IRSHAD
International Journal of Law and Policy | Volume: 3, Issue: 9
2025

Legal Nature and Classification of Biotechnology Objects in Private Law

Mamanazarov Sardor
Tashkent State University of Law

Abstract

This comprehensive study examines biotechnology objects as fundamental subjects of contemporary private (civil) law relations, analyzing their distinctive characteristics, comprehensive classification systems, and evolving legal frameworks across multiple jurisdictions. The research employs comparative legal analysis methodology to investigate the complex dialectical relationship between natural and artificial elements inherent in biotechnology objects, their unique reproducibility capabilities, and the multifaceted risk factors they present to legal systems worldwide. The study systematically reveals that biotechnology objects constitute an exceptionally complex legal category requiring highly specialized jurisprudential approaches due to their inherent dual nature, which fundamentally combines natural biological materials with sophisticated technological intervention processes. The comprehensive classification framework developed encompasses three primary categories: biological materials including genetic sequences and cellular preparations, biotechnological processes encompassing genetic engineering methodologies, and biotechnological products including pharmaceutical preparations and diagnostic systems, each demanding distinct intellectual property protection mechanisms and regulatory oversight approaches.

Keywords: Biotechnology Objects, Civil Law Regulation, Intellectual Property Protection, Patent Law, Biological Materials, Genetic Engineering, Bioethics Frameworks, Legal Classification Systems

APA Citation:

Mamanazarov, S. (2025). Legal Nature and Classification of Biotechnology Objects in Private Law. *International Journal of Law and Policy, 3* (9), 01-20. https://doi.org/10.59022/ijlp.362

I. Introduction

Contemporary jurisprudence extensively investigates the complex determination and systematic classification of biotechnology objects within the evolving landscape of modern legal relations, representing one of the most challenging frontiers in intellectual property law. Legal relationships fundamentally associated with this rapidly advancing technological field possess extraordinary significance not merely at national levels but increasingly demand coordinated international regulatory approaches and harmonized legal frameworks. Understanding the intricate legal nature of biotechnology objects constitutes an absolutely essential component for developing and systematically improving modern legal systems worldwide, particularly as these systems grapple with unprecedented technological innovations. This complex issue assumes particular critical importance because groundbreaking scientific achievements in biotechnology consistently test and challenge the traditional boundaries of established legal categories, simultaneously demanding innovative legal approaches and adaptive regulatory mechanisms.

Modern biotechnology arguably represents the most strategically important technological field in contemporary society due to its profound and transformative impact on healthcare systems, agricultural productivity, industrial manufacturing processes, and global food security initiatives (Singh, 2015). In this rapidly evolving context, accurately determining the comprehensive legal status of biotechnology objects holds tremendous significance not only from theoretical jurisprudential perspectives but also from practical implementation and enforcement standpoints affecting billions of individuals worldwide. The American Chemical Society provides a foundational definition recognizing biotechnology as the systematic application of living organisms, biological systems, or natural processes by various industrial sectors to advance scientific knowledge about life itself and to improve materials and organisms including pharmaceuticals, agricultural crops, and livestock breeding programs. This comprehensive definition strategically emphasizes the multifaceted functional aspects of biotechnology objects while simultaneously demonstrating their fundamental orientation toward practical real-world applications with measurable societal benefits.

According to the authoritative European Biotechnology Federation, biotechnology fundamentally represents the sophisticated integration of natural sciences with living organisms, cellular structures, their constituent molecular components, and precisely engineered molecular analogs specifically designed for developing innovative products and specialized services across multiple economic sectors. This nuanced definition effectively reflects the remarkably multifaceted nature of biotechnology objects while

clearly illustrating their comprehensive incorporation of various hierarchical levels of biological systems ranging from molecular to organismal complexity.

When providing systematic legal characterization of biotechnology objects within contemporary civil (private) law frameworks, legal scholars and practitioners must carefully consider several highly specific distinguishing features that fundamentally differentiate these objects from traditional categories (Ogbogu, 2017). These distinctive characteristics unequivocally distinguish biotechnology objects from conventional industrial property objects and categorically require specialized legal approaches incorporating novel jurisprudential concepts. These unique characteristics conclusively demonstrate the fundamental uniqueness of biotechnology objects and their categorical demand for specialized attention within comprehensive legal regulation frameworks.

The increasingly complex relationship between biotechnology innovation and established intellectual property rights systems has become progressively more intricate as revolutionary scientific advances systematically push the traditional boundaries of conventional patent law doctrine and established property rights concepts. The fundamental intersection of natural biological discovery processes with human technological invention in biotechnology creates uniquely challenging problems for legal classification systems and established intellectual property protection mechanisms. This mounting complexity becomes further compounded by significant ethical considerations surrounding the fundamental patentability of natural life forms, human genetic materials, and essential biological processes.

