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# Intellectual Property Rights for Biotechnological Inventions

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**Abstract**

This article enumerates the intellectual property rights (IPR) that govern Biotechnological inventions. The IPR should not only take into consideration the three criteria of patentability namely, novelty, inventive step and industrial applicability but also the moral and social aspects of the inventions. Apart from this the IPR should also focus on the benefits that the invention can bring to the society by making it more affordable and at the same time keeping in mind the costs incurred by the inventors.

**Keywords**: Intellectual Property Rights, Biotechnology, inventions, TRIPS agreement, Patent

## Introduction

Biotechnology is a rapidly growing field that involves the use of living organisms or their products to create useful products and technologies [1-5]. Biotechnological inventions refer to innovations that involve the use of biological systems, organisms, or derivatives to develop new technologies, products, or processes. These inventions harness the principles of biology, genetics, and molecular biology to address various challenges in fields such as medicine, agriculture, industry, and the environment. Here are some examples of biotechnological inventions. Here are some examples of biotechnology inventions:

1. Genetically modified crops: These are crops that have been modified using biotechnology to introduce new traits, such as resistance to pests or herbicides.
2. Enzymes: Enzymes are proteins that catalyse chemical reactions, and they have a wide range of industrial applications, including in the production of food, paper, and textiles.
3. Biopharmaceuticals: These are drugs that are produced using biotechnology, such as insulin, which is used to treat diabetes.
4. Biofuels: These are fuels that are derived from biological sources, such as algae or plant material.
5. Biodegradable plastics: These are plastics that are made from renewable resources and can be broken down by microorganisms.
6. Bioremediation: This is the use of microorganisms to clean up environmental pollutants, such as oil spills.
7. Gene therapy: This is a type of medical treatment that involves the introduction of genetic material into a patient's cells to treat or prevent disease.
8. Diagnostic tools: Biotechnology has led to the development of a wide range of diagnostic tools, such as genetic tests for inherited diseases.

These are just a few examples of the many biotechnology inventions that have the potential to transform a wide range of industries and improve people's lives.

**Ethical considerations**

Biotechnological inventions raise a number of ethical considerations, including Safety, Equity, Privacy, Autonomy, Environmental impact, Religious and cultural values and lastly but mist importantly Intellectual property rights. Biotechnological inventions can have unknown or unintended effects on living organisms and the environment. It is important to ensure that new technologies are safe and do not harm human health or the environment. Biotechnological inventions can exacerbate social and economic inequalities, especially if they are controlled by a small number of powerful companies or countries. It is important to consider the impact of new technologies on marginalized or vulnerable populations. Biotechnological inventions can involve the collection and use of sensitive personal information, such as genetic data. It is important to ensure that individuals have control over their own data and that it is used in a responsible and transparent manner. Biotechnological inventions can raise questions about individual autonomy and the right to make decisions about one's own body and genetic information. Biotechnological inventions can have significant impacts on the environment, both positive and negative. It is important to consider the potential long-term effects of new technologies on ecosystems and biodiversity. Biotechnological inventions can conflict with religious or cultural values, such as the use of genetically modified organisms in food or the creation of genetically modified humans. Biotechnological inventions can raise questions about intellectual property and the control of scientific discoveries and technologies. It is important to balance the need for innovation and investment with the public interest and access to essential technologies.

These ethical considerations highlight the need for careful regulation and oversight of biotechnological inventions, as well as open and transparent dialogue between scientists, policymakers, and the public.

**Case Studies**

One notable American case study related to the intellectual property rights (IPR) of biotechnological inventions is the Association for Molecular Pathology v. Myriad Genetics case [6]. This case, decided by the U.S. Supreme Court in 2013, focused on the patentability of human genes. Myriad Genetics had obtained patents on isolated DNA sequences associated with an increased risk of breast and ovarian cancer, particularly the BRCA1 and BRCA2 genes. The plaintiffs, including the Association for Molecular Pathology, argued that genes are products of nature and, therefore, not eligible for patent protection. In a unanimous decision, the Supreme Court ruled that isolated naturally occurring DNA sequences are not eligible for patent protection because they are products of nature. However, the Court also held that synthetic DNA, known as cDNA, which is not naturally occurring, could be patented. This case had significant implications for the biotechnology industry, shaping the boundaries of what could be patented in the field of genomics and molecular biology. It clarified the distinction between naturally occurring biological material and human-made inventions in the context of patent law.

