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Research Article

Investigation of the Non-Obviousness in Biotechnology Inventions with Landscape of Patenting

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ABSTRACT: Biotechnology is set to revolutionize various aspects of human life, including drug discovery, delivery, diagnostic methods, clinical trials, and overall societal health, particularly with the mapping of the human genome. The patent system plays a crucial role in protecting biotechnological inventions, which span biological, microbiological, genetic, medical, and agricultural domains. These innovations are not limited to genetic engineering but extend to compounds derived from microorganisms, plants, insects, and animals. In developing countries like India, biotechnology has gained increasing importance for economic growth and societal development. However, the evolution of this field has been marked by challenges and a lengthy struggle for recognition. The path has been shaped by both setbacks and successes. Importantly, biotechnology has introduced new biological materials and substances that were previously unavailable, leading to debates on their patentability. Consequently, biotechnological patenting was introduced in India to safeguard the intellectual property rights of inventors, ensuring that their contributions are protected. The concept of patent protection for biotechnological inventions recognizes the application of human creativity to biological processes, granting these innovations rightful patent protection. This development reflects the growing need to balance innovation with legal frameworks that support the interests of inventors and the broader society.

KEYWORDS: Genetic, Non-Obviousness, Genome, Inventions, Microorganisms, Novelty.

INTRODUCTION

The importance of intellectual property (IP) for the economy is growing, especially with new technologies like biotechnology. The issue, however, lies not in the basic understanding of IP but in how it is applied to specific situations, particularly with new technologies that often challenge traditional IP models [1]. Biotechnology, as a rapidly advancing field, presents unique challenges when it comes to intellectual property rights. The three main approaches to protecting new technologies, including biotechnology, can be broadly categorized as (a) no protection at all, (b) protection that balances incentives with access, and (c) protection through a tailored, sui generis system. Biotechnology, which involves the manipulation of living organisms and biological systems to create new products and processes, raises complex questions regarding its protection under intellectual property laws [2]. These products, which are not naturally occurring, can be considered inventions if they meet the patentability criteria of novelty, utility, and inventive steps. However, the application of IP laws to biotechnology

inventions, such as genetically modified organisms, biological processes, and other life-related products, is not always straightforward. Different jurisdictions approach the protection of biotechnological inventions in distinct ways, creating an evolving and dynamic legal landscape.

One of the critical considerations for biotechnology patents is the balance between incentivizing innovation and ensuring public access. Patents give inventors exclusive rights to their creations for a set time, which helps encourage investment in research and development (R&D). On the other hand, these patents can also limit access to new technologies, especially when it comes to life-saving products or processes [3]. This tension often leads to debates about the ethical implications of patenting life forms or biotechnological processes. For example, while some argue that patenting biotechnology is essential for promoting innovation, others express concerns about the potential monopolization of life-related products and the exploitation of natural resources.

In the past, the patent system generally focused on protecting tangible inventions, such as mechanical devices, machines, or chemicals. The introduction of biotechnology, however, challenged this traditional approach. The question arose as to whether living organisms, including genetically modified plants, animals, and microorganisms, could be patented as inventions [4]. Early legal battles led to the development of new rules for patenting life forms. Initially, patent law in many countries, including the United States and Europe, was hesitant to grant patents on living organisms or biological processes. However, as biotechnology became more prominent, the scope of patent protection gradually expanded, especially as biotechnological inventions began to show significant commercial potential [5]. In considering biotechnology from the perspective of intellectual property rights, courts, and legislatures have grappled with issues like whether naturally occurring organisms could be patented, whether biotechnological products or processes are sufficiently novel, and whether their commercialization would unduly limit public access to critical life-related innovations [6]. In countries like the United States, patent law has evolved to include biological inventions, with a key focus on ensuring that such inventions satisfy the traditional patent criteria of novelty, utility, and inventive step [7]. Nevertheless, the courts have also introduced some judicial exceptions, such as prohibitions on patenting certain life forms or biological materials that are considered products of nature.