The rapidly expanding global biotechnology market, conservatively valued at over 1.5 trillion dollars in 2023 with projected annual growth rates exceeding twelve percent, clearly demonstrates the critical economic significance of establishing comprehensive legal frameworks for biotechnology objects across international markets. The unprecedented pace of innovation in revolutionary areas including CRISPR gene editing technologies, synthetic biology applications, personalized medicine approaches, and advanced therapeutic modalities requires legal systems to adapt quickly to emerging technological realities while maintaining fundamental consistency with well-established intellectual property principles and constitutional protections.

Recent landmark legal cases, including the groundbreaking Association for Molecular Pathology v. Myriad Genetics decision and the foundational Diamond v. Chakrabarty precedent, have established critically important legal precedents for biotechnology patentability determinations across multiple jurisdictions worldwide. These influential judicial decisions clearly highlight the ongoing fundamental tension between promoting technological innovation through robust patent protection systems and ensuring equitable public access to fundamental biological processes, naturally

occurring genetic sequences, and essential medical technologies.

The significant research gap in current legal literature centers specifically on developing comprehensive legal classification systems for rapidly emerging biotechnology objects and establishing appropriate regulatory frameworks that can effectively balance competing interests (Staunton et al., 2022). While existing scholarly studies examine specific limited aspects of biotechnology law, insufficient comprehensive analysis exists regarding how traditional civil law concepts can be systematically applied to the complete spectrum of modern biotechnology objects, ranging from basic genetic materials to complex integrated biotechnological systems.

The primary aim of this comprehensive study involves developing a systematic legal framework for effectively classifying biotechnology objects within established civil law systems while thoroughly analyzing their unique distinguishing characteristics that fundamentally separate them from traditional property objects. The specific research objectives systematically include examining the complex dialectical relationship between natural and artificial elements within biotechnology objects, analyzing current classification systems and evaluating their adequacy for emerging technologies, comprehensively evaluating existing legal protection mechanisms and their demonstrated effectiveness, and identifying critical gaps in current legal frameworks while proposing innovative adaptive solutions.

The fundamental research questions systematically addressed include: How do biotechnology objects fundamentally challenge traditional civil law categories of property rights and ownership concepts? What comprehensive classification framework most effectively captures the remarkable diversity of modern biotechnology objects across multiple application domains? How can contemporary legal systems effectively balance innovation incentives with ethical considerations and public interest protections in biotechnology regulation? What specific mechanisms can ensure international harmonization while respecting national sovereignty over ethical and cultural considerations? The profound significance of this comprehensive study lies in its substantial potential to inform evidence-based policy development for biotechnology regulation across multiple jurisdictions, contribute meaningfully to the progressive harmonization of international biotechnology law principles, provide authoritative guidance for patent offices and regulatory agencies dealing with emerging biotechnology objects, and establish foundational principles for future legal developments in this rapidly evolving field.

II. Methodology

This comprehensive research employs a sophisticated multi-methodological approach systematically combining rigorous doctrinal legal analysis, extensive

comparative legal analysis, systematic review methodology, and empirical data analysis techniques. The study systematically examines comprehensive primary legal sources including constitutional provisions, statutory frameworks, administrative regulations, judicial decisions, and international treaty obligations from major jurisdictions including the United States, European Union member states, Germany, United Kingdom, Australia, Japan, China, Canada, and emerging biotechnology markets. The extensive comparative legal analysis specifically focuses on jurisdictions with well-established biotechnology legal frameworks, systematically examining how different legal systems approach biotechnology object classification, patent protection mechanisms, regulatory oversight procedures, and enforcement strategies. The comprehensive systematic review covers scholarly literature published between 2010-2025, with particular emphasis on recent developments in biotechnology law, emerging technologies, and international harmonization efforts.

Database searches systematically included Westlaw International, LexisNexis Academic, Google Scholar, PubMed, specialized patent databases including USPTO, EPO, WIPO Global Brand Database, and regional patent office databases. Search terms encompassed biotechnology patents, genetic materials, synthetic biology, CRISPR technology, biosimilars, nanobiotechnology, and related legal terminology across multiple languages. The comprehensive case study analysis examines landmark judicial decisions that have fundamentally shaped biotechnology law development, including Diamond v. Chakrabarty (1980), Moore v. Regents of the University of California (1990), Association for Molecular Pathology v. Myriad Genetics (2013), and recent CRISPR patent disputes involving University of California versus Broad Institute (2025). These cases provide crucial insights into judicial reasoning regarding biotechnology object classification, patentability standards, and ethical considerations.

The research methodology incorporates detailed analysis of international patent classification systems, particularly the World Intellectual Property Organization International Patent Classification system, European Patent Office classification schemes, and national patent office classification frameworks. This comprehensive analysis reveals how biotechnology objects are currently categorized within existing intellectual property frameworks and systematically identifies areas where current classification schemes prove inadequate for emerging technologies. Expert interviews were systematically conducted with twenty-five patent attorneys specializing in biotechnology, fifteen biotechnology researchers from academic institutions, ten regulatory officials from patent offices, and eight industry representatives from major biotechnology companies. This qualitative data substantially supplements the doctrinal analysis and provides essential real-world perspectives on the practical effectiveness of current legal frameworks.

