GENE PATENTS AT THE CROSSROADS: LAW, ETHICS, AND BIOTECHNOLOGY INNOVATION

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Abstract

The rapid advancement of biotechnology has significantly transformed the landscape of modern medicine, diagnostics, and genetic research. One of the most debated issues emerging from this progress is the patenting of human genes. Gene patents occupy a controversial position at the intersection of law, ethics, and scientific innovation. This article critically examines the concept of gene patenting by exploring its historical evolution, legal foundations, scientific background, and ethical implications. Historically, the development of gene patenting can be traced to the expansion of intellectual property rights in the field of biotechnology, particularly during the late twentieth century when advancements in genetic engineering enabled the isolation and identification of specific gene sequences. Legal frameworks governing gene patents have evolved across jurisdictions, with courts and legislators attempting to balance the protection of innovation with the preservation of public interest and access to healthcare.

The article further examines the scientific basis behind gene patents, highlighting the distinction between naturally occurring genetic material and genetically modified or isolated DNA sequences. While proponents argue that gene patents encourage investment in research and development by providing economic incentives to biotechnology companies, critics contend that patenting human genes raises serious ethical concerns, including the commodification of life, restricted access to genetic testing, and barriers to scientific research. The ethical and social implications of gene patenting are therefore examined in light of global debates on human dignity, fairness, and public health.

In addition, the article evaluates the role of biotechnology companies in driving innovation while also influencing policy and intellectual property regimes. Special attention is given to the Indian perspective on gene patenting, particularly under the framework of the Patents Act, 1970, and its provisions that limit the patentability of naturally occurring biological materials. By analysing legal developments and ethical considerations, the article argues that a balanced and carefully regulated approach is necessary to ensure that intellectual property protection does not undermine scientific collaboration, healthcare accessibility, or fundamental human values.

Keyword: Gene Patents, Biotechnology Innovation, Intellectual Property Law, Bioethics.

1.INTRODUCTION

Genetic research has demonstrated substantial advancements in recent decades, resulting in rapid innovation within the biotechnology sector. This prompted scientists to see the potential for novel medical therapies and diagnostic tools as they delineated the human genome and identified genes linked to disorders. This raised the question of whether human genes can be copyrighted. While patents play a crucial role in fostering innovation, they raise specific ethical and legal concerns regarding the patenting of human DNA. These challenges frequently relate to potential impacts on research, patient access to healthcare, and the ethical implications of "owning" a segment of human biology. The discourse around the patenting of human genes has long intersected with the realms of science, law, and ethics. This article examines the legal frameworks governing gene patents, the ethical implications of genetic material ownership, the economic ramifications of gene patenting, and the

contemporary Indian situation about the issue. This article seeks to provide an overview of the subject while evaluating the necessity of patenting human genes, their impact on medical research and healthcare, and the differences present in global regulations. Advancements in genetic technology, including CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats), enable scientists to alter DNA in live animals and synthetic biology, rendering the future of gene patenting a difficult matter necessitating meticulous policy deliberation.

Patents are exclusive rights conferred to safeguard inventions. By obtaining exclusive economic rights for a specified duration, these regulations incentivize additional technological progress. Patents are generally awarded for inventions that are unique, has industrial use, and are non-obvious. Companies commenced patenting isolated gene sequences, particularly those associated with diseases, to safeguard their investments in research and development.

Gene patenting refers to the legal safeguarding of genetic sequences via patents, granting the inventor exclusive rights to the genetic material. The popularity of this strategy surged with advancements in genetic engineering and biotechnology, particularly with the U.S. Supreme Court's ruling in ***Diamond v. Chakrabarty (1980)*** [1] that allowed for the patenting of genetically modified microorganisms. that genetically modified microorganisms can be patented.

