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Biotechnology And Patent Laws: Indian And International Perspective

Adv. Astha Gupta[1]

[1]*LLM scholar renaissance university, Indore*

Abstract

Innovations in biotechnology have transformed the scientific landscape, bringing forth groundbreaking advancements that have significant implications for healthcare, agriculture, and industry. This paper provides a critical examination of the relationship between biotechnology and patent law, exploring the ethical and legal challenges associated with the patenting of genetic material, bioengineered organisms, and therapeutic techniques. By conducting a thorough analysis of pertinent case law, legislative changes, and international viewpoints, this research aims to illuminate the fragile balance between promoting innovation and guaranteeing fair access to biotechnological advancements.

Keywords; Biotechnology, Patent Law, Genetic Material, Bioengineered Organisms, Ethical Challenges, Innovation Access.

INTRODUCTION

The biotechnological innovations have provided the paradigm shift in the worlds of various practices and have led to the development of innovations in healthcare, agriculture, and industry. Such inventions, however, require a strong intellectual property system in order to safeguard and encourage scientific inventiveness. In India, biotechnological inventions are eligible to patentation, but only after meeting the major requirements to patentability, novelty, inventive step and industrial applicability. To establish consistency and uniformity in the review of biotechnology patent applications, the Indian Patent Office has provided the Biotechnology Patent Guidelines which are periodically revised to incorporate judicial reviews, legislative changes and comments by the stakeholder.

What Is Biotechnology?

- World Health Organization (WHO) defines biotechnology as the use of biologically engineered processes. It is widely divided into:
- Biotechnology in Healthcare (Red) Medicines, diagnostics and therapeutics.
- **Biotechnology in Agriculture (Green) -** Enhancement of crops and resilience to stress.
- **Industrial Biotechnology (White) -** Environmentally friendly production of bio-based products such as biofuels and bioplastics.
- Biotechnology industry is in biopharmaceuticals, bio agriculture, bio services, bio industrial, and bioinformatics with effects in the diagnostic process, vaccine manufacturing, drug manufacturing, etc.,

Patents in Biotechnology.

A patent provides an inventor with the exclusive right to keep off any other inventor, user or seller of an invention, which is normally a term of 20 years. Patents safeguard inventions in biological material, procedure and product in biotechnology, which assists in research, investment and the creation of unparalleled remedies in the medical, farming and industry sectors.

1.1 SCOPE OF THE STUDY

The seminar will discuss the legal and ethical issues of biotechnology patents both in the Indian and international context. It is concerned with the impact of patent legislation on innovation, research, and popular good in the biotechnological field.

1. Indian Framework

Discusses the Patents Act, 1970, and Biotechnology Patent Guidelines, emphasizing the novelty, inventive step and the industry applicability requirement of biotechnology patent.

2. International Framework

Examines the international treaties like the TRIPS Agreement, the Budapest Treaty, and the WIPO guidelines as compared to the practices in India.

3. Relevance in Economy and Future.

Remarks on the emerging biotech sector in India and the necessity to create a balanced patent protection to encourage innovation, investment, and societal good will, in particular, with new technologies such as gene editing and synthetic biology.

1.2 RESEARCH OBJECTIVES

- To look at the scope and challenges of patent protection in biotechnology under Indian law.
- To compare the international framework on biotechnology patents, including the U.S., EU, TRIPS, and others.
- To study how patent law connects with biodiversity conservation and farmers' rights in India.
- To review important court decisions that influence biotechnology patent law in India and around the world.
- To identify ethical, social, and policy issues related to granting or limiting biotech patents.
- To propose reforms that balance the need for innovation with access to medicines, food security, and fairness.

1.3 RESEARCH PROBLEMS

With the advent of biotechnology, the scope of the law on patents has been reestablished with the advent of inventions into living organisms, genetic materials, and biological processes. Although India has revised the Patents Act,1970 to cover biochemical/ biotechnological and microbiological processes, there remains ambiguity on the scope of patentability of life forms under Section 3(c) [1]and 3(j). This has resulted in discrepancies in the interpretations of patent authorities and courts.

At the international level, TRIPS Agreement offers protection of patents in all technological sectors, but exceptions are made on plants, animals, and biological processes. Nevertheless, lack of clear definitions of such concepts as microorganisms or biological materials has led to varying national standards and ethical issues, especially with regards to biopiracy, traditional knowledge and access to genetic resources.

