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Ethics in DNA Patenting: A Critical Outlook as Per Indian Scenario

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ABSTRACT

"It's because of your genes."

This statement has likely been encountered on multiple occasions throughout your lifetime when discussing our height, weight, eye colour, hair colour, and so on. Genetic makeup is a constituent element of deoxyribonucleic acid (DNA), encompassing pertinent information regarding said characteristics. How implausible would it appear if you were informed that one of these genes could be subject to patenting? Is it verifiable that individuals can indeed obtain patents for genes? Given that organisms, their constituents, and any natural entities are not eligible for patenting, how does such a patent come about? To a certain extent, your line of reasoning is valid, yet it is crucial to acknowledge that gene patenting does indeed exist, with over 5,000 genes having been patented in the United States. However, whether gene patenting should be legally permissible is currently debated. Before exploring the numerous socio-legal and ethical quandaries surrounding this issue, it is essential to establish a concrete definition of this concept.

The double helix structure of DNA, the genetic makeup of living things, was discovered, completely altering the study of biology. Since then, scientists have made significant progress in their knowledge of how DNA functions and how variations in DNA result in individual variances. However, the recent decade's quick advancements in biotechnology have made it possible for businesses, researchers, and "bioprospectors" to change nature's creations for financial gain. Getting the patent rights to an organism or one of its elements is a crucial technique for private exploitation in this domain. We must decide whether any company, organisation, or person should have the right to private ownership of life because these advances impact every aspect of society. It is widely acknowledged that the patent system's benefits to the community cannot be discounted. However, it is still being determined whether applying the patent system to DNA sequences accomplishes its intended objectives, including encouraging innovation for the common good and rewarding individuals for useful new inventions. Although their legitimacy is questionable, some patents that claim ownership of DNA sequences have already been granted. Because inventors who assert rights over DNA sequences get protection on all uses of the sequences, many patents have wide-ranging and contentious impacts because they directly collide with

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numerous moral and ethical dilemmas. We have tried to analyse several aspects of DNA patenting in light of this dispute.

***Keywords**: Patent, Ethics, DNA, Biotechnology.*

I. INTRODUCTION

Genetic advancements have recently provided novel insights and facilitated new interventions that challenge established ethical principles. The revelation of the DNA structure, the hereditary material of organisms, in 1953 brought about a revolutionary transformation in biology. Subsequently, scientists have made substantial strides in comprehending the functioning of DNA and how genetic variations contribute to differences among individuals. The Human Genome Project, established in 1990, aimed to coordinate research endeavors to identify all genes within human DNA and determine the sequence of the three billion chemical base pairs constituting human DNA. Following the monumental revelation of the DNA molecule's structure, technological advancements have experienced substantial progress. Subsequently, researchers have diligently endeavored to ascertain the sequences of these molecules, their functionalities, and techniques for manipulating them to achieve the intended outcomes. Patentability obstacles frequently arise in biotechnology patents due to their intricate interplay with the natural world and their utilization to accomplish desired objectives. Notably, patents on genes and nucleic acids have recently ignited global discourse. It is approximated that approximately 20% of the human genome possesses the potential for patenting. While this statement is quite broad, it is likely to be met with some degree of disapproval by most individuals. On opposite ends of the spectrum, some hold disdain for “Microbesofts” and those who wholeheartedly embrace them as a pathway to creativity. Due to its relatively nascent state and extraordinary possibilities, synthetic biology undeniably sparks substantial controversy surrounding gene patenting in moral, practical, and legal domains.

The act of acquiring the exclusive privilege of a specific gene is called gene patenting. This privilege is bestowed upon by either the government or an organization to the individual who originated or discovered the gene. This privilege entails complete ownership and authority over its utilization for typically 20 years. Now, we come to the subject of patentability. Anything that exists in nature, whether it be plants, animals, rocks, mountains, bodies of water, or any living organism or a natural occurrence, cannot be subject to copyright. Why is this the case? This is because patents are reserved for unique inventions, and all aforementioned entities fall under the discovery classification. If gene patenting is permitted, the inventor must genetically modify the gene before submitting a patent application. The patent also encompasses genes

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that are created synthetically or artificially. This would classify it as a new and inventive concept since once altered, it becomes distinctive and, therefore, does not occur naturally. This is the point at which the gene may qualify for patent protection. A gene patent would also encompass potential components or segments of a gene. In certain circumstances, generating such modification may be subject to copyright if it is genuinely innovative and not obvious or simply a routine mental activity rather than an intellectual action or process. Essentially, it must be an invention that does not fall within the realm of natural laws or phenomena and must possess the quality of being non-obvious.[3]

II. ADVANTAGES OF GENE PATENTING

1. A patent is an entitlement the inventor deserves and must acquire due to their diligent efforts in the creation. This fosters a favorable environment for scientists interested in advancing advantageous products as it serves as a motivating factor to work within the realm of bioengineering, which has the potential to yield numerous inventions that contribute to the well-being of the general public. Numerous diseases are caused by gene damage or incorrect wiring. Although some medications may be of assistance, therapeutic gene therapies are known to be more beneficial. Many medicinal proteins have benefited from gene patents. In-depth research and analysis of the genetic composition of the human body could lead to further breakthrough ideas in the healthcare business as a result of the study and application of genes in various scenarios.
2. Once a patent has been granted, the organization or individual may seek an investor's support in conducting research and development. Following the acquisition of the patent, the researcher is no longer constrained by any crucial time limitations, in contrast to those imposed by intensifying market competition and the race for obtaining the patent.
3. There exist a multitude of diseases that are triggered by gene impairment or incorrect connectivity. Although some medications may offer aid, therapeutic gene therapies are recognized to have more advantageous effects. Numerous medicinal proteins have benefitted from gene patents. Through thorough investigation and examination of the human body's genetic makeup, there is the potential for further revolutionary concepts in the healthcare industry due to the exploration and utilization of genes in diverse

[3] Abhishek Kurian, Legal, social and ethical implications of gene patenting, iPleaders https://blog.ipleaders.in/legal-social-and-ethical-implications-of-gene-patenting/ (Last visited on January 20, 2023 at 03:45PM)

scenarios.

