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Contemporary Issues of Patenting of Biotechnology in India: Think Beyond Boundaries

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ABSTRACT: The Intellectual Property Rights (IPR) have become more popular nowadays. It leads to the growth of patents in every country. Patents are given to new inventions with innovation and applicability. Patents play crucial role in the biotechnological field by providing protection and exclusive rights over discoveries related to living systems. Biotech inventions include genetic sequences, micro-organisms, pharmaceuticals, and bioengineering processes. After the development of biotechnology, many issues and problems emerged in patenting biotechnological inventions. This paper aims to understand the nature of biotechnology patenting through an examination of literature, judicial precedents and the socio-economic and Legal effects of the process. This research paper will also discuss the development of biotechnology with its relation to the patent legal system, and emerging challenges in biotechnology patenting.

KEYWORDS: Biological Diversity, Biotechnology, Invention, Industrial application & Patent.

I. INTRODUCTION

Biotechnology which applies the principles of biology, chemistry and engineering in the development of products has affected many sectors ranging from health, food production, conservation and environmental studies. Biotechnology is quite unique since it has developed a new way of innovation including Genetically Modified Organisms (GMOS), biopharmaceuticals and enhanced diagnosing equipment by using biological systems and organisms. These developments have defined the world's health and economic status, progress and solutions to issues such as disease, famine, water shortage and weather changes[3].The major spur to advancement in biotechnology is the patent regime, which grants the patentee the legal monopoly in the patented invention for a certain period. Patents protect ideas and innovation, and thus motivate the expenditures on technologies with long developmental cycles and high costs of R&D. Without such protection, the expensive costs and enormous risks involved in biotech innovations may discourage innovation and thus slow down development[4].Yet biotechnological inventions have become a subject of enormous concern to the public domain as has been echoed by the international community due to the numerous ethical, economic and legal issues surrounding the patenting of inventions. Legal issues emerge on the questions of ownership of genetic material, a notion that many critics suggest that genes are invulnerable structural units of living organisms and should not be patented. While discussing economic aspects, one can recall that too many patents turn into a monopoly that allows only limited access to essential technologies in low-income countries. This is so because legally, the problems associated with patents arise due to disparities in legal provisions in different jurisdictions, which causes confusion for firms that engage in international business[5].

Historical Development of Patenting of Biotechnology

Biotechnology is one of the oldest disciplines known to people, as well as the respective science, that might be a part of history and traditions. Some of the earliest types of biotechnology include fermentation which was used by ancient civilization in preparation of bread, beer and wine as well as selective breeding where individuals selected

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animals and plants with preferred qualities. [6]From such simple and crude practices, early forms of biotechnological development began gradually to emerge as harbingers of great change to agriculture, food processing, and medicine. For example, yeast to make bread, grape juice turned into wine, crop cultivation and domestication of animals all this to begin to utilize biological processes in the interest of human need. Thus, the theoretical platform of modern biotechnology has roots in the science of biology that formed in the 19th and early twentieth century. For the work in the mid-1800s Gregor Mendel developed the principles of inheritance and such concepts as dominance and recursiveness. This work became the foundation of classical genetics that later combined itself with the rising science of molecular biology. The search for cells as the structure of life in combination with the improvement in the use of microscopes contributed to the flow of knowledge of life. Years later in the middle of the twentieth century, Oswald Avery and associates elicited that DNA was the molecule of heredity. This laid the groundwork for James Watson and Francis Crick to give the structure to DNA double helix in 1953 a discovery which provided the foundation of the entire prospect of molecular genetics[7]. The grand international project called Human Genome Project was introduced to identify and to define every human gene. Concluded in 2003, it was attempted to outlined roughly 20,000 genes and became the great reference source for genetic diseases. It has spurred the advancement of what is known as 'precision medicine'; whereby, treatment depends on one's genetic make-up. Apart from health, the project brought out relatedness of all beings showing human relations to form of life, useful in evolutionary science, drug development, and wildlife protection[8].

