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BIOTECHONOLOGY PATENTING

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ABSTRACT

Patents in the field of Biotechnology are pertinent to be discussed since it is not only significant industrial sector but also overlaps with several other markets and industries such as pharmaceuticals, industrial processes and the agriculture which all rely on the patenting inventions made in the field of biotechnology

The issues that that biotechnology patenting must deal with is that some of these materials are naturally occurring substances or organisms within the nature as biological materials and therefore the mere discovery of the same would not classify as an invention. Therefore, the complexity lies in proving that the biotechnology product or process is novel and not a natural biological substance and the inventor further should reveal that their invention is the first in the world to attain a specific purpose.

INTRODUCTION

Biotechnology is the process that pertains to the application of molecular and cellular biology to create, modify any products or processes. It therefore is the scientific discipline that focuses on manipulating the genetic material of living beings or biologically active material that helps in improving the quality of human life, health, and different organisms. It includes harnessing the bio-molecular processes and cellular commonly involving DNA techniques and analyzing the genetic makeup. Modern biotechnology is significant in various fields such as food, medicine, energy, and environment. It also helps in developing technologies to combat rare and life-threatening diseases and assist industrial processes[2].

While the criterion of patentability of inventions exists for inventions made in all fields, the application of the patent laws to the biotechnological inventions must deal with some

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considerable oppositions due to its unique features that may not exist in other fields of technology. The issue with patentability of the biotechnological inventions must deal with various unique issues which are absent in the other areas of technological inventions.

The controversy surrounding these biotechnological patents is if the essential preconditions for patentability exist or if they merely classify as discoveries. Another problem is that some of these biological materials are capable of reproduction meaning that the biological material that is patented today can morph and mutate into something different, therefore the question is what the scope of what the patent would cover i.e., original state in which the invention was made or if the patent would include the future generations of the biological organisms which can possibly include the morphing and mutations.

1. HISTORY OF BIOTECHONOLOGICAL PATENTS

The earliest patents originating from the field of biotechnology is from Europe which claimed a patent for the yeast like material which is used in baking and making mashed potatoes. Further in the year 1873, a microbiologist, Louis Pasteur patented the process of fermentation of beer and acetic fermentation and improved yeast making[3].

The recombinant DNA technology (rDNA) where the genetic material such as DNA molecules from multiple sources or organisms formed by recombination has enhanced the comprehension of molecular and genetic expression of life forms. Following the first rDNA insertion into a host in 1973, scientists concluded that, there was a high potential for the cellular processes to develop new products and processes which can be used in many industrial sectors. The development of the rDNA technology first initiated the issue of patenting a biotechnological invention[4].

The US Supreme court in the case of *Diamond v Chakrabarty*[5], in the year 1980 decided upon this issue where Ananda Chakrabarty, a microbiologist in the General Electric research in New York, developed a genetically engineered bacterium which can split the components of crude oil, and this was a character which was not possessed by any naturally occurring bacteria and this bacterium could hold significant value for clearing any oil spillage. Chakrabarty filed a patent application for the process of producing the bacteria, the product claims of the bacteria. While the patent examiner allowed for the process but rejected the product claims on the ground

[3] The complications around patenting Biotechnology (https://www.labiotech.eu/in-depth/biotechnology-patents-intellectual-property/)
[4] First Recombinant DNA https://www.genome.gov/25520302/online-education-kit-1972-first-recombinant-dna
[5] 477 U.S. 303(1980)

that the living organisms cannot be patentable. On multiple appeals, the case on reaching the Supreme Court held that a live, human made microorganism can constitute a patentable subject matter as a composition. It also drew a distinction between human made bacterium and bacterium which occurred naturally. Since it has a human made genetically engineered microbe created with a unique function to dissolve the oil components[6], it could be subject to patent laws.

In Europe, a very similar case called the *Rote Taube*[7] decision, the patent application was denied on the grounds in the complexities in reproducing the invention but affirmed that the process of animal breeding based on selection and cross selection was a patentable subject matter. The decision in the German case of *BpatG (Bundespatentgericht)* in the case of *Antamanid*[8], there is a clear distinction between invention and discovery. Any substances which are naturally occurring can be patented if they have been isolated due to a technical intervention which is facilitated by the human beings, such that the nature is incapable of accomplishing it by itself.

