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A Critical Analysis of The Biological Patent In India

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ABSTRACT

Bio-patenting is a rapidly growing field that encompasses a rapidly expanding field of genetic research and technology. Its advanced medical discoveries, diagnostic techniques, genetically modified crops and gene therapy are benefits of genetic research and technology. The rapidly growing field of legal support structures, such as bio patents, it also emerged and gained importance as well as some fame associated with it this year. The nature of genetic bio patents is often debated with mixed results. It has become a topic of interest to many people. This paper aims to delve deeper into the complex scope and provide a comprehensive analysis of the various impacts of bio patenting. On the one hand, patenting genetic material leads to economic investment and encourages innovation, but on the other hand it can limit research and raise many ethical concerns such as the ethics of commoditizing genetic material and commercializing it. We want to find balance protecting the rights of patent holders and respecting ethical boundaries promoting the well-being of the public. It can be said that bio patents are two-fold. The legal scope of bio patents in India is unclear and needs clarification and a clearly defined legal framework to qualify for patenting of genetic material. This article takes an in-depth look at the evolving timeline of the gene patenting landscape in India and aims to highlight the much-needed legal clarity in this particular area. This document highlights the legal, and Ethical aspects of bio patenting in India and address key issues It requires critical evaluation.

Keywords: *Patent, Technology, Genetic, Legal, Intellectual Property.*

1. INTRODUCTION

A biological patent can be understood as a branch of science Biology and technology combine to create innovations that are extremely beneficial to humanity. This article has explained to biological activities, components and processes at the developed technologies such as biological inventions. Innovations in this field have found a place in everyday life in the form of genetically modified crops, and disease diagnostic procedures and how to use drugs and medicines to treat diseases effectively and economically, and find smart solutions for materials such as biodegradable plastic, etc. The important and indispensable inventions in this field, it is not surprising that they are related to each other. Supporting legal structures are also growing rapidly, especially patents in the biological patent sector. Biological patents are of great importance because they provide legal protection to researchers and inventors and grant the right to exploit their inventions commercially. It requires investing more time and money in this area. It also contributes to promoting and facilitating healthy competition and cooperation between companies and companies in this field. Biotechnology patents can be of many different types, each related to a different topic in the field of biological patents. As biological patents such as gene patents, plant patents, pharmaceutical patents, utility patents, etc. Outside Among these patents, gene patents are the most controversial due to the many controversies surrounding this issue. Ethics and consequences of patenting specific sequences of DNA and RNA, genetic manipulation code, cloning, stem cells, etc.

Article 2 of the United Nation Convention on Biological Diversity (UNCBD) says: “Any technological application that uses biological systems, living organisms or derivatives thereof, to make or modify products or processes for specific use"[1] . It is crucial to remember that all DNA is composed of a base, which includes one nitrogen base, sugar, and phosphate. There are four nitrogen bases: adenine (A), thymine (T), guanine (G), and cytosine (C). These nitrogen bases are found in pairs, with A & T and G & C paired together. The nitrogen bases have a structure known as the “double helix” and may be assembled in an unlimited number of ways. It may be noted that the four nitrogen bases are the same for all organisms. Discovery of Recombinant DNA technology changed everything: Recombinant DNA (rDNA) involves taking one strand of the DNA and combining it with different strands of DNA to effectuate a desired trait.

[1]https://www.un.org/en/observances/biological-diversity-day/convention access on 28/09/2024

Indian biotech companies have done so-called special production processes "Biological" derived forms. First generation genetic microarray technology. An organism that has been granted a patent in the field of biology This technology has achieved great importance for transgenic plants and human genetic materials. The global adoption of the patent system began in the city of Venice when the first patent law was issued in 1494, which is considered the basis for the patent system worldwide. Requirements such as utility, novelty, and non-obviousness remain the foundation of modern patent law throughout the world. India is a species with great potential for biological use Leveraging technology to solve some problems and difficult to treat production, health and environmental problems. The possibility of obtaining a patent for genes and other nucleic acids sequencing is justified when they have been treated with microorganisms or in a non-biological way The process, i.e. gene sequencing, is itself a process. The standard process is patentable and a patent can be obtained under the applicable patent laws for this invention. Patent for the genome raises questions about function Genome. The genome can't do anything on its own. Patents are generally recognized as one Measuring innovation activity in different technological fields. Patents are involved in the field of biotechnology creativity; field of genetic modification, However, communicating raw patents is challenging Data with business technology. Various aspects of research, such as gene structures, genetic modification tools, and utility patents on GMOs, contribute to this field. One A clear understanding of basic reality[2].

