IJNRD.ORG ISSN : 2456-4184
INTERNATIONAL JOURNAL OF NOVEL RESEARCH AND DEVELOPMENT (IJNRD) | IJNRD.ORG
An International Open Access, Peer-reviewed, Refereed Journal

A COMPARARTIVE STUDY ON GENE PATENTING: ANALYZING LEGAL AND ETHICAL DILEMMAS

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ABSTRACT

Gene patenting is the practice of claiming ownership rights over specific DNA sequences, allowing the patent holder to control their use. This raises ethical and legal concerns, especially regarding access to genetic research and treatments. This can undermine human dignity by treating parts of the human genome as commercial property, reducing individualsto patentable biological components. Also patenting for genetically modified plant varieties
raises the concerns of local cultivators. This commodification of genetic material can conflictwith the intrinsic value and respect owed to human life. This can lead to exploitation and inequities in access to genetic resources and healthcare. The TRIPS agreement where India is also a member country, neither mandates gene patenting nor denies which creates an uncertainty. This paper argues for a re-evaluation of the ethical frameworks guiding gene patenting. It calls for policies that curtails the exploitation while fostering innovation in genetic research, proposing alternatives that balance the interests of patent holders, researchers, and the public health and benefits sharing. Ultimately, this study aims to contribute to a more just and advanced approach to genetic science and its application in society.

Keywords: Gene Patent, Genetic Engineering, cDNA, Isolated Gene, DNA sequence

CHAPTER- I

1.1. INTRODUCTION

Promoting research and innovation as well as enabling the return of novel, advantageous outcomes to benefit society have historically been the goals of the patent institution. In exchange, the innovator receives a limited-time exclusivity that allows them to prevent othersfrom using their idea.
Although patents are a very old institution, many people are perplexed by their introduction into the field of genetics. Particularly in Europe, the proliferation of patents on human genes has sparked ethical and practical questions. A significant portion of the public opposes both the patentability of human genes and the idea that life is patentable. The predictable constraints of their field research programs are a concern of the research community.

According to a recent estimate, over 20% of human genes have had patents awarded orapplications filed:

1. Underlying example, important genes underlying monogenic illnesses (e.g., Huntington's disease, cystic fibrosis) and several common predisposition genes (e.g., BRCA1 and BRCA2) have already been patented.
2. However, with the publishing of the human genome in 2001, there was a significant decline in patent submissions, and the bar for patentability has gradually been raised.
3. In particular, European and Japanese patent examiners have taken a stricter approachthan the United States Patent and Trademark Office (USPTO).
4. Many international and national organisations have addressed the subject of patentingDNA, and while many of them essentially acknowledge the favourable impacts of patents on public interest, they need clearer guidelines.
5. Is a more conservative approach.
6. Access to diagnostic tests, in particular, has prompted significant concerns as a result of various licensing processes that have limited or impeded access.

The Nuffield Council (2002) identified four areas where DNA sequence patents have beenconcentrated

1. Diagnostic tests: The inventiveness criteria require rigorous application. Possibility of 'usepatents'.

2. Research instruments must strictly adhere to the utility criterion. Patents should beavoided.

3. Gene therapy: Identifying a disease-specific gene should not lead to product patents. Instead, support the development of safe and effective gene delivery systems.

4. Therapeutic proteins refer to the corresponding protein, not the DNA sequence.

Several papers have claimed that patents stifle research and development while also limitingpatients' access to recently accessible diagnostic technologies. According to a survey conducted by patents and licenses have had a considerable detrimental impact on clinical laboratories' ability to produce and administer genetic testing, as well as conduct research.
On the contrary, it has been argued that if inventors were not paid for their ideas, some essential developmental projects with a high chance of failure could be hampered and have a negative impact on research in specific disciplines. Industry has a big influence on scientific innovation in the sphere of biomedical advancement. Creating research tools, for example, requires time and effort, but once they are publicly available, numerous biotech companies can use them to improve their own research. Many of the difficulties are considered to be caused by the patent holder's unreasonably restrictive or monopolistic licensing arrangements, rather than the patent system itself.

