

MEDICAL BIOTECHNOLOGY- SCOPE OF PATENT PROTECTION

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Abstract: *Utilising biological systems and living things, biotechnology creates new products and technologies. The process of modifying biological entities through biotechnology boosts their productivity and increases their usefulness to people. The idea of biotechnology is not new. The term "biotechnology" encompasses both the new biotechnology made feasible by genetic engineering and recombinant technology as well as the older biotechnology, such the traditional way of producing fermented goods. It has origins in antiquity and has been evolved over many years. Biotechnology is rapidly expanding and changing people's lives, opening up new research opportunities. It is a dynamic field where several advancements are occurring. All industrial sectors, including the food, medicinal, and waste management sectors, have adopted biotechnology. Many issues are being addressed by biotechnology, which has also made life easier for people. In the area of health, biotechnology has produced wonders. New treatments and medications have been created to protect people from diseases. Recombinant DNA, cell fusion, and monoclonal antibody technology are recent advancements in biotechnology that have substantial ethical and societal implications as well as concerns about intellectual property rights. The scope of Patentability of life forms and legal standards will be examined in this paper. This paper will explain about protection of intellectual property rights of biotechnology inventions in medical field.*

Biotechnology

The field of biotechnology is quickly expanding and changing people's lives. It is a dynamic field where several advancements are occurring which gave rise to fresh research prospects. All industrial sectors, including the food, medicinal, and waste management sectors, have adopted biotechnology. In the area of health, biotechnology has created wonders. New treatments and medications have been developed to protect people from diseases. India is concentrating on R&D, particularly in the pharmaceutical and biotech industries.¹

Recombinant DNA, cell fusion, and monoclonal antibody technology are recent advancements in biotechnology. It is crucial to safeguard the intellectual property rights of biotechnological

inventions. But as biotechnology advanced over time and from many generations, it became necessary to have a legal system with suitable regulation. Regulations created in the field of biotechnology inventions are likewise protected by the TRIPS agreement. Biotech ideas can be protected by patents if they meet specific requirements for patentability, notwithstanding the complexity of modifying living creatures.

Biotechnology companies invest millions of dollars in the creation of new goods and technologies, thus they want to safeguard their financial commitments by patenting their innovations. Patenting biological elements, according to some, results in the privatisation of life and limits access to scientific knowledge, making it a divisive topic.

Biotechnology Patent Law

Machines, apparatus, and other inventions are granted patents. With the most recent advancements in biotechnology, biological things are being granted patents as well. Nobody has ever considered patenting biological forms. Genes,

¹Chowdhury, P., Khan, S., Dutta, P. *et al.* "Pharmaceutical and biotech product patents in India: doldrums or blissfulness?." *Nat Biotechnol* **32**, 133–134 (2014)

proteins, and living things can all now be changed. The use of biotechnology has the potential to fundamentally alter how diseases are diagnosed and treated, as well as how food is grown, energy is generated, and waste is disposed of. A genetically engineered microbe with increased industrial applications was created by scientists in the landmark case of *Diamond v. Anand Chakrabarty*. After being initially denied, his patent was eventually approved after an appeal. According to the court, "His claim is to a non-natural product of the human brain, not to a previously unknown natural phenomenon."

The basic regulations that apply to other technologies also typically apply to the patenting of biological inventions. The same criteria for originality, creativity, and industrial usefulness are used. Every step taken to implement the invention must be fully disclosed by the applicant. For biotechnological inventions, the law of patents has developed several distinctive rules, including exceptions to patentable subject matter that are in the public interest. For instance, some countries forbid the granting of patents on plants or animals, and others impose additional disclosure requirements on creations based on genetic resources. There are also other unusual legal techniques, such as the deposit of microorganisms, when access to the real components is necessary to understand the innovation.

It has long been disputed whether human DNA and other naturally existing life forms belong under the categories of invention or discovery. The European Patent Convention's Article 52 (1) permits the patenting of inventions, but Article 52 (2) prohibits the patenting of discoveries, scientific theories, and mathematical procedures. Given this, genes should be viewed as inventions rather than findings if they are patentable.²

Genes do not originate from humans; they exist irrespective of human logic. For instance, the creation of an enzyme and the finding of the DNA sequence must be completely dissimilar. Genes cannot be patented due to their inherent state. An enzyme was artificially created. Because gene sequences fall under the legal definition of a discovery, they cannot be patented.

² European Patent Convention 1973, Article 52

Patentability of Inventions - TRIPS

The international standards for the patentability of inventions are covered in Article 27 of TRIPS. TRIPS stipulates that in order for a product or technique to qualify for patentability, it must be novel, include an inventive step, and have industrial application. This must be followed by all nations that have ratified the TRIPS Agreement. The TRIPS Agreement's Article 27 specifies that "Members may also exclude from patentability: plants and animals other than microorganisms, including biological processes for the development of animal plants. It is possible to patent both non-biological and microbiological procedures. However, members are required to take steps to protect plant varieties, whether through the use of patents, a successful *sui generis* system, or a mix of the two."³ Both non-biological and microbiological processes are patentable. Members must, though, take action to safeguard plant varieties, whether by utilizing patents, a productive *sui generis* system, or a combination of the two.

