion and potential for legislative changes in the US, with the proposed Patent

Eligibility Restoration Act of 2023 aiming to modify the current eligibility standards, potentially impacting the patentability of certain genetic inventions.

In the **European Union**, the approach to patenting genetic inventions is largely governed by the Biotech Directive (Directive 98/44/EC) and the European Patent Convention (EPC). Unlike the US, the EU generally permits the patenting of naturally occurring genetic sequences if they have been isolated from their natural environment or produced through a technical process and have a disclosed industrial application. The Biotech Directive specifies that inventions that are new, involve an inventive step, and are susceptible of industrial application are patentable, even if they concern biological material. However, the simple discovery of a gene sequence is not considered patentable. The EPO guidelines further detail the patentability of biological materials, plants, and animals, including exclusions for essentially biological processes for plant and animal production and considerations related to animal suffering. Overall, the EU adopts a more permissive stance on patenting isolated natural genetic sequences compared to the US, with a strong emphasis on the requirement of industrial applicability and ethical considerations within the framework of biotechnology patents.

Other countries have established their own regulations regarding the patentability of genetic inventions. In **Japan**, isolated genes are generally considered patentable as long as they meet the standard patentability criteria of novelty, inventive step, and industrial applicability, and their function is sufficiently described in the patent application. **India** takes a more restrictive approach, with its patent law stating that the mere discovery of a natural substance is not considered an invention. However, patents can be granted for genetically modified gene sequences that demonstrate novelty, involve an inventive step, and have industrial application. **Australia**, following a similar legal trajectory to the US, has also invalidated patents on naturally occurring DNA sequences, aligning with the view that such sequences are products of nature and thus not patentable subject matter. These examples illustrate the lack of complete global harmonization in the patenting of genetic inventions, with each country or region balancing its own legal, economic, and ethical considerations in this complex area.

CHAPTER – 11

Comparative Study

A comparative analysis of Patent Laws for genetic inventions in the USA, UK, China, Russia, Germany, France, India and Switzerland.

The field of genetic inventions has witnessed remarkable growth, yielding innovations with profound implications across medicine, agriculture, and industry. From groundbreaking diagnostic tools and life-saving therapies to enhanced crop yields and sustainable industrial processes, these inventions are increasingly central to addressing global challenges. However, the patenting of genetic material remains a complex and often contentious issue, fraught with legal, ethical, and societal considerations. This report undertakes a comparative analysis of the patent laws governing genetic inventions in eight key jurisdictions: the United States of America, the United Kingdom, China, the Russian Federation, Germany, France, India, and Switzerland. The primary objective is to delineate the similarities and differences in their legal frameworks concerning the patentability of genetic material, including isolated genes, DNA sequences, and genetically modified organisms. A particular emphasis will be placed on examining the specific provisions and unique aspects of Indian patent law in this domain, comparing it with the approaches adopted by the other seven countries. Understanding the nuances of these legal landscapes is crucial for researchers, policymakers, and businesses operating in the rapidly evolving field of biotechnology. The

interplay between national patent laws and international agreements, such as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and regional directives like the European Union's Biotech Directive, further complicates this landscape, necessitating a detailed comparative study.

11.1. Patent Laws of Key Jurisdictions United States

Patentability Criteria for Genetic Material in the US

Historically, the United States Patent and Trademark Office (USPTO) granted patents on isolated gene sequences, considering the act of isolation sufficient to confer patentability. This perspective was rooted in earlier legal precedents, such as the 1911 *Parke-Davis v. Mulford* case, which suggested that purified natural substances were patentable due to their increased utility compared to their naturally occurring forms. However, a landmark decision by the US Supreme Court in 2013, *Association for Molecular Pathology v. Myriad Genetics, Inc.*, fundamentally altered this position. The Court unanimously ruled that merely isolating a naturally occurring DNA segment does not render it patentable, as it remains a "product of nature". This decision invalidated Myriad Genetics' patents on the BRCA1 and BRCA2 genes, which are naturally occurring human genes associated with an increased risk of breast and ovarian cancer. The Supreme Court's reasoning was based on the principle that laws of nature, natural phenomena, and abstract ideas are not patentable, and that isolated but otherwise unaltered DNA falls within the category of natural phenomena.

Conversely, the Court in *Myriad* also affirmed that synthesized DNA molecules, such as complementary DNA (cDNA), which are created in the laboratory and do not occur naturally, remain eligible for patent protection. The rationale is that cDNA is a product of human ingenuity and does not exist in nature. Furthermore, the USPTO has granted patents on isolated gene sequences with known functions, implying that while mere isolation of a naturally occurring gene is insufficient, an isolated sequence with a demonstrated utility might still be patentable. The function of the gene must be more than simply of scientific interest; it usually requires a description of the gene's role and its practical application.

The US also permits the patenting of genetically modified organisms (GMOs). This was first established in the landmark 1980 case of *Diamond v. Chakrabarty*, where the Supreme Court upheld the patentability of a genetically engineered bacterium capable of breaking down crude oil. The Court reasoned that the modified bacterium was a "non-naturally occurring manufacture or composition of matter – a product of human ingenuity having a distinct name, character and use". This precedent has since been extended to various other genetically modified organisms, including bacteria, viruses, seeds, plants, cells, and even non-human animals. Isolated and manipulated cells, including human cells that have been sufficiently transformed, can also be patented.

Exclusions to Patentability for Genetic Inventions in the US

The US patent law, while broad, contains implicit and explicit exclusions to patentable subject matter relevant to genetic inventions. The Supreme Court has long held that laws of nature, natural phenomena, and abstract ideas are not patentable. This exclusion is the primary basis for the non-patentability of naturally occurring genes post-*Myriad*, as they are considered products of nature. Furthermore, the America Invents Act, enacted in 2012, explicitly prohibits the patenting of human organisms.

While ethical concerns about dignity and the sanctity of life have been raised regarding human gene patents, they have not directly translated into significant policy barriers within the USPTO. However, inventions whose commercial exploitation would violate public order or morality could potentially be excluded under existing legal principles. Additionally,

methods of treatment and diagnosis *per se* have faced increased scrutiny and may be considered unpatentable if they are deemed to claim abstract ideas or laws of nature, as highlighted in *Mayo Collaborative Services v. Prometheus Laboratories, Inc...*

Scope of Patent Protection for Genetic Inventions in the US

A biological patent in the US grants the patent holder the right to exclude others from making, using, selling, or importing the claimed invention for a limited period, typically 20 years from the filing date for patents filed after 1998. This protection can extend to isolated gene sequences with known functions, their use in diagnostic testing, and natural sequences that have been altered to enhance their utility. The scope also encompasses genetically modified organisms, including a wide range of biological entities. However, the claims define the precise boundaries of the patent protection, and these can be subject to limitations imposed by the courts or the USPTO. While a research exemption exists, allowing for the use of patented inventions for experimental purposes, its statutory basis is debated, and its scope is primarily defined by case law.

Patenting Naturally Occurring vs. Modified Genes in the US

The US patent law, particularly after the *Myriad* decision, draws a clear distinction between naturally occurring and modified genes. Naturally occurring DNA segments, even when isolated, are not patentable as they are considered products of nature. In contrast, synthesized DNA, such as cDNA, which does not exist in nature, is patentable. Furthermore, naturally occurring sequences that have been modified or engineered, for example, by adding a promoter to make them more useful, can also be patented, provided they meet the criteria of novelty, non-obviousness, and utility. The key factor is whether the genetic material has been altered by human intervention to create something with markedly different characteristics from what occurs in nature.

United Kingdom

Patentability Criteria for Genetic Material in the UK

In the United Kingdom, the Patents Regulations 2000, which implemented the EU Directive 98/44/EC on the legal protection of biotechnological inventions, confirmed that inventions concerning biological material, including gene sequences, are patentable. To be eligible for patent protection, genetic material must satisfy the standard criteria of novelty, inventive step, and industrial application. Additionally, for gene sequences, the industrial application must be disclosed in the patent application as filed. Unlike the US post-*Myriad*, the isolation of a naturally occurring substance that was previously unknown can be considered novel in the UK.

Exclusions to Patentability for Genetic Inventions in the UK

Schedule A2 of the Patents Act 1977 sets out exclusions from patentability for biotechnological inventions. These include the human body at various stages of its formation and development, as well as the simple discovery of one of its elements, including the sequence or partial sequence of a gene. Also excluded are processes for cloning human beings, processes for modifying the germ line genetic identity of human beings, and the uses of human embryos for industrial or commercial purposes. Furthermore, processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes, are not patentable. Similar to other European jurisdictions, plant and animal varieties and essentially biological processes for their production are also excluded from patentability. Finally, discoveries *as such* are not patentable.

Scope of Patent Protection for Genetic Inventions in the UK

A patent in the UK grants the holder the right to exclude others from making, using, selling, or

importing the invention for a limited period, typically 20 years from the filing date. This protection can cover biological material isolated from its natural environment or produced by a technical process. However, for a gene sequence, the protection is limited to the industrial application disclosed in the patent application. The UK also has an experimental use defence to patent infringement, which means that research to develop new genetic tests is unlikely to constitute patent infringement, although the limits of this defence have not been fully tested.

Patenting Naturally Occurring vs. Modified Genes in the UK

In the UK, the simple discovery of a gene sequence cannot be patented. However, an element isolated from the human body or produced by a technical process, including a gene sequence, may be patentable even if its structure is identical to a natural element. Artificial DNA constructs or sequences altered by humans remain patentable, as does cDNA, which is synthetically produced and does not occur naturally.

China

Patentability Criteria for Genetic Material in China

To be patentable in China, genetic material must meet the general criteria of novelty, inventiveness, and practical applicability. Additionally, for an invention accomplished by relying on genetic resources, the applicant must indicate the direct and original source of these resources in the patent application. If the original source cannot be provided, the applicant must state the reasons. For a gene or DNA fragment to be patentable, its base sequence must be unknown in the prior art, it must be capable of being definitely characterized, and it must have industrial application.

Exclusions to Patentability for Genetic Inventions in China

The Patent Law of China excludes several categories of inventions related to genetics. Invention-creations that violate the law or social ethics, or harm public interests, are not patentable. Furthermore, patent rights are not granted for inventions accomplished by relying on genetic resources that were obtained or used in violation of laws or administrative regulations. Scientific discoveries are also excluded from patentability. While animal and plant varieties are not patentable, methods of breeding that are not "essentially biological" may be patentable. Transgenic animals and plants are considered to fall under the category of animal and plant varieties and are thus not patentable. Methods for the diagnosis or treatment of diseases are also excluded, although products used in these methods may be patentable. The exclusion of human embryonic stem cells and methods of preparing them was removed in 2019, but inventions violating social morality can still be rejected.

Scope of Patent Protection for Genetic Inventions in China

The scope of patent protection in China is defined by the claims of the patent. The written description and attached drawings can be used to interpret these claims. For inventions based on genetic resources, the patent application documents must include a disclosure of the source. Patents on substances found in nature are generally not granted unless they are isolated or extracted for the first time, have an unknown structure or morphology, can be precisely characterized, and have industrial use.

Patenting Naturally Occurring vs. Modified Genes in China

In China, finding a gene or DNA fragment existing in its natural state is considered a non-patentable discovery. However, if a gene or DNA fragment is isolated or extracted for the first time from its natural state, has an unknown base sequence, and has industrial application, it can be patentable. Genetically modified gene sequences or amino acid sequences can be claimed if they are novel, involve an inventive step, and have industrial applicability.

Russian Federation

Patentability Criteria for Genetic Material in Russia

In Russia, an invention must be a technical solution relating to a product (which includes a substance, microorganism strain, or cell culture) or a method. It must also satisfy the criteria of novelty, inventive step, and industrial applicability. Notably, chemical compositions, pharmaceuticals, biological materials, gene sequences, and medical treatments are considered patentable subject matter in Russia. For inventions that relate to the "use" of a product or method for a certain purpose, the patent claim must specify this purpose.

Exclusions to Patentability for Genetic Inventions in Russia

Russian patent law excludes methods of cloning a human being and a clone, as well as methods for modifying the genetic integrity of cells of the embryonic line of a human being. The use of human embryos for industrial and commercial purposes is also excluded. Furthermore, solutions that are contrary to public interest, humanity, or morality are not patentable. Like many other jurisdictions, Russia does not grant patents for discoveries. Plant varieties and animal breeds, along with their biological methods of production (excluding microbiological methods and their products), are also excluded from patentability.

Scope of Patent Protection for Genetic Inventions in Russia

A patent for an invention in Russia grants exclusive rights for a term of 20 years from the filing date, with a possible extension for patents relating to pharmaceuticals, pesticides, or agrichemicals. The scope of protection covers the technical solution, whether it is a product (including a substance, microorganism strain, or cell culture) or a method (a process of performing actions). A patented invention is considered used if the product contains or the process involves every feature of an independent claim in the patent, or uses or includes an equivalent feature known as such in the art by the priority date. For genetic constructs, patent claims should be restricted to the drug's purpose or the biological function that determines this purpose.

Patenting Naturally Occurring vs. Modified Genes in Russia

The Civil Code of Russia permits the patenting of almost every product or method that was not created by nature. Complementary DNA (cDNA) synthesized from messenger RNA is considered a "manufactured" strand of DNA and is likely patentable, although the Civil Code does not explicitly state this. While the patentability of isolated naturally occurring, genes is not explicitly detailed in the provided snippets, the general principle suggests they might be patentable if they meet the standard criteria and are not considered mere discoveries. Ros patent considers biotechnological products isolated from the environment or produced through a technical process protectable even if they previously existed in nature. Genetic constructs, including plasmids, vectors, transformed cells of microorganisms, plants, and animals, as well as transgenic plants and animals, are patentable.

Germany

Patentability Criteria for Genetic Material in Germany

German patent law grants patents for inventions in all fields of technology, including products consisting of or containing biological material, as well as processes for their production, processing, or use. If the subject of an invention is a human gene sequence, the German Patent Act requires the disclosure of not only the sequence but also at least one application. Without such disclosure, a human gene sequence is not patentable. Biological material that is isolated from its natural environment or produced by means of a technical process can be the subject of an invention, even if it previously occurred in nature. All inventions must also meet the standard criteria of novelty, inventive step, and industrial

applicability.

Exclusions to Patentability for Genetic Inventions in Germany

The German Patent Act excludes the human body at the various stages of its formation and development, including germ cells, as well as the simple discovery of one of its elements, including the sequence or partial sequence of a gene, from being patentable inventions. Also excluded are processes for cloning human beings, processes for modifying the germ line genetic identity of human beings, and uses of human embryos for industrial or commercial purposes. Processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes, are not patentable. Similar to the approach in the UK, plant and animal varieties and essentially biological processes for their production are excluded, and this exclusion extends to plants and animals exclusively obtained by such processes. Discoveries *as such* are also not patentable.

Scope of Patent Protection for Genetic Inventions in Germany

Patents in Germany grant exclusive rights to make, use, offer for sale, put on the market, or import the patented product for a term of 20 years from the date of filing. For human gene sequences whose structure corresponds to that of a natural sequence or partial sequence of a human gene, the patent claim must include its use for which industrial application is disclosed. This implies a purpose-bound protection for human gene sequences. If the patent refers to a process that enables a biological material to be produced possessing specific characteristics as a result of an invention, the effects of the patent extend to the biological material directly obtained through that process and to any other biological material derived from the directly obtained material and possessing the same characteristics.

Patenting Naturally Occurring vs. Modified Genes in Germany

The simple discovery of a human gene is not patentable in Germany. However, an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element. For human gene sequences whose structure is identical to a natural sequence, the patent claim must include the disclosed industrial application. Plants or animals with properties changed by genetic engineering or other technical measures are patentable, but plant and animal varieties are not.

France

Patentability Criteria for Genetic Material in France

In France, new inventions that involve an inventive step and are capable of industrial application are patentable in all fields of technology. This includes inventions relating to a product consisting wholly or partly of biological material, or to a process for producing, treating, or using biological material, which are patentable under the same conditions. However, for a product containing or consisting of genetic information, the protection awarded by a patent covers only the specific industrial application disclosed in the patent application.

Exclusions to Patentability for Genetic Inventions in France

French patent law does not regard discoveries, as well as scientific theories and mathematical methods, as inventions. Furthermore, the human body, at the 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 constitute patentable inventions. Patenting whole or partial human gene sequences *per se* is banned in France. Other exclusions include

processes for cloning human beings, processes for modifying the germ line genetic identity of human beings, and uses of human embryos for industrial or commercial purposes. Plant varieties and animal breeds, as well as essentially biological processes for the production of plants or animals, are also not patentable. Finally, methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body are not patentable, although products for use in these methods are patentable.

Scope of Patent Protection for Genetic Inventions in France

A patent in France confers a monopoly to use or sell an invention. For a product containing or consisting of genetic information, the protection awarded by the patent covers only the specific industrial application disclosed in the patent application. This function-specific protection aims to limit overly broad claims. Rights conferred by a patent including a gene sequence may not be asserted against a later claim on the same sequence if the later claim satisfies the requirements of Article L611-18 of the French Intellectual Property Code and discloses any other particular application of this sequence.

Patenting Naturally Occurring vs. Modified Genes in France

In France, the simple discovery of a gene sequence cannot constitute a patentable invention, and the patenting of whole or partial human gene sequences *per se* is banned. However, an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention. The patent protection for a product containing or consisting of genetic information covers only the specific industrial application disclosed in the patent.

India

Patentability Criteria for Genetic Material in India

To be patentable in India, genetic material must meet the standard criteria of novelty, inventive step, and industrial applicability. For genetic material, novelty is often considered met if the sequence is purified and isolated from its natural form. Recombinant DNA and Plasmids, as well as their production procedures, are patentable if the process involves significant human intervention, although the necessity of "substantial human interaction" was removed in the 2011 Manual of Patent Practice and Procedure. The Indian Biotechnology Guidelines of 2013 state that a recombinant gene with an inventive step and industrial application is patent eligible. India also has provisions for the deposit of biological material in lieu of a detailed written description in the patent application, with a requirement to disclose the source and geographical origin of the material.

Exclusions to Patentability for Genetic Inventions in India

Section 3 of the Indian Patents Act, 1970, lays out several exclusions to patentability relevant to genetic inventions. The discovery of any living thing or non-living substance occurring in nature is not patentable. This generally prohibits the patenting of naturally occurring genetic sequences. Plants and animals in whole or any part thereof other than micro-organisms, including seeds, varieties, and species, as well as essentially biological processes for the production or propagation of plants and animals, are also excluded. However, the Indian Patent Office interprets this exclusion as not applicable at the molecular level of genes. Other exclusions include the mere discovery of a scientific principle, methods for the diagnosis or treatment of diseases, and inventions contrary to public order or morality.

Scope of Patent Protection for Genetic Inventions in India

The scope of patent protection in India is defined

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by the claims of the patent. Following a 2005 amendment to align with the TRIPS Agreement, product patents are now permissible in the biotechnology, chemical, and pharmaceutical industries. For genetically modified gene sequences or amino acid sequences that are novel, inventive, and industrially applicable, claims can cover the sequence itself, a method of expressing it, an antibody against the resulting protein, and a kit made from the antibody or sequence.

Patenting Naturally Occurring vs. Modified Genes in India

The mere discovery of naturally occurring living or non-living substances is not patentable in India, which generally excludes naturally occurring genes. However, genetically modified gene sequences are potentially patentable if they meet the criteria of novelty, inventiveness, and industrial applicability. cDNA has been granted patents in India and is considered "new and novel". There is also a possibility that isolated natural gene sequences might be patentable if they are an integral part of an artificially created microorganism.

Special Provisions and Interpretations of Indian Patent Law Concerning Genetic Inventions

The Indian Patent Office has interpreted the Section 3(j) exclusion of plants and animals and parts thereof as not applicable at the molecular level of genes. Higher utility standards may be applied to genetic inventions compared to other types of inventions. There is a specific requirement to disclose the source and geographical origin of biological material used in an invention.

Key Case Laws and Legal Precedents Shaping Genetic Invention Patents in India

The Calcutta High Court's decision in *Dimminaco A.G. v. Controller of Patents and Designs* (2002) held that a process for manufacturing a product containing living organisms is patentable. This case was a significant step in the patenting of life forms in India. In *Monsanto Technology LLC v. Nuziveedu Seeds Ltd.* (2018/2019), the Delhi High Court initially ruled that genetically modified seeds and gene sequences providing traits to plants are not patentable. However, the Supreme Court set aside this decision and remanded the case, without making conclusive remarks on the patentability of isolated DNA and cDNA, highlighting the ongoing judicial debate in this area.

Switzerland

Patentability Criteria for Genetic Material in Switzerland

In Switzerland, biotechnological inventions concerning biological material are patentable if they meet the general requirements of inventive step, novelty, and industrial applicability. "Biological material" is defined as material that contains genetic information, is reproducible, and is highly complex. Notably, a naturally occurring sequence or partial sequence of a gene is not patentable *as such*. However, sequences derived from a naturally occurring sequence or partial sequence of a gene may be patented as an invention. Furthermore, patent applicants in Switzerland must provide information on the source of a genetic resource or traditional knowledge of indigenous peoples and local communities if the invention is directly based on such resources or knowledge. Deliberate misrepresentation of the source is punishable by a fine.

Exclusions to Patentability for Genetic Inventions in Switzerland

Swiss patent law excludes inventions whose exploitation is contrary to human dignity or that disregard the integrity of living organisms, or that are otherwise contrary to public policy or morality. Specifically, processes for cloning human beings and the clones obtained thereby, processes for forming hybrid organisms using human germ cells or embryonic stem cells, processes for modifying the germ line genetic identity of human beings, unmodified human embryonic stem cells and stem cell lines, and

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the use of human embryos for non-medical purposes are not patentable. Plant varieties and animal varieties or essentially biological processes for the production of plants or animals are also excluded, although microbiological or other technical processes and the products obtained thereby, as well as inventions that concern plants or animals, are patentable.

Scope of Patent Protection for Genetic Inventions in Switzerland

A patent in Switzerland confers the right to prohibit others from commercially using the invention. If the invention concerns a manufacturing process, the protection extends to the products directly obtained, and if those products are biological material, to products obtained by propagating it with the same characteristics. If the invention concerns a product consisting of or containing genetic information, the protection extends to any material in which the product is incorporated and in which the genetic information is contained and performs its function. For a nucleotide sequence derived from a naturally occurring sequence, the protection is limited to the sequence segments that perform the function specifically described in the patent.

Patenting Naturally Occurring vs. Modified Genes in Switzerland

In Switzerland, a naturally occurring sequence or partial sequence of a gene is not patentable *as such*. However, sequences derived from a naturally occurring gene sequence may be patented as an invention. The protection for such derived nucleotide sequences is limited to the function specifically described in the patent.

Comparative Analysis

The patent laws related to genetic inventions across the eight countries exhibit both commonalities and significant differences. All jurisdictions require adherence to the fundamental patentability criteria of novelty, inventive step, and industrial application. Ethical considerations also play a role in shaping exclusions to patentability, particularly concerning human cloning, germline modification, and the use of human embryos. Plant and animal varieties, as well as essentially biological processes for their production, are generally excluded across the European countries and China, reflecting a desire to protect traditional agricultural practices.

However, the approach to naturally occurring genes varies considerably. The US, following the *Myriad* decision, does not allow patents on merely isolated naturally occurring DNA, while the UK, Germany, and France permit patenting of isolated natural substances, including gene sequences, under certain conditions, such as prior unknown existence or disclosed industrial application. Switzerland explicitly excludes naturally occurring gene sequences *as such* but allows patents on derived sequences. China takes a similar stance to the US, considering naturally occurring genes as non-patentable discoveries unless isolated and characterized for the first time with a known industrial application. Russia's stance on isolated natural genes is less clear from the provided material but appears more permissive towards patenting non- natural entities.

The patentability of cDNA, being synthetically produced, is generally accepted across most of these jurisdictions, including the US, UK, China, and Russia. GMOs are also widely patentable, particularly in the US following *Chakrabarty*. The scope of patent protection typically extends for 20 years, with some variations for specific types of inventions. Purpose-bound protection for gene sequences, where the patent claim must include the disclosed industrial application, is a feature in the UK, Germany, and France, reflecting a more cautious approach to granting broad monopolies on genetic information. Switzerland also limits the protection of derived nucleotide sequences to their specifically described function.

A notable distinction arises in the requirement for disclosing the source of genetic resources. India and Switzerland have specific provisions

mandating such disclosure in patent applications, reflecting their commitment to transparency and addressing concerns related to biopiracy

CHAPTER - 12

CONCLUSION

The conclusion regarding the intersection of patents on genetic inventions within the framework of intellectual property law highlights the complex and evolving nature of this legal domain. As advancements in biotechnology and genetic research continue to accelerate, the implications for patentability raise significant ethical, legal, and economic questions. The interplay between protecting innovative genetic discoveries and ensuring public access to essential biotechnological advancements necessitates a careful balancing act.

Furthermore, the legal landscape surrounding genetic patents is characterized by ongoing debates about the extent to which genetic material can be owned and the potential consequences for research and development. The challenges posed by the commodification of genetic resources underscore the need for a nuanced approach that considers both the rights of inventors and the broader societal implications. As courts and policymakers grapple with these issues, the outcomes will likely shape the future of innovation in the life sciences and influence the accessibility of genetic technologies.

In summary, the intersection of patents on genetic inventions and intellectual property law represents a critical area of inquiry that demands ongoing attention. The resolution of these complex issues will not only impact the legal rights of inventors but also have far-reaching effects on public health, scientific progress, and ethical standards in the field of biotechnology. As such, it is imperative for stakeholders to engage in informed discussions that consider the multifaceted implications of patenting genetic inventions.

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Abstract

The current landscape of intellectual property rights concerning patents on genetic inventions is characterized by a complex interplay of legal, ethical, and scientific considerations. As advancements in biotechnology and genomics continue to accelerate, the question of patentability has become increasingly contentious. The exploration of patents related to genetic inventions within the realm of intellectual property is a critical area of research that addresses the intersection of innovation, ethics, and legal frameworks. This investigation seeks to understand how genetic inventions, which encompass a wide range of biotechnological advancements, are protected under existing patent laws and how these protections influence both scientific progress and public access to genetic resources. By analysing the implications of patenting genetic materials and processes, researchers aim to uncover the potential benefits and drawbacks of such intellectual property rights, particularly in terms of fostering innovation while ensuring equitable access to genetic technologies. This study is based on doctrinal research methodology for data collection and interpreting legal texts, statutes, and case law. This methodology emphasizes the examination of existing legal principles and doctrines to derive insights and establish a coherent understanding of the law. Ultimately, the findings from this research could inform policymakers, legal experts, and the scientific community about the need for a balanced approach that promotes innovation while safeguarding public interests and ethical standards in the rapidly evolving field of genetics. And suggest, need for new legal awareness programmes to address the unique challenges posed by Patent on genetic inventions.

CHAPTER - 1

INTRODUCTION

The interplay between patents on genetic inventions and the broader intellectual property landscape presents a complex and evolving scenario. As advancements in biotechnology and genetic research continue to accelerate, the legal frameworks governing these innovations must adapt to address the unique challenges they pose. The intersection of genetic patents with intellectual property rights raises critical questions about ownership, ethical considerations, and the implications for innovation and public health. This dynamic environment necessitates a thorough examination of how existing intellectual property laws can accommodate the rapid pace of scientific discovery while ensuring equitable access to genetic resources.

In recent years, the debate surrounding the patentability of genetic inventions has intensified, particularly in light of landmark legal cases and shifting public perceptions. The tension between protecting the rights of inventors and fostering an open environment for research and development is at the forefront of discussions among policymakers, legal experts, and scientists. As genetic inventions often involve naturally occurring sequences and biological processes, the criteria for patent eligibility become increasingly contentious. This situation underscores the need for a nuanced understanding of intellectual property principles as they apply to the life sciences, balancing the interests of innovation with societal needs.

Furthermore, the implications of genetic patents extend beyond legal considerations, influencing ethical discussions and access to medical advancements. The commercialization of

genetic technologies can lead to disparities in healthcare access, particularly in low-income populations or developing countries. As such, the intersection of genetic invention patents and intellectual property rights not only shapes the landscape of innovation but also raises important ethical questions about the ownership of life itself. Addressing these multifaceted issues requires a collaborative approach that includes stakeholders from various sectors, ensuring that the benefits of genetic research are shared equitably while still incentivizing innovation in this critical field.

Research Questions:

1) CRISPR Cas 9 technique – Human genetic invention?

2) Patent on GMO?