Policy-making in the realm of patents is complicated due to the numerous parties with competing interests. The public debate over patenting human genes has been described as ‘mixing oil and water' since professionals' and laypeople's understandings and perspectives on the topic are frequently divergent. Furthermore, not only can laypeople and experts holdopposing viewpoints, but there are significant discrepancies within professionals.
Furthermore, it has been alleged that policymakers have responded to high-profile media issues rather than methodical data on real-world problems and situations.

1.2. LITERATURE REVIEW

According to author **Luigi Palombi** written in the book **‘Gene Cartels’** as a chapter, gene patents are unjustified because they do not constitute inventions. He claims that genes were created by no man and are "free to all men and reserved exclusively to none." Luigi strongly criticises human gene patents, claiming that they are the product of biotech businesses abusing the patent system in order to monopolise human DNA. Gene patents, rather than encouraging research and development, have stifled innovation in the quest of monopolies on naturally occurring biological materials.

In the paper written by **S. Suresh Kumar** titled **‘Patentability of Biological Inventions: AReview of Indian and International Perspectives’** claims that licenses provide significant motivation for organisations and experts to invest in the development of novel hereditary advancements, which can lead to crucial advances in

domains such as medicine and agriculture. He also claims that patents can assist innovators in protecting their rights and ensuring that they can recover their investment in research and development.

The research paper written by **K.S. Jayaraman,** in his article **'Gene Patents and Biotechnology Innovation in India'** the author points out that the patent system is an important instrument for preserving inventors' intellectual property rights, which can serve to promote investment in research and development. He contends that without the opportunity to get patents, businesses and researchers may be less willing to invest in genetic engineering technology, thus slowing the rate of innovation in this area.

This research paper written by **J Goldstein and E Golod** titled **'Human Gene patent'** argue that genetic patents should be awarded, but only if the material is separated from its surroundings. Genes found spontaneously in the body are not purified or extracted. Thus, gene patents exclusively grant rights to these separated genes. The authors seek to show that there are no legal issues linked with gene patents and concluded that society benefits by allowing the privatisation of these pure human genes and granting gene patents.

In the research paper **titled 'Some Legal Issues Regarding the Patenting of Human Genetic Materials'** written by Peter **MacFarlane, Betty Kontoleon**. The paper discusses the

legal implications of gene patenting, particularly regarding the BRCA1 gene, highlighting ethical concerns about ownership of human genetic materials and the requirements under the Patents Act 1990 for granting patents involving such materials.

In the paper titled **'Isolated gene patenting: ethical implications or future promises, looking ahead'** written by **Smita Sahu, Ritika Sharma** argues that Gene patenting raiseslegal and ethical implications regarding access to genetic testing and healthcare. It creates
barriers for patients seeking treatments and diagnostics, while also influencing IP policies that view genes as mere chemical substances, impacting innovation and research dissemination.

1.3. RESEARCH PROBLEM

The research problem is whether India balance the regulation of gene patenting by completely enabling patents for agricultural applications with benefit sharing while retainingthorough scrutiny and regulation of gene patents for medicinal uses to preserve public healthand innovation. This paper involves a comparative study of the laws of USA, EU and India on gene patenting.

1.4. RESEARCH OBJECTIVE

1. To examine the current legal framework for gene patenting focusing on agricultural and therapeutic uses.
2. To evaluate the ethical and legal implications posed by the gene patents.
3. To compare the laws of EU, US and India with respect to gene patenting.

1.5. RESEARCH HYPOTHESIS

1. If India's legal framework provides gene patents for plaint varieties and other biotechnological products to industries without benefit sharing, then it affects themoral and legal rights of the cultivators and it affects the local economy
2. If gene patenting is not allowed for therapeutic purposes of humans, then it affects thepublic health and innovation

1.6 RESEARCH QUESTIONS

1. Whether India's legislative framework for gene patenting, primarily for plant varieties and biotechnological products, has an impact on cultivators' moral and legal rights, as well as the local economy's benefit-sharing.
2. Whether India's prohibition on gene patenting for therapeutic applications has an influence on public health and biomedical innovation.

CHAPTER- II

2.1. RESEARCH METHODOLOGY

We have adopted the doctrinal method of research for our paper which includes both primary sources and secondary sources

- **PRIMARY SOURCES** such as Indian Patents Act, TRIPS agreement
- **SECONDARY SOURCES** such as thesis, research papers, research articles, journalsetc.

