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The Holy Trinity of Patents, Biotechnology and Sustainability. Review of Biotech Patents in the Scope of US Patent Case Law

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Patent law plays a crucial role in all three pillars of sustainable development. Economically, patents serve as a highly valuable competitive tool, socially, they promote advancements that benefit public health and nutrition, and environmentally, patents facilitate the development and dissemination of environment-friendly technologies. In recent decades, biotechnology has emerged as one of the most significant patent-intensive industries. This paper examines the evolution of the patentability of biotechnological inventions from the early 1970s to the present day, with a primary focus on the case law of the United States, a predominant actor in this field. The main contributions of this paper are twofold. First, it explores the framework of patentability for biotechnological inventions, particularly focusing on different genomes. Second, the paper considers the potential future of biotechnology, particularly in light of ongoing litigation over CRISPR-Cas9 gene-editing technology. The findings suggest that recent US case law, particularly regarding CRISPR-Cas9, will shape patentability criteria and market access. Over-protection of biotechnology may hinder the fulfillment of sustainable development goals, while the lack of exclusive rights would hold back innovation, which is also harmful to these goals.

1. Introduction and aim of the paper

Initially, reconciling the science of biology with the patent system proved a challenging task, as it was widely accepted that patentable technologies were confined to inventions related to inanimate objects capable of being exploited and controlled through physics and synthetic chemistry. However, numerous technological processes applying living organisms to execute chemical reactions have demonstrated undisputed industrial applicability and technical character (Szarka, 1992). The legal protection of biotechnological inventions has gained rising prominence since the 1970s and 1980s. Consequently, the economic, ethical, and legal issues related to biotechnology and biodiversity have also grown in significance. Biotechnology has emerged (Farkas, 2003, Sümeghi, 2000) as one of the fastest-growing industries of our era, alongside information technology.
While patent law has evolved to accommodate biotechnological innovations, especially with advancements such as CRISPR-Cas9, significant gaps remain in how these technologies align with sustainability goals. This paper aims to address these gaps by analyzing the interplay between patentability criteria and sustainable development, focusing on key case law and its implications for future innovations. The main contribution of the study is that it provides a review of the most relevant state-of-the-art literature in this field until the latest court decisions shaping the patentability of biotechnology, while the author adds his own perspective to the discussion. The relevance of the unique approach of the paper is that it makes a strong connection between sustainability goals and patenting, which offers an additional interpretation level to the generally profit-driven patentability debate.

2. Methods

The paper falls within the domain of law and does not delve deeply into biotechnological issues through the lens of any STEM disciplines. Instead, it relies on basic and widely accepted notions of biology without challenging them to provide context for readers unfamiliar with biotechnology. The primary methods of investigation are

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governed by jurisprudence. Throughout the paper, a legal dogmatic approach and text-based qualitative analysis are applied. The legal research methodology includes focuses on statutory provisions and judicial decisions pertinent to biotechnology patents. Legal hermeneutics is utilized to interpret legislative texts and case law, ensuring a thorough understanding of the legal principles and doctrines involved. The research incorporates doctrinal analysis to assess scholarly opinions and theoretical perspectives on the patentability of biotechnological inventions. By integrating these methodologies, the study provides an analysis of the legal framework governing biotechnology patents.

3. The growing importance of biotechnology and its relationship with sustainability

The advent of modern biotechnology can be traced back to the 1970s, specifically to a decisive moment in 1972 when eight articles on genetic engineering were published within one month in the official journal of the US National Academy of Sciences. Seminal articles like (Petzné, 1992) described experiments that enabled the cleaving and recombination of DNA (deoxyribonucleic acid). In the same year, another Nobel Prize laureate, Paul Berg, marked a new era in genetics by successfully linking two genes through biochemical means. This groundbreaking research laid the foundation for the industrial utilization of biology, heralding the birth of biotechnology. Since then, biotechnology has become a huge industry globally. Figure 1 depicts the number of employees in R&D in biotechnology in the last decade. The data make it clear that the USA has an enormous advantage in this field compared to the EU.