The study employs a comprehensive framework analysis approach to

systematically categorize biotechnology objects according to multiple criteria including material composition, structural complexity levels, origin classification (natural versus artificial), application fields, regulatory requirements, and available protection mechanisms. This multidimensional classification system enables comprehensive analysis of how different types of biotechnology objects interact with various areas of civil law. Statistical analysis included comprehensive review of international patent databases covering biotechnology applications from 2015-2024, examining trends in patent grants, rejection rates, litigation outcomes, and licensing agreements. Quantitative analysis reveals significant patterns in how biotechnology objects are classified and protected across different jurisdictions, strengthening qualitative legal analysis with empirical evidence.

III. Results

A. Fundamental Characteristics of Biotechnology Objects

The comprehensive research systematically identifies four fundamental distinguishing characteristics that categorically separate biotechnology objects from traditional civil law objects across all examined jurisdictions. First, the dialectical relationship between naturalness and artificiality represents the most critically important characteristic of biotechnology objects within contemporary legal frameworks. According to authoritative guidelines from the German Patent Office, biological material inventions are generally considered worthy of patent protection under specific circumstances meeting established criteria. While biotechnology objects are fundamentally created based on natural biological materials, they must necessarily be created through sophisticated technological intervention processes and produce something that differs substantially from the original natural source material in terms of function, structure, or application.

This fundamental dialectic plays an absolutely central role in biotechnology object patentability determinations across multiple jurisdictions, requiring patent examiners to carefully evaluate the degree of human intervention and the significance of modifications made to natural materials. The European Patent Office Guidelines specifically require that biotechnology inventions demonstrate technical character and reproducibility while contributing to solving technical problems through non-obvious means. Second, reproducibility capability constitutes the second critically important characteristic of biotechnology objects presenting unique challenges for intellectual property law systems. Biological materials inherently possess the natural ability to reproduce themselves autonomously or reproduce within appropriate biological systems through natural cellular processes. This distinctive characteristic creates fundamental problems in applying traditional patent system concepts to biotechnological innovations because living

organisms retain their inherent ability to reproduce themselves even when subject to patent protection.

This situation clearly demonstrates the absolute necessity of adapting traditional patent system frameworks specifically for biotechnology objects, requiring new approaches to patent scope, infringement analysis, and enforcement mechanisms (Potter Clarkson, 2024). The reproducibility challenge has led to development of specialized licensing frameworks and novel approaches to patent claim drafting in biotechnology cases. Third, elevated risk and uncertainty levels represent the third characteristic of biotechnology objects requiring specialized legal consideration. These sophisticated objects often present significantly elevated risk levels to human health, environmental safety, and social welfare, with their long-term effects potentially not being fully predictable through current scientific methodologies. According to Article 1a of the German Patent Law, the human body at various stages of its formation and development, including reproductive cells, cannot be subject to patent protection.

This categorical restriction is specifically imposed due to fundamental ethical and social concerns regarding the commodification of human life and the potential for exploitation of vulnerable populations. Similar restrictions exist across multiple jurisdictions, though with varying scope and specific applications. Fourth, elevated ethical and social significance constitutes the fourth critically important characteristic requiring careful balancing of competing interests. European Patent Office patent standards explicitly prohibit patent grants for inventions that would be contrary to public order principles or accepted morality standards within European societies. Complex issues including genetic engineering applications, genetic testing methodologies, and protection of human subjects in research raise fundamental ethical questions that must be systematically addressed.

B. Comprehensive Classification of Biotechnology Objects

1. Classification by material nature and composition

The comprehensive research reveals a sophisticated classification system based on fundamental material composition and structural characteristics. Biological materials comprise the first major category, systematically including genetic materials such as DNA sequences, genes, genome fragments, plasmids, and other nucleic acid structures, which serve as fundamental building blocks of biotechnological research and development activities. Genetic materials and DNA sequences enable revolutionary applications including early disease detection through genetic screening, advanced gene therapy treatment modalities, creation of new and highly effective pharmaceutical drugs, and improvement of plant varieties to increase agricultural productivity, and development of personalized treatment methods tailored to individual genetic profiles. The potential

applications continue expanding as scientific understanding advances and new technologies emerge.

The complex legal status of genetic materials as civil law objects presents multifaceted challenges requiring careful analysis. In the landmark Association for Molecular Pathology v. Myriad Genetics case (2013), the United States Supreme Court definitively ruled that naturally occurring biological relationships and isolated DNA sequences extracted from natural sources are not suitable for patent protection under current law. This groundbreaking decision systematically invalidated Myriad Genetics company's controversial patents on BRCA1 and BRCA2 genes associated with hereditary breast and ovarian cancer susceptibility. However, according to the specific court decision, synthetic DNA sequences created through human intervention, including complementary DNA and artificially designed genetic constructs, can be subject to patent protection if they meet traditional patentability requirements.

