
BIOTECHNOLOGY PATENTING: LEGAL AND ETHICAL PERSPECTIVES

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ABSTRACT

Intellectual property is an intangible property which is the creation of human mind. Protecting intellectual property is crucial in this competitive environment. Therefore, patents can be used to reward a researcher's scientific efforts by protecting their intellectual property. The relationship between humans and the environment is significantly impacted by technological advancements. The science of using biological systems and living things to develop novel goods or procedures is known as biotechnology. The patent's biotechnological innovation system comprises innovations in biology, microbiology, genetics, medicine, and agriculture. Bioprocess-related inventions are not just found in advancements in genetic engineering, but also incorporate substances from plants, animals, insects, and microbes. Due to technological breakthroughs and growing economic significance, biotechnology patenting in India has experienced tremendous expansion and development in recent years. The purpose of this research study is to examine the main obstacles and possibilities associated with biotechnology patenting in India as it is today. In order to interpret the Indian system of laws, rules, and case law, the paper will explore the international legal framework governing biotechnology patents, looking at pertinent conventions and treaties. Additionally, it will examine the standards for novelty, inventiveness, and industrial applicability that are technical and procedural criteria for biotechnology inventions to qualify for patents. With an emphasis on the distinctions between the US and India, the study examines the complexity of biotechnology patents. To sum up, this study will offer a thorough examination of biotechnology patenting in India. It will make suggestions for enhancing the patent system and encouraging creativity in the field of biotechnology.

Keywords: Biotechnology patenting, International and legal framework, Microorganisms, Technical and procedural requirements.

INTRODUCTION

Biotechnology is one of the most fascinating and challenging issues facing the patent system. The technical use of biological components, such as cells or enzymes, to create medications is known as biotechnology. Nucleotide and amino acid sequences, microorganisms, methods or processes for modifying these products, uses in pharmaceutical manufacturing, etc are examples of biotechnology goods that are patentable. As long as an invention satisfies the three main requirements for patentability industrial application, inventive step, and novelty it can be protected in a number of ways. Biotechnology can use an organism, or a portion of an organism or other biological system, to create a product or process for a specific use. At first, India only issued patents for manufacturing process not products. When India signed the TRIPS Agreement, which sought to harmonize intellectual property laws among participating nations, this was altered. Member nations were urged to modify their laws in accordance with TRIPS, even if they were not obligated to do so precisely. India revised its 1970 Patent Act in 2005 to define inventions as products or processes that incorporate an innovative step and have potential for industrial application.¹ Patentable subject matter was not specifically listed in the 1970 Act. Rather, it included a list of topics that are not patentable. An innovation may be given patent protection if it wasn't on this list and was judged to be novel, creative, and useful in industry.² Three primary issues surrounded the patentability of biotechnological inventions: 1) whether they qualified as living things and thus as patentable subject matter; 2) whether they were natural products as opposed to artificial inventions; and 3) the challenge of characterizing biotechnological inventions in patent applications.³ Biotechnological inventions might be protected provided they satisfied the conventional patentability requirements of novelty, utility, non-obviousness, and written description, according to the landmark 1980 U.S. Supreme Court case *Diamond v. Chakrabarty*.³ The inventor must also place microorganisms or other living materials in a lab at the patent office. After the Budapest Treaty went into effect, this condition was added.

Microorganisms were now specifically awarded patent protection under the 2005 amendment to the 1970 Act, which left out plants, animals, and vital biological processes. Accordingly, patent protection is only available in India for biotechnological innovations that

¹ The Patents Act 1970 (as amended by 2005) , s 2(j)

² The Patent Act 1970, s(3)

³ *Diamond v Chakrabarty*, 447 (1980) U.S. 303

predominantly use microorganisms.⁴ Biotechnology has advanced significantly in India, a country known for its rich biodiversity and expanding scientific community. However, the biotechnology patenting environment in India has been complicated and dynamic, impacted by a number of elements such as public attitudes, economic policies, and legal frameworks. The purpose of this research study is to examine the complexities of biotechnology patenting in India by examining important elements such the legislative framework, historical background, patentable subject matter, eligibility requirements for patents, opportunities, and obstacles.