2.2. GENE PATENTING

2.2.1. MEANING OF GENE PATENTING

A gene patent is a type of intellectual property protection that grants exclusive rights to the first entity, whether an individual, organization, or corporation, to identify and sequence a certain DNA region. These patents, issued by the government, give the holder the right to control the use of the patented gene in both commercial and non-commercial situations, such as genetic testing services and research. Gene patents are normally valid for 20 years from the date of filing; this exclusivity frequently results in sole ownership of genetic testing for the patented genes by the individual corporations or entities. This approach tries to reward innovation and investment in genomics while raising challenging ethical and accessibility issues in the area of healthcare and scientific research.

While gene patents differ from other types of patents, they must meet a common set of standards in order to be patentable. Gene patents, like normal patents, must meet certain criteria, including novelty, non-obviousness, and utility. This agreement with traditional patent rules emphasizes the shared base of principles controlling intellectual property, even inthe fast-changing field of genetic discoveries:

1. **Novel:** Novelty requires that the gene sequence be truly novel and not previouslydisclosed
2. **Inventive:** A non-obvious alteration that assures the gene's properties are more than just a simple extension of previous knowledge.
3. **Capable of applications:** The gene must have practical utility, contributing toadvances in fields such as medicine, agriculture, and industry.

2.2.2. TRIPS AGREEMENT ON GENE PATENTING

Article 27(3) of TRIPS agreement states that Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof.

The international patent law has a significant problem in keeping up with emerging biotechnology breakthroughs. The worldwide patent law fails to offer enough patent protection for biotechnology inventions (particularly genetic breakthroughs). The TRIPS

Agreement establishes baseline requirements for member states to follow when granting patents; nonetheless, it allows significant gaps in the meaning of many terms, including innovation, microorganisms, microbiological processes, and biological processes. Given the slow pace of scientific and technical advancement in developing nations, these gaps and uncertainties have a significant impact. TRIPS' technology-neutral nature precludes special treatment of biotechnology inventions. The international patent regime is the outcome of member nations' efforts to harmonise patent laws and establish a uniform set of requirements for the international community

However, in the case of biotechnology patents, the disparity in patent policies among membercountries makes it difficult to establish a global norm. Furthermore, there is a political gap between developed and developing countries, as developed countries advocate for broadeningthe scope of patentable subject matter by eliminating exceptions from the TRIPS language, whilst developing countries oppose this strategy. In the biotechnological setting, creating a uniform set of patenting principles for the entire world has proven extremely difficult to achieve given the disagreement over problems such as patenting plants and animals.

2.2.3. GENE PATENTING IN THE EU AND THE US

Gene patenting in the **European Union (EU) and the United States** share a key principle: neither state normally allows the patenting of native gene and protein sequences. However, there are exceptions, particularly in the case of biological materials and similar gene or protein sequences present in nature. In certain circumstances, these elements may be eligible for patent protection. Despite this common ground, the patentability standards for gene and protein sequences differ between the EU and the United States, providing a complex landscape for patent holders and legal drafters. Navigating these differences presents difficulties, requiring a thorough awareness of the nuanced differences in each region's
intellectual property laws.

For players in the field of genetic innovation, understanding these distinctions is critical fordeveloping effective strategies to protect biological materials in both the EU and the United States, assuring a holistic approach to gene patenting across varied legislative regimes.

2.2.4. EUROPEAN UNION

Gene patents in the European Union (EU) are governed by Directive 98/44/EC and the **European Patent Office (EPO) Guidelines**, which establish a framework for patenting biological material. The EU defines "biological material" as everything that contains genetic information and may reproduce itself, including nucleotide sequences, complete genes, cDNA, and fragments thereof. To be patentable under the Biotech Directive, the biological material must be novel, include an inventive step, and be industrially relevant.

Notably, separated or technologically created biological material can be patented, even if it exists naturally. However, there are various rules for patenting biological material derived from the human body. The simple discovery of a gene sequence is not patentable; instead, it must be isolated or purified from the natural environment, produced by a technical process (such as identification, purification, or classification), or discovered in nature with a demonstrated technical effect (for example, for use in polypeptide production or gene therapy). Gene patents in the EU, like all other patents, must meet utility or application

criteria, which need a demonstrated practical purpose rather than simply identifying thestructure of a protein.