3) Commercialising Biodiversity?

4) Intersection of Public Health & Patent on genetic inventions?

5) How genetic inventions, prevent us from diseases?

6) Challenges faced by inventor on inventions? Research Hypothesis:

By enforcing a strong legislation on 'Patent on Genetic Inventions' in India, it will incentivize the inventor's work and benefit for the public at large.

CHAPTER – 2

CONCEPT OF THE RESEARCH

The concept of the 'intersection of intellectual property and patent on genetic inventions' refers to the complex and evolving relationship between legal frameworks designed to protect innovative ideas (intellectual property) and their specific application to discoveries and creations in the field of genetics. Patents, a key form of intellectual property, grant inventors' exclusive rights for a limited period to prevent others from making, using, selling, or importing their inventions. When these rights are applied to genetic inventions, a unique set of scientific, ethical, and societal considerations arise.

1. Subject Matter of Genetic Inventions:

- Patents in this area can cover a wide range of biological materials and processes, including:
  - Isolated and purified gene sequences (DNA, RNA, cDNA).
  - Genetically modified organisms (GMOs) like bacteria, plants, and animals.
  - Diagnostic tests based on genetic markers.
  - Therapeutic methods involving gene therapy or gene editing.
  - Proteins and enzymes produced through genetic engineering.
  - Vectors and other tools used in genetic manipulation.

2. Patentability Criteria Applied to Genetic Inventions:

To be patentable, a genetic invention must generally meet the standard criteria of patent law:

Novelty: The invention must be new and not previously disclosed.

Non-obviousness (Inventive Step): The invention should not be obvious to someone skilled in the relevant field.

Utility (Industrial Applicability): The invention must have a specific, substantial, and credible use.

Enablement and Sufficiency of Disclosure: The patent application must describe the invention in enough detail for others to understand and reproduce it.

3. Unique Challenges and Considerations:

Product of Nature vs. Invention: A central debate revolves around whether genes as they exist in nature can be patented. Landmark legal cases (like *Association for Molecular Pathology v. Myriad Genetics*[1]) have clarified that isolated but otherwise unmodified natural gene sequences are not patentable in some

jurisdictions (e.g., the US), as they are considered products of nature. However, manipulated or synthetic DNA constructs (like cDNA) may be patentable.

Utility: Establishing a specific and substantial utility for gene sequences has been a challenge. Early patents on gene fragments with unknown functions faced scrutiny. Guidelines now often require a well-defined and credible utility.

Scope of Claims: The breadth of patent claims on genetic inventions can be controversial. Overly broad patents might hinder further research and development.

Ethical Implications: Patenting genes raises ethical concerns about the ownership of fundamental building blocks of life, access to healthcare (especially genetic testing and therapies), the potential for monopolies, and the impact on scientific research.

4. Impact on Innovation and Access:

Incentive for Innovation: Proponents of gene patents argue that they incentivize investment in research and development by providing a return on investment for costly and time-consuming genetic research.

Potential Barrier to Research and Access: Critics argue that gene patents can stifle innovation by limiting access to essential genetic information and tools needed for further research. They can also lead to higher costs for genetic testing and therapies, limiting patient access.

Balancing Competing Interests: The intersection of IP and genetic inventions requires a careful balancing act between encouraging innovation and ensuring public access to healthcare and the benefits of scientific progress.

5. International Variations:

Patent laws regarding genetic inventions vary significantly across different countries and regions, leading to complexities in global research and commercialization.

Note: The intersection of intellectual property and patent on genetic inventions is a dynamic field shaped by scientific advancements, legal interpretations, ethical debates, and societal needs. It involves determining the appropriate scope and limitations of patent rights on biological materials and processes to foster innovation while ensuring equitable access and ethical considerations are addressed.

CHAPTER – 3

Understanding Intellectual Property intersection with patent on genetic inventions

3.1 The Dawn of Genetic Inventions:

The impact of genetic inventions is not confined to a single sector; rather, it permeates diverse fields simultaneously. In medicine, they hold the key to potential cures for genetic disorders and the development of personalized therapies. In agriculture, they offer the promise of enhanced crop yields and resilience to environmental stresses. In biotechnology, they drive the creation of new biological processes and materials with industrial and environmental applications. This interdisciplinary nature underscores the broad implications of patenting these inventions, necessitating a comprehensive understanding of the various perspectives and potential consequences.

3.2 The Role of Intellectual Property:

In this era of rapid genetic innovation, intellectual property rights play a crucial role in protecting these novel creations and discoveries. Intellectual property encompasses a range of legal mechanisms designed to safeguard the creations of the mind, granting creators certain exclusive rights over their inventions, designs, or artistic works. Among these mechanisms, patents stand out as a particularly relevant tool for genetic inventions. Patents provide inventors with a government-granted right to exclude others from making, using, selling, or importing their invention for a limited period, typically 20 years. This system aims to encourage public disclosure of inventions, as the details of the invention are

made public in the patent document, thereby stimulating both follow-on research and, in some cases, public benefit. By enabling patent holders to control the commercial exploitation of their inventions, patents also offer an opportunity to recoup the often-substantial investments required for research and development, creating an incentive for licensees to invest in further development and market introduction.

However, the application of patents to genetic inventions presents a complex scenario. While patents are intended to incentivize innovation through the grant of exclusivity, they can also potentially restrict access to essential technologies and hinder further research. This creates a fundamental tension: balancing the reward for the inventor, which is crucial for driving investment and innovation, with the broader societal benefit of the invention, particularly in areas as critical as healthcare and food security. The exclusivity granted by patents can lead to the development of valuable new products and processes, but it might also impede the dissemination and application of crucial genetic knowledge if licensing terms are restrictive or costs are prohibitive. Therefore, a careful and nuanced approach is required when considering the intersection of intellectual property and patents on genetic inventions.

3.3 Defining Genetic Inventions:

Core Definitions:

A genetic invention refers to a novel and innovative creation or discovery related to genetics. It encompasses the identification, development, or manipulation of genes, DNA sequences, or genetic materials that hold the potential to significantly impact various fields, including biotechnology, medicine, and agriculture. These inventions often lead to the development of groundbreaking technologies such as new therapies, diagnostic tools, and genetically modified organisms, which can positively influence human health and the environment. Another perspective defines a genetic invention as a creation involving the manipulation or alteration of genetic material using biotechnology to produce new, useful genetic sequences, organisms, or biological processes that do not occur naturally. This type of invention is at the forefront of biomedical research and agricultural development, employing techniques like gene editing, synthetic biology, and recombinant DNA technology. Essentially, genetic inventions represent human-engineered modifications or applications of genetic material that result in something new and useful. The key element across these definitions is the notion of human intervention in altering or utilizing genetic material in a way that produces a novel outcome or application. This distinction from naturally occurring genes and genetic processes is fundamental when considering the applicability of patent law. Terms often used synonymously with genetic invention include genetic discovery, genetic breakthrough, and genetic innovation.

Key Technologies Involved:

Several key technologies underpin the creation and development of genetic inventions. **Gene editing technologies**, such as CRISPR-Cas9, are at the forefront, allowing scientists to precisely add, remove, or alter genetic material at specific locations within the genome. These modifications can lead to the creation of organisms with desirable traits or the correction of genetic defects in humans, animals, and plants. **Synthetic biology** involves designing and constructing new biological parts, devices, and systems that do not exist naturally, as well as redesigning existing biological systems for useful purposes. This can include the creation of synthetic organisms capable of producing pharmaceuticals or biofuels. **Recombinant DNA technology** is another crucial technique that combines DNA molecules from different sources into a single molecule, forming a new set of genes. This modified DNA is then transferred into an organism, giving it altered or novel genes to produce the desired traits. These technologies, along with others in the realm of genetic

engineering and biotechnology, enable the manipulation of genetic material to achieve specific goals, driving the creation of a wide array of genetic inventions. Understanding these underlying technologies is essential for appreciating the scope and potential of genetic inventions and for navigating the complexities of their patenting. Each technology presents unique considerations regarding the inventive step involved and the potential industrial applications.

Examples of Genetic Inventions:

The field of genetic inventions has yielded numerous examples with significant impact across various sectors:

Medicine: Gene therapies designed to target and correct the underlying genetic causes of diseases like sickle cell anaemia or cystic fibrosis are prime examples. Diagnostic tools that can detect genetic predispositions to diseases such as certain types of cancer, allowing for early intervention and personalized treatment strategies, also fall under this category. The production of synthetic insulin using genetically modified bacteria to treat diabetes was a landmark achievement. Similarly, recombinant vaccines, such as the hepatitis B vaccine produced by genetically modified baker's yeast, represent crucial medical advancements. The development of genetically modified animal models of human genetic diseases has enabled researchers to test novel therapies and explore disease mechanisms. Furthermore, genome editing techniques are being explored for treating various diseases, including cancer, HIV, and muscular dystrophy.

Agriculture: Genetically modified crops engineered for pest resistance, such as Bt corn which contains a gene from *Bacillus thuringiensis* that produces a natural insecticide, have significantly reduced the need for chemical pesticides. Herbicide-tolerant crops allow farmers to use specific herbicides for weed control without harming the crops themselves. Genetic engineering has also led to the development of crops with enhanced nutritional value, such as Vitamin D tomatoes and bio-fortified rice with increased levels of vitamin A or iron. Efforts are also underway to create livestock with improved disease resistance through genetic modification.

Biotechnology: Genetically modified microorganisms are being utilized for the production of biofuels, offering a sustainable alternative to fossil fuels. Bioremediation, the process of using genetically engineered organisms to clean up pollutants from the environment, is another significant application. The development of new enzymes with enhanced properties for industrial processes, such as in the production of detergents or pharmaceuticals, is also a result of genetic invention. Synthetic biology is enabling the creation of entirely new biological systems for various applications, ranging from producing novel biomaterials to developing new diagnostic tools.

These examples illustrate the broad spectrum of genetic inventions and their potential to address critical challenges in human health, food security, and environmental sustainability. The diverse applications across these sectors underscore the significant economic and social value associated with these inventions, making the debate surrounding their patenting all the more pertinent.

3.4 The Importance and Applications of Genetic Inventions: Advancements in Medicine and Healthcare:

Genetic inventions hold immense importance in the realm of medicine and healthcare, offering a multitude of applications and potential benefits. One of the most promising applications lies in the **development of gene therapies**, which aim to potentially cure genetic disorders by addressing the root cause – the defective genes responsible for the disease. Technologies like CRISPR-Cas9 have significantly advanced the field of **gene editing**, enabling scientists to precisely modify genetic material at specific locations in the genome, offering the possibility

of correcting genetic defects in humans. Furthermore, genetic inventions have revolutionized the **production of life-saving pharmaceuticals**. For instance, synthetic insulin, crucial for managing diabetes, is now produced using genetically modified organisms. Similarly, recombinant versions of growth hormone, clotting factors for haemophiliacs, and vaccines like the hepatitis B vaccine are manufactured through genetic engineering.

Genetic inventions are also pivotal in the development of **new diagnostic tools** for the early detection and personalized treatment of diseases. Genetic testing can identify inherited gene variants, aiding in the diagnosis of rare diseases and providing individuals with valuable medical information and family history insights. The ability to analyse large-scale DNA data helps researchers understand the impact of genes on health, potentially leading to treatments tailored to an individual's specific genetic makeup – the cornerstone of personalized medicine. Novel approaches like **edible vaccines**, where antigenic proteins are produced in the consumable parts of plants, and **DNA vaccines** may offer safer, cheaper, and more accessible ways to prevent diseases like HIV/AIDS, tuberculosis, and cancer. Moreover, genetically modified animal models of human genetic diseases are invaluable tools for researchers to test novel therapies and explore the roles of candidate risk factors. The rapid advancements in genetic technologies, moving from theoretical concepts to practical applications, offer a beacon of hope for preventing and curing diseases, managing chronic conditions, and ultimately improving human health.

3.5 Improvements in Agriculture and Food Security:

Genetic inventions have brought about significant improvements in agriculture, playing a vital role in enhancing food security and promoting sustainable practices. One of the most impactful applications is the development of **crop varieties with enhanced traits**. These include increased yield, making more food available from the same land; improved tolerance to environmental stresses like drought, heat, and salinity, allowing for cultivation in challenging conditions; and enhanced resistance to pests and diseases, reducing the need for harmful chemical pesticides. A notable example is **insect-resistant crops** like Bt corn, which contains a gene from the soil bacterium *Bacillus thuringiensis* that produces a natural insecticide, effectively protecting the crop from specific pests and reducing the reliance on synthetic pesticides. Similarly, **herbicide-tolerant crops** have been engineered to withstand the application of specific herbicides, facilitating weed management and promoting conservation tillage practices.

Genetic modification has also been employed to **enhance the nutritional content of crops**, a strategy known as bio-fortification. Examples include the development of rice, maize, and wheat varieties with increased levels of essential vitamins, minerals, and micronutrients like vitamin A, iron, and zinc, offering potential health benefits for millions facing malnutrition. Furthermore, genetic inventions are contributing to the development of **climate-resilient crop varieties** that can better withstand changing environmental conditions such as prolonged droughts and extreme temperatures. Techniques like CRISPR are being used to optimize crop architecture for more efficient harvesting and to extend the shelf life of produce, reducing food waste. In livestock agriculture, gene discovery has led to advancements in breeding for desirable traits such as disease resistance and improved production efficiency. Overall, genetic inventions are crucial for ensuring a sustainable and secure food supply for a growing global population while minimizing environmental impact.

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3.6 Advances in Biotechnology and Industrial Applications:

Beyond medicine and agriculture, genetic inventions are driving significant advances in biotechnology and various industrial applications. One important application is **bioremediation**, where genetically modified microorganisms are used to break down and clean up pollutants from the environment, offering a more efficient and sustainable approach to environmental cleanup compared to traditional methods. In **industrial biotechnology**, genetic engineering is employed to develop more efficient and sustainable processes for producing a wide range of chemicals, enzymes, and other materials. For example, genetically modified microorganisms can be used in fermentation processes to produce chemicals that were previously derived from petroleum, offering a more environmentally friendly alternative.

Genetic inventions are also playing a key role in the development of **biofuels and other renewable energy sources**. Scientists have created several liquid biofuels, such as ethanol and biodiesel, from plant material and other natural substances using genetically engineered organisms or enzymes. Furthermore, the power of bacterial anaerobic decomposition, a process that can be enhanced through genetic modification, is being leveraged to create and capture methane gas from waste materials. This not only provides a renewable energy source but also helps mitigate greenhouse gas emissions. The field of synthetic biology is further expanding the possibilities by enabling the design and construction of new biological parts, devices, and systems with novel functionalities for industrial and environmental applications. For instance, researchers are exploring the use of synthetic organisms to produce biodegradable plastics and other sustainable materials. Overall, genetic inventions are proving to be powerful tools for refining industrial processes, addressing environmental challenges, and fostering a more sustainable future.

3.7 Arguments in Favor of Patenting Genetic Inventions:

Incentivizing Innovation and Research:

A primary argument in favour of patenting genetic inventions centres on the premise that patents serve as a crucial incentive for innovation and research. The process of discovering and developing genetic inventions often requires substantial financial investment, time, and resources. Patents, by granting exclusive rights to the inventors for a limited period, provide a mechanism for them and their affiliated companies to potentially recoup these investments. This prospect of financial return acts as a powerful motivator, encouraging researchers and companies to undertake the often risky and expensive endeavours associated with genetic research and development. Without the assurance of patent protection, there is a concern that companies might be less inclined to invest in such long-term and high-risk projects, potentially slowing down the overall pace of discovery and the development of new genetic technologies.

Furthermore, the patent system encourages researchers to think more creatively and work diligently to achieve breakthroughs that can be protected by patents. The lure of obtaining a patent for a novel gene sequence, a new gene editing technique, or a genetically modified organism can drive researchers to push the boundaries of scientific knowledge and explore innovative approaches. In addition to incentivizing the initial invention, patents also play a role in promoting the public disclosure of these advancements. In exchange for the exclusive rights, inventors are required to disclose the details of their invention in the patent application. This disclosure serves a vital function by adding to the body of scientific knowledge, inspiring follow-on research by other scientists, and potentially leading to further innovations and improvements in the field. The information contained within patents can provide a foundation upon which future research can build, fostering a cycle of

continuous innovation.

3.8 Attracting Investment and Facilitating Commercialization:

Patents on genetic inventions are also instrumental in attracting the necessary investment for their further development and eventual commercialization. The development of a genetic invention from a laboratory discovery to a marketable product, such as a new gene therapy or a genetically modified crop, often requires significant capital investment. This includes funding for clinical trials, regulatory approvals, scaling up production, and marketing efforts. Patents provide a degree of exclusivity that makes these inventions more attractive to investors, who are more likely to provide financial support when there is a potential for a protected market and a return on their investment. The exclusive rights granted by a patent reduce the risk of immediate imitation by competitors, offering a window of opportunity for the patent holder to establish a market presence and generate revenue.

Moreover, patents facilitate the transfer of technology from research institutions to companies that have the resources and expertise to bring these inventions to the market. Through licensing agreements, patent holders can grant others the right to use, manufacture, or sell their patented invention in exchange for royalties or other forms of compensation. This process allows for the broader application of genetic inventions, ensuring that they reach the individuals and industries that can benefit from them. Patents also play a crucial role in helping companies establish markets for new discoveries. For example, companies like Myriad Genetics invested in educating patients and doctors about their BRCA gene tests and worked to facilitate insurance reimbursement for the cost of testing, actions that were incentivized by their patent protection. In essence, patents serve as a bridge between the initial discovery of a genetic invention and its widespread availability and utilization, fostering the translation of scientific breakthroughs into tangible benefits for society.

3.9 Promoting Economic Growth and Market Competition:

The patenting of genetic material has also been credited with fostering economic growth and promoting a dynamic innovation ecosystem within the biotechnology sector. The ability to secure patent protection has created a substantial market for private investment capital in biotechnology, supporting the growth of numerous companies and contributing to job creation. The biotechnology industry, fuelled in part by the patent system, has witnessed tremendous advancements and product development, boosting economies worldwide. While patents grant temporary exclusive rights, the information disclosed within patent documents can also inspire other companies and researchers to develop their own unique innovations, potentially leading to alternative or improved technologies. This process fosters a healthy market competition, as companies strive to create novel solutions that can also be protected by intellectual property rights.

Furthermore, the economic benefits of patenting extend across various sectors impacted by genetic inventions, including medicine, agriculture, and industrial biotechnology. The development of new pharmaceuticals, diagnostic tools, and gene therapies can lead to significant economic opportunities in the healthcare industry. In agriculture, the creation of improved crop varieties and more efficient farming practices can enhance productivity and profitability. Similarly, advancements in industrial biotechnology can drive the development of new materials, processes, and energy sources, contributing to economic growth and sustainability. While concerns exist about the potential for patents to create monopolies and restrict competition in certain instances, the overall effect of the patent system in the context of genetic inventions is often viewed as a positive driver of economic development and

technological advancement.

3.10 Intellectual Property Law and the Patenting of Genetic Inventions: Defining "Invention" and "Patentable Subject Matter" in the US:

In the United States, the foundation of patent law lies in 35 U.S.C. § 101, which defines

patentable subject matter as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof". This broad definition has been the subject of interpretation by the courts over time, particularly in the context of living organisms and biological materials. Historically, the United States Patent and Trademark Office (USPTO) had granted patents on natural biological substances, including isolated gene sequences, if they were considered sufficiently "isolated" from their naturally occurring state. This practice was based on the argument that the act of isolation and purification transformed the substance into a patentable "composition of matter."

A significant turning point in the patenting of living organisms came with the landmark Supreme Court case of **Diamond v. Chakrabarty** in 1980. The Court ruled that a genetically engineered bacterium capable of breaking down crude oil was indeed patentable subject matter, affirming that the question of whether an invention embraces living matter is irrelevant to patent eligibility. The Court famously stated that patentable subject matter includes "anything under the sun that is made by man". This decision paved the way for the patenting of various genetically modified organisms, including bacteria, viruses, seeds, plants, cells, and even non- human animals.

However, the landscape of gene patenting in the US underwent a major shift with the Supreme Court's 2013 decision in **Association for Molecular Pathology v. Myriad Genetics**. The case challenged the patentability of isolated DNA sequences for the BRCA1 and BRCA2 genes, mutations of which are linked to an increased risk of breast and ovarian cancer. The Supreme Court unanimously ruled that naturally occurring DNA segments are products of nature and are not patent eligible merely because they have been isolated from the human body. The Court reasoned that the process of isolating a gene does not alter its fundamental characteristics as they exist in nature and therefore does not constitute an invention. This decision invalidated Myriad's patents on the isolated BRCA1 and BRCA2 genes and effectively overturned the long-standing policy of the USPTO that allowed for the patenting of thousands of human genes based solely on their isolation. Importantly, the Court clarified that synthetically created complementary DNA (cDNA), which is produced by reverse transcribing messenger RNA and does not contain non-coding regions (introns), remains patent eligible because it is not a naturally occurring product. The *Myriad* decision marked a significant re-evaluation of the boundary between patentable human-made inventions and unpatentable products of nature in the realm of genetics.

Defining "Invention" and "Patentable Subject Matter" in Europe:

In Europe, the patenting of genetic inventions is primarily governed by the European Patent Convention (EPC) and the EU Biotechnology Directive (Directive 98/44/EC), which has been incorporated into the Implementing Regulations of the EPC. Article 52(1) of the EPC states that European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step, and are susceptible of industrial application.

While the simple discovery of an element of the human body, including the sequence or partial sequence of a gene, is not considered a patentable invention under Rule 29(1) of the EPC, Rule 29(2) provides an important exception. It states that an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a

patentable invention, even if the structure of that element is identical to that of a natural element. This provision reflects a broader view on the patentability of isolated gene sequences compared to the post-*Myriad* stance in the US. However, Rule 29(3) of the EPC emphasizes that the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application. This requirement ensures that a mere discovery of a gene sequence without any indication of its function or potential use is not patentable.

European patent law also takes ethical considerations into account. Article 53(a) of the EPC excludes inventions whose commercial exploitation would be contrary to "ordre public" or morality. This provision was central to the **Brustle v. Greenpeace** case, which involved a patent on neural progenitor cells derived from human embryonic stem cells. The Court of Justice of the European Union (CJEU) interpreted the concept of "human embryo" broadly and ruled that an invention requiring the destruction of a human embryo is unpatentable. This case highlights the significant role of ethical considerations in shaping the patentability of certain genetic inventions in Europe, particularly those involving human biological material.

3.11 Comparison of US and European Approaches:

The approaches to patenting genetic inventions in the US and Europe exhibit both similarities and key differences. While both jurisdictions adhere to the fundamental criteria of novelty, inventive step (non-obviousness), and industrial applicability (utility), their stances on the patentability of naturally occurring gene sequences have diverged, particularly after the *Myriad* decision in the US. In the US, the Supreme Court explicitly ruled that isolated naturally occurring DNA is not patentable as it is considered a product of nature. In contrast, European patent law, under the EPC and the Biotechnology Directive, continues to allow the patenting of isolated gene sequences derived from the human body or produced through a technical process, provided that their industrial application is disclosed. This reflects a more permissive stance on the patentability of isolated genetic material in Europe.

However, it is important to note that both the US and Europe generally permit the patenting of artificial DNA constructs, such as cDNA, and methods of manipulating genes, as these are considered to be human-made inventions. Additionally, both legal frameworks emphasize the need for a disclosed utility or industrial application for a genetic sequence to be patentable. The *Brustle v. Greenpeace* case underscores the greater emphasis on ethical considerations in European patent law, particularly concerning inventions involving human embryonic material, a factor that plays a less direct role in the US patentability criteria, although ethical arguments were raised in the *Myriad* case. These differing legal landscapes necessitate careful consideration for companies and researchers seeking global patent protection for their genetic inventions, as patenting strategies may need to be tailored to the specific requirements and interpretations in each jurisdiction.

3.12 Criteria for Patentability of Genetic Inventions:

Novelty:

In the United States, **novelty** is a fundamental requirement for patentability, codified in 35

U.S.C. § 102. An invention is considered novel if it has not been previously known, used, patented, or described in a printed publication anywhere in the world before the effective filing date of the patent application. This means the claimed invention must be new in relation to the "prior art," which encompasses all existing knowledge in the relevant field. The concept of **anticipation** dictates that a claimed invention is not novel if a single prior art reference discloses every element of the invention, either explicitly or inherently. Importantly, the discovery of a new property or use for a known substance or composition does not automatically render it

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novel for patent purposes. For genetic inventions, this means that simply identifying a previously unrecognized DNA sequence that was inherently present in prior art would not meet the novelty requirement.

Similarly, in Europe, **novelty** is a prerequisite for obtaining a patent, as outlined in Article 54 of the European Patent Convention (EPC). An invention is considered novel if it does not form part of the state of the art, which comprises everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application. Interestingly, in the context of genetic inventions, European patent law considers that biological material isolated from its natural environment or produced by means of a technical process can be patentable, even if it previously occurred in nature. This implies that the act of isolating a gene sequence from its natural environment can confer novelty, even if the sequence itself is identical to the naturally occurring one. This contrasts with the US position post-*Myriad*, where mere isolation of a naturally occurring gene is not sufficient for patentability.

Non-obviousness (Inventive Step):

In the United States, an invention must also be **non-obvious** to be patentable, as stipulated in 35 U.S.C. § 103. This means that the invention, considering the prior art, would not have been obvious to a person having ordinary skill in the art (PHOSITA) at the time the invention was made. Determining non-obviousness involves a factual analysis, often guided by the factors outlined in the Supreme Court case *Graham v. John Deere Co.*, which include assessing the scope and content of the prior art, the differences between the claimed invention and the prior art, and the level of ordinary skill in the pertinent art. Secondary considerations, such as commercial success, long-felt but unresolved needs, and unexpected results, can also be relevant in determining non-obviousness[2]. Applying the non-obviousness standard to genetic inventions can be challenging due to the vast amount of genetic information and the rapid advancements in the field. For example, the mere identification of a gene or protein sequence might be considered obvious if the prior art suggested its existence or function.

In Europe, the requirement analogous to non-obviousness is the **inventive step**, as defined in Article 56 of the EPC. An invention is considered to involve an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art. The European Patent Office (EPO) employs a "problem-solution approach" to assess inventive step. This involves identifying the closest prior art, determining the objective technical problem solved by the invention, and then assessing whether the claimed solution would have been obvious to a skilled person. Generally, the standards for inventive step are considered to be higher in Europe compared to the non-obviousness standard in the US, making it comparatively more difficult to satisfy this requirement. In the context of genetic inventions, the inventive step might lie in identifying a gene with a previously unknown function or in developing a novel method for manipulating genetic material that yields unexpected results.

Industrial Applicability (Utility):

In the United States, an invention must have a **specific, substantial, and credible utility** to be patentable under 35 U.S.C. § 101. This **utility** requirement mandates that the invention must have a practical application and provide a tangible benefit. The USPTO guidelines specify that for genetic inventions, the patent application must disclose a "specific, substantial, and credible utility for the claimed isolated and purified gene". This means that a mere discovery of a gene sequence without a known function or a speculative utility is unlikely to be considered patentable. The claimed utility must be more than just an object of further research; it should offer a concrete benefit to the public.

Similarly, in Europe, an invention must be

susceptible of industrial application, as stated in Article 57 of the EPC. An invention is considered industrially applicable if it can be made or used in any kind of industry, including agriculture. For genetic inventions, Rule 29(3) of the EPC explicitly requires that the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application. This means that the patent application must indicate how the genetic sequence can be used in a practical or commercial sense. For instance, disclosing the function of a gene and its use in producing a specific protein or in gene therapy would typically satisfy the industrial applicability requirement.

3.13 Impact of Patenting Genetic Inventions:

On Scientific Progress:

The impact of patenting genetic inventions on scientific progress is a subject of ongoing debate, with compelling arguments on both sides. Proponents argue that patents incentivize research by offering a period of exclusivity that allows inventors to recoup their investments and potentially fund further research. The prospect of patent protection can drive researchers to pursue novel and innovative approaches, ultimately leading to scientific breakthroughs that might not otherwise occur. Additionally, the patent system encourages the public disclosure of inventions, which can stimulate follow-on research and the development of new technologies.

