

Intellectual Property Protection of Biotechnology Inventions in India

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ABSTRACT: *It was in 1919 when the term biotechnology was invented and since then it was developed expeditiously that we have adopted many biotech products in our daily life. It does not mean that there was no use of the biotechnology before 1919. But before the term “Biotechnology” was invented any developments in the field of microorganism or living system were referred as “discoveries”. In today’s 21st centuries the term was frequently used from the classroom to the market. It cannot be denied in upcoming days we wake up with biotechnology and we go to bed with biotechnology. However, at the same time from the intellectual law perspective it raises the question whether biotechnology invention can be protected or not? Since the biotechnology product is also an invention one has to prove his/ her novelty in the product. Thus, in this review paper the researcher will discuss the stages of development of the biotechnology, its relationship with intellectual property, appropriate intellectual property for the protection of the biotechnological inventions and challenges in protecting biotechnological invention.*

KEYWORDS: *Biotechnology, Discoveries, Invention, Novelty, Patent.*

INTRODUCTION

The term biotechnology was invented from the two words “Biology” and “Technology” meaning thereby use of biological resources like living cells and microorganism to develop or produce new product with the help of the technology. Biotechnology can be defined as “the use of living organism/s or their product/s to modify or improve human health and human environment”.¹ Thus it can be said that the biotechnology invention is used for the benefit of human beings. However, at the same time one cannot deny the development of the Bioterrorism in the field of the biotechnology inventions. In short, bioterrorism can be explained as use of a cellular or cellular microorganisms in such a way to harm large quantities of people or communities. In bioterrorism the weapons are outspread in the air or water. Bioterrorism is not the new concept and was also used in the ancient period. Bioterrorism are also frequently used during the first and second world war.

For the sake of understanding biotechnology can be divided into three stages viz.

- Ancient Biotechnology
- Classical Biotechnology
- Modern Biotechnology

As mentioned in the abstract the term biotechnology was invented in 1919 but the application of the biotechnology was in existence in Ancient Period. In ancient period the application of the biotechnology was generally based on the common observation made by the people for their survival. For example, in ancient period people used to eat raw meat gained from dead animals for their survival. However, at a time there was scarcity of the raw meat which will led to the agriculture.

Now, for their survival they used to grow food plant and move towards the domestication of the food plants and animals for their survival. After that they observed by-product made up from the milk like curd, cheese etc. It is pertinent to note that CHEESE is the one of the first biotech product invented in the ancient period. It is because the cheese was prepared from rennet, a complex set of enzymes. Yeast, is another microorganism used for preparing foods. However, the subject is not limited to the food product and one can also record the cross breed, a subset of the microorganism. For example, MULE is one of the best examples of crossbreeding in the ancient period. A Mule is a child of the female horse and male donkey. Mule was generally used for transportation purpose.