2.2.5. CASE LAW ON UNITED STATES GENE PATENTING- *ASSOCIATION FOR MOLECULAR PATHOLOGY V. MYRIAD GENETICS, INC*[1]

The United States has a fundamentally different approach to gene patenting than the European Union, particularly in terms of biological material and genetic sequence
patentability. Until 2013, the conventional view was that natural chemicals might be patented if "sufficiently isolated." However, the seminal Myriad case changed the landscape that year.The court determined that simply extracting genes from an organism could not be protected since DNA was considered a "product of nature," with no production of something truly new and beneficial. This ruling indicated a shift from prior procedures by denying the exclusive right to isolate genes and produce complementary DNA (cDNA). The Myriad ruling had a far-reaching influence, invalidating over 4,300 patented human genes and setting a precedent that changed the scope and limits of gene patenting in the United States.

While gene patenting policies differ between the European Union (EU) and the United States,some similarities and differences impact the landscape in both regions. The Myriad rulings in the United States and the EU's Directive present opposing viewpoints. In the United States, the Myriad verdicts represented a dramatic shift, making genes obtained from organisms unpatentable because they were considered natural products. However, both jurisdictions allow for the patenting of artificial DNA constructs or human-altered sequences. Given its synthetic nature, cDNA is still patentable in both the EU and the United States.

The Myriad verdicts in the United States had no influence on method claims, allowing gene alteration methods to be patented. Despite these distinctions, both the EU and the United States encourage innovation by allowing patents for applications involving newly discovered or modified gene sequences and gene manipulation methods. The delicate interaction of rules reflects a dynamic landscape that promotes developments in genetic research and technologyin both regions.

The United States Supreme Court determined that "naturally occurring" human genes cannot be patented since they are natural products, not inventions. However, the Court granted patents for laboratory-created DNA, specifically complementary DNAs (cDNAs), which differ from natural DNA. The lawsuit revolved around Myriad Genetics, whose patents on theBRCA1 and BRCA2 genes were challenged by the ACLU and PUBPAT, which claimed that Myriad's patents limited independent testing. The Court's judgement was a triumph for those arguing for free access to genetic testing, particularly for breast and ovarian cancer, as it
invalidated patents on natural DNA while upholding patents on cDNAs. The ruling was seen positively for research and public access to genetic data since it prevents firms from monopolizing naturally occurring DNA sequences, which could impede research and testing.Myriad Genetics, on the other hand, kept its cDNA patents as well as other claims connectedto their cancer risk test, BRAC analysis. Although the decision was broadly in favor of openaccess, Justice Antonin Scalia had concerns about the technical aspects of the issue.

[1] *Myriad Genetics, Inc., 569 U.S. 576*

2.2.6. INDIAN REGULATION ON GENE PATENTING

The "discovery of any living thing or non-living substance occurring in nature" is not permitted as patentable subject matter in India under **Section 3(C) of the Patent Act, 1970**. Furthermore, the Indian Patent Act of 1970's **section 3(j)** prohibits the patenting of plants and animals in whole or in part, with the exception of microorganisms. This includes seeds, varieties, and species, as well as essentially biological processes used in the production or propagation of plants and animals.

Nonetheless, patenting in India has changed significantly in recent years. The Indian Patent Office published the Manual of Patent Office Practice and Procedure, 2005, and the Indian Biotechnology Guidelines, 2013 to address the global advancements in biotechnology and theconcomitant expansion of the Indian economy.

Recombinant DNA, plasmids, and manufacturing techniques are patentable as long as they are created through significant human interaction, according to the 2005 Manual of Patent Office Practice and Procedure. The following requirements are listed in the Manual and mustbe met in order to award a patent for any gene:

The gene or amino acid sequence that has been genetically altered must be unique, creative, and applicable to industry. The genetically altered gene sequence or amino acid sequence can be expressed in a novel way; an antibody against the genetically altered protein or sequence can be said to be protected; or a kit derived from the antibody or sequence can be said to be protected. Recombinant DNA must meet the requirement of "novelty owing to substantial human intervention" in order to be patented.