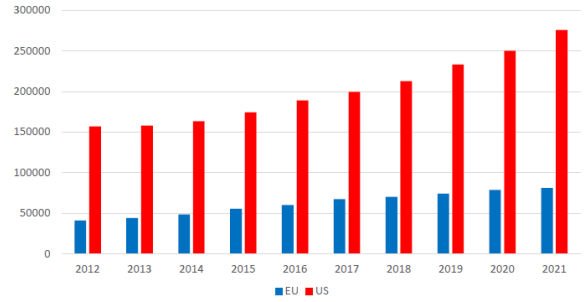

Figure 1: Number of employees in research and development in biotechnology, summarised by (Grassano et al., 2024)

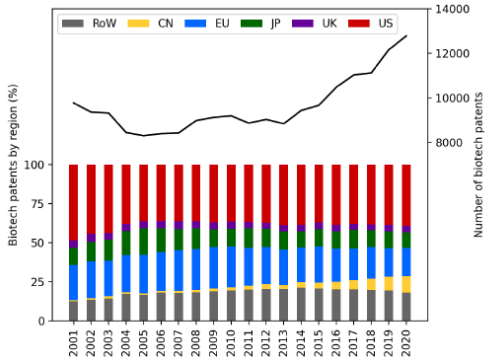

Figure 2: The trends of biotechnology patents, summarised from (Grassano et al., 2024)

The advantage in human resources in favor of the USA is transferred into the volume of biotechnology patents. Figure 2 outlines the trends of biotechnology patents worldwide between 2001 and 2020. Since 2013, the level of these patents has considerably climbed. The overall leading share of the USA stays constant, but there is a continuous slight progression by China, whose increase is mainly suffered by the EU with the slow decline of its share. One of the most important biotechnology advancements is the CRISPR-Cas9 gene editing technology (Martin-Laffon et al., 2020), which raised a global patenting race, where the USA focuses on healthcare while China leads in agricultural and industrial applications.

Defining the scope of biotechnology is complex, particularly due to the divergence between legal and biological concepts. Biotechnology serves as an umbrella term for the industrial application of methodologies and tools

developed through biological research (Turcsányi, 2006). Broadly, the primary objective of biotechnology is to utilize living cells and their components to create products or develop processes.

Biotechnology encompasses a wide array of techniques and technologies that induce structural changes in organic living matter, including animal and plant cells, cell lines, enzymes, plasmids, and viruses. This includes (Tattay, 1999) DNA recombination, gene transfer, embryo manipulation, embryo transfer, plant regeneration, cell culture, monoclonal antibodies, and the technical knowledge of biological processes. While biotechnology is primarily significant in the health and pharmaceutical industries, its importance is also rapidly growing in manufacturing technology and agriculture, as the patent statistics demonstrate in China.

Hughes (2001) carried out her often-cited analysis of the biotechnology industry. The study highlighted the shift in biotechnology from pure scientific research to a commercially driven model. In this way – through the patenting of genes and genetic processes – large biotech firms could control the economic benefits of biotechnological discoveries, which were usually publicly funded research.

Sustainability is a multifaceted phenomenon aiming to balance economic, environmental, and social needs. It provides a guiding principle for individuals, communities, businesses, and governments (Hulkó et al. 2023). For the above reasons, biotechnology has a strong relationship with more sustainable development goals. The following table summarizes how biotechnology could support sustainable development.

Table 1: Examples of how biotechnology may contribute to SDGs. Compiled by the author

SDGs	Examples of the role of biotechnology
No. 2. End hunger, achieve food security and improved nutrition, and promote sustainable agriculture	Crops created by biotechnology may be more resistant to pests and climate changes
No. 3. Ensure healthy lives and promote well-being for all at all ages	A vast number of medicines are developed and produced by biotechnological means
No. 6. Ensure availability and sustainable management of water and sanitation for all	Biotechnology allows microbial and enzymatic solutions for water and waste treatment
No. 14. Conserve and sustainably use the oceans, seas, and marine resources for sustainable development	Marine biotechnology can be used to develop microbial-based bioremediation strategies for cleaning up oil spills and other hazardous substances in marine environments
No. 15. Protect, restore, and promote sustainable use of terrestrial ecosystems, sustainably manage forests, combat desertification, and halt and reverse land degradation and halt biodiversity loss	Higher yields on cultivated land could reduce the need for cropland expansion, preserving biodiversity. The use of pesticides can be reduced significantly.

