



Intellectual Property Law and Microbiology: Patenting Microorganisms and Genetic Material

Nwakoby, I. P.^{1*}, Iheukwumere, I. H.^{2*}, Iheukwumere, C. M.³, Nwakoby, N. E.², Idigo, M. A.⁴ and Ike, V. E.⁵

¹Department of Private and Public Law, Faculty of Law, Chukwuemeka Odumegwu Ojukwu University, Anambra State, Nigeria.



²Department of Microbiology, Faculty of Natural Sciences, Chukwuemeka Odumegwu Ojukwu University, Anambra State, Nigeria.

³Department of Applied Microbiology & Brewing, Faculty of Biosciences, Nnamdi Azikiwe University, Awka, Anambra State, Nigeria.

⁴Department of Biological Sciences, Faculty of Natural Science, Chukwuemeka Odumegwu Ojukwu University, Anambra State, Nigeria.

⁵Department of Microbiology, University of Agriculture and Environmental Sciences, Umuagwo, Imo State, Nigeria.

*Corresponding authors' emails: ip.nwakoby@coou.edu.ng / ik.iheukwumere@coou.edu.ng

Abstract	Article History
<p>The intersection of intellectual property (IP) law and microbiology represents a critical frontier in biotechnology, driving innovation while posing profound ethical, legal, and practical challenges. This comprehensive review examines the evolution and current landscape of patenting microorganisms and genetic material. It begins by tracing the historical jurisprudential shift, notably the landmark U.S. Supreme Court case <i>Diamond v. Chakrabarty</i> (1980), which established that live, human-made microorganisms are patentable subject matter. The paper delves into the core patentability requirements—novelty, inventive step (non-obviousness), and industrial application (utility)—as they apply to biological entities, which often exist in nature but are modified by human intervention. Further, the review explores the unique logistical mechanisms for patenting microbiological inventions, specifically the international deposit system governed by the Budapest Treaty. A significant portion is dedicated to the contentious issue of gene patents, analyzing the legal arguments for and against the patenting of isolated DNA sequences and the impact of pivotal cases like <i>Association for Molecular Pathology v. Myriad Genetics, Inc</i> (2013), which drew a critical distinction between naturally occurring genes and synthetic cDNA. The analysis also addresses emerging issues, including patenting CRISPR-Cas9 gene-editing technologies, synthetic biology, and microbiomes. Finally, the paper confronts the ethical objections and policy concerns surrounding the privatization of the fundamental building blocks of life, including implications for research freedom, healthcare access, and global equity. The conclusion argues that while patent protection is an indispensable incentive for biotechnological advancement, a carefully calibrated legal framework is essential to balance private innovation with public good.</p> <p>Keywords: Intellectual Property Law, Patent Law, Microbiology, Biotechnology, Genetic Material, <i>Diamond v. Chakrabarty</i>, <i>Myriad Genetics</i>, Budapest Treaty, Gene Patents, CRISPR, Synthetic Biology, Bioethics, Novelty, Non-obviousness.</p>	<p>Received: 20 Sept 2025 Accepted: 14 Oct 2025 Published: 18 Oct 2025</p> <p>Scan QR code to view*</p>  <p>License: CC BY 4.0*</p>  <p>Open Access article.</p>
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1.0 INTRODUCTION

The last five decades have witnessed an unprecedented revolution in the life sciences, fundamentally altering our understanding and manipulation of biological organisms. Microbiology, once confined to observation, now enables the precise engineering of microorganisms and their genetic blueprints for applications in medicine, agriculture, energy, and environmental remediation (Iheukwumere *et al.*, 2025a;

Iheukwumere *et al.*, 2025b; Iheukwumere *et al.*, 2025c). This technological prowess, however, exists within a complex socio-legal framework. Intellectual property law, particularly the patent system, serves as the primary engine for incentivizing and protecting such high-risk, high-reward innovation. By granting inventors a time-limited monopoly in exchange for public disclosure of their invention, patents aim to fuel progress (Amani, 2019). The application of this system

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to living organisms—microorganisms, genes, and cells—has been anything but straightforward, generating a persistent tension between the desire to reward innovation and concerns about the moral and practical implications of owning life itself (Resnik, 2018; Iheukwumere *et al.*, 2025d; Iheukwumere *et al.*, 2025e). This paper reviews the legal doctrines, practical mechanisms, and fierce debates that define the patenting of microbiological and genetic inventions.