In the European Union, genetic materials can be patented under carefully defined conditions based on the comprehensive Biotechnological Inventions Directive (98/44/EC), which attempts to balance innovation incentives with ethical considerations and public access to essential genetic information (Directive 98/44/EC, 1998). China's Civil Code Article 1009, adopted on May 28, 2020, strictly regulates research activities related to human DNA modification and genetic engineering, reflecting growing international concern about genetic manipulation technologies. Cellular lines and cellular preparations form a critically important component of this category and are extensively used in medical research, pharmaceutical development, and biotechnology manufacturing processes. Cellular lines play particularly important roles in modern biotechnology for systematically testing whether new pharmaceutical drugs are harmful or beneficial to human health, conducting comprehensive studies of cancer diseases and developing novel treatment approaches, developing effective vaccines against viral diseases and emerging pathogens, and restoring damaged tissues and organs through advanced stem cell technologies.

The legal status of these complex materials often becomes highly complicated because they involve sophisticated combinations of natural biological elements with artificial modification processes (Moore v. Regents of the University of California, 1990). Specifically, in the influential Moore v. Regents case, the California Supreme Court definitively rejected the patient's claimed property rights over his own biological cells used for research purposes. John Moore specifically claimed the legal right to benefit financially from patented products (Mo cell line) developed based on his own lymph node cells, but the court systematically rejected his claim, establishing important precedent regarding patient rights in biological materials (Moore v. Regents of the University of California, 1990). This decision continues to influence biotechnology law

development and patient rights discussions.

Microorganisms are universally considered classic objects of the biotechnology field across all major jurisdictions. This comprehensive group systematically includes bacteria and other prokaryotic organisms, fungi (including various yeast species), algae, protozoa, viruses, prions, and other microscopic biological entities. According to the foundational United States Supreme Court decision in Diamond v. Chakrabarty (1980), the fundamental principle "anything under the sun made by man" specifically applies to the biotechnology field. This landmark precedent created an absolutely essential foundation for determining the artificial nature of biotechnology objects and established crucial principles for biotechnology patentability that continue influencing legal developments worldwide. In this precedential case, Ananda Chakrabarty successfully obtained patent protection for a genetically engineered bacterium capable of breaking down crude oil for environmental remediation purposes.

The Supreme Court ruled 5-4 in favor of patentability, emphasizing that "anything under the sun that is made by man" can be patented if it meets traditional patentability requirements. This decision became a fundamental milestone in biotechnology law development and subsequently opened pathways for patenting numerous other biotechnology objects. The practical significance of microorganisms includes enabling production of life-saving medicines such as penicillin and streptomycin, preparation of food products including vinegar, beer, and yogurt, breakdown of oil and harmful substances for environmental remediation, production of industrial enzymes for manufacturing processes, and creation of environmentally clean fuels including ethanol and biogas (Costa, 2024).

Plant and animal tissues also belong to the biological materials category and are extensively utilized in regenerative medicine and tissue engineering applications. Pure frozen tissue represents ideal samples for RNA extraction processes, because genetic material in FFPE tissues becomes degraded due to formalin-induced cross-linking between nucleic acids. Microorganism metabolites also constitute an integral part of this category and often play crucial roles in industrial biotechnology applications. According to comprehensive guidelines from IP Australia, patents can cover a wide range of biological inventions, including isolated bacteria and other prokaryotes, fungi, plant cells, protozoa, plasmids, viruses, and prions. This broad coverage demonstrates the diversity of the biological materials category and the complexity of their legal protection requirements.

2. Classification by application field and advanced color-based taxonomy

The research identifies a highly sophisticated color-based classification system that effectively reflects both complex scientific-technical processes and comprehensive legal

regulatory frameworks across multiple jurisdictions (Costa, 2024; Green-eNotes, 2023). Red biotechnology systematically encompasses medical-pharmaceutical applications, representing the most economically significant and legally complex sector of biotechnology. This comprehensive category includes gene therapy vectors and delivery systems, cell therapy preparations and regenerative medicine products, monoclonal antibodies and recombinant proteins, diagnostic test systems and advanced biosensors, personalized medicine tools and pharmacogenomics applications, vaccines and immunotherapy preparations, and orphan drugs for rare diseases.

Safety and efficacy evaluation of red biotechnology products follows exceptionally stringent standards established by regulatory authorities. The Food and Drug Administration in the United States and the European Medicines Agency in the European Union implement comprehensive clinical testing requirements and rigorous licensing procedures designed to ensure patient safety while facilitating innovation. Patent protection in this sector typically extends for twenty years from filing date, with possible extensions under specific circumstances, while biosimilar products benefit from abbreviated development and approval procedures designed to increase competition and reduce healthcare costs. Products developed specifically for rare diseases receive special orphan drug status, providing manufacturers with significant financial incentives and regulatory advantages including market exclusivity periods and tax credits.

As of May 2024, the FDA has approved fifty-three biosimilar products, while the European Medicines Agency has approved nearly one hundred biosimilar products, reflecting the growing importance of follow-on biologics in healthcare systems. These approval numbers continue increasing as patent protections expire on innovative biologics and competitive pressures drive development of similar products. Biosimilar manufacturers and regulatory authorities conduct extensive research on intellectual property protections and abbreviated approval pathways, demonstrating that simplified regulatory approval procedures for biosimilars are specifically designed to encompass intellectual property protection, encourage competition, and reduce pharmaceutical prices while maintaining safety standards (Bergin, 2024).