Therefore, the research problem that is to be addressed is the way in which patent legislation, either Indian or foreign, can secure sufficient protection of the biotechnological innovations without infringing on the ethical dimension, the interest of the population, and the conservation of the biodiversity.

1.4 LITRATURE REVIEW

Biotechnology and patent law have been developing in a specific way, which can be interpreted as the tension between the encouragement of the innovative process and the ethical principles. Researchers such as Dutfield (2009) and Eisenberg (1987) point out that patents in biotechnology enhance research and commercialization especially in the fields of pharmaceuticals and agriculture.

The landmark case Diamond v. Chakrabarty (1980) initiated the patenting of living beings, and this has affected the world regimes in the TRIPS Agreement (1995). But Association for Molecular Pathology v. Myriad Genetics (2013) limited claims to patenting the genes but pointed out that the natural sequences of DNA are not an invention.

Post-TRIPS reforms in India In India, the Patents (Amendment) Act, 2005, which introduced product patents in biotechnology, preserved ethical safeguards in Section 3(b), 3(c) and 3(j) of the Indian Patent Act (1970).

[1] *Indian Patents Act, No. 39 of 1970, § 3, India Code, https://www.indiacode.nic.in/show-data?abv=CEN&statehandle=123456789/1362&actid=AC_CEN_11_61_00002_197039_1517807321764&sectionId=15871&sectionno=3&orderno=3&orgactid=AC_CEN_11_61_00002_197039_1517807321764.*

According to scholars such as Mamta Mittal and H. Herath (2022), India balances between innovation and social welfare with the help of such tools as compulsory licensing.

1.5 RESEARCH QUESTIONS

- What is the scope of biotechnology patentability under Indian law compared to international frameworks like the U.S., EU, and TRIPS?
- How do statutory exclusions, such as Section 3 of the Indian Patents Act, affect biotechnology innovation?
- How can patent systems support biodiversity conservation, farmers' rights, and protecting traditional knowledge?
- What ethical and socio-economic challenges come from granting patents on life forms and biological material?

1.6 HYPOTHESIS

Strong patent safeguarding in biotechnology based on very good ethics and good innovation supports innovation and also ensures fair access to life-saving technologies.

The current Indian patent regime is more than adequate to support international standards but must be regularly updated to keep pace with the new technology such as gene editing and synthetic biology.

The law on patenting biotechnology in the world needs to be harmonized to avoid legal disparities and encourage responsible science research.

Ethical protections built into patent systems could decrease the abuse and commercialization of genetic resources and still maintain innovation motivation**.**

1.7 RESEARCH METHODOLOGY

This research paper adheres to a doctrinal and analytical methodology with the specific attention to legal principles and guidelines that regulate bio-technology patents in India and the world on the whole. It is descriptive and qualitative as it is founded on the understanding of laws, international treaties and judicial decisions as opposed to empirical data.

Primary Sources: The Patents Act, 1970; TRIPS Agreement; international conventions; and precedent decisions.

Secondary One: Books, research journals, WTO and WIPO reports, publications by scholars on biotechnology and intellectual property law.

Indian and international patent systems are analyzed comparatively and interpretatively with an aim of pointing out gaps and discussing ethical and policy concerns in patenting biotechnology.

PATENT IN BIOTECHNOLOGY

Patents are a very critical part of biotechnology industry, and it offers legal protection where the inventors can secure their invention and get the commercial rewards out of their research work. Since the cost and risks involved in biotechnology research and development (R&D) are high, patent protection acts as one of the principal motivators to innovation. It makes sure that the investment of inventors will be compensated, it will attract more investors and will encourage new achievements in science and technology.

The biotechnology industry cannot do without patents since they ensure that inventors have their rights and damages are upheld and also create a culture of innovation. They have various purposes which lead to the advancement of technology as well as economic development.

- **Fostering Innovation**

Patents support that innovative ideas are created with the inventor being given exclusive rights over the product at a certain time. This monopoly encourages scientists and businesses to allocate their time and resources to the development of new and better biotechnological products, processes and materials.[2]

- **Securing Investment**

The research in biotechnology requires high financial investment. The use of patent protection assures an innovator that his or her invention cannot be replicated or utilized without permission, that is, then it can retrieve R&D investment, and gain profitability.

- **Attracting Investors**

Patents are considered a sign of technological prowess and potential in the market by investors. Firms with good biotechnology patents are more competitive in terms of attracting funds, alliances and strategic alliances.