While patent law offers a robust framework for protecting biotechnological inventions, it is not the only system available. Another approach that has been considered for protecting biotechnology is the development of a sui generis system, which is a tailored legal framework designed to address the specific needs of biotechnology without relying solely on patent law [8][9]. In some jurisdictions, especially in the early stages of biotechnology development, this approach has been favored to address the unique challenges posed by life-related products and processes. For instance, the sui generis system allows for the protection of genetic resources, traditional knowledge, and innovations that do not fit easily into the conventional patent system [10]. Biotechnology patents have changed a lot over time, mainly because of global trade and international agreements like the TRIPS agreement. TRIPS, managed by the World Trade Organization (WTO), established basic rules for intellectual property (IP) laws in countries around the world. This includes specific guidelines on how biotechnology inventions can be patented, ensuring that countries follow similar standards for protecting innovations in the field. Article 27 of the TRIPs agreement requires WTO member countries to provide patents for inventions in all areas of technology, including biotechnology [11][12]. This global

standard has had a profound effect on how countries regulate biotechnological inventions and has led to a worldwide push to align patent laws with international expectations.

The evolution of biotechnology patenting has been shaped by both global trends and domestic legal developments. The Indian Patent Act, enacted in 1970, initially did not accommodate biotechnological inventions, as the field had not yet developed in India. However, as biotechnology began to grow globally, especially in industrialized countries, India recognized the need to update its patent laws. In response to the growing demand for biotechnological patents, India amended its Patent Act in 1999 and again in 2002 to include biotechnology-related inventions, including genetic engineering, microorganisms, and other life-related products [13]. The amendments allowed for the patenting of not only biotechnological products but also the processes used to create them [14]. India's participation in the TRIPs agreement played a key role in aligning its patent laws with international standards. By ratifying TRIPs, India agreed to grant patents for biotechnological inventions, including life forms and living processes [15]. The amendments to the Indian Patent Act also facilitated the protection of biotechnological inventions related to genetically modified organisms (GMOs), microorganisms, and biopharmaceuticals. These changes have had a profound impact on the Indian biotech industry, enabling companies to develop new products and processes while benefiting from the commercial incentives offered by patents [16].

However, despite the progress made in India, the debate over biotechnology patenting remains contentious. There are concerns about the ethical implications of patenting life forms and the potential for biotechnological patents to lead to monopolies over essential products [17]. Critics argue that patenting biotechnological innovations could result in the exploitation of natural resources and traditional knowledge, especially in developing countries. Moreover, there are concerns that the patenting of genetically modified organisms and other life-related products could have unforeseen environmental and social consequences.

LITERATURE REVIEW

Lawson *et al*. [18] discussed that the patenting of genetic materials raises several unresolved issues, particularly around balancing patent protection with competition. One major challenge in biotechnology patents is figuring out what counts as a truly new and valuable invention, which involves deciding what makes something original and non-obvious. Another problem is deciding which genetic materials should not be allowed for patenting and ensuring that these resources are accessible for further research and innovation. To solve these issues, solutions may include raising the standards for patents, using international IP laws to guide practices, and considering compulsory licensing, which allows others to use patented materials under certain conditions, to reduce the negative effects of current patenting practices on genetic resources. In countries like India, the evolution of biotechnology patenting has been influenced by international agreements like TRIPs and the need to align domestic laws with global standards. However, the ethical and social implications of biotechnology patenting remain important considerations, and there is a need for continued dialogue and research to ensure that intellectual property laws are effectively applied to this rapidly advancing field. As biotechnology continues to shape industries such as agriculture, healthcare, and environmental conservation, intellectual property law will play a crucial role in determining how these innovations are protected and commercialized on a global scale.

Murthy *et al*. [19] examined that genomics, a branch of biotechnology focused on gene mapping has become increasingly important in the field of patents. As patent filings related to genomics grow rapidly, there are growing concerns about their real-world usefulness and their overall benefit to society. While many genomic patents meet the invention and non-obviousness criteria, they often fail to meet the utility criterion, meaning they do not have practical applications. For example, patent applications for Expressed Sequence Tags (ESTs) have sometimes been found to have no real utility. In response, patent regulators have created various tests, such as specificity, substantiality, and credibility tests, to address these issues. Notably, both the U.S. and Europe have made efforts to standardize utility tests for genomic inventions, particularly for ESTs, cloning, and chimeras, through specific regulations.

Thomas *et al*. [20] discussed that intellectual property protection is essential for the biotechnology industry, as it helps protect the inventions and developments in this field. Their study examines the challenges of patenting recombinant proteins by looking at recent legal cases involving tissue-plasminogen activator (t-PA), a therapeutic protein drug. t-PA and its variations were developed around the same time in different labs, as many researchers work on similar medical goals. The study focuses on whether these inventions are obvious and how broad the patents should be, especially when it comes to second-generation drugs or modifications made with advanced genetic techniques. The results show that patents with wide claims have been upheld, which has limited the creation of new drug versions that could be helpful. This emphasizes the need for clear public policies that balance rewarding inventors and allowing broader use of natural biological resources through more specific patents.