III. DISADVANTAGES OF GENE PATENTING

1) Gene patents can enhance research for individuals who possess or obtain a license for the patent. Conversely, all other entities are prohibited from exploiting these genes for research, study, testing, or other beneficial purposes. Furthermore, due to the patent holder's ability to assert their rights in other countries, the ability to conduct further research on these specific genes is believed to be limited to the patent holders.

2) The entitlement to rights granted by these patents may result in a monopolization of the genes by organizations. Consequently, all research, analysis, and further development on these genes would be exclusively conducted by the patent owner, who would charge exorbitant fees for issuing licenses to other organizations. This significant drawback of gene patents, particularly concerning human genes, could lead to the marketing and commodification of an individual's or organism's life, which can be considered disrespectful and abusive.

3) Another contentious aspect of the pros and cons is that, in theory, gene patents should lead to improved and effective medical care by facilitating high-quality research. However, as the patent owner would have exclusive rights to utilize these genes, they would establish a monopoly over them, severely restricting the extent of medical research conducted by other institutions. This limitation would hinder progress in the field, as any advancements in therapy and testing would depend on the patent owner. Consequently, an individual's right to access high-quality healthcare facilities would be violated.

IV. HISTORICAL PRECEDENT

Historically, the objective of the patent institution was to foster research and innovation to promote novel advantageous outcomes. This entails a temporary exclusivity bestowed upon the inventor to prevent others from utilizing the invention. Patents have had a longstanding presence. However, their emergence in genetics has engendered bewilderment among numerous individuals. The patenting of human genes has engendered practical and ethical quandaries on a global scale. The majority of the populace opposes the concept of granting patents for living organisms, including human genes. The scientific community is apprehensive about the restrictions that impede the study of this particular field. Healthcare providers and payers harbor concerns regarding the impact of patents on the costs associated with tests. Many industry members, minimal and medium-sized enterprises, and patent attorneys express

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apprehension about the potential challenges that may arise due to the diverse licenses required to produce a novel diagnostic kit or medication. Scientists possess knowledge regarding breakthroughs in the field of biotechnology. However, it is the general public's responsibility to ascertain the social and moral complexities that arise from these innovations. The assessment of the advantages and risks of gene patenting, as well as its impact on society, can only be carried out by the collective. This can be made possible through the establishment of a comprehensive legal framework. Each day, novel imaginative phases in research are being introduced. The remarkable prospect of patenting genes leads to increased intricacy and challenges in patent granting. From an ethical standpoint, living beings are divine creations that cannot be subject to ownership by humans through patents. God is the creator and ultimate proprietor of all living entities on our planet. A living organism possesses inherent worth and wholeness, which must be preserved and guaranteed. The manipulation of living beings should not be utilized as a means to test the wisdom of God. The genetic modification of organisms and protection of their patents have long sparked moral and ethical apprehensions. Regarding ethics and morality, it is self-evident that patent law cannot safeguard immoral inventions.[4]

When considering the realm of gene patenting and other forms of patenting biological inventions, much criticism has been directed towards patenting living organisms or their constituents and the regulations that delineate the legal boundaries of such patents. Additionally, the consequences associated with gene patents have garnered attention from numerous critics due to the various legal, economic, social, and ethical implications that accompany these patents.Most of the criticism pertains to the potential impact on future biotechnology innovations. While it is acknowledged that such patents would play a substantial role in expanding genetic engineering, the laws governing these patents have faced widespread condemnation. Particular emphasis has been placed on the judgments that will serve as crucial guidance for the rationale behind the granting of gene patents, necessitating efforts to enhance the current state of the laws to provide clarity. Another crucial concern, or legitimate uncertainty, regarding gene patents revolves around their biological and ethical ramifications. Since patents bestow exclusive rights to study, analyze, and exploit genes commercially, further investigation is necessary to ascertain the potential negative consequences of acquiring or utilising these genes. Genes serve as an inherited source of information within the human body, playing a pivotal role in its genetic composition. Before granting exclusive ownership, utilisation, and modifications of such genetic makeup, thorough research is required to

[4] Neeta, Legal, social and ethical implications of gene patenting, iPleaders https://blog.ipleaders.in/legal-social-and-ethical-implications-of-gene-patenting-2/ (Last visited on January 23, 2023 at 06:49PM)

understand the potential impact these changes may have on the human body. For instance, if a specific gene contains information about an individual's cognitive memory and mutations occur within this gene, the person may endure significant impairment to a vital cognitive asset. Additionally, it is crucial to consider the potential future outcomes of genetically modified genes, such as their potential toxicity or dormancy. Adequate investigation must be conducted to address these considerations before granting such patents. Furthermore, and of utmost importance, given that gene patents confer extensive rights over an individual's genes, it is imperative to ensure that these rights are not misused or exploited by the patent owner. The limitless capabilities of the human mind raise concerns that these patents could potentially lead to biological terrorism. Consequently, it is imperative for precautionary measures and safeguards to be established before the granting of such patents.[5]

V. TECHNIQUES USED IN BIOTECHNOLOGY

Before we study the legal and ethical concerns surrounding biotechnological inventions and gene patenting, we must have a basic understanding of the sciences that support biotechnology. Biotechnological inventions relate to a product made of or containing biological material or a method for creating, modifying, or using natural material. Any substance with genetic information and the ability to self-replicate in a natural system is considered biological material.