However, it explicitly restricts the patenting of any human parts and the genetic modification and genetic identity of human beings used for processes of cloning human beings. In 1973, European Patent office leads the development of the European Patent Convention (EPC) based on the domestic laws of various nations within the EU. In the year 1998, an EU Directive[9] was proposed to extend legal protection to biotechnological inventions and distinguishes between what is patentable and what cannot be patented. However, this directive received some opposition where Netherlands proposed an amendment and Germany, France denied its implementation till 2004.

2. INTERNATIONAL LANDSCAPE OF BIOTECHONOLOGY PATENTING

According to Article 27 of TRIPS, patents would be extended to any inventions, products, and processes in various fields of technology provided that such an invention involves an inventive step, is novel and capable of industrial application or usage. In the United States, the novelty requirement is that the inventor should not patent something that is present within the public domain where it has not been patented priorly or the information for the same has not been published elsewhere. In the case of Europe, the invention has not been available or presented to

[6] Patenting Of Microorganisms and Cells (https://www.princeton.edu/~ota/disk1/1989/8924/892406.PDF)
[7] 2BGH, Beschluss vom 27.03.1969 – X ZB 15/67 (BPatG)
[8] BpatG, Beschluss vom 28.07.1977 – 16 W (pat) 64/75 "Naturstoffe."
[9] Directive 98/44/EC on 6th July 1998 on the legal protection of the Biotechnological inventions (accessible at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A31998L0044)

the public. In case of isolation of gene sequences when the function is unknown, even if there is a structural similarity between claimed gene and the existing gene sequence, the inventor can acquire the patent even if they can describe a new function emerging from such a sequence.

Article 3 of the EC Directive states that the invention shall be patentable if they pertain to a product consisting or sustaining biological material or the process by which such a biological material is produced, processed, or utilized. This essentially implies that any biological material which is removed from the natural environment or produced by undergoing any technical process can be patented even if it previously exists or occurs in the nature. The patent laws does not focus on protecting the living organisms but specific reliance is placed on the substance although naturally occurring in nature when is isolated to produce a specific element which is capable only through technical processes such as identification, purification, engineering and classification. The reproduction outside of the human body which is techniques those are only possible to be performed by human beings and techniques which cannot be achieved by the nature itself.

About patentable inventions and non-patentable inventions or discoveries excludes the human body which at various stages at the time of development or formation, an easy discovery of its elements that includes the sequencing or partial sequencing of gene. It further elaborates that any element which is isolated from the human body or by the any technical process can be patentable even if the structure of the element that is invented is like the natural element, this should be followed by an industrial application of the invented sequence or the partial sequence which should be revealed in the patent application.

ESTs (Expressed Sequence Tags and their patentability)

Article 5 of the EC directive raises concern about the patentability of ESTs. ESTs are smaller portions of the DNA nucleotides which compose the structural component of the DNA, contain, and provide information for carrying out the cellular functions. They act as genetic markers or tags which help in picking out the genes from the DNA. ESTs aid in searching and identification of hereditary diseases and cancer cells. This method helps in isolating genes in several diseases such as Alzheimer's and cancer research.

While many researchers argue that ESTs constitute a discovery and thus cannot be patented. However, others argue that the preparation involves technical processes which does not occur in the nature and thus may be an invention and thus capable of industrial application. The EC has

clarified that the ESTs should meet the utility requirement and without the specification of the function of the ESTs, they would not be patented[10].

The patentability of ESTs has significant economic, social implication which needs to be accurately decided by the law and hold them towards clearer standards for granting patents[11].

Ethical dilemma concerning Biotechnology Patenting

The ethical concerns revolve around the exclusion of the plant and animal varieties or any biological processes to produce any plants or animals. This includes the modification of the human germ line, using human embryos for any industrial or commercial purposes and the genetic modification of animals without any purpose that causes suffering and does not prove any greater medical incentive or benefits, will be restricted under the patent regime. In accordance with Article 53 of the EPC (European Patent Convention) any invention that is in contravention with the *ordre public*. This word has a characteristic meaning within Europe and as a result it means public order and security and is very expansive to include the accurate order or to retain the order within the whole of the society. The concerns surrounding morality within patent law is very uncanny as it revolves around economics, competition and production and business and the subjective and contextual element within morality provides it with a character which is very difficult to determine and can vary from the domestic laws of one country to another. However, the dilemma arises out of the consequences and the probable harms that can be incurred due to negligent or irresponsible and monopolistic behavior while undertaking any invention that can lead to widespread societal implications [12]if there is no barrier or restrictions or ethics in place for conducting and undertaking any research activities.