2.0 HISTORICAL FOUNDATIONS: FROM PRODUCTS OF NATURE TO PATENTABLE SUBJECT MATTER

2.1. The Pre-Chakrabarty Landscape

Traditionally, patent law drew a bright line between human inventions and "products of nature." The U.S. Patent Act (35 U.S.C. § 101) defines patentable subject matter as any "new and useful process, machine, manufacture, or composition of matter." For most of history, living organisms were considered unpatentable discoveries, not inventions (Mills, 2021; Iheukwumere *et al.*, 2025f; Iheukwumere *et al.*, 2025g). This began to change with patents for plant varieties under the Plant Patent Act of 1930 and later the Plant Variety Protection Act of 1970, which created *sui generis* systems for agricultural innovation but left microbes unprotected.

2.2. *Diamond v. Chakrabarty*: A Paradigm Shift

The modern era of biotechnology patents was inaugurated by the U.S. Supreme Court's 1980 decision in *Diamond v. Chakrabarty*. Microbiologist Ananda Chakrabarty had developed a genetically engineered *Pseudomonas* bacterium capable of breaking down crude oil, a potential tool for mitigating oil spills (Iheukwumere *et al.*, 2025h; Iheukwumere *et al.*, 2025i). The patent application was rejected by the Patent Office on the grounds that microorganisms were products of nature. The Supreme Court, in a landmark 5-4 decision, reversed this ruling. Chief Justice Warren Burger, writing for the majority, famously stated: "The patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly, it is patentable subject matter." The Court held that the relevant distinction was not between living and inanimate things, but between natural phenomena and human-made inventions (*Diamond v. Chakrabarty*, 1980; Iheukwumere *et al.*, 2025j). This decision opened the floodgates for the biotechnology industry, establishing the legal precedent that genetically modified life forms are patentable.

3.0 THE PILLARS OF PATENTABILITY: APPLYING TRADITIONAL CRITERIA TO BIOLOGICAL INVENTIONS

Beyond being eligible subject matter, an invention must meet three substantive criteria to be patented.

3.1. Novelty and the Prior Art Hurdle

An invention must be new. For microorganisms, this often means that the specific strain, whether isolated from nature or engineered in a lab, must not have been previously known or available to the public. A naturally occurring microbe discovered in a unique environment may be novel if it has never been previously isolated and characterized (Holman, 2015; Iheukwumere *et al.*, 2025k; Iheukwumere *et al.*, 2025l).

However, mere discovery without a disclosed utility is often insufficient.

3.2. Inventive Step (Non-Obviousness)

The invention must not have been obvious to a person skilled in the relevant art at the time the invention was made. Modifying a bacterium using routine genetic engineering techniques (e.g., standard plasmid insertion) may fail this test (Ekechukwu *et al.*, 2025a; Ekechukwu *et al.*, 2025b; Ekechukwu *et al.*, 2025c). However, achieving a surprising and useful result, such as engineering a novel metabolic pathway to produce a complex drug, would likely clear the non-obviousness hurdle (Mills, 2021). This requirement ensures that patents are only granted for genuine advances, not trivial modifications.

3.3. Industrial Application (Utility) and Enablement / Written Description

The invention must have a specific, substantial, and credible utility. A patent must also enable a person skilled in the art to make and use the invention without "undue experimentation." This is particularly challenging for biological inventions. How does one "describe" a unique microbe in words alone? The solution, addressed in the next section, is the international deposit system. Furthermore, the written description must prove the inventor was in possession of the invention, which for genetic material means disclosing the sequence and its function (Amani, 2019; Dim *et al.*, 2025a; Dim *et al.*, 2025b).

4.0 THE BUDAPEST TREATY: THE PRACTICAL MECHANISM FOR DISCLOSURE

The requirement to disclose an invention fully is logistically impossible for a microorganism if described only textually (Dim *et al.*, 2025c; Ike *et al.*, 2025a). In response, the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure was established in 1977. This treaty allows an applicant to deposit a sample of a microorganism in an International Depository Authority (IDA), such as the American Type Culture Collection (ATCC) or the Deutsche Sammlung von Mikroorganismen und Zellkulturen (DSMZ) (Ike *et al.*, 2025b; Ike *et al.*, 2025c). This single deposit is recognized for patent purposes in all member states, satisfying the disclosure requirement for the life form itself (Budapest Treaty, 1977; Ike *et al.*, 2025d). The sample is kept confidential during the patent application process and is typically made available to the public after the patent grants, facilitating further research.

5.0 THE GENE PATENTING DEBATE: ISOLATION, PURIFICATION, AND INVENTION

5.1. The Legal Rationale for Gene Patents

Following *Chakrabarty*, patent offices began granting patents on isolated DNA sequences. The rationale was that isolating a gene from its natural chromosomal environment required human intervention, creating a purified chemical entity distinct from its natural state. These patents could cover the isolated DNA sequence, its use in diagnostics, the protein it coded for, and even vectors containing the sequence (Resnik, 2018; Ike *et al.*, 2025e). This practice fueled the growth of genomics companies but also drew criticism for potentially stifling research and diagnostic testing.

