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## Patent Law in Relation to Biotechnology

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Tusharika Mohan Singh Gaharvar<sup>1</sup>

### ABSTRACT

*A patent is an exclusive privilege given to an inventor that allows them to utilize their creation without hindrance from others for a period of 20 years. Given its enormous economic value, a patent can be regarded as one of the most significant types of intellectual property rights. The history of patents is extensive, and the laws governing them have changed throughout time based on societal needs, the pace of innovation, and the complexity of those innovations. The Patent Act, 1970, as amended by the Patents (Amendment) Act, 2005, and the Patents Act RULES, 2006, governs patent law in India. In addition to inspiring the development of several innovators and playing a significant part in enhancing the country's health, biotechnology has emerged as a valuable instrument for many researchers. Biotechnology requires major expenditure and research; patenting biotech inventions is important in the current era. According to recent case law, biological elements or chemicals that are created in laboratories but previously unavailable in the natural environment have won the right to be patented. Thus, the Biotechnology Patents in India were developed in order to safeguard the inventor's interests and rights to patentability. In India, the application and grant processes for biotechnology patents are drawn out and time-consuming.*

**KEYWORDS-** *Biotechnology, Patent, Pharmaceutical Industry, Compulsory licensing, biological inventions.*

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## 1. INTRODUCTION

*"Biotechnology can transform humanity provided humanity wishes to be transformed"*

*-Geoffrey Carr*

The modification of natural phenomena by human creations is known as biotechnology. The development of humanity depends on the progress of biotechnology. It is not a very brand-new idea; it has been developed over many years and has roots in antiquity. The term "biotechnology" encompasses both the new biotechnology made possible by genetic engineering and recombinant technology as well as the old biotechnology, such as the conventional method of creating fermented products.<sup>2</sup> Innovations in biotechnology are crucial for the advancement of humanity. It is a vast field of biology that involves the use of living systems and organisms to create or develop products, or any technological application that makes use of biological systems, live creatures, or their derivatives to create or alter products or processes for particular uses.<sup>3</sup> The field of biotechnological inventions has expanded during the past 25 years. It is a tremendously active field where advancements are ongoing.<sup>4</sup>

A patent is an exclusive privilege given to an inventor that allows them to utilize their creation without hindrance from others for a period of 20 years. Given its enormous economic value, a patent can be regarded as one of the most significant

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<sup>2</sup> BY Sofia Bambri; *Patents on biotechnology and related laws in India*; <https://www.sbhambriadvocates.com/post/patents-on-biotechnology-and-related-laws-in-india>; Last Visited- 26-August-2021.

<sup>3</sup> BY Monika Shailesh; *India: Biotechnology Patent And Related Moral Issues*; <https://www.mondaq.com/india/patent/758110/biotechnology-patent-and-related-moral-issues#>; Last Visited- 26 November 2018.

<sup>4</sup> BY Lexorbis; *Issues related to Patentability of Biotechnological Inventions*; <https://www.lexology.com/library/detail.aspx?g=31da78dc-a407-407d-ab04-d3efa5e0ddbc>; Last Visited- 1- June-2020.

types of intellectual property rights. The history of patents is extensive, and the laws governing them have changed throughout time based on societal needs, the pace of innovation, and the complexity of those innovations. The Patent Act, 1970, as amended by the Patents (Amendment) Act, 2005, and the Patents Act RULES, 2006, governs patent law in India. In addition to inspiring the development of several innovators and playing a significant part in enhancing the country's health, biotechnology has emerged as a valuable instrument for many researchers. The preservation of these inventors' rights becomes problematic, therefore numerous biotechnological innovations including drugs, microbes, and transgenic animals have been granted patent protection globally.<sup>5</sup> Thomas Jefferson, the creator of the first Patent Act, was unaware that living things may potentially be subject to patent protection. A biochemist at General Electric (GE) created a genetically engineered creature that could break down crude oil in the case of *Diamond v. Anand Chakrabarty*. The inventor's patent application was first turned down. However, a later appeal was filed, and the court ultimately granted the patent to the inventor with the stipulation that the claim of the inventor is not to a previously undiscovered natural phenomena but rather to a synthetic composition or manufacturing of matter – a creation of human ingenuity.<sup>6</sup>

## 2. HISTORICAL BACKGROUND OF PATENT ACT IN INDIA

The British monarch "the act VI of 1856" on the protection of inventions, which was based on the British patent law of 1852, passed India's first patent law. The consolidated Indian Patents and Designs Act 1911, which provides protection for inventions, was implemented after we made a number of revisions. The Patents Act, 1970 was enacted

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<sup>5</sup> BY Aryan Chitra and Nitika Rawat; *Patent Law and Biotechnology*; <https://www.ijlmh.com/paper/patent-law-and-biotechnology/>.