While genetically modified foods can keep longer and possibly taste better, they can also greatly benefit populations living in impoverished countries by producing more robust types of animals and plants that can endure harsh circumstances and give superior output.[6]

The biotechnology sector has used a variety of techniques. They are listed below:

- The creation of cell lines is a step in the process of tissue and cell culture technology. These cells, bacteria, plants, animals, or people, were produced outside their original host and are immortal self-replicating samples. Such cell lines' significance stems from their homogeneity. Because samples from each cell line share a common progenitor, they are genetically identical. This enables researchers to conduct exact comparative tests. Cell lines help study biological processes and determine whether medications and other substances adversely affect living things. Stem cell lines have a great deal of potential for creating medicines independently.
- White blood cells and antibodies are two components of the human immune system

[5] Ibid
[6] Ibid

that hybridoma technology is concerned with. The process entails fusing white blood cells that produce antibodies with tumour cells (myeloma). Due to the immortal characteristics inherited from the tumour cells, myeloma reproduces when introduced into an antigen (a foreign body that triggers an antibody response). The study of the immune system has shown to be a significant application of hybrids.

- Genetic engineering is a term that also applies to recombinant DNA technologies. The procedures and methods used in rDNA technology entail the subcellular modification of material. Genetic engineering is distinct from its partner technologies in this regard. Another name for DNA is deoxyribonucleic acid. Almost all living cells have DNA in their nuclei, except for the most primitive life forms, like bacteria. The function of the cell in which DNA is present is determined by it. Genes play a role in this. Genes are sections or sequences of DNA that activate the production of proteins by combining various amino acid combinations, which in turn connect to form multiple proteins by combining various amino acid combinations in specific orders. Different amino acids are drawn to multiple genes, which then combine to form various proteins. This is the procedure known as protein-coding. Other proteins influence how cells behave and perform. Polypeptides are another name for proteins commonly utilised in case laws. Genes are sections or sequences of DNA that activate the production of proteins by combining various amino acid combinations, which in turn connect to form multiple proteins by combining various amino acid combinations in specific orders. Different amino acids are drawn to multiple genes, which then combine to form various proteins. This is the procedure known as protein-coding. Other proteins influence how cells behave and perform. Polypeptides are another name for proteins commonly used in case laws.

Using in silico methods, which combine genetic and bioinformatics expertise, it is possible to search and compare databases of gene sequences to assign functions to as-yet-unprotected lines based on similarities to proteins with known functions.

Chemical bases make up the DNA sequences that are known as genes. These bases are just four, and their names begin with the letters A, T, C, and G. (Adenine, Thymine, Cystosine, and Guanine). “Genome” refers to the genetic instructions required to make a single creature. Recombinant DNA technology is the most innovative of all the methods used by the biotechnology sector in recent decades.

The creation of tests and vaccines based on genetic material, the identification of complete or

incomplete gene sequences, the development of genetically engineered organisms and genetic research tools, and the identification of complete or incomplete gene sequences have all been the focus of patent applications. Although many of them have been successful, many legal challenges to biotechnological patents have been made, and we will address each one at a time.

VI. ETHICAL ISSUES

Inventions whose publication or exploitation would be against the "*ordre public*" or morality are not accepted, according to Article 53(a) of the European Patent Convention[7], "*provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the contracting states.*"[8] In other words, it has a provision that allows a patent to be rejected on moral or "contrary to public order" reasons rather than only because it contains an explicitly illegal feature. Although there is no specific phrase like this in US patent law, this does not indicate that US law does not consider a patent's moral (as opposed to legal) character. It is reasonable to infer that gene patents would be illegal if they were unethical because of this. Therefore, discussing moral and ethical questions based on a philosophical perspective is essential. Though the same debate may be made about other living things, it goes without saying that protecting human integrity is the most crucial issue.

Some people believe that the human genome is a component of "common humanity" and that "patenting" human genetic material violates this idea.[9] A human gene is a component of all humans, and no one has the right to "possess" one; others compare it to slavery in this context.

In addition to the notion that the human genome is a shared resource, there are allegations that gene patents frequently benefit from the uniqueness of a gene at the individual level. In some research, a patent on a gene whose malignant mutation is specific to patient X would serve as an illustration (which was the case in Moore v. Regents of the University of California[10] for a patent and commercialization of a manipulated cell line originating from John Moore). They, as individuals, contain this gene variant. Patents on a particular strain or mutation of a gene can be compared to invading the privacy of a diary: they may all read quite similarly, but each author's tiny deviations make them distinct. There is no inherent right to "own" it (says Annabelle Lever, Professor of Political Science at MIT). There is cause to think that these ideas are unfounded, nevertheless.

[7] European Patent Convention, art.53(a)
[8] Thambisetty, Sivaramjani. "Understanding Morality as a Ground for Exclusion From Patentability Under European Law." Eubios Journal of Asian and International Bioethics 12 (2002): 48-53. Eubios.
[9] Gabriel Ben-Dor, Ethics of Gene Patenting: Moral, Legal, and Practical Perspectives, https://static.igem.org/mediawiki/2012/d/dc/Gene_Ethics.pdf (last visited on January 24, 2023, at 06:23 PM)
[10] 51 Cal. 3d 120

"Patenting" is not the same as "owning," according to Pilar Ossorio, an associate professor of law and bioethics at Wisconsin Law School. According to her, "gene patents do not threaten an individual's bodily integrity or their use of their genes in living and reproducing" because patents on human genes "do not, and legally cannot, apply to genes as they naturally occur in our body."[11] In other words, it is impractical and unpractical to believe that a gene that is a component of a human may be patented. Ossorio states, "*The sole legal right conferred by a patent is the right to prevent others from using or possessing one's innovations.*" For some people, it comes down to what legal rights the patent grants you. Simply put, a patent can be obtained without actually "owning" something, but it prevents others from using your concept without your consent.

The right to exclude is strong and acts like "ownership," which would be a response. The authority to exclude under a patent, according to Annabelle Lever, professor of political science at MIT, "may change anything 'collective; into a private object. The only right to use and possess something defines it as one's property. What distinguishes that from forbidding others from using it?

