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Intersection of Biotechnology and Patent Law in India: A Critical Study on The Impact of Human Genetics Innovation

RAMYA NAGARAJ[1]

ABSTRACT

India's laws, especially those that protect intellectual property (IPR), are having a hard time keeping up with the rapid development of biotechnology, which includes genetic engineering and genetically modified organisms. The Indian Patents Act, 1970 gives patents to biotechnological innovations that are novel, non-obvious, and industrially applicable. However, there are ethical concerns about genetic testing and personalized medicines. Patents can encourage people to invest in biotechnology, but they can also lead to monopolies that make it harder to get essential genetic tests and treatment. This could put individuals suffering from genetic disorders at risk and make it harder for them to get the care they need. This study looks at India's biotechnology patent rules and how they compare to global standards, such as the TRIPS Agreement, which says that innovations in all areas of technology must be eligible for patents, but exceptions can be made for reasons of public health or morals. The Indian Patents Act, 1970 has certain exceptions that do not apply to genetic innovations. India tries to find this balance by selectively patenting innovative concepts and following TRIPS flexibility provisions. New technologies like CRISPR-Cas9 gene editing are testing the limits of what is legal and ethical. International standards, like UNESCO's Universal Declaration on the Human Genome and Human Rights and the ICMR guidelines, stress patient rights, informed permission, and responsible innovation. The Indian Supreme Court has said that Article 21's right to health is an important part of the right to life. They have also said that any laws that deal with human genetic patents must take public health into account. This study takes a close look at how biotechnology, especially genetic innovations involving humans, interacts with Indian patent law. It also looks at how this affects public health and moral issues.

***Keywords**: Patent Law, Biotechnology, Genetic Innovation, TRIPS, Public Health, Genetic Testing, Ethical Concern.*

I. INTRODUCTION

Biotechnology is a multifaceted area that harnesses living organisms or their constituents to

[1] Author is a LL.M. Student at St. Joseph's College of Law, India.

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develop products and procedures that are beneficial to mankind. This field of science incorporates several scientific fields like as molecular biology, genetics, biochemistry, and engineering, and has achieved substantial progress in recent times. Biotechnology has had a profound influence on several facets of human life, including healthcare, agriculture, environment, industry. The importance of biotechnology is to the advancement of new medications, immunizations, and medical tests has been immeasurable, while its involvement in boosting agricultural productivity while improving the nutritional value of crops has contributed to security of food. Additionally, biotechnology has facilitated the manufacturing of sustainable and ecologically friendly goods and materials. Biotechnology is a promising

technology that has the capacity to enhance human health, elevate living conditions, and safeguard our planet.[2] The Indian Patents Act regulates the field of biotechnology in India, allowing the patenting of biotechnological innovations that are novel, non-obvious, and have industrial applications. Nevertheless, there has been much controversy over the capacity to patent human genetics innovations in India, specifically regarding their ethical implications and possible influence on public health. An important concern about human genetics innovation in India is the availability of genetic testing and customized therapy. Although patent protection might encourage investment in research and development in the biotechnology industry, it can also result in monopolies that limit access to vital genetic testing and treatments. These circumstances have sparked concerns over the accessibility and cost of healthcare treatments for persons who have genetic illnesses or predispositions.[3]

(A) Objectives of study

This research looks at how biotechnology, especially genetic innovations concerning humans, integrates into Indian Patent law. There are also moral and public health concerns that are looked at. The rules in India, especially those that protect intellectual property (IPR), are not able to keep up with the rapid development of biotechnology. This includes genetic engineering and animals that have been genetically modified. India's patent laws support biotechnology to advance forward, but there are not any clear or explicit rules about gene rights or how the public can access genetic tests. This makes things both probable and challenging. The Indian government might want to make gene patenting regulations that are comprehensive and viable to help the biotechnology industry last. These laws should make it easier for people and

[2] Bentahar, Soumia & Abada, Rafia & Ykhlef, Nadia. (2023). BIOTECHNOLOGY: DEFINITIONS, TYPES AND MAIN APPLICATIONS. Ymer. 22. 563-575. 10.37896/YMER22.04/49.