Sternitzke *et al*. [21] stated that obtaining patent protection for an invention can be an expensive and uncertain process. Many patent applications, particularly in chemicals, pharmaceuticals, and biotechnology, are often not approved by the European Patent Office (EPO), even though they are submitted as global patent applications. This means that even if a patent is filed internationally, it may not meet the requirements set by the EPO for approval, making it harder for inventors in these fields to secure patents in Europe. Their study examines why these applications are rejected by reviewing the examination reports, focusing on references that question the novelty or inventiveness of the invention. The findings suggest that in many cases, an invention's novelty is already covered by existing patents, and non-patent sources often question whether the invention is truly innovative. When searching for patents in the same field, the most relevant prior art is usually found. It was also noted that inventors, especially from large companies, often know about prior patents that could invalidate their invention but still file the application as a calculated risk. In contrast, small and medium-sized businesses (SMEs) often have a harder time assessing the novelty and creativity of their inventions, making it more difficult for them to navigate the patent process.

DISCUSSION

The Non-Obviousness in Patent Law and Requirement for Innovation

Non-obviousness, or "inventive step" as known in Europe, is one of the critical requirements for granting a patent, alongside novelty, utility, and enablement. The non-obviousness ensures that the invention is sufficiently inventive and not just an obvious improvement of existing knowledge or technology. This principle asks whether the invention exceeds the existing state of the art and involves a significant creative leap. Unlike novelty, which focuses on prior art, non-obviousness requires a subjective judgment, determining whether the invention represents

an advancement that would not have been obvious to someone skilled in the relevant field at the time of the invention. Historically, the U.S. did not include a statutory non-obviousness requirement until the Patent Act of 1952, although it had been a topic of court discussions for years, most notably in the 1851 case Hotchkiss v. Greenwood. In the mid-20th century, the U.S. Supreme Court introduced a "flash of creative genius" standard to address non-obviousness, emphasizing that patents should only be granted to inventions that significantly contribute to the progress of useful arts. This requirement ensures that patents incentivize true innovation rather than trivial or incremental changes.

Patent Licensing and Technology Transfer in Biotechnology for Innovation and Collaboration

Patent licensing and technology transfer are fundamental components of the biotechnology sector, acting as key enablers for transforming scientific research into commercial products. These mechanisms facilitate the movement of intellectual property (IP) from academic institutions, startups, and established companies to commercial entities, thus accelerating the development of therapies and technologies [22]. In biotech, where the complexity of inventions often requires significant investment, patent licensing serves as a vital tool to leverage research efforts as shown in Figure 1. Licensing agreements allow research institutions and startups to monetize their discoveries, ensuring that the substantial resources invested in R&D are recouped and further innovations are supported.

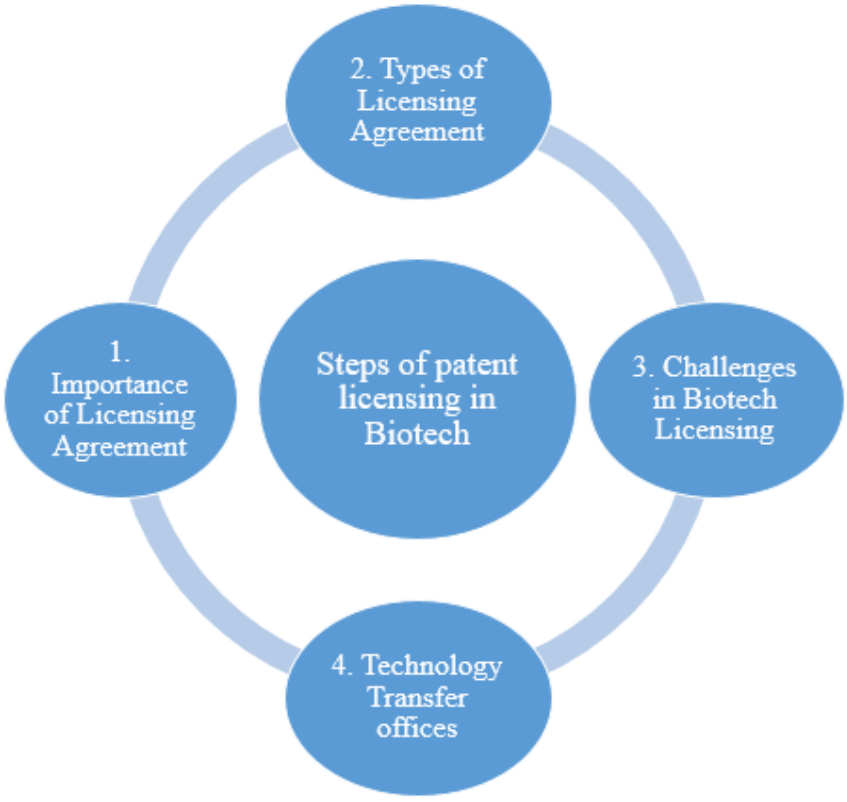

Figure 1: Illustrates the different types of patent licensing in biotech.

