Navigating Legal Grey Areas: Biotechnology Patenting Challenges and Regulatory Gaps in the EU and the US Legal Systems

by Nursultan Toktonazarov

CEU eTD Collection

LLM/MA Capstone / Final Thesis
SUPERVISOR: Marco Botta
Central European University - Private University

© Central European University - Private University
2024

TABLE OF CONTENTS

CEU eTD Collection

Abstract

This thesis explores the intricate challenges of biotechnological patenting within the legal frameworks of the European Union (EU) and the United States (US), focusing on the dynamic intersection of scientific innovation, ethical considerations, and legal complexities. The rapid advancements in biotechnological fields such as gene editing, synthetic biology, and personalized medicine raise significant questions regarding patent eligibility, non-obviousness, and ethical implications. Central to this discourse are the controversies and legal puzzles presented by groundbreaking technologies like CRISPR-Cas9, which not only revolutionize biological research but also provoke debates on the boundaries of patentability, ownership, and ethical permissibility. The study employs a comparative analysis method, delving into legal texts, directives, regulations, case law, and scholarly works to expose and scrutinize the legal gaps and challenges across the EU and US jurisdictions. This paper aims to provide insights into optimizing patent systems to foster innovation while addressing ethical and legal concerns, and to understand how these legal frameworks contribute to and influence policies and innovations in the sphere of biotechnology.

CEU eTD Collection

Introduction

Biotechnology stands at the forefront of scientific innovation, utilizing the power of biological processes to revolutionize fields ranging from medicine to agriculture and environmental management. This multidisciplinary field merges concepts from biology, technology, and engineering to address some of the most pressing global challenges of our time. However, the rapid advancements in biotechnology not only push the boundaries of scientific possibility but also present profound legal and ethical dilemmas, particularly in the sphere of intellectual property rights.

The path of biotechnology from ancient fermentation techniques to sophisticated gene editing highlights a trajectory of remarkable scientific achievements. Early biotechnological applications such as yeast-based fermentation date back thousands of years, but it was not until the 20th century that major scientific breakthroughs, such as the discovery of DNA's structure by Watson and Crick in 1953, set the stage for today's genetic engineering marvels[1]. These advancements have led to innovative applications like CRISPR-Cas9, which offers unprecedented precision in gene editing, heralding new healing possibilities and raising complex patent-related issues[2].

As biotechnological innovations evolve, so does the landscape of patent law, tasked with balancing the encouragement of innovation against the protection of public welfare and ethical norms. Patent systems in the EU and the US have been particularly challenged by the

CEU eTD Collection

[1] Francis Crick. “Molecular Structure of Nucleic Acids: A Structure for Deoxyribose Nucleic Acid.” “Molecular structure of Nucleic Acids: A structure for deoxyribose nucleic acid.” April 25, 1953. - published papers and official documents - Linus Pauling and the race for DNA: A documentary history, April 25, 1953. http://scarc.library.oregonstate.edu/coll/pauling/dna/papers/corr68.11-reprint-19530425.html.

[2] Jinek, M., et al. (2012). "A Programmable Dual-RNA-Guided DNA Endonuclease in Adaptive Bacterial Immunity." Science, 337(6096), 816-821; https://www.science.org/doi/10.1126/science.1225829?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed.

complexities introduced by biotechnological inventions. These challenges include defining what constitutes patentable subject matter, handling the non-obviousness criterion in a rapidly advancing field, and addressing the ethical implications of patenting life forms and genetic material.

One of the most contentious issues in biotechnology patenting is the eligibility of genetically modified organisms and genetic sequences. Legal frameworks in both the EU and US have struggled with these questions, often arriving at divergent conclusions based on differing legal precedents and policy priorities. In the EU, the Biotech Directive (98/44/EC) attempts to clarify the boundaries of biotechnological patents, stipulating that biological material which is isolated from its natural environment or produced via a technical process may be patentable[3]. Meanwhile, the US has seen significant legal developments such as the Diamond v. Chakrabarty case, which set a precedent for the patentability of genetically modified organisms, affirming that "anything under the sun that is made by man" is patentable[4].

The ethical dimensions of biotechnology patents further complicate the legal landscape. Debates often center around the moral implications of patenting life forms, the potential for commodification of biological substances, and the societal impacts of biotechnological monopolies. These ethical concerns are not merely academic but influence legislative and judicial outcomes that directly affect biotechnology patenting strategies and practices.

This thesis seeks to explore these intricate intersections of biotechnology, law, and ethics, with a particular focus on the comparative analysis of the EU and US patent systems. It aims to provide a comprehensive overview of the current state of biotechnological patenting, identify the key legal challenges and ethical dilemmas, and offer insights into how these systems can

CEU eTD Collection

[3] European Parliament and Council Directive 98/44/EC of 6 July 1998 on the Legal Protection of Biotechnological Inventions. 1998. Official Journal L213, 30 July 1998, pp. 13-21.
[4] U.S. Supreme Court. Diamond v. Chakrabarty, 447 U.S. 303 (1980).

evolve to better accommodate the rapid pace of scientific innovation while ensuring ethical standards and public benefit.

Chapter 1. Overview of biotechnologies

a. Historical developments of biotechnologies

The journey of biotechnology begins in the prehistoric era when humans unknowingly employed biotechnological processes to ferment food and drink. The transition from these early applications to the sophisticated, life-altering technologies of today demonstrates a rich spectrum of human ingenuity and scientific curiosity.

Historically, biotechnology's roots relate to the earliest agricultural practices. Fermentation, one of the oldest biotechnological processes, was used by ancient civilizations to produce bread, beer, and wine. These processes, though not understood at the molecular level, strapped the power of microorganisms to transform food and beverages, making them safer to consume and longer-lasting. The discovery of these fermentation processes can be traced back to the Neolithic period, around 6000 BC, marking the dawn of human exploration into biotechnology[5]. The ancient world also saw the use of selective breeding, where plants and animals were selectively bred to produce offspring with desirable traits. This early form of genetic manipulation laid the groundwork for modern genetic engineering, showcasing humanity's long-standing quest to belt and direct the forces of biology[6].

CEU eTD Collection

[5] Mashing and Fermenting in Deep Time Uncorking the Past: The Quest for Wine, Beer, and Other Alcoholic Beverages . By Patrick E. McGovern . Berkeley: University of California Press, 2009; https://www.researchgate.net/publication/259707908_Mashing_and_Fermenting_in_Deep_Time_Uncorking_the_Past_The_Quest_for_Wine_Beer_and_Other_Alcoholic_Beverages_By_Patrick_E_McGovern_Berkeley_University_of_California_Press_2009.

[6] Zeder, Melinda A. "Domestication and early agriculture in the Mediterranean Basin: Origins, diffusion, and impact." Proceedings of the National Academy of Sciences 105, no. 33 (2008): 11597-11604; https://www.pnas.org/doi/full/10.1073/pnas.0801317105.

The period of 17th and 18th centuries witnessed the birth of microbiology, thanks to Antonie van Leeuwenhoek, who discovered microorganisms using a microscope[7], and Louis Pasteur, who debunked the theory of spontaneous generation and introduced the principles of vaccination and pasteurization (heat treatment of food to kill bacteria)[8]. These discoveries laid the foundation for germ theory and sterile techniques, drastically changing the fields of medicine and food preservation. Louis Pasteur's work not only provided a deeper understanding of microorganisms but also introduced the concept of using microbes for fermentation, a cornerstone of modern biotechnology[9]. The 20th century announced the era of genetic engineering, beginning with the rediscovery of Gregor Mendel's work on genetics in the early 1900s[10]. This period saw rapid advancements in our understanding of DNA and genetics, culminating in the discovery of the DNA double helix by James Watson and Francis Crick in 1953[11].

The discovery of the DNA's structure paved the way for molecular biology and genetic engineering, transforming biotechnology from a collection of empirical practices into a dynamic and rapidly advancing scientific field. The completion of the Human Genome Project (HGP) in 2003 marked a monumental achievement in the field of biotechnology[12]. By mapping all human genes, the HGP provided an unprecedented understanding of the human genome, opening doors to the possibilities of personalized medicine and gene therapy[13]. This endeavor

CEU eTD Collection

[7] Nick Lane. The Unseen World: Reflections on Leeuwenhoek (1677) 'concerning little animals' | philosophical transactions of the royal society B: Biological Sciences, April 15, 2015. https://royalsocietypublishing.org/doi/10.1098/rstb.2014.0344.
[8] Louis Pasteur. "Pasteur's Papers on the Germ Theory The Physiological Theory Of Fermentation." Pasteur's papers on the germ theory, n.d. https://biotech.law.lsu.edu/cphl/history/articles/pasteur.htm.
[9] See Note 6.
[10] Gregor Mendel. "Gregor Mendel's 'Experiments in Plant Hybridization.'" Gregor Mendel's "Experiments in Plant Hybridization" | Villanova University, 1866. https://www1.villanova.edu/villanova/president/university_events/mendelmedal/aboutmendel/experiments.html;
[11] Francis Crick. "Molecular Structure of Nucleic Acids: A Structure for Deoxyribose Nucleic Acid." "molecular structure of Nucleic Acids: A structure for deoxyribose nucleic acid." April 25, 1953. - published papers and official documents - Linus Pauling and the race for DNA: A documentary history, April 25, 1953. http://scarc.library.oregonstate.edu/coll/pauling/dna/papers/corr68.11-reprint-19530425.html.
[12] "The Human Genome Project." Genome.gov, 2003. https://www.genome.gov/human-genome-project.
[13] *Ibid.*

demonstrated the power of international collaboration and the potential of biotechnological research to address complex biological and medical challenges[14].