[3] Dr Faiza Nur Rahman, Patenting Biotechnological Inventions: Social, Legal and Ethical Issues. www.researchpaedia.in

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biotechnology industry to make rightful contributions' and give public the opportunity to utilize advances in technology.

II. LAWS REGULATING GENETIC INNOVATIONS IN INDIA

India's legal framework for biotechnology patents, particularly in relation to innovations in human genetics, is structured to conform to global norms and agreements. Ensuring this harmony is crucial for maintaining India's competitive edge in the global biotechnology industry, as well as for resolving the country's specific ethical, environmental, and socio-economic concerns. India's legal systems are in accordance with important international norms and agreements.[4]

The patent laws mention's, exclusions under Section 3(b): This section excludes from patentability any invention whose primary use or exploitation would be contrary to public order or morality.

This can include certain human genetic innovations that raise ethical concerns, such as cloning or germline modifications. Section 3(c): Excludes the mere discovery of scientific principles or the discovery of any living thing or non-living substance occurring in nature, which applies to naturally occurring genetic materials. Section 3(i): Excludes methods of treatment, surgery, or diagnosis applicable to the human body from patentability. This could impact patents on certain genetic therapies or diagnostic methods. Section 3(j): Excludes from patentability plants and animals in whole or any part thereof, but allows for patenting of microorganisms and certain microbiological processes.[5]

The TRIPS Agreement, which is overseen by the World Trade Organization (WTO), is the primary global regulation that governs patents and has significant influence. contracting states, including India, are obligated to grant patents for innovations in all areas of technology, including biotechnology, if they fulfil the requirements of being novel, including an inventive step, and having industrial application. However, it allows exclusions for certain inventions on the grounds of public order, morality, or health. If WTO members want to protect public health and make sure everyone can get drugs, they can use the TRIPS Agreement's flexibility. This is what the Doha Declaration says. India has implemented its patent laws more in line with these ideas, especially when it comes to genetic breakthroughs.[6]

[4] Adv. Sakshi Kothari, Intellectual Property Law Framework in India with respect to Biotechnological Inventions, www.jpassociates.co.in
[5] THE PATENT ACT,1970. www.ipindia.gov.in
[6] Nanditta Batra, Lessons from India's Implementation of Doha Declaration on TRIPS and Public Health. www.nls.ac.in

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Due to the limited scope in Indian law, it remains uncertain whether genes, which are integral parts of plants and animals, may be copyrighted. This ambiguity arises from the prohibition on patenting plants and animals, without specifying whether it includes genes, either in their whole or in part. Nevertheless, a sudden change in India's position was seen when the Draft Patent Practice and Procedure Manual was introduced.[7] According to the appendix, biological materials like as recombinant DNA and Plasmids, together with their production methods may be patented if the process requires substantial human involvement. The 2011 edition of the Manual of Patent Practice and Procedure removed the need for 'significant human interaction'.[8]

INDIAN AND INTERNATIONAL VIEWS ON PATENTING HUMAN GENES

The Dimminaco A. G[9]case had a significant impact on the field of micro-biological study and gene patenting in India. Dimminaco A.G filed a patent application for an innovation related to the process of creating a vaccination using a live virus. The Patents Officer Examiner thoroughly examined the patent application in accordance with Section 12[10]. The application was denied on the basis that the vaccination did not meet the criteria for being considered an innovation, as defined in Section 2(j) of the Act.[11] In Monsanto case,[12] Monsanto alleged that Nuziveedu Seeds Ltd was infringing on the patent rights pertaining to a genetically modified seed variety that Monsanto owned. The Division Bench ruled that genetically engineered plants, genetically modified seeds, and gene sequences that confer genetic features to plants are not eligible for patent protection in India. The Supreme Court overturned the ruling and conducted another review of the issue. The Supreme Court has yet to render its verdict on the patentability of isolated DNA and cDNA. Recently, India has allowed the patenting of cDNA. The cDNA of the Japanese Encephalitis Virus was awarded a patent because it was deemed "new and novel" according to Section 2.