There is a balance to be struck between rewarding a patentee for their efforts and the public's access to the benefits of an invention, especially in the healthcare industry. A landmark case illustrating this dilemma is that of Myriad Genetics, whose patent was recently upheld in an appeals court this past August. Myriad became notorious for its exclusive rights to testing BRCA1 and BRCA2 genes, which assesses a woman's likelihood of developing breast and ovarian cancer. Women with mutations in these genes are seven times more likely to create breast cancer. The most controversial aspect of this patent is that Myriad's licensing terms are such that all tests are only to be done in and by its lab and at a price of approximately $3,000.

Some people believe that Myriad has unethical policies. Due to the BRCA testing monopoly, Sandra Park, an attorney with the ACLU, states that "*women have only one option for determining their hereditary risk for breast and ovarian cancer.*"[12] According to Nobel Prize winner John Sulston, people are not only "*led to pay thousands of dollars for treatment*" but also have little possibility of getting a second opinion.[13] The cost is around three times greater

[11] Lever, Annabelle. "Ethics and the Patenting of Human Genes." The Journal of Philosophy, Science & Law 1 (2001): Manuscripts and Articles. http://www6.miami.edu/ethics/jpsl/ (last visited on January 24, 2023, at 06:34 PM)

[12] Stempel, Jonathan. "Myriad Wins Gene Patent Ruling from US Appeals Court."Reuters. Thomson Reuters http://www.reuters.com/article/2012/08/16/ (last visited on January 26, 2023, at 04:11 PM)

[13] Cairns, David. "Don't Let Venter Patent Artificial Life, Says Rival" The Week. Dennis Publishing http://www.theweek.co.uk/politics/14403/don%E2%80%99t-let-venter-patent (last visited on January 26, 2023, at 04:16 PM)

than many similar-scale genetic tests, and even though it might be justified in some way, it still seems excessive. According to some economists, the laws of supply and demand would determine the most "fair" price for any good or service. Many in the healthcare sector think this is an incorrect notion. Regarding their health, people won't act as logically and will be willing to spend substantially more than what a good or service should cost (though there is substantial disagreement on this notion). The business can benefit from this thanks to Myriad's exclusive patents.

To safeguard against such issues, therapeutic devices and methods are not patentable under the European Patent Convention. Some people disagree with this strategy, even if the goal is to advance public health. The value of DNA-based ideas, according to biotech patent attorney Tim Worral of Dorsey & Whitney, "*relies largely on the notion that they are patentable.*" Healthcare products without competition will be far more appealing to investors and businesses. He believed that BRCA testing would not exist if it weren't for patents.

Global and societal implications of the Myriad patent's problems are possible. Healthcare disparities between the rich and the poor risk worsening, and they might even keep developing nations from gaining from first-world nations' breakthroughs and discoveries. Consider a mutant crop that can grow in harsh settings that is the subject of a patent in the United States. The creator might then refuse or make licencing the development of the strain in the areas that need it the most exceedingly expensive (e.g., starving regions of Africa).

VII. SOCIAL IMPLICATIONS

Genetic testing can provide people and families with new knowledge and the possibility of being identified as at risk. Those who receive a positive genetic test result might also need to explain complicated information to other family members, which can be difficult. An additional constraint is the potential effect on their ability to obtain insurance and find employment. Genetic disorders cause family health issues. When a person is identified as having a problem or being in danger, other blood relations may likewise be recognised as (or discoverable to be) similarly at risk. A tested person may opt to withhold their genetic information or be picky about how it is disseminated. A currently asymptomatic person who has undergone a genetic test may also greatly interest commercial organisations like insurance firms and employers. They might try to control such people or be able to in some situations. This creates the possibility of "genetic discrimination," which is defined as an unjustifiable

course of action based on a person's genetic composition who is asymptomatic.[14]

A genetic test may cause excellent and adverse emotional and psychological reactions. Positive reactions can include confirmation that they did not inherit the problematic gene implicated, or they can frequently feel relieved and empowered even if they did.[15] Uncertainty removal can be freeing. Many people find great comfort in finally having a term or label to describe their cluster of symptoms and, in turn, knowing, at least in part, what the future may hold. The desire to share even bad news in our society of dispersed families can encourage and improve previously unsupported communications.

Reproductive confidence can be restored by the availability of a prenatal diagnostic test or by receiving a negative genetic carrier, predictive, or presymptomatic test result. Such confidence can also be corrected when there is a chance for treatment or surveillance. Genetic testing is also more acceptable when a cure is available. The global uptake of testing for Huntington's disease, for which there is no cure, is around 20%. In contrast, hemochromatosis testing is becoming more popular because it is easy to get treatment, monitor the condition, and avoid it.

On the other hand, a genetic diagnosis or a positive genetic test result can cause grief, which is frequently expressed as feelings of blame, guilt, humiliation, denial, rage, and sadness. The statements "*It didn't come from my side of the family*" and "*There are poor genes in her/his side*" can significantly impact family dynamics. Even when a person is proven hazardous based on a specific genetic test result, they may experience shame for having "escaped" and feel cut off from the family that shared the tie of being "at risk." Expectations of a child or family member can be restricted when they have a label or name for their condition. As a result, the variety of symptoms may occasionally come true. The destruction of future hopes and goals may be the most harmful. Treatment and monitoring may be possible, but they come with difficult decisions: a prophylactic mastectomy will unavoidably change a woman's sense of herself. Because genetics and phenotype frequently do not correlate, for some people, a positive genetic test result does not free them from ambiguity. Knowledge regarding the prognosis or course of the problem may be available if the ailment is unusual. Uncertainty is made worse when clinical indicators show that, for instance, cancer runs in the family, but no mutation can be detected in the genes examined. As a result, the variety of symptoms may occasionally come