[2] *Rohini Akshay Bhapkar & Prajakta Pimpalshende, Understanding Biotechnology Patents: Key Requirements and Legal Framework in India, 5 Int'l J. Research Publication & Reviews 2483 (Sept. 2024)*

In biotechnology, patentable subject matter is not limited to drugs or devices since it also applies to genetically modified plants. human biotechnology, patentable subject matter is not restricted to drugs or devices as it also includes genetically modified plants.

Not every invention in the field of biotechnology can be patented. To be patentable, an invention should meet the simple qualifications of the basic criteria of novelty, inventive step, and industrial applicability. The invention of genetic materials, altered organisms, and new diagnostic tools are some of the more frequently patentable inventions in the biotechnology industry.

There are eight categories of Patents in Biotechnology.

- **Utility Patents:** Protect new and useful processes, compositions or machines including genetically modified organisms (GMOs), DNA sequences, and bioengineered drugs.
- **Plant Patents:** Safeguard asexual breeds of plants-essential in biotechnology in agriculture.
- Design Patents are used in regard to the original ornamental design of equipment or device in laboratories or healthcare.
- **Gene Patents:** Give special privileges against certain gene sequences or genetic materials, but they are unpopular because of the limitations in ethics and research.
- **Patients of Diagnostic Methods:** Patent new techniques of detecting diseases, such as new assays and diagnostic equipment.

Ethical and legal aspects of Biotechnological Patents.[3]

The science of biotechnology is associated with manipulation of living organisms, and it is subject to intense ethical and legal issues. Conventionally, life forms were deemed to be the creation of nature and thus unpatentable. Nevertheless, the scientific developments have erased the recognition of both natural and man-made things.

Natural Life: Invented by nature and therefore it cannot be patented.

Non-Natural Life: This refers to the product of human effort like genetically modified organisms and is thus patentable.

This change has necessitated the adjustment of legal systems in all parts of the world to broaden the horizons of patents law to adapt to the biotechnological advancements. International harmonization of the Biotechnology patent laws is practiced in this section of the patents act.

CLASSIFICATION AND LEGAL FRAMEWORK OF BIOTECHNOLOGY PATENTS

The nexus of biotechnology and patent law has been changing spectacularly within the last several decades. With the development of biotechnological research in areas like genetic engineering, pharmaceuticals, bioinformatics, among others, patent systems in different countries across the globe have needed to adapt to safeguard innovations in such areas. To strike a balance between the aspects of innovation, ethical issues, and the common good, it is necessary to categorize biotechnology patents and address the creation of a proper legal framework.

The US patent laws have divided biotechnology patents into three distinct categories.

The patents of biotechnology are widely classified in terms of the nature of the invention and the type of protection required. The knowledge of these classifications is useful in determining the extent of legal rights and coverage of innovations in this industry.

1. Product Patents

Protecting the specific biological products or a combination of matter, such as new proteins, genetic sequences, enzymes, vaccines, and pharmaceutical compounds, product patents. The patents are prevalent in the pharmaceutical and healthcare industry where they grant an exclusive right over new therapeutic molecules and biologically derived drugs.

An example here is that a new gene sequence or a recombinant protein that was created because of biotechnological manipulation can be patented as a product.

2. Process Patents[4]

Process patents protect the procedures or processes of manufacturing a product or biomaterial. They could involve

[3] *Renu Raina Sehgal et al., Biotechnology Patents: Legal and Ethical Implications, J Postgrad Med Educ Res 53, 123 (2020)*

[4] *Renu Raina Sehgal et al., Biotechnology Patents: Legal and Ethical Implications, J Postgrad Med Educ Res 53, 123*

approaches to the synthesis of a given protein, the creation of a genetically modified organism (GMO) or the design of diagnostic tests.

Process patents in India have helped to strike a balance between innovation and accessibility particularly in pharmaceuticals where alternative methods of production are promoted.

Comprehensive Protection

Innovators in most instances pursue product and process patents so as to provide the full security of their inventions. Nevertheless, it is too complicated and expensive to get this protection, and it frequently demands extensive scientific revelation and professional legal advice.

Legal Framework in India

The biotechnology patent regime in India is based on the Indian Patents Act, 1970 which is supplemented by the Patents Rules, 2003. According to the Act, an innovation or discovery of a new product or process, which is associated with an inventive act and can be patented on an industrial scale is termed as an invention as defined by the act, in Section 2(1)(j).