HISTORICAL EVOLUTION OF BIOTECHNOLOGICAL PATENTING

Evolution within the Framework of International Conventions

International treaties and agreements have had a major impact on the development of biotechnology patents. An important turning point was the 1973 Convention on the Grant of European Patents (EPC), which established a framework for patent protection throughout the European Union.⁵ Notably, it covered topics pertaining to microbes and other biological material's patentability. A system for depositing microorganisms needed for patent applications was established in 1977 by the Budapest Treaty on the International Deposit of Microorganisms for the Purposes of Patent Procedure.⁶ The evaluation of novelty and adequate disclosure in biotechnology patents was made easier by this uniform procedure.

Patent Cooperation Treaty (PCT)

An international agreement known as the Patent Cooperation Treaty (PCT) makes it easier to file for and get patent protection across several nations. The World Intellectual Property Organization (WIPO) is in charge of overseeing it. As the PCT offers a useful tool for inventors, including those in the biotechnology sector, looking to obtain patent protection in several nations. Among the PCT's salient features are:

International Application: Inventors can designate several nations in which they wish to obtain patent protection by submitting a single International Application (PCT application) to

⁴ The Patents Act 1970, s 2 (l)

⁵ European Patent Convention 17th Edition November 2020 available at <https://www.epo.org/en/legal/epc> accessed 21 March 2025

⁶ WIPO, Summary of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (1977) available at https://www.wipo.int/treaties/en/registration/budapest/summary_budapest.html accessed on 21 March, 2025.

WIPO.

Search and Examination: In order to provide input on whether the invention is patentable, WIPO does an international search and preliminary examination.

National Phase Entry: Inventors can join the national phase in selected nations after their invention passes the international phase. There, their patent application will be reviewed in accordance with each nation's laws⁷.

PCT enables biotechnology inventors to receive patent protection in numerous nations at once, the PCT can be very helpful in lowering the expenses and complications involved in submitting individual national applications. Additionally, it offers a uniform process for international patent applications, which is beneficial for innovators from various nations. It is crucial to remember that the PCT does not ensure that a patent will be approved in a certain nation. The national patent offices have the last say on whether to grant a patent. As a result, inventors must to thoroughly examine the particular regulations and protocols in each nation where they wish to obtain protection.⁸

Trade-Related Intellectual Property Rights Agreement (TRIPS)

An international agreement known as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) establishes minimal requirements for the protection of intellectual property rights, such as trade secrets, copyrights, patents, and trademarks. It is applicable to all WTO member nations and is a component of the WTO agreements. The patenting of innovations in biotechnology has been significantly impacted by TRIPS. It mandates that patent protection be offered by member states for innovations in all technological domains, including biotechnology. Accordingly, nations must establish legislation that permits the patenting of biotechnological innovations, including genetically modified organisms, their production methods, and their byproducts¹⁸. TRIPS also lays out requirements that must be fulfilled in order for an innovation to be eligible for patent protection. These standards consist of:

⁷ WIPO, Patent Cooperation Treaty, available at <https://www.wipo.int/treaties/en/registration/> accessed on 24 March 2025.

⁸ WIPO, available at <https://www.wipo.int/pct/en/> accessed on 24 March 2025.

Novelty: The invention must be brand-new and not disclosed to the public before.

Inventive Step: An inventive step is required for the invention to be one that is not immediately apparent to a person skilled in the art.

Industrial Applicability: The invention needs to be able to be used in an industrial setting.

Sufficient Disclosure: The invention must be fully and clearly described in the patent application.

TRIPS permits member states to exclude specific subject matter, including plants, animals, and vital biological processes, from patent protection in addition to these broad standards. Member states are urged to allow for a few exceptions to these prohibitions, nevertheless, such as in cases where the invention entails a novel application of a well-known plant or animal. All things considered, TRIPS has been essential in advancing the global protection of biotechnology innovations. It has set a minimal requirement for patent protection in this field, which has sparked investment and innovation in biotechnology R&D.