Biotechnology Patent in India

A patent is an exclusive right granted by the government to the inventor for a limited period. It is issued by the patent office where you want to protect your valuable invention. It covers every field of technology such as the Pencil on the helicopter. The advent of biotechnology has led to patent laws being modified accordingly to meet the needs of science and technology. Industries using biotechnology believe that there is a need to protect intellectual property rights for biotechnology-related inventions. It arises from research and is commercial in nature value. Biotechnology researchers at academic institutions increasingly share this view because their need for research funding depends in part on patentability. But many people do not support patenting biotechnology because they believe that "patenting life" is unethical in principle. Biotechnology-related inventions also cause a lot of controversy in India. Establishing general laws or regulations for biotechnology patents is as complex a process as the industry in question.

Biotechnology is divided into many subfields. Subfields such as genomics and tissue culture Plants and animals have their own characteristics. Properties, applications, processes and Products vary in different areas of biotechnology as well[3].

2. ISSUES RELATED BIOLOGICAL PATENTING IN INDIA

Controversy over Patenting of Living Organism

Article 27(3)(b) of the TRIPS Agreement allows Member States to refuse to grant patents on "plants and animals, other than microorganisms, and biological processes essential for the production of plants or animals, excluding a biotic and microbiological processes." Therefore, the TRIPS Agreement obligates all signatories to renew patents relating to microorganisms, non-biological processes and microbiology[4]. Furthermore, animal and plant parts, as well as genetically modified plants and animals, are not explicitly included in the exception, so the TRIPS Agreement may also require patenting of biological organisms. Under the TRIPS Agreement, the Patents Act 1970, as amended in June 2002, grants patent rights to new microorganisms. Section 3(j) of the Act excludes from patentability "plants and animals, in whole or in part, other than microorganisms, but including seeds, varieties, species and learning processes essential for the production or propagation of plants and animals." A 2002 amendment to the Indian Patents Act added a statement on chemical processes that said: Chemical processes include biochemical, biotechnical and microbiological processes. Other areas containing microorganisms are also patented in India. For example, it is possible to patent a synergistic formulation containing a new or known microorganism and a method for using the microorganism to produce a substance. A patent can also be obtained for the biomedical creation process for a new accurate organism. The freeze-dried microorganisms are patentable end products[5]. The law does not specifically stipulate the scope of inventions that can be patented, but it specifically limits the topics that cannot be patented. But even before the amendment, the Calcutta High Court was concerned with the question of whether a process using microorganisms as the end product could be patented. At this point, it should be noted that the definition of the invention in question in the proceedings has changed after the decision in this case. The applicant has previously applied for a patent for a process for manufacturing a vaccine to protect poultry from infectious brucellosis. The patent examiner declared that the process was not an invention because the final product obtained from the process contained a living organism and hence could not be patented. The appellant appealed the decision of the Comptroller to the Calcutta High Court. The responsible person stated that a patent is only granted for the process of making a product, substance, or product, and that a vaccine that contains a living organism is not a product, substance, or product[6]. The court used the ordinary

[2] Kshitij Kumar Singh, Biotechnology and Intellectual Property Rights: Legal and Social Implications (2015 springer publication)

[3] Department of Biotechnology. Available at http://www.dbtindia.nic.in/ access on 02/10/2024

[4] Article 27 (3) (b) of the TRIPS Agreement

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

[6] Bioethics and Patent Law: *The Case of the Onco mouse*, WIPO Magazine (2006) https://abg-ip.com/living-beings-patented/ access on 08/10/2024

dictionary meaning of manufacture, as it is not defined in patent law, stating that "after having undergone production through the inventive process, the material in question has undergone a change and has become a material" different from the source material. "The court ruled that this meaning does not prevent the granting of a patent for the production of a product containing living matter[7].