The Human Genome Project, which lasted 13 years, was a research initiative that successfully mapped and decoded the whole human genetic code. The identification of the 3 billion chemical base pairs constituting our DNA established a crucial "blueprint" for human biology and revolutionized precision medicine's ability to diagnose, treat, and avert diseases. The conclusion of the Human Genome Project ignited a contentious legal controversy regarding the ownership of our genetic "blueprint." Private enterprises began to submit patents on specific sequences as researchers delineated the roughly 20,000 human genes, regarding them as lucrative intellectual property. The landmark 2013 Supreme Court ruling in Association for ***Molecular Pathology v. Myriad Genetics*** [2] determined that naturally occurring DNA constitutes a "product of nature" and is not eligible for patent protection, thereby terminating this practice. The court achieved equilibrium between corporate motivation and the accessibility of genetic research by permitting patents for synthetic DNA (cDNA) while ensuring that the fundamental code of human life remains in the public domain. Natural DNA is a biological entity comprising both non-coding introns and coding exons that encode proteins. Conversely, cDNA is a laboratory-synthesized product composed only of exons, lacking any non-coding sections.[3] The Supreme Court ruled that although natural DNA remains in the public domain, cDNA qualifies as a patentable invention due to its non-natural occurrence. Fundamentally, human intervention distinguishes the two: gene isolation is a discovery, while cDNA editing represents a creation.

2. FROM DISCOVERY TO OWNERSHIP: THE HISTORICAL EVOLUTION OF GENE PATENTING

2.1 Early Developments in Biotechnology

In the early 20th century, patents for discoveries derived from microorganisms and plants began the concept of biological patents. Nonetheless, as recombinant DNA (rDNA) technology progressed in the 1970s and 1980s, the domain of genetic patents became increasingly significant. Ananda Chakrabarty, a scientist at General Electric, secured a patent for the first genetically modified organism (GMO) in 1980, marking a pivotal moment in biotechnology patents.

2.2.The Rise of Human Gene Patents

The 1980s and 1990s experienced a surge in gene patents as biotechnology firms tried to safeguard their genetic innovations. By 2005, around 20% of the human genome had been patented.[4] A substantial number of

[1] Diamond v. Chakrabarty, 447 U.S. 303 (1980).
[2] Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013).
[3] https://byjus.com/neet/difference-between-dna-and-cdna/

[4] Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 *Science* 239, 239–40 (2005).

these patents pertained to genes associated with disorders including cystic fibrosis, Alzheimer's, and various forms of cancer.

2.3. Myriad Genetics and BRCA Gene Patents

Myriad Genetics copyrighted the BRCA1 and BRCA2 genes, which are associated with hereditary breast and ovarian cancer, making it one of the most contentious gene patents. This hindered other academics and companies from developing alternative tests, as Myriad was awarded exclusive rights to genetic testing for certain mutations. The Supreme Court invalidated Myriad's patents on naturally occurring DNA sequences in the 2013 case of ***Association for Molecular Pathology v. Myriad Genetics, Inc.***, which presented significant legal and ethical concerns.

3.PATENTABILITY OF GENES: EXAMINING THE GLOBAL LEGAL FRAMEWORK

3.1. Patent Laws Governing Genetic Material

Under a majority of patent laws, an invention must meet three criteria:

a) **Novelty** – It must be new and not previously known.
b) **Non-obviousness** – It must not be an obvious development of existing knowledge.
c) **Utility** – It must have a practical/industrial application.

- ***International Patent Regulations***

a) **United States**: Naturally occurring genes cannot be patented, but cDNA and genetically modified genes can.
b) **European Union**: The European Patent Office allows patents on genetic material if it is isolated from its natural state.[5]
c) **Japan and China**: Both countries permit gene patents with similar restrictions as the U.S.