Evolution within the Framework of Indian Legislation

The 1970 Indian Patent Act lacked specific provisions for biotechnology patents. India was less developed in biotechnology compared to the U.S. and Europe. Biotechnology patent grants in India began in 2002, influenced by the TRIPS Agreement. As a WTO member, India signed TRIPS to harmonize intellectual property rights among nations. TRIPS required members to amend their national laws, but strict adherence to all provisions wasn't mandatory. The patentability of microorganisms and living products has been a subject of debate. In *Dimminaco A.G. v. Controller of Patents and Trademarks*⁹, the patentability of a process involving living organisms was challenged. The invention, a medicine for poultry bursitis, was initially rejected as it contained a living virus. The patent examiner and controller cited Section 3(j) of the Patents Act, 1970¹⁰, which defines "invention" as excluding living organisms. Dimminaco appealed to the Calcutta High Court, arguing that the Patents Act did not restrict the patentability of processes involving living organisms. The court analysed Section 5 of the Act and introduced the "vendibility test." This test establishes whether an invention qualifies

⁹ *Dimminaco A.G. v Controller of Patents and Trademarks* (2002) I.P.L.R.255 (Cal).

¹⁰ Plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals.

for patent protection based on its capacity to create a marketable product, enhance an already-existing one, or prevent deterioration¹¹. By using this criteria, the court determined that the vaccine's production technique was patentable since it resulted in a marketable product (the vaccine). In India, this decision established a precedent for the patentability of procedures involving live things. Genetically modified organisms, their production methods, and their derivative products are among the biotechnological innovations that can be patented in India. Therefore, an innovation needs to fulfil the following requirements in order to be eligible for a biotech patent in India:

Novelty

The first prerequisite that must be met is novelty. The Indian Patent Act's Section 2(1)(j) stipulates that the invention must be novel and distinct from the "prior Art." An invention will no longer be considered novel if it has already been publicized in any form before a patent application is filed¹². The Supreme Court ruled in *Bishwanath Prasad Radhe Shyam v. Hindustan Metal Industries*¹³ that a patent can only be issued for a novel innovation. Since genes and gene products are chemical entities that can be copyrighted in the majority of patent office's once they are separated and purified from their original form found in nature, it is simple to meet the novelty requirement in this scenario.¹⁴

Non-Obviousness

The patent act's Section 2(ja) addresses non-obviousness. It describes an invention that is not immediately apparent to an expert in the subject and that either represents a technological advancement over current knowledge, is commercially significant, or both. The existence of a specific gene with a certain nucleotide sequence is evident in theory, but it is unclear whether identifying and isolating it would be clear to a professional practitioner¹⁵.

¹¹ Wordpress, available at <https://iiprd.wordpress.com/tag/dimminaco-a-g-v-controller-of-patents-designs/> accessed on 24, march 2025.

¹² S.K. Singh, intellectual property rights law, 146 (central law agency, 1st ed. 2009)

¹³ *Bishwanath Radhe Shyam v. Hindustan Metal Industries*, AIR 1982 SCC 1444

¹⁴ Malati Lakshmikumaran, patenting of genetic invention, 48, JOURNAL OF INTELLECTUAL PROPERTY RIGHT, (2007)

¹⁵ Jidesh kumar, Biotechnology patenting, 474, JOURNAL OF INTELLECTUAL PROPERTY RIGHTS, (2004)

Utility

A patent needs to be useful. The product should be able to do some types of tasks. A related industry should be able to use the invention. Whatever the market price is, according to economists, will hold up in a utilitarian test. If a method is employed to separate previously unknown partial complementary DNA sequences, the usefulness test may allow for the patenting of these partial cDNA sequences¹⁶.

Inventive Step

Technical steps that are not readily apparent to a skilled individual must be included in the innovation. One way to describe the steps that give an invention its uniqueness is as inventive steps.