Green biotechnology focuses specifically on agricultural applications and plays an absolutely crucial role in ensuring global food security for growing world populations (Costa, 2024). This comprehensive category systematically includes genetically modified plants engineered for improved characteristics, biopesticides derived from natural sources, microbial fertilizers that enhance soil nutrition, probiotic preparations for plant and animal health, and stress-resistant plant varieties adapted to climate change. Green biotechnology applications can demonstrably increase agricultural productivity by six to thirty percent, significantly reduce pesticide usage and environmental contamination, facilitate adaptation to climate change through drought-resistant crops, and improve

nutritional value of food products through biofortification (Green-eNotes, 2023). Global approaches to genetically modified organisms vary significantly among different jurisdictions.

The United States and Canada have adopted relatively permissive regulatory approaches based primarily on product characteristics rather than production methods, while the European Union maintains strict safety and environmental assessment requirements emphasizing precautionary principles. In developing countries, particularly India and Mexico, genetically modified crops such as Bt cotton have demonstrated positive economic results including increased farmer incomes and reduced pesticide usage (Kathage & Qaim, 2012; Traxler et al., 2001). Legal regulation in green biotechnology encompasses genetically modified organism safety assessments, environmental release permits and monitoring requirements, plant breeder's rights and variety protection systems, and intellectual property protection mechanisms including utility patents and plant variety protection. International trade agreements increasingly include specific requirements for genetically modified organism labeling and certification to facilitate trade while respecting national regulatory preferences.

White biotechnology represents industrial applications systematically using biological processes and organisms in manufacturing and chemical production (Environmental and Energy Study Institute, 2024). Main objects systematically include biofermentation processes and industrial enzymes, bioplastics and biodegradable polymer materials, biotechnological production of chemical substances and intermediates, biofuels including ethanol, biodiesel, and biogas, and specialized industrial catalysts for green chemistry applications. Technologies in white biotechnology constitute more than one-third (36.1%) of global biotechnology patents, with Japan, China, Germany, and Denmark leading in this direction through substantial research investments and supportive regulatory policies. Environmental benefits include reducing carbon dioxide emissions by fifty to eighty percent, decreasing energy consumption by twenty to forty percent, reducing water usage in manufacturing processes, and minimizing industrial waste generation.

Legal regulation in this sector encompasses intellectual property protection for industrial processes, manufacturing standards and quality control requirements, environmental regulations for industrial biotechnology, and waste management rules designed to ensure sustainable production. The distinctive characteristic of white biotechnology lies in its ability to balance environmental requirements with economic efficiency, leading many countries to implement tax incentives and grant programs supporting this sector. Blue biotechnology applies biological resources obtained from marine organisms to medicine, food production, and industrial applications. Main objects systematically include medicines derived from marine organisms with unique bioactive

properties, cosmetics and health products utilizing marine extracts, food supplements such as omega-3 fatty acids and spirulina, specialized marine enzymes for industrial applications, and aquaculture and mariculture technologies for sustainable seafood production.

Ninety percent of marine biodiversity remains scientifically unstudied, offering tremendous potential for discovering new biotechnological products with novel properties and applications. Unique characteristics of marine organisms, including adaptation to extreme pressures and temperatures, serve as sources of novel enzymes and biologically active compounds with potential pharmaceutical and industrial applications. Legal aspects include international water resource rights under the Law of the Sea Convention, benefit-sharing arrangements under the Nagoya Protocol, marine protected area regulations, and traditional knowledge rights of indigenous coastal communities. Blue biotechnology involves complex intersections of maritime law, environmental law, and intellectual property law requiring specialized expertise and international coordination.

Purple biotechnology encompasses the legal and ethical dimensions of biotechnology development, including intellectual property issues and patent law, processes related to living organisms and genetic materials, bioprotection and safety measures for laboratory and industrial settings, and ethical standards and social responsibility frameworks guiding biotechnology research and development. Purple biotechnology serves the essential function of coordinating ethical and legal aspects in biotechnology development, creating necessary balance between scientific advancement and societal concerns. This field plays crucial roles in creating harmony between biotechnology innovation and social acceptance through transparent governance mechanisms and stakeholder engagement processes.

3. Classification by legal protection type and intellectual property mechanisms

The comprehensive research reveals three primary legal protection mechanisms with distinct characteristics and applications. Patent-protected objects systematically include biotechnological inventions meeting three fundamental patentability criteria: novelty, inventive step (non-obviousness), and industrial applicability (utility). Patent protection grants owners exclusive rights to use, sell, manufacture, and import protected objects for specified periods, typically twenty years from filing date. This protection type is most widely used and economically effective in biotechnology, providing essential investment protection and enabling recovery of substantial research and development costs often exceeding hundreds of millions of dollars (MoloLamken, 2025). Patent protection encourages disclosure of technical information while providing temporary exclusivity, balancing innovation incentives with eventual public access to protected

technologies.

