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An Analysis on Patentability of Biotechnological Invention in India

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Intellectual property is an intangible property which is created by the human mind. In this competitive world it is very important to protect intellectual property. So, a researcher's scientific endeavors can be rewarded with patents for protecting their intellectual property. Man uses the science and technology as an instrument of development. The progress in biotechnology has profound implications on the relationship between humans and the environment. Biotechnology is the science where biological systems and living organisms are used to create new products or processes. Biotechnology will substantially shape drug discovery, delivery, diagnostic methodology, clinical trials, and to a large extent the major lifestyle of human society once the availability of the human genomes traced. The biotechnological invention in the patent system includes biological, microbiological, genetics, medical and agricultural inventions. Inventions relating to biological processes are not limited to developments in genetic engineering but also include compounds derived from microorganisms, plants, insects, and animals. Article 27 of the Trade Related Aspects of Intellectual Property (TRIPs) agreement covers the patenting of living organisms and living processes. TRIPs is an international agreement administered by the World Trade Organization that determines minimum standards of Intellectual Property regulations applicable to member countries of world trade organization. In India, patentability of the invention is covered by Indian Patent Act 1970. At the beginning it had nothing specific addressing the biotechnology inventions and protection but later by witnessing massive increase in the biotechnology invention and application for the Patent, the demand to amend and introduce patentability of biotechnology gained voice in India which resulted in alteration of section 3(j) of the Patent Act. The researcher in this paper mainly focusing upon the criteria for patenting, subject matter of the patents and ethical issues involved in patentability of biotechnological inventions.

Keywords: *Intellectual property, Patents, Invention, Biotechnology, Micro-organisms, Ethics*

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I. INTRODUCTION

The economic growth and development has highly impacted the technology and sparked the competitiveness in every field. This resulted in rapid technological advances on the worldwide trade and business environment. There are three dimensions to the evolution of biotechnology in advanced industrialized countries i.e. the science and technology on which biotechnology is based, biotechnology-related companies and government policies.² Biotechnology can be referred to as one of the fastest-growing technology. The science of biotechnology involves the manipulation of living organisms using biological systems and living organisms to create new or modified products and processes.³ The product of biotechnology is neither naturally occurring in living organisms nor the product of nature. But they can be called an invention if it involves inventive steps and can be applicable in industry along with satisfying the criteria of patentability. It is important for companies to develop biotechnological patents so that they can develop, for example, life-related products. By granting IP rights for a limited period of time, patents provide companies with an opportunity to recover investment in developing the patented invention, launching the new products into the market, or licensing or transferring the rights to other companies.⁴ But countries like India are not completely accepting the concept of biotechnological patenting and addressing it as an unethical practice.

Research Objective

The aim of this research is

- To identify the position of the patentability of biotechnological inventions.
- To understand the difference between biotechnological patenting and other invention patenting.
- To trace out and examine ethical issues.
- To provide better possible solutions to the existing issues for the better policy formation and regulations thereof.

Research Question

- Does patent law differentiate between Biotechnological inventions and other

² V. Sita, Intellectual property rights in biotechnology - an empirical analysis in Andra Pradesh, *INTELLECTUAL PROPERTY RIGHTS*, 87,91 (2008)

³ Dr. Jayanta Lahiri, Lectures on IP laws, 118 (R. Cambray &co pvt. Ltd. 2009)

⁴ Alfredo Mateos García, Key Points in Biotechnological Patents to be Exploited, *RECENT PATENTS ON BIOTECHNOLOGY*, 84, (2013)

inventions?

- Whether our country has any policy framework in the field of biotechnology patenting?
- Whether the patenting of biotechnology will be ethical?

Hypothesis

- The criteria under which biotechnological inventions were granted patent needs review.
- Biotechnological inventions are not completely ethical.

Research Methodology

The methodology adopted by the researcher in this paper is doctrinal that is purely based on the secondary sources like books, journals and articles which are selected from library and internet sources. Selected books and other materials referred in this research paper are provided at the end of the research paper.

Scope and Limitation of the Study

The scope of this research is comparatively narrow as the researcher has restricted the research relating to patentability of biotechnological invention to only India.

II. CONTENT ANALYSIS

➤ Evolution of biotechnology patenting in India

In India, patent act was enacted in the year 1970. It does not mention anything about biotechnological invention because during that time biotechnology was not developed in India. Evolution and expansion of biotech industry sparked the grant of patent for different biotechnological invention in United States and European Union, the demand spread worldwide including India to adopt the same approach and significance. It also paved the way for the adoption of International conventions like Trade related Aspects of intellectual property rights (TRIPs) agreement and changed the history of patent law⁵.