The court held that there is no law that excludes finished products from the definition of manufacturing. Furthermore, the court ruled that "since the process of filing a patent application creates a salvable product, it is inevitably an article after it has undergone a manufacturing process." Ultimately, the court concluded that "a new and useful art or process is an invention" and because the process is new and useful, "it is clearly patentable under Section 5, Section 2(j)(i)" of the Patent Act. The court ruled that "when the finished product is new, the process by which it is produced is an invention." Although the definition of an invention has changed, this change may actually improve the court's argument regarding invention, because the factors of production, the material, or the substance are no longer necessary. Rather, the new definition simply requires a new, less obvious and useful product or process. As stated above, the court determined that the vaccine was novel and useful and did not discuss the final product containing live material to reach this conclusion[8]. However, other changes in the law could change the outcome of the case. For example, after this case, Art 3 (j) was added to the Patent Law and now excludes basic biological processes for the production or propagation of plants and animals from the definition of patentability. In this case, the court warned that a patent application must be "examined by the controlling authority in accordance with the principles of Art 3" of the Patent Law.

Issues related to Patenting alteration of human genes

Genetic material that can be reproduced by artificial means, such as isolation and gene cloning, is considered an artefact, or a man-made invention, and can therefore be patented if the material, its function, or the method of producing it. The invention, if new, has a specific function that has been disclosed It is not clear to current knowledge and can be used in industry. At John Moore, a patent was claimed for the first time on "human cell lines." In the case mentioned above, John Moore suffered from leukaemia due to "hairy cell leukaemia"[9]. During treatment, the doctor discovered that his cell lines were useful in preparing a certain drug and applied for a patent. Moore argued that this was his cell phone line and therefore he must be the property owner. Hence, we conclude that granting rights to a part of the human body is a violation of human dignity and moral principles. He has sued doctors, pharmaceutical companies and university hospitals, among others, for infringement of his copyrights. This argument has been withdrawn. The court decided that Moore's argument was inadmissible because there could be no property rights to the human body. However, the California Supreme Court upheld complaints alleging breach of fiduciary duty and lack of informed consent[10].

Human genetic research has opened the door to "human genome" research, "human cell research," and "stem cell" research. These areas involve serious ethical concerns. Human genome research, which uses the extraction of genetic material from an individual, involves many complex ethical issues. Prohibiting engineering-related research or prohibiting the development of full human beings. The ban and exclusion of stem cells has been strongly criticized[11].

In the United States, ethical controversy escalated when Stuart Newman patented a non-human being. He genetically transformed a human into an animal. He is neither a human nor an animal. The Patent Office first considered ethical principles, and after granting the patent concluded that if the patent were granted it would be an affront to the moral standards of society. The court held that genetically modified people could not be patented under the principles laid down in the Thirteenth Amendment to the United States Constitution, so a patent was not granted. This clearly states that humans are not allowed to patent inventions for ethical reasons. The judiciary also clarified that patenting human beings and cloning are prohibited under the US Constitution and patent laws. Cloning refers to a scientific process in which biological materials including "DNA", "cells" or "organisms" are copied because the thirteenth amendment limits human slavery, prohibitions on human cloning and human patenting are similarly taken into account[12].

Issues Related to the Tragedy of "*Anticommons*"

Analysis of the *"Tragedy of the Anti-Communists"* Competition for freely available shared resources has always been part of the evolution and survival of all entities, including living organisms. When resources are limited, competition will be fiercer and the strongest will gain maximum benefits[13]. However, continued exploitation for personal gain will deplete

[7] D.E.Komb, "Patent and Trade Secret Protection in University-Industry Research in Biotechnology" 24

HJL 210.