Furthermore, a gene that is recombinant, has an inventive step, and has an industrial use is considered patent eligible under the 2013 Indian Biotechnology Guidelines. It should be stressed, though, that the guidelines do not need to meet the Manual's earlier requirement formeaningful human intervention. It should be mentioned that the holder of a gene patent in India is entitled to the patent's commercial benefits after it has been awarded.

Given that India has a thriving agricultural economy and that the great majority of its people work in agriculture, the country may suffer from strict legislative protections for plant geneticengineering. Through their traditional traditions, Indian farmers and the surrounding community have made major contributions to the creation, conservation, exchange, and
utilization of genetic variety. However, as gene patenting is permitted in other nations, this legal framework might benefit agro-biotech businesses outside of India that have several patents on plant-related genetic innovations. "Bio-piracy" and "cultural piracy" are the results of industrialized countries' unrestricted access to the biological resources and related knowledge of developing nations.

India has recently awarded patents for cDNA utilized in a number of advancements that meet the previously stated requirements of the Acts. For instance, the Japanese Encephalitis Virus (Patent No. 243799) provided the basis for the Genetically Stable JEV cDNA, a recombinantviral construct designed to induce the expression of a foreign polypeptide in a cell. The Japanese Encephalitis Virus-based genetically altered and stable gene JEV cDNA was deemed original, innovative, and industrially applicable by the Indian Patent Office, which iswhy the patent was awarded.

Additionally, in the January 8, 2019, case of ***Monsanto Technology LLC v. Nuziveedu SeedsLtd***[2]., the Supreme Court of India overturned the Division Bench's ruling and reinstated the Single Judge's order from March 28, 2017. In addition, the case was remanded to the single judge for legal resolution. The Supreme Court of India's ruling has recognized BT crops as significant inventions that are patentable. This ruling not only gives businesses confidence tokeep up their innovations and apply for protection under the Patents Act of 1970, but it also resolves patent law concerns pertaining to biotechnological inventions such as DNA, RNA, and rDNA as well as additional biotechnology research.

Human existence is significantly influenced by biological factors. Therefore, it is important for everyone to have access to these natural resources and profit from them. Access and Benefit Sharing (ABS) is a common name for this idea. The idea enables innovation and biodiversity conservation incentives by facilitating the fair and equitable sharing of biologicalresources, particularly genetic resources, between innovators/users and creators/conservers/providers.

Innovations and technical breakthroughs utilizing these resources must benefit the developersand be distributed to the creators and conservationists. As a signatory, India adheres to the concepts and foundations of the Biodiversity Convention, which specifically addresses ABS in its rules.

The fair benefit sharing resulting from the use of biological resources is decided by the National Biodiversity Authority (NBA). An applicant must pay a fee in exchange for the commercial exploitation of a genetic resource, with 95% of the charge going to the local andindigenous population. 'Benefit Claimers' are the locals who are involved in biological resource conservation and who create and preserve knowledge and information about biological resource utilization under BDA. Both monetary and non-monetary rewards are possible.

However, the BDA's provisions outline specific limitations and exclusions depending on the activity being carried out (e.g., research for the creation of intellectual property rights or collaborative non-commercial research under Section 5 of BDA) and the identity of the individuals accessing and using the biological resource (e.g., Indian or foreign; local or commercial enterprise).

The ***NBA v. Sunev Pharma Solutions*** [3]case is a prime illustration of improper information and incorrect reference to the biological resource's origin and geographic source. A third party may specifically submit a post-grant opposition under Section 25(2) of the Patents Act on the grounds of improper disclosure of the geographical origins and origin of biological resources used in the invention. The NBA used the provision to file a post-grant opposition against Sunev Pharma Solutions (Applicant) before the Indian Patent Office. The applicant had been granted patents on inventions that used biological components, such as those involving Azadirachta indica, Berberis aristata or Berberis vulgaris, Glycyrrhiza glabra, Jasminum officinale, Picrorhiza kurroa, Pongamia pinnata, Rubia cordiflia, Saussurea lappa,Terminalia chebula, Capsicum abbreviata, Nymphea lotus, and Curcuma longa.