¹Biotechnology in the Realm of History, by Ashish Swarup Verma and Others

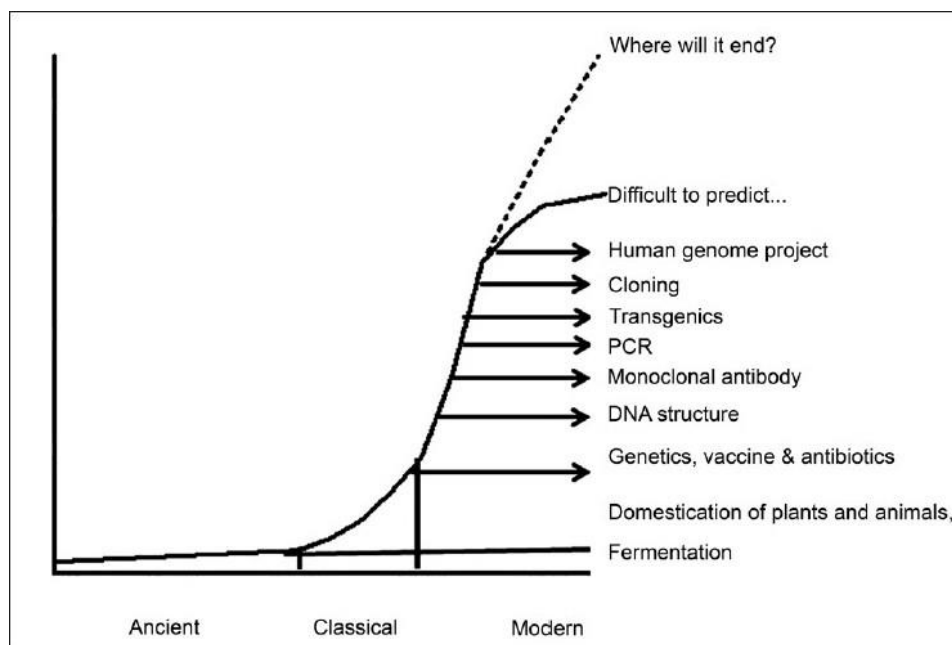


Figure 1: Stages of development of biotechnology (Image Source: Web²)

Figure 1 illustrate stages of development of biotechnology. Now in the second stage i.e. Classical Biotechnology some scientific evidences are observed in understanding the biotechnology. Classical Biotechnology started from 1800 and continued up to middle of 20th century. During these period the genetic transformation within the plant and discovery of nucleus in cell are the two prominent discoveries in the field of biotechnology. During the same time period the first ever vaccine was developed by the Edward Jenner for the smallpox. At the same time, in Britain, Alexander Fleming a physician discovered antibiotics, when he observed that one microorganism can be used to kill another microorganism, a true representation of the ‘divide and rule’ policy of humans.³ The discovery of the vaccine, antibiotics and other biological science are the reason behind biotechnology to be renowned at that time.

Now in the third stage i.e. Modern Biotechnology which is observed after the Second World War have reported very important discoveries. During this time period the Double Helix Model of DNA was identified, first ever monoclonal antibodies were produced, cloning, and in vitro fertilization (IVF) are few of the discoveries in biotechnological field.⁴ In the whole phenomenon of the development of the biotechnological invention it has brought us to that level; that the next question is what’s next and where will it end? The concept of reproductive cloning, embryo stem cell research, gene modification is some of the area of biotechnology which raises both legal and moral concern for/against their use. The Indian Patent Law to some extent have tried to answer these question by prohibiting many inventions from getting patent. Let us understand the patentability of the biotechnology invention in brief.

1. Intellectual Property Rights and Biotechnology:

Biotechnological inventions are held across the world where the new inventions open the door for their application in the Agriculture, Healthcare, Environment and Industrial Sector. These application in respective fields have capability to generate the revenue. Since these inventions are product of the intellectual creation and have commercial gain, it attracted the protection under the Intellectual Property Regime. Figure 2 illustrate the application of biotechnology.