Trade secret-protected objects systematically encompass confidential formulas and proprietary processes, unique production technologies and manufacturing know-how, specialized cell lines and biological materials, proprietary databases and analytical methods, and undisclosed research results and development strategies (Potter Clarkson, 2024). This protection type applies to any undisclosed information possessing economic value and maintains protection indefinitely provided secrecy is maintained. Trade secrets create long-term strategic advantages for biotechnology companies, enhance competitive positioning, and may prove more effective than patent protection in certain circumstances where disclosure would enable competitors to design around protected inventions (Potter Clarkson, 2024). However, trade secret protection provides no protection against independent development or reverse engineering by competitors.

Copyright-protected objects systematically include scientific publications and research reports, bioinformatics programs and software applications, algorithm codes and computational methods, genomic databases and sequence collections, sequence analysis results and computational outputs, and biotechnology project documentation and technical specifications. This protection type assumes primary importance for digital biotechnology products, software solutions, and comprehensive data collections that increasingly drive biotechnology innovation. With the growing importance of big biological data analytics and artificial intelligence algorithms in modern biotechnology, copyright protection plays increasingly significant roles in protecting valuable computational assets.

C. Emerging Biotechnology Object Categories Requiring Novel Legal Frameworks

The comprehensive research systematically identifies several emerging categories requiring innovative legal frameworks adapted to their unique characteristics (Schneider & Hengen, 2004). Synthetic biology products enable creation of entirely new metabolic pathways not existing in nature, design of targeted biological systems for specific applications, optimization of natural processes through engineering approaches, creation of biological functions with no natural equivalents, and production of biofuels and chemical substances through designed biological systems. United States Patent and Trademark Office Patent Number 6,774,222, issued August 10, 2004, demonstrates complex patent issues in synthetic biology, specifically covering "Molecular computing elements, gates, and flip-flops" utilizing combinations of nucleic acid binding proteins and nucleic acids for computational applications (Schneider & Hengen, 2004). This patent illustrates the convergence of biotechnology with information technology and the resulting challenges for traditional patent classification systems.

Biobanks and genomic data collections enable large-scale genomic research projects, comprehensive epidemiological studies of disease patterns, personalized medical approaches based on individual genetic profiles, systematic study of pharmaceutical drugs' genetic effects, and identification of disease causation mechanisms through population-level analysis (Staunton et al., 2022). The General Data Protection Regulation established exceptionally strict requirements for biobank research throughout Europe, recognizing that genomic data always constitutes personal data due to its unique identifying characteristics (Staunton et al., 2022). GDPR Article 89(1) specifies comprehensive measures required to protect data subjects' rights while enabling legitimate research activities. However, informed consent issues remain prominent challenges in utilizing biobanks and genomic data for research and commercial applications.

Contemporary legal frameworks struggle with questions of data ownership, benefit-sharing with data contributors, cross-border data transfers, and long-term storage and usage rights (Staunton et al., 2022). The complex intersection of privacy law, medical research ethics, and commercial biotechnology creates ongoing regulatory challenges requiring adaptive solutions. Nanobiotechnology objects systematically enable creation of nanorobots and molecular motors for targeted applications, direct drug delivery systems reaching specific cellular targets, early disease detection through highly sensitive nano-biosensors, development of nanostructured biomaterials with enhanced properties, and advancement of sophisticated implants and biointerface technologies.

However, nanobiotechnology objects do not fit easily into traditional patent categories due to their hybrid nature. These objects simultaneously possess biological, chemical, and mechanical characteristics, requiring multi-field protection strategies and interdisciplinary regulatory approaches. Current patent classification systems require updating to accommodate these hybrid technologies effectively. Quantum biotechnology represents the emerging future of modern biotechnology, systematically enabling application of quantum mechanical principles in photosynthesis and enzyme activity studies, creation of quantum-based biosensors with unprecedented sensitivity, drug design through quantum computing approaches offering exponential computational advantages, and development of therapeutic methods utilizing quantum effects for targeted interventions.

IV. Discussion

A. Legal Framework Adequacy and Systemic Challenges

The comprehensive analysis systematically reveals significant gaps between existing legal frameworks and the complex realities of modern biotechnology development and commercialization (Singh, 2015). Traditional civil law categories,

originally developed for conventional tangible property objects, prove fundamentally inadequate for addressing the unique characteristics of biotechnology objects that blur boundaries between natural and artificial, living and non-living, and individual and collective property concepts. The dialectical relationship between natural discovery and artificial invention in biotechnology objects challenges fundamental assumptions about property ownership, patentability standards, and the appropriate scope of intellectual property protection. This complexity creates legal uncertainty that can impede innovation while potentially allowing inappropriate commodification of natural biological processes.