Conversely, critics contend that gene patents can impede scientific progress by limiting access to essential genetic information and creating a complex "patent thicket". The exclusive rights granted by patents may restrict other researchers from working with patented genes, potentially hindering the discovery of new diagnostic methods or therapeutic applications. The need to navigate licensing agreements and pay royalties can also add significant costs and administrative burdens to research, potentially diverting resources from actual scientific investigation. The impact of the *Myriad* case, which restricted the patentability of isolated human genes in the US, has been analysed for its effect on research, with some studies suggesting that it had a limited negative impact and may have even fostered innovation by opening up the field to more researchers. The overall effect of gene patenting on scientific progress appears to be nuanced and may vary depending on the specific context, the breadth of the patents granted, and the licensing practices of patent holders.

On Economic Development:

Patenting has played a significant role in the economic development of the biotechnology industry, which is heavily reliant on genetic inventions. The ability to obtain patent protection for genetic discoveries and inventions has attracted substantial private investment, leading to the growth of numerous biotechnology companies and the creation of a significant number of jobs. Patents facilitate the commercialization of genetic inventions by providing a period of market exclusivity, allowing companies to develop and market new products and services, such as pharmaceuticals, diagnostic tests, and genetically modified crops. This commercialization can lead to significant economic benefits across various sectors, including healthcare, agriculture, and industrial biotechnology.

The patent system also encourages technology transfer and the development of specialized expertise within the biotechnology sector. Companies often build their business models around patented technologies, leading to further investment in research and development to improve existing products or create new ones. While concerns exist about the potential for overly broad patents to stifle competition and create monopolies, the overall impact of patenting on economic development in the field of genetic inventions has generally been viewed as positive, driving innovation and fostering the growth of a vital industry.

On Public Health:

The patenting of genetic inventions has the potential to significantly impact public health, both positively and negatively. On the positive side, patents can incentivize the development of new diagnostics and therapeutics for a wide range of diseases, including genetic disorders, cancer, and infectious diseases. The exclusivity provided by patents can encourage companies to invest in the often lengthy and expensive process of bringing new medical treatments to market, ultimately benefiting public health by offering solutions for previously untreatable conditions.

However, concerns have been raised about how gene patents might limit access to essential genetic tests and treatments, potentially exacerbating health disparities. The monopolization of genetic testing due to patent protection can lead to higher costs, making these tests unaffordable for some individuals. The *Myriad* case highlighted these concerns, as the company's exclusive rights over BRCA1 and BRCA2 testing limited the availability of second opinions and potentially hindered the development of more comprehensive or affordable testing options. Ensuring equitable access to the benefits of genetic research, particularly in healthcare, remains a critical challenge in the context of patenting genetic inventions. Striking a balance between incentivizing innovation and ensuring that essential medical advancements are accessible to all segments of the population is crucial for maximizing the positive impact of genetic inventions on public health.

CHAPTER – 4

The Legal Framework for Patenting Genetic Inventions in India

4.1 The Indian Patents Act, 1970: The Cornerstone of Patent Law

The foundation of patent law in India is the Patents Act, 1970. This legislation, enacted to protect innovation, has undergone several amendments over the years, notably in 2002 and 2005, to align with international standards, particularly the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). These amendments reflect a gradual evolution in India's stance towards patenting biotechnological inventions. Initially, India held a strong reservation against patenting life forms. However, to meet its international obligations, the Act was modified to accommodate certain categories of biological inventions, such as microorganisms and genetically modified entities. This evolution indicates a reactive adaptation to global intellectual property norms, rather than a purely independent development of the legal framework.

A. Section 3: Defining What is Not Patentable

Section 3 of the Indian Patents Act, 1970, is crucial in delineating the subject matter that is not considered an invention and therefore not patentable. Several clauses within this section have significant implications for the patentability of genetic inventions.

B. Section 3(c): Discovery vs. Invention

Clause (c) of Section 3 explicitly prohibits the patenting of "the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature". This provision lies at the heart of the debate surrounding gene patenting in India. While naturally occurring genes are excluded from patentability under this clause, the Act does not explicitly define the boundary between a "discovery" and an "invention" when it comes to genes that have been isolated or modified through human intervention. The core challenge in this context is the interpretation of "discovery." Arguments exist that isolating a gene from its natural environment or manipulating its sequence requires significant human effort and ingenuity, thereby transforming it from a mere discovery into a patentable invention. This ambiguity presents a considerable hurdle for inventors seeking patent protection for genetic material.

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2. Section 3(j): Plants, Animals, and Biological Processes

Section 3(j) objects to the patentability of "plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals". This clause establishes a clear distinction regarding the patentability of different life forms. Microorganisms are explicitly excluded from this prohibition, making them potentially patentable subject matter. Furthermore, processes involving microorganisms are also generally considered patentable. However, the patentability of genetically modified organisms (GMOs) falling outside the definition of microorganisms is more nuanced. The prevailing understanding is that GMOs may be patentable if their development involves significant human intervention, distinguishing them from essentially biological processes. This creates a grey area where the degree of human intervention becomes a critical factor in determining patent eligibility.

3. Other Relevant Subsections of Section 3

Beyond the direct exclusions related to natural substances and life forms, other subsections of Section 3 indirectly influence the patenting of genetic inventions. Section 3(b) excludes inventions who's primary or intended use could be contrary to public order or morality. This can be relevant to certain genetic modifications that raise ethical concerns. Section 3(h) prohibits the patenting of "a method of agriculture or horticulture", which may impact the patentability of certain genetically modified crops or methods of plant breeding. Additionally, Section 3(i) excludes "any process for the medicinal, surgical, curative, prophylactic diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals". This clause can affect the patentability of certain gene-based diagnostic or therapeutic methods. These additional exclusions underscore the broader societal values and public interest considerations embedded within Indian patent law, which extend beyond the specific realm of genetic inventions.

C. Section 10: Disclosure Requirements for Biological Material

Section 10 of the Indian Patents Act, 1970, lays down the requirements for the specification of a patent application. It mandates that every complete specification must fully and particularly describe the invention. Recognizing the challenges in providing a detailed written description for biological materials, the Act allows for the deposit of such materials in a recognized depository institution as an alternative. Furthermore, Section 10 makes it obligatory to disclose the source and geographical origin of any biological material used in the invention, particularly if the material originates from India. In cases where the biological material is sourced from India, obtaining necessary permission from the competent authority is also a prerequisite before the grant of a patent. These disclosure requirements emphasize transparency and accountability in the patenting of genetic inventions, reflecting India's commitment to preventing the unauthorized exploitation of its biological resources and ensuring fair benefit sharing.

D. Patent Rules, 2003

The Patent Rules, 2003, provide the procedural framework for the implementation of the Patents Act, 1970. These rules offer detailed guidelines on various aspects of patent applications, including the examination process for biotechnological inventions. The rules also provide a definition for "biological material," encompassing any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.

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4.2 Scope of Patentable Genetic Inventions in India

A. Categories of Patentable Genetic Inventions

Despite the restrictions outlined in Section 3, several categories of genetic inventions are considered patentable in India. Recombinant DNA and plasmids can be patented, provided their creation involves significant human intervention, demonstrating a departure from naturally occurring forms. Complementary DNA (cDNA), a synthetic form of DNA, is also generally patentable, particularly if it exhibits novelty and non-obviousness. Genetically modified microorganisms are explicitly patentable under the Act. Furthermore, processes for producing genetically modified organisms that involve substantial human intervention are also eligible for patent protection. While diagnostic methods are generally excluded under Section 3(i), diagnostic products such as kits and devices that utilize genetic principles can be patented.

The underlying principle is that inventions demonstrating a significant degree of human manipulation and exhibiting novelty are more likely to be considered patentable in the realm of genetics.

B. Criteria for Patentability Applied to Genetic Inventions

Genetic inventions, like all other inventions, must meet the standard patentability criteria of novelty, inventive step, and industrial applicability to be granted a patent in India.

1. Novelty

To be patentable, a genetic invention must be genuinely new and not have been disclosed to the public in any form before the date of filing the patent application. Establishing novelty for biological materials can be particularly challenging due to the inherent complexity and variability of biological systems. Subtle variations in gene sequences or the existence of similar biological entities in nature can complicate the assessment of whether an invention is truly new. Inventors must provide robust scientific evidence to demonstrate that their genetic invention is distinct from existing knowledge and prior art.

2. Inventive Step (Non-Obviousness)

A genetic invention must also involve a technical advance that would not be obvious to a person skilled in the relevant field. Determining what constitutes an inventive step in biotechnology can be problematic. The assessment often involves considering whether the invention offers unexpected properties or advantages compared to existing technologies. For instance, a minor modification to a known gene sequence might not be considered inventive unless it results in a significant and unpredictable improvement in function or efficacy.

3. Industrial Applicability (Utility)

The genetic invention must be capable of being made or used in an industry. The utility standards for genetic inventions can sometimes be higher than for other types of inventions. This means that the patent application must clearly disclose a specific, substantial, and credible utility for the claimed genetic invention. A mere theoretical application or a function that is not well-defined may not suffice to meet this criterion.

4.3 Rights Conferred by Patents on Genetic Inventions in India

A. Exclusive Rights of the Patent Holder

A patent granted for a genetic invention in India confers upon the patent holder certain exclusive rights for a period of 20 years from the date of filing the patent application. These rights include the authority to prevent others from making, using, selling, or importing the patented invention without the patent holder's permission. This exclusivity provides the patent holder with significant market power to commercially exploit their innovation and recoup their investment in research and development.

B. Licensing and Assignment

The patent holder also has the prerogative to license or assign their patent rights to other entities for commercial benefits. Licensing allows the patent holder to grant permission to others to use their invention under specific terms and conditions, often in exchange for royalties. Assignment involves the complete transfer of ownership of the patent rights to another party. These mechanisms enable broader utilization of the patented genetic invention and can generate revenue streams for the inventor.

C. Legal Recourse Against Infringement

In the event that others infringe upon their patent rights by making, using, selling, or importing the patented genetic invention without authorization, the patent holder has the right to initiate legal proceedings in court to seek remedies or damages. To effectively protect their rights, patent holders need to actively monitor the market for potential infringements. The legal framework provides avenues for seeking interim injunctions to prevent further infringement during the course of litigation.

4.4 Challenges Faced by Inventors in the Realm of Genetic Patenting in India

A. Demonstrating Novelty and Inventive Step

The inherent complexity and variability of biological systems present a significant challenge for inventors in demonstrating novelty and inventive step for their genetic inventions. The distinction between what exists naturally and what constitutes a novel human invention can be subtle and difficult to establish. Patent examiners often scrutinize claims related to genetic material to ensure they are not merely discoveries of naturally occurring substances or obvious modifications of existing knowledge.

B. Ethical and Moral Considerations

The patenting of life forms, including genetic material, raises profound ethical concerns regarding the ownership and control of fundamental biological resources. Critics argue that granting patents on genes can lead to the commodification of life and may have detrimental impacts on healthcare access and affordability. Balancing the incentives for innovation with broader societal values and preventing the patenting of inventions that could be harmful or contrary to public morality remains a significant challenge.

C. Biopiracy and Traditional Knowledge

India, being a biodiversity-rich country, places significant emphasis on safeguarding its biological resources and traditional knowledge from misappropriation. Inventors seeking patents on genetic inventions that utilize biological resources originating from India face the additional challenge of complying with the Biological Diversity Act, 2002, which mandates the disclosure of the source and origin of the biological material and requires obtaining prior approval from the National Biodiversity Authority (NBA). Navigating this regulatory landscape is crucial to avoid potential legal challenges and ensure ethical sourcing of biological materials.

D. Navigating the Regulatory Landscape

The Indian Patents Act and its associated rules constitute a complex regulatory framework that can be challenging for inventors, particularly those new to the field of patent law. The interpretation of specific provisions, especially those related to biotechnology, can evolve over time through judicial pronouncements and amendments. Inventors need to stay informed about these developments and ensure their patent applications align with the current legal understanding. The need for clear and consistent patent laws in the face of rapid advancements in biotechnology further underscores the ongoing challenges in this domain.

E. Challenges Specific to Gene Editing Technologies (e.g., CRISPR)

The emergence of gene editing technologies like CRISPR has introduced new and complex

challenges to the existing patent framework. Determining the original inventor of GMOs developed using these technologies can be difficult, especially given the collaborative nature of scientific research. Assessing the industrial applicability of gene-edited organisms and addressing the ethical dilemmas related to their commercial exploitation, particularly in the context of human rights, are also significant hurdles. Furthermore, the ongoing patent disputes over CRISPR technology in other parts of the world have implications for the Indian patenting system, creating uncertainty and potentially slowing down the development and commercialization of CRISPR-based products in India.

4.5 Ethical and Societal Implications of Gene Patenting in India

A. Commodification of Genetic Material

A central ethical debate surrounding gene patenting revolves around the question of whether genes and other fundamental components of life should be treated as private property. Opponents argue that patenting life forms amounts to a violation of their inherent dignity and could have far-reaching moral and philosophical consequences. Conversely, proponents contend that the process of isolating, characterizing, and modifying genes involves significant human innovation deserving of patent protection to incentivize further research and development.

B. Impact on Healthcare Access and Affordability

A significant societal concern associated with gene patenting is its potential impact on healthcare access and affordability. Granting exclusive rights over genes involved in genetic testing or therapeutic development can lead to monopolies, potentially increasing the costs of these essential services and limiting access for patients who need them most. Striking a balance between incentivizing innovation in the healthcare sector and ensuring affordable access to medical technologies is a critical ethical and societal imperative.

C. Environmental Concerns

The patenting of genetically modified organisms, particularly in the agricultural sector, raises environmental concerns. Potential hazards to the environment due to the release of GMOs, their impact on ecological balance, and the potential for unintended consequences on biodiversity are important ethical considerations that need to be carefully evaluated. Regulatory frameworks and rigorous risk assessments are crucial to mitigate these potential environmental impacts.

D. Intersection with Traditional Knowledge and Biodiversity Rights

India's rich biodiversity and the traditional knowledge associated with it necessitate careful consideration in the context of genetic patenting. Ensuring fair and equitable sharing of benefits arising from the use of genetic resources and protecting the rights of indigenous communities who have traditionally conserved and utilized these resources are paramount ethical considerations. The role of the National Biodiversity Authority in regulating access to biological resources and ensuring benefit sharing is crucial in this regard.

4.6 Illustrative Case Studies

A. *Dimminaco A.G. v. Controller of Patents & Designs* (2002)

This landmark case in the Calcutta High Court played a pivotal role in shaping the understanding of patentability for inventions involving living organisms in India. The court ruled that a process for preparing a live vaccine against bursitis was patentable, establishing that the presence of a living organism in the final product does not automatically disqualify the process from being considered an invention under the Indian Patents Act, 1970. This decision was significant in clarifying that methods involving microbiological processes could be patentable, even if the resulting product contained a living entity.

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B. *Monsanto Technology LLC v. Nuziveedu Seeds Ltd* (2019)

The legal battle between Monsanto and Nuziveedu Seeds over patent rights related to genetically modified cotton seeds is a significant case illustrating the complexities of genetic patenting in India. The Division Bench of the Delhi High Court initially held that genetically modified plants, seeds, and gene sequences providing traits to plants were not patentable subject matter in India. However, the Supreme Court later set aside this decision and re- examined the case. While the Supreme Court has not yet given a final ruling on the patentability of isolated DNA and cDNA in plants, the case highlights the ongoing legal uncertainty and debate surrounding the patentability of genetically modified crops and related genetic material in India.

C. *Novartis Ag v. Union of India* (2013)

Although primarily focused on pharmaceutical patents, the Supreme Court's decision in the *Novartis* case has broader implications for the patentability of biotechnological inventions, including those related to genetics. The court emphasized the stringent criteria for novelty and inventive step required under the Indian Patents Act, particularly concerning the patenting of modified forms of known substances. This ruling underscore the principle that minor modifications to existing biological entities or sequences, without a significant enhancement in efficacy or a demonstrable inventive step, are unlikely to be granted patent protection in India.

D. *Association for Molecular Pathology v. Myriad Genetics, Inc.* (US Supreme Court, 2013)

This landmark case in the United States Supreme Court addressed the patentability of human genes. The court ruled that naturally occurring human genes are products of nature and therefore not patentable. However, it also held that complementary DNA (cDNA), a synthetic form of DNA, is eligible for patenting because it is not naturally occurring. While this decision is not binding in India, it has significantly influenced the international debate on gene patenting and provides a comparative perspective on how other jurisdictions grapple with similar issues.

4.7. Recent Trends and Ongoing Debates in Genetic Patenting in India

A. Judicial Interpretations of Section 3

Recent judicial pronouncements in India indicate a trend towards a more nuanced interpretation of Section 3 of the Patents Act, 1970, particularly in the context of biotechnological inventions. Courts have clarified that while naturally occurring substances are excluded from patentability under Section 3(c), engineered or synthetic substances or molecules that are products of human intervention can be patented, provided they meet the criteria of novelty and inventive step. This distinction emphasizes the role of human ingenuity in transforming a natural substance into a patentable invention. Furthermore, courts have acknowledged that significant human intervention in biological processes can distinguish them from "essentially biological processes" excluded under Section 3(j), potentially opening avenues for patenting certain biotechnological methods.

B. Patentability of Gene Editing Technologies

The patentability of gene editing technologies, such as CRISPR, remains a subject of ongoing debate in India, mirroring discussions taking place globally. The complexity of these technologies and the ethical considerations surrounding their use, particularly in human germline editing, add layers of intricacy to the patenting process. The outcomes of patent disputes related to CRISPR in other jurisdictions are likely to influence the approach taken by the Indian Patent Office and courts in determining the patentability of such inventions in India.

C. International Harmonization Efforts

India's patent law framework for genetic inventions is influenced by its obligations under international agreements like TRIPS and the

Convention on Biological Diversity. There is a growing global recognition of the need for greater harmonization of patent laws across different jurisdictions to facilitate international collaboration in genetic research and development and to streamline the patenting process for inventions with global applications. However, achieving complete harmonization remains a challenge due to differing national interests and ethical considerations.

4.8. Resources for Inventors Seeking Patents on Genetic Inventions in India

A. Guidelines and Practices of the Indian Patent Office

The Indian Patent Office provides guidelines for the examination of biotechnology applications for patents, which serve as a valuable resource for inventors. These guidelines offer insights into the Patent Office's interpretation of the relevant sections of the Patents Act, particularly Section 3 and Section 10, in the context of genetic inventions. Inventors should pay close attention to the requirements related to the written description of the invention and the process for depositing biological material. The guidelines also emphasize the importance of accurately disclosing the source and geographical origin of any biological resources used in the invention. Understanding and adhering to these guidelines can significantly enhance the chances of a successful patent application.

B. Interacting with the National Biodiversity Authority (NBA)

Inventors whose genetic inventions are based on biological resources obtained from India must be aware of the mandatory requirement to obtain prior approval from the National Biodiversity Authority (NBA) before applying for a patent, whether in India or abroad. The NBA has prescribed specific application forms and procedures for seeking this approval. Providing detailed information about the biological resource, its source, and its intended use in the invention is crucial for the NBA's review process. Initiating the NBA approval process early in the patent application timeline is highly recommended to avoid potential delays.

C. Intellectual Property Organizations and Legal Firms

Intellectual property organizations and legal firms specializing in biotechnology patents in India can provide invaluable assistance to inventors navigating the complexities of genetic patenting. These experts possess in-depth knowledge of the Indian Patents Act, relevant case laws, and the practices of the Indian Patent Office and the NBA. Seeking advice from patent attorneys specializing in this field can help inventors understand the specific requirements for their inventions, draft comprehensive patent applications, and navigate potential legal challenges.

CHAPTER - 5

Patenting Human Genetic Inventions and Gene Editing Technologies

The rapid advancements in the field of human genetics, coupled with the emergence of powerful gene editing technologies such as Clustered Regularly Interspaced Short Palindromic Repeats-associated protein 9 (CRISPR-Cas9) and Transcription Activator-Like Effector Nucleases (TALEN), have ushered in a new era of biological research with profound implications for human health. These technologies provide unprecedented capabilities to manipulate the fundamental building blocks of life, offering potential therapeutic solutions for a wide range of diseases previously considered untreatable. The ability to precisely alter the genetic code holds immense promise for correcting genetic defects, developing novel treatments for cancer, and combating infectious diseases.

Securing patent protection for these groundbreaking inventions is a critical step in incentivizing innovation and attracting the substantial investment required for their further development and eventual commercialization. Patents grant inventors a temporary period of exclusivity, allowing them to recoup the

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significant research and development costs associated with bringing these complex technologies to market. This is particularly vital in the biotechnology sector, which is characterized by high investment risks and lengthy development timelines.

However, the patenting of human genetic material raises a multitude of complex legal, ethical, and societal questions, leading to significant debates and diverse patent laws across different jurisdictions. The very idea of claiming proprietary rights over aspects of the human genome sparks ethical concerns about the ownership of life and the potential for hindering research and limiting access to essential healthcare.

This report aims to provide a comprehensive analysis of the current landscape of patenting for human genetic inventions and related technologies. It will focus on key jurisdictions, including the United States, Europe, and India, and highlight the major trends and challenges that define this dynamic field. By examining the legal frameworks, the patent landscapes of prominent gene editing technologies, and the associated ethical implications, this report seeks to offer a nuanced understanding of the intricate relationship between human genetics, gene editing, and patent law.

5.1. Defining the Foundational Concepts Gene Editing: Mechanisms and Applications

Gene editing, also known as genome editing, refers to a collection of technologies that provide scientists with the ability to precisely alter an organism's DNA. These technologies enable the addition, removal, or alteration of genetic material at specific, targeted locations within the genome. While several approaches to gene editing have been developed, the CRISPR-Cas9 system has emerged as a particularly impactful tool due to its advantages in speed, cost- effectiveness, accuracy, and efficiency compared to earlier methods such as Zinc Finger Nucleases (ZFNs) and TALENs.

The CRISPR-Cas9 system is derived from a natural immune defence mechanism used by bacteria to protect themselves against viral infections. When a bacterium is infected by a virus, it captures small fragments of the viral DNA and integrates them into its own genome in specific patterns known as CRISPR arrays. These arrays allow the bacterium to "remember" the virus. Upon subsequent viral attacks, the bacterium produces RNA segments from the CRISPR arrays that recognize and bind to specific regions of the invading virus's DNA. The bacterium then employs a Cas enzyme, most commonly Cas9, to cut the viral DNA, thereby disabling the virus.

Scientists have ingeniously adapted this bacterial defence system for genome editing in various organisms, including humans. They design a small piece of RNA, known as a guide RNA, with a short sequence that is complementary to a specific target sequence in the cell's DNA. This guide RNA then directs the Cas9 enzyme to the precise location in the genome. Once the guide RNA binds to the target DNA sequence, the Cas9 enzyme acts as a molecular scissor and cuts the DNA at that specific site.

Following the DNA cut, the cell's natural DNA repair mechanisms are activated. Researchers can then leverage these repair pathways to introduce desired changes to the genome. This can involve deleting or inserting specific DNA sequences, correcting disease-causing mutations, or even replacing an existing segment of DNA with a customized sequence.

Gene editing technologies hold immense potential for the prevention and treatment of a wide array of human diseases. This includes inherited genetic disorders such as cystic fibrosis and sickle cell disease, as well as more complex conditions like cancer, heart disease, mental illness, and human immunodeficiency virus (HIV) infection. Beyond therapeutic applications, gene editing is also a powerful tool in research laboratories for understanding gene function through the creation of animal models of disease and in drug discovery. Furthermore,

these technologies have applications in agriculture for improving crop yields and disease resistance, as well as in the production of biofuels.

The application of gene editing technologies, particularly CRISPR-Cas9, to human genomes raises significant ethical concerns. A key distinction is made between somatic cell editing, which involves modifying genes in non-reproductive cells and affects only the individual being treated, and germline editing, which targets the DNA of egg and sperm cells or embryos, leading to heritable changes that can be passed on to future generations. While somatic cell editing generally faces fewer ethical objections, germline editing raises profound ethical challenges related to the potential for unintended consequences for offspring and the broader societal implications of altering the human gene pool. Questions also exist regarding the ethical permissibility of using gene editing for human enhancement purposes beyond treating disease.

Gene Silencing: Methods and Biological Significance

Gene silencing refers to the regulation of gene expression in a cell to prevent or reduce the production of a specific gene product, typically a protein. This can occur at the transcriptional level, by preventing the gene from being transcribed into RNA, or at the translational level, by preventing the RNA from being translated into protein. The term gene silencing is often used interchangeably with gene knockdown, which describes a significant reduction in gene expression, typically by at least 70%, but not a complete elimination, as seen in gene knockout.

Various methods are employed to achieve gene silencing, including the use of antisense oligonucleotides (ODNs), ribozymes, and RNA interference (RNAi). Antisense ODNs are short, single-stranded DNA or RNA molecules designed to bind to specific messenger RNA (mRNA) molecules, thereby blocking their translation into proteins. Ribozymes are catalytic RNA molecules that can cleave specific mRNA molecules, leading to their degradation and subsequent gene silencing.

RNA interference (RNAi) is a naturally occurring post-transcriptional gene silencing mechanism found in many eukaryotic organisms. This process is triggered by the presence of double-stranded RNA (dsRNA) in the cell. An enzyme called Dicer processes the dsRNA into smaller fragments, including small interfering RNAs (siRNAs) and microRNAs (miRNAs), which are typically 21-23 nucleotides in length. These small RNA fragments are then incorporated into a protein complex known as the RNA-induced silencing complex (RISC). RISC uses one strand of the siRNA or miRNA, the guide strand, to target and degrade complementary mRNA molecules or to suppress their translation into proteins.

Gene silencing plays a fundamental role in normal biological processes, including development, cell differentiation, and the regulation of metabolism and gene expression throughout the life of an organism. In plants, gene silencing is a key defence mechanism against pathogens and also regulates developmental processes.

The ability to artificially induce gene silencing has significant applications in therapeutics. By specifically targeting and silencing genes that contribute to disease, such as those involved in cancer, infectious diseases, and neurodegenerative disorders, researchers are developing novel treatment strategies. Gene silencing offers a potentially controllable and reversible approach to treating genetic conditions by targeting the underlying disease mechanism. This reversibility can be advantageous compared to gene therapy, which often involves permanent genetic modifications.

5.2. The Legal Landscape of Human Genetic Invention Patenting Patenting in the United States: Key Legislation and Landmark Cases

In the United States, patent law is primarily governed by Title 35 of the United States Code.

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Section 101 of this title defines patentable subject matter broadly as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof". However, this broad definition is subject to judicial interpretation, which has established exclusions for laws of nature, physical phenomena, and abstract ideas. This principle is crucial in the context of patenting human genetic inventions, as it directly relates to whether naturally occurring genetic material can be considered patentable.

The landmark Supreme Court case of *Association for Molecular Pathology v. Myriad Genetics, Inc.* (2013) significantly reshaped the legal landscape for patenting human genetic material in the United States. The case involved patents held by Myriad Genetics on the BRCA1 and BRCA2 genes, which are associated with an increased risk of breast and ovarian cancer. The Court unanimously ruled that isolated naturally occurring human genes are products of nature and are therefore not patentable simply because they have been isolated from the human body. The Court's reasoning emphasized that the sequence and order of nucleotides in a gene are dictated by nature, not by human invention. The act of merely isolating a gene, even if it requires significant effort, does not transform it into a patentable invention.

However, the *Myriad* decision also clarified that complementary DNA (cDNA) is patentable. cDNA is a synthetic DNA molecule created in the laboratory from messenger RNA (mRNA) and lacks the non-coding regions (introns) present in genomic DNA. The Court reasoned that cDNA is not naturally occurring because humans create it through a technical process. This distinction is critical, as many diagnostic tests and therapeutic proteins are based on cDNA sequences.

Prior to the *Myriad* ruling, the United States Patent and Trademark Office (USPTO) had generally granted patents on isolated gene sequences with known functions. The rationale was that isolating and purifying a gene sequence from its natural state differentiated it sufficiently to be considered patentable. The first patent on an entire human gene was awarded in 1982. This practice fuelled significant investment and innovation in the biotechnology sector.

The USPTO has also granted patents on biological materials derived from humans, including isolated and manipulated cells such as human embryonic stem cells (hESCs). However, the patentability of human-related inventions has faced legal and ethical scrutiny.

The patenting of human genetic inventions in the US has been a subject of considerable debate, with concerns raised about its potential to impede scientific research and limit access to genetic testing and therapies. Critics argued that patents on genes could lead to monopolies, increase the cost of healthcare, and hinder further innovation. The *Myriad* decision aimed to address some of these concerns by clarifying that naturally occurring genes are not patentable.

Patenting in Europe: The European Patent Convention and Biotechnology Directive

In Europe, the patentability of inventions is governed by the European Patent Convention (EPC). Article 52(1) of the EPC states that European patents shall be granted for any inventions which are susceptible of industrial application, which are new, and which involve an inventive step. This framework differs from the US approach in its treatment of naturally occurring substances.