[2] *CIVIL APPEAL NOS. 46164617 OF 2018*
[3] *2648/DEL/2006*

2.2.7. ETHICAL IMPLICATIONS OF GENE PATENTING

Ethics advises us to explain our intentions and provide justifications for our conduct. It doesn't matter if you want to do good; what matters is that you explain why you are doing that specific activity and what you are doing. Three primary areas need to be addressed by thebiotechnology field:

1. Incentives: the method used to encourage scientists to conduct research.
2. Intentions: the final findings of that study.
3. Actions: the research's potential relevance.

Biotechnology's advantages are heavily promoted, but its drawbacks are rarely adequatelydiscussed. We cannot continue to ignore the ethical, legal, and societal issues surroundingbiotechnology.

The following are the moral issues with gene patenting:

1. Human cloning: the genetic structure should not be changed for practical purposes. Peoplenot suitable for usage as a commodity. Genetic material is a shared inheritance that cannot beseparated possess a monopoly on it.
2. It is unethical to exchange genetic material and cross biological boundaries. For instance,human genes were put into the genes of the "Dolly" sheep.
3. All of the inherent value of genetically modified organisms will be gone since they wouldbe viewed as commodities.
4. The employment of biotechnology in reproductive biology leads to the exploitation ofwomen.
5. There are discussions on the possibility of the creation of slaves as a result of humancloning.
6. Since many research organizations employ humans as subjects, care should be taken beforebeginning any study and all methods should be discussed before beginning any experiments.

The "cell line" of humans was the subject of a patent claim for the first time in ***John Moore Vs University of California***[4]. John Moore had "hairy cell leukemia" in the aforementioned case. While he was receiving treatment, the doctor discovered that his cell lines might be usedto make a specific medication and filed for a patent. Moore argued that since it was his cell
line, he ought to be the property's owner. Subsequently, it was determined that granting rightsover a portion of the human body is against ethical standards and human dignity. Among other things, he claimed that the doctor, the pharmaceutical firm, and the University Hospitalhad violated his proprietary rights.

2.2.8. LEGAL IMPLICATIONS OF GENE PATENTING

Research into the "human genome," "human embargo," and "stem cell" has been made possible by advances in human genetics. There are significant ethical issues in these disciplines. Utilizing an individual's genetic material is a component of human genomic
research, which presents many ethical challenges. Engineering or embargoes to become fullyhuman is known as embargo research. Removing the stem cells and manipulating the embargo are highly condemned.

[4] *No. S006987. Supreme Court of California. Jul 9, 1990*

The definition of a patient's rights is negative. For instance, a product patent grants its owner the sole authority to stop others from developing, utilizing, importing, or selling that product for these purposes without the owner's consent. The active supervision of the patent holder is required to exercise this power. A patent holder might permit third parties to exploit his invention by offering licenses on his patent. To encourage study and progress in the area of biotechnological innovations, gene licensing is crucial. If the patent rights should be licensed, it would ease the organization and research load and allow for the expansion of research through the licensing of patents.

The issue of royalty stacking is closely related to the license fee's cost. According to the Organization for Economic Co-operation and Development, measures for establishing a fair total royalty burden for genetic invention products and services, including research tools, should be included in license agreements. More traditionally, tools to lower transaction costs in obtaining technological rights should be developed by the public and commercial sectors.

CHAPTER- III

3.1. CONCLUSION

Gene patenting offers both advantages and downsides. Genetic alterations benefit medical research and meet India's requirement for food security. However, the law governing plant biotechnology is required to protect the interests of local farmers in India, who make up the large bulk of the Indian population. The benefit claimants (mostly peasants and farmers with traditional seed knowledge) have no say in the determination and bargaining of benefit sharing. A significant number of adjustments are required at the legislative level to reinforce the norms and regulations that bind gene patenting in India, while offering reasonable benefits to the owners of traditional knowledge that has been passed down for thousands of years.