The development of CRISPR-Cas9 technology has been one of the most significant advancements in biotechnology in recent years[15]. Discovered as a part of bacterial immune systems, CRISPR-Cas9 allows for precise editing of DNA, offering potential cures for genetic disorders and enabling targeted modifications in plant and animal genomes[16]. Its relative simplicity and efficiency compared to previous gene-editing methods have revolutionized the possibilities within genetic engineering and have ignited discussions around the ethical implications of gene editing[17].

Synthetic biology, emerging from the foundations laid by genetic engineering and biotechnology, seeks to redesign natural biological systems for useful purposes and to construct entirely new forms of life[18]. This field combines the principles of biology, engineering, and computer science, enabling the creation of synthetic organisms that can produce pharmaceuticals, biofuels, and new materials[19]. The development of the first synthetic bacterial genome by Craig Venter and his team was a landmark achievement, showcasing the potential to "write" genetic information and create life with specified functions[20].

The 21st century has seen the convergence of biotechnology with digital technologies, leading to significant advancements in bioinformatics, genomics, and personalized medicine[21]. The ability to sequence and analyze large datasets of genetic information has transformed our

CEU eTD Collection

[14] Collins, Francis S., et al. "A Vision for the Future of Genomics Research." Nature 422, no. 6934 (2003): 835-847; https://www.nature.com/articles/nature01626.
[15] Doudna, Jennifer A., and Emmanuelle Charpentier. "The New Frontier of Genome Engineering with CRISPR-Cas9." Science 346, no. 6213 (2014); https://www.science.org/doi/10.1126/science.1258096.
[16] *Ibid.*
[17] *Ibid.*
[18] Church, George, and Ed Regis. Regenesis: How Synthetic Biology Will Reinvent Nature and Ourselves. New York: Basic Books, 2012; http://dk.fdv.uni-lj.si/db/pdfs/TiP2014_5_Pustovrh1.pdf.
[19] *Ibid.*
[20] *Ibid.*
[21] Joyner, Michael J., and Nigel Paneth. "Promises, Promises, and Precision Medicine." Journal of Clinical Investigation 129, no. 3 (2019): 946-948; https://www.jci.org/articles/view/126119.

understanding of diseases, leading to the development of targeted therapies and diagnostics[22]. Furthermore, the advent of bioprinting technologies promises to revolutionize the fields of tissue engineering and organ transplantation, offering new hope for patients awaiting transplants[23].

As biotechnology continues to advance, it faces ethical and regulatory challenges, particularly in areas such as genetic privacy, biosecurity, and the equitable distribution of its benefits. The power to edit genes, create synthetic life, and manipulate biological systems carries significant responsibilities. "It's crucial that we find the right tempo for integrating emerging technologies into society to foster a healthier interaction with these advancements going forward"[24]. Ensuring that the advancements in biotechnology are used ethically and benefit society remains a paramount concern. The dialogue among scientists, ethicists, policymakers, and the public is essential in navigating these challenges and utilizing the full potential of biotechnologies.

b. Types and applications

Biotechnology, an interdisciplinary field, curbs cellular and biomolecular processes to develop technologies and products that address complex challenges across various sectors, including medicine, agriculture, and environmental management. The vast field can be categorized into several types, each with unique applications: medical (red), agricultural (green), industrial (white), and environmental biotechnology[25].

CEU eTD Collection

[22] *Ibid.*

[23] Joyner, Michael J., and Nigel Paneth. "Promises, Promises, and Precision Medicine." Journal of Clinical Investigation 129, no. 3 (2019): 946-948; https://www.jci.org/articles/view/126119.

[24] Innovative Governance Models for Emerging Technologies. Chapter 9. Properly Paced or Problematic: Examining Past and Present Governance of GMOs in the United States. Kuzma, J.; https://www.researchgate.net/publication/310606866_Innovative_Governance_Models_for_Emerging_Technologies_Chapter_9_Properly_Paced_or_Problematic_Examining_Past_and_Present_Governance_of_GMOs_in_the_United_States_Kuzma_J.

[25] European Patent Office. "Red, White, Green: Biotechnology Patents." Last modified 2023. https://www.epo.org/en/news-events/in-focus/biotechnology-patents/red-white-green.

Medical biotechnology, or red biotechnology, involves using living cells and cell materials to research and develop pharmaceutical and diagnostic products that help treat and prevent human diseases[26]. This sector has seen substantial growth due to advancements in genetic engineering, monoclonal antibody techniques, and recombinant DNA technology[27].

Genetic Engineering and Disease Treatment. Genetic engineering has opened the door for the development of gene therapy, which treats or prevents diseases by modifying or introducing genes into a patient's cells. Recent advancements in CRISPR-Cas9 technology have significantly enhanced the precision and efficiency of gene editing, offering potential cures for genetic disorders[28].

Monoclonal Antibodies for Targeted Therapy. Monoclonal antibodies, engineered in the lab to target specific antigens, have revolutionized cancer treatment. By hiding specific proteins on cancer cells, these antibodies can inhibit cancer cell growth and trigger the immune system to attack the cells[29].

Vaccines. Biotechnological methods are crucial in vaccine development, with recombinant DNA technology enabling the creation of safer and more effective vaccines. The development of the Hepatitis B vaccine marked a significant landmark in the use of genetic engineering for vaccine production[30].

Agricultural biotechnology, or green biotechnology, applies to agricultural processes that may be used to enhance the yield, nutritional value, and resistance to crops to diseases and

CEU eTD Collection

[26] See Note 25.
[27] *Ibid.*
[28] Jinek, M., et al. (2012). "A Programmable Dual-RNA-Guided DNA Endonuclease in Adaptive Bacterial Immunity." Science, 337(6096), 816-821; https://www.science.org/doi/10.1126/science.1225829?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed.
[29] Leavy, Olive. "The Birth of Monoclonal Antibodies." Nature News, December 2, 2016; https://www.nature.com/articles/ni.3608.
[30] National Research Council (US) Committee on Opportunities in Biotechnology for Future Army Applications. "Vaccination - Opportunities in Biotechnology for Future Army Applications." Opportunities in Biotechnology for Future Army Applications., January 1, 2001. https://www.ncbi.nlm.nih.gov/books/NBK207433/.

pests[31]. Genetic modification and tissue culture techniques have been instrumental in developing drought-resistant and pest-resistant crops, improving global food security[32].

Genetically Modified Organisms (GMOs). GMOs are organisms whose genetic material has been altered to achieve desirable traits, such as increased resistance to pests or improved nutritional content. The introduction of Bt cotton, genetically engineered to produce Bt toxin that is harmful to certain insects, has significantly reduced pesticide use and increased yields[33].

Tissue Culture and Cloning. Plant tissue culture techniques allow for the cloning of genetically identical plants from a single parent plant, facilitating the rapid propagation of disease-resistant and high-yield varieties[34].

Industrial biotechnology, white biotechnology, utilizes enzymes and microorganisms to produce bio-based products, such as chemicals, materials, and biofuels, sustainably[35]. This field aims to reduce energy and water usage, lower greenhouse gas emissions, and minimize waste production in industrial processes[36].

Biofuel Production. The development of biofuels, such as ethanol and biodiesel, from plant biomass and microalgae, offers a renewable alternative to fossil fuels. Advances in metabolic engineering have improved the efficiency of biofuel production processes[37].

CEU eTD Collection

[31] See Note 25.
[32] *Ibid.*
[33] James, Clive. 2014. Global Status of Commercialized Biotech/GM Crops: 2014. ISAAA Brief No. 49. ISAAA: Ithaca, NY; https://www.isaaa.org/resources/publications/briefs/49/download/isaaa-brief-49-2014.pdf.
[34] Smith, Roberta H. "Plant Tissue Culture: Techniques and Experiments." Academic Press, 2012; https://books.google.co.ve/books?id=SUbi3gCg2PsC&pg=PA1&source=gbs_toc_r&cad=2#v=onepage&q&f=false.
[35] See Note 25.
[36] *Ibid.*
[37] Fortman, J.L., et al. "Biofuel Alternatives to Ethanol: Pumping the Microbial Well." Trends in Biotechnology, vol. 26, no. 7, 2008, pp. 375-381; https://www.researchgate.net/publication/313655878_Biofuel_alternatives_to_ethanol_pumping_the_microbial_well/link/58c2f5f492851c0ccbf14056/download.

Bioplastics. Biotechnological processes are used to produce bioplastics from renewable biomass, which are biodegradable and offer an environmentally friendly alternative to conventional plastics made from petroleum[38].

Enzyme Engineering for Industrial Applications. Enzymes, produced using recombinant DNA technology, are widely used in various industries, including the textile, paper, and detergent industries, for their ability to catalyze specific reactions under mild conditions, thereby saving energy and reducing the use of harsh chemicals[39].