4. The beginning of patentability of biotechnological inventions and the requirement of disclosure in the US case law

4.1 The advent of biotechnological inventions and their patentability

As mentioned earlier, humans have been harnessing biology in agriculture and pharmacology for thousands of years. The earliest biotechnology inventions were patented in the 18th century. For example, the GB 178701625 patent in the United Kingdom was granted in 1787 for a yeast-like composition to be used for baking prepared from mashed potatoes. In 1873, Loius Pasteur patented the improved yeast-making method in France. However, the modern era of biotechnology has started with DNA recombination.

Until the mid-1970s, biotechnology patenting was predominantly confined to the fermentation industry. However, by the late 1970s, patents expanded (Petzné, 1992) into the antibiotics and steroid transformation sectors, and by the 1980s, advances in immunology and molecular biology broadened the scope of biotechnology.

The Cohen-Boyer cloning technique and its application in a foreign DNA bacterial host were described in US Patent No. 4,237,224, granted on December 2, 1980. In the same year, the US Supreme Court decision in the Chakrabarty case [U.S. Supreme Court, Diamond V. Chakrabarty, 447 U.S. 303 (1980)] established that a living, man-made microorganism could be patentable. The microorganism in question was a crude oil-degrading Pseudomonas sp. created through synthetic plasmid injection. The Court held that the mere fact that the problem of genetic engineering inventions could not even have been raised at the time of the adoption of the Patent Act does not mean that micro-organisms can become patentable inventions solely by means of legislation to that end. This precedent-setting decision (Olasz, 1996) established the patentability of micro-organisms, but despite this decision, national positions on patentability remained divergent.

Most countries have struggled to keep pace with rapid technological advancements, and specific patent measures tailored to biotechnology have often not been implemented. Consequently, biotechnological inventions have had to be incorporated into existing legal frameworks through appropriate legal interpretation.

This incorporation was more straightforward in countries with relatively liberal patent regimes and more challenging in countries where patent laws were legally over-constrained and biotechnological inventions could not or could only with difficulty be included in any patent category (Petzné, 1992).
In biotechnology, there are two primary types of patents. The first category encompasses those techniques and methods that are related to recombinant DNA technology or its improvements, while the second category comprises products derived from biotechnological methods. However, significant differences exist (Petzné, 1992) in the patentability of these two categories, particularly between processes and products.
In the past, patent law in several countries, including Hungary, excluded pharmaceuticals, chemically manufactured products, and products intended for human or animal consumption from patentability. The prohibition applied only to the products themselves, while the processes for their manufacture remained eligible for protection. This exclusion extended to microorganisms, as some genetic engineering steps are carried out using enzymes, classifying microorganisms as chemically manufactured products and, depending on their use, as medicinal products or consumables (Petzné, 1992). Compared to plant and animal species and microorganisms (Szarka, 1992), there is a separate category for intermediates and other microscopic and submicroscopic molecules, which have been considered by analogy as microorganisms in patent case law, complicating the question of patentability.
In countries where the prohibition of product protection meant that microorganisms themselves could not be protected, but only the processes for their creation, the feasibility of the subject matter of the invention required a full description of the steps of the process since feasibility could only be supported by the reproducibility of the process. In contrast, in countries where biotechnological products were patentable in themselves (Petzné, 1992), as seen in the USA, the existence of the product sufficed to evidence of the feasibility and reproducibility of the invention, allowing for a more general description of the process steps.
This brings us to a key point in patent law, particularly relevant for biotechnological inventions: the scope of the requirement of disclosure. Generally, adequate disclosure of inventions is provided through a written description, supplemented by drawings if necessary. However, in the case of inventions involving biological material not available to the public, the applicant may not be able to describe the invention sufficiently in the specification to the extent that it fulfills the disclosure requirement. For such inventions, the deposit of biological material with an institution authorized by the applicable law has been a traditional means available to applicants to satisfy the obligation of disclosure. The deposit should be considered part of the specification if the requirements for disclosure cannot be fulfilled by other means. National rules generally require that the deposit be duly referred to in the specification. However, the fact of the deposit alone is not necessarily sufficient and cannot replace the description. Consequently, patent law in many countries requires the applicant to describe in the specification the characteristics of the biological material or a process for obtaining or using the biological material, as these details would not be apparent from the deposit alone. Some jurisdictions, however, do not require deposition (WIPO, 2022) if the biological material is readily accessible to professionals.