One of the central characteristics of the Indian legal system is as follows.

Criteria of patentability Biotechnological inventions have to be novel, non-obvious and industrially applicable to be patentable.

Exclusions: Sections 3(b), 3(c), and 3(j) provide that inventions that contradict morality, natural living organisms and the natural processes are not patented.

The Act permits third parties to make use of patented inventions under some circumstances, including in the case of public health emergency or where the invention is not sufficiently being worked in India.

Guidelines The Biotechnology Patent Examination Guidelines (2016) are clear on assessing biotechnology applications, including such matters as sufficiency of disclosure, biological material deposits, and ethical issues.

The Indian legal system aims at the promotion of innovativeness and creation, preserving the balance between the intellectual property rights and the state interests, making them open and morally sound.

The Landmark Case: Diamond v. Chakrabarty (1980)[5]

The shift was initiated by the verdict of the U.S. Supreme Court in the case of Diamond v. Chakrabarty (1980). The Court held a genetically engineered bacterium that had the capability to digest crude oil could be patented because it was not a natural organism, but a product of human ingenuity.

The case provided a precedent throughout the world of patent protection, where non-natural, man-made living entities could be patented.

Global Developments

After the decision of the case of Chakrabarty, the other countries started to modify their patent laws to adapt to biotechnology. The European Patent Convention (EPC) made certain provisions on biotechnological inventions and the exclusion of naturally occurring processes and human embryo as patentable.

On the same note, the laws of the countries of the world, such as, Japan, Korea, and Thailand, were revised to align with international standards under the **TRIPS Agreement (1995) to facilitate uniformity in patenting biotechnology.

New Ethical and Legal dilemmas.[6]

With the development of biotechnology, new ethical issues emerged - especially on the issues of gene patenting, genetic manipulation and biological materials ownership.

Gene Patents: Humane genes and DNA sequences were patented, and this raised an international controversy. The Human Genome project brought more debates on, who ought to own the genetic information, the individual companies or the entire human race.

Gene Editing Technologies: The recent technologies such as the use of **CRISPR-Cas9 have presented the largest opportunity as well as ethical dangers as before. Although they allow the precise editing of genes used in the treatment and agriculture of diseases, they also lead to the question of bioethics, abuse, and human germline editing.

(*2020), **https://www.jpmer.com/doi/JPMER/pdf/10.5005/jp-journals-10028-1205***.

[5] *Diamond v. Chakrabarty, 447 U.S. 303 (1980)*

[6] *Biotechnology Patents: Legal and Ethical Implications, J Postgrad Med Educ Res 53, 123 (2020)*

The patent offices and the courts are still grappling with such difficult cases and are balancing between incentives of innovation and ethical responsibilities.

PATENTING BIOTECHNOLOGY IN INDIA

The patent system in India has changed very much to cope with a lot of complexities that have been faced with in the biotechnology. Experience over colonial and modern times of genetic engineering and pharmaceuticals has seen Indian patent law to shift towards balancing innovation, ethics and welfare of the people. Biotechnology being a fast-developing discipline undermines traditional concepts of patentability especially on living organisms and biological processes.

1 Historical Background

In India, patent system appeared in the form of the Patent Act of 1856 which was based on the British legislation. It has undergone a series of amendments over time leading to the present Patents Act, 1970 that established the key principles of novelty, inventive step and industrial application.

In 2002, the Act was revised in India to cover biochemical, biotechnological, and microbiological inventions, which is consistent with the international requirements of the TRIPS Agreement (1995). This was the beginning of the Indian penetration into the realm of patenting biotechnology in the world.

2 Legal Framework in India

Biotechnology patents in India are regulated by the patents Act of 1970 as well as the Patents Rules, 2003. [7]The system is focused on innovation, but it balances between intellectual property and the availability of the crucial technologies to the population.

Legal Provisions

Section 2(1)(j): The term invention is defined as a new process or product that contains an element of innovativeness and can be industrialized.

Section 3(b), 3(c) and 3(j): Exempt inventions that are against morality, discoveries of living or non-living substances in nature and essentially biological process to produce plants and animals.

10(4) and 13(8) Rule: The biological material should be deposited under a recognised depository under the Budapest Treaty (e.g. Microbial Culture Collection, Pune; MTCC, Chandigarh).