Environmental biotechnology refers to the application of biotechnological solutions to environmental problems, including pollution control and waste management[40]. By exploiting the capabilities of microorganisms and plants, environmental biotechnology aims to restore and protect ecosystems[41].

Bioremediation. The use of microorganisms to degrade or detoxify pollutants in the environment, such as oil spills and heavy metal contamination, is known as bioremediation. This technique offers a cost-effective and environmentally friendly alternative to traditional cleanup methods[42].

Phytoremediation. Phytoremediation utilizes plants to absorb, sequester, and detoxify pollutants from soil and water. Certain plants can accumulate heavy metals or degrade organic pollutants, making them useful for cleaning contaminated sites[43].

CEU eTD Collection

[38] Chen, Guo-Qiang. "Plastics Completely Synthesized by Bacteria: Polyhydroxyalkanoates." In Plastics from Bacteria, Springer, Berlin, Heidelberg, 2009, pp. 17-37; https://www.researchgate.net/publication/225712341_Plastics_Completely_Synthesized_by_Bacteria_Polyhydroxyalkanoates/link/54b66e950cf2e68eb27e8b69/download?_tp=eyJjb250ZXh0Ijp7ImZpcnN0UGFnZSI6InB1YmxpY2F0aW9uIiwicGFnZSI6InB1YmxpY2F0aW9uIn19.

[39] Bornscheuer, U.T., et al. "Engineering the Third Wave of Biocatalysis." Nature, vol. 485, 2012, pp. 185-194; https://www.nature.com/articles/nature11117.

[40] Chen, Wilfred, Ashok Mulchandani, and Mark A. Deshusses. "Environmental Biotechnology: Challenges and Opportunities for Chemical Engineers." *AIChE Journal* 51, no. 3 (2005): 690–695.

[41] *Ibid.*

[42] Vidali, M. "Bioremediation. An Overview." Pure and Applied Chemistry, vol. 73, no. 7, 2001, pp. 1163-1172; https://www.degruyter.com/document/doi/10.1351/pac200173071163/html?lang=en.

[43] Odjegba, Victor J., and Ishola O. Fasidi. "Phytoremediation of Heavy Metals by Eichhornia Crassipes - Environment Systems and Decisions." SpringerLink, July 1, 2007. https://link.springer.com/article/10.1007/s10669-007-9047-2.

Bioaugmentation. Bioaugmentation involves introducing specific strains of bacteria or consortia into polluted environments to enhance the natural biodegradation processes. This approach has been applied successfully in treating wastewater and remediating oil-contaminated oil[44].

c. Current trends and advancements

Diving deeper into the specifics, let's explore precise examples of current trends and advancements in biotechnology, focusing on groundbreaking applications and innovations across different sectors.

Example: CRISPR and Sickle Cell Disease. One of the most significant advancements in precision medicine is the use of CRISPR-Cas9 technology for treating genetically inherited diseases[45]. Sickle cell disease, caused by a single gene mutation, has been a target for CRISPR due to its clear genetic basis. In a groundbreaking study, patients with sickle cell disease underwent a treatment involving CRISPR to correct the mutation in their hematopoietic (formation of blood or blood cells) stem cells[46]. The edited cells, when reintroduced into the patients, showed a restored ability to produce normal hemoglobin, leading to significant improvements in symptoms and quality of life.[47] This treatment exemplifies the potential of CRISPR technology to provide curative therapies for genetic disorders, marking a significant moment in the field of gene therapy and precision medicine[48].

CEU eTD Collection

[44] Kanissery, Ramdas Gopinath, and Gerald K. Sims. "Biostimulation for the Enhanced Degradation of Herbicides in Soil." Applied and Environmental Soil Science, September 15, 2011. https://www.hindawi.com/journals/aess/2011/843450/.
[45] Frangoul, Haydar, et al. "CRISPR-Cas9 Gene Editing for Sickle Cell Disease and β-Thalassemia." The New England Journal of Medicine, vol. 384, 2021, pp. 252-260; https://www.nejm.org/doi/full/10.1056/NEJMoa2031054.
[46] *Ibid.*
[47] *Ibid.*
[48] *Ibid.*

Example: Synthetically Engineered Bacteria for Plastic Degradation. Among growing concerns about plastic pollution, synthetic biology offers innovative solutions for environmental stability. A remarkable example is the engineering of *Ideonella sakiensis* to degrade PET (polyethylene), a common plastic[49]. By optimizing the bacterium's PETase enzyme, researchers have significantly improved its efficiency in breaking down PET plastics[50]. This development not only highlights the potential of synthetic biology to address environmental challenges but also opens avenues for recycling plastics into useful products, thereby contributing to a circular economy.

Example: Improving Crop Resilience and Yield with CRISPR. CRISPR-Cas9 technology has transcended its origins as a basic research tool, demonstrating profound impacts in agriculture. By precisely editing the genomes of crops, scientists have been able to introduce desirable traits such as drought resistance, improved nutritional content, and enhanced yield[51]. Notably, CRISPR has been utilized to develop rice varieties with increased yield and nitrogen-use efficiency, addressing both food security and environmental sustainability[52]. This application underscores the versatility of CRISPR technology in improving agricultural practices and its potential to contribute to global efforts to feed a growing population sustainably[53].

Example: AI-Powered Drug Discovery. The integration of AI in biotechnology, particularly in drug discovery, is revolutionizing the pace at which new treatments are developed. A notable example is the use of AI to identify halicin, a novel compound with antibiotic properties, from

CEU eTD Collection

[49] Yoshida, Shosuke, et al. "A bacterium that degrades and assimilates poly(ethylene terephthalate)." Science, vol. 351, no. 6278, 2016, pp. 1196-1199; https://www.researchgate.net/publication/297743309_A_bacterium_that_degrades_and_assimilates_polyethylene_terephthalate/link/5a857fa9a6fdcc201ba0f53f/download.
[50] *Ibid.*
[51] Chen, Keping, et al. "CRISPR/Cas9 Genome Editing and Precision Plant Breeding in Agriculture." Annual Review of Plant Biology, vol. 70, 2019, pp. 667-697; https://www.researchgate.net/publication/331538032_CRISPRCas_Genome_Editing_and_Precision_Plant_Breeding_in_Agriculture.
[52] *Ibid.*
[53] *Ibid.*

a database of chemical structures[54]. This AI-driven approach, which can predict the efficacy of compounds as antibiotics, represents a significant leap forward in identifying new drugs[55]. Such innovations not only accelerate the drug discovery process but also hold the potential to tackle antibiotic resistance by bringing new classes of antibiotics to the market more efficiently.

Example: Machine Learning in Genomic Analysis. Machine learning (ML) algorithms are making substantial contributions to genomics, enabling researchers to analyze and interpret vast amounts of genetic data with unprecedented speed and accuracy[56]. An example of this application is the use of ML to identify genetic markers associated with diseases, significantly advancing our understanding of complex diseases like cancer[57]. By analyzing patterns within the genetic data, ML algorithms can predict disease susceptibility, outcome, and response to treatment, thereby informing more personalized healthcare strategies.[58]

These examples show how diverse and exciting the field of biotechnology is. It's not just about exploring new scientific ideas; it's about finding real ways to solve some of the biggest challenges we face today, like fighting diseases, protecting our environment, and making sure we can produce enough food for everyone. Thanks to breakthroughs in areas like genetic editing, creating life from scratch, using computers to speed up discoveries, and finding new ways to clean up the planet, biotechnology is rapidly changing. This wave of innovation is opening up new possibilities for making our lives better, from improving our health and how we grow food to taking better care of our environment.

CEU eTD Collection

[54] Stokes, Jonathan M., et al. "A Deep Learning Approach to Antibiotic Discovery." Cell, vol. 180, no. 4, 2020, pp. 688-702.e13; https://www.sciencedirect.com/science/article/pii/S0092867420301021?via%3Dihub.
[55] *Ibid.*
[56] Infante, Deliana. "AI-Powered Genomic Analysis: Revolutionizing the Detection of Genetic Mutations." News, November 8, 2023. https://www.news-medical.net/health/AI-Powered-Genomic-Analysis-Revolutionizing-the-Detection-of-Genetic-Mutations.aspx#:~:text=AI%20algorithms%2C%20such%20as%20machine,on%20training%20from%20large%20datasets.
[57] *Ibid.*
[58] *Ibid.*

Chapter 2. Subjects of patentability in the EU and US

a. Patent Eligibility Criteria in the EU and the US

The landscape of patent law is characterized by a complex interplay of innovation, legal standards, and policy objectives. In the realm of global intellectual property (IP) law, the EU and the US) represent two of the most influential jurisdictions, each with its unique approach to determining what constitutes a patentable invention. Understanding the patent eligibility criteria in these jurisdictions is crucial for inventors, corporations, and legal practitioners navigating the global IP ecosystem.

The European Patent Convention (EPC) serves as the foundation of patent law, setting forth the criteria under which inventions are considered patentable[59]. These criteria include novelty, inventive step (non-obviousness), and industrial applicability[60]. Additionally, the EPC articulates exclusions to patentability, aiming to strike a balance between promoting innovation and safeguarding public interests[61].

Novelty: An invention is considered novel if it does not form part of the state of the art. The state of the art comprises everything made available to the public before the date of filing of the patent application, through written or oral description, use, or any other means[62].