[14] ALRC–NHMRC (Australian Law Reform Commission and National Health and Medical Research Council) (2003). Essentially Yours — The Protection of Human Genetic Information in Australia. ALRC https://www.alrc.gov.au/publication/essentially-yours-the-protection-of-human-genetic-information-in-australia-alrc-report-96/ (Last visited on January 30, 2023 at 07:16 PM)

[15] Kristine Barlow-Stewart and Leslie Burnett, Considerations in the use of DNA for the diagnosis of diseases. Clin Biochem Rev. 2006 Feb;27(1):53-61. PMID: 16886047; PMCID: PMC1390792.

true. The destruction of future hopes and goals may be the most harmful. Treatment and monitoring may be possible, but they come with difficult decisions: a prophylactic mastectomy will unavoidably change a woman's sense of herself. Because genetics and phenotype frequently do not correlate, for some people, a positive genetic test result does not free them from ambiguity. Little knowledge regarding the prognosis or course that the problem will take may be available if the ailment is unusual. Uncertainty is made worse when clinical indicators show that, for instance, cancer runs in the family, but no mutation can be detected in the genes examined.

Social factors may also have an impact on this choice. For example, discussing ending pregnancies publicly is taboo, and the neighborhood may have substantial ethical disagreements. When a family member receives a genetic diagnosis, the affected individual or parent is forced to break the news to others. Decisions must be taken on who to notify (such as children, grandparents, other family members, or coworkers), when to talk, and how much to disclose. Genetic counselling must cover the potential responses that the individual may feel and the potential reactions of others. Exploring the support networks that already exist or need to be created may involve discussing respite, the financial effects on the family, and the possibility of prejudice. Support groups are an essential resource in this area. Thus, knowledge of them is crucial.

There may be a conflict between the person's or family's views and values and the scientific ('biomedical') information regarding the hereditary causes of the ailment or its heredity. For instance, reasons for cancer running in the family can include karma, fate, or ancestral vengeance.[16] This tension can make it challenging to get the word out to families who are "in danger" or to get them to accept the suggested surveillance methods or treatments. For fear of spreading the disease, people may be reluctant to talk about specific diseases like cancer or to record relatives who may have been affected. This can result in erroneous family history documentation and incorrect triaging for genetic counselling. Non-Western notions of kinship may also misrepresent family history.[17] Additionally, because different societies have varied perspectives on disability, decisions about abortion for disabilities that are offensive to some cultures may run counter to the principles upheld by the genetic counselling team. However, non-judgmental support of the client's decisions is the fundamental concept of genetic counselling. The stage of pregnancy at which a pregnancy can be terminated will also depend

[16] Du, L., Lin, S., & Kamenova, K. (2020). Framing Ethical Concerns and Attitudes towards Human Gene Patents in the Chinese Press. *Asian Bioethics Review*, *12*(3), 307-323. https://doi.org/10.1007/s41649-020-00136-0 (Last visited on February 4, 2023, at 09:18PM)
[17] Ibid

on cultural perceptions of when life begins.

VIII. LEGAL CHALLENGES

Though the morality of gene patenting is a topic worth debating and may result in pertinent legislation, the current legal discussions are more directly relevant to the development of gene patenting. Under current law, genes and other naturally occurring biological substances (together with their associated uses) may be patented in the United States if they are sufficiently isolated or altered from their existing state. This is debatable; pertinent patent cases have resulted in affirmative and harmful decisions. One of the arguments supporting the more actual implementation of these rules contends that genes are information and remain fundamentally merely information even after being extracted and modified. The Nuffield Council on Bioethics, a UK think tank that studies these matters, claimed in 2002 that a gene patent is simply an information patent, making the problem of how "isolated" or "manipulated" a gene is of little consequence.[18] The following is what James Watson, a co-discoverer of the double helix, stated: [DNA] is a chemical substance, but DNA's relevance stems from its ability to encode and transmit the instructions for producing people. Legal monopolies shouldn't have the power to dictate how to live. Watson acknowledges that DNA is technically a chemical, much like many less contentious, patented enzymes and medications. However, its usefulness comes more from the data it holds than from some unique ability. So, patenting it would be similar to patenting a poem.

The argument that isolated or altered genes result from human intellect and can be protected by patents works against this. According to this line of reasoning, a rock is just as unpatentable as a "gene," but breaking down a rock into new, different chemicals and patenting those compounds should be possible (and they are). Ossorio uses DNA sequencing as an example and claims that even this procedure involves a lot of manipulation, including cloning, denaturing, isolating DNA from its location in the genome, and utilising radioactive or fluorescent detection methods, among other things. Before the Federal Circuit appeals ruling in the Myriad Genetics case, the District initially invalidated the separated genes patent. They contended that isolating genes from patients alters the genes' original chemical structure. The following testing was based on the new gene as it existed in its revised structure. The Parke-Davis v. H. K. Mulford and Co.[19] case affirmed a human adrenaline patent because "*by*

[18] The ethics of patenting DNA: A discussion paper, Nuffield Council on Bio-ethics, https://www.nuffieldbioethics.org/assets/pdfs/The-ethics-of-patenting-DNA-a-discussion-paper.pdf (Last visited on March 18, 2023 at 09:39PM)
[19] 362 US 29 (1960)

purification, it became for all practical purposes a new thing economically and medically." A synthetic biologist would frequently be unimpressed. A gene can practically behave the same in or out of the body in these situations, frequently including techniques common to synthetic biology. Does adding bio-brick cut sites and conducting a PCR constitute isolation or manipulation? Although there are more complicated patents than this, it is reasonable to anticipate criticism from the academic community regarding how "isolated" and "manipulated" a gene is in circumstances where many believe something that belongs in the BioBrick registry is being patented instead. The first case to be filed for the application of a gene patent is known to be Diamond v. Chakrabarty[20]. Scientist Anand Chakrabarty discovered that a specific bacterium (singular for bacteria) could break down or digest the components of crude oil. He believed that if such technology were to be created, it might help repair any harm that oil spills would cause, rescuing marine life and maintaining the purity of water sources. However, he had to transform the bacterium for the procedure to function, and it was only after genetically altering this bacterium that he level technique, as mentioned earlier. He initially submitted a patent in 1972 with three claims:

1. The method utilised to create the bacterium that powers it can degrade crude oil.
2. the material that served as the bacterium's storage container.
3. The bacterium has been genetically modified alone.