<sup>6</sup> BY Sakshi Sharda; *Biotechnology Patents in India: A Complete Outlook*; <https://corpbiz.io/learning/biotechnology-patents-in-india/>; Last Visited- 7- May-2020

as a result of numerous revisions and amendments made to the law as a result of the passage of time and changing sociopolitical conditions in India. The Patents Act of 1970 highlights inventions that meet the requirements for patentability, such as novelty, inventiveness, and industrial use. The patents act of 1970 also underwent a number of amendments before the final patents (amendment) act of 2005 (also known as the patents act) was introduced. This act also introduced the possibility of obtaining product patents on substances that could be used as drugs, food, or medicine once India had finished implementing the TRIPS-required amendments to its law. Through the establishment of patent rights 2003, which was updated and resulted in a new practise and procedure, additional significant modifications in the patenting process were implemented.<sup>7</sup> However, there was nothing particular about biotechnology creation and protection in this iteration. The demand to update the Indian Patent Act to include biotech patentability gained traction in India at the same time as the patent offices and courts in the US and EU were experiencing an increase in the number of biotech inventions and patent applications. In order to specifically include biochemical, biotechnological, and microbiological processes in the definition of potentially patentable process, an amendment was made in 2002.<sup>8</sup>

### 3. WHAT IS PATENTABLE?

Inventions that pass the three precondition conditions are given a patent under the Patent Act of 1970.

- The invention must be original and must not have existed before in order to pass the test.

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<sup>7</sup> BY Sofia Bambri; *Patents on biotechnology and related laws in India*; <https://www.sbhambriadvocates.com/post/patents-on-biotechnology-and-related-laws-in-india>; Last Visited- 26-August-2021.

<sup>8</sup> BY Monika Shailesh; *India: Biotechnology Patent And Related Moral Issues*; <https://www.mondaq.com/india/patent/758110/biotechnology-patent-and-related-moral-issues#>; Last Visited- 26 November 2018.

- Second, the invention must significantly advance technology; as a result, it must be novel and not just a straightforward modification of already existing devices.
- Finally, the innovation must be helpful, which can be taken to mean that no patent can be issued for an invention that can be utilized only for unlawful and immoral activities.

#### **4. SUBJECT MATTER OF BIOTECHNOLOGY THAT IS NOT PATENTABLE**

A variety of biotechnology inventions are included in the lengthy list of inventions that are excluded from being eligible for patent protection under the Patents Act of 1970.

The following topics are not included:

- The discovery of living organisms in nature, including seeds, plants, animals, and their various kinds and species,
- The discovery of living organisms in nature, including seeds, plants, animals, and their various kinds and species,
- Multicellular organisms that have undergone genetic modification, such as plants, people, animals, and their parts;
- The use of embryonic stem cells in treating humans;
- The medical procedures.<sup>9</sup>

##### **4.1. INDUSTRIAL APPLICABILITY**

If any biotechnology inventions can be created, applied in a field, and replicated as often as necessary, they meet India's requirements for industrial applicability. The Manual of Patent Practice and Procedure contains standards for evaluating biotechnology. The standards for gene and DNA sequences state that if the functions of

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<sup>9</sup> BY Sakshi Sharda; *Biotechnology Patents in India: A Complete Outlook*; <https://corpbiz.io/learning/biotechnology-patents-in-india/>; Last Visited- 7- May-2020.

these sequences are not revealed, they do not meet India's requirement for industrial applicability for biotechnology patents.

## **4.2. NOVELTY**

Regarding the uniqueness of biotechnology inventions in India, the Patents Act, 1970, makes no explicit provisions. The majority of biotechnology-related inventions are natural products or goods that already exist in living things; as a result, these products or goods might be considered discoveries and are not subject to patent protection under Indian law. However, the Manual of Patent Practice and Procedure states that some biological products, such as plasmids and recombinant DNA, as well as the manufacturing processes for these products, are eligible for patentability in India, provided that the products are made with the direct involvement of humans.

## **4.3. ENABLEMENT**

The law includes provisions for the deposition of such biological materials or substances at an authorized depository in India for biotechnology inventions in India that describe biological material or substances in the whole specification. According to the Manual of Patent Practice and Procedure, the inventor must fully describe the innovation in the specification. The inventor must offer such a thorough description in order for any individual practicing the same art to be able to implement the invention after reading the whole description.