Trade related Aspects of intellectual property rights (TRIPs) is an agreement administered by the World Trade Organization (WTO). It formulates the minimum standards for intellectual property regulations for all the member countries of WTO. As per TRIPs every invention must be patented if it fulfills the patentability criteria, whether they are product or process in the field of technology without discrimination as to the place of invention and field

⁵ Dr.Sreenivasalu N.S.& Dr. Raju C.R., biotechnology and patent law,56, (Manupatra 1st ed. 2008)

of technology.⁶

Article 27 of the TRIPs agreement covers the patenting of life- forms and living process. The agreement mandates patenting of biotechnology invention in the member states. TRIPs ratification prompted India to amend its intellectual property laws including patent law in order to patent biotechnological inventions.

Indian patent act 1970 amended in the year 2002 for the second time after first amendment in 1999. This second amendment brought major amendments by permitting patenting of products of chemical, biochemical, biotechnological and microbiological.

India, after recognizing Budapest treaty, facilitated the deposits of biotechnological inventions. Further, the third amendment of 2005 omitted section 5 of the original act which restricted patents only to the process of manufacture. Now both products and processes are patentable in the field of biotechnology. Inventions such as micro-organisms, genetically modified plants and animals and processes to manipulate living beings are patentable.⁷

➤ **Judicial initiative**

After the amendment, the exclusionary provision of section 3(j) permits grant of patent to micro-organisms. In the case *Dimminaco AG v. Controller of Patents*⁸ the High Court of Calcutta on 15th January, 2002 has given a landmark decision by allowing grant for Patent application for a genetically modified microbe called infectious bursitis vaccine.

In this case the application of the applicant was rejected on the ground that the process includes living entity in its preparation, the process does not come under the invention according to section 2(1) of the patent act 1970. The applicant contended that the process involves inventive steps and the vaccine is useful to protect poultry against infectious bursitis. Further, the applicant argued that there are no restrictions against patenting of end product and living entity according to the latest amendment. Considering both parties contention court held that the claim is patentable and directed the controller to reconsider the application and to grant patent to applicant.⁹

➤ **Criteria for grant of Patent**

An invention as a patentable subject matter must satisfy certain criteria.

⁶ Supra note 3, 85

⁷ Supra 4, 59

⁸ *Dimminaco AG v. Controller of Patent* AID No. 1 of 2002

⁹ Dr. M K. Bhandari , law relating to intellectual property Rights, 118-119, (central law publication, 1st ed. 2008)

1. Novelty

Novelty is the first requirement that need to be fulfilled. Section 2(1)(j) of the Indian patent act states the invention must be new and different from the ‘prior Art’. Inventions which have already been published in any form anywhere before filing a patent application will ceases to be new.¹⁰ In *Bishwanath Prasad Radhe Shyam v. Hindusthan Metal Industries*¹¹ the Supreme Court held that patent will be granted only if the invention is new. In case of genes and gene products, it is easy to meet the principle of novelty as they are chemical entities that are able to be patented in most patent office once they are isolated and purified from the original form appearing in nature.¹²

2. Non-Obviousness

Section 2(ja) of patent act deals with non obviousness. It states an invention that involves a technical advance over existing knowledge, or is economically important, or both, and that makes the invention not obvious to someone skilled in the field. The obviousness that a particular gene having a particular nucleotide sequence exists in principle, but whether it would be obvious to one skilled in the art to identify and isolate it¹³.

3. Utility

Patent must possess utility. Product should have some capacity to perform some kinds of work. The invention should be applicable to relating industry. Economists say whatever commands the price in marketplace will holds good in utility test. Suppose process used to isolate not previously known partial complementary DNA sequences, then these partial cDNA sequences may be patentable if it satisfies the utility test.¹⁴

4. Inventive step

The invention must contain technical steps which should not be obvious for the skilled person. Inventive steps can be said as the step which makes an invention unique.

➤ **Conceptual framework**

The department of biotechnology which was set up by the government of India within the Ministry of science and technology has established a “Biotechnology patent facilitation Cell (BPFC)” to promote research and development in the field of biotechnology. Funding for

¹⁰ S.K.Singh, intellectual property rights law, 146 (central law agency, 1st ed. 2009)

¹¹ *Bishwanath Radhe Shyam v. Hindustan Metal Industries*, AIR 1982 SCC 1444

¹² Malati Lakshmikumaran, patenting of genetic invention, 48, JOURNAL OF INTELLECTUAL PROPERTY RIGHT, (2007)

¹³ Jidesh kumar, biotechnology patenting, 474, JOURNAL OF INTELLECTUAL PROPERTY RIGHTS, (2004)

¹⁴ Ibid

biotechnological research and development very limited.¹⁵Funds will be granted only for government institutions and laboratories. At present times, even private research and development setups like Dr. Reddy's laboratories, Biocon India, Bharat Biotech and Biological Evans etc. are investing on research and development of biotechnology in the country.¹⁶

➤ **Ethics in patenting biotechnological invention**

In India ethics and morality plays an important role because here in India ethics and morals are respected and adhered to at the same level as the law. The concept of morality is related to the belief where one behaviour is considered as right and the other one wrong. This belief is based on the accepted norms which are ingrained in the particular culture. Indian culture is well known for worshipping plants and animals by consider them as God.