Biotechnology Inventions and Agreement on Trade Related Aspects of Intellectual Property Rights

The TRIPs agreement was established in 1955 by the WTO and it is known as Trade Related Aspect of Intellectual Property Rights (TRIPs) . This deals with the basic obligation for all WTO members States to introduce certain level of protection to intellectual property, including biotechnology inventions. Its talks about patenting of biotech inventions and commercialization of those inventions. The Article 27 of the TRIPS Agreement is related to patentability on biotechnology. It mandates that patents must be made available for inventions in all fields of technology, when they meet the fundamental criteria of patentability: art, creativity, non-obviousness and industrial use[9] . This directive applies non-discriminatorily to biotechnological inventions which cover genetically modified organisms (GMO), isolated genetic sequences, recombinant processes, bioengineered proteins and diagnostic methods. The extension coverage of the TRIPS agreement towards the recurrent sector embraces the initiation of the reception of biotechnology as a highly effective generalized method in sectors including agriculture, health, and common environmental resolution. This innovation in industries is beneficial since it encourages companies to commit capital to R&D since the results can be protected through certificates and patents[10].Relation with public order and morality: TRIPS has a broad coverage; it offers crucial cross- sensitivity options to address the ethical and societal issues of biotechnology. According to article 27.2, each member state has the right to refuse some inventions patents if the industrial application of an invention would be contrary to public order or moral or if it opposes the public interest or human, animal or plant life or health. For example; Human Cloning and Embryo Modification: Human cloning and to manipulation of embryos for stem cells has meant that most countries do not allow the cloning technology for patenting. Biopiracy Concerns: The agreement also enables countries to continue providing further protection where unauthorized use of genetic resources or other traditional knowledge was a problem. These provisions make it possible for countries to keeps a check on biotechnological advancement that may otherwise present an ethical or culturally and socially sensitive issue. Policies for Conservation of Bio-Richness and Indigenous Know- How: One of the most difficult issues in biotechnology patenting is how to address questions of biological and cultural diversity and indigenous knowledge especially in the Third World[11].While promoting intellectual property, TRIPs enjoins member states to use measures to prevent biopiracy whereby commercial entities or researchers use the genetic resource and or traditional knowledge from communities without remunerating the rightful owners. For instance: The products derived

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from genes collected from biodiverse countries like Brazil or India which have been patented while the source or any benefits from such source have not been acknowledged[12].

Many different medicinal recipes used in different cultures, for instance neem from India or turmeric have been taken by foreign entities for proprietary rights. Many nations have made responses through the establishment of national legislation uphold the principles the ABS (Access and Benefit Sharing) according to the Convention on Biological Diversity. Such measures include making applicants to explain the source of genetic materials and implement the provisions on the sharing of the accruing benefits. TRIPS and Access to Life-saving Products: One of the most important impacts of TRIPS are related to biotechnology derived drugs and vaccines and public health. Most of them are official products like monoclonal antibodies (insulin), and European vaccines for different infectious illnesses. [13]Those products get Patents which are responsible for encouraging inventions, by granting rights for a given number of years, to the inventor; however, they may result in these products being very expensive, which may not be affordable in poor areas of the world. It is also pertinent to note about UPOV Convention. The entity previously known as the International Union for the Protection of New Varieties of Plants (UPOV), which was established in 1961, has had its convention amended in 1972, 1978, and most recently in 1991, to provide full protection for plant breeders' rights. UPOV is composed of conventions ratified by member nations to strictly safeguard the rights of plant breeders, hence promoting product development and commercialization. These rights allow breeders to prevent others from reproducing, selling, or propagating their new plant varieties for a period of 20 to 25 years. The UPOV Convention mainly aims at protecting the creation of new agricultural plant varieties and promoting food security and sustainable development[14].The objective of the UPOV Convention is to provide a framework that encourages innovative development of new plants, satisfying the breeders with the potential economic rewards of their work. Due to grant of exclusive rights, UPOV helps in the development of plant varieties possessing such desirable characteristics as higher productivity, resistance to diseases and insects, potentiality to withstand unfavorable conditions and higher nutritional value. Such innovations are crucial for responding to some of the world's problems such as population increment, climatic change and food scarcity. UPOV system is related only to plant breeders' rights and is based on a sui generis system which is different from patent law[15]. While patents require strict criteria such as novelty, inventive step, and industrial applicability, UPOV grants protection based on the principles. New plant variety should contain;1.Distinctness: For the new variety to be recognized in the marketplace, it must be different from all the existing varieties or brands.;2.Uniformity: It means the characteristics of the plants of the variety must have to be same through different generations of the plant.;3.Stability: This variety must remain to be unique, whether in propagated concurrently. This specialised system addresses the issues of plant breeding program where the outcome of the multiple generations is a basic requirement to arrive at the correct modification[16].