The European Union's Biotechnology Directive (Directive 98/44/EC) provides specific rules concerning the patenting of biotechnological inventions, including those related to human genetic material. Article 5(2) of the Directive clarifies that while the simple discovery of a gene sequence or a partial gene sequence is not patentable, an element isolated from the human body or produced by a technical process, including a gene sequence or partial gene

sequence, can be patentable even if its structure is identical to that of a natural element. This provision allows for the patenting of isolated gene sequences provided that their industrial application is disclosed in the patent application. The disclosed industrial application must be specific and substantial, going beyond mere scientific interest.

The European Patent Office (EPO) examines patent applications for biotechnological inventions based on the criteria of novelty, inventive step (non-obviousness), and industrial applicability (utility). For gene patents, the function of the gene sequence or the protein it encodes must be clearly disclosed in the patent application to demonstrate industrial applicability. The EPO also assesses whether the claimed invention involves an inventive step, meaning it would not have been obvious to a person skilled in the art.

While the Biotechnology Directive aims to harmonize patent law across EU member states, some national laws may impose additional limitations. For example, France has banned the patenting of whole or partial human gene sequences per se. Similarly, Germany and Italy allow for purpose-bound patent protection for gene sequences, limiting the scope of the patent to the specific industrial application disclosed. However, the validity of national laws that significantly deviate from the Directive is questionable, and applicants often file directly with the EPO.

The European Court of Justice (ECJ) has addressed the ethical dimensions of gene patenting, ruling in 2001 that patenting genetic material isolated from the human body does not violate principles of human dignity. This ruling affirmed the legality of the Biotechnology Directive.

Patenting in India: The Indian Patents Act and Evolving Jurisprudence

The Indian Patents Act, 1970, governs patent law in India and includes specific provisions relevant to the patenting of human genetic inventions. Section 3 of the Act outlines categories of inventions that are not patentable. Section 3(c) explicitly prohibits the patenting of "the discovery of any living thing or non-living substance occurring in nature". This provision serves as a primary barrier to patenting naturally occurring genes or their mere isolation.

Furthermore, Section 3(j) of the Act excludes from patentability "plants and animals in whole or any part thereof including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals". This section, added through a 2002 amendment, has been interpreted to restrict the patenting of genes that are considered part of plants or animals.

Initially, the Indian Patents Office (IPO) had a more permissive stance on patenting isolated genomic DNA. However, the Indian Biotechnology Guidelines of 2013 brought a change, classifying such isolated material as a "mere discovery" and therefore not patentable under Section 3(c). Additionally, Section 3(d), which prohibits patenting "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance," can also be used to argue against the patentability of isolated DNA.

Despite these restrictions, the Indian patent law offers some flexibility for patenting modified genetic material. Isolated and purified gene sequences, particularly complementary DNA (cDNA), may be patentable if they meet the criteria of novelty under Section 2(1)(j) of the Act, involve an inventive step (non-obviousness), and demonstrate industrial applicability, especially when significant human intervention is involved in their creation. The Manual of Patent Practice and Procedure in India has seen changes over time regarding the requirement of "substantial human interaction," with the 2011 version removing this specific criterion.

Several judicial decisions have influenced the understanding of gene patentability in India. The Calcutta High Court's ruling in *Dimminaco A.G.*

v. Controller of Patents & Designs (2001) was a significant case that upheld the patentability of a process for manufacturing a vaccine containing a live virus, stating that there was no legal bar to patenting a method of manufacture even if the final product is living. However, the Supreme Court has not yet provided a definitive judgment on the patenting of isolated DNA and cDNA, although a patent was granted for the Japanese Encephalitis Virus cDNA, as it was deemed "new and novel" under Section 2 of the Patents Act, 1970. The case of *Monsanto Technology LLC v. Nuziveedu Seeds Ltd* (2019) saw the Division Bench stating that genetically modified plants, seeds, and gene sequences providing genetic traits to plants are not patentable in India. The Supreme Court re-examined this case, but a final decision on the patenting of isolated DNA and cDNA is still pending.

The implementation of the TRIPS agreement by the WTO has also influenced India's patent regime. While Article 27(3) of TRIPS allows member states to exclude plants, animals, and essentially biological processes from patentability, it remains silent on the patenting of genetic material like DNA sequences. However, Article 8 of TRIPS allows member states to take measures to protect public health and nutrition, which could be used to justify restrictions on gene patenting. The Indian Patents Act was amended in 2005 to align with TRIPS, including the removal of Section 5, which previously restricted patentability to methods or processes of manufacture, thus allowing product patents in biotechnology. The Indian patent system has also been influenced by the US legal framework in this area, and the *Myriad* decision has had an impact on the interpretation of gene patentability in India.

5.3. The CRISPR-Cas9 Patent Arena Key Patent Holders and Their Claims

The patent landscape for CRISPR-Cas9 technology is intensely competitive and characterized by a complex web of intellectual property rights, primarily held by the University of California, Berkeley (UC Berkeley), and the Broad Institute of MIT and Harvard (Broad Institute).

UC Berkeley, led by Jennifer Doudna and Emmanuelle Charpentier, filed its initial patent application in May 2012, broadly covering the fundamental mechanism of the CRISPR-Cas9 system and its potential for genome editing in vitro. Their claims were not initially limited to specific cell types, encompassing the general application of the technology. UC Berkeley has subsequently been granted multiple patents in the US for CRISPR technologies across various cellular and non-cellular settings and holds over 50 CRISPR patents globally.

The Broad Institute, spearheaded by Feng Zhang, filed its first patent application in December 2012, specifically describing and enabling the use of CRISPR-Cas9 for genome editing in eukaryotic cells, including plant and animal cells, which are crucial for human therapeutic applications. The Broad Institute demonstrated the successful adaptation of CRISPR-Cas9 for genome editing in these more complex cell types. The Broad Institute received its first US patent for this specific application in April 2014. By late 2020, the Broad Institute had been granted 26 patents specifically for CRISPR-Cas9 in the United States and 29 in Europe.

In addition to these two primary entities, other biotechnology companies such as Editas Medicine, CRISPR Therapeutics, and Intellia Therapeutics have also established significant patent portfolios focusing on specific applications and enhancements of CRISPR-Cas9 technology. These companies often license foundational patents from either UC Berkeley or the Broad Institute to support their research and development efforts.

5.4. The Protracted Patent Disputes: UC Berkeley vs. Broad Institute and Beyond

The groundbreaking nature and immense commercial potential of CRISPR-Cas9 technology ignited an intense and long-running

patent dispute, primarily between UC Berkeley and the Broad Institute, which unfolded in patent offices and courts in the United States and Europe.

In the United States, the USPTO initiated several interference proceedings to determine which party was the first to invent the use of CRISPR-Cas9 in eukaryotic cells. The first interference, commencing in 2016, concluded in 2017 with the PTAB ruling that there was no "interference- in-fact" because the Broad Institute's claims, specific to eukaryotic cells, were deemed patentably distinct from UC Berkeley's broader claims[3].

However, UC Berkeley subsequently filed new patent applications with claims specifically directed to eukaryotic cells, leading to a second interference proceeding initiated in 2019. In a significant ruling in February 2022, the PTAB sided with the Broad Institute, concluding that UC Berkeley had not provided sufficient evidence of successfully using CRISPR-Cas9 in animal and plant cells before the Broad Institute's demonstration of such use. This decision represented a major setback for UC Berkeley, potentially resulting in the loss of significant licensing revenue related to human therapeutics. UC Berkeley has expressed its disagreement with the ruling and is exploring options for further legal challenges.

The patent dispute has also unfolded in Europe with differing outcomes. The European Patent Office (EPO) initially granted a broad patent to Jennifer Doudna and Emmanuelle Charpentier. However, the EPO also revoked a key patent held by the Broad Institute due to a technicality concerning priority claims. These divergent rulings in major jurisdictions underscore the complexities of patent law and its application to groundbreaking scientific discoveries.

The CRISPR-Cas9 patent landscape is further complicated by the involvement of other entities, such as ToolGen in South Korea, which also holds patents related to the technology.

5.5. Scope and Implications of Granted CRISPR-Cas9 Patents

The granted CRISPR-Cas9 patents, held by UC Berkeley, the Broad Institute, and other entities, encompass a wide range of claims related to the technology. These claims cover the fundamental CRISPR-Cas9 system itself, its individual components such as the Cas9 enzyme and guide RNAs, methods for using the system to edit genes in various cell types and organisms (including eukaryotic cells), and specific applications in diverse fields including human therapeutics, agriculture, and diagnostics.

Ownership of these foundational patents grants the patent holders significant control over the use and commercialization of CRISPR-Cas9 technology. This control can influence who can utilize the technology, for what purposes, and under what terms, potentially impacting the pace and direction of innovation within the field.

The ongoing patent disputes and the resulting fragmented ownership of CRISPR-Cas9 patents have created a complex licensing landscape that can be challenging for researchers and companies to navigate. Securing the necessary licenses to conduct research or develop commercial products may necessitate engaging with multiple patent holders, potentially leading to delays and increased costs.

To address these challenges and promote broader access to CRISPR-Cas9 technology, efforts have been made to establish patent pools or joint licensing strategies involving the key patent holders. The Broad Institute has been a proponent of such approaches, aiming to create a more streamlined and equitable licensing framework. However, achieving a comprehensive agreement among all relevant parties has proven to be difficult.

The broad scope of some CRISPR-Cas9 patents has also raised ethical concerns regarding potential limitations on research and the accessibility of future therapeutic applications,

particularly if exclusive licenses result in high treatment prices.

5.6. TALEN Technology: Patent History and Current Status Evolution of TALEN Patents and Key Players

Transcription Activator-Like Effector Nucleases (TALENs) emerged as a significant genome editing tool in the years preceding the widespread adoption of CRISPR-Cas9. TALENs are engineered proteins created by fusing DNA-binding domains known as TAL effectors to the catalytic domain of the FokI nuclease. The DNA-binding specificity of TAL effectors is determined by a series of repeated amino acid sequences that can be designed to recognize and bind to specific DNA sequences.

Key patent holders in the TALEN technology space include Cellectis, a genome engineering company, as well as academic institutions such as the University of Minnesota and Iowa State University.

Cellectis was a pioneer in the development and commercialization of TALEN technology, establishing a strong partnership with the University of Minnesota and Iowa State University in 2011. Cellectis holds exclusive rights to a portfolio of patents owned by these universities related to TAL-effector nucleases, covering various aspects of the technology, including the nucleases themselves and the polynucleotides encoding them.

The University of Minnesota System also holds patents related to TALEN-mediated DNA editing for the treatment of disease-causing mutations in the human genome and human cells. These patents cover methods for personalized gene therapy using TALENs to correct mutations while preserving the integrity of the rest of the genome.

Cellectis was the first company to bring TAL-effector nucleases to the market in 2011, commercializing them under the trademark TALEN™. The company provides its customers with TALEN™ products under license of these patents, enabling researchers to undertake a wide range of genome engineering projects.

While TALENs represented a significant advancement in DNA targeting and genome editing, the emergence of CRISPR-Cas9, with its relative ease of implementation and lower cost, has led to its more widespread adoption in research laboratories. However, TALENs continue to be utilized and offer certain advantages in specific applications.

5.7. Comparative Analysis of TALEN and CRISPR-Cas9 Patent Landscapes

CRISPR-Cas9 has rapidly become the dominant genome editing technique due to its exceptional ease of design and use compared to earlier methods like TALENs. Designing guide RNAs for CRISPR-Cas9 is significantly simpler and less expensive than engineering TALEN arrays to target specific DNA sequences.

Both TALENs and CRISPR-Cas9 offer high target site specificity, enabling precise genetic alterations. However, TALENs are generally considered to have less off-target activity compared to early CRISPR-Cas9 systems, although advancements in CRISPR specificity have narrowed this gap. TALENs require a pair of nucleases to bind on opposite sides of the target site for cleavage, resulting in a longer recognition sequence (approximately 36 base pairs), which is less likely to be found elsewhere in the genome, thus enhancing specificity. In contrast, CRISPR-Cas9 relies on a 20-nucleotide guide RNA sequence followed by a PAM motif.

A key advantage of TALENs over CRISPR is their flexibility in targeting virtually any specific locus in the genome without the constraint of a nearby PAM sequence, which is required by the commonly used Cas9 enzyme. This allows researchers to access a broader range of genomic sites for editing using TALENs. For instance, TALENs have been the primary tool for targeting and manipulating mitochondrial genomes, as early CRISPR systems were less efficient in this cellular compartment. The patent landscape for CRISPR-Cas9 is significantly more complex and contentious

than that of TALENs. The ongoing high-profile patent disputes between UC Berkeley and the Broad Institute over CRISPR-Cas9 contrast with the more settled IP situation for TALENs, where Cellectis has a strong licensing position.

While CRISPR-Cas9 is generally less expensive to use than TALENs, the potential licensing costs associated with the complex CRISPR patent landscape could offset this advantage in some cases. Researchers and companies need to carefully consider the IP implications when choosing between these technologies for their specific applications.

5.8. Patenting Other Significant Genetic Techniques

RNA Interference (RNAi): Patent Holders and Therapeutic Potential

RNA interference (RNAi) is a naturally occurring gene silencing mechanism that has been harnessed for therapeutic applications, leading to a significant body of patents in this area.

Key patent holders in the RNAi field include Alnylam Pharmaceuticals, Thermo Fisher Scientific (which acquired Dharmacon), and Sirnaomics. Alnylam Pharmaceuticals has established a dominant patent position in RNAi therapeutics, with a vast portfolio of patents covering various aspects of the technology.

The foundational patents for siRNA technology, often referred to as the "Tuschl II" patents, are exclusively licensed to Alnylam from their originators at the Max Planck Institute, MIT, Whitehead Institute, and the University of Massachusetts. These patents cover the structural characteristics of siRNA molecules crucial for their gene silencing activity.

Recent patent analysis indicates a growing trend in RNAi innovation, particularly in the development of treatments for metabolic, infectious, neurological, and cardiovascular diseases. The majority of patent activity in this area is driven by universities and research institutions, with an increasing number of filings from companies in Southeast Asia.

The first FDA-approved RNAi therapeutic, ONPATTRO™ (patisiran) developed by Alnylam, targets a protein involved in hereditary transthyretin-mediated amyloidosis. This approval validated the therapeutic potential of RNAi and the importance of patent protection in this field.

Zinc-Finger Nucleases (ZFNs): Key Patents and Applications

Zinc-Finger Nucleases (ZFNs) were among the first programmable gene editing tools, enabling targeted modifications to the genome. ZFNs consist of engineered zinc finger proteins that bind to specific DNA sequences and a nuclease domain that cuts the DNA.

Sangamo Therapeutics holds a dominant patent position in the ZFN technology field, with a significant portfolio of patents covering various aspects of ZFN design and application. Sangamo has actively acquired and licensed ZFN-related intellectual property from academic institutions.

ZFNs have been used in various applications, including creating HIV-resistant human cells and in clinical trials for genetic disorders. They also have applications in plant genetic engineering and the production of biopharmaceuticals.

Antisense Technology: Patent Strategies and Market Players

Antisense technology utilizes antisense oligonucleotides (ODNs) to silence gene expression by binding to specific mRNA sequences and preventing their translation into proteins.

Patenting strategies in antisense technology often involve developing comprehensive patent portfolios covering the oligonucleotide sequence, chemical modifications, manufacturing processes, and therapeutic applications.

Ionis Pharmaceuticals is a key player in the antisense technology field, holding numerous patents and having successfully developed and

commercialized several antisense drugs.

5.9. Ethical and Societal Ramifications of Patenting Human Genetic Inventions and Gene Editing Technologies

Moral and Philosophical Considerations of Gene Ownership

The patenting of human genetic inventions raises fundamental moral and philosophical questions about the ownership of life's building blocks. Many argue that genes, as naturally occurring components of the human body, should not be subject to proprietary rights. This perspective views the patenting of genes as a form of commodification of human life, potentially undermining human dignity.

Conversely, proponents argue that patents on genetic inventions do not confer ownership of the gene itself but rather a limited right to exclude others from using the specific invention as claimed in the patent. This exclusivity is seen as a necessary incentive to encourage investment in the costly and time-consuming research and development required to translate genetic discoveries into useful diagnostic tools and therapeutic treatments.

A crucial ethical distinction is often drawn between naturally occurring genes and human- altered genetic sequences, such as cDNA. Many believe that while naturally occurring genes might be considered discoveries, human-engineered sequences involve an element of invention and are therefore more ethically justifiable for patenting. The *Myriad* case in the US reflected this distinction by invalidating patents on isolated natural genes but upholding the patentability of cDNA.

Concerns also exist that gene patents could lead to monopolies that restrict access to vital genetic information and technologies, potentially hindering medical progress and creating inequities in healthcare. The balance between commercial interests and the public good remains a central ethical consideration in this debate.

5.10. Impact on Scientific Research and Innovation

The patenting of human genetic inventions and gene editing technologies has a complex and sometimes conflicting impact on scientific research and innovation.

On one hand, patents are intended to incentivize innovation by providing a period of exclusivity that allows inventors to recoup their investment and potentially profit from their discoveries. This can be particularly important in the biotechnology industry, where research and development costs can be substantial. Furthermore, the patent application process requires inventors to disclose the details of their inventions, which can contribute to the broader scientific knowledge base.

However, concerns have been raised that gene patents can sometimes hinder rather than promote scientific progress. Patent holders may restrict the use of patented genes or technologies by other researchers, potentially impeding further investigation and the development of new applications. The existence of "patent thickets," where multiple overlapping patents cover different aspects of a particular technology, can also create barriers to research and innovation by requiring researchers to navigate a complex web of intellectual property rights and potentially obtain licenses from multiple parties. The *Myriad* case highlighted concerns that patents on the BRCA genes might have limited research on these important cancer-related genes.

5.11. Accessibility and Affordability of Genetic Diagnostics and Therapies

A significant societal concern related to the patenting of human genetic inventions and gene editing technologies is their potential impact on the accessibility and affordability of genetic diagnostics and therapies.

Patents can grant exclusive rights to patent holders, allowing them to control the market for specific genetic tests or therapies. This monopoly power can lead to higher prices,

making these essential healthcare tools unaffordable for many patients. The case of Myriad Genetics' BRCA tests, which were priced at a premium due to patent exclusivity, is a prime example of this issue.

The high costs of patented genetic tests and therapies can also exacerbate existing healthcare disparities, particularly in low- and middle-income countries where access to advanced medical technologies is already limited.

There is a growing recognition of the need to balance intellectual property rights with the public interest in ensuring access to essential healthcare. Policy measures such as compulsory licensing have been suggested as potential tools to address situations where patents may be hindering access to critical genetic tests or treatments.

Broader Societal Implications and Public Perception

The patenting of human genetic inventions and gene editing technologies has broader societal implications that extend beyond the realms of research and healthcare.

The prospect of using gene editing to alter the human germline raises profound ethical questions about the potential long-term consequences for the human gene pool and future generations. Concerns about unintended genetic mutations and the potential for misuse of these powerful technologies are also prominent in public discourse.

The use of gene editing for human enhancement purposes, beyond treating or preventing disease, raises further ethical dilemmas related to the definition of normalcy, the potential for creating social inequalities, and the concept of "playing God".

Public perception of gene patenting and gene editing technologies is often influenced by a complex interplay of hope for medical advancements and apprehension about the ethical and societal ramifications of manipulating the fundamental building blocks of life.

The high-profile patent disputes surrounding CRISPR-Cas9 have also contributed to public awareness and discussion about the implications of intellectual property rights in this rapidly evolving field.

5.12. Illustrative Case Studies in Human Genetic Invention Patenting Examples of Successful Patent Applications and Their Impact

Despite the limitations set by the *Myriad* decision on patenting isolated naturally occurring genes in the US, successful patent applications related to human genetic inventions continue to be granted, particularly for complementary DNA (cDNA). Patents covering cDNA-based diagnostic tests and therapeutic proteins have been successfully obtained and have significantly contributed to advancements in personalized medicine and biopharmaceuticals.

Patents on specific therapeutic applications of gene editing technologies, such as CRISPR-Cas9 modified hematopoietic stem cells for treating sickle cell disease and beta-thalassemia, as described in patent application WO2019113149A1, exemplify successful patenting strategies focused on utility and human intervention. The FDA approval of Casgevy, the first CRISPR-based therapy, highlights the value of patents in this area.

Historically, the Cohen/Boyer patents on recombinant DNA technology and the Axel patents on co-transformation were foundational to the biotechnology industry. These patents, while not directly on natural human genes, enabled the manipulation of genetic material and the production of recombinant proteins, generating significant revenue through broad licensing.

Patents covering methods of using genetic sequences for diagnostic testing, provided they meet the criteria of novelty, non-obviousness, and utility, have also been successfully patented. The key is often to claim a specific

method or process that involves more than just observing a natural phenomenon.

Analysis of Unsuccessful Patent Applications and Key Reasons for Rejection

The *Association for Molecular Pathology v. Myriad Genetics, Inc.* case serves as a prime example of unsuccessful patent applications for isolated naturally occurring human genes. The Supreme Court invalidated Myriad's patents on the BRCA1 and BRCA2 genes, concluding that these DNA sequences were products of nature and not patent-eligible merely by virtue of their isolation.

The initial NIH application to patent expressed sequence tags (ESTs) also faced challenges and was largely abandoned due to concerns about the lack of a specific and substantial utility for these gene fragments.

In Europe, the rejection of European patent No. 1 407 044 related to RNA interference illustrates how insufficient disclosure can lead to the failure of a patent application. The EPO found that the application did not adequately describe the structural requirements for the claimed dsRNA molecules to mediate RNAi.

CHAPTER - 6

Patenting Genetic Inventions in GMOs and the Monarch Butterfly Issue

6.1. Understanding Patent Law and GMOs

A. Types of Intellectual Property Protection for GMOs

Patents serve as a fundamental mechanism for protecting intellectual property, granting inventors exclusive rights to their creations for a defined period. This exclusivity aims to encourage innovation by allowing inventors to potentially recoup their investment in research and development. In the realm of biotechnology, particularly concerning Genetically Modified Organisms (GMOs), several types of patents and intellectual property protections are relevant, including utility patents, plant patents, and Plant Variety Protection Certificates (PVPCs).

1. Utility Patents

Utility patents represent a broad category of intellectual property protection, covering novel inventions that possess practical uses. These patents can encompass a wide array of innovations, such as new technologies, processes, machines, and compositions of matter. When applied to GMOs, utility patents are frequently used to safeguard the underlying technology and methods employed in their creation. The scope of protection offered by utility patents for GMOs can be quite extensive, potentially covering the genetically modified plants themselves, new plant strains derived from various breeding methods, and specific genetic modifications that confer desirable traits. For instance, utility patents can protect GMO plants, new plants discovered or invented in a cultivated state that can be asexually reproduced, new plant strains resulting from crossbreeding, and even plants that are sexually reproduced by licensees, with restrictions on the licensees' ability to further distribute the seeds.

Compared to other forms of intellectual property protection available for GMOs, utility patents generally offer stronger safeguards, particularly concerning the saving of seeds by farmers and the use of patented material in breeding programs. Unlike PVPCs, utility patents do not typically include exemptions for farmers to save seeds or for breeders to use the patented invention for further breeding without a license from the patent owner. This robust protection can grant patent holders significant control over the utilization of their GMO technology. Obtaining a utility patent requires meeting stringent criteria, including providing a detailed description of the invention. For GMOs, the availability of comprehensive molecular information often facilitates meeting these demanding requirements.

2. Plant Patents

Plant patents constitute a specific type of patent designed to protect new varieties of plants that are asexually reproduced. To be eligible for a

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plant patent, a genetically modified plant variety must be new and distinct, possessing characteristics that differentiate it from existing plants. Additionally, the plant must be capable of asexual reproduction, meaning that plants reproduced through natural methods like seeds are generally not eligible for plant patents. While plant patents grant exclusive rights to the inventor, their scope has certain limitations Notably, a plant patent does not prevent others from using the patented plant for research or breeding purposes, as long as such use does not involve commercial propagation. This limitation aims to foster further innovation and scientific advancement in plant breeding. Furthermore, plant patents protect the specific new plant variety itself and do not necessarily cover the broader genetic modification technology or methods used to create the GMO; for more comprehensive protection of these aspects, utility patents are often preferred. Consequently, GMO companies typically Favor utility patents over plant patents due to the broader protection offered by the former.

3. Plant Variety Protection Certificates (PVPCs)

In the United States, Plant Variety Protection Certificates (PVPCs), established by the Plant Variety Protection Act (PVPA) of 1970, provide another form of intellectual property protection for new plant varieties. PVPCs are administered by the U.S. Department of Agriculture (USDA) and protect sexually reproduced crops and tubers. Unlike utility patents, PVPCs include exemptions that allow breeders to use protected varieties for breeding other varieties and permit farmers to save seeds of protected varieties for their own subsequent plantings. This approach represents a different balance between protecting the rights of plant breeders and ensuring access for researchers and farmers. However, utility patents offer stronger intellectual property protection compared to PVPCs because they do not have these breeder or farmer-use exemptions, granting a greater degree of control to the patentholder. This difference in the strength of protection has contributed to the preference for utility patents in the context of GMOs.

B. Criteria for Patenting Genetic Inventions

To secure patent protection for an invention, including genetic inventions in GMOs, the invention must generally meet three fundamental criteria: novelty, non-obviousness, and utility. These criteria are designed to ensure that patents are granted for genuine advancements that represent a significant contribution to the field.

1. Novelty

The criterion of novelty dictates that an invention must be new and not previously disclosed to the public in any form. In the context of GMOs, this means that the specific genetic modification or the resulting genetically modified organism must be unique and not already existing in nature. The introduction of foreign DNA or the alteration of existing genetic material in a way that does not occur naturally can satisfy the novelty requirement for patenting a GMO.

2. Non-Obviousness

Non-obviousness requires that the invention is not an evident or obvious improvement over existing technologies to someone with ordinary skill in the relevant field. For GMOs, this implies that the genetic modification must involve an inventive step and should not be a routine or straightforward alteration of the organism's genome. The process of genetically engineering an organism to express a new trait or to enhance an existing one often involves complex techniques and specialized knowledge, thus typically meeting the non-obviousness standard.

3. Utility

The criterion of utility mandates that the invention must have a practical application and provide a tangible benefit. In the case of GMOs, this means that the genetically modified organism must have a demonstrated use or purpose. This could include traits such as

increased crop yield, resistance to pests or diseases, tolerance to herbicides, enhanced nutritional value, or other beneficial characteristics that offer a practical advantage in agriculture or other fields. A mere discovery of a gene or genetic sequence without a demonstrated use is generally not sufficient for patentability; a specific and practical application must be disclosed.

C. Scope of Patent Protection for GMOs

Utility patents can provide a broad scope of protection for GMOs, potentially encompassing not only the genetically modified plant itself but also the specific genetic traits introduced and the processes used to create the organism. This multi-layered protection allows patent holders to control various aspects of their GMO innovations. For example, patents have been granted for GMOs exhibiting herbicide resistance, such as Monsanto's Roundup Ready soybeans, which are engineered to tolerate the herbicide glyphosate. Similarly, insect resistance, as seen in Bt corn which produces a toxin harmful to certain insect pests, is another aspect of GMOs commonly protected by utility patents. Modifications for enhanced traits, such as faster maturation in the case of AquAdvantage salmon, have also been subject to utility patent protection. Furthermore, patent protection extends to the gene targeting technologies themselves, such as CRISPR/Cas9, which are used to create GMOs, as well as to the specific methods applied to genetically modified organisms to achieve desired outcomes. While naturally occurring DNA sequences are generally excluded from patentability in some jurisdictions like the United States, engineered genes or complementary DNA (cDNA), which is a variation of the original gene, can be patented, offering protection for the specific genetic modifications introduced.

6.2. Global Perspectives on GMO Patent Regulations

A. United States

The United States has been a pioneer in offering patent protection for GMOs, including both genetically modified plants and animals. This approach stems from landmark legal precedents that affirmed the patentability of living organisms created through human intervention. Utility patents serve as the primary mechanism for protecting GMO innovations in the US, providing comprehensive coverage for the genetically modified organisms, their specific traits, and the methods of their production. The regulatory landscape in the US for GMOs is governed by the Coordinated Framework for Regulation of Biotechnology, which involves the USDA, FDA, and EPA, focusing on ensuring the safety of GMO products rather than the process by which they are developed. Key legal decisions, such as *Diamond v. Chakrabarty* in 1980, which established the patentability of genetically engineered microorganisms, and *JEM Ag Supply v. Pioneer Hi-Bred* in 2001, which extended utility patent protection to include plants, have significantly shaped the patenting of GMOs in the US. Despite the robust patent protection offered, there remains an ongoing debate in the US regarding the appropriate level of protection for GMO companies and the balance of rights with farmers, particularly concerning issues like seed saving and the potential for corporate control over the food supply.