4.2 The recent case law in the USA related to biotechnology patents

It should be noted that the boundaries of patentability of biotechnological inventions are still unsettled. This is illustrated by several US cases. In Mayo v. Prometheus [566 U.S. 66, Supreme Court, Mayo Collaborative Services, DBA Mayo Medical Laboratories, et al. v. Prometheus Laboratories, Inc.], the US Supreme Court concluded that patenting requires more than the simple application of natural law; it requires a new way of applying it. According to the court (Palágyi, 2016), holding Prometheus's patent in force would impede the use of natural laws, limiting their application in future discoveries. Prometheus' patent was directed to a diagnostic method. The case has been a source of uncertainty in the biotechnology community ever since, as it is unclear where the boundaries of patentability laid down for diagnostic inventions, which if based on the use of natural laws, are excluded from protection under US patent law.
Another landmark decision in the biotechnology field is the US Federal Circuit Court of Appeals' Myriad decision [U.S. Supreme Court, Association for Molecular Pathology v. Myriad Genetics Inc. 569 U.S. (2013)], which has sparked considerable controversy over the patentability of human gene sequences. The court found that "Myriad has identified an important and useful gene, but the isolation of that gene from surrounding genetic material is not an inventive step." (Palágyi, 2013). Essentially, the court ruled that a DNA segment could be patentable if it significantly differed from its natural state. However, a naturally occurring DNA fragment, even if isolated, remains part of nature and is not patentable. (Domokos, 2013) In 2014, Smith argued that the impact of Myriad's decision could have wider implications, as its ruling could be applied to stem cells. Like isolated DNA, human embryonic stem cells (hESC) may not meet the requirement of inventive steps prescribed by US patent law. According to his position, isolating stem cells from an embryo does not fundamentally alter their natural properties, failing to constitute a patentable invention. (Smith, 2014)
The US jurisprudence following these cases (such Ariosa Diagnostics, Inc. V. Sequenom, Inc., 788 F.3d 1371, 1376 (Fed. Cir. 2015), Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Limited, West-

Ward Pharmaceuticals Corp. No. 2016-2707, 2018, Exergen Corporation v. Kaz USA, Inc. No. 16-2315 (March 8, 2018), The Cleveland Clinic Foundation, Cleveland Heartlab, Inc. v. True Health Diagnostics Llc 859 F. 3D 1352, 2019, Athena Diagnostics, Inc., Oxford University Innovation Ltd., Max-Planckgesellschaft Zur Forderung Der Wissenschaften E.V. v. Mayo Collaborative Services, Llc, Dba Mayo Medical Laboratories, Mayo Clinic, 2019) has progressively narrowed the general rule defining patentability conditions by excluding the discovery of natural laws, natural phenomena, and abstract ideas from protection. Following the Myriad decision, the USPTO has instructed examiners to reject patent applications that relate only to DNA sequences found in nature, even if they are intended to be patented in isolated form. Some scholars argue that the Mayo and Myriad decisions will lead to a situation where personalized medicine methods will be unpatentable despite their rapid development and increasing importance in biotechnology. To address these uncertainties, the USPTO introduced a new examination method to develop consistent practice. The method requires, in the first step, examining whether the invention in question defines a law of nature and, if so, determining whether the invention applies it in a way that overrides the requirement that a law of nature cannot be patentable. However, this is a soft-law solution, and legislative attempts to resolve the legal uncertainty stalled by the end of 2022. (Geyer-Hirt, 2022)