Licensing plays a critical role in fostering collaboration within the industry. Through exclusive, non-exclusive, and field-of-use licenses, various stakeholders can gain access to novel technologies and incorporate them into their pipelines. Exclusive licenses provide sole rights to a licensee, offering predictability, while non-exclusive licenses allow broader dissemination of technology, facilitating faster adoption across the sector. Field-of-use licenses restrict usage

to specific applications, ensuring targeted innovation. These diverse licensing models help to balance the interests of inventors, investors, and companies, promoting the commercialization of breakthrough discoveries. However, challenges abound in biotech licensing, especially in negotiating fair royalty structures and addressing the complexities of highly specialized technologies. Defining the scope of licensed technologies, navigating legal and regulatory hurdles, and balancing the protection of IP with the need for broader innovation remain ongoing issues. Technology Transfer Offices (TTOs) play a pivotal role in managing these processes, providing expertise in IP management, negotiations, and compliance. Through strategic licensing agreements and effective technology transfer, biotech companies and research institutions can accelerate the path from discovery to market, ultimately improving healthcare and advancing scientific progress.

The Controversy Surrounding the Patenting of Human Genes

The issue of patenting human genes has sparked significant ethical, legal, and scientific debates. The European Biotechnology Directive outlines that while the human body and its components cannot be patented, isolated elements, such as gene sequences, may be eligible for patent protection if they are produced through technical processes. However, this directive excludes inventions that could be deemed immoral or harmful, such as processes for cloning humans or altering germ-line genetics [23]. Despite this, the directive has not resolved the controversy surrounding gene patenting, as many countries have yet to implement it. Myriad's patents included not only the genes themselves but also their diagnostic and therapeutic uses. The extensive scope of these patents raised concerns about their potential impact on medical research and patient care. Critics argue that granting patents on human genes could limit scientific progress by restricting access to crucial genetic information. In response to the BRCA1 patent, the Institute Curie in France launched opposition proceedings, challenging the patent on both technical and public policy grounds. These proceedings sparked renewed public discussion and prompted the European Parliament to urge Member States to ensure that the human genetic code remains freely available for global research. The case highlights the tension between protecting intellectual property and ensuring access to genetic knowledge for the advancement of science and medicine. As the debate continues, it underscores the need for a careful balance between patent law and the broader public interest in promoting health and innovation.

The Challenges of Patenting Bioinformatics and Divergence Between the US and Europe

Bioinformatics represents a fascinating convergence of two of the most rapidly evolving fields: biotechnology and computer software. As bioinformatics plays a crucial role in advancing areas like genomics, drug development, and personalized medicine, its intersection with patent law presents unique challenges. One of the most significant divides in the patenting of bioinformatics innovations is between the United States and Europe. In the US, patent laws are relatively broad, allowing inventions in biotechnology and computer software to be patented as long as they meet the general requirements for patents. This inclusive approach has led to the granting of patents in the bioinformatics field, encouraging innovation and commercialization.

In contrast, Europe maintains a more restrictive stance on patentability, particularly concerning computer programs. The European Patent Office (EPO) has taken the view that computer programs, 'as such,' are not patentable. However, there is a critical distinction: if a computer program contributes to a technical solution, it may still be patentable. This has led to varying

interpretations across European countries, and the specific application of bioinformatics software to biological problems has become a point of contention. Notably, the German Supreme Court has ruled that when software is applied to biological issues, it may be considered a technical invention, potentially qualifying for a patent. The European Union is working on a draft directive to harmonize patent laws concerning software, but its progress has been slow, with the proposal remaining controversial. This ongoing divergence between the US and Europe on bioinformatics patenting raises important questions about the future of innovation in this field. The outcome will likely shape how bioinformatics technologies are developed, protected, and commercialized across global markets.