Inventive Step: An invention involves an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art[63]. This criterion is aimed at ensuring that patents are granted only for inventions that represent a genuine technological advancement[64].

CEU eTD Collection

[59] Convention on the Grant of European Patents (European Patent Convention), October 5, 1973, entered into force October 7, 1977.
[60] *Ibid.*
[61] *Ibid.*
[62] Supra, art.54.
[63] Supra, art. 56.
[64] *Ibid.*

Industrial Applicability: An invention is considered capable of industrial application if it can be made or used in any kind of industry, including agriculture[65].

The EPC also outlines explicit exclusions from patentability, designed to balance the right to patent protection with public policy considerations. These exclusions include discoveries, scientific theories, mathematical methods, aesthetic creations, schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers "as such"[66].

The US defines patent eligibility through the United States Code (Title 35), underpinned by several key Supreme Court decisions that have shaped the interpretation of these laws[67]. The US criteria for patentability include the requirements that an invention must be useful, novel, and non-obvious. *Usefulness:* The utility requirement specifies that an invention must have a specific, substantial, and credible utility. This criterion ensures that patents are awarded for inventions that provide a tangible benefit[68]. *Novelty:* An invention must be novel, meaning it cannot be identical to any prior art. The prior art includes anything that has been publicly disclosed, patented, or described in a published publication before the invention's filing date[69]. *Non-obviousness:* The invention must not be obvious to a person having ordinary skill in the art at the time the invention was made. This requirement is intended to ensure that patents are granted for truly innovative ideas rather than incremental improvements[70].

Significant court rulings have further defined exceptions to patent eligibility, including abstract ideas, natural phenomena, and laws of nature. The landmark case of Alice Corp. v. CLS Bank

CEU eTD Collection

[65] Supra, art.57.
[66] Supra, art.52(2).
[67] Section 1 of act July 19, 1952, ch. 950, 66 Stat. 792, provided in part that this title may be cited as "Title 35, United States Code.
[68] Title 35, United States Code, § 101.
[69] *Supra* § 102.
[70] *Supra* § 103.

International clarified the framework for determining the patent eligibility of inventions related to abstract ideas, particularly in the context of computer-implemented inventions[71].

Both the EU and US systems are designed to promote innovation by protecting new, non-obvious inventions that can be industrially applied or useful. While rooted in similar foundational principles, the specific applications of these criteria reflect the distinct legal and cultural landscapes of each jurisdiction. For instance, the EPO's Guidelines for Examination provide detailed insight into the interpretation of inventive steps and industrial applicability within the European context[72], whereas the Manual of Patent Examining Procedure (MPEP)[73] offers a comprehensive guide to the application of novelty and non-obviousness standards in the US. In examining the patent eligibility criteria further, both the EU and the US emphasize the importance of detailed disclosure and the application's clarity to ensure that the patent system supports genuine innovation and public access to technological advancements. Both jurisdictions require that a patent application discloses the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. This requirement ensures that the public can benefit from the knowledge of the invention once the patent expires, furthering the progress of science and technology.

The US, however, following the Alice Corp. v. CLS Bank International decision, applies a two-part test to determine the patent eligibility of software-related inventions, focusing on whether the claims are directed to an abstract idea and, if so, whether they contain an 'inventive concept' sufficient to transform the abstract idea into a patent-eligible invention[74].

CEU eTD Collection

[71] Alice Corp. v. CLS Bank Int'l, 573 U.S. 208 (2014).
[72] New revised version of the Guidelines for Examination in the European Patent Office dated 01 March 2021; https://www.boehmert.de/en/new-revised-version-of-the-guidelines-for-examination-in-the-european-patent-office-dated-01-march-2021/.
[73] Manual of Patent Examining Procedure (MPEP) Ninth Edition, Revision 07.2022. https://www.uspto.gov/web/offices/pac/mpep/index.html.
[74] See Note 38.

b. Comparison of patent law in the EU and the US

While both the EU and US aim to foster innovation through patent protection, their approaches reflect different legal traditions, policy considerations, and societal values. A comparative analysis reveals these nuances, offering insights into how each jurisdiction balances the interests of inventors with broader societal goals.

The EPC provides a centralized procedure for patent applications but does not replace national patent laws. Instead, it allows inventors to seek patent protection in up to 38 European countries through a single application process[75].

The United States Patent and Trademark Office (USPTO) governs the granting of patents in the US, operating under the United States Code (Title 35)[76]. The USPTO examines patent applications and grants patents based on compliance with US patent laws.

The EPO's stance on software patents is restrictive, allowing them only when the invention provides a technical solution to a technical problem[77]. Pure software inventions are generally not patentable unless they have a direct technical effect on a physical process[78].

The US allows broader patent protection for software-related inventions, provided they meet the criteria of novelty, non-obviousness, and utility. The landmark Supreme Court case Alice Corp. v. CLS Bank International established a two-part test to determine software patent eligibility, focusing on the presence of an abstract idea and the inventive concept that 'transforms' it into a patent-eligible invention[79].

Both jurisdictions exclude abstract ideas from patentability to prevent monopolization of fundamental scientific and mathematical principles. However, the US approach, particularly post-Alice, requires that an inventive concept significantly more than the abstract idea itself

CEU eTD Collection

[75] See Note 29.
[76] See Note 40.
[77] See Note 39.
[78] *Ibid.*
[79] See Note 38.

must be present for patent eligibility, a principle not explicitly mirrored in the EPC but observed in practice through the requirement of a technical solution to a technical problem.

Ethical considerations are explicitly integrated into the EU's patent law framework, with prohibitions on patents for inventions that could violate public order or morality[80]. This includes a specific prohibition on patenting human embryos and processes for cloning human beings[81].

While the US does not have explicit legal provisions on ethical considerations in patent law, such concerns are reflected in the patent eligibility of medical procedures and certain biotechnological inventions, as seen in the judicial interpretation of patent laws.

Despite these differences, both the EU and US participate in international treaties and agreements aimed at harmonizing patent law to facilitate global innovation. The Patent Cooperation Treaty (PCT), for instance, allows inventors to file a single patent application to seek protection in multiple countries, including both EPO member states and the US[82].

The quest for harmonizing patent law, especially between such significant players as the EU and the US, faces inherent challenges. These include reconciling different legal traditions, societal values, and policy objectives. However, the ongoing dialogues facilitated by international treaties and organizations, such as the World Intellectual Property Organization (WIPO), highlight a collective commitment to fostering a global innovation ecosystem that respects these diverse perspectives[83].

Both jurisdictions are struggling with the implications of emerging technologies like artificial intelligence, CRISPR gene editing, and nanotechnology on patent law. These technologies challenge existing legal frameworks, prompting both the EPO and USPTO to refine their guidelines and interpretations to keep pace with innovation.

CEU eTD Collection

[80] Convention on the Grant of European Patents (European Patent Convention), October 5, 1973, art.53, entered into force October 7, 1977; https://www.epo.org/en/legal/epc.
[81] *Ibid.*
[82] World Intellectual Property Organization. "Patent Cooperation Treaty (PCT)." 2021; https://www.wipo.int/publications/en/details.jsp?id=4548.
[83] *Ibid.*

AI as Inventor: Recent debates around AI's role as a potential "inventor" in patent applications underscore the need for legal frameworks to adapt to technological advancements. Both the EU[84] and the US[85] have faced patent applications listing an AI system as the inventor, raising fundamental questions about the nature of invention and creativity.

Gene Editing Technologies: The CRISPR-Cas9 technology's emergence has led to a re-evaluation of biotechnological invention patentability. Both jurisdictions are navigating the complex interplay between encouraging biomedical innovation and addressing ethical concerns related to genetic modifications.[86].

The influence of public policy and ethical considerations on patent eligibility criteria continues to be a focal point of discussion in both the EU and the US. As biotechnology and medical research push the boundaries of what can be invented, both jurisdictions strive to ensure that patent law aligns with broader societal values and ethical standards.

Environmental Sustainability: As global attention turns to environmental sustainability and combating climate change, both jurisdictions recognize the role of patent law in promoting green technologies. Incentives for environmentally beneficial inventions, such as expedited patent examination procedures for green technologies, reflect this commitment[87].

The comparison of patent law in the EU and the US reveals a landscape shaped by a complex interplay of legal principles, technological innovation, societal values, and policy objectives. While rooted in the common goal of fostering innovation and protecting inventors' rights, the

CEU eTD Collection

[84] Daniel, Carlton. "UK Supreme Court Rules on AI and Patent Applications - Patent - Worldwide." UK Supreme Court Rules On AI And Patent Applications - Patent - Worldwide, January 10, 2024. https://www.mondaq.com/uk/patent/1409936/uk-supreme-court-rules-on-ai-and-patent-applications.

[85] "USPTO: Artificial Intelligence Systems Cannot Legally Invent." McDermott Will & Emery, January 24, 2023. https://www.mwe.com/insights/uspto-artificial-intelligence-systems-cannot-legally-invent/.

[86] Harrison, C. EPO revokes Broad's CRISPR patent. Nat Biotechnol 36, 209 (2018). https://doi.org/10.1038/nbt0318-209b; and "CRISPR Patent Interference Updates." Broad Institute, March 15, 2016. https://www.broadinstitute.org/what-broad/areas-focus/project-spotlight/crispr-patent-interference-updates.