## **4.4. MORALITY**

According to Section 3(b) of the Patent Act of 1970, an invention cannot be granted a patent in India if its primary or intended use is against public morality or order, or if it has the potential to seriously harm human, animal, or plant life and health, or the environment. According to the Manual of Patent Office Practice and Procedure, no biological substance or material, or method of producing it, that has the potential to

seriously harm human, animal, or plant health or the environment, or whose use would be in violation of public morality and order is permitted to be patented.

Furthermore, according to the Manual of Patent Office Practice and Procedure, it is forbidden to patent inventions that violate public morality or order, such as those that involve cloning people or animals, altering their germ lines, using human or animal embryos, or changing their genetic identities. The Indian Patent Law makes it explicitly illegal to grant biotechnology patents for inventions that are motivated by morality.

## **5. WHAT IN INDIA IS NOT PATENTABLE UNDER BIOTECHNOLOGY LAWS?**

In India, biotechnology patents do not grant patent protection for the following items:

- According to Section 3(b) of the Patents Act of 1970, the inventor's innovation is immoral, contrary to public order, damaging to human, animal, or plant life, or harmful to the environment;
- According to Section 3(c) of the Patents Act of 1970, the invention relates to the discovery of living or non-living substances or materials in nature;
- According to Section 3(j) of the Patents Act of 1970, the invention relates to plants and animals in whole or in any of their parts other than microorganisms but includes varieties, seeds, and species;
- According to Section 3 (j) of the Patent Act of 1970, the invention relates to any essentially biological processes for the production or propagation of plants and animals;
- The invention relates to any process for the medical, curative, surgical, prophylactic, diagnostic, or therapeutic treatment of humans or animals to rid them of disease or to increase their economic value or that of their products;



- According to Section 3 (h) of the Patents Act of 1970, the invention relates to particular agricultural or horticultural processes; in accordance with Section 3 (p), the invention incorporates traditional knowledge.

## **6. BIOLOGICAL INVENTIONS**

The term "biotechnological invention" refers to a process that uses living creatures, or any portion of them/components, etc., to build microorganisms and organisms that are designed for certain uses, or to construct or refine products or to make them better. Agriculture, agro-industry, fertilizers, the food business, diagnostics, zoo methods, semiconductors, pharmaceuticals, the trash industry, fuel, chemistry, etc. are just a few of the many industries that utilize biotechnological inventions. The rules relating to the patenting of innovations are applied for biotechnological inventions, despite everything else being set aside and what has already been established. Additionally, the pharmaceutical industry and the life sciences have had a significant impact on life expectancy and quality of life. Today, biotechnology is the foundation of most modern medications. The use of biotechnology and/or micro-biotechnology has made it possible for inventions relating to processes or methods of producing tangible and intangible substances (such as enzymes, antibiotics, insulin, interferon, alcohols, vaccines, etc.) by using such microorganisms or by utilizing the aforementioned biologically referred chemical substances produced by using genetically engineered organisms and substances more economically.

The Patent Office also gives patents to procedures and methods for producing things, in addition to items like pharmaceuticals, DNA, and antibodies. The actions that need to be done in the invention's technique or process will be reflected in the claims of these patents.

Genes, proteins, and organisms can now be used for exploitation thanks to biotechnological innovations. It has the ability to alter how illnesses are identified and

treated, how food is grown, how energy is produced, and how trash is disposed of. Similar to other inventions, the validity of biotechnological inventions is determined by their novelty, originality, and viability for commercial use.

The pharmaceutical industry is associated with economic activity centered on the development, production, and marketing of pharmaceuticals, whereas biotechnology refers to any technological innovations that utilize biological material to develop or improve goods or procedures.

## **7. PATENT IN PHARMACEUTICAL INDUSTRY**

India's pharmaceutical sector is one of the biggest in the developing world and is regarded as the fourth largest in terms of production and the thirteenth largest in terms of domestic consumption value. It has transformed over the past 30 years from being virtually nonexistent to a global leader in the manufacture of generic medications. By becoming professionals in reverse engineering, Indian pharmaceutical companies were able to boost the availability of less priced versions of the most popular patent-protected medicines in the world. This was made possible by the Indian Patent Act of 1970.

By becoming professionals in reverse engineering, Indian pharmaceutical companies were able to boost the availability of less priced versions of the most popular patent-protected medicines in the world. This was made possible by the Indian Patent Act of 1970. All of this was only feasible since there was no products patent system for pharmaceuticals and medicines, despite the fact that section 5 of the act of 1970 did offer an exception by allowing process patents for meals, medicines, or drug substances while expressly excluding product patents for the same. As a result, India was able to replicate patented medications without having to pay a license fee, allowing the companies to sell the medications to the general public at affordable prices.