Future Trends in Biotech Patenting for Navigating Innovation, Ethics, and Global Challenges

The future of biotech patenting is poised to evolve alongside cutting-edge technologies and innovations, shaping the way new therapies and treatments are developed, protected, and commercialized. A key trend is the rise of personalized medicine and gene therapies, where advancements in genomics and targeted therapies are creating new patent opportunities as shown in Figure 2. Startups focused on gene therapies must navigate complex licensing and cross-licensing arrangements to access foundational patents, which have revolutionized gene editing. For instance, a startup developing a personalized cancer vaccine may seek patents on the vaccine's composition, delivery system, and diagnostic methods to protect its innovations. Artificial Intelligence (AI) and machine learning are also transforming biotech, particularly in drug discovery and patient monitoring. As AI algorithms become integral in the healthcare sector, patent office's face challenges in granting patents for AI-generated inventions. Ethical considerations, such as addressing biases in AI-driven diagnostics and determining the patentability of AI algorithms that predict drug reactions, will be pivotal for future biotech patent strategies. A startup creating an AI-powered platform for predicting adverse drug reactions, for example, would need to secure patents for its algorithm and integration with healthcare systems.

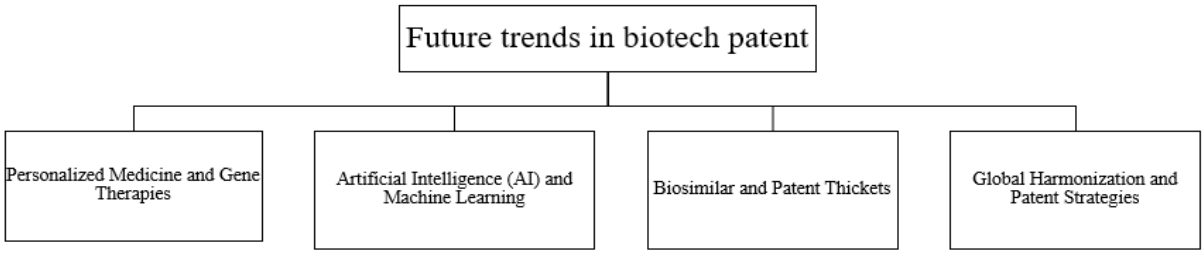

Figure 2: Exploring the emerging trends shaping the future of biotech patenting, from personalized medicine to AI-driven innovations.

The rise of biosimilars, or generic versions of biological drugs, introduces another complex trend. Navigating patent thickets overlapping patents covering different aspects of biologics poses significant challenges for startups. Strategic licensing agreements and challenging overly broad patents are essential to clear the path for biosimilar development. Blockchain technology is also gaining traction in biotech for data security, offering solutions for secure patient data sharing, clinical trials, and supply chain management. Patenting blockchain innovations will focus on data encryption, smart contracts, and decentralized networks. Finally, global patent harmonization remains a challenge for biotech startups that operate across jurisdictions. Crafting a patent strategy that aligns with regional differences, such as through the Patent Cooperation Treaty (PCT), is critical to succeed in international markets. The future of biotech

patenting will rely on a balanced approach to innovation, collaboration, and legal protection to ensure that groundbreaking therapies reach those in need.

CONCLUSION

The rapid innovations in fields like biotechnology have become inevitable, driven largely by advancements in bioinformatics. The integration of IT tools into biotechnology has spurred groundbreaking developments, reshaping industries ranging from healthcare to agriculture. Patents, as a form of intellectual property protection, have become a crucial mechanism for safeguarding these innovations, ensuring that inventors are rewarded for their work and creativity. However, the patenting process, particularly in biotechnology, is fraught with complexities. One major issue lies in defining what constitutes an "obvious" innovation, and the unpredictable nature of biological research further complicates the criteria for patentability. While patents are necessary to protect novel inventions, they must be carefully regulated to avoid stifling further research or creating monopolies on fundamental discoveries. If patents are granted too easily, they could prevent competition and hinder the open exchange of ideas, which are vital to fostering future advancements. As countries globally compete for dominance in technological innovation, intellectual property has become a critical tool for asserting leadership in the global market. Companies and research institutions increasingly recognize the importance of patents not only for protecting their innovations but also as a measure of their competitiveness. Thus, while patents serve to incentivize innovation, there is a need for a balanced approach ensuring that patent laws are designed to promote, rather than restrict, further scientific exploration and competition. The challenge moving forward will be to establish clear and consistent guidelines for patenting in biotechnology, fostering an environment where innovation can thrive without stifling progress.

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