[87] WIPO. Intellectual property offices and sustainable innovation, n.d. https://www.wipo.int/edocs/pubdocs/en/wipo-pub-rn2023-10-en-intellectual-property-offices-and-sustainable-innovation.pdf.

nuanced differences in eligibility criteria, treatment of specific types of inventions, and the integration of ethical considerations highlight the unique approaches of each jurisdiction.

As technology continues to advance and global challenges prompt a reevaluation of priorities, both the EU and the US are likely to see ongoing evolution in their patent laws. The dialogue between these jurisdictions, facilitated by international frameworks and treaties, remains critical in shaping a cohesive global patent system that supports innovation while addressing ethical considerations and societal needs. In this dynamic legal and technological landscape, the ability of patent systems to adapt and respond will be crucial in ensuring that they continue to serve as engines of innovation and progress.

Chapter 3. Biotechnology patentability in the EU and US

Biotechnology patentability stands at the intersection of innovation, ethics, and law, significantly impacting public health and economic development. In both the EU and the US, comprehensive legal frameworks have been established to regulate the patentability of biotechnological inventions. These frameworks aim to incentivize innovation while addressing ethical and public interest concerns. However, the rapid pace of technological advancements and differing ethical perspectives lead to ongoing challenges and controversies.

CEU eTD Collection

a. European Union

The EU has established a detailed legal framework for the patentability of biotechnological inventions through various legislative instruments, most notably the European Patent

Convention[88] and the Biotechnology Directive[89]. The Biotechnology Directive is crucial for harmonizing the patent laws of EU member states concerning biotechnological inventions and provides specific provisions that address the unique nature of biotechnology.

Key Provisions of the Biotechnology Directive:

Patentable Biotechnological Inventions: According to Article 3 of the Directive, biotechnological inventions that involve biological material isolated from its natural environment or produced through a technical process are patentable, even if such material previously occurred in nature[90]. This provision ensures that innovations involving genetic engineering and modification can be protected under patent law.

Non-Patentable Inventions: Article 5 of the Directive stipulates that the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot be patented[91]. This provision aligns with ethical considerations that prevent the commercialization of the human genome in its natural state.

Ethical Considerations: Articles 6 and 7 emphasize that inventions whose commercial exploitation would be contrary to public order or morality are not patentable[92]. This includes processes for cloning human beings, modifying the germ line genetic identity of humans, and using human embryos for industrial or commercial purposes[93]. These ethical safeguards ensure that the patent system does not endorse biotechnological practices that could be deemed morally unacceptable.

CEU eTD Collection

[88] Convention on the Grant of European Patents (European Patent Convention), October 5, 1973, art.53, entered into force October 7, 1977; https://www.epo.org/en/legal/epc;
[89] European Parliament and Council Directive 98/44/EC of 6 July 1998 on the Legal Protection of Biotechnological Inventions. 1998. Official Journal L213, 30 July 1998, pp. 13-21.
[90] Supra, art.3.
[91] Supra, art.5.
[92] Supra, art. 6 and 7.
[93] *Ibid.*

Several key cases have shaped the interpretation and application of biotechnology patent law in the EU. These cases highlight the complexities and ethical considerations involved in the patenting of biotechnological inventions.

Harvard Oncomouse Case: The Oncomouse, a genetically modified mouse developed for cancer research, was one of the first genetically modified animals to be considered for patent protection[94]. The European Patent Office (EPO) granted the patent in 1992, but it was subsequently challenged on ethical grounds[95]. The EPO's Technical Board of Appeal ultimately upheld the patent, emphasizing the potential benefits for cancer research[96]. The ruling facilitated advancements in biomedical research by allowing patent protection for genetically modified animals used in disease research. This encouraged investment and innovation in the development of new animal models for studying human diseases.

Brüstle v. Greenpeace: In this case, the Court of Justice of the European Union (CJEU) ruled that inventions involving human embryonic stem cells could not be patented if the use of such cells entailed the destruction of human embryos[97]. The ruling highlights the need to balance innovation in biotechnology with ethical considerations, particularly concerning the use of human embryos. It ensures that ethical concerns are integrated into the legal framework governing biotechnological patents. While it restricts the patentability of processes involving human embryonic stem cells, it encourages researchers to explore alternative methods that do not involve the destruction of embryos, such as induced pluripotent stem cells (iPSCs)[98].

CEU eTD Collection

[94] European Patent Office (EPO). "Decision T 19/90 of the Technical Board of Appeal of 3 October 1990 (Harvard Oncomouse).
[95] *Ibid.*
[96] *Ibid.*
[97] Court of Justice of the European Union (CJEU). "Judgment of the Court (Grand Chamber) of 18 October 2011 (Brüstle v. Greenpeace, Case C-34/10).
[98] Nuffield Council on Bioethics. The Ethics of Patenting DNA: A Discussion Paper. London: Nuffield Council on Bioethics, 2002. https://www.nuffieldbioethics.org/assets/pdfs/The-ethics-of-patenting-DNA-a-discussion-paper.pdf.

Monsanto's Roundup Ready Soybeans: Monsanto's patent on genetically modified soybeans resistant to glyphosate herbicide was another landmark case[99]. The EPO initially granted the patent, but it faced numerous challenges, particularly concerning the scope of patent protection and its implications for farmers[100]. By upholding the patentability of GMOs, the decision encouraged further investment and innovation in agricultural biotechnology. Companies were assured that their significant investments in developing genetically modified crops could be protected by patents[101]. The case also brought to light various environmental and ethical concerns associated with GMOs. Opponents argued that the widespread use of glyphosate-resistant crops could lead to increased herbicide use, environmental damage, and the development of herbicide-resistant weeds[102]. These concerns have sparked ongoing debates about the regulation and use of GMOs in agriculture.

The patentability of biotechnological inventions often raises ethical and moral questions. The European Union's legal framework attempts to balance these concerns by integrating ethical considerations into patent law. The Biotechnology Directive, for instance, excludes from patentability any inventions whose commercial exploitation would be contrary to public order or morality.

Key Ethical Issues:

The patenting of genetic material, living organisms, and human biological materials raises concerns about the commodification of life. The patenting of genetic material and living organisms challenges the intrinsic value of life[103]. By allowing patents on these entities, the law essentially views them as commodities, reducing their inherent worth to their economic

CEU eTD Collection

[99] European Patent Office (EPO). "Decision T 356/93 of the Technical Board of Appeal of 21 February 1995 (Monsanto's Roundup Ready Soybeans)."
[100] *Ibid.*
[101] *Ibid.*
[102] *Ibid.*
[103] Nuffield Council on Bioethics. The Ethics of Patenting DNA: A Discussion Paper. London: Nuffield Council on Bioethics, 2002. https://www.nuffieldbioethics.org/assets/pdfs/The-ethics-of-patenting-DNA-a-discussion-paper.pdf.

value[104]. This perspective is fundamentally at odds with the belief that life should be respected and preserved for its own sake, independent of its commercial potential. Patents confer exclusive rights to inventors, granting them ownership over the patented material. This can lead to situations where companies or individuals control access to essential genetic resources, potentially limiting their use for research, conservation, and public health purposes. For example, the patenting of human genes can restrict access to genetic information that is crucial for medical research and diagnostics. The Nuffield Council on Bioethics emphasizes that such control over genetic material can have significant implications for scientific progress and public health.[105] The commercial exploitation of life forms, particularly human biological materials, raises several ethical issues. The patenting of human genes and tissues can lead to scenarios where these materials are treated as commercial goods, subject to market forces. This commodification can undermine the dignity and sanctity of human life, reducing individuals to mere sources of valuable genetic material. The Nuffield Council on Bioethics points out that the commercialization of human genetic material can lead to ethical dilemmas regarding consent and the fair distribution of benefits derived from genetic research[106]. Public perception of biotechnology patents is significantly influenced by the issue of commodification[107]. There is often considerable public resistance to the idea that life forms can be patented, stemming from a broader discomfort with the notion of commodifying nature. The Nuffield Council on Bioethics highlights that this resistance can lead to a lack of trust in the biotechnology industry and the regulatory frameworks that oversee it[108]. Building public trust requires addressing these ethical concerns and demonstrating that the benefits of biotechnological innovation can be realized without compromising ethical standards[109].

CEU eTD Collection

[104] *Ibid.*
[105] *Ibid.*
[106] *Ibid.*
[107] *Ibid.*
[108] *Ibid.*
[109] *Ibid.*

b. United States

The United States has developed a comprehensive legal framework to address the patentability of biotechnological inventions. This framework is primarily governed by the Patent Act and interpreted through landmark judicial decisions[110]. This section will explore the key provisions and significant court cases that have shaped biotechnology patent law in the U.S., highlighting the complexities and ongoing debates within this dynamic field.

The Patent Act provides the statutory basis for patent law in the United States[111]. It outlines the criteria for patentability, including novelty, non-obviousness, and utility, and defines what constitutes patentable subject matter[112].

Key Provisions:

Patentable Subject Matter: This section states that patents may be granted for any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof[113]. This broad definition encompasses a wide range of biotechnological inventions, from genetically modified organisms to biopharmaceuticals[114].

Utility Requirement: Inventions must have a specific, substantial, and credible utility[115]. This requirement ensures that patents are only granted for inventions that provide a tangible benefit[116].