TRIPS do not include an article that specifically prohibits the patenting of genetic material, such as DNA sequences, and does not address the problem directly. Nevertheless, the TRIPS Agreement is not inflexible, as shown by Article 8[13], which allows member states to adopt appropriate regulations to safeguard public health and nutrition. These measures may be used to limit the patenting of genetic material. In addition, the TRIPS agreement acknowledges the existence of the public and morality exception, which member nations may use to prohibit the

[7] The Draft Manual of Patent Practice and Procedure, 2005.
[8] The Manual of Patent Practice and Procedure, 2011.
[9] Dimminaco A.G. v. Controller of Patents and Designs, (2002) I.P.L.R. 255 (Cal).
[10] Patent Act, 1970. EBC, 30TH Edition, 2024.
[11] Id
[12] Monsanto Technology LLC v. Nuziveedu & Ors AIR 2019 SC 559
[13] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994

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patenting of genes based on ethical and social factors. The Indian Patent Act was amended in 2005 with the purpose of aligning it fully with the TRIPS agreement, ensuring perfect consistency between the two. The international debate on the patentability of genes gained prominence in the case of Myriad.[14] This case revolved around the issue of patent rights for the DNA code responsible for instructing a cell to produce BRCA amino acids and cDNA code segments. The Supreme Court observed that granting Myriad's claims would confer upon them the only power to isolate an individual's BRCA genes and produce BRCA cDNA, thereby leading to the denial of the patent. India's patent system has drawn inspiration from the legal structure of the United States in this field. Myriad's decision, which finds problems with previous important decisions, limits it.[15]

The CRISPR Patent Battle[16] is one of the most important intellectual property cases concerning cutting edge DNA technology. The case is a well-known instance of how science, law, and innovation can work in tandem. The main issue in the case is who owns the rights for the cutting edge CRISPR-Cas9 gene-editing technology, which can be used in biotechnology, medicine, and farming. CRISPR-Cas9 is a powerful tool for editing genes that lets scientists make precise changes to DNA sequences. It has huge effects on how genetic diseases are treated, how crops are improved, and how new treatments are created. The main question here is which invention came first, the UC patent for CRISPR-Cas9, which was filed in 2012, covers its use in eukaryotic cells, or Broad's patent application for CRISPR's use in eukaryotes, which was filed in 2013, is a different invention that can be patented. People at UC say that their patent application covers all uses of CRISPR-Cas9, even those that involve eukaryotic cells. Broad says its patents are unique to how CRISPR-Cas9 was changed to work with eukaryotic cells, which needed more creativity. Patents from the Broad Institute cover the use of CRISPR-Cas9 in biological systems in the United States. This includes editing genes in humans. UC still retains broad patent rights in other regions and for uses in prokaryotic systems.

CRISPR-Cas9's eukaryotic uses, but UC is still very important in moving the technology forward and licensing it to other countries.[17] The CRISPR-Cas9[18] method is a revolutionary

[14] Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013)
[15] Diamond v. Chakrabarty, 447 U.S. 303 (1980)
[16] Regents of the University of California v. Broad Institute, Inc. (Fed. Cir. 2018). www.patentdocs.org
[17] United States Court of Appeals for the Federal Circuit. REGENTS OF THE UNIVERSITY OF CALIFORNIA, UNIVERSITY OF VIENNA, EMMANUELLE CHARPENTIER, v. BROAD INSTITUTE, INC., MASSACHUSETTS INSTITUTE OF TECHNOLOGY, PRESIDENT, AND FELLOWS OF HARVARD COLLEGE. www.cafc.uscourts.gov
[18] Redman M, King A, Watson C, King D. What is CRISPR/Cas9? Arch Dis Child Educ Pract Ed. 2016 Aug;101(4):213-5. doi:10.1136/archdischild-2016-310459. Epub2016 Apr 8. PMID: 27059283; PMCID: PMC4975809.