In India, Monsanto was involved in a legal dispute related to its genetically modified cotton seeds, which contained a toxin derived from the bacterium Bacillus thuringiensis (Bt) that made them resistant to certain pests [7]. The Indian government allowed Monsanto to sell the Bt cotton seeds under a licensing agreement, which required the company to charge a royalty fee to farmers. However, in 2015, the Indian government reduced the royalty fee that Monsanto could charge, prompting the company to take legal action. In 2018, the Indian Supreme Court ruled in favour of the government, stating that the price reduction was justified given the importance of the cotton industry to India's economy and the fact that many farmers were struggling with high debts. The ruling was seen as a blow to Monsanto's business in India, which was one

of the company's largest markets for its Bt cotton seeds. The case also highlighted the tensions between multinational agribusiness companies and small-scale farmers in developing countries, as well as the challenges of regulating and protecting IPR in emerging markets.

**Indian Jurisdiction**

Like other inventions, biotechnological inventions must meet the general patentability criteria outlined in Sections 2(1)(j), 3, and 4 of the Patents Act. The invention should be novel, involve an inventive step, and have industrial applicability. Section 3 of the Patents Act specifies certain categories that are not considered inventions and are not patentable. However, the interpretation of these exclusions can be complex. In the past, there has been debate and legal scrutiny regarding the patentability of certain biotechnological inventions, such as genetically modified organisms (GMOs) and methods of agriculture or horticulture. Section 3(j) of the Patents Act excludes the patenting of plants and animals in whole or any part thereof, but it allows for the patenting of microorganisms. The definition and scope of what constitutes patentable subject matter in biotechnology are continuously evolving. Biotechnological inventions, like any other inventions, need to demonstrate novelty and non-obviousness. The examination process by the Indian Patent Office involves assessing these criteria. The patent application must provide sufficient disclosure to enable a person skilled in the art to carry out the invention. Clear and comprehensive descriptions of the invention and its practical implementation are essential.

India is a party to the TRIPS Agreement. The 2005 Amendment of The Patents Act, 1970, by omission of Section 5 as well as through various amendments made the intellectual property laws of India fully TRIPS-complaint. The Several questions are always raised: Are microorganisms patentable? Yes, a microorganism whose discovery involves human intervention is patentable and qualifies for a product patent. Is human cloning patentable? No, because human cloning is not subject to patentability on the grounds of Section 3(b). Is stem cell research patentable? Are genetically modified seeds patentable? Yes, they are. Are genetically modified plants and animals patentable? Any invention must satisfy the three universal criteria of patentability namely, novelty, inventive step (non-obviousness) and industrial applicability. Inventions that concern biological processes and software are challenging because in these cases the identification of inventive step becomes difficult. In the former it is important to identify the step where human intervention stops and biological process takes over. In the latter the incremental changes make the identification of inventive step a very difficult process [8-10].

**Conclusion**

The encouragement of biotechnological inventions is a topic that involves weighing various considerations, including scientific, economic, ethical, and societal factors. Here are arguments both in favour of and against encouraging biotechnological inventions. Biotechnological inventions have the potential to drive significant scientific and technological progress. They contribute to our understanding of living organisms and offer innovative solutions to challenges in healthcare, agriculture, and the environment. Biotechnology can stimulate economic growth by creating new industries, generating employment, and fostering innovation. The development of biotechnological products, such as pharmaceuticals and agricultural innovations, can lead to economic benefits. Biotechnological advancements in medicine can lead to the development of novel therapies, personalized medicine, and improved diagnostic tools. This has the potential to enhance healthcare outcomes and quality of life. Biotechnological inventions in agriculture, such as genetically modified crops, can contribute to increased crop yields, resistance to pests, and improved nutritional content, addressing global food security challenges. Some biotechnological inventions raise ethical concerns, particularly when they involve genetic manipulation or interventions. Issues such as consent, privacy, and the potential for unintended consequences must be carefully considered. The release

of genetically modified organisms into the environment can pose ecological risks. Concerns include unintended crossbreeding with wild species and the potential disruption of ecosystems. Benefits of biotechnological inventions should be distributed equitably. There are concerns that certain advancements may disproportionately benefit specific populations or exacerbate existing social and economic inequalities. Some may argue that certain biotechnological interventions, such as human genetic editing, may interfere with the concept of human dignity by allowing the modification of fundamental biological traits.

In practice, the responsible development and application of biotechnological inventions require careful consideration of ethical guidelines, regulatory frameworks, and public engagement. Encouraging innovation while addressing potential risks and ethical considerations is essential for a balanced and sustainable approach to biotechnological advancements.

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**Conflict of Interest**
The author confirms that there is no conflict of interest related to the manuscript.

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