Section 84: [8]Entails the provision of the mandatory licensing whereby patented inventions of biotechnology are made to be used by the people, especially during emergencies in health care.

Guidelines for Examination (2016)

Guidelines for Examination of Biotechnology Applications to Patents (2016) have been proposed to enable patent examiners to assess complicated biotechnology applications. They offer the understanding of biological material disclosure, gene sequences, and ethical limitations.

3 Biotechnology Patentability Requirement in India.

To secure a patent on biotechnology in India, an invention should fulfil the following requirements.

- **Novelty:** The invention should be novel, and it should not reveal in any part of the world prior to the filing date.
- **Inventive Step:** This should entail some technical development which cannot be seen by a person knowledgeable in the art.
- **Industrial Use:** The invention should be practically useful, and it should be able to be put into use in industry or research.

4 The Biotechnology patenting is an area with difficulties.

Patenting biotechnology in India however has a number of challenges:

- **Complexity of Technology**

Most biotechnological inventions consist of complex scientific information, which is difficult to articulate using legal language, and therefore, drafting of application and examination prove difficult.

- **Research Restrictions**

Patents have the potential of restricting access to vital materials or techniques, blocking research and the invention of new therapies.

- **High Costs**

Complete procedure of patents filing, maintenance and defence is costly, particularly to small companies and academic institutions.

[7] *The Patents Rules, 2003, India Code*

[8] *The Patents Act, 1970, No. 39 of 1970, India Code*

- **Slow Processing**

The process of patent examination in the biotechnology field is very demanding; there are delays in the process since patent offices have a shortage of technological experts.

- **Patent Trolls**

Other organizations patent just to impose royalty, or in order to block competition between others.

- **Lack of Transparency**

Complicated documentation and less awareness of people put small inventors at a disadvantage of navigating the system.

5 Landmark Case Law Analysis[9]

Novartis AG v. Union of India (2013)

This was in case of the anti-cancer drug Glivec. The Indian Supreme Court rejected the patent on grounds of Section 3(d), which prohibits evergreening i.e. patenting slight modifications of known drugs.

The ruling highlighted the significance of national wellness and the availability of drugs, and it has set the case of India with regard to the balancing of the requirements of TRIPS and national wellness.

Ferid Allani v. Union of India (2020)

Even though it mostly concerns inventions related to computers, the Delhi High Court reasserted that technical development is the most important towards patentability. The case depicted the way the patent law in India is still changing according to the technical advancement, such as AI and bioinformatics.

This case showed how the judiciary is flexible in its interpretation of the patent laws to fit the new technologies into the wider perspective of the intellectual property rights.

Dimminaco A.G. vs. the Controller of patents and designs (2002).

The Calcutta High Court was concerned with whether a living organism process could be patented. The court held that a procedure to manufacture a live vaccine could be patented asserting that biological processes could be patented as long as they produced a physical product.

This historic ruling paved way to biotechnological process patenting in India.

PATENTING BIOTECHNOLOGICAL PRODUCTS AND PROCESSES: AN INTERNATIONAL PERSPECTIVE

Biotechnology has transformed the contemporary science, and it has led to the emergence of innovations in the fields of medicine, agriculture and environmental management. Nevertheless, these developments come with thorny legal and ethical challenges especially on the patentability of living organisms and biological materials. The history of biotechnological patenting in the world is an indication of the persistence of a conflict over the promotion of innovation, ethics, and social good.

Biotechnological Product Patenting: History.

No patent was registered on living beings in the world up to the year 1980. Such patents were usually denied morally and naturally by the courts. Indicatively, in Funk Brothers Seed Co. v. Kalo Inoculant Co. (1948), the U.S Supreme Court did not provide a patent on non-natural seeds as they were deemed to be the products of nature. In like manner, the German Supreme Court in the case Red Dove (1976) refused the patent of non-natural living beings.

The case in point was a milestone change with Diamond v. The U.S. Supreme Court declared a genetically engineered bacterium that was able to hydrolyze crude oil as patentable (Chakrabarty 1980). The Court decided that such non-naturally occurring organism was a composition of matter and thus qualified as a patentable organism.

This ruling allowed the floodgates of biotechnology patenting in the world. European courts started to accept genetically modified organisms (GMOs) as patentable when certain conditions were met after the U.S, and this was the case in Genentech I/Polypeptide Expression. Later on the genetically modified plants and animals also received patents such as the Harvard Oncomouse (1990) - a transgenic animal developed to study cancer.