B. Europe

In Europe, the patenting of genetically engineered plants is permitted, although the regulatory environment tends to be more stringent compared to the United States. A significant recent development in Europe is the proposed ban on patenting plants engineered using new genomic techniques (NGTs) like CRISPR/Cas. This initiative aims to prevent legal uncertainties and reduce the dependence of farmers and breeders on large aggrotech companies. The European Parliament has voted in Favor of this ban, which would apply to NGT plants, plant parts, and the genetic information they contain. The current legal framework in Europe includes the Biotech Directive (98/44/EC) and the European Patent

Convention (EPC), which provide the basis for the patentability of biological inventions. However, concerns have been raised in Europe that the patenting of plants, including those derived from conventional breeding, could hinder innovation in plant breeding and increase the market power of a few major agribusiness corporations. Additionally, there is a strong emphasis in Europe on the labelling of GMOs and ensuring traceability throughout the food supply chain to protect consumer rights and allow for the withdrawal of GMOs from the market if safety concerns arise.

C. India

India's patent law takes a distinct approach to the patenting of GMOs. Section 3(j) of the Patents Act, 1970, explicitly excludes plants in whole or any part thereof, seeds, and essentially biological processes for the production and propagation of plants from being patentable. This provision reflects India's commitment to protecting farmers' rights and preserving biodiversity. While direct patenting of plants and seeds is prohibited, there is a possibility of obtaining patents on recombinant genes if they demonstrate an inventive step, industrial application, and significant human intervention. Furthermore, India has the Protection of Plant Variety and Farmer's Rights Act, 2001 (PPVFR Act), which provides a framework for protecting plant varieties and the rights of farmers, including those related to transgenic varieties. In India, there is an ongoing debate regarding the potential impact of GMOs on farmers' dependence on multinational corporations and concerns about maintaining seed sovereignty, with legal provisions aiming to balance intellectual property rights with the interests of farmers and local companies.

6.3. Ethical and Societal Debates Surrounding GMO Patents

A. Arguments for Patenting Living Organisms

The patenting of living organisms, including GMOs, is supported by several arguments. A primary justification is that patents serve as a crucial incentive for innovation in the biotechnology sector. The development of GMOs requires substantial investment in research, development, and navigating complex regulatory approval processes.[1] By granting inventors exclusive rights for a limited period, patents provide a mechanism for them to potentially recoup these investments and generate profits, thereby encouraging further advancements in the field. Furthermore, patents are seen as facilitating the commercialization and wider dissemination of GMOs. Patent holders can control the production and distribution of their GMOs, which proponents argue helps ensure that they are produced according to high standards of quality and safety. The patent system also promotes transparency and the sharing of knowledge, as inventors are required to publicly disclose the details of their inventions in exchange for exclusive rights. The landmark US Supreme Court decision in *Diamond v. Chakrabarty* (1980) played a pivotal role in establishing the patentability of genetically engineered microorganisms, significantly stimulating patent activity within the genetic engineering sector.

B. Arguments Against Patenting Living Organisms

Despite the arguments in favour, the patenting of living organisms, particularly GMOs, raises significant ethical and societal concerns. A central ethical objection revolves around the idea of ownership of life itself. Critics argue that life forms are products of nature or creation and should not be subject to private ownership and commercial exploitation. There are also significant concerns about the potential for GMO patents to lead to monopolies within the agriculture sector. Patents can limit farmers' access to certain seeds, potentially impacting agricultural diversity and undermining farmer autonomy. Furthermore, the patenting of GMOs creates a tension with the traditional practice of farmers saving and replanting seeds from their harvest, a practice often prohibited by patent agreements. The issue of biopiracy also arises,

where corporations may patent genetic resources or traditional knowledge originating from indigenous communities without providing fair compensation or obtaining proper consent. Environmental concerns are another key aspect of the debate, with critics arguing that GMOs could lead to unintended ecological consequences, such as the loss of biodiversity and cross- contamination with non-GMO species. Additionally, some argue that the patenting of genes can hinder scientific research by restricting access to and use of genetic information, potentially slowing down medical and agricultural advancements.

C. Societal Perceptions and Controversies

GMOs and their associated patents are a subject of considerable public debate and controversy. These controversies often stem from concerns about the safety of GMO foods, their potential environmental impacts, and the increasing control that large corporations exert over the global food supply through patent rights. There is a notable divergence in views between scientists, who generally agree on the safety of currently available GMOs, and the general public, where scepticism and distrust are more prevalent. The significant role of large agribusiness companies in the GMO sector, holding numerous patents and wielding considerable market power, fuels concerns about corporate dominance over food production. Moreover, there are worries that the patenting and commercialization of GMOs could exacerbate existing socio-economic disparities, potentially limiting access to food and agricultural technologies in developing countries.

6.4. The Impact of GMO Patents on Agricultural Innovation and Food Systems

A. Driving Agricultural Innovation

Patent protection plays a significant role in driving agricultural innovation by providing incentives for seed companies and biotechnology firms to invest in the research and development of new GMO traits. These innovations can include traits such as increased crop yield, enhanced resistance to pests and diseases, tolerance to herbicides, and improved nutritional content. The prospect of obtaining patents and the associated market exclusivity encourages companies to undertake the often costly and time-consuming process of developing new GMOs. Following the expansion of intellectual property rights protections for crop seeds, including utility patents for GMOs, there has been a notable increase in research and development spending by seed companies. This investment has led to the commercialization of a variety of innovative GMOs that have transformed agricultural practices. Examples of such innovations include herbicide-tolerant crops like Roundup Ready soybeans, insect-resistant crops such as Bt corn, and crops with modifications aimed at improving nutritional value. Furthermore, patents are expected to play a crucial role in the ongoing development and commercialization of gene-editing technologies like CRISPR, which are opening up new possibilities for creating crops with desirable traits. The ability to patent these advanced gene- editing tools and the resulting genetically modified crops is likely to further accelerate the pace of innovation in the agricultural biotechnology sector.

B. Implications for Food Security

GMOs hold the potential to contribute to global food security by increasing crop yields and enhancing the resilience of crops to various environmental stresses, particularly in the context of a growing global population and the challenges posed by climate change. Traits like drought tolerance, pest resistance, and improved nutritional content, often introduced through genetic modification, could play a role in ensuring a more stable and sufficient food supply. However, concerns have been raised that the patenting of GMOs could lead to increased corporate control over the food system, potentially limiting access to essential agricultural resources, especially for small-scale farmers in developing countries.

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Dependence on patented seeds and technologies, coupled with restrictions on the traditional practice of saving seeds, could undermine the livelihoods and autonomy of farmers, particularly in regions where affordability and access are significant issues. The necessity of GMOs to feed the world is also a subject of debate, with some arguing that other factors, such as political instability, conflict, and food waste, are more significant drivers of global hunger. Additionally, the focus on profit-driven innovation through the patent system may not always prioritize research and development efforts that could benefit smaller markets or address the specific needs of poorer populations.

C. Accessibility of Seeds for Farmers

GMO patents, particularly utility patents, often impose restrictions on farmers regarding the saving and replanting of seeds harvested from patented crops. Unlike conventional seeds, where farmers have a long-standing tradition of saving and reusing seeds, GMO patents typically require farmers to purchase new seeds for each planting season. This can lead to increased costs for farmers and create a dependence on seed companies that hold the patent rights. Furthermore, farmers often enter into contractual agreements with seed companies when purchasing GMO seeds, which can further limit their rights concerning seed use and may even grant seed companies the right to inspect farmers' fields to ensure compliance with the patent terms. Concerns have also been raised about the consolidation of the seed industry, where a few large companies control a significant portion of the market for patented GMO seeds, leading to increased seed prices and potentially impacting farmers' profitability. The enforcement of GMO patents has also resulted in patent infringement lawsuits against farmers who have unknowingly grown patented GMO crops due to unintentional contamination from neighbouring fields, adding another layer of complexity to the issue of seed accessibility. In contrast, some forms of intellectual property protection for plants, such as Plant Variety Protection certificates, include exemptions that allow farmers to save seeds for their own use, offering a different model that seeks to balance the rights of breeders with the needs of farmers.

6.5. The Monarch Butterfly Decline: Causes and Concerns

A. Factors Contributing to Population Decline

Monarch Butterfly populations have experienced a significant decline in recent decades, affecting both the eastern and western migratory populations. The eastern monarch population, which overwinters in central Mexico, saw a concerning 59% decrease in its wintering grounds in 2023-2024 compared to the previous year. Similarly, the western monarch population, which overwinters along the California coast, has plummeted by more than 90% since the ^1980s. Several factors contribute to this decline. A major cause is habitat loss, particularly the loss of milkweed, which is essential for monarch breeding. Agricultural practices, including the widespread use of herbicides on herbicide-resistant crops, have significantly reduced milkweed availability in agricultural landscapes, which were once important breeding grounds for monarchs. Pesticide and herbicide use also directly harm monarchs and degrade their habitat by killing non-target insects and reducing the availability of nectar plants for adult butterflies. Climate change is another significant factor, affecting monarch populations through erratic weather patterns, changes in the timing of milkweed emergence, and harsher conditions at their overwintering sites. Other contributing factors include logging and development in the oyamel fir forests of Mexico, where eastern monarchs overwinter, and the loss of overwintering sites in California due to development.

B. The Importance of Milkweed

Milkweed is the sole host plant for Monarch Butterfly caterpillars, meaning that monarch larvae feed exclusively on milkweed leaves. This obligate relationship underscores the critical importance of milkweed for the survival and

reproduction of Monarch Butterflies. Adult female monarchs lay their eggs exclusively on milkweed plants, ensuring that the newly hatched caterpillars have an immediate and essential food source. The significant decline in milkweed abundance, particularly within agricultural landscapes across the United States, is strongly correlated with the observed decline in Monarch Butterfly populations. The loss of this crucial breeding habitat has had a profound negative impact on the Monarch's life cycle and overall population numbers.

6.6. Investigating the Link Between GMOs and Monarch Butterfly Decline

A. Herbicide-Resistant GMO Crops and Milkweed Loss

The widespread adoption of herbicide-resistant Genetically Modified Organisms (GMOs), such as corn and soybeans engineered to tolerate broad-spectrum herbicides like glyphosate (the active ingredient in Roundup), has been identified as a major contributor to the decline in milkweed availability. These GMO crops allow farmers to spray their fields with herbicides to control weeds without harming the crop itself. However, this practice has also led to the indiscriminate killing of milkweed plants that once grew abundantly in and around agricultural fields, which were significant breeding habitats for Monarch Butterflies. Several studies have highlighted the strong correlation between the increased use of herbicides in conjunction with herbicide-resistant GMOs and the subsequent decline in milkweed populations, which in turn has negatively impacted Monarch Butterfly numbers. Research indicates that a substantial percentage of the milkweed plants utilized by Monarch Butterflies were found in agricultural landscapes, making the loss of this habitat due to herbicide use particularly detrimental to their populations.

B. Scientific Studies and Findings

Initial scientific investigations in the late 1990s raised concerns about the potential harm of pollen from genetically modified *Bacillus thuringiensis* (Bt) corn to Monarch Butterfly larvae. A 1999 study reported that Monarch larvae in laboratory settings died after consuming milkweed plants dusted with Bt corn pollen. This finding sparked significant public debate about the safety of GMOs and their potential impact on non-target organisms like the Monarch Butterfly. However, subsequent field studies conducted by various research groups indicated that the actual risk to Monarch larvae from Bt corn pollen under real-world agricultural conditions is relatively low. These studies found that the levels of Bt corn pollen typically deposited on milkweed plants in and around cornfields were generally not high enough to cause significant mortality in Monarch larvae. While some early Bt corn varieties were found to have higher pollen toxicity, they were quickly replaced by other types with lower risk.

More recent research has suggested that the decline in both Monarch Butterfly and milkweed populations began several decades before the widespread introduction of herbicide-resistant GMO crops in the mid-1990s. These studies, utilizing long-term datasets from museum records and herbaria, indicate that the decline started around 1950, suggesting that factors other than herbicide use associated with GMOs have also played a significant role. Variables such as a decline in the number of farms, changes in farming practices predating GMOs, and weather patterns have also been identified as potentially important contributors to the trends in milkweed and monarch abundance. These findings highlight the complexity of the issue and suggest that while the use of herbicides with GMOs has likely exacerbated the decline in milkweed, it may not be the sole or primary driver of the long-term trends in Monarch Butterfly populations.

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CHAPTER – 7

Commercializing Biodiversity on Patent on Genetic Inventions

7.1. The International Legal and Policy Landscape Governing Patents and Biodiversity

The commercialization of biodiversity related to genetic inventions is significantly shaped by a complex web of international legal and policy frameworks, primarily cantered around the Convention on Biological Diversity (CBD) and its supplementary agreements.

The Convention on Biological Diversity (CBD), adopted in 1992, serves as a comprehensive global framework for biodiversity conservation and sustainable use. Its primary objectives are the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of benefits arising from the utilization of genetic resources. A cornerstone of the CBD is the recognition of the sovereign rights of states over their natural resources, including genetic resources within their borders. This principle grants national governments the authority to determine access to these resources and is subject to national legislation. The CBD also establishes the requirement for prior informed consent (PIC) from the contracting state providing the resources before access is granted. Furthermore, the convention mandates the fair and equitable sharing of benefits arising from the use of genetic resources with the contracting party providing them. This framework marked a significant shift from the historical perspective of genetic resources as freely available, establishing national ownership and the necessity for benefit-sharing, which has fundamentally altered the landscape for research and commercialization endeavours.

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, adopted in 2010 and entering into force in 2014, is a supplementary agreement to the CBD specifically focused on implementing the third objective of fair and equitable benefit-sharing. The protocol sets out obligations for its contracting parties related to access to genetic resources, benefit-sharing (which can be monetary, such as royalties, or non-monetary, such as sharing research results or technology transfer), and compliance with the access and benefit-sharing legislation of provider countries. It also includes provisions addressing traditional knowledge associated with genetic resources, recognizing the rights of indigenous and local communities to grant access to this knowledge and to a fair and equitable share of the benefits arising from its utilization. To facilitate the implementation of the Nagoya Protocol, the Access and Benefit-sharing Clearing-House (ABS Clearing-House) was established as a platform for exchanging information on access and benefit-sharing procedures and for monitoring the utilization of genetic resources. While the Nagoya Protocol aims to create legal certainty and transparency for both providers and users of genetic resources, its implementation at the national level has been uneven and faces challenges due to varying national interpretations and enforcement capacities.

A significant development in the international landscape is the recent adoption of the WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge on May 24, 2024. This treaty, the first WIPO treaty in over a decade, specifically addresses patent rights in the context of genetic resources and associated traditional knowledge. A key provision of the treaty is the establishment of a mandatory patent disclosure requirement, obligating patent applicants to disclose the country of origin or source of any genetic resources and the Indigenous Peoples or local community who provided any associated traditional knowledge if the claimed inventions are based on these resources or knowledge. This measure aims to enhance transparency in the patent system and facilitate the objectives of ABS legislation.

While patent offices will provide guidance on

this requirement, they will not be obligated to verify the authenticity of the disclosed information. Failure to disclose may be subject to appropriate measures, but the treaty includes a non-retroactivity clause, meaning its obligations will not apply to patent applications filed before it comes into force, subject to existing national laws on disclosure. The WIPO Treaty signifies a growing international recognition of the need for transparency regarding the origin of genetic resources and traditional knowledge within the patent system, potentially supporting the enforcement of ABS principles.

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), under the World Trade Organization (WTO), also plays a role in governing the patent protection of genetic inventions. The TRIPS Agreement mandates that members shall provide patent protection for inventions in all fields of technology, allowing for limited exceptions, such as for the protection of public order or morality, including the protection of health or the environment. It also requires the protection of plant varieties either by patents or by an effective *sui generis* system or a combination thereof. The patentability of life forms, particularly genes, has been a subject of intense debate, with potential conflicts arising between the objectives of the TRIPS Agreement, which focuses on promoting innovation and trade, and the CBD's goals of biodiversity conservation and equitable benefit-sharing. However, the TRIPS Agreement does offer flexibilities that allow member countries to exclude certain inventions from patentability, providing space for national policies that balance intellectual property rights with biodiversity concerns.

7.2. National Regulatory Frameworks: Implementing International Commitments

Countries around the world have adopted diverse approaches to implement the principles of the CBD and the Nagoya Protocol into their national legal frameworks. These national approaches vary significantly based on their specific biodiversity resources, economic priorities, and legal traditions.

India's Biological Diversity Act of 2002 provides a detailed example of national implementation. The Act mandates that foreign companies seeking to access biological resources in India for research or survey purposes, as well as anyone intending to provide the results of research obtained on Indian biological resources to foreign entities, must obtain approval from the National Biodiversity Authority (NBA). Furthermore, for inventions based on information or research results derived from biological resources acquired in India, all applicants, regardless of their nationality, are required to secure approval from the NBA before filing for any intellectual property rights, whether within or outside India. Violation of this disclosure requirement can lead to the rejection of the patent application or the invalidation of the granted patent, with opposition to a patent or revocation being possible based on these regulations.

Several countries and regions have also implemented disclosure requirements directly within their patent laws for inventions concerning genetic resources or traditional knowledge. For instance, the Andean Community, India, Brazil, the EU, and certain of its member states have introduced such legislation. These measures typically require patent applicants to disclose specific information about the genetic resources or traditional knowledge used in their invention, such as the country of origin or source. The primary objectives of these disclosure requirements are to prevent the erroneous granting of patents on inventions that are not novel or inventive in light of existing genetic resources or traditional knowledge, and to facilitate the fair and equitable sharing of benefits arising from their utilization. However, the effectiveness of these national disclosure requirements has been limited, partly because they generally apply only to patent applications filed nationally.

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National laws are instrumental in translating the broad principles of international agreements into concrete actions at the domestic level. However, the significant divergence in the scope and enforcement of these national regulations creates a complex and often challenging landscape for companies engaged in cross-border commercialization of biodiversity-related genetic inventions.

7.3. Strategies and Models for Commercializing Biodiversity-Related Genetic Inventions

Several strategies and models are employed for the commercialization of biodiversity-related genetic inventions, each with its own implications for access, benefit-sharing, and biodiversity conservation.

Licensing agreements represent a key mechanism for commercialization, allowing patent holders to grant permission to others to use their patented genetic inventions under specific terms and conditions. These agreements can be exclusive, granting rights to only one licensee, or non-exclusive, allowing multiple licensees. Cross-licensing, where two or more patent owners grant licenses to each other, can be particularly useful in fields with overlapping patent rights. In the context of genetic inventions, various models exist to facilitate access. Patent pools, for example, involve agreements where multiple patent owners license their patents to each other or to third parties willing to pay royalties, which can help overcome issues of stacking licenses and reduce transaction costs. The Golden Rice Pool, aimed at providing royalty-free licenses for humanitarian purposes in developing countries, and the SARS Corona Virus Pool, intended to facilitate access to technologies relevant to the pandemic, illustrate the potential of this model. Clearing-house mechanisms, such as information exchanges, technology-exchange platforms, and royalty-collection systems, also serve to connect providers and users of patented genetic technologies. The BiOS (Biological Innovation for Open Society) license, promoting cooperative invention and sharing of improvements, and the SNP Consortium, aiming to create a public map of human genome SNPs without proprietary rights, represent examples of such mechanisms. Careful management of intellectual property issues during the negotiation and drafting of access and benefit-sharing agreements is crucial to ensure equitable outcomes that respect the interests of resource providers.

Product development across various sectors heavily relies on biodiversity and genetic inventions. In the pharmaceutical industry, natural compounds derived from diverse organisms continue to be a vital source for drug discovery and development. Examples include the development of Calanolides, with potential for treating HIV and cancer, derived from a Malaysian rainforest tree. Agricultural biotechnology utilizes genetic resources to develop genetically modified crops with enhanced traits such as increased yield, drought tolerance, and pest resistance, contributing to food security. Industrial biotechnology leverages genetic resources for the development of specialty enzymes and molecules used in various industrial processes, including the production of specialized chemicals and bioremediation. The use of genetic resources in product development is rarely a simple process, often involving multiple research steps from accessing the resource to the final commercial product.

Research collaborations play a critical role in advancing genetic inventions related to biodiversity. These collaborations, spanning public and private sectors and often involving international partnerships, are essential for leveraging diverse expertise and resources. Indigenous knowledge, held by communities with generations of experience in managing and utilizing biodiversity, can provide valuable insights for research and development. Numerous collaborative projects focused on genomics and biodiversity are underway, such as the Darwin Tree of Life Project aiming to sequence the genomes of all known species in

Britain and Ireland, and the Vertebrate Genomes Project. These initiatives underscore the importance of equitable partnerships and benefit-sharing in research collaborations, particularly when they involve genetic resources and traditional knowledge from specific regions or communities.

Bioprospecting, the systematic exploration of biodiversity for new biological resources of social and economic value, is a key strategy for discovering genetic resources with commercial potential. This activity is undertaken across various industries, including pharmaceuticals, agriculture, and biotechnology, in search of new chemical compounds, genes, and organisms with potential applications. However, bioprospecting has also been associated with ethical concerns related to biopiracy, where genetic resources and traditional knowledge are exploited without prior informed consent and fair benefit-sharing with the originating countries and communities. Models for sustainable and ethical bioprospecting emphasize the importance of obtaining PIC, establishing mutually agreed terms for benefit-sharing, and ensuring that bioprospecting activities contribute to biodiversity conservation and the socio-economic development of the resource-providing countries.

7.4. Economic Valuation and Market Dynamics in the Commercialization of Biodiversity

The economic landscape surrounding the commercialization of biodiversity in the context of genetic patents is characterized by significant market opportunities, diverse revenue streams, and complex valuation challenges.

The global market for genome editing technologies, a key area related to genetic inventions and biodiversity, was estimated at USD 7.96 billion in 2023 and is projected to grow to USD

25.00 billion by 2030, with a significant adoption in agricultural biotechnology and a substantial share held by biotechnology and pharmaceutical companies. The market for marine biotechnology is also substantial, expected to reach $6.4 billion by 2025, spanning pharmaceuticals, biofuels, and chemicals. Bioprospecting activities and the resulting biodiversity-based products constitute a booming business across various sectors, including cosmetics and pharmaceuticals. These market analyses indicate the significant economic potential associated with the commercialization of biodiversity through genetic inventions.

Commercializing biodiversity-related genetic inventions can generate revenue through various streams. Royalties derived from licensing agreements for patented genetic technologies represent a direct revenue source for patent holders. The sale of products developed using these inventions, such as genetically modified crops or novel pharmaceuticals, forms another primary revenue stream. Furthermore, revenue-sharing models are increasingly being explored, particularly in the context of access and benefit-sharing agreements, where a portion of the profits generated from commercialized products is shared with the providers of the genetic resources or associated traditional knowledge. The concept of a multilateral fund, financed by contributions from companies benefiting from the use of digital sequence information (DSI) derived from genetic resources, is also gaining traction as a potential mechanism for revenue sharing and supporting biodiversity conservation.

Investment in the commercialization of biodiversity related to genetic patents is influenced by several considerations. Intellectual property rights, particularly patents, play a crucial role in attracting investment by providing a degree of exclusivity and the potential for a return on the often-substantial costs incurred during research and development. The return on investment in human genetics and genomics research has been shown to be significant, with substantial

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contributions to the US economy and job creation. However, balancing the incentives for innovation provided by patents with ensuring public access to essential technologies remains a critical consideration for sustainable investment in this field.

The valuation of genetic resources presents a complex challenge, particularly given their historical status as public goods. Traditional market mechanisms are often inadequate for determining the true value of these resources, which can have both direct use value in research and product development, and indirect use value in supporting ecosystem functions. Various methods are being explored to assess the economic value of genetic resources, including stated preference methods and analysis of their contribution to agricultural productivity and pharmaceutical development. Accurate valuation is crucial for informing conservation efforts and for establishing fair and equitable benefit-sharing agreements between providers and users of these resources.

7.5. Ethical Dilemmas in Patenting and Commercialization of Genetic Resources

The patenting and commercialization of genetic resources raise several profound ethical dilemmas that necessitate careful consideration.

At the heart of these dilemmas lies the principle of access and benefit-sharing, which calls for the fair and equitable sharing of benefits arising from the utilization of genetic resources.[6] While widely endorsed, the practical implementation of this principle faces numerous challenges. These include the complexity of establishing mutually agreed terms between diverse stakeholders, the difficulty in tracing the origin and use of genetic resources, and the varying interpretations of "fair and equitable" across different national contexts. Ensuring that benefits, both monetary and non-monetary, flow back to the providers of genetic resources, particularly developing countries and indigenous communities, remains a significant ethical and practical hurdle.

The issue of biopiracy, defined as the misappropriation of genetic resources or traditional knowledge for commercial gain without proper consent or compensation, represents a major ethical concern. This can take various forms, including the patenting of traditional knowledge or genetic resources that are already in the public domain, or accessing these resources from developing countries or indigenous communities without obtaining prior informed consent or establishing benefit-sharing agreements. Alleged cases of biopiracy, such as the patenting of neem extracts and turmeric's medicinal uses, highlight the ongoing power imbalances between developed and developing nations and the urgent need for stronger mechanisms to protect the rights of traditional knowledge holders and resource-rich countries.

The patenting of genes themselves is a particularly contentious ethical issue. Arguments against gene patenting often centre on the idea that genes are naturally occurring and part of the common heritage of humanity, thus should not be owned or controlled by private entities. Concerns also exist that gene patents can hinder scientific research and limit access to essential diagnostic tests and treatments, potentially leading to monopolies and higher healthcare costs. The landmark case of *Association for Molecular Pathology v. Myriad Genetics*, which challenged the patentability of human genes, underscores the ongoing ethical and legal debates in this area. Conversely, proponents argue that gene patents incentivize innovation by providing a mechanism for companies and researchers to recoup the substantial investments required for genetic research and development.

7.6. Case Studies: Successes and Failures in Commercializing Biodiversity

Numerous case studies illustrate both the successes and failures in the commercialization of biodiversity associated with patented genetic inventions across various sectors.

Successful commercialization attempts can be

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found in pharmaceuticals, agriculture, and biotechnology. In the pharmaceutical sector, the development of Captopril, an ACE inhibitor derived from the venom of the Brazilian pit viper, stands as a significant success, demonstrating how studying biodiversity can lead to major medical breakthroughs. The potential of Calanolides, compounds derived from a tree in the Malaysian rainforest, for treating HIV and certain cancers also highlights the value of natural resources in drug discovery. Trabectedin, an anti-cancer drug developed from a marine organism, represents another successful example of commercializing marine biodiversity through patented inventions. In agriculture, the soybean breeding industry in countries like Brazil, Canada, and the US has seen significant success through advances in crop technology. The development of gene-edited crops with enhanced traits like increased yield and resilience also holds promise for successful commercialization. The biotechnology sector boasts successes such as the discovery and commercialization of Pfu polymerase, an enzyme from a hyperthermophilic archaeon used in genetic engineering. Additionally, the development of Luminase, an enzyme used in the pulp and paper industry for bio bleaching, demonstrates the potential for environmentally beneficial products derived from biodiversity. These successes often involve substantial research and development, effective intellectual property protection, and increasingly, a consideration for ethical sourcing and benefit-sharing.

Conversely, several attempts to commercialize biodiversity have faced failures and challenges. In pharmaceuticals, Myriad Genetics encountered significant controversies and legal challenges regarding its patents on the BRCA genes associated with breast and ovarian cancer, highlighting issues related to restricted access and high costs. The commercialization of Hoodia, a cactus with appetite-suppressing properties, also faced setbacks. Agriculture has seen its share of unsuccessful attempts, such as the failure of a virus-resistant GM sweet potato project in Kenya. Controversies surrounding GM crops like Golden Rice and Bt cotton in various regions also underscore the challenges in gaining widespread acceptance and realizing the intended benefits. Numerous cases of alleged biopiracy, including W.R. Grace's patent on neem tree seed extract and attempts to patent the uses of turmeric and Basmati rice, illustrate the ethical and legal hurdles in commercializing biodiversity without proper consent and compensation. These unsuccessful attempts often highlight issues related to biopiracy, overly broad patent claims, lack of novelty, ethical concerns, technical limitations, and market acceptance challenges.

