



Understanding Biotechnology Patents: Key Requirements and Legal Framework in India

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ABSTRACT

This article provides a comprehensive overview of the patenting process for biotechnology inventions in India, focusing on the essential requirements and legal framework governing such patents. It explores the fundamental criteria necessary for patentability, including novelty, inventive step, and industrial applicability, as stipulated under Indian patent law. The article also examines the specific provisions related to the deposition of biological materials and the exclusions of certain inventions from patentability, as outlined in Sections 3 and 4 of the Patent Act. Additionally, it discusses the impact of the TRIPS Agreement on biotechnology patents and the ongoing challenges in distinguishing between patentable and non-patentable inventions. By addressing these aspects, the article aims to provide clarity on the complexities of securing patent protection for biotechnological innovations in India.

Keywords: Biotechnology patents, patentability, India, novelty, inventive step, industrial applicability, Patent Act, biological materials, legal framework.

Introduction:

Biotechnological innovations have precipitated a paradigm shift across various disciplines, necessitating the establishment of a robust intellectual property framework. In India, the grant of patents for biotechnological inventions is contingent upon the fulfilment of patentability criteria, including novelty, inventive step, and industrial applicability. To ensure consistency and uniformity in the evaluation of biotechnology patent applications, the Indian Patent Office¹ has promulgated Biotechnology Patent Guidelines². These guidelines, subject to periodic revisions in response to judicial interpretations, legislative amendments, and stakeholder feedback, provide a standardized framework for patent examiners. As the biotechnology sector in India experiences exponential growth, with projected valuations of \$100 billion by 2025³, this article provides a comprehensive exposition on the significance, scope, and procedure for obtaining biotechnology patents, encompassing historical context, legal provisions, and judicial precedents.

What Is Biotechnology?

Biotechnology is defined by the World Health Organization (WHO) as the application of "engineered biological processes"⁴. This multidisciplinary field serves as the cornerstone of pharmaceutical sciences and healthcare. Biotechnology can be broadly categorized into three distinct domains⁵:

1. Healthcare Biotechnology (Red Biotechnology): This sector focuses on the application of technological innovations in the development of medicines and other healthcare products.
2. Agricultural Biotechnology (Green Biotechnology): This domain involves the utilization of technology to enhance plant tolerance to environmental stresses and increase crop yields.

¹ PATENT OFFICE OF INDIA, <https://ipindia.gov.in/>.last seen on 23/8/24

² The Office of the Controller General of Patents, Designs and Trade Marks, *Guidelines for Examination of Biotechnology Applications for Patent*, INTELLECTUAL PROPERTY INDIA (2013), http://ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_38_1_4-biotech-guidelines.pdf.last seen on 25/8/24

³ *Biotechnology*, MAKE IN INDIA, <http://www.makeinindia.com/sector/biotechnology>.last seen on 23/8/24

⁴ World Health Organization, *Food, Genetically modified*, WORLD HEALTH ORGANIZATION, <https://www.who.int/health-topics/food-genetically-modified>.last seen on 25/8/24

⁵ Kafarski, Pawel, *Rainbow code of biotechnology*, 66 CHEMIK 814, 814-816, https://www.researchgate.net/publication/287253802_Rainbow_code_of_biotechnology.last seen on 25/8/24

3. Industrial Biotechnology (White Biotechnology): This sector encompasses bioprocessing, which integrates biotech-based tools with traditional processes, and the production of bio-based products, such as bioplastics and biofuels. The primary objective of industrial biotechnology is to develop sustainable goods and processes⁶.

The biotechnology industry comprises five primary segments: biopharmaceuticals, bioagriculture, bioservices, bioindustrial, and bioinformatics⁷.

many rapid and precise diagnostic tools for disease detection. Biotechnology encompasses a wide range of applications within the medical field, contributing significantly to therapeutic development, diagnostics, forensic investigations, vaccine production, and the synthesis of antibiotics and other drugs.