Patentability of Biotechnology Inventions

Biotechnology challenges the patentability due to its interdisciplinary nature. Compared to mechanical or chemical inventions, which often take quite straightforward applications of technology. Biotechnology requires manipulating living organisms, genetic material, and biological processes. So, these three patentability criteria: novelty, inventive step, and industrial applicability, are applied differently across jurisdictions[17]. The United States was the first country to evolve into biotechnology patenting, with its case of Diamond v. Chakrabarty[18] in 1980, which was a landmark case that paved the way for patentability on genetically altered organisms. The USPTO [19] considers biotechnological inventions eligible for patent protection if they fulfill the statutory criteria presented under Title 35 of the United States Code. These inventions included isolated genes, recombinant DNA, genetically modified

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microorganisms, and proteins bioengineered. Human genes, however, emerged as the talking point in Association for Molecular Pathology v. Myriad Genetics (2013)[20], where the Supreme Court ruled that naturally occurring DNA sequences are not patentable but laboratory-created complementary DNA is patentable. This ruling thus balanced the interests of innovation with the ethical issue over the commercialization of a natural product: genetic material. Processes that involve human cloning or genetic alterations raising ethical or moral issues are excluded from the realm of patentability. The guidelines for the USPTO show a clear emphasis on the utility requirement. Biotechnological inventions, for instance, should have specific, substantial, and credible applications in industries[21].

The European Patent Convention (EPC) and the Biotech Directive (Directive 98/44/EC) regulate biotechnology patents in the EU. These frameworks provide a comprehensive approach to the patentability of biological materials and processes with patents on genetically modified organisms, DNA sequences, and biopharmaceuticals[22]. However, these cause stricter ethical constraints that imposed by the U.S. The Biotech Directive identifies certain areas of inventions that are prohibited from receiving patents, such as the processes of human cloning, human genetic identity changes, and use of human embryos for industrial or commercial purposes. Patents cannot conflict with the "public order" and morality provisions defined in the EPO, failing to meet the criteria set out by the community's standard. One such example is *Brustle v. Greenpeace* of 2011, which had the Court of Justice of the European Union declaring that inventions concerning human embryonic stem cells derived from the destruction of embryos are not patentable. In fact, this reflects the EU's cautious approach towards the ethical dimensions of biotechnology. India's approach is governed by the Patents Act, 1970, as amended in 2005. The act takes a restricted view of patentability over living organisms; however, patents can be awarded over microorganisms and biotechnological processes, but it bars those higher life forms such as plants and animals[23].Section 3 of the Patents Act categorises several exclusions that apply to biotechnology. Section 3(j), which contains provisions against patents on plants, animals, and essentially biological processes for their production[24]; Section 3(b) excludes inventions which are contrary to public order or morality, such as cloning humans or mutations that can threaten biodiversity[25].Of course, despite these limitations, India has been patenting innovations in the fields of genetic engineering, recombinant DNA technology, and bio-similars. The Indian Patent Office applies novelty, inventive step, and industrial applicability considerations toward an application, keeping in its mind ethical and environmental implications[26].India's risk-averse approach manifests its dual commitments to innovation and conservation. Being a party to the Convention on Biological Diversity, it has enforced the Biological Diversity Act, 2002, by which access to genetic resources is regulated and the malice of biopiracy is hindered.

Patenting of Biotechnology in India

Biotech patents in India are granted through several stages: application, publication, examination, opposition, and grant. Descriptions of inventions must be given in extensive detail, including specifications, claims, and supporting data for applicants. In the case of biotechnology patents, some additional requirements, such as the deposit of biological material in a recognized depository, may apply. The patenting process ensures that the invented product qualifies under statutory criteria for patentability and meets ethical and environmental regulations. The patent awarded is maintained for 20 years when renewal fees are paid annually on time. If renewal fees are not paid in time, then the patent lapses. India also has provisions for pre-grant opposition and post-grant opposition so that third parties can challenge the validity of the patents. This makes the patent system more transparent and fairer, preventing the monopolisation of basic biotechnologies[27].While the Indian patent system has grown up with the complexities of biotechnology, it has quite a few challenges to face in the form of limited experience in examination of biotechnological inventions, lengthy

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timelines of examination, and much stronger mechanisms of enforcement. All these will be critical to fostering a robust ecosystem for biotechnology innovation in India. In the case of Dimminaco A.G. v. Controller of patents and Designs[28],the scope of patentability has been expanded by the High court for process involving living organisms(virus).