The case study of Dr. Paul Cox and the Falealupo community in Samoa provides an example of an ongoing effort to commercialize biodiversity with a strong focus on benefit-sharing. Research on the Mamala tree (Homalanthus nutans) led to the discovery of prostratin, a molecule with potential anti-viral properties. Agreements were established to ensure that the Falealupo community would benefit from any commercial success, including debt repayment, a rainforest preserve, and potential royalties. While the research has faced challenges in reaching commercialization, this case demonstrates a model for engaging local communities in bioprospecting research and emphasizing equitable benefit-sharing from the outset, highlighting both the potential and the complexities involved in such endeavours.

7.7. Navigating the Key Challenges in the Commercialization Process

The commercialization of biodiversity related to patented genetic inventions is fraught with several key challenges that stakeholders must navigate.

Regulatory hurdles represent a significant obstacle, as the landscape governing genetic inventions is complex, constantly evolving, and often fragmented across different jurisdictions. Navigating diverse national regulations for areas like gene editing and genetic testing can be particularly challenging for companies

seeking to commercialize products internationally. In the US, for example, gene-edited plants face oversight from the USDA, FDA, and EPA, each with specific regulatory requirements. The lack of harmonization across national regulatory frameworks can lead to delays and increased costs for commercialization.

Technological limitations also pose challenges in the development and application of genetic inventions related to biodiversity. While genetic engineering technologies have made remarkable progress, limitations persist in areas such as data analysis, scalability for industrial applications, and the potential for unintended consequences, including harm to non-target organisms or ecosystems. Specific technologies like synthetic biology and gene drives, while holding great promise, still face technical hurdles related to precise genetic manipulation, delivery methods, and potential ecological impacts. Continued research and development are necessary to overcome these limitations and ensure the safe and effective application of genetic inventions.

Market acceptance and public perception can significantly influence the success of commercializing biodiversity-related genetic inventions. Genetically modified organisms (GMOs), in particular, have faced challenges related to public perception and ethical concerns, impacting their market uptake in some regions. Societal concerns about the safety of genetically modified foods, the potential environmental impacts, and the ethical implications of altering living organisms can affect consumer preferences and regulatory decisions. Building public trust through transparent communication, addressing ethical considerations proactively, and demonstrating the benefits of these technologies are crucial for gaining market acceptance.

7.8. The Dual Role of Intellectual Property Rights (Patents) in Biodiversity Commercialization

Intellectual property rights, particularly patents, play a dual role in the commercialization of biodiversity related to genetic inventions, acting as both facilitators and potential hindrances.

Patents serve as crucial facilitators of commercialization by providing inventors with exclusive rights to their inventions for a determined period, typically 20 years. This exclusivity incentivizes innovation by allowing inventors to recoup the often-substantial investments made in research and development. Patents can also attract investment by providing legal security to companies that their intellectual property will be protected, fostering an environment where research and development can flourish. For small agrochemical businesses or startups, the strength of their patents can be particularly vital, as it can deter larger companies from simply copying their products. By establishing a proprietary leadership position in the market, patents can provide a commercial advantage and generate financial rewards through royalty-bearing licenses.

However, patents can also act as potential hindrances to the commercialization of biodiversity and can restrict access to genetic resources and related technologies. The increasing number of patents on genetic inventions has raised concerns about restricted access to research and healthcare, potentially leading to the creation of "patent thickets" where a dense web of overlapping patents held by different owners can stifle innovation and commercialization. Overly broad patent claims can also hinder the use of biodiversity for further research and development, potentially monopolizing genetic resources and limiting the development of new varieties or products. In agriculture, for instance, patents on specific gene variants can exclude other breeders from using them, potentially hindering conventional breeding practices. Furthermore,

patents on genetic technologies can limit domestic production of generic versions, impacting access to life-saving diagnostics and therapeutics, particularly in developing countries. The granting of patents on inventions derived from genetic resources or traditional knowledge without adequate compensation or permission from the original holders has also led to accusations of biopiracy, further highlighting the potential negative impacts of patents on equitable commercialization.

7.9. Impact of Commercialization on Biodiversity Conservation and Sustainable Use

The commercialization of biodiversity in the context of genetic patents holds the potential to both incentivize and negatively impact biodiversity conservation and sustainable use, depending on how it is approached and regulated.

Commercialization can potentially incentivize biodiversity conservation by assigning economic value to genetic resources and the ecosystems that harbor them. Market-based approaches, such as biodiversity credits that allow businesses to invest in ecosystem restoration, and sustainable bioprospecting models that ensure benefits flow back to conservation efforts, can help bridge the funding gap for biodiversity protection. Access and benefit-sharing mechanisms, as outlined in the Nagoya Protocol, can provide economic incentives for countries and communities to conserve their genetic resources, knowing that they will receive a fair share of any benefits arising from their use.

However, unsustainable commercialization practices can have significant negative impacts on biodiversity. Overexploitation of certain species for commercial purposes, such as in commercial fishing and the wildlife trade, can lead to drastic declines in populations and even extinctions. Habitat destruction, often driven by the expansion of agriculture and infrastructure to support commercial activities, is a leading cause of biodiversity loss. The promotion of monoculture in agriculture, often associated with the commercialization of patented seeds, can reduce genetic diversity and increase the vulnerability of crops to pests and diseases. If commercialization efforts prioritize short-term economic gains without considering the long-term ecological consequences, they can ultimately lead to the degradation and loss of the very biodiversity resources upon which future innovation and economic benefits depend.

7.10. The Crucial Role of Local and Indigenous Communities

Local and indigenous communities play an indispensable role in biodiversity conservation and the sustainable commercialization of genetic resources. Their traditional knowledge, accumulated over generations through a deep connection with their local environments, provides invaluable insights into the sustainable use and conservation of biodiversity. Recognizing, respecting, and integrating this knowledge into both conservation efforts and commercialization initiatives is crucial for ensuring their long-term success and sustainability.

Ethical and legal frameworks, such as the CBD and the Nagoya Protocol, emphasize the requirement for obtaining prior informed consent from local and indigenous communities before accessing their genetic resources or traditional knowledge. Furthermore, establishing fair and equitable benefit-sharing mechanisms with these communities is essential, ensuring that they receive a just return for their contributions to the commercialization process. When commercialization initiatives are designed to include local and indigenous communities as active partners and ensure they benefit directly, it can contribute to their well-being, support their economic development, and foster a sense of stewardship towards biodiversity conservation. Meaningful consultation, respect for traditional practices, and equitable distribution of benefits are therefore not just ethical imperatives but also critical factors for

the sustainable commercialization of biodiversity.

CHAPTER – 8

Intersection of Patent Law and Public Health: The Case of Genetic Inventions

8.1. Defining Genetic Inventions in Patent Law

Within the realm of patent law, "genetic inventions" encompass a range of innovations related to genetic material. In the United States, these can include patents on specific isolated gene sequences, their chemical composition, the processes for obtaining or utilizing them, or a combination of such claims. Biological patents, a broader category that includes genetic inventions, grant the patent holder the exclusive right to prevent others from making, using, selling, or importing the protected invention for a limited time. Historically, in the U.S., isolated natural biological substances, including genes, were patentable if sufficiently "isolated" from their natural state. However, a landmark Supreme Court ruling in 2013 in the case of *Association for Molecular Pathology v. Myriad Genetics* established that mere isolation of naturally occurring DNA sequences is not sufficient for patent eligibility, though synthesized DNA sequences not found in nature can still be patented.

Several examples illustrate the scope of genetic inventions that can be patented. **Gene sequences** themselves, such as isolated DNA, cDNA (complementary DNA), RNA, expressed sequence tags (ESTs), and single nucleotide polymorphisms (SNPs), have been subjects of patent claims. Early patents were granted on isolated natural substances like adrenaline and insulin. The *Myriad Genetics* case, however, significantly altered the landscape for patenting naturally occurring DNA. **Diagnostic tests** that detect genetic variations associated with diseases are another category of genetic inventions covered by patents. A prominent example is the BRCA1/2 test for assessing the risk of breast and ovarian cancers, which was previously under patent by Myriad Genetics. Patents in this area can cover specific mutations or methods of testing. **Gene therapies**, which involve altering genes to treat or prevent diseases, also fall under the umbrella of genetic inventions. Recombinant insulin, one of the first gene-based therapeutics, was also patented. **Genetically Modified Organisms (GMOs)**, including genetically engineered bacteria, plants, and animals, can also be patented. The *Diamond v. Chakrabarty* case in 1980 was a pivotal moment, establishing that genetically modified bacteria could be patented as a "man-made" invention. Finally, **research tools** used in genetic research, such as the polymerase chain reaction (PCR) and recombinant DNA technology, have also been patented. The Cohen/Boyer patents, which covered fundamental techniques for splicing genes, are a key example.

To be eligible for patent protection, genetic inventions must generally meet the criteria of novelty, non-obviousness (inventive step), and utility. For genetic inventions, the utility standards have often been higher. Additionally, the patent application must adequately describe the invention to enable someone skilled in the field to reproduce it, a requirement known as enablement and sufficiency of disclosure. A central debate in the patenting of genetic inventions revolves around whether a DNA sequence is a discovery of nature or a human invention. While discoveries of naturally occurring, phenomena are generally not patentable, isolated and purified genes with a demonstrated technical effect have often been considered inventions, although this view has been challenged and refined over time, as evidenced by the *Myriad* ruling.

The definition of a genetic invention under patent law is not static; it has undergone significant evolution, particularly shaped by landmark legal decisions such as *Diamond v. Chakrabarty* and *Association for Molecular Pathology v. Myriad Genetics*. The core distinction between a naturally occurring "product of nature" and a "man-made invention" remains a critical point of contention. Initially,

the patenting of isolated genes as "compositions of matter" was predicated on the argument that the act of isolation itself constituted sufficient human intervention to render them patentable. However, the *Myriad* case directly challenged this premise, leading to the prevailing understanding that naturally occurring gene sequences are not patentable solely by virtue of their isolation. This shift reflects a growing appreciation for the informational content inherent in DNA and its fundamental role within the natural world. Nevertheless, the continued patentability of cDNA and other forms of modified genetic material underscores that the boundary between discovery and invention in the field of genetics remains a subject of ongoing interpretation and legal development[4].

8.2. The Rationale Behind Granting Patents for Genetic Inventions

The primary rationale for granting patents on genetic inventions centres on the idea of **incentivizing innovation**. Patents provide a temporary period of market exclusivity, allowing companies and researchers to potentially recoup the substantial costs and time invested in the research and development of genetic technologies. It is argued that without the prospect of patent protection, there would be significantly less incentive for private entities to invest in the often high-risk and long-term endeavour of genetic research.

Patents are also believed to play a crucial role in **promoting research and development (R&D)** within the biotechnology and pharmaceutical industries. Bringing new drugs and diagnostic tools to market can involve hundreds of millions of dollars in investment. Patents can attract investment from both companies and individuals by offering the potential for a return on that investment through the exclusive rights granted.

Furthermore, the patent system encourages **disclosure and transparency**. In exchange for the grant of exclusive rights, inventors are required to publicly disclose the details of their invention. This disclosure can prevent the duplication of research efforts and can facilitate further innovation by allowing other scientists to build upon the disclosed knowledge.

Finally, patents can be instrumental in **facilitating technology transfer and commercialization** of basic research findings into products and services that can benefit public health. By providing a degree of market exclusivity, patents can attract venture capital and foster the development of public-private partnerships necessary to bring genetic technologies from the laboratory to the patient.

The fundamental justification for patenting genetic inventions rests on the idea that it provides necessary incentives for innovation and investment in a field characterized by high risk and potentially high reward. However, the empirical evidence regarding the direct impact of gene patents on innovation is a subject of ongoing debate, with some studies suggesting a limited or even negative effect in certain contexts. The traditional economic argument supporting patents as a driver of innovation is frequently invoked in the context of genetic inventions, particularly given the substantial financial resources required for research and development. The underlying principle is that the exclusive rights granted by patents enable companies to recoup their investments and subsequently reinvest profits into further research endeavours. Nevertheless, research indicates that the influence of gene patents on subsequent innovation may not always be beneficial. For instance, the National Centre for Human Genome Research (NCHGR) previously advised against patenting raw genomic sequence data, expressing concerns about a potential "chilling effect" on the development of future useful products. This suggests a more complex relationship where patents might incentivize initial discoveries but could potentially hinder downstream research and development by creating intricate webs of patent rights and restricting access to foundational genetic information.[5]

8.3. Potential Negative Impacts of Patents on Genetic Inventions on Public Health

While patents on genetic inventions aim to foster innovation, they also carry potential negative impacts on public health. One significant concern is **limited access to essential medicines and diagnostic tools**. Patents can create monopolies, allowing patent holders to set high prices for life-saving medicines and crucial diagnostic tests, making them unaffordable or inaccessible to many patients. The case of Myriad Genetics, which held patents on the BRCA1/2 genes, exemplifies this issue, with the cost of testing reaching several thousand dollars. Exclusive licensing practices can further restrict access by limiting the number of laboratories or providers authorized to offer a particular test or therapy. Moreover, royalties and licensing fees associated with patented genetic inventions can contribute to increased healthcare costs.

Another significant concern is that patents on genes or genetic sequences can **hinder research and development**. The existence of "patent thickets," where numerous patents cover related genes or technologies, can create a complex and costly landscape for researchers seeking to advance scientific understanding and develop new applications. Researchers might choose to avoid working on patented genes altogether to circumvent potential legal issues and licensing negotiations, thereby slowing down the pace of scientific discovery. Furthermore, when a single entity holds a patent on a gene, it can lead to delays in obtaining medical results due to the centralized nature of testing.

The **monopolization of genetic information** is another critical issue associated with gene patents. Granting exclusive rights to fundamental genetic information raises ethical concerns about treating genes, which are essential to human biology, as mere commodities. Patent holders may also exert control over the use and interpretation of genetic data, potentially hindering the broader scientific understanding of these complex biological systems.

Finally, limited access and the absence of competition resulting from gene patents can negatively impact the **quality of healthcare**. When a single entity holds exclusive rights to a genetic test, patients may be unable to obtain confirmatory testing from another laboratory, which is a crucial aspect of quality assurance in medical diagnostics. Furthermore, patent holders may effectively dictate the standard of care by controlling which tests are available and how they are performed.

The intended benefits of patents on genetic inventions to stimulate innovation are juxtaposed with significant risks to public health, including restricted access, increased costs, impeded research, and the monopolization of fundamental biological information. The case of Myriad Genetics serves as a stark illustration of these potential negative consequences.

8.4. Specific Examples or Case Studies of Patents on Genetic Inventions Affecting Public Health Outcomes

While the primary aim of genetic patents is to incentivize innovation, their impact on public health has been a subject of considerable scrutiny, with both potential benefits and significant drawbacks.

On the positive side, it is argued that patents can indeed incentivize the development of novel diagnostic and therapeutic inventions that might not otherwise be pursued due to the high costs and risks involved. A notable example is the development of recombinant human insulin, which was facilitated by early patents in biotechnology. Patent protection in the biotechnology sector has also been credited with attracting substantial private investment, which has fuelled further innovation. In some instances, patent holders have argued that their patented technologies have led to improvements in the accuracy and efficiency of testing compared to earlier methods.

However, numerous case studies highlight the

negative impacts of genetic patents on public health. The case of **Myriad Genetics and its patents on the BRCA1 and BRCA2 genes** is perhaps the most well-known example. For many years, Myriad held exclusive control over testing for these genes, which are associated with an increased risk of breast and ovarian cancer. This monopoly led to high testing costs, limited the availability of second opinions, and was argued to have hindered further research on these critical genes. The American Civil Liberties Union (ACLU) filed a lawsuit challenging these patents, arguing that human genes are products of nature and should not be patentable. In 2013, the U.S. Supreme Court ruled against the patentability of naturally occurring DNA, a decision that significantly impacted the landscape of gene patenting.

Another case involved **hereditary hemochromatosis**, where the enforcement of a gene patent led to a reduction in the number of laboratories offering testing for this condition. Similarly, patents related to **Canavan disease**, a rare genetic disorder, sparked controversy due to concerns about restricted access to testing. The **COVID-19 pandemic** also highlighted potential negative impacts, with concerns raised about how patents on viral genetic material could impede the rapid development and widespread accessibility of diagnostics and vaccines. Furthermore, patents on innovative gene editing technologies like **CRISPR** have raised concerns about potential limitations on their use in research and therapy.

These case studies illustrate the complex and often contentious relationship between genetic patents and public health. While patents can provide incentives for innovation, their broad application and enforcement can lead to significant barriers in accessing essential healthcare technologies and hindering further scientific progress.

8.5. Analysing the Legal and Ethical Debates Surrounding the Patenting of Genetic Material

The patenting of genetic material has ignited significant legal and ethical debates. At the heart of the ethical arguments lies the question of **ownership of life**. Many argue that genes, as fundamental building blocks of life, should not be owned or treated as commodities. This perspective often draws a distinction between genetic identity and personal identity, suggesting that while a patent might cover a specific gene sequence, it does not confer ownership over an individual's genetic makeup. Furthermore, some argue that the human genome represents a common heritage of humanity and should not be subject to private ownership.

The patenting of genetic material also raises concerns related to **human rights**, particularly the right to health and access to healthcare. High costs and limited access to essential medicines and diagnostic tools resulting from gene patents can disproportionately affect vulnerable populations, thus undermining the principle of equitable access to healthcare. This can also place a significant burden on healthcare systems and public funding for genetic testing.

A central challenge lies in **balancing innovation and access**. While patents are intended to incentivize the costly and time-consuming research and development of genetic technologies, concerns exist about whether they are truly necessary for driving innovation in this field. The debate continues on how to best foster scientific progress in genetics while ensuring that the resulting technologies are accessible and affordable to those who need them.

The ethical considerations surrounding gene patenting are deeply intertwined with legal interpretations of patent law. The fundamental question of whether human genetic material should be patentable touches upon deeply held beliefs about the nature of life and the right to

health. The tension between the desire to incentivize innovation through patent protection and the imperative to ensure equitable access to healthcare advancements remains a central challenge for policymakers and legal scholars alike.

8.6. Examining Existing Legal Frameworks and Regulations in Different Countries

The legal frameworks and regulations concerning the patenting of genetic inventions vary significantly across different countries, reflecting diverse legal traditions, ethical considerations, and public policy priorities.

In the **United States**, the legal landscape has been significantly shaped by landmark Supreme Court cases. *Diamond v. Chakrabarty* established the principle that living organisms could be patentable if "made by man." However, the more recent case of *Association for Molecular Pathology v. Myriad Genetics* ruled that isolated naturally occurring DNA sequences are not patentable because they are products of nature. Conversely, the Court held that cDNA, a synthetic form of DNA, is patentable. The U.S. Patent and Trademark Office (USPTO) also has specific guidelines regarding the utility requirement for patenting genetic inventions.

In **Europe**, the legal framework is guided by the European Union's Biotech Directive, which allows for the patenting of natural biological products, including gene sequences, if they are isolated from their natural environment or produced through a technical process. The European Patent Office (EPO) examines patent applications based on criteria of novelty, inventive step, and industrial applicability. However, patents can be refused if the invention is deemed contrary to public order or morality.

Australia initially affirmed the patentability of isolated, naturally occurring DNA sequences, but the High Court of Australia later overturned this, ruling that naturally occurring genes cannot be patented. The Australian framework requires that patentable biological inventions must be isolated or synthetically produced and have a demonstrated use resulting from technical intervention.

In **Canada**, while the Canadian Intellectual Property Office (CIPO) grants patents for isolated gDNA and cDNA, the Supreme Court of Canada has not yet issued a definitive ruling on the patentability of genes. However, a settlement in 2016 concerning patents related to Long QT syndrome allowed Canadian health institutions to conduct testing on a non-profit basis, indicating a complex legal environment.

Japan examines patent applications for biological inventions, including those related to genetics, under general patent guidelines, with specific guidelines for biology-related inventions. Patented inventions must be industrially applicable, but methods of surgery, therapy, and diagnosis of human diseases are excluded.

The **TRIPS Agreement**, an international agreement administered by the World Trade Organization, requires member countries to have intellectual property protection for most biological innovations, including biotechnological inventions. However, it also allows for certain exceptions and flexibilities, which contribute to the variations observed in national legal frameworks.

8.7. Investigating Alternative Models or Mechanisms for Promoting Research and Development

Given the potential downsides of relying solely on the traditional patent system to incentivize research and development in genetic technologies, several alternative models and mechanisms have been proposed and, in some cases, implemented. **Open science initiatives** emphasize the free and unrestricted sharing of research data, materials, and findings to accelerate the pace of scientific discovery. The establishment of open access databases and collaborative research platforms can foster a more rapid dissemination of knowledge and potentially reduce redundancy in research

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efforts.

Government funding and public research play a crucial role in supporting both basic and translational research in genetics and biotechnology. Increased public investment in these areas could potentially lessen the reliance on patent-driven innovation, particularly for research with significant public health implications.

Patent pools and clearinghouses offer mechanisms for pooling patents related to a specific technology, allowing broader access to these technologies for research and development, often under fair, reasonable, and non-discriminatory (FRAND) terms. This approach can help to overcome the challenges posed by patent thickets and facilitate innovation.

Compulsory licensing is another tool that can be used in certain circumstances, particularly in public health emergencies, to ensure access to essential medicines and diagnostics, even when they are under patent protection. This mechanism allows governments to authorize the use of a patented invention without the patent holder's consent, subject to certain conditions and the payment of reasonable royalties.

Research use exemptions in patent law aim to allow non-commercial research activities on patented inventions without infringing the patent. Strengthening and clarifying the scope of these exemptions could help to ensure that patents do not unduly hinder basic scientific inquiry.

Alternative incentive mechanisms such as **prizes and rewards** for significant breakthroughs in genetic research and development could also be explored. These approaches could provide recognition and financial support for innovation without granting exclusive rights that might limit access.

Finally, encouraging **socially responsible licensing practices** among companies and institutions that hold genetic patents could promote wider access to these technologies. This could include offering licenses on more affordable terms, particularly for applications that address critical public health needs, or granting non-exclusive licenses to allow for broader use.

Exploring these alternative models and mechanisms is crucial for finding a more balanced approach that fosters innovation in genetic technologies while ensuring that the resulting benefits are accessible to all and serve the broader public health needs.

8.8. Considering the Role of International Organizations and Initiatives

International organizations and initiatives play a vital role in addressing the complex intersection of genetic patents and global public health. The **World Health Organization (WHO)** has been actively involved in discussions and initiatives concerning intellectual property and public health, particularly in the context of access to medicines and promoting research for diseases that disproportionately affect developing countries.

The **World Intellectual Property Organization (WIPO)**, a specialized agency of the United Nations, works to develop a balanced and accessible international intellectual property system. Its work on international patent law has significant implications for the patenting of genetic inventions and their impact on public health.

The **United Nations (UN)** has various initiatives and declarations related to human rights, access to health, and the role of technology in development, which provide a broader ethical and policy context for considering the intersection of genetic patents and public health.

The **Human Genome Project (HGP)**, an international collaborative research program, aimed to map the entire human genome and made its data publicly available, significantly influencing the debate around gene patenting

and highlighting the importance of open access to fundamental genomic information.

Numerous **international research collaborations** focus on understanding and addressing genetic diseases and public health challenges on a global scale. These collaborations often involve the sharing of data and expertise across borders, which can be crucial for advancing scientific knowledge and developing effective interventions.

Furthermore, there are ongoing **efforts to promote access and equity** in the realm of genetic technologies and the benefits of genomic research, particularly for developing countries. These efforts aim to ensure that the advancements in genetic research translate into tangible benefits for all populations, regardless of their economic status or geographical location.

Through their various activities, these international organizations and initiatives contribute to shaping the global discourse and policy landscape surrounding genetic patents and public health, striving to find solutions that balance the need for innovation with the imperative of ensuring equitable access to healthcare for all.

CHAPTER – 9

Patenting Genetic Inventions in India: Legal Framework, International Conventions, and Ethical Considerations

9.1. Patentability Criteria for Genetic Inventions under the Indian Patents Act 1970

To be eligible for patent protection in India, a genetic invention must satisfy the general criteria of patentability as outlined in Section 2(1)(j) of the Patents Act 1970, which includes novelty, inventive step, and industrial applicability.

For a genetic invention to be considered **novel**, it must be new and not anticipated by prior art, meaning it has not been disclosed to the public in any form before the date of filing the patent application. Prior art encompasses any information that has been made publicly available through publication, public use, or prior patent filings. Determining novelty in the context of genetic sequences and biological materials can be particularly challenging, especially when dealing with substances that occur naturally. While a gene in its native state within an organism is not considered novel, the isolation and purification of a gene from its natural environment might meet the criteria for novelty if the process of isolation and the resulting purified form were previously unknown. However, Section 3(c) of the Patents Act explicitly excludes the "discovery of any living thing or non-living substance occurring in nature" from patentability, creating a complex interplay between the concept of novelty and the exclusion of discoveries.

The criterion of **inventive step** requires that the genetic invention involve a technical advance compared to existing knowledge or have economic significance, and it must not be obvious to a person skilled in the art. A person skilled in the art is defined as someone having ordinary technical knowledge and experience in the specific field of the invention. In the context of biotechnology and genetics, this would typically refer to a researcher or scientist with a standard level of expertise in the relevant area. Assessing non-obviousness for genetic inventions, such as isolated genes, modified sequences, and biotechnological processes, involves determining whether a person skilled in the art would have considered the invention an obvious development based on the existing state of knowledge. While the isolation of DNA sequences using well-known techniques might generally be considered obvious, the isolation of a specific gene with a previously unknown function or a significantly improved property might be deemed to involve an inventive step.

Finally, the genetic invention must possess **industrial applicability**, meaning it is capable of being made or used in some kind of industry, including manufacturing, agriculture, or healthcare. This criterion necessitates that the invention has practical utility and is not merely

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a theoretical or abstract concept. For genetic inventions, demonstrating industrial applicability often involves disclosing a specific and substantial use for the gene sequence, diagnostic method, or therapeutic application being claimed. A mere identification of a gene sequence without any known function or practical application would likely not satisfy this requirement. The utility standards for genetic inventions are often considered higher than for other types of inventions, requiring a credible and well-established real-world use.

The rapid advancements and evolving nature of biotechnology present ongoing challenges to the application of these traditional patentability criteria to genetic inventions. One significant hurdle lies in clearly distinguishing between a "discovery" of something that already exists in nature and a genuine "invention" that involves human ingenuity and a novel application.

Furthermore, the standard of a "person skilled in the art" can be difficult to apply in a field where knowledge and techniques are constantly advancing.

9.2. Key Provisions of the Indian Patents Act 1970 Relevant to Genetic Inventions

The Indian Patents Act 1970 contains several key provisions that are particularly relevant to the patenting of genetic inventions, most notably Section 3, which lists categories of inventions that are not patentable, and Section 10, which outlines the requirements for patent specifications.

Section 3 of the Act enumerates various exclusions to patentability, many of which have direct implications for genetic inventions. **Section 3(b)** excludes inventions that are contrary to public order or morality or which cause serious prejudice to human, animal, or plant life or health or to source 3, 22, 23, 24] This provision is particularly relevant to genetically modified organisms (GMOs) and processes that raise ethical concerns or have the potential for harmful consequences. The interpretation of the "morality clause" in the context of biotechnology is often debated, as seen in cases involving genetic modifications. **Section 3(c)** explicitly states that "the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature" is not patentable. This section is crucial for genetic material, as it necessitates a clear distinction between the mere identification of a naturally occurring gene or DNA sequence (considered a discovery) and an invention that involves a significant degree of human intervention, such as genetic modification or a novel application. While isolated and purified genes might be considered patentable under certain circumstances, the baseline exclusion of naturally occurring substances poses a significant hurdle. **Section 3(d)** further restricts patentability by stating that "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance" is not patentable. This provision has implications for patents on modified genetic sequences that do not demonstrate a significant improvement in efficacy compared to known sequences, as exemplified by the landmark *Novartis AG v. Union of India* case. **Section 3(j)** specifically excludes "plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties, and species and essentially biological processes for production or propagation of plants and animals" from patentability. This section allows for the patenting of microorganisms, including genetically modified microorganisms, but excludes plants and animals, impacting the landscape of agricultural biotechnology, as seen in the *Monsanto Technology LLC v. Nuziveedu Seeds Ltd.* case. Finally, **Section 3(k)** excludes "a mathematical or business method or a computer program per se or algorithms" from patentability, which is relevant to bioinformatics tools and software used in genetic analysis, although software with

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a demonstrable technical contribution may be patentable.