Many people consider this concept of patenting life as an unethical practice therefore they are not in favour of this. The objection raised by them lead to potential structural changes in the agricultural industry that could result from biotechnology, especially if large corporations acquire legal rights to the advancements being made.¹⁷ The ownership of living beings is discouraged in India because there has been a longstanding tradition of not encouraging private ownership over living and natural things. But India being a member of TRIPs agreement must adhere to it in patenting of inventions like micro-organisms and other inventions which are produced through microbiological, non- biological or biotechnological process.¹⁸

According to the amendment, any invention that is contrary to public order or morality or may result in serious harm to human or animal health or environment cannot be patented. It also cleared that plants, animals, and essentially biological processes for production of plant and animals are not patentable on the basis of ethics.

III. RESEARCH QUESTION ANSWERS WITH REASONING

- Does patent law differentiate between Biotechnological inventions and other inventions?

No, the procedure for patenting of biotechnological invention is same as that of any other

¹⁵ Rahuldev, biotech patents in India, available at <https://patentbusinesslawyer.com/biotech-patents-in-india> (last visited on Dec. 9,2021 7:45PM)

¹⁶ Braj B. Lohray, Medical biotechnology in India, 277 *ADV BIOCHEM ENGIN/BIOTECHNOL* (2003)

¹⁷ Archana K, Do We Need Patent Protection to Biotechnology Inventions?, 01, *INTERNATIONAL JOURNAL OF SCIENTIFIC AND RESEARCH PUBLICATIONS*,(2013)

¹⁸ *Supra* 4, 223

invention. The invention must fulfill the criteria of novelty, utility and non-obviousness but along with that there is an additional requirement of sufficient disclosure for which the invention is needs to be deposited at an authorized Depository Authority.

- Whether our country has any policy framework in the field of biotechnology patenting?

Yes, The department of biotechnology which was set up by the government of India within the Ministry of science and technology has established a “Biotechnology patent facilitation Cell (BPFC)” which look after the issues relating to biotechnology patenting.

- Whether the patenting of biotechnology will be ethical?

We cannot say it is completely ethical. Because India being a traditional country and which values ethics and morals is actually against the biotechnological invention but there are certain convincing factors which ensures it will not hurt the ethical values of the country and such inventions can be considered as ethical.

IV. HYPOTHESIS TESTED WITH REASONING

- The criteria under which biotechnological inventions were granted patent needs review.

Yes, the procedure followed for the grant of biotechnological patent is the same as for other inventions. But the review is necessary as it includes ethical complications. The procedure must be transparent and there should be sufficient disclosure.

- Biotechnological inventions are not completely ethical

Yes, biotech inventions are not completely ethical ownership of living being is not encouraged in India as we Indians consider them as God. But we can say the invention is ethical until it does not hurt the moral values of the society and free from causing serious prejudice to environment.

V. RECOMMENDATION

- This biotechnological patenting is under controversy because of ethical issues involved in it and ethical issues differ from country to country, so local laws must be modified by providing clarity regarding ethical issues.

- The time period of granting of patents must be reduced. Because biotechnology being rapidly developing technology may overlap on the inventions.

- Expert committee on patenting of biotechnology must be constituted to assist, adjudicate and enforce the invention.
- Strict laws must be adopted and grant of license should be made mandatory on satisfying the required conditions
- Bio-safety measures must be adopted to ensure safe production, use, storage, transfer and exploitation.
- BPFC must make its policy framework more efficient and ensure good governance.

VI. CONCLUSION

Biotechnology has become increasingly significant for the growth and development of developing nations like India. An unpredicted evolution of biotechnology has been accompanied by a long struggle for recognition and reward. It wasn't easy, as there were negative and positive phases of progress. There is no doubt that the biological materials or substances that are designed in the labs and weren't available in the natural environment have earned some rights to patentability. As a result, biotechnological patenting was introduced in India to protect the inventor's interests and right to patent. A biotechnological invention, which results from the application of man's creativity to a biological process, must deserve patent protection. But one must make sure that the invention is not harming any moral values or is unethical.

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