The plaintiff contended that the relevant laws were implemented to ensure that a substance occurring in nature and something created by humans were not confused and that only novel and beneficial human-made products were eligible for patents. Anand Chakrabarty's improvements to the bacteria in this instance gave it the capacity to disassemble the components of crude oil; as a result, it should be regarded as a novel innovation. It was suggested that although patents may protect the method and carrier, the bacteria itself could not do so because it would not qualify as a novel invention. It was a living thing, and according to patent laws, bacteria cannot be patented. The United States Supreme Court ruled that patent statutes, particularly those relating to a thing's 'manufacture' or development, must be interpreted more broadly. It was argued that although things that naturally arise cannot be trademarked, artificially made organisms do require intelligence and creativity. Ibe t must, therefore, be patentable. The court further stated that as the patent law's authors could not have anticipated biotechnological advances, its scope should be expanded under the current state of biotechnology.

[20] 100 S. Ct. 2204

How "inventive" the assertions on a gene patent are is a related matter. A patent must have non-obvious subject matter to be valid; subject matter that "*would have been obvious at the time the invention was produced to a person having ordinary skill in the art to which said subject matter pertains*" is considered a violation. There are worries that the bar for what qualifies for this requirement needs to be higher; by comparison, Europe has one-seventh as many patents on DNA sequences as the US.[21] Routine approaches acquire many patented gene sequences (think BioBricking processes), not displaying anything genuinely inventive.

As a result, the nature of the genes and other patent information can satisfy the nonobviousness requirement. However, a scientist might view patentable elements as commonplace and anticipated rather than prominent, contrary to what a Federal Appeals Court might think. The gene patent "Molecular Computing Elements, Gates and FlipFlops" (US patent #6,774,222) serves as an illustration. The patent claims concern molecular data, a storage system that uses logic gates, DNA, and proteins that bind to DNA.[22] The claims are sufficiently broad to cover the fundamental computing operations made possible by genetic means. The problem is that many molecular and synthetic biologists knew that "computing operations might be achieved utilising DNA-based genetic switches" when this patent was granted in 2004.[23] In other words, the concept was evident to many. A court would be hesitant to utilise this information and sentiment to establish "non-obviousness," nevertheless, because it was unwritten. In contrast, a comparable patent was invalidated in the case of Prometheus v. Mayo[24], where it was determined that a blood test created by Prometheus Laboratories was just a patent of observations on natural events.

John Sulston's criticism of gene patents offers an alternative perspective pushing for stricter non-obviousness standards, arguing that they are frequently more appropriately classified as "discoveries" than inventions. The synthesis of a functional unit (E. coli expressing X isolated gene and a related protein, for example) is different from the assembly of nuts and bolts, so applying a non-obviousness criterion to synthetic biology may be as challenging as it was to other sciences. Instead, it is more frequently a test of actual biological data (genes) to see if a desired outcome (functional attribute in an engineering model) can be produced despite the unpredictability of biological systems (at least with our current knowledge set). Therefore, even

[21] Kumar, Sapna, and Arti Rai. "Synthetic Biology: The Intellectual Property Puzzle."Texas Law Review 85 (2007): 1745-768

[22] Rai, Arti, and James Boyle. "Synthetic Biology: Caught between Property Rights, the Public Domain, and the Commons." PLoS Biol. E58 5.3 (2007): n. pag. PMC. NCBI http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1821064 / (Last visited on April 12, 2023, at 10:08 PM)

[23] Kumar, Sapna, and Arti Rai, Supra note 14

[24] 132 S. Ct. 1289

while it can be acknowledged that there are novel artificial sequences, many synthetic biology products could be said to have more of a "discovery" nature than a "creation."

There is concern that the US patent usefulness criterion must be sufficiently upheld, fueled by a desire to prevent patents from making overly broad and vague claims. A US patent must offer a "specific benefit existing in currently available forms," which is one of the requirements for "usefulness."[25] This discussion focused on EST patenting, which attracted much media attention. The claim of Canadian patent 1,313,830, the controversial patent for Monsanto's Round-Up Resistant Canola Seed, is a minor but practical illustration of this problem. The "chimeric plant gene" is what the patent claims to be, and it contains a glyphosate-resistant coding sequence and "*a promoter sequence which works in plant cells*," which is more intriguing. This is reasonably general information for a synthetic biologist. The plant does go on to identify three potential promoters. Still, it appears that the patent holder was just trying to cover every promoter that could be used, even though it is reasonable to believe that the finished product would only contain one. A more extreme example would be the previously cited "*Molecular Computing Elements, Gates and FlipFlops*" patent, which includes 65 claims, many of which seem to list every conceivable arrangement of components that could be used to create a system that could perform Boolean algebra. When it is uncertain how "specific" the claims are and what the "current available forms are," it is feared that accepting patents recklessly on these grounds could result in excessively restricting patents.