Section 10 of the Patents Act outlines the requirements for patent specifications, which are crucial for inventions involving biological material. It mandates a full and particular description of the invention, its operation, and the best method of performing it. For inventions involving biological material, specific requirements include the mandatory disclosure of the source and geographical origin of the biological material used in the invention. Furthermore, under certain conditions, such as when the biological material is not fully described in the specification and is not available to the public, the applicant may be required to deposit the biological material with a recognized depository. If a deposit is made, a reference to it, including the depository details and accession number, must be included in the patent specification within a specified timeline. For genetic inventions involving genes, nucleotide sequences, and polypeptide sequences, the patent application must also include a sequence listing in electronic form.

The numerous exclusions under Section 3 demonstrate a cautious approach to patenting genetic inventions in India, reflecting a policy aimed at safeguarding public health, morality, biodiversity, and traditional knowledge. The strict interpretation of Section 3(c) emphasizes the need for more than just the identification of naturally occurring substances to qualify for patentability. The requirements under Section 10 for disclosing biological material, particularly its source and origin, underscore the importance of aligning patent law with biodiversity conservation efforts and preventing the misappropriation of biological resources.

9.3. International Conventions and Treaties Pertaining to Genetic Patents

India's patent law framework for genetic inventions is significantly influenced by its membership in various international conventions and treaties.

The **TRIPS Agreement**, administered by the World Trade Organization (WTO), sets minimum standards for intellectual property protection among its member countries, including India.[1] Article 27 of the TRIPS Agreement mandates that patents should be available for inventions in all fields of technology, including biotechnology. However, it also allows for certain flexibilities, such as the exclusion from patentability of inventions that are contrary to public order or morality (Article 27.2) and plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals (Article 27.3(b)). India's Patents Act was amended several times between 1999 and 2005 to align with its obligations under the TRIPS Agreement, including the introduction of product patents in the pharmaceutical and biotechnology sectors. India has also strategically utilized the flexibilities within TRIPS, such as those related to compulsory licensing and the provisions of Section 3(d) of the Patents Act, to balance patent rights with public health concerns and ensure access to affordable medicines.

The **Convention on Biological Diversity (CBD)**, to which India is a signatory, aims to conserve biological diversity, promote the sustainable use of its components, and ensure the fair and equitable sharing of benefits arising from the utilization of genetic resources. Article 15 of the CBD recognizes the sovereign rights of states over their natural resources and emphasizes the importance of prior informed consent (PIC) and mutually agreed terms (MAT) for access to genetic resources. The principles of the CBD have significantly influenced India's approach to patenting genetic resources, leading to the enactment of the Biological Diversity Act 2002. This Act mandates the disclosure of the source and geographical origin of biological material in patent applications and requires prior approval from the National Biodiversity Authority (NBA) for certain entities seeking to access and utilize India's biological resources for research or commercial purposes, including patenting. The CBD also emphasizes the principle of benefit

sharing, ensuring that the benefits derived from the use of genetic resources are shared fairly and equitably with the providers, including local communities and conservers.

India is also a signatory to the **Paris Convention for the Protection of Industrial Property**, which provides for the principles of national treatment and the right of priority for patent applications. This convention allows Indian applicants to claim priority for a patent application filed in India when filing in other member countries within a 12-month period, and vice versa.

The **Patent Cooperation Treaty (PCT)** facilitates the filing of international patent applications, including those for genetic inventions, through a unified procedure. India is a member of the PCT, and the Indian Patent Office acts as a receiving office, as well as an International Searching Authority (ISA) and International Preliminary Examining Authority (IPEA) for PCT applications.

Finally, the **Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure** streamlines the process for depositing microorganisms required for patent applications. This is particularly relevant for patenting genetically modified microorganisms in India, as it provides a mechanism for fulfilling the disclosure requirements of patent law when the invention involves biological material that cannot be adequately described in writing.

India's patent law framework for genetic inventions is thus intricately linked with its international obligations and commitments. The TRIPS Agreement necessitates providing patent protection in biotechnology, while the CBD mandates the protection of biodiversity and the fair sharing of benefits. The Paris Convention and the PCT facilitate international patenting, and the Budapest Treaty addresses the specific requirements for biological inventions involving microorganisms.

9.4. Implementation and Interpretation of International Conventions in India

India has taken significant steps to align its patent law with its international obligations. The Patents Act 1970 has been amended to incorporate provisions of the TRIPS Agreement, most notably the introduction of product patents in the pharmaceutical and biotechnology sectors. Furthermore, the enactment of the Biological Diversity Act 2002 serves as a key mechanism for implementing the principles of the CBD within the Indian legal framework, particularly concerning access to genetic resources and benefit sharing. India also adheres to the procedures and requirements of the Paris Convention and the PCT, facilitating international patent applications for genetic inventions. The recognition of the Budapest Treaty further streamlines the patenting process for inventions involving microorganisms.

The Indian Patent Office (IPO) plays a crucial role in the implementation and interpretation of these international conventions within the domestic context. It issues guidelines and manuals for the examination of patent applications, including the "Guidelines for Examination of Biotechnology Applications for Patents," which provide specific guidance on assessing novelty, inventive step, and industrial applicability for genetic inventions. The IPO also functions as a receiving office and an International Searching Authority/International Preliminary Examining Authority under the PCT, ensuring that Indian patent practices align with global standards. Moreover, the IPO is responsible for ensuring compliance with the disclosure requirements for biological material, including the source and origin, and for requiring permission from the National Biodiversity Authority for inventions based on Indian biological resources.

The Indian judiciary also plays a vital role in interpreting the provisions of the Patents Act and international conventions through various case laws. Landmark cases have provided clarifications on the patentability criteria for genetic inventions and the application of Section 3 exclusions, such as the *Novartis* case concerning enhanced efficacy. The judiciary

also addresses disputes related to patent infringement and revocation in the context of biotechnology, further shaping the practical application of the law.

The Indian Patent Office's guidelines serve as a vital link between the broad principles of the Patents Act and the specific challenges posed by genetic inventions, offering a practical framework for examiners. The judiciary's role in interpreting the law, particularly in significant cases, provides crucial precedents that guide the application of patent law to this complex field. The implementation of the CBD through the BDA adds a unique dimension to the patenting of genetic inventions in India, ensuring that biodiversity protection and benefit sharing are integral considerations in the patenting process.

9.5. Key Doctrines and Legal Principles in the Examination of Genetic Patents

Several key doctrines and legal principles are applied by the Indian Patent Office and courts when examining patent applications for genetic inventions.

The **doctrine of novelty** requires a thorough examination of prior art to ascertain whether the genetic invention has been previously disclosed. This assessment considers novelty in the context of gene sequences, proteins, and other biological molecules, adhering to the principle of absolute novelty under Indian patent law.

The assessment of **inventive step** involves evaluating the technical advancement or economic significance of the genetic invention and determining whether it would have been obvious to a person skilled in the art of biotechnology. This requires considering the level of skill and common general knowledge prevalent in the relevant field at the time of the invention.

The **requirement of industrial applicability** necessitates demonstrating that the genetic invention can be made or used in an industry, with a specified practical utility for gene sequences, diagnostic methods, or therapeutic applications. Disclosing a specific and substantial utility is crucial for meeting this requirement.

The **public trust doctrine**, while not explicitly codified in the Patents Act, raises debates about whether fundamental genetic resources, such as the human genome, should be subject to private ownership through patents, as these resources are often considered to belong to the public.

Finally, the **principles of benefit sharing**, as mandated by the CBD and the Biological Diversity Act 2002, are increasingly relevant in the examination of genetic patents, particularly those involving biological resources sourced from India. These principles aim to ensure a fair and equitable distribution of benefits arising from the use of such resources, often through mechanisms involving monetary and non-monetary compensation to local communities and knowledge holders.

The specialized knowledge required to assess novelty and inventive step in the complex field of biotechnology underscores the need for examiners with expertise in genetics and related areas. The public trust doctrine introduces a philosophical debate about the boundaries of patentability concerning essential genetic resources. The principles of benefit sharing add an important ethical layer to the patenting of genetic resources, particularly those originating from India, reflecting a commitment to equity and the recognition of traditional knowledge.

9.6. Case Studies and Legal Precedents in India

Several case studies and legal precedents in India have significantly shaped the understanding and application of patent law to genetic inventions.

The Supreme Court's decision in **Novartis AG v. Union of India (2013)** remains a landmark case, emphasizing the strict interpretation of Section 3(d) of the Patents Act. The court rejected Novartis's patent application for the beta-

crystalline form of imatinib mesylate (Gleevec), a cancer drug, holding that the new form did not demonstrate a significant enhancement in therapeutic efficacy compared to the known alpha-crystalline form. This case has had a lasting impact on pharmaceutical patents in India, preventing the "evergreening" of patents through minor modifications without substantial improvement.

In **Monsanto Technology LLC v. Nuziveedu Seeds Ltd. (2018)** , the Delhi High Court addressed the patentability of genetically modified plants and seeds under Section 3(j) of the Patents Act. The court clarified that plants and seeds are excluded from patentability under this section, with the exception of microorganisms. This ruling has significant implications for the agricultural biotechnology industry in India, limiting the scope of patent protection for genetically modified crops.

Dimminaco A.G. v. Controller of Patents & Designs (2002) is another important precedent, where the Calcutta High Court allowed the patenting of a process for manufacturing a product containing living organisms. This case was significant in establishing the patentability of certain biotechnological processes in India, marking a shift in the patent office's approach to inventions involving living entities.

Beyond these landmark cases, numerous other legal precedents have contributed to the interpretation of novelty, inventive step, and industrial applicability in the context of genetic inventions. Courts have also addressed disputes related to the disclosure of biological material and compliance with the Biological Diversity Act, as well as patent infringement cases involving genetic inventions. These cases collectively demonstrate the ongoing judicial engagement with the complex legal and scientific issues surrounding the patenting of genetic inventions in India. Recent cases like *University Health Network vs Adiuvo Diagnostics Private Limited* on jurisdictional aspects and *Microsoft Technology Licensing vs Assistant Controller of Patents and Designs* on the patentability of software related to biotechnology further illustrate the evolving legal landscape.

These case studies highlight the Indian judiciary's role in interpreting and applying the provisions of the Patents Act to the specific context of genetic inventions. The *Novartis* case underscores the strict standards for pharmaceutical patents, while the *Monsanto* case clarifies the exclusions for plants and seeds. The *Dimminaco* case represents an early recognition of the patentability of certain biotechnological processes. The broader body of case law reflects a continuous effort to balance the promotion of innovation with public interest concerns in this rapidly advancing field[5].

9.7. Guidelines and Clarifications from the Indian Patent Office

The Indian Patent Office (IPO) issues guidelines and clarifications to provide a framework for the examination of biotechnology patent applications, including those related to genetic inventions.

The "Guidelines for Examination of Biotechnology Applications for Patents" outline the IPO's approach to assessing the patentability criteria of novelty, inventive step, and industrial applicability for biotechnology inventions, including genetic material. These guidelines offer specific instructions on the patentability of gene sequences, proteins, and genetically modified organisms. Notably, they emphasize the requirement of "substantial human intervention" for patenting isolated biological material, suggesting a stricter standard than mere isolation. The guidelines also highlight the consideration of traditional knowledge during the patent examination process, aligning with India's commitment to protecting its cultural heritage.

The Manual of Patent Office Practice and Procedure provides detailed procedures for filing and prosecuting patent applications involving biological material. It includes specific

information on the requirements for disclosing the source and origin of biological material, as well as guidelines on the deposit of microorganisms under the Budapest Treaty.

The IPO may also issue other relevant notices and clarifications regarding the patenting of genetic inventions, providing updates on the examination process and timelines for biotechnology patent applications.

The IPO's guidelines serve as a crucial tool for ensuring consistency and clarity in the examination of biotechnology patents, offering a practical interpretation of the Patents Act in this specialized field. The emphasis on "substantial human intervention" reflects a cautious approach to patenting naturally occurring biological material. The consideration of traditional knowledge underscores India's commitment to preventing the misappropriation of its cultural and biological heritage through the patent system.

9.8. Ethical and Societal Considerations in Patenting Genetic Inventions in India

The patenting of genetic inventions in India is accompanied by significant ethical and societal considerations.

Ethical implications include concerns about the "commodification of life" and the patenting of genetic material that is naturally occurring. Opponents argue that patenting genes can diminish human dignity by treating fundamental components of life as mere commercial commodities. There are also concerns that gene patents could hinder scientific research and restrict access to essential genetic testing and therapies, potentially jeopardizing public health. Issues of privacy and consent related to genetic information further complicate the ethical landscape. The "morality clause" in Section 3(b) of the Indian Patents Act reflects some of these ethical concerns and can be invoked to refuse patents on inventions considered contrary to morality.

The societal impacts of patenting genetic inventions in India are far-reaching. In agriculture, the patenting of genetically modified crops and seeds raises concerns about farmers' rights, food security, and the potential for corporate control over essential agricultural resources. The patenting of genetic resources also has implications for biodiversity conservation and the potential for biopiracy, where traditional knowledge and biological resources are exploited without fair compensation. In the realm of public health, gene patents can affect access to affordable healthcare, including genetic diagnostics and treatments, by creating monopolies that drive up prices. Balancing commercial interests with the broader public good remains a central challenge in this context. Public opinion and ongoing debates in India reflect the complex and often conflicting perspectives on gene patenting.

These ethical and societal considerations are reflected in the restrictive provisions of Section 3 of the Indian Patents Act, which excludes certain categories of inventions from patentability. Judicial decisions, such as the *Novartis* case, demonstrate a cautious approach to patenting in areas with significant public health implications. The Biological Diversity Act further addresses concerns about biopiracy and benefit sharing, reflecting India's commitment to its rich biodiversity and traditional knowledge.

The ethical dilemmas surrounding gene patenting in India highlight the tension between incentivizing scientific advancement and protecting fundamental principles of human dignity and equitable access. The societal impacts, particularly in agriculture and healthcare, necessitate a careful regulatory approach that balances innovation with the broader public interest. Indian legislation and judicial interpretations reveal a tendency towards a more restrictive stance on gene patenting compared to some other jurisdictions, reflecting a prioritization of public health, biodiversity, and traditional knowledge.

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CHAPTER – 10

The Significance of Patent Protection for Genetic Inventions in Protecting Against Human Diseases

10.1. Defining the Landscape: Genetic Inventions in Patent Law

Understanding the scope of patent protection for genetic advancements requires a clear definition of what constitutes a "genetic invention" within the realm of patent law. Gene patents, a specific category of intellectual property rights, grant exclusive rights to individuals, organizations, or corporations over particular DNA sequences for a defined period, typically 20 years from the patent's filing date. This exclusive ownership often encompasses crucial genetic information, allowing the patent holder to control its utilization. This definition extends beyond mere gene sequences to include various forms of genetic material, such as DNA, RNA, complementary DNA (cDNA), expressed sequence tags (ESTs), single nucleotide polymorphisms (SNPs), and recombinant vectors, which are considered analogous to chemical inventions within the patent system. Patenting can also cover isolated natural gene sequences, their specific uses in diagnostic testing, or gene sequences that have been altered through human intervention to enhance their utility by adding promoters or other modifications. Furthermore, the scope of patentable genetic inventions includes not only the genetic material itself but also the processes and methodologies for obtaining or utilizing these sequences. The breadth of this definition underscores the potential reach of patent protection in the field of genetics.

A central point of contention in the patenting of genetic material revolves around the distinction between a discovery and an invention. This debate is particularly relevant when considering naturally occurring DNA sequences. Legal precedents, most notably the 2013 United States Supreme Court decision in *Association for Molecular Pathology v. Myriad Genetics*, have significantly impacted the patentability of such sequences in the US. The court ruled that naturally occurring isolated genes are considered "products of nature" and, therefore, are not eligible for patent protection simply by virtue of their isolation. In contrast, manipulated or synthetic forms of DNA, such as cDNA, which is created in the laboratory and does not occur naturally, can still be patented. This stance reflects a legal philosophy that favours patent protection for human-made innovations over naturally existing substances. Interestingly, the approach in the European Union (EU) differs in this regard. While both jurisdictions generally prohibit the patenting of native gene and protein sequences, the EU allows for exceptions, particularly for biological materials and identical gene or protein sequences found in nature when they have been isolated or technologically produced. This divergence highlights differing legal interpretations of what constitutes patentable subject matter in the context of genetic material.

Several landmark legal cases have played a crucial role in shaping the patentability landscape for genetic inventions. The 1980 Supreme Court case of *Diamond v. Chakrabarty* established a significant precedent by allowing the patenting of genetically modified organisms, recognizing that a "man-made" organism with markedly different characteristics from naturally occurring ones could be patentable. This decision paved the way for patents on various genetically engineered entities, including bacteria, viruses, seeds, plants, and even non-human animals, as well as isolated and manipulated cells, including human cells. Furthermore, the *Cohen/Boyer patents*, invented by Stanley Cohen and Herbert Boyer, covered fundamental techniques for splicing genes to create recombinant proteins, laying the groundwork for the entire biotechnology industry. However, the *Association for Molecular Pathology v. Myriad Genetics* case in the US stands out as particularly pivotal for gene patenting. The Supreme Court's ruling in this case invalidated

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Myriad's patents on the BRCA1 and BRCA2 genes, which are associated with increased risk of breast and ovarian cancer, on the grounds that the isolated gene sequences were products of nature. This decision marked a significant shift in US patent law concerning genetic material. In contrast, the European Patent Office (EPO) guidelines permit the patenting of isolated genes, even if their structure is identical to that of a natural element, provided that the patent application discloses the industrial application of the sequence. This contrast underscores the differing regulatory environments for genetic invention patents in the US and the EU.

10.2. Navigating the Process: Patenting Genetic Inventions

Securing patent protection for a genetic invention involves a well-defined process that requires meticulous attention to detail and adherence to specific legal criteria. To initiate this process, an inventor must file a patent application with the relevant patent office, such as the United States Patent and Trademark Office (USPTO) in the US or the European Patent Office (EPO) in Europe. This application must include a comprehensive description of the invention, providing sufficient detail to enable a person skilled in the relevant field to reproduce it. The application typically includes a detailed written description, drawings or diagrams where necessary, and specific claims that define the scope of the patent protection sought. For those seeking international protection, the Patent Cooperation Treaty (PCT) offers a mechanism to file a single international patent application that can then be pursued in multiple member countries. Once a patent is granted, research institutions may engage in technology transfer processes, often involving licensing the patented inventions to commercial entities to facilitate their development and market availability.

Patent offices around the world evaluate patent applications based on a set of fundamental criteria. **Novelty** is a primary requirement, meaning that the invention must be new and not previously disclosed to the public in any form before the date of the patent application. This ensures that patents are granted for truly new advancements rather than existing knowledge. Another crucial criterion is **non-obviousness**, also referred to as inventive step in some jurisdictions. This requires that the invention must involve an inventive step and should not be obvious to a person skilled in the relevant technical field at the time the invention was made. The invention must also possess **utility**, meaning it must have a practical application or be capable of industrial use. In the context of genetic inventions, the standards for utility can sometimes be more stringent, requiring a specific and substantial use to be disclosed. Finally, the patent application must provide a **sufficiency of disclosure**, also known as enablement. This means that the invention must be described clearly and comprehensively enough to allow a person skilled in the art to understand and reproduce it without undue experimentation. These core patentability criteria serve as the foundation for evaluating genetic inventions, although their specific application can be nuanced and subject to interpretation by patent offices and courts.

In addition to the general patentability criteria, there are specific considerations that apply to genetic material. In the United States, the *Myriad* decision established that the mere isolation of a naturally occurring gene is not sufficient for patentability. Generally, some form of human intervention that significantly alters the naturally occurring state, such as creating cDNA or genetically engineering an organism, is required for patent eligibility in the US. This reflects a legal stance against patenting products of nature. Conversely, in the European Union, isolated naturally occurring genetic sequences can still be eligible for patent protection, provided they meet other requirements such as industrial applicability and the disclosure of their function in the patent application. This difference highlights a key divergence in the legal frameworks of the US and the EU regarding the patentability of

genetic material. Similarly, in Australia, biological materials must be isolated from their natural environment or produced synthetically or recombinantly to be patentable. Furthermore, patents are not granted for gene sequences, DNA, or RNA that simply replicate the genetic information found in the blueprint of any human or other organism. These variations across jurisdictions underscore the importance of understanding the specific legal landscape when seeking patent protection for genetic inventions in different parts of the world.

10.3. Fuelling Innovation: Incentivizing Research and Development

The patent system serves as a powerful engine for driving research and development in the field of genetic inventions aimed at protecting against human diseases. By granting inventors and their assignees exclusive rights for a limited time, patents create a crucial financial incentive for investing in this often expensive and time-consuming area of research. The potential for market exclusivity allows companies to recoup the substantial investments made in the lengthy and risky process of discovering, developing, and bringing new genetic-based diagnostics and therapies to market. This prospect of a return on investment is particularly vital in the biotechnology and pharmaceutical industries, where research costs can be exceptionally high and the path to a marketable product can be arduous. Furthermore, patents enable the collection of fees through licensing agreements, offering inventors an opportunity to transfer their rights to others who may be better positioned to further develop and commercialize the invention, thus creating a secondary incentive for investment and innovation. Investors are also more inclined to support potentially groundbreaking genetic research when they have the assurance that their investments will be protected by exclusive patent rights, reducing the risk of competitors immediately copying successful innovations.

The promise of patent protection directly stimulates the development of novel diagnostic tools and therapeutic strategies for human diseases. By offering the potential for market exclusivity, patents encourage researchers and companies to pursue innovative approaches to disease prevention, diagnosis, and treatment that might otherwise be deemed too financially risky. Gene patents, in particular, have been credited with elevating genetic engineering beyond the realm of basic science, spurring significant advancements in therapeutic technologies. The patenting of genetic material has also fostered a substantial market for private investment capital in the biotechnology sector, leading to the emergence of numerous new diagnostic and therapeutic inventions based on genomics and proteomics. This cycle of patent protection leading to investment and then to the development of new healthcare solutions underscores the critical role of patents in driving progress in this field.

Interestingly, the patent system also fosters a degree of transparency and knowledge sharing within the scientific community. In exchange for the grant of exclusive rights, inventors are required to publicly disclose the details of their inventions in the patent application. This public disclosure can prevent the duplication of research efforts across different institutions, as researchers can learn from the patented findings of others. It also reduces the incentive for secrecy within the scientific community, allowing scientists access to each other's findings in a way that can potentially accelerate the overall pace of research. While the primary function of a patent is to grant exclusivity, the accompanying requirement for disclosure contributes to the broader dissemination of scientific knowledge, which can, in turn, catalyse further innovation.

However, it is important to acknowledge the counterarguments and potential hindrances associated with gene patents. Concerns have been raised that the exclusivity granted by patents can sometimes impede rather than stimulate research. Restricting access to patented genes or genetic technologies could

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potentially lead to monopolies, increased costs for diagnostic tests and treatments, and a slowdown in the translation of research findings into clinical applications. Some argue that gene patents can violate patients' rights to access potentially life-saving genetic information and treatment, without necessarily fulfilling the patent system's intended goal of promoting innovation. The debate surrounding the optimal balance between incentivizing innovation through patent protection and ensuring broad access to genetic healthcare innovations remains a critical one.

10.4. Pioneering Progress: Examples of Patented Genetic Inventions and their Impact

Several specific examples of patented genetic inventions illustrate their significant impact on preventing or treating human diseases. The *Cohen/Boyer patents*, for instance, were foundational to the entire biotechnology industry, providing the essential technology for splicing genes to produce recombinant proteins. This breakthrough paved the way for the development of numerous life-saving therapeutics, such as recombinant insulin for diabetes and human growth hormone (HGH) for growth disorders, which are often protected by composition of matter patents. Another notable example is the *Winter patent*, which covered key methods for manipulating DNA to create chimeric and humanized antibodies. This patented technology has been licensed to approximately fifty companies and has been instrumental in the development of a wide range of antibody-based therapies for various diseases, including cancer and autoimmune disorders. In the realm of diagnostics, Foundation Medicine has successfully obtained patents for its comprehensive genomic profiling methods. These patented techniques analyse multiple cancer-related genes to guide treatment decisions, representing a significant advancement in personalized medicine for cancer patients. These examples demonstrate how patent protection has facilitated the development and commercialization of crucial genetic inventions that have had a profound impact on human health.

10.5. Empowering Progress: Benefits of Patent Protection for Companies and Institutions

Patent protection offers numerous benefits to companies and institutions involved in developing genetic inventions for disease prevention and treatment. A primary advantage is the ability to attract investment and funding. In the highly competitive and capital-intensive field of biotechnology, patents serve as a crucial signal to investors that an innovation is protected and has the potential for commercial success. This assurance of intellectual property rights makes companies and research institutions more attractive to venture capitalists, pharmaceutical companies, and other funding sources, enabling them to secure the substantial financial resources required to conduct further research, development, and clinical trials. For early-stage biotech companies, having secured patents is often a prerequisite for attracting significant investment.

Furthermore, patent protection provides companies and institutions with vital market exclusivity and a significant competitive advantage. The exclusive rights granted by a patent allow the patent holder to prevent competitors from making, using, or selling the patented invention for a specified period, typically 20 years. This temporary monopoly enables the patent holder to establish a strong market position, recoup their R&D costs, and potentially generate significant revenue from their innovation. Owning a patent can also strengthen a company's brand and reputation, differentiating them from competitors and positioning them as leaders in specific technological areas.

Patents also play a crucial role in facilitating licensing agreements and collaborations. Companies and institutions that hold patents on genetic inventions can license these rights to other entities, allowing them to further develop or commercialize the technology in exchange for licensing fees or royalties. This can be

particularly beneficial when the patent holder lacks the resources or expertise to fully exploit the invention themselves. Licensing can generate valuable revenue streams and foster collaborations that can accelerate the development and broader adoption of genetic-based healthcare innovations. Moreover, for biotechnology companies, a strong patent portfolio can significantly enhance their overall valuation, making them more attractive targets for strategic alliances, mergers, or acquisitions by larger pharmaceutical companies.

10.6. Bridging the Gap: Patents, Commercialization, and Accessibility

Patents are instrumental in bridging the gap between scientific discovery and the availability of genetic-based healthcare innovations to patients. By providing a framework for ownership and exclusivity, patents encourage the often complex and expensive process of translating research breakthroughs into commercially viable products and services. The protection afforded by patents incentivizes companies to invest in the necessary steps for commercialization, including scaling up production, conducting further clinical testing, navigating regulatory approvals, and establishing distribution channels. Furthermore, the requirement for public disclosure in patent applications can facilitate the dissemination of knowledge, allowing other researchers and companies to build upon patented inventions and potentially develop improved or complementary technologies. This interplay between protection and disclosure is a key mechanism through which the patent system aims to promote overall technological advancement.

However, the impact of patents on the accessibility and affordability of genetic-based healthcare innovations is a complex and often debated issue. While patents are intended to incentivize the development of new technologies, the market exclusivity they grant can also lead to increased prices for genetic tests and therapies, potentially limiting patient access. There have been instances where patents have been used to consolidate the market for genetic testing, resulting in sole providers and potentially higher costs for patients. For example, the patents held by Myriad Genetics on the BRCA1 and BRCA2 genes led to the company becoming the sole provider of testing for these genes in the US for a period, raising concerns about cost and access. Conversely, the Supreme Court's decision in the *Myriad* case, which invalidated patents on naturally occurring genes, has been credited with leading to a substantial drop in the prices of genetic testing for these genes and increased accessibility. This highlights the delicate balance between incentivizing innovation through patents and ensuring that essential healthcare technologies remain accessible and affordable. Policy mechanisms such as compulsory licensing have been suggested as potential tools to mitigate the adverse effects of gene patents on public health in certain circumstances.

Various commercialization strategies can be employed for patented genetic inventions. These include directly manufacturing and selling products based on the patented invention, licensing the patent to other companies for them to commercialize, identifying and pursuing infringers, forming patent pools with other patent holders to cross-license technologies, and outright selling the patent. In the biotechnology industry, licensing is a particularly common strategy, allowing research institutions and smaller companies to partner with larger pharmaceutical or diagnostic companies that have the resources and infrastructure to bring genetic innovations to market. While the prospect theory of patents suggests that broad patent rights can streamline commercialization by reducing rivalry, concerns remain about the potential for such broad protection to lead to supercompetitive pricing and limited access, particularly in the context of essential healthcare technologies.