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way to edit genes that lets you make specific, tailored changes to genome DNA. It has a lot of potential to make medicine, farming, and many areas of biology better, but it also brings up big social, legal, and governmental problems around the world, including in India. India is a member of the CBD[19], which deals with problems linked to biotechnology and genetic materials. India's rules for gene-editing tools like CRISPR are affected by discussions in the CBD framework, especially about the Cartagena Protocol on Biosafety. The rules set a framework for gene therapy research in India. They stress ethical issues like patient safety, informed permission, and the possible long-term effects of genetic change. These rules are not just for CRISPR, but they would apply to any gene-editing tests that use CRISPR.

III. ETHICAL CONSIDERATIONS TO OBSERVE

It was Moore case that made people aware of how complicated genetic patenting is and who owns human biological materials particularly when these materials could lead to profitable innovations. This ruling made it possible for genetic research to continue innovation, but it also brought up deep ethical questions about the connection between patients and researchers, informed consent, and the commercialisation of human genetic. The case continues to be relevant in discussions about genetic patenting and the rights of individuals over their genetic material.

A major decision by the Court of Justice of the European Union (CJEU) in 2011 about the patentability of ideas involving human embryonic stem cells also known as the Brüstle case. The case is about a German researcher named Oliver Brüstle, who tried to get a patent for a way to make neural precursor cells from human embryonic stem cells so that they could be used to treat neurological conditions such as Parkinson's.[20] The main question was whether these patents went against the moral standards set by Directive 98/44/EC on the legal protection of biotechnological innovations. This directive says that patents cannot be issued for methods that use human embryos for commercial or industrial purposes. The CJEU said,

the word "human embryo" refers to any living thing that can start the process of human growth.

This includes fertilized eggs, sperm, and cells made through nuclear transfer; therefore, it is not possible to get a patent for such innovations.

The Oncomouse case is a turning point in the discussion about whether genetically modified animals (GMOs) can be patented. It also brought up ethical concerns about gene patenting. In

[19] UNEP and Biodiversity, United Nations Environment programme, www.unep.org 21 The Biological Diversity Act, 2002.Act 18 of 2003, Published in Gazette 18 on 1 January 1980, www.indiankanoon.org
[20] Oliver Brüstle v Greenpeace eV. www.eur-lex.europa.eu

the 1980s, Harvard University genetically modified a mouse with the goal of finding a fix for cancer. This made research into cancer treatment easier. Harvard tried to get patent rights all over the world. The patent was given by the U.S. Patent and Trademark Office (USPTO) in 1988, saying that the genetically modified mouse met novelty, utility, and non-obviousness, which are all requirements in U.S. for patents. The patent was initially granted by the European Patent Office (EPO) in 1992, But later the resistance came due to ethical concerns with genetic modification that use animals for benefits such cancer research were greater than any ethical worries. The patent was only limited to rats. In Canadian higher life forms like animals are not patentable so the Oncomouse claim was turned down by the Supreme Court.[21]

The Universal Declaration on the Human Genome and Human Rights[22] adopted by UNESCO, says that the human DNA in its natural state should not be used to make money. It makes rules about what is right and wrong for genetic study and innovation involving humans, and these rules affect how national laws handle patenting human genes. There is an international set of rules for how to do responsible genomic research and utilization of genetic information in Declaration. It strikes a balance between the possible benefits of genetic progress and the need to safeguard human rights, dignity, and diversity. The declaration's ethical guidelines are still used to help lawmakers, researchers, and practitioners deal with the problems and chances that modern genetics and biotechnology present.