Patents in Biotechnology

Through the production of enhanced nutrients in food products like Golden Rice, potatoes, maize, groundnuts, soybeans, etc., biotechnology has significantly improved human health. Genetically engineered crops and novel disease therapies are only two of the fascinating inventions that have resulted from the quickly expanding science of biotechnology. It should come as no surprise that patents are essential to the sector given the magnitude of the achievements. The importance of patents in biotechnology and their effects on the sector will be discussed in this article.

A Patent: What Is It⁸?

An inventor is granted the exclusive right to prevent others from creating, utilizing, or commercializing their invention for a set amount of time, usually 20 years from the day the patent application was filed. This is known as a patent. Patents are used in the biotechnology sector to safeguard creations involving biological materials, processes, and products.

The Significance of Patents in Biotechnology

Because they enable innovators to safeguard their intellectual property rights and profit from their creations, patents are crucial to the biotechnology industry. They give businesses a means of recovering their R&D expenses, which in the biotechnology sector can be high.

Additionally essential to promoting innovation are patents. Since they would not be able to profit from their discoveries, inventors could be less inclined to devote their time and resources to creating new technologies in the absence of patent protection.

Patents play a crucial role in biotechnology by granting exclusive rights to inventors for a certain period. In this industry, a patent allows the holder to prevent others from making, using, or selling the patented invention⁹.

1. **Fostering Innovation:** Patents drive innovation by protecting inventors' intellectual property. They enable inventors to recover their research and development costs and secure the financial means to continue creating new and improved products.
2. **Securing Investment:** Biotechnology research is costly. Patents safeguard the inventor's financial commitment by providing exclusive rights, which can be leveraged to generate income through licensing or commercialization.
3. **Attracting Investors:** Patents signal the value of intellectual property, making biotechnology companies more appealing to investors. Investors are more inclined to support companies with patented inventions due to the assurance of potential returns.
4. **Encouraging Collaboration:** Patents can facilitate partnerships between biotechnology firms. Companies with complementary technologies can license each other's patents to develop new products or enhance existing ones.
5. **Promoting Competition:** Patents stimulate competition by encouraging inventors to improve existing technologies. Once a patent expires, the invention enters the public domain, allowing others to build upon it and create new innovations.

patents are crucial to the biotechnology industry, as they provide incentives for innovation, protect investments, attract investors, facilitate collaborations, and promote competition.

⁶ Rahul Dev, *Advantage Of Patent Filing*, <https://patentbusinesslawyer.com/biotech-patents-in-india/>. last seen on 25/8/24

⁷ *Indian Biotechnology Industry Analysis*, IBEF <https://www.ibef.org/industry/biotechnology-presentation>. last seen on 25/8/24

⁸ <https://www.legalserviceindia.com/legal/article-10884-patents-in-biotechnology-.html#:~:text=In%20biotechnology%2C%20utility%20patents%20may,varieties%20of%20asexually%20reproduced%20plants>. LAST SEEN ON 25/8/24

⁹ <https://www.legalserviceindia.com/legal/article-10884-patents-in-biotechnology-.html#:~:text=In%20biotechnology%2C%20utility%20patents%20may,varieties%20of%20asexually%20reproduced%20plants>. last seen on 25/8/24

What in Biotechnology Is Patentable?

In the field of biotechnology, many types of inventions are patentable. These include genetic engineering technologies and procedures, proteins, DNA sequences, drugs, and diagnostic instruments and methodologies. But not every biotechnology innovation qualifies for patent protection. An invention needs to be novel, practical, and non-obvious in order to be given a patent.

Utility Patents: Cover new and useful processes, machines, or compositions of matter, such as novel DNA sequences or genetically modified organisms.

Plant Patents: Protect new varieties of asexually reproduced plants, important in agricultural biotech.

Design Patents: Focus on the ornamental design of inventions, like unique lab equipment or medical devices.

Gene Patents: Grant exclusive rights to specific gene sequences, though controversial due to concerns about limiting research.

Diagnostic Method Patents: Protect innovative methods for diagnosing conditions, such as new assays or diagnostic tools.

Classification of Biotech Patents¹⁰

Biotech patents can also be classified based on the type of invention:

1. Product Patents:

- Product patents protect specific products or compositions of matter, such as novel proteins, new genetic sequences, or pharmaceutical compounds. These patents are frequently used in the pharmaceutical industry to protect new drugs and therapies.