Written Description and Enablement: The patent application must include a detailed description of the invention, enabling a person skilled in the art to make and use the invention without undue experimentation[117].

CEU eTD Collection

[110] See Note 46.
[111] *Ibid.*
[112] *Ibid.*
[113] See Note 46.
[114] *Ibid.*
[115] *Ibid.*
[116] *Ibid.*
[117] Note 46, section 112.

Landmark Judicial Decisions

Several landmark judicial decisions have significantly influenced the interpretation and application of the Patent Act[118] in the context of biotechnology patents. These cases provide critical insights into the evolving legal landscape and the challenges of balancing innovation with ethical and public policy considerations.

Diamond v. Chakrabarty (1980): This landmark Supreme Court decision marked a turning point in biotechnology patent law[119]. The Court held that genetically modified microorganisms are patentable subject matter under 35 U.S.C. § 101[120], as they are not naturally occurring and involve human ingenuity. The ruling clarified that living organisms, if human-made and not naturally occurring, could be considered patentable inventions. This opened the door for a wide range of biotechnological patents, including genetically modified plants, animals, and microorganisms. The decision provided a significant boost to the thriving biotechnology industry by ensuring that inventors could secure intellectual property rights for their biotechnological innovations.

Mayo Collaborative Services v. Prometheus Laboratories, Inc. (2012): The Supreme Court ruled that a diagnostic method based on the correlation between drug dosages and treatment outcomes is not patentable because it effectively claims a natural law[121]. The ruling reinforced the principle that laws of nature, natural phenomena, and abstract ideas are not patentable. This decision clarified the boundaries of what constitutes patentable subject matter, particularly in the field of medical diagnostics. Moreover, the decision had far-reaching implications for the biotechnology and pharmaceutical industries, where patents on diagnostic methods are common. It raised the bar for patent eligibility, requiring that such methods must involve more than just applying a natural law in a routine and conventional manner.

CEU eTD Collection

[118] See Note 46.
[119] U.S. Supreme Court. Diamond v. Chakrabarty, 447 U.S. 303 (1980).
[120] *Ibid.*
[121] U.S. Supreme Court. Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66 (2012).

Association for Molecular Pathology v. Myriad Genetics, Inc. (2013): In this case, the Supreme Court ruled that naturally occurring DNA sequences cannot be patented simply because they have been isolated[122]. However, complementary DNA (cDNA), which is synthetically created, is patentable because it is not naturally occurring[123]. The ruling clarified that naturally occurring substances, even when isolated, are not patentable. This principle reinforces the distinction between discoveries of natural phenomena and inventions that involve human ingenuity. The decision has had a profound impact on the biotechnology industry and genetic research. It opened access to genetic information, allowing more research and development in genetic testing and personalized medicine without the constraints of gene patents.

J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc. (2001): The Supreme Court held that newly developed plant breeds are patentable under the general utility patent provisions of 35 U.S.C. § 101[124]. Justice Clarence Thomas, writing for the majority, stated that nothing in the text or legislative history of the Plant Patent Act[125] or Plant Variety Protection Act[126] indicated that these acts were intended to be the exclusive means of protecting plant inventions[127]. Thus, the Court affirmed that utility patents could be used to protect plants[128]. The ruling clarified that utility patents can be applied to plants, providing broader intellectual property protection than that available under the PPA and PVPA. This includes protection for a wider range of plant characteristics and genetic modifications. By affirming that plants are patentable under 35 U.S.C. § 101, the decision incentivized greater investment and innovation in agricultural biotechnology[129]. Companies can secure more robust protection for their genetically engineered plants, encouraging further research and development.

CEU eTD Collection

[122] See Note 66
[123] *Ibid.*
[124] U.S. Supreme Court. J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc., 534 U.S. 124 (2001).
[125] Plant Patent Act (PPA): 35 U.S.C. §§ 161-164.
[126] Plant Variety Protection Act (PVPA): 7 U.S.C. §§ 2321-2582.
[127] See Note 105.
[128] See Note 90.
[129] See Note 105.

In re Wands (1988): This Federal Circuit case established important criteria for determining whether a patent application meets the enablement requirement under 35 U.S.C. § 112[130]. The court provided a set of factors to assess whether undue experimentation would be required to practice the claimed invention, which is particularly relevant in the complex field of biotechnology[131]. The case has had a considerable impact on biotechnology patents, where the complexity and unpredictability of the field often make enablement a critical issue[132]. Patent applicants in biotechnology must ensure that their disclosures provide enough detail to meet the enablement requirement, considering the Wands factors. This includes providing sufficient guidance, working examples, and addressing the state of the art to enable skilled practitioners to reproduce the invention.

Amgen Inc. v. Chugai Pharmaceutical Co. (1991): This case addressed the written description requirement under 35 U.S.C. § 112 in the context of biotechnology patents[133]. The Federal Circuit held that a patent applicant must provide a precise definition of the genetic material claimed, sufficient to distinguish it from other materials and to show possession of the claimed invention[134]. The decision reinforced the importance of detailed and specific disclosures in biotechnology patents. Patent applicants must ensure that their applications include sufficient detail to satisfy the written description and enablement requirements, particularly when claiming genetic sequences or complex biotechnological methods.

Merck KGaA v. Integra Lifesciences I, Ltd. (2005): The Supreme Court ruled that the use of patented compounds in preclinical studies, reasonably related to the development and submission of information to the Food and Drug Administration, is exempt from infringement

CEU eTD Collection

[130] U.S. Court of Appeals for the Federal Circuit. In re Wands, 858 F.2d 731 (Fed. Cir. 1988).
[131] *Ibid.*
[132] *Ibid.*
[133] U.S. Court of Appeals for the Federal Circuit. Amgen Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200 (Fed. Cir. 1991).
[134] *Ibid.*

under the "safe harbor" provision of 35 U.S.C. § 271(e)(1)[135]. By interpreting the safe harbor provision broadly, the Supreme Court facilitated the drug development process, allowing researchers to use patented inventions in early-stage research without facing infringement liability[136]. This helps in accelerating the development of new drugs and bringing them to market more efficiently.

Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co. (2010): This Federal Circuit en banc decision clarified the written description requirement under 35 U.S.C. § 112[137]. The court held that the requirement is separate from enablement and requires a patent specification to describe the invention sufficiently to demonstrate that the inventor was in possession of the claimed invention at the time of filing[138]. The decision has significant implications for biotechnology and pharmaceutical patents, where inventions often involve complex biological processes and pathways. Patent applicants in these fields must provide detailed and precise descriptions of their inventions to meet the written description requirement[139].

c. Comparison on biotechnology patentability

The legal frameworks governing the patentability of biotechnological inventions in the EU and US exhibit both significant differences and notable similarities. These frameworks reflect the respective jurisdictions' approaches to balancing innovation, ethical considerations, and public interest.

The EU's biotechnology patentability is primarily governed by the European Patent Convention[140] and the Biotechnology Directive[141]. These instruments harmonize patent laws

CEU eTD Collection

[135] U.S. Supreme Court. Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193 (2005).
[136] *Ibid.*
[137] U.S. Court of Appeals for the Federal Circuit. Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co., 598 F.3d 1336 (Fed. Cir. 2010).
[138] *Ibid.*
[139] *Ibid.*
[140] See Note 39.
[141] See Note 65.

across EU member states and address the unique aspects of biotechnological inventions, incorporating ethical considerations directly into their provisions. In contrast, the US framework is established under the Patent Act[142] and interpreted through landmark judicial decisions. This includes broad provisions for patentable subject matter, utility, and requirements for written descriptions and enablement.

The EU framework integrates ethical considerations more stringently. Article 5 of the Biotechnology Directive excludes the human body and its elements at various stages of formation and development from patentability, emphasizing the protection of human dignity[143]. Moreover, Article 6 excludes inventions whose commercial exploitation would be contrary to public order or morality, such as human cloning and the use of human embryos for industrial purposes[144].The Brüstle v. Greenpeace case illustrates this approach, where the CJEU ruled against the patentability of inventions involving the destruction of human embryos[145]. In contrast, the US framework, while addressing ethical concerns, is generally more permissive. The decision in Myriad Genetics allowed patents on synthetically created complementary DNA (cDNA) but excluded naturally occurring DNA, reflecting a nuanced approach to ethical issues[146].

The EU takes a narrower approach, with strict limitations on patenting genetic material and living organisms. For example, the Harvard Oncomouse case demonstrated the EU's cautious stance, granting patents under significant ethical scrutiny and limiting the scope to ensure compliance with ethical standards[147]. Additionally, the EU excludes certain biotechnological processes that involve ethical concerns, such as those involving human embryos[148]. In contrast,

CEU eTD Collection

[142] See Note 40.
[143] Note 65, art. 5.
[144] Supra, art.6.
[145] See Note 73.
[146] See Note 94.
[147] See Note 70.
[148] See Note 73.

the US framework allows for a broader scope of patentable subject matter, including genetically modified organisms and newly developed plant breeds, as seen in Diamond v. Chakrabarty [149]and J.E.M. Ag Supply cases[150]. This broad scope promotes extensive innovation in biotechnology by providing robust intellectual property protection.