² <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3178936/>

³ *ibid*

⁴ *ibid*

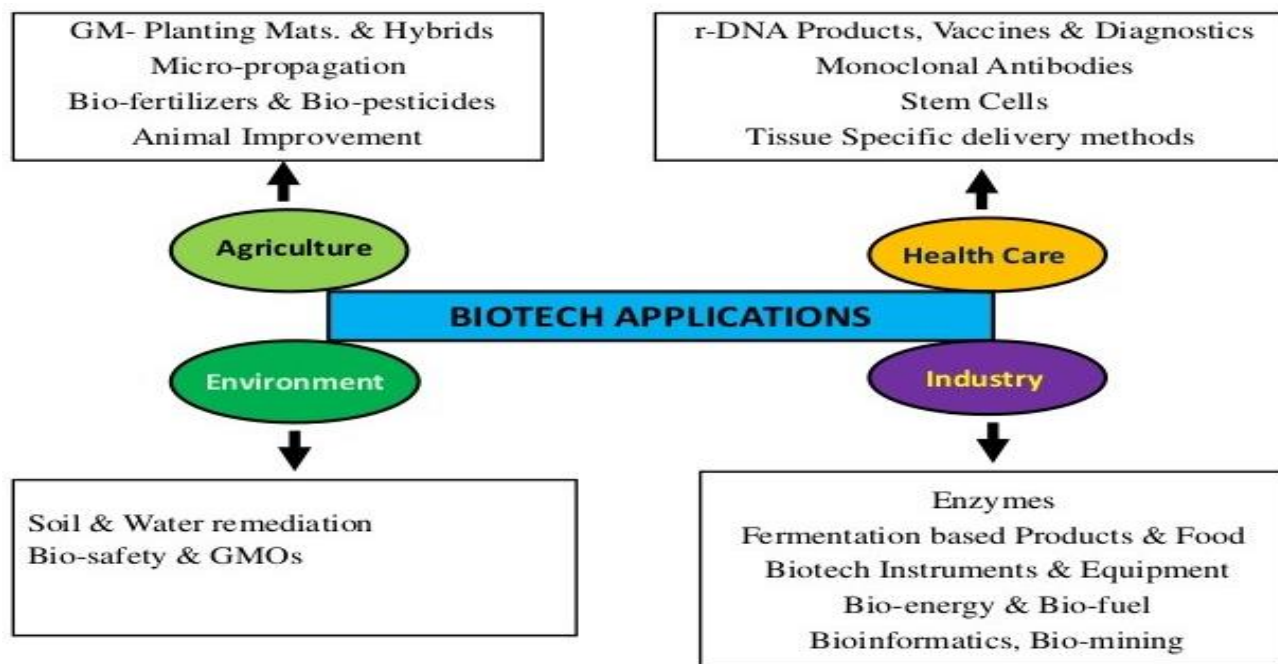


Figure 2: Application of biotechnology (Image Source: Web⁵)

2. Which Intellectual Property would be better for their protection?

The appropriate intellectual properties for protection depends upon the subject matter of protection. For example, the appropriate protection of the literary work is copyright. Similarly, for invention the appropriate protection would be patent. Here in this case, for protecting biotechnological invention the most appropriate ways of the protection are Patents. However, the other mode of protection would be Trade Secret and trademarks.

When we talk about Intellectual Properties Protection, Trade Secret is rarely used for any subject matter. It is mostly used for recipe like Coca Cola, KFC, Krispy Kreme Doughnut, etc. Inventor mostly go with the trade secret when the level of complexity and novelty is so high that it is almost impossible to reverse engineering. Secondly, they adopt trade secret as protection when they did not want to disclose their invention to public even after 20 years. Thus it protects valuable non-public information. The most important thing in the trade secret is to keep secrecy of the invention, which is almost next to impossible in Biotechnology where huge level of research is involve, marinating secrecy at each level is quite difficult and risk taking task. Thus, trade secret is not an appropriate protection for the biotechnology invention.

It seems quite interesting in relating biotechnology invention with the law of trademark but there are few things which might be interlinked with together. For example, in GMO labeling is required on the product which is part of the trademark law as well. It also helps the customer to distinguish between GMO food and Non-GMO foods. It was observed that name of drugs, vaccine is often used as trade mark/name. However, trademark law to limited with their scope for protecting biotechnology invention. Since apart from the above mentioned examples there is no way the trademark law helps the biotechnological invention. Thus it can be better to say that trademark law is not an appropriate protection for the biotechnology invention.

Now, we left with one more option i.e. Patent protection for the biotechnological invention which sound much better than the trade secret and trademark law. Thus, we will discuss the patent protection to biotechnology in brief as follows:

⁵ <https://www.askiitians.com/biology/biotechnology-and-its-applications/>

3. Patent protection for the biotechnological invention

It cannot be denied that patent protection is most widely accepted protection for biotechnological invention. Since the when the commercialization of the biotechnological invention were started there is huge demand of protecting of the invention. And thus the TRIPS Agreements conclusively accepts patent as the most appropriate option for the protection of biotechnological invention.⁶

It is to be noted that until 2002 judgment of the Hon'ble Calcutta High Court the patents were not granted for invention pertaining to-

- Natural or artificial living individual or organisms,
- Biological materials or other materials having replicating properties,
- Substances derived from such materials and
- Processes of producing living individual or organisms