2. Process Patents:

- Process patents safeguard specific methods or processes for producing a product or composition. For example, a process patent might cover a particular method for producing a protein, a genetically modified organism, or a medical device.

Securing both product and process patents can be vital for comprehensive protection of biotech innovations. However, obtaining a patent can be a complex and costly process, and not all inventions may be eligible for protection. Professional advice from a patent attorney or agent is recommended for navigating patent eligibility and the application process.

Legal Framework in India

In India, the regulatory framework for biotechnology patents is governed by the Patents Act, 1970, and the Patents Rules, 2003¹¹, as amended. This legislation stipulates that patents may be granted for inventions that are new, non-obvious, and capable of industrial application. The Patents Act, 1970¹², defines an "invention" as any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof. It also includes provisions for the patentability of biological materials, such as microorganisms, plants, and animals, provided they meet the requisite criteria. The Act encompasses provisions for compulsory licensing, allowing third parties to use a patented invention under certain conditions, including public health emergencies and when the invention is not sufficiently utilized in India. The Guidelines for Examination of Biotechnology Applications for Patents, 2016, provide specific directives for evaluating patent applications in biotechnology. These guidelines address various aspects, including the patentability of biological materials, the sufficiency of disclosure, and patentability requirements. India's legal framework aims to foster innovation while balancing intellectual property rights with public interest.

Biotechnology Patents in India

Historical Background: India's patent system began with the Patent Act of 1856. Over time, the Act has been updated and revised. A major update came in 1970, which aligned Indian patent laws with international standards by covering aspects like novelty, inventive steps, and industrial application. However, this version of the Act did not include biotechnology inventions.

Amendments for Biotechnology: In response to the growing number of biotechnology inventions worldwide, including those in the US and Europe, there was a push to update the Indian Patent Act. By 2002, amendments were made to include biotechnology inventions. These changes specifically covered biochemical, biotechnological processes, and microbiology.

¹⁰ <https://www.legalserviceindia.com/legal/article-10884-patents-in-biotechnology-.html#:~:text=In%20biotechnology%2C%20utility%20patents%20may%20varieties%20of%20asexually%20reproduced%20plants.last> seen on 25/8/24

¹¹ The Patents Rules, 2003

¹² The Patents Act, 1970

Notable Cases:1. **Diamond v. Anand Chakrabarty**¹³:

- In this famous case, a biochemist developed a genetically modified organism capable of breaking down crude oil. Initially, his patent application was rejected. However, after appealing, the court granted the patent, recognizing the organism as a non-naturally occurring product of human invention. This case is significant in biotechnology law.

2. **Dimminaco A.G. v. Controller of Patents and Designs**¹⁴:

- Dimminaco A.G. invented a process for creating a live vaccine to treat Bursitis, an infectious poultry disease. The patent office initially refused the patent. Dimminaco appealed to the High Court of Calcutta, which ruled that there was no legal barrier to patenting a method that involves a living organism, thus allowing the patent.

These cases highlight how biotechnology patents are evolving in India and the legal precedents being set to accommodate new biotechnological inventions.

Key Requirements for Patenting in India¹⁵

To get a patent in India, an invention must meet certain requirements:

1. **Novelty:** The invention must be new and not known or used before.
2. **Inventive Step:** The invention must not be obvious to someone skilled in the field based on existing knowledge.
3. **Industrial Application:** The invention must be useful and capable of being used in some industry.

Sections of the Patent Act¹⁶

- **Section 2(1)(j):** This section defines the basic criteria for patentability: novelty, inventive steps, and industrial applicability.
- **Sections 10(4) and Rule 13(8):** These sections deal with the deposition of biological material. If the material is not publicly available or cannot be described in detail, it must be deposited with an international depository authority according to the Budapest Treaty. In India, the Microbial Culture Collection Pune, the Microbial Type Culture Collection, and the Gene Bank Chandigarh serve as these authorities.