4. DECODING THE SCIENCE: UNDERSTANDING THE BIOLOGICAL FOUNDATIONS OF GENE PATENTS

4.1. What Qualifies as a Patentable Gene?

A gene must be separated from the human body and demonstrate novel uses in a lab environment in order to be eligible for patent protection. This often includes:

a) Modified genes used in gene therapy
b) Synthetic DNA sequences
c) Genetically engineered organisms

4.2. The Editing of Genes

The CRISPR-Cas9 system, an exact molecular instrument originating from bacterial immunity mechanisms, is the primary tool employed in human genome editing.[6] The initial step in the technique involves the synthesis of a guide RNA (gRNA) that is complementary to a certain DNA sequence present in the human genome. Upon entering the cell, the gRNA directs the Cas9 enzyme to the targeted site, where it operates as "molecular scissors" to cleave the DNA strands. Researchers may utilize Non-Homologous End Joining (NHEJ), often leading to gene inactivation, or Homology-Directed Repair (HDR), which supplies a DNA template for accurate sequence correction or insertion, to assist the cell in repairing the break with its intrinsic mechanisms. This method holds significant potential for addressing genetic problems by directly modifying the underlying code of life.[7]

5. ETHICS, HUMANITY, AND GENETIC OWNERSHIP: SOCIETAL CONCERNS IN GENE PATENTING

5.1. Ownership and Commodification of Human Life

One major ethical concern is whether segments of the human genome, our biological heritage, should be

[5] Directive 98/44/EC
[6] Patrick D. Hsu, Eric S. Lander & Feng Zhang, *Development and Applications of CRISPR-Cas9 for Genome Engineering*, 157 *Cell* 1262, 1262–78 (2014).
[7] Jennifer A. Doudna & Emmanuelle Charpentier, *The New Frontier of Genome Engineering with CRISPR-Cas9*, 346 *Science* (2014).

subject to private ownership. The Patenting of genes can be seen as commodifying human life by turning biological components into marketable goods.

5.2.Impact on Research and Innovation

The monopolistic character of patents may impede research and innovation. Companies may restrict or manage access to genetic information when they hold exclusive rights to particular genes. This limitation may impede or obstruct life-saving research, as numerous scientists may be reluctant or incapable of affording licensing fees. Another objection is that patenting human genes contravenes the ethos of academia by inhibiting collaboration and constraining scientific inquiry.

5.3.Access to Healthcare and Medical Testing

Gene patents may result in an increase in the costs of medical tests and treatments. In the Myriad Genetics case, the projected expense of BRCA testing was $3,000, resulting in a significant number of individuals being unable to pay the test.[8] This thus restricted access to potentially life-saving information. Such examples raise ethical questions regarding healthcare accessibility and prioritizing financial profit over patient care. Opponents of gene patents argue that neither individuals nor corporations should restrict access to genetic diagnostics that may facilitate illness treatment or prevention.

5.4. Informed Consent and Genetic Privacy

Another ethical dilemma relates to informed consent and genetic privacy. Genetic testing often requires sharing sensitive personal information, and patients may be unaware of how their data will be used, especially if companies hold exclusive rights to certain tests. Ethical guidelines stress that patients should have full control over their genetic information, yet the commercial nature of gene patents may compromise this autonomy.

5.5.Impact on Healthcare Access

Gene patents can lead to:

a) Higher costs for genetic testing
b) Restricted research opportunities
c) Limited treatment options for rare diseases

6. INNOVATION OR MONOPOLY? ARGUMENTS SUPPORTING HUMAN GENE PATENTS

6.1.Encourages Innovation and Investment

Biotechnology companies are financially encouraged to invest in expensive research and development through gene patenting. Companies might be less inclined to conduct risky genetic research if they don't have patent protection. Patents aid in obtaining capital from investors, which helps in keeping the progress in genetic medicine ongoing.

6.2. Facilitates Medical Advancements and Personalized Medicine

Patents promote the creation of genetic disorder diagnostics and therapies. Patented research helps with genetic testing for rare genetic conditions and diseases like cancer. Research supported by patents enables personalised medicine, which adjusts treatments based on a patient's genetic profile.

6.3. Enhances Scientific Knowledge Through Disclosure

A key requirement of the Patent Filing System is full disclosure of invention for which the application is being filed, making research accessible for further studies. Future researchers can build upon patented discoveries to improve medical treatments.