Plant and Human Genetic Material Expansion.

Following these evolutions, the genetically modified plants were also patented including in Ex parte Hibber where a mutant maize plant was found to be patentable. Others include Ciba-Geigy/Propagating Material, Lubrizol/Hybrid Plants, and Plant Genetic Systems which broadened the patents of plant biotechnology even more.

[9] *Varun Kumar Singhal & Shashi Kiran, Analysing Legal Issues in Indian Patent Law with Reference to International Intellectual Property Standards, 11 Int'l J. L. 18 (2025)*

But the patenting of human genetic material brought about ethical and legal arguments. In John Moore v. The University of California established a patent on human cell lines which were used in cancer research. Subsequent rulings like the In re Bell and In re Deuel permitted human DNA and RNA sequence patents.

Howard Florey/Relaxin Case also supported the issue of patenting of genetic material based on human DNA. But still the Pioneer Hi-Bred International v. Holden Foundation Seeds (1994) case and later EU Directive (1998) outlawed any patents on human cloning and human beings and this represented clear ethical limits.

This argument was further enhanced by the Myriad Genetics Case (2013) in which the U.S. Supreme Court decided that naturally found genes could not be patented, even when extracted out of the body. The case highlighted that genes, being an output of nature, should not be patented.

Biotechnological Process Patenting, Legal Position.

Other than products, patent claims have also been directed towards the processes that are involved in biotechnology. The patentability of a biotechnological process is only achievable where it entails human ingenuity and converts a natural process into the non-natural or an artificial process.

In the case of Hybertech Inc. v. Monoclonal Antibodies Inc. (1986), the patent was granted on the use of proteins that were produced within the body in order to combat the diseases - a process that was considered to be non-natural. Subsequent cases such as In re Wands and In re Farrell stated patents on the methods of detecting viruses and making proteins in bacteria artificially. Similarly, the Chiron v. Progressing the biotechnology patents in processes, a case in Europe Murex Diagnostic (1996) identified a process of in vitro Hepatitis C virus propagation to be patentable.

The World Views on Biotechnology Patent.[10]

The patenting of biotechnology is a global issue as it is subject to various cultures, ethical, and economic factors.

- **United States:**

The U.S. has a liberal policy, and most of the genetically modified organisms and biotechnological processes are patented. The Diamond v. The onset of liberal patent regime was the Chakrabarty case. The boundaries have however been narrowed down to include natural genes with later cases such as Myriad Genetics.

- **European Union:**

The European Patent Convention (EPC) is restrictive on this matter, and any invention that is against ordre public or morality is excluded. Although non-natural organisms can be patented, patents cannot be made on human cloning or patents concerning embryos. This is an ethical issue of morality in patent law.

- **Japan and China:**

The two nations have embraced policies which focus on innovation thus promoting biotechnology patents as a way of enhancing their international technological stand. Japan has already patented GMOs and stem cells, and the patent applications of biotechnology in China have increased at an accelerated rate, in line with its national innovation agenda.

EMERGING TECHNOLOGY AND FUTURE CHALLENGES IN BIOTECHNOLOGY AND PATENT LAW

Biotechnology industry is in a transformation phase that has never been witnessed before due to the rapid scientific discovery and the application of technology. Gene editing, synthetic biology and bioinformatics are new biotechnologies that are blurring the borders of life science and redefining humanity's relationship with nature. Nevertheless, the breakthroughs are also accompanied by serious challenges to patent law which has to adapt in order to follow new inventions which tend to blur natural and artificial life.

Dynamics in relation to biotechnology and patent law have, thus, reached a dynamic stage in which the legal, ethical, and international factors intersect. The fact that patent systems should promote innovations and at the same time protect ethical standards and the good of the people has become a primary challenge in the 21st century.

New Biotechnologies and their jurisprudence.

The latest advances in the biotechnology field today are gene editing systems such as CRISPR-Cas9, synthetic biology and drug design based on bioinformatics. These technologies make genetic and molecular manipulation possible, and the possibilities of these technologies are

[10] *Prasanna S & Lavanya P, Biotechnology and Patent Law, 2 ILE Intell. Prop. & Corp. L. Rev. 36 (2023)*

revolutionary in terms of medicine, agriculture, and environmental management.