Non-Patentable Inventions in India¹⁷

According to **Sections 3 and 4** of the Patent Act, certain inventions cannot be patented in India. These include:

- **Section 3(b):** Inventions that go against morality or could harm human, animal, or plant life.
- **Section 3(c):** Discoveries of natural substances or living things that already exist in nature.
- **Section 3(d):** Mere discoveries of new forms of known substances that do not improve their effectiveness or simply uncover new properties or uses.
- **Section 3(e):** Inventions that are just mixtures of known substances without any new effect.
- **Section 3(h):** Methods of agriculture are not patentable.
- **Section 3(i):** Methods of treatment or diagnosis are not patentable.
- **Section 3(p):** Inventions based on traditional knowledge cannot be patented.

The Difficulties of Biotechnology Patenting¹⁸

In the biotechnology industry, obtaining a patent can be a difficult and drawn-out procedure. Innovations in biotechnology are frequently complicated and demand a high level of technical expertise to comprehend and explain. Because of this, preparing patent applications in this area might take a lot of

¹³ *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). This landmark U.S. Supreme Court case established the patentability of genetically modified organisms.

¹⁴ *Dimminaco A.G. v. Controller of Patents and Designs*, AIR 1998 Cal 78.

¹⁵ <https://www.epo.org/en/news-events/in-focus/biotechnology-patents/what-is-patentable> last seen on 26/8/24

¹⁶ <https://www.legalserviceindia.com/legal/article-12133-biotechnology-patent-in-india-and-issues-related-with-patentability-of-biotechnology.html> last seen on 26/8/24

¹⁷ Ahuja, V.K., *Intellectual Property Rights in India* (Lexis Nexis, New Delhi, Vol. 1, 1st Edn., 2009)

¹⁸ Balasubramanian, D., C.F.A. Bryce et.al., *Concepts in Biotechnology* (Uni. Press, Hyderabad, 2004)

time and money. The patent disputes can be expensive and time-consuming. Due of the high stakes involved, businesses frequently spend a large amount of money opposing or defending the patents of their rivals. Long-running legal disputes and postponements in the use of new technology may result from this.

Some of the key criticisms include¹⁹:

Research restrictions: By prohibiting others from utilizing or experimenting with the patented technology, patents might restrict research. This can impede the advancement of novel therapies and remedies, especially when a single organization or business owns a sizable portion of the patents in a certain field.

Exorbitant costs: Getting and maintaining a patent can be highly costly, especially in the biotechnology industry where R&D expenses are already rather high. Smaller businesses and individual inventors may find it challenging to compete with larger organizations by protecting their discoveries.

Slow Processing Times: The process of applying for and reviewing patents can be slow, especially in biotechnology. This delay happens because patent examiners might not always have the specialized knowledge needed to fully understand complex technologies. As a result, getting new products to market can take longer, which can affect how quickly patients benefit from innovations.

Patent Trolls²⁰: Patent trolls are entities that buy patents not to develop or use the technology, but just to enforce them and collect licensing fees. They often do this without any real intention of making products themselves. This practice can hinder innovation and limit competition, especially if patent trolls hold many patents in a particular field.

Lack of Transparency: The patent system can be complicated and hard to navigate, especially for smaller companies or individual inventors. This complexity can limit access to the system and create issues with understanding who owns what patents and how they can be licensed.

Conclusion

Patents are crucial in the biotechnology industry as they help protect inventors' rights and support innovation. They allow inventors to secure their ideas and potentially earn revenue, which drives progress in the field. However, there are valid concerns about how patents can affect the availability of essential medicines and overall innovation. As biotechnology continues to advance, it will be important to find a balance between the benefits of patents and the need for broad access and ongoing innovation. The biotechnology industry has contributed significantly to developments in patent laws. Because it involves the patenting of living things, biotechnology patenting raises complex concerns. Indian patent laws address this issue of patentability in this field without breaching the TRIPS Agreement. The strongest form of intellectual property protection is a patent, since it gives the owner of the rights the most control over how the content is used. Patenting in biotechnology is a crucial issue because it involves life forms. The potential for mankind to investigate and utilise biological resources is greatly anticipated by the use of current biotechnology in the agricultural, ecological, pharmaceutical and other sectors.

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