IX. GENE PATENTING: THE INDIAN PERSPECTIVE

Section 3(c) of the Patent Act, 1970[26] renders as non-patentable subject matter the "*unearthing of any living entity or inanimate material found in the natural environment.*" The mere revelation of a scientific principle or the development or revelation of any living entity or inanimate material occurring naturally is not regarded as an innovation but said principle, when utilized in a manufacturing process that leads to the creation of a substance or an object, might be deemed an innovation.[27]

Similarly, a scientific theory is an assertion regarding the natural world. Regardless of their revolutionary or radical insights, these theories are not classified as inventions due to their lack of resulting in a tangible product or procedure. However, should said theory lead to a practical application within an article or substance's manufacturing process, it may become eligible for

[25] Chris Jackson, An IGEM-Specific Guide to U.S. Intellectual Property and Patent Law, http://2012.igem.org/Team:Stanford-Brown (Last visited on May 24, 2023, at 10:24PM)
[26] The Patents Act, 1970, s.3(c), No.39, Acts of Parliament, 1970 (India)
[27] Dr. VK Ahuja, Law Relating to Intellectual Property Rights, 491 [3rd ed.2017]

a patent. A theory formulation claim that is abstract is not deemed an invention. To illustrate, unearthing a previously unknown characteristic in a known substance or object is categorized as a discovery rather than an invention. Nevertheless, if this discovery determines that the material can be employed in creating a specific product or process, then said article or process may be considered an invention. Identifying a novel material or microorganism that occurs naturally in the environment is referred to as a discovery instead of an invention.[28] A gene manifests in the natural environment and should not be subject to patentability under the provisions stipulated in Section 3(c). Although this assertion holds, it is imperative to acknowledge the substantial level of proficiency required to discern its operational capacity, spatial disposition, and extraction.[29]

Plants and animals, whether in their entirety or part, except microorganisms but encompassing seeds, variations, and species, as well as biologically fundamental methods for the production or propagation of plants and animals, are ineligible for patent protection under Section 3 (j)[30] of the Patent Act, 1970. As stipulated by this section, plants and animals in their entirety or part, seeds, variations, and species, as well as biologically fundamental methods for producing or propagating plants and animals, do not meet the criteria for innovation. However, it should be noted that if microorganisms are not naturally discovered and have undergone substantial human intervention, they may be eligible for patent protection. Genetically modified microorganisms, for instance, may be subject to other patentability criteria and potentially patentable. It is important to mention that plant variations are safeguarded by the Protection of Plant Varieties and Farmers' Rights (PPFVR) Act, 2001. The Act contains several provisions that must be duly noted. One such provision is the Disclosure Requirement, which necessitates that the applicant furnish all pertinent data regarding the origin of the parent variety of the gene. Additionally, the applicant must declare that the genetic material was legally obtained. Another provision, known as "Benefit Sharing," grants individuals or groups of citizens in India the opportunity to claim some of the advantages derived from the genetic material. The specific amount and nature of the use of the genetic material in generating the variety, as well as the commercial utility and market demand for the variety, will determine the extent of the benefits. It is crucial to critically analyze the benefit-sharing provisions to ensure that the objectives of the PPFVR Act are effectively realized, particularly concerning the inclusion of local people

[28] Ibid
[29] Ravi, Bhavishyavani, Gene Patents in India: Gauging Policy by an Analysis of the Grants made by the Indian Patent Office (July 15, 2013). Journal of Intellectual Property Rights 2013, Available at SSRN: https://ssrn.com/abstract=3963077 (Last visited on September 29, 2023, at 01:13 PM)
[30] The Patents Act, 1970, s.3(j), No.39, Acts of Parliament, 1970 (India)

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and peasants in a vast country like India, primarily through traditional societies in various states.

India's flourishing agricultural economy, which relies heavily on the majority of its population engaged in agriculture, may suffer negative consequences due to stringent legal protection for genetic engineering in plants. The ancient practices of farmers and local communities in India have made significant contributions to the development, conservation, exchange, and utilization of genetic diversity. It is worth noting, however, that gene patenting is permitted in other countries, which puts India at a disadvantage. This legal framework may inadvertently benefit agro-biotech enterprises outside India that have secured numerous patents on plant genetic breakthroughs. Consequently, the industrialized world has unrestricted access to the biological resources and accompanying knowledge of poorer countries, resulting in acts of "bio-piracy" and "cultural piracy."[31]

Another vital section is 3(i)[32], which specifies that plants and animals, in whole or in part, other than microorganisms but including seeds, varieties, and species, as well as biological methods for producing or propagating plants and animals, cannot be patented. While plants and animals are unpatentable in whole or in part, would genes be regarded as a part of a plant or animal and hence unpatentable? Second, what qualifies a gene for patentability? These are questions that the Act does not explicitly address. The exclusion of animal or plant parts should be treated seriously because it is stated differently than the TRIPS provision, which excludes plants and animals but does not include a particular provision for "parts." Between 1999 and 2005, India made revisions to the Patents Act of 1970 on three separate occasions. The initial revision took place in 1999 to implement the TRIPS clauses and fulfill the initial deadline. Specific provisions of this revision were applied retroactively to the year 1995. The second amendment was enacted in 2002, aligning Indian law more closely with the Agreement. The third amendment was passed in December 2004 and was enacted on January 1, 2005, to ensure full compliance of the Patents Act with TRIPS. Removing Section 5 from the Act was crucial in granting product patents in biotechnology, chemicals, and pharmaceuticals.[33] Article 27(1)[34] of the TRIPS Agreement states that patents must be granted without discrimination for inventions in all technology sectors, with certain conditions applied. This indicates that it is