Following the introduction of the 2005 modification to comply with Trade Related Aspects of Intellectual Property Subjects, this situation changed (TRIPS). Thus, this amendment added patent protection for pharmaceutical items and expanded TRIPS' complete coverage to include foods, medications, and medicines. In addition, it increased the duration of patent protection from the legislation of 1970's 7 years to 20 years. The introduction of product patents was done to promote the development of new and more potent medications in India and offer an alternative strategy to address the issue of lack of access to medications, not to hinder the mass production of generic medications at low rates.

The product patent, however, raises concerns about the public paying more for pharmaceuticals and the patent holder abusing their position by refusing to market or produce their invention in wealthy nations in order to increase profits. TRIPS (Agreement on Trade Related Aspects of Intellectual Property Rights) established the provision of a compulsory license to prevent the use of the invention on grounds of public morality in order to combat such abuses of patent rights.<sup>10</sup>

## **8. COMPULSORY LICENSING**

Compulsory licensing is used when the government permits a third party to exercise the same rights as the patent holder without the patent holder's approval. It is a permission granted by the Controller General to a third party to create, use, or sell a specific product or employ a specific procedure that has been patented, without the need for the consent of the patent owner. Compulsory licensing prevents the exploitation of patent rights and assists in resolving conflicts of interest between parties, which promotes innovation and equitable compensation. The Indian Patent Act of 1970 and the TRIPS Agreement both make clear reference of the compulsory licensing system, which is recognized on both a national and international scale. A compulsory license may be granted suo moto by the controller pursuant to section 92 of the Patent

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<sup>10</sup> Love J, Recent examples of compulsory licensing of patents, KEI, Research Note 2007:2.

Act of 1970 following notification from the Central Government in circumstances of public non-commercial use, extraordinary urgency, or national emergency.

The Patent Office issued the first compulsory license in India on March 9, 2012, in the matter of *Natco Pharma Ltd. v. Bayer Corporation*.<sup>11</sup>In this instance, Natco Pharma received a compulsory license to produce generic versions of Nexavar, a life-saving drug used to treat liver and kidney cancer produced by Bayer Corporation. Where Bayer's drugs were being sold Natco Pharma promised to sell this drug around for Rs 9000 making it affordable for individuals of every stratum. This drug was being sold at exorbitant prices, with one month's worth of dosage costing about Rs 2.8 Lakh. As a result, all three requirements of section 84 were met, and a decision was made that would benefit the entire public. As according to Section 84 the three requirements are:

1. That the reasonable requirements of the public with respect to the patented invention have not been satisfied, or
2. That the patented invention is not available to the public at a reasonably affordable price, or
3. That the patented invention is not worked in the territory of India.<sup>12</sup>

## 9. CONCLUSION

Because biotechnology requires major expenditure and research, patenting biotech inventions is important in the current era. According to recent case law, biological elements or chemicals that are created in laboratories but previously unavailable in the natural environment have won the right to be patented. Thus, the Biotechnology Patents in India were developed in order to safeguard the inventor's interests and rights

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<sup>11</sup> *Bayer Corporation v. Natco Pharma Ltd.*, Order No. 45/2013, 40 (Intellectual Property Appellate Board), Chennai.

<sup>12</sup> Patents Act, 1970, Section 84, cl. 1.

to patentability. In India, the application and grant processes for biotechnology patents are drawn out and time-consuming.

The TRIPS agreement mandates that microorganisms and non-biological and microbiological production of plants and animals be subject to patent protection on a global scale. Because of this, it is challenging for developing nations to completely avoid utilizing inventions in this category. So, controlling the scope of these provisions should be the goal of the strategy. In terms of microbe patent protection, TRIPS does not provide a definition of the term. Mandatory licensing is essential for developing or impoverished nations. The resources that are unavailable in a certain country may represent a vital need for that nation.

Compulsory licensing is essential for developing or impoverished nations. The resources that are unavailable in a certain country may represent a vital need for that nation. Medicine is a crucial necessity for society, thus if a patented drug is offered in a nation but is so expensive that the average person cannot buy it, the government of that nation must take action to help those who cannot afford it. The mandatory license is crucial in this situation. Required licenses will make comparable goods accessible to those who cannot afford the medicine.

Patenting in the case of protecting animal patents for the development of the pharmaceutical industry can promote the availability of medicines because many pharmaceutical products come from transgenic animals. Transgenic animals are also very important because the main applications for transgenic animals are in the pharmaceutical, agricultural, and medical research industries. Thus, a patent is crucial for defending the rights of an inventor, business owner, practitioner, or anyone else who has an idea that satisfies the criteria for applying for a patent. It also protects ideas, innovations, and products from being improperly used.

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