10.7. Ethical Crossroads: Considerations and Potential Drawbacks

The patenting of genetic inventions raises several profound ethical considerations and potential drawbacks that warrant careful examination. One of the most fundamental ethical debates centres on the ownership of genetic information. Critics argue that genes are products of nature, intrinsic to human life, and should not be owned or controlled by private entities. Patenting human genetic material is seen by some as setting a troubling precedent for the commodification of human life and potentially granting undue control over information that is essential for understanding and treating human health. The question of whether a private company should have the right to own or control information about our bodies is a central point of contention in this ethical debate.

Another significant ethical concern revolves around the potential for gene patents to limit research and innovation. By granting exclusive rights, patents can restrict the ability of other researchers to use patented genes or genetic sequences in their work, potentially increasing research costs and slowing down the pace of scientific discovery and medical advancement. While the patent system is designed to incentivize innovation, there is a valid concern that in the realm of fundamental genetic information, overly broad patent protection could inadvertently stifle further research and the development of new and improved diagnostic and therapeutic tools.

The impact of gene patents on patient access and healthcare disparities also raises serious ethical issues. The potential for patent-driven monopolies to lead to increased prices for genetic tests and treatments raises concerns about justice and equity in healthcare. Limited access to essential genetic testing and therapies due to patent restrictions could disproportionately affect underserved populations and exacerbate existing healthcare disparities between wealthier and poorer nations. The case of Myriad's patents on BRCA1 and BRCA2, which for a time gave the company exclusive rights to testing for these genes, exemplifies these concerns.

Finally, the patenting of gene editing technologies introduces a new set of ethical considerations. While these technologies hold great promise for treating genetic diseases, they also raise ethical questions about their potential impact on the human genome and the implications of altering the fundamental building blocks of life. The fact that patents are routinely granted for gene editing technologies like CRISPR-Cas9, even as ethical guidelines and societal debates surrounding their use continue to evolve, highlights the complex interplay between innovation, patent law, and ethical responsibility in this rapidly advancing field.

10.7. Global Perspectives: Legal Frameworks and Regulations Worldwide

The legal frameworks and regulations governing the patenting of genetic inventions vary significantly across different countries and regions, reflecting diverse legal traditions, economic priorities, and ethical considerations.

In the **United States**, the legal landscape has been significantly shaped by the Supreme Court's 2013 decision in *Association for Molecular Pathology v. Myriad Genetics*. This landmark ruling established that naturally occurring isolated human genes are not patentable as they are considered products of nature. However, the Court clarified that manipulated or synthetic forms of DNA, such as cDNA, which are created through human intervention, remain eligible for patent protection. The US patent law framework, as outlined in Title 35 of the US Code, defines patentable subject matter broadly as "any new and useful process, machine, manufacture, or composition of matter". To be patentable, an invention must also meet the criteria of novelty, non-obviousness, and utility. Notably, there is ongoing discussion and potential for legislative changes in the US, with the proposed Patent

Eligibility Restoration Act of 2023 aiming to modify the current eligibility standards, potentially impacting the patentability of certain genetic inventions.

In the **European Union**, the approach to patenting genetic inventions is largely governed by the Biotech Directive (Directive 98/44/EC) and the European Patent Convention (EPC). Unlike the US, the EU generally permits the patenting of naturally occurring genetic sequences if they have been isolated from their natural environment or produced through a technical process and have a disclosed industrial application. The Biotech Directive specifies that inventions that are new, involve an inventive step, and are susceptible of industrial application are patentable, even if they concern biological material. However, the simple discovery of a gene sequence is not considered patentable. The EPO guidelines further detail the patentability of biological materials, plants, and animals, including exclusions for essentially biological processes for plant and animal production and considerations related to animal suffering. Overall, the EU adopts a more permissive stance on patenting isolated natural genetic sequences compared to the US, with a strong emphasis on the requirement of industrial applicability and ethical considerations within the framework of biotechnology patents.

Other countries have established their own regulations regarding the patentability of genetic inventions. In **Japan**, isolated genes are generally considered patentable as long as they meet the standard patentability criteria of novelty, inventive step, and industrial applicability, and their function is sufficiently described in the patent application. **India** takes a more restrictive approach, with its patent law stating that the mere discovery of a natural substance is not considered an invention. However, patents can be granted for genetically modified gene sequences that demonstrate novelty, involve an inventive step, and have industrial application. **Australia**, following a similar legal trajectory to the US, has also invalidated patents on naturally occurring DNA sequences, aligning with the view that such sequences are products of nature and thus not patentable subject matter. These examples illustrate the lack of complete global harmonization in the patenting of genetic inventions, with each country or region balancing its own legal, economic, and ethical considerations in this complex area.

CHAPTER – 11

Comparative Study

A comparative analysis of Patent Laws for genetic inventions in the USA, UK, China, Russia, Germany, France, India and Switzerland.

The field of genetic inventions has witnessed remarkable growth, yielding innovations with profound implications across medicine, agriculture, and industry. From groundbreaking diagnostic tools and life-saving therapies to enhanced crop yields and sustainable industrial processes, these inventions are increasingly central to addressing global challenges. However, the patenting of genetic material remains a complex and often contentious issue, fraught with legal, ethical, and societal considerations. This report undertakes a comparative analysis of the patent laws governing genetic inventions in eight key jurisdictions: the United States of America, the United Kingdom, China, the Russian Federation, Germany, France, India, and Switzerland. The primary objective is to delineate the similarities and differences in their legal frameworks concerning the patentability of genetic material, including isolated genes, DNA sequences, and genetically modified organisms. A particular emphasis will be placed on examining the specific provisions and unique aspects of Indian patent law in this domain, comparing it with the approaches adopted by the other seven countries. Understanding the nuances of these legal landscapes is crucial for researchers, policymakers, and businesses operating in the rapidly evolving field of biotechnology. The

interplay between national patent laws and international agreements, such as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and regional directives like the European Union's Biotech Directive, further complicates this landscape, necessitating a detailed comparative study.

11.1. Patent Laws of Key Jurisdictions United States

Patentability Criteria for Genetic Material in the US

Historically, the United States Patent and Trademark Office (USPTO) granted patents on isolated gene sequences, considering the act of isolation sufficient to confer patentability. This perspective was rooted in earlier legal precedents, such as the 1911 *Parke-Davis v. Mulford* case, which suggested that purified natural substances were patentable due to their increased utility compared to their naturally occurring forms. However, a landmark decision by the US Supreme Court in 2013, *Association for Molecular Pathology v. Myriad Genetics, Inc.*, fundamentally altered this position. The Court unanimously ruled that merely isolating a naturally occurring DNA segment does not render it patentable, as it remains a "product of nature". This decision invalidated Myriad Genetics' patents on the BRCA1 and BRCA2 genes, which are naturally occurring human genes associated with an increased risk of breast and ovarian cancer. The Supreme Court's reasoning was based on the principle that laws of nature, natural phenomena, and abstract ideas are not patentable, and that isolated but otherwise unaltered DNA falls within the category of natural phenomena.

Conversely, the Court in *Myriad* also affirmed that synthesized DNA molecules, such as complementary DNA (cDNA), which are created in the laboratory and do not occur naturally, remain eligible for patent protection. The rationale is that cDNA is a product of human ingenuity and does not exist in nature. Furthermore, the USPTO has granted patents on isolated gene sequences with known functions, implying that while mere isolation of a naturally occurring gene is insufficient, an isolated sequence with a demonstrated utility might still be patentable. The function of the gene must be more than simply of scientific interest; it usually requires a description of the gene's role and its practical application.

The US also permits the patenting of genetically modified organisms (GMOs). This was first established in the landmark 1980 case of *Diamond v. Chakrabarty*, where the Supreme Court upheld the patentability of a genetically engineered bacterium capable of breaking down crude oil. The Court reasoned that the modified bacterium was a "non-naturally occurring manufacture or composition of matter – a product of human ingenuity having a distinct name, character and use". This precedent has since been extended to various other genetically modified organisms, including bacteria, viruses, seeds, plants, cells, and even non-human animals. Isolated and manipulated cells, including human cells that have been sufficiently transformed, can also be patented.

Exclusions to Patentability for Genetic Inventions in the US

The US patent law, while broad, contains implicit and explicit exclusions to patentable subject matter relevant to genetic inventions. The Supreme Court has long held that laws of nature, natural phenomena, and abstract ideas are not patentable. This exclusion is the primary basis for the non-patentability of naturally occurring genes post-*Myriad*, as they are considered products of nature. Furthermore, the America Invents Act, enacted in 2012, explicitly prohibits the patenting of human organisms.

While ethical concerns about dignity and the sanctity of life have been raised regarding human gene patents, they have not directly translated into significant policy barriers within the USPTO. However, inventions whose commercial exploitation would violate public order or morality could potentially be excluded under existing legal principles. Additionally,

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methods of treatment and diagnosis *per se* have faced increased scrutiny and may be considered unpatentable if they are deemed to claim abstract ideas or laws of nature, as highlighted in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*..

Scope of Patent Protection for Genetic Inventions in the US

A biological patent in the US grants the patent holder the right to exclude others from making, using, selling, or importing the claimed invention for a limited period, typically 20 years from the filing date for patents filed after 1998. This protection can extend to isolated gene sequences with known functions, their use in diagnostic testing, and natural sequences that have been altered to enhance their utility. The scope also encompasses genetically modified organisms, including a wide range of biological entities. However, the claims define the precise boundaries of the patent protection, and these can be subject to limitations imposed by the courts or the USPTO. While a research exemption exists, allowing for the use of patented inventions for experimental purposes, its statutory basis is debated, and its scope is primarily defined by case law.

Patenting Naturally Occurring vs. Modified Genes in the US

The US patent law, particularly after the *Myriad* decision, draws a clear distinction between naturally occurring and modified genes. Naturally occurring DNA segments, even when isolated, are not patentable as they are considered products of nature. In contrast, synthesized DNA, such as cDNA, which does not exist in nature, is patentable. Furthermore, naturally occurring sequences that have been modified or engineered, for example, by adding a promoter to make them more useful, can also be patented, provided they meet the criteria of novelty, non-obviousness, and utility. The key factor is whether the genetic material has been altered by human intervention to create something with markedly different characteristics from what occurs in nature.

United Kingdom

Patentability Criteria for Genetic Material in the UK

In the United Kingdom, the Patents Regulations 2000, which implemented the EU Directive 98/44/EC on the legal protection of biotechnological inventions, confirmed that inventions concerning biological material, including gene sequences, are patentable. To be eligible for patent protection, genetic material must satisfy the standard criteria of novelty, inventive step, and industrial application. Additionally, for gene sequences, the industrial application must be disclosed in the patent application as filed. Unlike the US post-*Myriad*, the isolation of a naturally occurring substance that was previously unknown can be considered novel in the UK.

Exclusions to Patentability for Genetic Inventions in the UK

Schedule A2 of the Patents Act 1977 sets out exclusions from patentability for biotechnological inventions. These include the human body at various stages of its formation and development, as well as the simple discovery of one of its elements, including the sequence or partial sequence of a gene. Also excluded are processes for cloning human beings, processes for modifying the germ line genetic identity of human beings, and the uses of human embryos for industrial or commercial purposes. Furthermore, processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes, are not patentable. Similar to other European jurisdictions, plant and animal varieties and essentially biological processes for their production are also excluded from patentability. Finally, discoveries *as such* are not patentable.

Scope of Patent Protection for Genetic Inventions in the UK

A patent in the UK grants the holder the right to exclude others from making, using, selling, or

importing the invention for a limited period, typically 20 years from the filing date. This protection can cover biological material isolated from its natural environment or produced by a technical process. However, for a gene sequence, the protection is limited to the industrial application disclosed in the patent application. The UK also has an experimental use defence to patent infringement, which means that research to develop new genetic tests is unlikely to constitute patent infringement, although the limits of this defence have not been fully tested.

Patenting Naturally Occurring vs. Modified Genes in the UK

In the UK, the simple discovery of a gene sequence cannot be patented. However, an element isolated from the human body or produced by a technical process, including a gene sequence, may be patentable even if its structure is identical to a natural element. Artificial DNA constructs or sequences altered by humans remain patentable, as does cDNA, which is synthetically produced and does not occur naturally.

China

Patentability Criteria for Genetic Material in China

To be patentable in China, genetic material must meet the general criteria of novelty, inventiveness, and practical applicability. Additionally, for an invention accomplished by relying on genetic resources, the applicant must indicate the direct and original source of these resources in the patent application. If the original source cannot be provided, the applicant must state the reasons. For a gene or DNA fragment to be patentable, its base sequence must be unknown in the prior art, it must be capable of being definitely characterized, and it must have industrial application.

Exclusions to Patentability for Genetic Inventions in China

The Patent Law of China excludes several categories of inventions related to genetics. Invention-creations that violate the law or social ethics, or harm public interests, are not patentable. Furthermore, patent rights are not granted for inventions accomplished by relying on genetic resources that were obtained or used in violation of laws or administrative regulations. Scientific discoveries are also excluded from patentability. While animal and plant varieties are not patentable, methods of breeding that are not "essentially biological" may be patentable. Transgenic animals and plants are considered to fall under the category of animal and plant varieties and are thus not patentable. Methods for the diagnosis or treatment of diseases are also excluded, although products used in these methods may be patentable. The exclusion of human embryonic stem cells and methods of preparing them was removed in 2019, but inventions violating social morality can still be rejected.

Scope of Patent Protection for Genetic Inventions in China

The scope of patent protection in China is defined by the claims of the patent. The written description and attached drawings can be used to interpret these claims. For inventions based on genetic resources, the patent application documents must include a disclosure of the source. Patents on substances found in nature are generally not granted unless they are isolated or extracted for the first time, have an unknown structure or morphology, can be precisely characterized, and have industrial use.

Patenting Naturally Occurring vs. Modified Genes in China

In China, finding a gene or DNA fragment existing in its natural state is considered a non-patentable discovery. However, if a gene or DNA fragment is isolated or extracted for the first time from its natural state, has an unknown base sequence, and has industrial application, it can be patentable. Genetically modified gene sequences or amino acid sequences can be claimed if they are novel, involve an inventive step, and have industrial applicability.

Russian Federation

Patentability Criteria for Genetic Material in Russia

In Russia, an invention must be a technical solution relating to a product (which includes a substance, microorganism strain, or cell culture) or a method. It must also satisfy the criteria of novelty, inventive step, and industrial applicability. Notably, chemical compositions, pharmaceuticals, biological materials, gene sequences, and medical treatments are considered patentable subject matter in Russia. For inventions that relate to the "use" of a product or method for a certain purpose, the patent claim must specify this purpose.

Exclusions to Patentability for Genetic Inventions in Russia

Russian patent law excludes methods of cloning a human being and a clone, as well as methods for modifying the genetic integrity of cells of the embryonic line of a human being. The use of human embryos for industrial and commercial purposes is also excluded. Furthermore, solutions that are contrary to public interest, humanity, or morality are not patentable. Like many other jurisdictions, Russia does not grant patents for discoveries. Plant varieties and animal breeds, along with their biological methods of production (excluding microbiological methods and their products), are also excluded from patentability.

Scope of Patent Protection for Genetic Inventions in Russia

A patent for an invention in Russia grants exclusive rights for a term of 20 years from the filing date, with a possible extension for patents relating to pharmaceuticals, pesticides, or agrichemicals. The scope of protection covers the technical solution, whether it is a product (including a substance, microorganism strain, or cell culture) or a method (a process of performing actions). A patented invention is considered used if the product contains or the process involves every feature of an independent claim in the patent, or uses or includes an equivalent feature known as such in the art by the priority date. For genetic constructs, patent claims should be restricted to the drug's purpose or the biological function that determines this purpose.

Patenting Naturally Occurring vs. Modified Genes in Russia

The Civil Code of Russia permits the patenting of almost every product or method that was not created by nature. Complementary DNA (cDNA) synthesized from messenger RNA is considered a "manufactured" strand of DNA and is likely patentable, although the Civil Code does not explicitly state this. While the patentability of isolated naturally occurring, genes is not explicitly detailed in the provided snippets, the general principle suggests they might be patentable if they meet the standard criteria and are not considered mere discoveries. Ros patent considers biotechnological products isolated from the environment or produced through a technical process protectable even if they previously existed in nature. Genetic constructs, including plasmids, vectors, transformed cells of microorganisms, plants, and animals, as well as transgenic plants and animals, are patentable.

Germany

Patentability Criteria for Genetic Material in Germany

German patent law grants patents for inventions in all fields of technology, including products consisting of or containing biological material, as well as processes for their production, processing, or use. If the subject of an invention is a human gene sequence, the German Patent Act requires the disclosure of not only the sequence but also at least one application. Without such disclosure, a human gene sequence is not patentable. Biological material that is isolated from its natural environment or produced by means of a technical process can be the subject of an invention, even if it previously occurred in nature. All inventions must also meet the standard criteria of novelty, inventive step, and industrial

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applicability.

Exclusions to Patentability for Genetic Inventions in Germany

The German Patent Act excludes the human body at the various stages of its formation and development, including germ cells, as well as the simple discovery of one of its elements, including the sequence or partial sequence of a gene, from being patentable inventions. Also excluded are processes for cloning human beings, processes for modifying the germ line genetic identity of human beings, and uses of human embryos for industrial or commercial purposes. Processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes, are not patentable. Similar to the approach in the UK, plant and animal varieties and essentially biological processes for their production are excluded, and this exclusion extends to plants and animals exclusively obtained by such processes. Discoveries *as such* are also not patentable.

Scope of Patent Protection for Genetic Inventions in Germany

Patents in Germany grant exclusive rights to make, use, offer for sale, put on the market, or import the patented product for a term of 20 years from the date of filing. For human gene sequences whose structure corresponds to that of a natural sequence or partial sequence of a human gene, the patent claim must include its use for which industrial application is disclosed. This implies a purpose-bound protection for human gene sequences. If the patent refers to a process that enables a biological material to be produced possessing specific characteristics as a result of an invention, the effects of the patent extend to the biological material directly obtained through that process and to any other biological material derived from the directly obtained material and possessing the same characteristics.

Patenting Naturally Occurring vs. Modified Genes in Germany

The simple discovery of a human gene is not patentable in Germany. However, an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element. For human gene sequences whose structure is identical to a natural sequence, the patent claim must include the disclosed industrial application. Plants or animals with properties changed by genetic engineering or other technical measures are patentable, but plant and animal varieties are not.

France

Patentability Criteria for Genetic Material in France

In France, new inventions that involve an inventive step and are capable of industrial application are patentable in all fields of technology. This includes inventions relating to a product consisting wholly or partly of biological material, or to a process for producing, treating, or using biological material, which are patentable under the same conditions. However, for a product containing or consisting of genetic information, the protection awarded by a patent covers only the specific industrial application disclosed in the patent application.

Exclusions to Patentability for Genetic Inventions in France

French patent law does not regard discoveries, as well as scientific theories and mathematical methods, as inventions. Furthermore, the human body, at the 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 constitute patentable inventions. Patenting whole or partial human gene sequences *per se* is banned in France. Other exclusions include

processes for cloning human beings, processes for modifying the germ line genetic identity of human beings, and uses of human embryos for industrial or commercial purposes. Plant varieties and animal breeds, as well as essentially biological processes for the production of plants or animals, are also not patentable. Finally, methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body are not patentable, although products for use in these methods are patentable.

Scope of Patent Protection for Genetic Inventions in France

A patent in France confers a monopoly to use or sell an invention. For a product containing or consisting of genetic information, the protection awarded by the patent covers only the specific industrial application disclosed in the patent application. This function-specific protection aims to limit overly broad claims. Rights conferred by a patent including a gene sequence may not be asserted against a later claim on the same sequence if the later claim satisfies the requirements of Article L611-18 of the French Intellectual Property Code and discloses any other particular application of this sequence.

Patenting Naturally Occurring vs. Modified Genes in France

In France, the simple discovery of a gene sequence cannot constitute a patentable invention, and the patenting of whole or partial human gene sequences *per se* is banned. However, an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention. The patent protection for a product containing or consisting of genetic information covers only the specific industrial application disclosed in the patent.

India

Patentability Criteria for Genetic Material in India

To be patentable in India, genetic material must meet the standard criteria of novelty, inventive step, and industrial applicability. For genetic material, novelty is often considered met if the sequence is purified and isolated from its natural form. Recombinant DNA and Plasmids, as well as their production procedures, are patentable if the process involves significant human intervention, although the necessity of "substantial human interaction" was removed in the 2011 Manual of Patent Practice and Procedure. The Indian Biotechnology Guidelines of 2013 state that a recombinant gene with an inventive step and industrial application is patent eligible. India also has provisions for the deposit of biological material in lieu of a detailed written description in the patent application, with a requirement to disclose the source and geographical origin of the material.

Exclusions to Patentability for Genetic Inventions in India

Section 3 of the Indian Patents Act, 1970, lays out several exclusions to patentability relevant to genetic inventions. The discovery of any living thing or non-living substance occurring in nature is not patentable. This generally prohibits the patenting of naturally occurring genetic sequences. Plants and animals in whole or any part thereof other than micro-organisms, including seeds, varieties, and species, as well as essentially biological processes for the production or propagation of plants and animals, are also excluded. However, the Indian Patent Office interprets this exclusion as not applicable at the molecular level of genes. Other exclusions include the mere discovery of a scientific principle, methods for the diagnosis or treatment of diseases, and inventions contrary to public order or morality.

Scope of Patent Protection for Genetic Inventions in India

The scope of patent protection in India is defined

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by the claims of the patent. Following a 2005 amendment to align with the TRIPS Agreement, product patents are now permissible in the biotechnology, chemical, and pharmaceutical industries. For genetically modified gene sequences or amino acid sequences that are novel, inventive, and industrially applicable, claims can cover the sequence itself, a method of expressing it, an antibody against the resulting protein, and a kit made from the antibody or sequence.

Patenting Naturally Occurring vs. Modified Genes in India

The mere discovery of naturally occurring living or non-living substances is not patentable in India, which generally excludes naturally occurring genes. However, genetically modified gene sequences are potentially patentable if they meet the criteria of novelty, inventiveness, and industrial applicability. cDNA has been granted patents in India and is considered "new and novel". There is also a possibility that isolated natural gene sequences might be patentable if they are an integral part of an artificially created microorganism.

Special Provisions and Interpretations of Indian Patent Law Concerning Genetic Inventions

The Indian Patent Office has interpreted the Section 3(j) exclusion of plants and animals and parts thereof as not applicable at the molecular level of genes. Higher utility standards may be applied to genetic inventions compared to other types of inventions. There is a specific requirement to disclose the source and geographical origin of biological material used in an invention.

Key Case Laws and Legal Precedents Shaping Genetic Invention Patents in India

The Calcutta High Court's decision in *Dimminaco A.G. v. Controller of Patents and Designs* (2002) held that a process for manufacturing a product containing living organisms is patentable. This case was a significant step in the patenting of life forms in India. In *Monsanto Technology LLC v. Nuziveedu Seeds Ltd.* (2018/2019), the Delhi High Court initially ruled that genetically modified seeds and gene sequences providing traits to plants are not patentable. However, the Supreme Court set aside this decision and remanded the case, without making conclusive remarks on the patentability of isolated DNA and cDNA, highlighting the ongoing judicial debate in this area.

Switzerland

Patentability Criteria for Genetic Material in Switzerland

In Switzerland, biotechnological inventions concerning biological material are patentable if they meet the general requirements of inventive step, novelty, and industrial applicability. "Biological material" is defined as material that contains genetic information, is reproducible, and is highly complex. Notably, a naturally occurring sequence or partial sequence of a gene is not patentable *as such*. However, sequences derived from a naturally occurring sequence or partial sequence of a gene may be patented as an invention. Furthermore, patent applicants in Switzerland must provide information on the source of a genetic resource or traditional knowledge of indigenous peoples and local communities if the invention is directly based on such resources or knowledge. Deliberate misrepresentation of the source is punishable by a fine.

Exclusions to Patentability for Genetic Inventions in Switzerland

Swiss patent law excludes inventions whose exploitation is contrary to human dignity or that disregard the integrity of living organisms, or that are otherwise contrary to public policy or morality. Specifically, processes for cloning human beings and the clones obtained thereby, processes for forming hybrid organisms using human germ cells or embryonic stem cells, processes for modifying the germ line genetic identity of human beings, unmodified human embryonic stem cells and stem cell lines, and

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the use of human embryos for non-medical purposes are not patentable. Plant varieties and animal varieties or essentially biological processes for the production of plants or animals are also excluded, although microbiological or other technical processes and the products obtained thereby, as well as inventions that concern plants or animals, are patentable.

Scope of Patent Protection for Genetic Inventions in Switzerland

A patent in Switzerland confers the right to prohibit others from commercially using the invention. If the invention concerns a manufacturing process, the protection extends to the products directly obtained, and if those products are biological material, to products obtained by propagating it with the same characteristics. If the invention concerns a product consisting of or containing genetic information, the protection extends to any material in which the product is incorporated and in which the genetic information is contained and performs its function. For a nucleotide sequence derived from a naturally occurring sequence, the protection is limited to the sequence segments that perform the function specifically described in the patent.

Patenting Naturally Occurring vs. Modified Genes in Switzerland

In Switzerland, a naturally occurring sequence or partial sequence of a gene is not patentable *as such*. However, sequences derived from a naturally occurring gene sequence may be patented as an invention. The protection for such derived nucleotide sequences is limited to the function specifically described in the patent.

Comparative Analysis

The patent laws related to genetic inventions across the eight countries exhibit both commonalities and significant differences. All jurisdictions require adherence to the fundamental patentability criteria of novelty, inventive step, and industrial application. Ethical considerations also play a role in shaping exclusions to patentability, particularly concerning human cloning, germline modification, and the use of human embryos. Plant and animal varieties, as well as essentially biological processes for their production, are generally excluded across the European countries and China, reflecting a desire to protect traditional agricultural practices.

However, the approach to naturally occurring genes varies considerably. The US, following the *Myriad* decision, does not allow patents on merely isolated naturally occurring DNA, while the UK, Germany, and France permit patenting of isolated natural substances, including gene sequences, under certain conditions, such as prior unknown existence or disclosed industrial application. Switzerland explicitly excludes naturally occurring gene sequences *as such* but allows patents on derived sequences. China takes a similar stance to the US, considering naturally occurring genes as non-patentable discoveries unless isolated and characterized for the first time with a known industrial application. Russia's stance on isolated natural genes is less clear from the provided material but appears more permissive towards patenting non- natural entities.

The patentability of cDNA, being synthetically produced, is generally accepted across most of these jurisdictions, including the US, UK, China, and Russia. GMOs are also widely patentable, particularly in the US following *Chakrabarty*. The scope of patent protection typically extends for 20 years, with some variations for specific types of inventions. Purpose-bound protection for gene sequences, where the patent claim must include the disclosed industrial application, is a feature in the UK, Germany, and France, reflecting a more cautious approach to granting broad monopolies on genetic information. Switzerland also limits the protection of derived nucleotide sequences to their specifically described function.

A notable distinction arises in the requirement for disclosing the source of genetic resources. India and Switzerland have specific provisions

mandating such disclosure in patent applications, reflecting their commitment to transparency and addressing concerns related to biopiracy

CHAPTER - 12

CONCLUSION

The conclusion regarding the intersection of patents on genetic inventions within the framework of intellectual property law highlights the complex and evolving nature of this legal domain. As advancements in biotechnology and genetic research continue to accelerate, the implications for patentability raise significant ethical, legal, and economic questions. The interplay between protecting innovative genetic discoveries and ensuring public access to essential biotechnological advancements necessitates a careful balancing act.

Furthermore, the legal landscape surrounding genetic patents is characterized by ongoing debates about the extent to which genetic material can be owned and the potential consequences for research and development. The challenges posed by the commodification of genetic resources underscore the need for a nuanced approach that considers both the rights of inventors and the broader societal implications. As courts and policymakers grapple with these issues, the outcomes will likely shape the future of innovation in the life sciences and influence the accessibility of genetic technologies.

In summary, the intersection of patents on genetic inventions and intellectual property law represents a critical area of inquiry that demands ongoing attention. The resolution of these complex issues will not only impact the legal rights of inventors but also have far-reaching effects on public health, scientific progress, and ethical standards in the field of biotechnology. As such, it is imperative for stakeholders to engage in informed discussions that consider the multifaceted implications of patenting genetic inventions.

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