The comprehensive case law analysis demonstrates inconsistent approaches across different jurisdictions, creating barriers to international biotechnology commerce and collaboration (Diamond v. Chakrabarty, 1980; Association for Molecular Pathology v. Myriad Genetics, Inc., 2013). While the United States has generally adopted a permissive approach to biotechnology patenting since the foundational *Diamond v. Chakrabarty* decision, the subsequent Myriad decision significantly restricted patentability of naturally occurring genetic sequences, creating uncertainty about the boundaries of patentable subject matter. European approaches, systematically governed by Directive 98/44/EC, attempt to balance patent protection with ethical considerations but create practical uncertainty regarding the precise boundaries between patentable and non-patentable subject matter (Directive 98/44/EC, 1998). These inconsistencies require harmonization efforts while respecting legitimate differences in national values and priorities.

The complex CRISPR patent landscape exemplifies the mounting complexity of modern biotechnology intellectual property issues. With over eleven thousand patent families related to CRISPR technology held by various institutions and companies, the fragmented patent ownership creates substantial barriers for small and medium enterprises seeking to access these fundamental gene editing technologies. This situation clearly demonstrates the urgent need for more coordinated approaches to biotechnology patent management and licensing, potentially including patent pools, compulsory licensing mechanisms, and international coordination of patent examination procedures. The ongoing patent disputes between University of California and Broad Institute illustrate how fundamental research tools can become locked in lengthy legal battles that impede scientific progress and technology transfer.

B. Classification System Effectiveness and Comparative Analysis

The color-based classification system provides a useful framework for understanding biotechnology applications across different sectors but proves insufficient for comprehensive legal purposes requiring more granular distinctions (Costa, 2024). Legal classification necessarily requires consideration of multiple interconnected factors including material composition, structural complexity levels, origin classification, application fields, regulatory requirements, and available protection mechanisms. The

research systematically reveals that different classification criteria may yield contradictory results for identical biotechnology objects, creating challenges for consistent legal treatment (Ogbogu, 2017). For example, a genetically modified microorganism used in pharmaceutical production could be classified as red biotechnology based on application, biological material based on composition, or patent-protected object based on legal status.

The material nature classification encompassing biological materials, biotechnological processes, and biotechnological products offers better alignment with existing legal protection mechanisms and established intellectual property frameworks (IP Australia, 2025). However, hybrid objects that combine multiple elements continue challenging this system, requiring adaptive approaches that can accommodate technological convergence. Drug-device combinations exemplify this challenge, requiring simultaneous compliance with pharmaceutical regulations and medical device requirements, creating regulatory complexity and potential conflicts between different regulatory frameworks. These products often require coordination between multiple regulatory agencies with different expertise and priorities. The emerging categories of synthetic biology, nanobiotechnology, and quantum biotechnology highlight the inherently dynamic nature of biotechnology and the absolute necessity for adaptive classification systems that can evolve alongside technological developments (Schneider & Hengen, 2004). Current patent classification schemes, including the WIPO International Patent Classification system, require systematic updating to accommodate these emerging technologies effectively while maintaining consistency with established principles.

C. Regulatory Challenges and International Harmonization Efforts

The research systematically identifies significant regulatory challenges arising from the inherently transnational nature of biotechnology innovation and global commercialization patterns (Singh, 2015). Different jurisdictions employ varying approaches to biotechnology regulation, creating substantial barriers to international collaboration, technology transfer, and efficient global markets for biotechnology products. The United States' focus on functionality and utility contrasts sharply with European emphasis on ethical considerations and public order requirements, creating challenges for companies seeking to commercialize biotechnology innovations globally. These differences reflect legitimate variations in cultural values and regulatory priorities but create practical obstacles for biotechnology development and commercialization.

Regulatory harmonization efforts face substantial challenges due to cultural, ethical, and economic differences among nations with different historical experiences and value systems (Staunton et al., 2022). The Nagoya Protocol's benefit-sharing requirements, GDPR's comprehensive data protection standards, and varying approaches

to genetically modified organism regulation create a complex regulatory landscape for biotechnology companies operating internationally. The research reveals particular challenges in regulating emerging technologies where established legal categories prove inadequate for effective oversight. Synthetic biology products, nanobiotechnology objects, and quantum biotechnology applications require entirely new regulatory frameworks that can balance innovation promotion with comprehensive risk management and ethical considerations.

D. Future Directions and Comprehensive Recommendations

The comprehensive analysis suggests several critical directions for legal framework development that could improve the effectiveness and consistency of biotechnology regulation globally (Singh, 2015). First, adaptive classification systems that can systematically accommodate emerging technologies while maintaining legal certainty are absolutely essential for effective biotechnology governance. This requires ongoing collaboration between legal experts, scientists, policymakers, and affected stakeholders to ensure that legal frameworks evolve alongside technological developments. Second, international harmonization efforts should focus systematically on developing common principles for biotechnology regulation while respecting national sovereignty over ethical and cultural considerations that reflect legitimate democratic choices. Model laws and international treaties could provide frameworks for consistent approaches to biotechnology object classification and protection while allowing flexibility for national implementation.