[8] Diamond v. Chakrabarty, 447 U.S. 303 (1980),

[9] Pioneer Hibbred International v. Holden Foundation Seeds Inc., 35F, 3d. 1226.3, USPQ, 2d. 1385 (8th Cir. 1994)

[10] Moore v. Regents of the University of California, (51 Cal. 3d 120; 271 Cal. Rptr. 146; 793 P.2d 479)

[11] SD Gangane, 'Human Genetics' (Third Edition), Elsevier (2008).

[12] https://blog.petrieflom.law.harvard.edu/2022/08/04/another-legislative-attempt-to-revive-gene-patenting/ access on 25/10/2024

[13] Michael A. Heller and Rebecca S. Eisenberg, "Can Patents Deter Innovation? The Anti- commons in

resources, harm the entire society, and give rise to what people call the *"tragedy of the commons."* Theories such as *"sustainable development"* and *"common heritage of humanity"* emerged in response to identifying this problem and proposed limited exploitation and equitable distribution of resources. Overuse must be addressed by restricting access[14]. This anti-universalist theory of tragedy is diametrically opposed. When a scarce resource has many attributes, no one is privileged to use it, and each person has the right to exclude others from using it, the most likely outcome is underutilization of the resource, other events that are highly undesirable.

Strengthening this increasingly popular set of rights to access patented products is a difficult task for those working downstream. This phenomenon is often called the *'patent dust'* problem. As Shapiro puts it, a patent jungle is "the dense web of overlapping intellectual property rights that a company must wade through to truly commercialize new technology". He also highlighted the problems associated with excessive patent growth, saying that patent rights can stifle innovation rather than encourage it, with more innovations accumulating and increasing patents hindering the return of innovation[15].

Issues Related to Disclosure, Best Mode and Utility Requirements

Given the usefulness and possibility of publication, exclusive rights should be permitted only if the patent application shows a sufficient level of actual and practical exploitation of Biotechnology innovation. The important point to make sure here is that the claims do not go beyond what is protected by the innovation disclosed in the patent claim, more specifically when it is early and the basic stage of development or a new gene with potential applications is still under investigation[16]. This condition is contained in Art 112 of the United States Patent Act and Sec 10 of the Indian Patents Act. The "best method claim," which has been the subject of widespread debate in the United States recently and has no place in the European Patent Convention, means that "the best method of carrying out the invention is known to the inventor at the time of filing the patent"[17]. The patent application must be disclosed in the patent application for all aspects of the invention. "Disclosure" is often considered an important prerequisite and is clearly a "best practice." The "request" is to harm, when what is essentially required is better disclosure[18].

The Creator contemplated it in practice, it is difficult to define "best-case requirements". The non-compliance must be proven by clear and unambiguous evidence. The best 'order system' has been heavily criticized for its implementation. The reporting obligation is very heavy about the innovator. The Q3 Special Products Inc. court concluded, "Two factual investigations are required to determine compliance with best practices: first, self-investigation is a method of verifying whether a better method of realizing the invention at the time of filing the patent application is already known to the inventor, and second, the objective is to determine whether such a product can be considered the best and such method can be practiced by those of ordinary skill in the art. However, in the case of Evans Medical Inc. 5th American Cinnamed "Opponents say the plaintiff knows a better way and that it is the best way.[19]" No antibodies are detected for the patented process. However, this request was rejected for reasons there could have been better methods, as the plaintiff chose this specific antibody for the purification process. Regarding the objectivity of the best practice disclosure, the plaintiffs asserted that their disclosure was enough for a person skilled in the art to perform the patented process. The court stated that "the descriptions are very vague and suspicious with not enough evidence to prove their existence at all violating the best system." Moreover, benefit requirements have always been interpreted restrictively by US courts as can be seen in Brenner v. Manson[20] where the Supreme Court rejected the patent because even though the supposed steroidal compound had a potential tumour A-suppressive effect in mice, there was no mention of any use for it in humans.

Issues Related to First Inventor to File System

In the sector of biotechnology, laboratory notebooks, which assume a noteworthy job in establishing the prior conception, seems to lose its noteworthiness under the "Leahy-Smith America Invents Act, 2011", wherein first to invent system has been replaced by first inventor to file system. Since this field is a plethora of uncertainties, first inventor to file system may prompt inventors to seek patent protection as early as possible, even at premature stage[21].