However, from the perspective of many scholars, the patent system is an improper instrument for determining the questions of public order, morality and questioning the ethical practices involved in the invention. The patent granted to an invention cannot possibly touch upon the consequences of how such an invention can be exploited. Therefore, in view of many scholars, they stated that the questions of ethics and morality should be dealt with by a different system and countries have their own Bioethics committee such as The French Bioethics Committee.

[10] Denver Law Review Volume 68, Issue 2 Symposium-Intellectual Property Law; Lorance L. Greenlee (1991) Biotechnology Patent Law: Perspective of the first Seven Years, Prospective on the next seventeen Years. (https://digitalcommons.du.edu/dlr/vol68/iss2/)

[11] Fisher of Genes: Patentability of Expressed Sequence Tags; Volume 29, Number 3, Article 3.

[12] Soini, S., Aymé, S., Matthijs, G. *et al*. Patenting and licensing in genetic testing: ethical, legal, and social issues. *Eur J Hum Genet* ;(2008). https://doi.org/10.1038/ejhg.2008.37

Hence the inventions which are patented upon commercial usage should nevertheless not cause any public order issues or pose determinantal to the public order of the society[13].

The requirement of ethics or morality rises not to hinder inventions and scientific advancement but rather promote them in an increasingly sustainable and responsible manner. Therefore, usually an impartial authority is necessary to discuss in detail any ethical issues surrounding inventions. For instance, Article 7 of the EC directive proposes the European Group on ethical aspects of biotechnology, and this is a group would evaluate any questions of patents on biotechnological inventions and the ethical principles surrounding it[14].

The issue however remains is that there is no standard framework for issuing or evaluating any ethical concerns. The legal standards are to be supplemented by an ethical standard. The ethical standards are subjective, relative and are not easily ascertainable which causes several problems in determining and raising questions on the grounds of morality or ethics as it is attributed to the lack of uniformity and rests on ambiguous principles of morality[15].

Patenting of Plant and Animal varieties

The positions of patenting plant vary from America to Europe. America does not restrict patenting biological material and is protected under the Plant variety Protection Act (PVPA) or as utility patents. The improvement of plant varieties is protected in various jurisdictions through the International Convention for the Protection of New Varieties of Plants, 1991 (UPOV) and countries that are members of the TRIPS agreement are obligated under Article 27.3(b) which provides for the protection of plant varieties either through the patent protection system or a system specifically created for the purpose of protecting plant varieties (sui generis systems) or a combination of both[16].

Before The Doha declaration, the review of Article 27.3 of TRIPS had been extensively discussed and there were several concerns that were raised, such as whether the TRIPS provisions extend to patent animals or plant. It also included ethical and moral issues and to the extent of which any life forms should be given patent protection. It raised questions about how

[13] See Tade Matthias Spranger, Ethical Aspects of Patenting Human Genotypes According to EC Biotechnology Directive, 31 INT'L REV. INDUS. PROP. COPYRIGHT L. 373, 376 (2000).

[14] https://www.wipo.int/wipo_magazine/en/2006/04/article_0003.html (Bioethics and Patent Law: The case law of Myriad)

[15] Minnesota Intellectual Property Review; Volume 3 Issue 2, 2002; Europe's Biotech Patent Landscape- Tade Matthias Spranger

[16] Michael Blakeney, Patenting of plant varieties and plant breeding methods, Journal of Experimental Botany, Volume 63, Issue 3, February 2012. (https://doi.org/10.1093/jxb/err368https://doi.org/10.1093/jxb/err368)

commercial utilization of Traditional knowledge by other countries except from where these countries originate. This led to the examination of the relationship between the Convention on Biological Diversity (CBD) and the TRIPS agreement and the Traditional Knowledge protection by other countries. There has been informal discussions with the WTO director general upon these subjects and different countries have submitted different proposals where India and other countries such as Brazil, Cuba, Colombia, Peru and Thailand backed by some of the African groups raised a suggestion to amend the TRIPS agreement that would make it obligatory for the patent applicants to disclose and inform the country of origin from any genetic resources and the traditional knowledge that has been used in such an invention . This also further includes the concept of obtaining the evidence through a prior informed consent adopted from the Biological Diversity convention which allows equitable benefit sharing[17].