The ICMR[23] is in charge of making sure that biomedical research is done in an ethical way. This includes how CRISPR is used in gene therapy and for human health. It has set rules for gene therapy studies that stress how important it is to think about ethics and get informed permission. Concerns about the possibility of "designer babies" and the moral implications of changing the DNA of humans are just a few of the issues that CRISPR has stirred up around the world.

Acquiring necessary medical technology may be challenging due to restrictions such as limited access to healthcare and constraints on patents and other intellectual property rights Some important genetic medicines or diagnostic tools may be protected by patents, which could make genetic engineering and gene editing harder for people who cannot afford to buy these trademarked and patented technologies. This causes concerns about the moral balance between private interests and the collective well-being, as well as the equitable access to healthcare. Genetic engineering and gene editing technology can change the basic traits and characteristics

[21] Bioethics and Patent Law: The Case of the Oncourse. www.wipo.int
[22] Federico Mayor, The Universal Declaration on the Human Genome and Human Rights, www.sciencedirect.com
[23] National Guidelines for Gene Therapy Product Development & Clinical Trials (2019), www.main.icmr.nic.in

of living organisms, including humans

When these technologies are used to change people's genes, especially through germline editing, they raise ethical concerns that could affect people's right to privacy, liberty, dignity, and limitations permissible interventions.[24] The use of genetic engineering and gene editing technology has the capacity to worsen existing economic and social gaps.[25]

IV. PUBLIC HEALTH AND GENETIC INNOVATIONS

In Chakrabarty's case the Supreme Court ruled that a genetically modified organisms that could break down crude oil could be protected by a patent. The main question was whether patents could be given for live things. ruling made it clear that living organisms could be patented if they were modified by humans' intervention. Genetic discoveries, such as genes and genetically modified organisms (GMOs), can now be patented. This case made it possible for new biotechnological innovations to come about, but it also raised ethical concerns regarding patenting organisms and raised concerns about how it might affect public health, especially when it comes about biotechnology.[26]

The Howard Florey/Relaxing Case[27] is considered landmark when it comes to genetic innovation and the right to protect human genetic material.

This case was about a European patent application that was made for the human gene encoding for Relaxing, a hormone that is important during pregnancy and childbirth. The patent covered both the gene's DNA sequence and its uses in industrial application, like using relaxing in medical treatments. Legal issues involved was whether a naturally occurring human gene could be considered an invention under the European Patent Convention (EPC) once it has been identified and isolated. Ethical concerns involved was whether patenting a human gene went against ethics or public order under Article 53(a) of the EPC, which says that ideas that are morally wrong are not allowed. The EPO supported the patent, saying that isolated DNA sequences were novel, had an inventive step and industrial applicability, which means they can be patented. The process of isolating and identifying the relaxing gene has rendered it something "man-made" that does not occur naturally. The patent did not break any ethical or public order rules because it did not claim ownership over the human body or the gene in its natural state. Instead, it claimed ownership over the gene and its isolated form and use. In terms of

[24] pooja, Genetic engineering and Intellectual property: Legal and Ethical Implications. www.legalvidhiya.com
[25] Kushagra Prasad, The Legal and Ethical Implications of Genetic Engineering and Gene Editing Technologies on India's Intellectual Property Laws, www.thelegallock.com
[26] Diamond v. Chakrabarty, 447 U.S. 303 (1980)
[27] T 0272/95 (Relaxing/HOWARD FLOREY INSTITUTE) of 23.10.2002. www.opusip.co.uk

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Applicability in Industry the use of relaxing in medical treatments made it useful as there was commercial viability which is exactly what was needed for a patent. This case made it clear that human genes can be patented in Europe and biotechnology innovations that use isolated genetic material can be protected. It made Article 53(a) clearer and said that rights on isolated genetic material used in medicine and industry are not inherently unethical. This case showed that patent laws can keep up with scientific innovations while also addressing ethical and public issues.