Legal Protection of Biotechnological Inventions

Given the ethical and technical issues involved in biotechnology in general and crop biotechnology in particular, granting

Biomedical Research" 280 Science 698 (1998).

[14] Ibid.

[15] http://www.genomicglossaries.com/content/intellectual_property.asp access on 03/11/2024

[16] http://www.wipo.int/patents/en/topics/biotechnology.html access on 04/11/2024

[17] Amgen Inc. v. Chugai Pharmaceutical Co., 927 F2d 1200 (Fed. Cir. 1991) at p. 329.

[18] Railroad Dynamics Inc. v. A. Stucki Co., 469 US 871 (1984).

[19] Aniruddha Sen, "Clear and Complete Disclosure in Biotechnology Patent Applications- A Comparison of the Laws in the USA, Europe and India" Hanse LR 95 (2006).

[20] 383 US 519, 86 S. Ct. 1033 (1965).

[21] Ibid.

legal protection remains a very sensitive and complex issue. The Indian biotechnology industry is currently facing particular difficulties due to the increasing 'commercial aspects of intellectual property rights (TRIPS)' in India since January 1, 2005. According to Article 27 of 3(b) of the TRIPS Agreement, "Although biological processes for the production of plants or animals are not considered patentable subject matter, microorganisms, non-biological processes and microorganisms used in plant and animal production have been eliminated[22]." They are retained within the scope of patentable subject matter. As gene transfer research increases in both the public and private sectors, issues relating to royalty payments, delivery of material in transfer agreements (MTAs), as well as legal restrictions and obligations need to be clearly resolved[23].

TRIPS Agreement: Uncertainty and Patentability Issues

Article 27(1) of the TRIPS Agreement provides that, subject to certain provisions, patents for inventions in any field of technology shall be granted without prejudice. There is no definition of the term "invention" attached to this article and is left to the interpretation of each country. Moreover, Art. Article 27(2) of the Convention allows member countries to exclude innovations from patenting in order to realize them "public order or morals". However, the essence of this regulation has not yet been proposed. Art. 27.3(b) of Tools related to innovation in biotechnology, in particular, exclude plants and animals Patentability, with the exception of mandatory intellectual property protection for bacteria and related processes. But the agreement remained silent Defines the phrase "microorganisms" or "microbiological processes" and imposes no restrictions break down the scope of these words. If includes multi cellular organisms, fungi and viruses' definition of microorganisms? Should cell lines be excluded from patent eligibility? Furthermore, does merely isolating or purifying microorganisms make them patentable or merely manipulating them? Can microorganisms produced/modified by biotechnology be granted patent protection? very huge There remains uncertainty about the level of patent protection granted for biotechnology inventions. Furthermore, Article 27.3(b) of the Convention provides that States may exclude the possibility of patenting "substantially". The biological process that produces plants or animals"; but no parameters are provided to determine it The field of basic biological processes[24].

Marginal Farmers under "The Protection of Plant Varieties and Farmers Right Act, 2000"

To protect new plant varieties, the TRIPS agreement offers Member States three options: use of the patent, use of the private system, or agreement of both[25]. India has opted for a 'unique' protection system under "The Protection of Plant Varieties and Farmers Right Act, 2000**"** (PPVFR Act), under which "farmers can save, use, plant, grow, exchanging or sharing seeds of protected varieties, in addition to protecting farmers' varieties, varieties of primary origin and existing varieties[26]. Although research in plant biotechnology could receive a boost from the public and private sectors through plant variety protection, there is still no support. There is a strong possibility that seed prices will rise, which will eventually drive new technologies out of the market accessibility for small and marginal farmers. Due to royalty payments, contract restrictions and raises marketing seeds will be more expensive for small farmers; So it can be said that patents will result on the one hand, there is a barrier between seeds and genetic resources and, on the other hand, access to them by farmers and breeders[27].