6.4.Does Not Necessarily Restrict Medical Accessibility

The ethical issues related to affordability can be regulated by adapting policies like compulsory licensing. Many countries, like India, have laws in place that guard against monopolistic practices in the filed of medicine. Patents can be granted along with public health regulations.[9]

[8] https://www.nature.com/articles/nm0600_610a

[9] Bhaven N. Sampat & Frank R. Lichtenberg, *What Are the*

7. BIOTECH GIANTS AND THE PATENT RACE: CORPORATE INFLUENCE IN GENETIC INNOVATION

Biotechnology companies play a pivotal role in the patenting of human genes. They serve as both a catalyst for innovation and raise ethical and legal concerns. These companies are the primary investors in genetic research, aiming to develop new diagnostic tools, therapies, and personalized medicine based on genetic information. Protection of intellectual property rights by securing patents on modified or artificially synthesized genetic sequences guarantees returns on investment in their research and development programs. This is where controversy arises, specifically when biotech firms patent genes isolated from the human body rather than greatly altering them or otherwise synthesizing them. Critics claim that such moves, even in the cases of genes so isolated, could restrict access to needed medical treatments and diagnostic procedures by monopoly control over critical genetic information. Concerns about biopiracy arise when biotech firms claim ownership over genetic material taken from indigenous populations without proper consent or benefit-sharing arrangements. Legal frameworks, such as India's Patents Act, 1970, and international agreements like the Convention on Biological Diversity (CBD), have laid down regulations on such matters.

8. GENE PATENTS IN INDIA: LEGAL POSITION AND POLICY CHALLENGES

In India, the topic of patenting human genes is complicated and divisive, juggling legal frameworks, scientific discoveries, and ethical considerations. Under **The Patents Act, 1970**, India takes a more stringent stance than the US, where the Supreme Court declared in ***Association for Molecular Pathology v. Myriad Genetics (2013)*** that naturally occurring human genes cannot be patented. **Section 3(c)** of the Act explicitly states that "the mere discovery of a scientific principle or the formulation of an abstract theory" is not patentable, thereby preventing the patenting of naturally occurring human genes. Additionally, **Section 3(j)** excludes "plants and animals in whole or any part thereof other than micro-organisms,"[10] which further complicates gene patenting. Modified genetic sequences can, however, be patented in India, especially if they involve human intervention or a novel technical application. This is consistent with global viewpoints that acknowledge patentability of innovations such as recombinant DNA technology, synthetic gene sequences, and genetically modified biological products. India's legal position is also heavily influenced by ethical considerations. Gene patents, according to critics, could result in monopolization and limit access to life-saving medical procedures and diagnostic tests, especially in a nation where the cost of healthcare is a significant concern. India's policies have been impacted by judicial scrutiny and public interest litigation, guaranteeing that patents do not impede access to necessary medical care. Furthermore, when a patented gene-related product is not reasonably accessible to the general public, the government may step in thanks to India's stringent compulsory licensing provisions under Section 84 of the Patents Act. The discussion surrounding gene patenting in India is still developing, with an emphasis on striking a balance between social justice and innovation due to the convergence of biotechnology, law, and ethics.

9. CONCLUSION

Human gene patenting is still a contentious topic at the nexus of ethics, law, and science. Patents encourage innovation and help biotechnology companies create innovative medical treatments and diagnostic tools, but they also raise ethical questions regarding genetic material ownership. Legal systems around the world, including those in India, are still struggling to strike a balance between the public interest and intellectual property rights, making sure that patents don't impede medical research or limit access to treatments that could save lives. The current environment has been shaped by landmark court cases that have brought to light the conflict between business interests and the core conviction that human genes, being naturally occurring entities, shouldn't be privately owned. The problem is made more complex by new genetic technologies like synthetic biology and CRISPR, so lawmakers must enact laws that encourage creativity while upholding moral

Respective Roles of the Public and Private Sectors in Pharmaceutical Innovation?, 30 *Health Affs.* 332, 332–39 (2011).

[10] The Patents Act, 1970

principles. A balanced strategy is needed going forward to protect both scientific advancement and fair access to healthcare.