[31] Archana Raghavendra, Gene Patenting: An India Perspective, mondaq https://www.mondaq.com/india/patent/1085392/gene-patenting-an-india-perspective (Last visited on September 29, 2023 at 03:51PM)
[32] The Patents Act, 1970, s.3(i), No.39, Acts of Parliament, 1970 (India)
[33] Malathi Lakshmikumaran, Patenting of Genetic Inventions, Vol.12, JIPR, 45, 45-46 (2007) http://docs.manupatra.in/newsline/articles/Upload/28657BF6-ADAE-43AD-A87F-0DBB440B8D75.pdf
[34] The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), 1995, Art.27(1)

possible to obtain patents for biotechnological inventions. The act of patenting genes and/or DNA sequences is widely practiced in the United States (US), the European Union (EU), and Japan. However, until January 2005, India did not allow the patenting of genes/DNA sequences, although procedures utilizing recombinant DNA technology to produce proteins involving a gene or DNA sequence were considered eligible for patents. With the introduction of the third amendment, it became possible to obtain product patents for DNA, RNA, or genetic inventions starting from January 2005. The Manual of Patent Office Practice and Procedure, 2005 focuses on patentable recombinant DNA, plasmids, and manufacturing methods developed through significant human interaction. The Manual stipulates that certain conditions must be satisfied to grant a patent for any gene. The genetically modified gene/amino acid sequence must possess novelty, innovativeness, and industrial utility. It represents a unique way of expressing the genetically modified gene/amino acid sequence. Moreover, an antibody against the genetically engineered protein/sequence can be protected. Similarly, the antibody/sequence-derived product can be asserted to be protected. The requirement for patenting the recombinant DNA fulfills the criterion of "novelty owing to substantial human intervention," as delineated in the Manual. This Manual offers comprehensive guidance for patenting biotechnological inventions and remains receptive to potential amendments in response to innovations.

The manual was expanded to include a special section dedicated to biotechnological and medicinal discoveries. This edition stated that any living organism artificially created, such as transgenic animals, plants, and any component thereof, is not eligible for patent protection. Creatures of natural origin, including animals, plants, plant variations, seeds, species, and genes, are also not considered patentable. However, it was noted that recombinant DNA and plasmids can be patented if there is significant human involvement. It is worth mentioning that the aforementioned annexure was absent in the subsequent edition of the manual in 2008. Section 3(j) of the manual exclusively addresses the patentability of microorganisms per the Dimminaco ruling.[35] Nevertheless, the manual offers an illustrative example further to elucidate the concept of the unity of an invention. According to this example, for a genetically modified gene sequence or amino acid sequence to be eligible for patent protection, it must meet the criteria of originality, involve an inventive step, and have industrial applicability. The following can be claimed in such cases:

A. Sequence of genes or amino acids

[35] Dimminaco AG v Controller of Patents and Designs, (2002) IPLR 255 (cal)

B. A method of expressing the aforementioned sequence

C. An antibody against a specific protein or sequence

D. A kit containing the aforementioned antibody or sequence.

This example implies that a gene can only be patented if it is recombinant, demonstrates an innovative step, and has industrial utility.

Moreover, following the Indian Biotechnology Guidelines of 2013, a gene artificially combined with creative innovation and practical industrial use is qualified for patent protection. Nevertheless, it is essential to underscore that the aforementioned criteria of substantial human involvement are not necessarily required to be met for these regulations. It is crucial to highlight that once a gene patent is granted in India, the owner is entitled to reap the commercial advantages associated with the patent.

X. CONCLUSION

Gene patenting has been a heated debate because granting inventors exclusive rights to genes would impose limitations on the development of medical management and impede progress. This would inevitably lead to conflicts between those individuals who require the utilization of such genes for healthcare purposes and the notion of Intellectual Property Rights. The lack of consistency in the Myriad ruling[36] proves that a comprehensive consensus on gene patenting has yet to be established, both at the domestic level in India and internationally. It is acknowledged that gene patenting may be perceived as a necessary but undesirable practice. In essence, the essential requirements for gene patentability are novelty and non-obviousness. Genes can indeed be eligible for patent protection whenever these criteria are met. It is crucial to distinguish between discovering creative elements in nature and utilizing intelligence to create an entirely new product. Furthermore, it is crucial to implement safeguards to manage the potential adverse consequences associated with gene patenting effectively. It is essential to maintain sight of the ultimate goal of patents, incentivizing inventors and scientists. To ensure proper oversight of the development of gene patenting, it is essential to consider ethical and moral criteria. The exploitation of biotechnological discoveries through viruses and bacteria has the potential to result in the creation of a highly destructive biological weapon. The consequences of such an invention would have significant implications for both humans and the environment. There exists a risk of introducing transgenic animals into the natural habitat, which could disrupt the ecological balance and undermine the concept of biosafety.

[36] Association for Molecular Pathology v. Myriad Genetics Inc., 569 US 576 (2013)

To effectively govern the realm of inventions, it is incumbent upon authorities to facilitate a comprehensive discourse regarding the scope of patent protection and the permissibility of bringing certain inventions to the market. Additionally, the need for collaboration among various stakeholders must be assessed. Policymakers bear the responsibility of overseeing research endeavors in a broader sense. If their objective is to foster the development of valuable products and processes, patent law is an effective mechanism for achieving this goal, owing to the incentives it offers inventors. Consequently, legislators must establish regulations that delineate the conditions under which an invention may be patented. Doing so may involve scientific and ethical experts in the rule-making process. Should policymakers desire patent officers to consider the ethical aspects of patents, they must explicitly identify the shortcomings in existing legislative safeguards. Alternatively, evaluating such ethical considerations could be entrusted to specialized agencies, such as ethical committees. Clear guidelines and institutional safeguards must be implemented, effective oversight systems should be guaranteed, and transparent public information should be provided. Conversely, individuals seeking patents must cultivate a moral compass and contemplate the potential socio-political ramifications of their breakthroughs.

Consequently, legislators bear the responsibility of enacting regulations that delineate the prerequisites for patenting an invention, and they can achieve this by engaging a broader array of scientific and ethical experts in crafting the rules. If policymakers desire patent examiners to address the ethical aspects of patents, they must explicitly define these inadequate legislative safeguards. If not, such assessment should be entrusted to other specialized agencies, such as ethics committees. Clear guidelines and institutional safeguards must be implemented, effective oversight systems should be guaranteed, and transparent public information should be provided. Conversely, individuals seeking patents must cultivate a moral compass and contemplate the potential socio-political ramifications of their breakthroughs.

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