Third, the development of specialized courts or administrative bodies with deep biotechnology expertise could significantly improve the quality and consistency of decisions regarding biotechnology objects. The complexity of biotechnology requires specialized knowledge that traditional generalist courts may lack, potentially leading to inconsistent or inappropriate decisions. Fourth, enhanced stakeholder engagement in regulatory development processes could improve the balance between innovation incentives and public interests while ensuring that affected communities have meaningful participation in decision-making processes. This includes systematic involvement of patient advocacy groups, environmental organizations, developing country representatives, and indigenous communities in international regulatory discussions. Fifth, adaptive licensing mechanisms including patent pools, compulsory licensing, and research exemptions could help address the growing complexity of biotechnology patent landscapes while ensuring access to fundamental research tools and essential medicines. These mechanisms require careful design to maintain innovation incentives while preventing excessive patent thickets.

Conclusion

This comprehensive research conclusively demonstrates that biotechnology objects represent an extraordinarily complex and rapidly evolving category within civil law that fundamentally challenges traditional legal concepts and categorically requires adaptive regulatory frameworks capable of responding to technological change. The four fundamental characteristics of biotechnology objects systematically identified through this research - their complex dialectical relationship between natural and artificial elements, unique reproducibility capabilities, elevated risk levels, and profound ethical significance - clearly distinguish them from conventional property objects and definitively necessitate specialized legal approaches incorporating novel jurisprudential concepts.

The comprehensive classification framework systematically developed in this study, encompassing material nature and composition, application fields and color-based taxonomy, complexity levels, and legal protection mechanisms, provides a solid foundation for improved legal regulation of biotechnology objects across multiple jurisdictions. The sophisticated color-based taxonomy offers valuable insights into application-specific regulatory needs and sectoral differences, while the legal protection type classification clearly clarifies available intellectual property mechanisms and their appropriate applications.

The systematic analysis reveals significant gaps in existing legal frameworks, particularly regarding rapidly emerging technologies including synthetic biology, nanobiotechnology, and quantum biotechnology applications. These revolutionary technologies require entirely new legal concepts and comprehensive regulatory approaches that can accommodate their unique characteristics while maintaining essential legal certainty and actively promoting beneficial innovation. The patent system remains the primary mechanism for protecting biotechnology innovations across all examined jurisdictions, but requires substantial adaptation to address the unique challenges posed by biotechnology objects including reproducibility, hybrid natural-artificial characteristics, and ethical considerations. The complexity of modern biotechnology, exemplified by the fragmented CRISPR patent landscape involving thousands of patents held by multiple institutions, clearly demonstrates the urgent need for more coordinated approaches to patent management and technology licensing.

Conflict of Interest Statement

The author declares no potential conflicts of interest with respect to the research, authorship, and/or publication of this article. This research was conducted independently without any financial support or commercial interests that could inappropriately influence or bias the content of this work.

Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Author Contributions

The author was solely responsible for the conception, design, execution, analysis, and writing of this research article.

Bibliography

Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013).

Bergin, L. C. (2024). The approval and substitutability of biosimilars: Potential impact on use and competition. *Food and Drug Law Institute, 78*(3), 234-267.

Civil Code of the People's Republic of China, Article 1009 (2020).

Costa, S. (2024). Applications of food biotechnology in sustainable food production. *Journal of Food Science and Nutrition, 7*(3), 236-248.

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

Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions. (1998). *Official Journal of the European Union*, L 213, 13-21.

Kathage, J., & Qaim, M. (2012). Economic impacts and impact dynamics of Bt cotton in India, 2006-2008. *Proceedings of the National Academy of Sciences, 109*(29), 11652-11656. https://doi.org/10.1073/pnas.1203647109

MoloLamken. (2025). *What rights do I get by obtaining a patent for my invention?* https://www.mololamken.com/knowledge-what-rights-do-i-get-by-obtaining

Moore v. Regents of the University of California, 51 Cal. 3d 120, 793 P.2d 479 (1990).

Ogbogu, U. (2017). What is a new object? Case studies of classification problems and practices at the intersection of law and biotechnology. *SSRN Electronic Journal*. https://doi.org/10.2139/ssrn.3073435

Potter Clarkson. (2024). *Protecting & leveraging trade secrets in biotech*. https://www.potterclarkson.com/insights/confidentiality-as-currency-protecting-and-leveraging-trade-secrets-in-biotech/

PubMed. (2023). *The CRISPR Cas patent files, part 1: Cas9*. https://pubmed.ncbi.nlm.nih.gov/37984590

Schneider, T., & Hengen, P. N. (2004). Molecular computing elements, gates and flip-flops. *U.S. Patent No. 6,774,222*. U.S. Patent and Trademark Office.

Singh, K. K. (2015). *Biotechnology and intellectual property rights: Legal and social implications*. Springer. https://doi.org/10.1007/978-81-322-2059-6

Staunton, C., Slokenberga, S., & Mascalzoni, D. (2022). Appropriate safeguards and Article 89 of the GDPR: Considerations for biobank, databank and genetic research. *Frontiers in Genetics, 13*, 719317. https://doi.org/10.3389/fgene.2022.719317

Traxler, G., Godoy-Avila, S., Falck-Zepeda, J., & Espinoza-Arellano, J. (2001). *Transgenic cotton in Mexico*. ISAAA Global Status of Commercialized Biotech/GM Crops.