Patenting of GMOs, Cloning, and Stem Cells in India and International Context Genetically Modified Organisms (GMOs): Patents on GMOs pose special concerns - environmental concerns, ethical, and societal pressure. In India, the country grants patents on genetically modified microorganisms but not on transgenic plants and animals. This prohibition is in line with India's focus on biodiversity preservation and small-scale farmers' welfare. Internationally, jurisdictions such as the U.S. and EU also adhere to this more liberal approach, awarding patents on GMOs provided certain conditions are met. The U.S. awards patents for genetically engineered crops like Bt cotton and Roundup Ready soybeans, provided such crops meet criteria for patentability[29].EU however applies stringent environmental and ethical tests before granting patents on GMOs. Cloning: Human cloning falls outside the purview of patentability on grounds of commodifying human life. India bars cloning technologies from patenting through Section 3(b) of the Patents Act, expressing societal denial towards such practices[30]. Animal cloning is comparatively less controversial, but most jurisdictions examine this area through ethical and regulatory lenses[31]. Stem Cells: A significant area of research is stem cell technologies that have vast regenerative and therapeutic applications. In India, patents on stem cell technology are granted with novel processes or new compositions whereas use of human embryonic stem cells is strictly prohibited because of ethical considerations. Internationally, patentability varies in stem cell technologies. The U.S. allows patents on stem cell lines derived without destroying embryos, while the EU imposes stricter limitations. These differences highlight the ethical and regulatory complexities of stem cell research[32].

Legal Issues of Life Patenting

The patenting of life forms invokes deep ethical and legal debates. Critics argue that the grant of patents on living organisms commodifies life and, therefore, undermines life's intrinsic value. Biopiracy, whereby genetic resources and traditional knowledge are exploited without compensation, is a major challenge, especially in developing countries. Patents on genetic materials and biotechnologies also raise access and affordability concerns as monopoly interests limit the potential benefit to the public. Balancing rights of innovators and the needs of society requires thought on these issues. International agreements including TRIPS and CBD underscore one basic requirement: there should be equitable sharing of benefits and biodiversity protection. These set up the very beginnings of a framework for legal and ethical aspects of life patenting.

Challenges in Patenting Biotechnology Inventions

Biotechnology patenting faces numerous obstacles such as, the main subject matter of biotech patents is mostly existing in nature which creates difficulty in the determination of novelty: The TRIPs and other conventions do not explain the term microorganisms and microbial processes. So, this paved the way for discussion among the countries and the inventors; Life form patenting like human genes, modified DNAs and cloning creates challenges relating to monopoly and owning of lives under a person. It may also affect the public interests; Invention can only get patent, not the discoveries. This is the major issue in the biotechnology patents which involves naturally present cells and proteins; Ethical Opposition: Moral concerns about GMOs, cloning, and stem cell technologies complicate patent approval processes[33];High Costs: Filing, maintaining, and enforcing patents is expensive, deterring small enterprises; Global Disparities: Differences in patent laws across countries create uncertainties for innovators seeking international protection[34]; Complexity of Inventions: Determining ownership and inventorship for interdisciplinary biotechnological

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innovations is challenging. Addressing these challenges requires collaboration among policymakers, researchers, and industry stakeholders to create a balanced and inclusive patent system.

II. CONCLUSION AND SUGGESTIONS

The patenting of biotechnology plays a critical role between innovation and living organisms which has legal challenges. The patenting of biotechnology must balance the drive for innovation with ethics and social needs. Even though biotech has great impact in the fields like agriculture, environment and medicines, legal frameworks related to patenting such inventions should be equally managed with public interest[35]. International frameworks, such as TRIPS and UPOV, offer valuable guidelines, but regional adaptations are necessary because of concerns specific to local societal needs. The international agreement and conventions should also be rectified and proper solutions should be made by the enactment of laws relating to high life patenting and ownership on life forms. Adaptive, inclusive, and ethical approaches by the global community will ensure that benefits from biotechnology continue to flow to humanity while respecting life and biodiversity. Policies should be formed both international and national bodies to control the misuse of biotech patents for monopolisation.

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