The EU's detailed and multi-layered legal framework, while ensuring rigorous ethical scrutiny, can create legal uncertainty and complexity for inventors and companies. The need for clear guidelines and consistent application of the Biotechnology Directive's ethical provisions across member states is crucial to mitigate these challenges. Inventors must navigate a complex landscape of ethical restrictions, which can limit the scope of patentable inventions and affect the commercialization of biotechnological innovations.

In contrast, the US reliance on judicial decisions for interpreting patent law provides a flexible and adaptive framework that can respond to technological advancements. However, this approach can also lead to unpredictability, as legal precedents may change over time. The case-by-case determination of patent eligibility criteria means that inventors must stay abreast of evolving judicial interpretations to ensure their inventions meet the necessary requirements.

CEU eTD Collection

[149] See Note 91.
[150] See Note 66.

Conclusion

Biotechnology patenting in the EU and the US presents a complex landscape shaped by differing legal frameworks, ethical considerations, and policy objectives. Both jurisdictions aim to foster innovation while balancing public welfare and ethical norms, yet they approach these goals through distinct legal paradigms.

In the EU, the Biotechnology Directive[151] and the European Patent Convention[152] serve as the foundational documents governing biotechnology patents. These frameworks emphasize ethical considerations, particularly concerning the patentability of human genetic material and embryonic stem cells. The Brüstle v. Greenpeace case exemplifies the EU's commitment to integrating ethical concerns, as the Court of Justice of the European Union ruled against the patentability of inventions involving human embryonic stem cells due to the destruction of embryos involved[153].

Conversely, the US framework, primarily guided by the Patent Act[154] and landmark Supreme Court decisions, adopts a more permissive stance. Notable cases such as Diamond v. Chakrabarty[155] and Association for Molecular Pathology v. Myriad Genetics, Inc.[156] have established the patentability of genetically modified organisms and synthetically created DNA sequences, respectively. These rulings underscore the US's broader interpretation of what constitutes patentable subject matter, promoting extensive biotechnological innovations.

Ethical concerns are paramount in the discourse on biotechnology patenting. In the EU, ethical guidelines are explicitly integrated into the legal framework. The Biotechnology Directive prohibits patents on processes for cloning human beings, modifying germ line genetic identity,

[151] See Note 68.
[152] See Note 67.
[153] See Note 76.
[154] See Note 46.
[155] See Note 94.
[156] See Note 66.

CEU eTD Collection

and using human embryos for industrial or commercial purposes[157]. This ethical rigor ensures that biotechnological advancements align with societal values and moral standards.

In contrast, while the US does consider ethical implications, these are often addressed through judicial interpretations rather than explicit statutory provisions. The Supreme Court's decision in Myriad Genetics, which differentiated between naturally occurring DNA and cDNA, reflects an attempt to balance innovation with ethical considerations by excluding naturally occurring genetic sequences from patent eligibility while allowing patents on synthetic DNA[158].

Both jurisdictions face significant challenges in the realm of biotechnology patenting. One major challenge is defining the scope of patentable subject matter. In the EU, the exclusion of the human body and its elements from patentability reflects deep ethical concerns, but it also poses challenges for innovators seeking protection for biotechnological inventions involving human genetic material. The US, on the other hand, struggles with balancing broad patent eligibility with the need to avoid granting patents on natural phenomena and abstract ideas, as highlighted in Mayo Collaborative Services v. Prometheus Laboratories, Inc[159]. Environmental and public health concerns also play a crucial role. The Monsanto's Roundup Ready Soybeans case raised significant issues regarding the environmental impact of genetically modified crops and the ethical implications of their widespread use[160]. These concerns are not limited to the EU, as the US also contends with the environmental and health implications of biotechnological patents.

A comparative analysis of the EU and US patent systems reveals both similarities and divergences. Both jurisdictions require that inventions be novel, involve an inventive step, and be capable of industrial application. However, the interpretation and application of these criteria differ. The EU's emphasis on ethical considerations results in a more restrictive approach to

[157] See Note 68.
[158] See Note 66.
[159] See Note 96.
[160] See Note 78.

CEU eTD Collection

patentability, particularly for biotechnological inventions involving human genetic material and embryonic stem cells. The US, with its broader statutory definitions and judicial precedents, offers a more permissive environment for biotechnology patents.

The handling of software-related inventions also illustrates differences. The EU allows patents on software inventions only when they provide a technical solution to a technical problem, reflecting a narrower approach compared to the US, which applies a two-part test from the Alice Corp. v. CLS Bank International decision to determine the patent eligibility of software-related inventions[161].

Reflecting on these frameworks and their implications, it becomes evident that both the EU and US patent systems strive to strike a balance between encouraging innovation and addressing ethical and public interest concerns. However, the rapid pace of technological advancements in biotechnology continually tests the adaptability of these legal frameworks. We can find it imperative that ongoing dialogue and international cooperation remain central to the evolution of patent law. The integration of ethical considerations, public welfare, and innovative progress must be harmonized to ensure that biotechnological advancements benefit society as a whole.

The legal frameworks governing biotechnology patenting in the EU and US each offer unique strengths and face distinct challenges. By learning from each other's approaches and fostering international cooperation, these jurisdictions can better navigate the complexities of biotechnology patenting, ensuring that legal systems evolve to support innovation while safeguarding ethical standards and public interest. This dynamic interplay between law, ethics, and innovation will continue to shape the future of biotechnology and its contributions to society.

Looking forward, both the EU and US must continue to adapt their legal frameworks to address the evolving landscape of biotechnology. This includes not only refining patent eligibility

[161] See Note 50.

CEU eTD Collection

criteria and ethical guidelines but also ensuring that policies are in place to promote equitable access to biotechnological innovations. The COVID-19 pandemic has underscored the importance of global cooperation in this regard, highlighting the need for mechanisms that ensure the rapid and equitable distribution of life-saving technologies.

In conclusion, the legal frameworks governing biotechnology patenting in the EU and US each offer unique strengths and face distinct challenges. By learning from each other's approaches and fostering international cooperation, these jurisdictions can better navigate the complexities of biotechnology patenting. This dynamic interplay between law, ethics, and innovation will continue to shape the future of biotechnology and its contributions to society. Ensuring that legal systems evolve to support innovation while safeguarding ethical standards and public interest will be critical to maximizing the benefits of biotechnological advancements for all.

CEU eTD Collection

Bibliography

Alice Corp. v. CLS Bank Int'l, 573 U.S. 208 (2014).

Amgen Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200 (Fed. Cir. 1991).

Bornscheuer, U.T., et al. "Engineering the Third Wave of Biocatalysis." Nature, vol. 485, 2012, pp. 185-194; https://www.nature.com/articles/nature11117.

Chen, Guo-Qiang. "Plastics Completely Synthesized by Bacteria: Polyhydroxyalkanoates." In Plastics from Bacteria, Springer, Berlin, Heidelberg, 2009, pp. 17-37; https://www.researchgate.net/publication/225712341_Plastics_Completely_Synthesized_by_Bacteria_Polyhydroxyalkanoates/link/54b66e950cf2e68eb27e8b69/download?_tp=eyJjb250ZXh0Ijp7ImZpcnN0UGFnZSI6InB1YmxpY2F0aW9uIiwicGFnZSI6InB1YmxpY2F0aW9uIn19.

Chen, Keping, et al. "CRISPR/Cas9 Genome Editing and Precision Plant Breeding in Agriculture." Annual Review of Plant Biology, vol. 70, 2019, pp. 667-697; https://www.researchgate.net/publication/331538032_CRISPRCas_Genome_Editing_and_Precision_Plant_Breeding_in_Agriculture.

Chen, Wilfred, Ashok Mulchandani, and Mark A. Deshusses. "Environmental Biotechnology: Challenges and Opportunities for Chemical Engineers." *AIChE Journal* 51, no. 3 (2005): 690–695.

Church, George, and Ed Regis. Regenesis: How Synthetic Biology Will Reinvent Nature and Ourselves. New York: Basic Books, 2012; http://dk.fdv.uni-lj.si/db/pdfs/TiP2014_5_Pustovrh1.pdf.

Collins, Francis S., et al. "A Vision for the Future of Genomics Research." Nature 422, no. 6934 (2003): 835-847; https://www.nature.com/articles/nature01626.

Convention on the Grant of European Patents (European Patent Convention), October 5, 1973, entered into force October 7, 1977.

Court of Justice of the European Union (CJEU). "Judgment of the Court (Grand Chamber) of 18 October 2011 (Brüstle v. Greenpeace, Case C-34/10).

Crick, Francis. "Molecular Structure of Nucleic Acids: A Structure for Deoxyribose Nucleic Acid." April 25, 1953. - published papers and official documents - Linus Pauling and the race for DNA: A documentary history, April 25, 1953. http://scarc.library.oregonstate.edu/coll/pauling/dna/papers/corr68.11-reprint-19530425.html.

Daniel, Carlton. "UK Supreme Court Rules on AI and Patent Applications - Patent - Worldwide." UK Supreme Court Rules On AI And Patent Applications - Patent - Worldwide, January 10, 2024. https://www.mondaq.com/uk/patent/1409936/uk-supreme-court-rules-on-ai-and-patent-applications.

CEU eTD Collection

Doudna, Jennifer A., and Emmanuelle Charpentier. "The New Frontier of Genome Engineering with CRISPR-Cas9." Science 346, no. 6213 (2014); https://www.science.org/doi/10.1126/science.1258096.