Legal Framework:

To encourage research and development in the field of biotechnology, the Indian government's biotechnology department, housed inside the Ministry of Science and Technology, established a "Biotechnology patent facilitation cell (BPFC)". Very limited funding is available for biotechnological research and development¹⁷. Only government labs and institutes will receive funding. Even private research and development facilities, such as Dr. Reddy's labs, Biocon India, Bharat Biotech, and Biological Evans, are currently funding biotechnology research and development in the nation.¹⁸

US PATENT LAW

The requirements for patenting an invention are outlined in 35 U.S.C. 103 of the United States Patents Act, and these must be met in order to prevent any predictable repercussions. When others in the same field can readily understand and determine a production method for the product using already-existing inputs, the invention is said to be "obvious." Given that biotechnology is known to combine several elements of production, the significance of this law is pertinent. The innovation must not be obtained by using and combining common inputs

¹⁶ *ibid*

¹⁷ Rahuldev, Biotech patents in India, available at <https://patentbusinesslawyer.com/biotech-patents-in-india> accessed on 26 March 2025

¹⁸ Braj B. Lohray, Medical biotechnology in India, 277 ADV BIOCHEM ENGIN/BIOTECHNOL (2003)

with simple approaches that produce predictable results for a person or entity applying for a patent¹⁹.

Unlike the USA, India does not have the source of precedent-setting case law. India has hardly ever made progress in gathering enough data to handle these innovative products. The USA has case law that can help define what constitutes a patentable biotechnological innovation. According to the ruling in *Association for Molecular Pathology v. Myriad Genetics Inc.*, a product may be patentable based on whether or not it permits changes to its manufacturing formula and how much of the product may be altered. According to Judge Lourie of the US Supreme Court, the modification of the chemical formula is permissible as it is a reality that the isolation of a DNA molecule results in a non-natural occurrence of the molecule but does not alter the DNA's quality²⁰

The case that brought the issue of microorganism patenting before the US Supreme Court was *Funk Bros. Seed Co. v. Kalo Inoculant Co.* The case discusses a finding of *Rhizobium* bacteria that can inoculate plant seeds to different cross-inoculation groups of the same group. Because the resulting species lacked unique bacteria and did not alter the six other bacterial species that were developed, the court determined that there was a slight elevation of species due to lack of innovation within the parameters of the patenting legislation²¹ The courts ruled in the famous *Diamond v. Chakrabarty* decision that anything created by human labor is entitled to patent protection. In its ruling, the court stated that the "product of nature" test is crucial for determining whether an invention was created naturally or as a result of human effort. If it is determined that the product in question was a natural product and did not need human effort, the patent rights will be revoked²². Additionally, this led to the USA granting patent rights to rare natural living things like bacteria, like in this instance. Congress is currently debating the issue of gene patenting. In a recent landmark ruling, the Supreme Court of the United States prohibited the patenting of human genes due to the risk of reducing the topic of medical research and development because private organizations would have the exclusive right to prohibit any research if the gene is owned by them. Nevertheless, patents have been granted to

¹⁹ Quinn, G., "When is An Invention Obvious?" – Ipwatchdog.com / Patents and Patent Law".
<https://www.ipwatchdog.com/2014/02/01/when-is-an-invention-obvious/id=47709/>

²⁰ The US Supreme Court, *Association for Molecular Pathology et Al. v. Myriad Genetics*, 2013,
https://www.supremecourt.gov/opinions/12pdf/12-398_1b7d.pdf

²¹ *Funk Bros. Seed co. v. Kalo Inoculant Co.*, US reports, vol. 333, 1948,
<https://www.lawcornell.edu/supremecourt/text/333/127>

²² *Diamond v. Chakrabarty*, Justice US Supreme Court, Vol. 447, 1980,
<https://supreme.justia.com/cases/federal/us/447/303/>

many multicellular organisms, rabbits, genetically modified rats, and so on. In the United States, gene sequences and genetic therapies are also permitted patent rights.