5. Further implications of the development of biotechnology

With the development of biotechnology, patent litigation has increased, and industry players expecting the final outcome of the decade-long CRISPR-Cas9 gene editing technology dispute in the USA. As a DNA-editing tool, CRIPSR-Cas9 can remove or introduce new genes as well as silence or activate them. (Nogel, 2022) The technology deeply relies on proteins and cellular materials found in nature, which pose a threat to the technique's eligibility for patent protection. (Mulligan, 2024) A review of the patent landscape for CRISPR-Cas technology was conducted in 2016, which elucidated the highly fragmented and competitive patent environment in this field, with numerous academic institutions (such as MIT, Harvard, UC Berkeley, Broad Institute) and major corporations (Dow AgroSciences and DuPont) competing. Overlapping patent claims have led to serious litigation, which has been a major obstacle to the widespread adoption of gene editing. (Egelie et. al., 2016) The outcome of the case will have a profound impact on the validity of patent licenses between major manufacturers. Decisions stemming from the aforementioned US case law could fundamentally alter the market balance, potentially invalidating patents, removing exclusive rights, and allowing new players to enter the market. Furthermore, the eligibility of CRISPR-Cas9 for patenting differs between the USA and Europe. As Sherkow summarizes, the US Patent Trial and Appeal Board found the application of Broad Institute as a nonobvious advance over the work of Jennifer Doudna (University of California, Berkeley) and Emmanuelle Charpentier (Umea University, Sweden), while the European Patent Office granted a patent for Doudna and Charpentier covering a broad range of uses of CRISPR-Cas9 for all cell types. (Sherkow, 2017)

By the 2020s, licensing practices for biotechnology patents had changed significantly. Option deals have become more prevalent, where large pharmaceutical companies outsource their R&D costs by obtaining exclusive licensing rights from smaller, innovative biotech companies. They pay a small initial fee and then significantly higher licensing fees for the option rights once development and testing reach the desired stage. This enables large pharmaceutical companies to participate as stakeholders in several innovative processes without drastically increasing their R&D expenditure. To protect the interests of large manufacturers, licensing agreements increasingly include alternative enforcement clauses. In the event of a serious breach of contract, these clauses provide for a drastic reduction of the sum to be paid by the aggrieved party while they maintain the contract. The complex technical background and numerous disputes affecting market conditions are increasingly encouraging licensees to include stronger disclaimers in their contracts. This slows down the contracting process, forcing the licensor to carry out very thorough research to ensure that the developed technology does not infringe any prior patents (freedom-to-operate search). (Ellis-Taitt, 2021)

6. Conclusion

The patentability of biotechnological inventions has brought up significant questions, especially regarding the monopolization of the health industry. The legal protection of biotechnological inventions is crucial, not only for supporting research and development but also for mitigating global challenges related to food security, healthcare, and environmental sustainability, as biotechnology could directly support more SDGs. Patenting genes can limit access to information and restrict the development of treatments for diseases. The evolving case law is reshaping the biotechnology sector. The author argues that a balanced approach is required to handle biotech patents. Those inventions can significantly contribute to SGD 2, 3, 6, 14, and 15 directly and indirectly; thus, the incentive for innovation is necessary. The best incentive is a patent as an exclusive reward for the investment. However, as many scholars pointed out and agreed with by the author, big companies can

monopolize the health or agriculture industry through patenting, especially with CRISPR patents. If patents do not foster innovation but create barriers to entry for others in the market, and sustainable development goals are hindered, then further restrictions shall be applied either on a case-by-case basis or on a legislative basis.

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