European Parliament and Council Directive 98/44/EC of 6 July 1998 on the Legal Protection of Biotechnological Inventions. 1998. Official Journal L213, 30 July 1998, pp. 13-21.

European Patent Office (EPO). "Decision T 19/90 of the Technical Board of Appeal of 3 October 1990 (Harvard Oncomouse).

European Patent Office (EPO). "Decision T 356/93 of the Technical Board of Appeal of 21 February 1995 (Monsanto's Roundup Ready Soybeans)."

European Patent Office. "Red, White, Green: Biotechnology Patents." Last modified 2023. https://www.epo.org/en/news-events/in-focus/biotechnology-patents/red-white-green.

Fortman, J.L., et al. "Biofuel Alternatives to Ethanol: Pumping the Microbial Well." Trends in Biotechnology, vol. 26, no. 7, 2008, pp. 375-381; https://www.researchgate.net/publication/313655878_Biofuel_alternatives_to_ethanol_pumping_the_microbial_well/link/58c2f5f492851c0ccbf14056/download.

Frangoul, Haydar, et al. "CRISPR-Cas9 Gene Editing for Sickle Cell Disease and β-Thalassemia." The New England Journal of Medicine, vol. 384, 2021, pp. 252-260; https://www.nejm.org/doi/full/10.1056/NEJMoa2031054.

Gregor Mendel. "Gregor Mendel's 'Experiments in Plant Hybridization.'" Gregor Mendel's "Experiments in Plant Hybridization" | Villanova University, 1866. https://www1.villanova.edu/villanova/president/university_events/mendelmedal/aboutmendel/experiments.html.

Harrison, C. EPO revokes Broad's CRISPR patent. Nat Biotechnol 36, 209 (2018). https://doi.org/10.1038/nbt0318-209b; and "CRISPR Patent Interference Updates." Broad Institute, March 15, 2016. https://www.broadinstitute.org/what-broad/areas-focus/project-spotlight/crispr-patent-interference-updates.

Infante, Deliana. "AI-Powered Genomic Analysis: Revolutionizing the Detection of Genetic Mutations." News, November 8, 2023. https://www.news-medical.net/health/AI-Powered-Genomic-Analysis-Revolutionizing-the-Detection-of-Genetic-Mutations.aspx#:~:text=AI%20algorithms%2C%20such%20as%20machine,on%20training%20from%20large%20datasets.

Innovative Governance Models for Emerging Technologies. Chapter 9. Properly Paced or Problematic: Examining Past and Present Governance of GMOs in the United States. Kuzma, J.; https://www.researchgate.net/publication/310606866_Innovative_Governance_Models_for_Emerging_Technologies_Chapter_9_Properly_Paced_or_Problematic_Examining_Past_and_Present_Governance_of_GMOs_in_the_United_States_Kuzma_J.

James, Clive. 2014. Global Status of Commercialized Biotech/GM Crops: 2014. ISAAA Brief No. 49. ISAAA: Ithaca, NY; https://www.isaaa.org/resources/publications/briefs/49/download/isaaa-brief-49-2014.pdf.

CEU eTD Collection

Jinek, M., et al. (2012). "A Programmable Dual-RNA-Guided DNA Endonuclease in Adaptive Bacterial Immunity." Science, 337(6096), 816-821; https://www.science.org/doi/10.1126/science.1225829.

Joyner, Michael J., and Nigel Paneth. "Promises, Promises, and Precision Medicine." Journal of Clinical Investigation 129, no. 3 (2019): 946-948; https://www.jci.org/articles/view/126119.

Kanissery, Ramdas Gopinath, and Gerald K. Sims. "Biostimulation for the Enhanced Degradation of Herbicides in Soil." Applied and Environmental Soil Science, September 15, 2011. https://www.hindawi.com/journals/aess/2011/843450/.

Lane, Nick. The Unseen World: Reflections on Leeuwenhoek (1677) 'concerning little animals' | philosophical transactions of the royal society B: Biological Sciences, April 15, 2015. https://royalsocietypublishing.org/doi/10.1098/rstb.2014.0344.

Leavy, Olive. "The Birth of Monoclonal Antibodies." Nature News, December 2, 2016; https://www.nature.com/articles/ni.3608.

Louis Pasteur. "Pasteur's Papers on the Germ Theory The Physiological Theory Of Fermentation." Pasteur's papers on the germ theory, n.d. https://biotech.law.lsu.edu/cphl/history/articles/pasteur.htm.

Mashing and Fermenting in Deep Time Uncorking the Past: The Quest for Wine, Beer, and Other Alcoholic Beverages. By Patrick E. McGovern. Berkeley: University of California Press,
2009; https://www.researchgate.net/publication/259707908_Mashing_and_Fermenting_in_Deep_Time_Uncorking_the_Past_The_Quest_for_Wine_Beer_and_Other_Alcoholic_Beverages_By_Patrick_E_McGovern_Berkeley_University_of_California_Press_2009.

Manual of Patent Examining Procedure (MPEP) Ninth Edition, Revision 07.2022. https://www.uspto.gov/web/offices/pac/mpep/index.html.

Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66 (2012).

Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193 (2005).

National Research Council (US) Committee on Opportunities in Biotechnology for Future Army Applications. "Vaccination - Opportunities in Biotechnology for Future Army Applications." Opportunities in Biotechnology for Future Army Applications., January 1, 2001. https://www.ncbi.nlm.nih.gov/books/NBK207433/.

New revised version of the Guidelines for Examination in the European Patent Office dated 01 March 2021; https://www.boehmert.de/en/new-revised-version-of-the-guidelines-for-examination-in-the-european-patent-office-dated-01-march-2021/.

Nick Lane. The Unseen World: Reflections on Leeuwenhoek (1677) 'concerning little animals' | philosophical transactions of the royal society B: Biological Sciences, April 15, 2015. https://royalsocietypublishing.org/doi/10.1098/rstb.2014.0344.

CEU eTD Collection

Nuffield Council on Bioethics. The Ethics of Patenting DNA: A Discussion Paper. London: Nuffield Council on Bioethics, 2002. https://www.nuffieldbioethics.org/assets/pdfs/The-ethics-of-patenting-DNA-a-discussion-paper.pdf.

Odjegba, Victor J., and Ishola O. Fasidi. "Phytoremediation of Heavy Metals by Eichhornia Crassipes - Environment Systems and Decisions." SpringerLink, July 1, 2007. https://link.springer.com/article/10.1007/s10669-007-9047-2.

Plant Patent Act (PPA): 35 U.S.C. §§ 161-164.

Plant Variety Protection Act (PVPA): 7 U.S.C. §§ 2321-2582.

Smith, Roberta H. "Plant Tissue Culture: Techniques and Experiments." Academic Press, 2012; https://books.google.co.ve/books?id=SUbi3gCg2PsC&pg=PA1&source=gbs_toc_r&cad=2#v=onepage&q&f=false.

Stokes, Jonathan M., et al. "A Deep Learning Approach to Antibiotic Discovery." Cell, vol. 180, no. 4, 2020, pp. 688-702.e13; https://www.sciencedirect.com/science/article/pii/S0092867420301021?via%3Dihub

The Human Genome Project." Genome.gov, 2003. https://www.genome.gov/human-genome-project.

Title 35, United States Code, § 101.

U.S. Court of Appeals for the Federal Circuit. Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co., 598 F.3d 1336 (Fed. Cir. 2010).

U.S. Supreme Court. J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc., 534 U.S. 124 (2001).

U.S. Court of Appeals for the Federal Circuit. In re Wands, 858 F.2d 731 (Fed. Cir. 1988).

USPTO: Artificial Intelligence Systems Cannot Legally Invent." McDermott Will & Emery, January 24, 2023. https://www.mwe.com/insights/uspto-artificial-intelligence-systems-cannot-legally-invent/.

U.S. Supreme Court. Diamond v. Chakrabarty.

Vidali, M. "Bioremediation. An Overview." Pure and Applied Chemistry, vol. 73, no. 7, 2001, pp. 1163-1172; https://www.degruyter.com/document/doi/10.1351/pac200173071163/html?lang=en.

World Intellectual Property Organization. "Patent Cooperation Treaty (PCT)." 2021; https://www.wipo.int/publications/en/details.jsp?id=4548.

CEU eTD Collection

WIPO. Intellectual property offices and sustainable innovation, n.d. https://www.wipo.int/edocs/pubdocs/en/wipo-pub-rn2023-10-en-intellectual-property-offices-and-sustainable-innovation.pdf.

Yoshida, Shosuke, et al. "A bacterium that degrades and assimilates poly(ethylene terephthalate)." Science, vol. 351, no. 6278, 2016, pp. 1196-1199; https://www.researchgate.net/publication/297743309_A_bacterium_that_degrades_and_assimilates_polyethylene_terephthalate/link/5a857fa9a6fdcc201ba0f53f/download.

Zeder, Melinda A. "Domestication and early agriculture in the Mediterranean Basin: Origins, diffusion, and impact." Proceedings of the National Academy of Sciences 105, no. 33 (2008): 11597-11604; https://www.pnas.org/doi/full/10.1073/pnas.0801317105.

CEU eTD Collection