Indian Patent Law and Perspective on Grant of Patents

The Patents Act, 1970 provides the law relating to granting patents for inventions in India. It entered into force in 1856 and has been amended several times. An important adjustment occurred in 1970 when the law was amended to meet international standards patentability covered the scope of novelty, inventive step and industrial application[28]. However, even after this review, biotechnology inventions are still not specifically mentioned. Protection has been implemented. The need for inclusion of biotechnology innovations in India has emerged Only after his application was seen in large numbers in patent offices and courts in the United States and the European Union. Then, by amendment in 2002, regulations relating to biochemistry and microbiology and Biotechnology processes have been included in the definition of patentable process[29].

As Geoffrey Carr: "Biotechnology has the potential to transform humanity, as long as it is humanity." Biotechnology inventions are essential for human development. This is the broad field of biology Includes living structures and organisms to create or manufacture things or any mechanical application that uses natural structures, life forms or their affiliates to create or modify products or processes for specific use[30].

[22] https://www.wto.org/english/tratop_e/trips_e/art27_3b_background_e.htm access on 05/11/2024

[23] http://fbae.org/2009/FBAE/website/our-position-ipr.html access on 08/11/2024

[24] https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm access on 13/11/2024

[25]https://www.insightsonindia.com/2019/04/25/protection-of-plant-varieties-and-farmers-rights-ppvfr-act-2001/ access on 20/11/2024

[26]https://vikaspedia.in/agriculture/policies-and-schemes/crops-related/protection-of-plant-varieties-and-rights-of-farmers/protection-of-plant-varieties-and-farmers-rights-act-2001 access on 22/11/2024

[27] http://www.ielrc.org/content/a0304.pdf access on 25/11/2024

[28] Musyuni, P. (n.d.). Patenting Of Biotechnological Products Issues Perspective To US, Europe and India. IJPSR.

[29] Marippan v. Safiullah, 2008 (38) PTC 341 (Mad)(DB).

[30] Biotechnology Patent and Related Moral Issues - Intellectual Property - India.

3. INDIAN PERSPECTIVE ON GRANT OF BIOLOGICAL PATENTS

Section 2(1) (j) of the Indian Patents Act prescribes the meaning of the term "invention". According to that section, the invention must be non-obvious, new or innovative and industrially applicable. The invention must be new, that is, it must be new and different from the prior technology, and here it refers to the prior technology[31].The fact that the invention has not been published in any public domain before obtaining a patent. In this case, two characteristics are emphasized essential to the validity of the patent, it is new and useful. The test is really new; it is essential because otherwise no benefit would be provided to the public and therefore no compensation would be transferred from the patent owner. If the invention is obvious, it invalidates the issue of inventive steps. Invention is not possible Obvious to those who have in-depth knowledge of the field to which the invention relates. Smart people are expected to search for ideas in adjacent fields, whether equivalent or otherwise similar problems appear in such areas, and the exchange of innovations of the game will occur. A field adjacent to your specific area of interest, if this exchange involves routine testing. The invention must be a discovery of the inventor, not a mere verification for something that existed and was known to everyone before the date of submitting the application Patent license[32].

The product must be new, better or cheaper than the existing product. The element of invention must be present in the manufactured product and must be patentable. Furthermore, the innovation must be repetitive. The question of whether substances such as microorganisms or other biological materials available in nature can be considered new must be determined by considering the basic criteria mentioned above. Determining whether or not an invention involves an inventive step is very complex. It is a mandatory requirement of patent law to provide complete information about the work that needs protection. Disclosure is defined as "full disclosure[33]." In the field of biotechnology, the requirement to declare complete information becomes difficult because Inventions in this field include living organisms. It is difficult to describe such documents in words. It is important to note that in most cases, the challenge of "full disclosure" must be met. Certainly, the practice has now evolved such that the innovator submits a sample of the organism under development to an authorized body[34].