ETHICS IN PATENTING BIOTECHNOLOGY

Since morality and ethics are valued and upheld in India on an equal footing with the law, they play a significant role in society. The idea of morality has to do with the conviction that certain actions are right and others are immoral. This conviction is founded on the widely recognized standards that are deeply embedded in the specific culture. It is commonly known in Indian culture that people worship plants and animals as gods. Many individuals are against the idea of patenting life because they believe it to be unethical. Their criticism raises the possibility of structural changes in the agriculture sector brought about by biotechnology, particularly if big businesses obtain legal rights to the developments²³ Due to a long-standing custom that discourages private ownership of living things and natural objects, owning living things is discouraged in India.

However, India must abide by the TRIPs agreement when it comes to patenting inventions such as microorganisms and other inventions made using non-biological, biotechnological, or microbiological processes. The amendment states that an innovation cannot be patented if it violates public morality or order, or if it poses a major risk to the environment or the health of people or animals. Additionally, it established that, for ethical reasons, plants, animals, and essentially biological processes used in their creation cannot be patented.

SUGGESTIONS

- The ethical concerns surrounding biotechnology patenting are controversial, and as these concerns vary from nation to nation, local laws must be changed to make ethical issues more explicit.
- It is necessary to shorten the time frame for patent issuance. Due to biotechnology's rapid technological advancement, inventions may overlap.
- A biotechnology patenting expert committee must be established to support, evaluate,

²³ Archana K, Do We Need Patent Protection to Biotechnology Inventions?, 01, INTERNATIONAL JOURNAL OF SCIENTIFIC AND RESEARCH PUBLICATIONS,(2013)

and uphold the innovation.

- Tough legislation needs to be passed, and licenses should only be granted after meeting the necessary requirements.
- To guarantee safe production, use, storage, transfer, and exploitation, biosafety measures must be implemented.
- BPFC must also improve the effectiveness of its regulatory framework and guarantee sound governance.

CONCLUSION

In India, it takes longer to obtain a biotech patent than in the US and Europe. Biotech patents are granted in roughly 1.5 years in the United States and 3 years in Europe. The procedure may take up to five years in India. Even though other biotech discoveries are frequently patentable, laws may need to be changed to exclude transgenic humans from patentability due to ethical and moral considerations. Human cloning for reproductive purposes and the development of transgenic humans could be prohibited by international agreement. Indian patents are subject to time constraints. Patents should be issued within three years in order to keep up with the quick advances in Biotechnology. Laws may be amended to prolong the patent period if delays happen. India has made great progress in biotechnology patenting, which is indicative of the nation's increasing significance in this area. Although the legal system has changed to meet the special opportunities and problems brought about by biotechnological innovations, there are still a few important areas that need to be addressed. First off, striking a balance between the public interest and intellectual property rights is still a difficult task. Patents are vital for encouraging innovation, but it's important to make sure they don't impede access to necessary technology, especially in sectors like agriculture and healthcare.

For lawmakers, finding the ideal balance between these conflicting interests is a crucial task. Second, there are still issues with the protection of intellectual property rights in the biotechnology industry. Issues including illegal use, infringement issues, and counterfeit goods continue to exist despite improvements in legal frameworks and enforcement techniques. Protecting inventors' interests requires stepping up enforcement actions and raising stakeholder understanding of intellectual property rights.

Thirdly, significant thought should be given to the ethical ramifications of biotechnology patenting. Important ethical concerns are brought up by topics like the influence on biodiversity, the possibility of genetic monopolies, and the patenting of living things. These issues can be addressed and responsible pursuit of biotechnology developments ensured by creating ethical frameworks and rules. Lastly, the global biotechnology patenting scene is still developing. To make sure that its patent laws comply with worldwide standards and to foster cooperation with other nations, India must actively participate in international organizations and global efforts like the TRIPS Agreement. In summary, even though India has achieved great strides in biotechnology patenting, more work is required to handle the potential and problems that still lie ahead. India can foster biotechnology innovation and support worldwide developments in this area by stepping up enforcement of intellectual property rights, resolving ethical issues, and interacting with the international community.