Inventions that represent a significant threat to the health and safety of humans, animals, or plants are exempt from patentability under Article 27.2, provided that this exclusion is not the result of exploitation being restricted by local law. In accordance with Article 27.3, it is prohibited to patent living things, animals, and medical procedures. Only microorganisms are an exception. Enhancing plant variety protection may also involve the employment of a *sui generis* system, patent, etc.

Patents in Medical Biotechnology

Members manage patent issues on a national scale with no restrictions. Any one of the following four applications of DNA sequences may give rise to a patent claim, notwithstanding the fact that Article 27 implies that the patent grant is a national matter: The creation of therapeutic proteins for drug delivery, research tools, diagnostic procedures, or gene therapy.⁴ Genetics research has developed internationally as a result of widespread interest in these four applications.

³ World Trade Organization, *TRIP Agreement*, Morocco, 1994.

⁴ *Ibid*

Access to healthcare is impacted by the global scope of gene patents, particularly in underdeveloped nations. Health care is now more widely available because to genetic research, but firms do not trust developing nations' patent systems. They often do not invest in technologies that are being patented in underdeveloped nations because they do not want to jeopardise their money. Developing nations are forced to rely on imports from developed nations since they are unable to produce diagnostic equipment and conduct genetic research on their own.⁵ As a result, even companies in poor countries who offer healthcare rely on developed countries.

Gene patents make it harder to pay for and receive therapy, as well as to get it at all. Chricton provided a full explanation of this problem in his paper. "Gene patents dramatically increase costs: a breast cancer test that was previously \$1,000 now costs \$3,000,"⁶ To discover inherited diseases, the diagnostic test, must be affordable.⁷ If diagnostic tests are pricey, people suffer. Price increases have created a discussion about public vs private interests. If gene owners are allowed to enhance their profits, the public good will be sacrificed in favour of the private good.

Indian Law- Medical Biotechnology:

In India, the Patent Act was passed in 1856. Since then, it has undergone a number of alterations. One significant modification was made in 1970 to meet the requirements for patentability, which included novelty, inventive step, and industrial application. The advancement and safeguarding of biotechnology, however, were not expressly included in this. The number of biotechnology inventions and patent applications in the US and EU increased along with the need for the Indian Patent Act to be revised to cover biotech patentability. A modification to the definition of a patentable process was adopted in 2002 in order to

explicitly cover biochemical, biotechnological, and microbiological processes.

An invention must satisfy the conditions of novelty, inventive step, and industrial usefulness in order to qualify for patent protection in India. Sections 3 and 4 of the Patents Act of 1970 provide the list of inventions that are not patentable. The following inventions are not eligible for biotech patents: 1. An invention won't be given a patent if it causes harm to people, animals, or plant life, offends morality or the law, or is destructive to the environment. 2. Identifying naturally occurring living or nonliving things 3. In whole or in part, all species of plants and animals, excluding microorganisms, including seeds. 4. the biological processes that are principally in charge of the growth or reproduction of plants and animals. 5. Any procedure used to treat people or animals in a medical, surgical, curative, preventative, diagnostic, therapeutic, or other way in order to make them disease-free, boost their market value, or improve the value of their goods. 6. A well-known chemical's trait or feature that has been improved. 7. Agriculture or horticultural practises. 8. Traditional Knowledge.

In the case of *Dimminaco A.G. vs. Controller of Patents, Designs & others*⁸, the court ruled that there is no law prohibiting the issuance of patents for live processes used to produce items requiring an innovative step. The largest challenge for biotech ideas, however, is that many claims for patent protection are filed for innovations that barely differ from those for which patents have already been issued. Indian patent law has not yet established a distinction between a gene that originates from nature and a gene that has been modified by humans.

Conclusion and Suggestions:

India is one of the top 12 biotechnology hubs in the world, accounting for more than 3% of the worldwide market. The public good should always take precedence above private gain, and biotechnology should improve people's quality of life, according to governments. Furthermore, scientific developments should not be seen as

⁵ World Health Organisation, "Genetics, genomics and the patenting of DNA" p.50 WHO Library Cataloguing-in-Publication Data (2005)

⁶ Micheal Crichton, "Patenting Life", *New York Times* 13 Feb. 2007 available at <https://www.nytimes.com/2007/02/13/opinion/13crichton.html> last visited on 28 August 2023

⁷ Supra 5 at 4

⁸ *Dimminaco A.G. v. Controller of Patents & Designs and others Case No.1 (2002)*

merely useful instruments for business. It is obvious that India is looking at whether biological and other life forms can be patented. As research and invention in this area develop, especially in light of India's rich biodiversity, it is imperative to protect inventors' interests. Even if few claims are really considered because they are handled more on a case-by-case basis and there are no set criteria, India must enable its innovators and ideas to compete on a worldwide scale.

Despite the possibility that biotechnology will alter the way we live, there are a number of social, legal, and ethical issues that need to be resolved. How people will use its benefits, how it will impact established industries and ways of life, and the potential for economic and political injustice are just a few of the social issues that need to be addressed.

1. Legal issues including intellectual property rights, bioethics, and regulatory monitoring must also be resolved in order to ensure that the benefits of biotechnology are accessible to everyone while maintaining safety standards.
2. To overcome these issues, governments, regulatory bodies, biotechnology companies, and the general public must collaborate.
3. When developing new products and technologies, businesses in the biotechnology sector must give top importance to social responsibility and ethical behaviour.
4. Regulatory bodies must ensure that biotechnology is controlled while promoting innovation.

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