An important landmark explained in the context of Section 3(j) of the Indian Patents Act, 1970 this is the case with Monsanto technology. In this case, the appellant applied for a patent to create a way to create genetically modified plants that can withstand bad weather. The Intellectual Property Office rejected the patent application under Section 3(j) of the Patent Law, It states that the invention relates to a biological process and is excluded from that process is protected under this Section and Section 3(d) because the invention is lost in the creative move. This was done even after the appellant claimed to be his own production. There is human intervention in the form of insertion of ribonucleic acid (rDNA) into plant cells and genetic modification the nature of the cell is such that it can withstand the climate. When this was appealed, the Intellectual Property Appellate Division upheld that there was no inventive step defence under sec 3(d). However, they disagreed with the IPO on the applicability of Section 3(j). The IPAB has made it clear that a method that aims to humanely intervene in plant cells and cause some type of change will not fall within the scope of section 3(j)[35].

4. SUGGESTIONS

Biotechnology inventions require in-depth examination and thorough investigation Better understanding of the meaning of biotechnology patents. Harmony the conflicting assessments of different countries will be the driving force and key to progress in the biotechnology sector in the field of patenting. Global patent system they should be combined so that the sovereignty of property is both modern and universal at the same time Joint biotechnology research efforts continue. In order to keep up with affordable and abundant supplies of biotechnology-based medicines and other medical products, countries should adopt several strategies to ensure that the new patent system does not hinder their return to their public freedom regarding their health. Furthermore, there is a need to ensure that their systems for securing intellectual property rights do not conflict with public welfare strategies and are reliable in securing public rights. Countries should take a series of steps to ensure that the new patent system works effectively and does not impede their human right to health in maintaining a fair and adequate supply of biotech medicines and other health care products. They should ensure that their IP and security systems do not conflict with their public health policies and respect the protection of human rights. In the area of utility claims, the granting of patents requires stringent requirements It applies high standards and only owns inventions that have a clear, reliable and meaningful meaning Existing facilities should be permitted. Such a strategy would block some patents that might do so They hinder research and also allow scientific progress to enter the public domain.

[31] 'Brief History of Patenting in India' Guidelines for examination of Biotechnological Patents by Office of Controller General of Patents and Designs of India (March 2013)

[32] Lallubhai v. Chimanlal, (1935) 37 BOMLR 665

[33] Section 10 of Indian Patents Act, 1970.

[34] https://www.mondaq.com/india/patent/758110/biotechnology-patent-and-related-moral-issues access on 02/12/2023

[35] Section 3(j) of the Indian Patents Act, 1970.

5. CONCLUSION

Biotechnology is the modern science of life. Biotechnology works on molecular elements (DNA/GENE) level. Using modern biotechnology tools and techniques, it is possible to reconstruct the genetic makeup of living organisms. Modern biotechnology is the most useful technology in human health care, agriculture and environment Protection etc Insulin, human growth hormone, and GMOs such as Bt cotton are some examples of modern technology. Recent and rapid progress in biotechnology poses complex challenges and problems in front of patent offices in developing countries. Patent offices in developing countries have no experience with biotechnology inventions, and patent laws in pre-colonial developing countries are a major cause of challenges and problems. In developing countries, the international legal framework explicitly linked to the patent regime

Together with the ongoing advancements in biotechnology, they need to be reinterpreted. By providing substantial benefits to food, medicine, health, and the environment, biotechnology may truly benefit the general people in a variety of ways. The approach should be practical and efficient in the biotechnology setting. The most effective method of patent protection is still a patent. The patent system provides the highest level of protection by allowing innovators to concentrate on commercial applications as well. The common law worldwide relating to the patent system specifically needs to be reclassified. Biotechnology is suitable to serve all populations in a variety of ways that bring great benefits. For health, food, medicine and climate. Technologies must be reasonable and feasible about biotechnology. Patents are still the most feasible solution for protecting inventions. The patent system, by providing maximum protection to inventors, allows them to concentrate Aimed at industrial applications. Due to the involvement of various stakeholders, a rational approach is followed Intellectual property has been controversial. Therefore, the application is necessary and the Harmonized System balances a human rights approach and aims to encourage growth of scientific methods. In general, this will automatically benefit both the individual and the group. It also approaches the source feature on both levels.