Conventional patenting systems were, however, meant to protect material, mechanical inventions, but not natural processes of replication and modification of life. The issue of whether genetic sequences, engineered cells, and computational biological designs should be considered patents or not is a new challenge. It has now become the role of legislators and courts to make sense of the existing laws in order to accommodate such non-traditional inventions without providing overly broad monopolies that inhibit further innovation.

Ethical and Moral Problems.

The ability to manipulate or even to create life brings up some serious ethical and moral issues. Human germline editing, production of chimeric organisms, and genetic enhancement are some of the possibilities that have emerged due to emerging technologies and that border the core beliefs concerning human dignity and the order of nature.

These ethical aspects may not be neglected in patent systems, which are mostly economic instruments. Allowing patents on human genes or altered embryos will create the commodification of life and it will dehumanize living organisms to intellectual property. Therefore, it is urgently required that ethical monitoring and legal protection be established where patents are not overstepped in terms of morality.

Policy errors must be integrated between encouraging creativity and protecting moral uprightness. The patent evaluation process must incorporate the use of ethical review boards, bioethics committees and consultations with the masses particularly where the invention involved has significant social or moral consequences.

Global harmonization is necessary.[11]

New biotechnologies no longer recognize national borders of research, clinical trials, and product development these are frequent multi-country endeavors. Nevertheless, patent standards differ greatly depending on the jurisdiction and this causes legal insecurity among inventors and investors.

A simple outline of protection of intellectual property is offered by the TRIPS Agreement of the World Trade Organization (WTO) though there is still not much specific harmonization related to biotechnology. Unequal treatment of U.S., European, and Asian patent law may be counter-productive to international innovation and commercialization.

Thus, it is necessary to cooperate with other countries. Coming up with standardized rules to qualify and publish patents and also review ethically will make sure that patents on biotechnology are acknowledged and honored internationally to enable life-saving inventions to be accessible to every person in the world.

Equal Access and Social Health Issues.

Although patents can form incentives in innovation, it can also act as a restricting factor to vital biotechnological products especially in the healthcare industry. Patent-protected medicines and genetic therapies have a high cost, and developing countries are usually not able to afford them.

Compulsory licensing, differential prices and public-private commercial relationships are among the critical mechanisms that can be used to reconcile the interests of the privately owned intellectual property with the interests of the population in health. This should be aimed at making sure that new biotechnologies, especially those that are associated with vital drugs, vaccines and genetic remedies, are affordable by everyone and no longer the privilege of a few.

Adjusting Legal and Regulatory Structures.

The rate at which biotechnological innovation is occurring usually surpasses the legal and regulatory frameworks. Regulators, patent offices, and courts should learn to live in new realities, by creating technology-neutral and flexible approaches.

Scientists, ethicists, legal professionals, and policymakers need to work interdisciplinarity to come up with strong but flexible laws. Patent laws need to be constantly revised and revamped to make sure that the rules do not lose their relevance, transparency or friendliness to innovation.

CONCLUSION

In conclusion, the rapid pace of innovation in biotechnology has fundamentally transformed global perspectives on ethics, intellectual property, and

[11] *Prasanna S & Lavanya P, Biotechnology and Patent Law, 2 ILE Intell. Prop. & Corp. L. Rev. 36 (2023)*

technological advancement. While patents serve as the cornerstone of this evolution by protecting inventors and driving investment, they simultaneously challenge traditional patent law paradigms by extending intellectual property rights to living organisms. The findings of this study yield specific conclusions regarding the core hypotheses. Hypothesis 1 is partially accepted, demonstrating that although patents successfully promote innovation, they can inadvertently limit public access in certain scenarios. Similarly, Hypothesis 2 is partially accepted; while the Indian patent system currently demonstrates a well-balanced approach that protects innovation alongside public interests, it requires continuous legal reform to adapt to new scientific realities. Hypothesis 3 is fully accepted, confirming that global inconsistencies in patent laws continue to create significant legal uncertainty and necessitate international harmonization. Furthermore, Hypothesis 4 is partially accepted, as it is evident that ethical safeguards are absolutely essential but must be carefully managed so as not to unduly restrict scientific progress. Overall, these findings culminate in the final result that the overarching hypothesis is partially accepted, underscoring that a balanced, adaptable framework—rooted in ongoing legal reform, global cooperation, and strong yet flexible ethical regulation—is imperative to ensure that biotechnological advancements benefit society as a whole.

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