Critics opined allowing patents on human genes could lead to monopolization by companies that would make it challenging for people to get genetic tests and treatments. The case was later heard again in different perspective like in the important U.S. case Myriad Genetics (2013), which restricted the ability to protect natural genes. The Howard Florey/Relaxing Case is still an essential case in intellectual property law as it changed the course of genetic patents by confirming that genetic material that can be used in industry can be protected under European law, if it meets ethical and legal standards.

The Myriad case was mostly about whether the BRCA1 and BRCA2 genes could be patented. These genes are linked to higher chances of breast and ovarian cancer. According to the Supreme Court, DNA patterns that happen spontaneously and cannot be copyrighted. However, manufactured DNA (cDNA) can be. This case made it clear that genes are natural products that cannot be patented just because they have been separated. People thought the ruling was good for public health because it made genetic testing and study easier for more people. There were worries that gene rights could make it harder to get important medical tests, which would make them more expensive and limit research. The Court help in making sure that more people could afford and get genetic information that is important for public health by striking out patents on natural DNA.[28]

The decision had substantial ethical and legal effects, showing how important it is to balance new science discoveries with moral concerns. It limited the scope of biological patents that could be used in Europe while still protecting people's rights to live even an embryo. Some critics felt that this decision might adversely impact stem cell research by taking away commercial advantages. The case continues to be very important in addressing issues concerning and intellectual property rights.[29]

An important role that the Indian Supreme Court does is to protect public health. The Supreme

[28] Assoc. for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013)
[29] Oliver Brüstle v Greenpeace eV. www.eur-lex.europa.eu

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Court has said many times that Article 21's word "life" refers to a life with human dignity not just survival or animal existence[30] the right to life includes many things, such as the right to livelihood, the right to a better standard of living, the right to safe working conditions, and the right to leisure. The right to health is an essential part of living a decent life. To fully understand what the state has to do in this situation, Article 21 should also be read along with the directive principles. Any laws or rules about inventions involving human genetic innovation should put public health first and make sure that these inventions do not make it harder for people to get medical care. DPSP Articles 38, 39, 47 States that Says that the state must maintain a social order that is good for the people, government must also protect the health and strength of workers, both men and women, as well as the tender age of children and government must improve public health and nutrition.

V. CONCLUSION

To summarize, the intersection of biotechnology and patent law in India presents both obstacles and opportunities, namely in the field of human genetics innovation. India does not have any regulations in this domain. The implications affect both the safeguarding of innovation and the availability of crucial genetic technology for patients. The lack of clarity in Indian patent laws might impede the progress and monetization of innovative genetic technologies, since businesses may hesitate to engage in research and development without sufficient intellectual property safeguards. Simultaneously, the lack of clear instructions might also restrict the availability of crucial genetic testing and treatments, especially for individuals belonging to economically weak families. Therefore, I concur that existing Indian patent laws pertaining to genetic innovations are inadequate and with multiple barriers. Clearer laws on genetic innovations in biotechnology and intellectual property will ensure that India possess an optimal environment for research, patenting, and commercialization so as to stay on par with global competition.

(A) Suggestions

1. In order to tackle these difficulties, the Indian government should think about developing of an exhaustive legal framework for gene patents that effectively manages to promoting innovation while also addressing issues about pricing and availability.

[30] Francis Coralie Mullin vs The Administrator, Union Territory of Delhi AIR 1981 746 36 'V.N. Shukla's', Constitution of India, EBC, 14TH Edition with supplement 202

2. Another possible solution is to create a regulatory body to supervise gene patents, while also putting in place measures that guarantee patients to access affordable genetic testing and treatments.

3. Partnerships among academics, businesses and the government might assist the advancement and widespread use of innovative genetic technology in India.

4. India can establish itself as an important player in human genetics research and development by creating a conducive environment for biotechnology innovation.

5. Provide Gene editing to those genetically debilitating disease which will not contravene with the ethical and public health.

6. Create an environment for genetic treatment tourism in India.

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