Global South has voiced several problems with the patenting of the plant materials and varieties as a patenting of the same would raise some serious implications upon the accessibility, availability and may hinder the process of research and breeding as there is patent on a plant type, then the breeding and research upon it would be difficult. Further the patents on the processes to produce the plant are patented, and then by extension of Article 28.1(b) of the TRIPS agreement, the processes which directly lead to the product obtained there-from would receive protection. This is of particular importance because when plant related patents are granted, they not only cover the processes but the produce from the plants such as food.

Patent laws in some countries such as China, Vietnam have followed the European Patent Convention which state that plant varieties are not patentable instead of plants. This exclusion is narrower than the exclusion of "plants" as transgenic plants and their parts and components such as their seeds, cells and genetic material can be patented. Therefore, some countries contain patent laws that specifically exclude plant varieties and other countries have a wider ambit which excludes plants or plant varieties from being patented as in the case of Brazil[18].

In India, there are specific guidelines such as the guidelines for examination of Biotechnology Applications for Patent which provide that pure hybrid seeds and plants under specific processes provided will constitute a biological process and hence would not be applicable for a patent under section 3(j) of the Patents Act, 1970.

[17] TRIPS: Reviews, Article 27.3(B), and related issues https://www.wto.org/english/tratop_e/trips_e/art27_3b_background_e.htm

[18] Correa, CM, Correa, JI, De Jonge, B. The status of patenting plants in the Global South. *J World Intellect Prop*. 2020; https://doi.org/10.1111/jwip.12143

3. BIOTECHNOLOGY PATENTING- AN INDIAN PERSPECTIVE

India is one of the most favorable places for biotechnology and is one of the major players of biotechnology industry in Asia- Pacific. The rapid growth of biotechnology India is associated with the demand and rise in healthcare, pharmaceuticals, and government investment in the field of Research and development. Therefore, it is significant to assess the patent protection regime and biotechnology inventions within India.

The Patent system in India is driven by the Indian Patent Act, 1970 which awards any invention with a patent if they are not specifically excluded within section 3 of the Act and pass the test of novelty, inventive step, and industrial application. However, the factors for granting patents on biotechnological inventions are of specific importance as they can be specifically excluded within the ambit of patentable subject matter in India.

Earlier, the position was in accordance with Section 3(c), where any living things or non-living things which are naturally occurring cannot be patentable and thus any DNA, RNA and sequences which are isolated from living organisms are not patentable and therefore any natural occurring microorganisms are merely discoveries and are not covered within the ambit of an invention. Genetically modified microorganisms can be patented, and vaccines are patentable as it requires a significant amount of human intervention. Till 2002, patents were not granted for inventions of living matter of natural or artificial origin, biological matter and any substances that are derived from such properties. This position was substantially changed post 2002 by the decision made by Calcutta High Court in the case of *Dimminaco AG v Controller of Patents and Designs*[19] concluded that a new and useful process will constitute an invention even if the result contains a living organism which can be utilized as a commercially viable entity and the process leading to the production or manufacture of the same would qualify as an invention. The Controller of patents refused to grant patents in this case for the invention of a vaccine for countering *Bursitis* infection within poultry. The refusal of grant of patent was because it contained a living organism within the product. This subsequently led to the amendment within patent laws i.e., the Patent (Amendment) Act, 2002 due to which the biochemical, biotechnological, and microbiological processes were included within the patent protection regime.

In accordance with Section 3(b) which restricts inventions from being granted patents if they

[19] Dimminaco A.G. v Controller of Patents and Designs, (2002) I.P.L.R. 255(Cal)

contradict with the public morality. Such discoveries are regarded with a very high degree of caution as it creates a space for misuse and commercial exploitation of any plant or animal life in the process. Since the process of biotechnology deals with tailoring living matter and engineering them in a manner favorable for gaining monetary benefit. These includes the process of cloning human beings or animals, the genetic modification of animals which results in harm and suffering without any medical benefit and the process of preparing seeds or genetic materials which can have detrimental impact on the environment and the utilization of human embryonic cells for commercial purposes. These are all some examples where considerable apprehension is raised and are usually limited or restricted on the grounds of public morality and ethics and their adverse impact on the environment, people, and the biodiversity.