Even before the 2005 Patent Amendment Act, the patent was not granted to any product only process patent was available for the inventor. The 2005 Amendment allows product patent but with certain restriction and limitation keeping in mind the national public interest. After the judgment given by the Hon'ble High Court in *Dimminaco AG v. Controller of Patents and Designs* patent was given to the processes producing living microorganisms. The court explains their stand that even if the end product is a living organism the whole process of producing the organism is new and useful. The court thus concluded that new and useful art or process is an invention.⁷

Just for your reference giving you the brief idea of the *The Dimminaco* case, it was relation to process patent for the producing vaccine. The vaccine was capable of protecting poultry from infection by Infectious Bursitis. Since the process of producing the vaccine involves microbial substances in their process the Controller of Patents refused the application for grant of patent.⁸

They further states that the claimed process is natural process and nothing else. Since it also involves the end-product which is a living material and thus the patent application can be refused on this ground alone.

In the same year the Patents (Amendment) Act, 2002 was enacted which opens the door for the microbiological, biochemical and biotechnological invention within the preview of the Patent Act, 1970. Before that in 2001, India becomes the signatory of the Budapest Treaty concerning International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure. And as a result section 10 of the Act was also amended in the Patent Amendment Act 2002 to add mechanism for depositing biological material.

4. First and Famous Case of Biotech Patent

The first Biotech. Patent was granted to Louis Pasteur in 1873. He claims patent on yeast free from organic germs of disease, as an article of manufacture. After that it took almost 100 years for the next biotech patent application filed in 1980 by Ananda Mohan Chakraborty. Though the Patent Application was rejected on the ground that living organism were not patented. The US Supreme Court overturned the decision of the Patent Office and held that "Anything under the sun that is made by man" is patentable.

5. Challenges in Patenting Biotechnological Invention

Since we have observed that for biological invention the most appropriate intellectual property protection is the Patent Law. However, at the same time there are various challenges in patenting the biological invention.

For example, patentability criteria of novelty, inventive step and industrial application plays and important role in granting patent. Further, Section 3 of the Patent Act 1970 bars certain invention from getting patent. The various challenges are discussed in brief as given below:

⁶ Law of patenting of biotechnological inventions in India and USA a comparative study on Sodhganga

⁷ GUIDELINES FOR EXAMINATION OF BIOTECHNOLOGY APPLICATIONS FOR PATENT

⁸ *ibid*

The Challenges in Patenting Biotechnological Invention can be classified in to two types:

- Traditional Challenges or Statutory Challenges and
- Modern Challenges;
- Moral Challenges

Traditional Challenges includes:

- Fulfilling the Criteria of Novelties
- Fulfilling the Criteria of Inventive Step
- The criteria of not falling under Section 3 of the Patent Act, 1970 (Relevant Clauses of Section 3 of the Patent Act 1970 are given in the Figure 3)

Modern Challenges includes:

- Scope of Protection of claims
- Protection for future innovations

S. No.	Section 3	Subject Matter
1.	Section 3(b)	Inventions which is contrary public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment
2.	Section 3(c)	discovery of any living thing or non-living substances occurring in nature
3.	Section 3(h)	Methods of agriculture or horticulture
4.	Section 3(i)	Any Process for the medicinal, surgical, curative, prophylactic, diagnostic or therapeutic or other treatment of human beings or animals to render them free of disease or to increase their economic value or that of their products
5.	Section 3(j)	Plants and animals in whole or any parts thereof other than micro-organisms but including seeds, varieties and species
6.	Section 3(j)	biological processes for production or propagation of plants and animals
7.	Section 3(p)	Traditional knowledge

Figure 3: Relevant Clauses of Section 3 of the Patent Act 1970

These Statutory, Modern and Moral challenges can be understood through following relevant examples:

5.1. Patenting of GMO

If we would discuss the patentability of the Genetically Modified Organisms Section 3 (c) attracts the controller in determining whether it can be patented or not. As given in the Figure 3 it prohibits discovery of any living thing or non- living substance occurring in nature. It can also be drawn that an isolated gene cannot be patented which is naturally occurring in the nature. However, for GMO, which is not naturally occurring and is a modified version of the organism can be patented.