There is an obvious need for further harmonisation or convergence of regulations governing human gene patents. Isolated gene patents are currently impeding research and development in diagnostic services, pharmaceuticals, and therapeutic care. Prohibiting such patents would be the wisest option, taking into account legal, ethical, and moral considerations. Bolivia, for example, suggested a change to Article 27.3(b) of the TRIPS agreement that would prohibit the patenting of living forms. Patenting living forms can limit access, with patent holders charging unreasonable fees or blocking access outright. We do not propose for an outright prohibition on all life form patents because patents incentivise innovation; yet, isolated human gene patents are clearly harmful and contradict the entire objective of patent rights.

3.2. SCOPE AND LIMITATION

This study investigates the legal and ethical dimensions of gene patenting in India's agricultural and health sectors, specifically whether unrestricted agricultural gene patents without benefit-sharing undermine cultivators' rights and local economies, as well as whether restrictions on therapeutic gene patents impede public health innovation. The study examines TRIPS Agreement frameworks as well as US, EU, and Indian laws in pursuit of balanced reforms to promote innovation, economic fairness, and public health. Comparative insights from other developing nations help to inspire recommendations, which aim for policies that

favour the full granting of agricultural patents with benefit-sharing and strict monitoring of pharmaceutical patents.

The study's primary emphasis on India and chosen overseas comparisons limits its ability to investigate broader global themes. It reflects the current state of biotechnology law in 2024, with significant improvements likely posing new challenges beyond the scope of the study. Economic analysis is provided at a high level, but there is no detailed modelling of benefit- sharing and patent restrictions. This research is mostly theoretical, with a focus on legal analysis and few direct insights from stakeholders. Its emphasis on copyright and public health concerns limits the scope, limiting topics such as environmental impact and patent licensing. Furthermore, the research is limited to agricultural and therapeutic applications, without delving into broader domains such as industrial biotechnology. Future research could broaden this analysis to include other jurisdictions, sectors, and stakeholder views.

CHAPTER- IV

RECOMMENDATIONS AND SUGGESTIONS

To protect growers' interests, agricultural gene patents should contain required benefit- sharing mechanisms like royalty agreements and community development projects. These would ensure that those who contribute to biodiversity receive compensation for its economic usage. Sections 3(c) and 3(j) of the Patents Act might be amended to establish clearer definitions of patentability of genetic materials that are consistent with TRIPS while also taking into account India's socioeconomic environment. A thorough assessment process for therapeutic gene patents should be developed, with each application assessed to ensure that it fulfils high ethical criteria and provides concrete benefits to public health while not limiting access to vital therapies.

Establishing a separate regulatory agency for biotechnology will improve oversight, ensuring that gene patents in agriculture and health are consistent with national aims. Increased openness and public awareness activities are also required; educating stakeholders, such as cultivators and healthcare experts, has the potential to develop confidence and include varied opinions into gene patent rules. International collaboration on gene patenting with TRIPS member states could result in shared frameworks that handle common issues in a morally responsible manner.

To further boost public health and innovation, India might look at non-patent methods such as open-source biotechnology and public-private partnerships. Such programs could promote biotechnology developments that are affordable and accessible, thereby promoting innovation while maintaining ethical norms. By implementing these measures, India might establish a gene patent system that strikes a balance between innovation, biodiversity protection, economic fairness, and public health concerns.

Several steps can be used to balance the greater prices and limited supply of medicines caused by therapeutic gene patents while also protecting public health. Compulsory licensing could be implemented during public health emergencies to enable generics to manufacture affordable therapies. Tiered pricing methods could ensure that drugs are priced based on regional purchasing power, making them more accessible in developing countries. Public- private partnerships could stimulate corporate investment in biotechnology by providing

financial assistance, tax breaks, and research funding. Innovation funds or patent pools couldalso be established to increase access to vital patents while reducing monopolistic control over essential therapies.

Furthermore, patent extensions should be subjected to a more stringent assessment process to avoid protracted monopolies on small innovations, allowing generics to reach the market sooner. Investing in local production capabilities for key medications may minimise dependency on costly imports and make treatments cheaper. Regulatory price restrictions or price caps could be implemented to limit exorbitant pricing for life-saving medicines.

Encourage collaboration between industry and academics to cut research expenses and produce more cost-effective inventions. Finally, pharmaceutical companies should be encouraged to practise ethical patenting that prioritises public health and fair pricing. Thesepolicies would ensure that while sector innovation is encouraged, the general public still hasaccess to important therapies.

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