Further, according to the Section 3(c) which restricts plant and seed varieties from being patented which use conventional biological processes for the fertilization process and breeding cannot be patented. Therefore, genetically modified seeds or plants cannot be patented but the processes for genetic modification can be patentable. The *Monsanto Case*[20] went into the detailed discussion where the patent claim was based on a transgenic plant which was rejected by the IPO. The IPAB agreed with the party on the ground that the plant cell was a result of the process initiated by human intervention. Although, the genetically modified seeds or plants cannot be patented, the process which involves such a genetic modification can nevertheless be patented[21].

Further the method of treatment cannot be patented under Section 3(I) of the Act which includes any surgical methods, therapeutic methods, diagnostic methods[22]. There are additional formal and procedural requirements that must be satisfied for biotechnological patent applications. India joined the Budapest Treaty on the International recognition of the Deposit of Microorganisms in the year 2001 and section 10 of the Act, was amended where the patent applicant must deposit the biological material which is involved in the invention and should be mentioned in the patent application if it cannot be properly or accurately disclosed to the public and cannot be adequately mentioned in accordance with the provisions of the patent laws. The material will be deposited with the international depository under the Budapest Treaty and the

[20] Monsanto Technology LLC v Controller of Patents and Design (2407/ DELNP/2006)
[21] Guidelines for Examination of Biotechnology Applications for Patent, March 2013; Office of controller General of Patents, Designs & Trademarks (Available at https://ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_38_1_4-biotech-guidelines.pdf)
[22] Patenting in Biotechnology – The Indian Scenario (https://www.iam-media.com/patenting-biotechnology-indian-scenario)

collection of the depositories within India are present in Pune and Chandigarh[23].

As a detailed discussion on ESTs has been carried out, the Indian framework proposes the patent application to disclose the sequence listing of any genes, nucleotide sequences, peptide, and amino acid sequences according to Rule 9(1) of the Patents Rules 2003 and this sequence listing is filled out in an electronic form. This helps the patent examiner to search a wide range of patent applications based on sequences submitted by various patent applicants. ESTs are only allowed to be patented if in addition to other requirements are useful and can be industrially applied. An EST which merely acts as gene marker would not be considered as a patent application since they are incapable of providing any industrial application. Therefore, the patentability of ESTs depends upon the feasibility and substantial usage to diagnose and identify a specific disease.

CONCLUSION

Biotechnology patenting is an evolving field and is in interplay with various fields and industries which contribute to its growth and impact on the human lives, the environment. The contentious issue with biotechnology patenting is that the approach taken by the countries in granting ownership and rights over the patents which are outweighed against the environmental implications and the societal and ethical concerns it poses. Several developing countries have taken a stricter view to prevent such patents from being granted on the grounds of public morality and commercial exploitation of the Traditional knowledge. An abundance of precedents has clarified the position of patenting of living organisms subject to the patentability requirements. While countries are rapidly pacing to include a wide array of subject matters within biotechnological inventions, it is necessary to take a balanced approach in a way that it does not pose detrimental effect upon the society and environment and incentivize and increase opportunities research and development. The legal framework of biotechnology patenting differs from geographical region and blocs and account for such differences owing to practicalities of political and economic climate within this region. However, most counties follow a general trend or practice when it comes to patenting of living organisms by human intervention.

The future of biotechnology will inevitably change or realign the patent systems in the world. This will be dependent upon the research and investments made in the fields and might lead to a

[23] India: Biotechnology Patent and Moral Related issues (https://www.mondaq.com/india/patent/758110/biotechnology-patent-and-related-moral-issues)

more uniform and aligned patent regime domestically and internationally in place.

BIBLIOGRAPHY

ACTS, TREATIES & CONVENTIONS

1. Budapest Treaty, 1977
2. Convention on Biological Diversity, 1992
3. Patents Act, 1970
4. Patent Rules, 2003
5. EC Directive of 1998
6. European Patent Convention (EPO), 1973
7. Trade Related Intellectual Property Rights (TRIPS)
8. Plant Varieties and Protection of Farmers Rights Act, 2001
9. International Convention for the Protection of New Varieties of Plants, 1991 (UPOV)