Further Section 3 (j) of Patents Act, 1970 excludes microorganism from its preview and thus it can be drawn that it can be patentable. Also as held in the *Dimminaco AG v. Controller of Patents and Designs* by the Hon'ble

High Court that even if the end product is a living organism the whole process of producing the organism is new and useful. The court thus concluded that new and useful art or process is an invention. The court further held that the Patent Act did not bar process of manufacturing even if the product contains a living organism.

However, granting patent to GMOs are ethically and morally challenged. For example, Golden Rice which is a GMOs product, reduces immune system and increase severity and mortality risk of infections. Wendell Berry and Vandana Shiva criticizes the Golden Rice and said that- “GM technology is a solution offered by industrial agriculture to address problems created by industrial agriculture”. Further, it was morally argued that does modifying organism affects the dignity or integrity of the organism.⁹ Since, the argument was based on nature of reality and religion and thus was overlooked.

5.2. Patenting of Cloning

Before questioning on patenting cloning process or product itself the first question arise is that Cloning being against the law of nature should not be legalized. With the development of science and instrument in the biotechnology filed research on cloning was frequently happening across the globe. Gradually, the research on therapeutic cloning is allowed. However, reproductive cloning is still not accepted. Patenting cloning was not considered as ethical as it would be against the public order and morality.

Dolly the sheep was the first animal cloned from adult cell and the patent application was filed for this invention. US Patent office rejected the patent application and the court upheld the decision given by the Patent Office. It may be noted that in this case process patent was allowed but the product patent was rejected.

5.3. Patenting of Stem Cell Research

The Section 3(j) of the Patents Act 1970 bars Stem cells from patentability. However, stem cell research for therapeutic purposes can be patentable provided they must be novel, involve inventive step, capable of industrial applicability and are not against the public morality. However, the patenting of stem cell research is also argued on moral ethical and religion grounds. Ethically, on the one hand it was argued that Embryo is only a spare part of the body and thus can be used to replace lost or damage cell in the body, whereas, on the other hand it was argued that using of stem cell can only be justified if the action is itself justified. Thus it raises ethical question whether the action of using embryo is justified in itself or not. Morally, it was argued that destruction of human embryos is morally equivalent to the killing of a human beings. On the other hand, few are of the view that it is not human beings and thus cannot be attributed to any moral status.

Religious arguments were also made against the Stem Cell Research that according to Jewish thinkers, a human embryo is not treated as religious until the 16 weeks of pregnancy and consequently, research on stem cells through human embryo is allowed under this period. According to Christian Views, the embryo has personhood from the time of conception only. According to Islamic view, cloning embryo stem cells for therapeutics purposes can be allowed but at the same time, they are against the use of reproductive stem cell research.

CONCLUSION

It was discussed above that inventions related to Biotechnology is nothing new but the term was coined in the year 1919, Before that there was application of the biotechnology invention since the beginning of time. Further we have observed that wider application of the biotechnological invention helps in gaining commercial gain from the invention and thus attracts intellectual property protection.

We have further discussed in brief that which intellectual property is suitable for the protection of the biotech invention. On analyzing trade secret, trademark and patent law one by one we have found that patent law is most appropriate intellectual property for the protection of the biotechnological invention.

We have further discussed the challenges we might face in patenting biotechnological invention. Since we have gone through three prominent examples and on the basis of the study one can conclude that there are various inventions which qualifies the statutory challenges or criteria of patentability but their patentability was objected on the ethical, moral or religious grounds. Thus based on the discussion and observation made above the legal

⁹ *ibid*

framework for protecting biotechnological invention is not transparent and Section 3 of the Patent Act, 1970 always raises statutory challenges. Thus as a suggestion it is necessary to have comprehensive legal framework on patenting of biotechnological invention. This can be achieved either by amending the Patent Act or enacting sue generis system for the protection of the biotechnological invention.