5.2. Association for Molecular Pathology v. Myriad Genetics, Inc.

The legal foundation for gene patents was shattered in the U.S. in 2013. Myriad Genetics held patents on the isolated BRCA1 and BRCA2 genes, associated with a high risk of breast and ovarian cancer. The Supreme Court unanimously held that "a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated." The Court reasoned that Myriad did not create or alter the genetic information encoded in the BRCA genes; it merely uncovered an existing law of nature (*AMP v. Myriad*, 2013).

5.3. The Aftermath of Myriad: cDNA and Synthetic Biology

Critically, the Court made a distinction: complementary DNA (cDNA), which is synthesized in a lab from messenger RNA and lacks non-coding introns, is patentable because it is not naturally occurring. This decision invalidated thousands of patents on isolated genomic DNA but preserved protection for engineered genetic molecules, synthetic biology constructs, and methods of using genetic information (Holman, 2015; Ugwu *et al.*, 2025b). The focus shifted from composition-of-matter claims on the genes themselves to method claims (e.g., diagnostic tests) and claims on synthetically created nucleic acids.

6.0 EMERGING FRONTIERS AND CONTEMPORARY CHALLENGES

6.1. Patenting CRISPR-Cas9 and Gene-Editing Technologies

The CRISPR-Cas9 system has ignited a new patent war. The core technology is the subject of a fierce, multi-jurisdictional dispute between the Broad Institute (MIT and Harvard) and the University of California. The dispute centers on priority dates and the non-obviousness of applying CRISPR-Cas9 in eukaryotic cells (Sherkow, 2017; Amadi *et al.*, 2017). This highlights the challenges of patenting foundational platform technologies with vast and unpredictable applications.

6.2. Synthetic Biology and Engineered Microorganisms

Synthetic biology aims to create entirely new biological systems. Patents in this field may cover minimally modified "chassis" organisms, synthetic pathways, and even entirely synthetic genomes. The legal questions revolve around how much modification is required to make a natural organism patentable and whether standard patent law is suitable for these complex, iterative technologies (Amani, 2019; Nwike *et al.*, 2017).

6.3. The Microbiome: A New Patent Landscape

Research into the human microbiome has led to patents on specific probiotic bacterial mixtures, engineered gut microbes, and diagnostic methods based on microbial populations. The novelty and non-obviousness of claims based on newly discovered but unmodified microbial communities are under intense scrutiny, echoing earlier debates about patenting products of nature (Bubela *et al.*, 2021; Ekesiobi *et al.*, 2025).

7.0 ETHICAL AND SOCIETAL IMPLICATIONS

7.1. The "Common Heritage" Argument and Bio-Banking

A central ethical objection is that life, in its fundamental form, should be considered a "common heritage of mankind" and not subject to private ownership. This argument extends to human genetic material, raising concerns about dignity and commodification (Resnik, 2018). The practice of bio-banking, where biological samples are collected from indigenous or isolated populations for commercial research, has led to accusations of biopiracy when benefits are not shared fairly.

7.2. Access to Medicine and the Research Exemption

Patent thickets—dense webs of overlapping patents—can hinder research by creating a "tragedy of the anti-commons," where the need to secure multiple licenses paralyzes innovation. This is acute in medicine, where gene patents can make diagnostic tests prohibitively expensive. While many jurisdictions have a limited "research exemption," its scope is often unclear, creating uncertainty for academics and companies alike (Bubela *et al.*, 2021).

7.3. Global Inequity and Biopiracy Concerns

The global IP framework, particularly the WTO's TRIPS Agreement, mandates minimum standards for patent protection. This can disadvantage developing countries with rich biodiversity but less capacity for research and patenting. Cases where Western companies patent compounds derived from traditional knowledge or native plants without benefit-sharing exemplify the problem of biopiracy, though legal instruments like the Nagoya Protocol aim to address it (Oguamanam, 2018).

8.0 CONCLUSION: BALANCING INCENTIVE AND INNOVATION WITH ETHICS AND ACCESS

The patenting of microorganisms and genetic material remains a dynamic and contentious field. The legal framework, established by Chakrabarty and refined by Myriad, has successfully incentivized a multi-trillion-dollar biotechnology industry, leading to groundbreaking therapies, agricultural products, and industrial processes. The Budapest Treaty provides a vital practical solution for disclosure. However, this system continues to be tested by rapid technological advances like CRISPR and microbiome science, while simultaneously facing enduring ethical challenges related to equity, access, and the very morality of owning life. The future of this field lies in finding a sustainable balance. This may require nuanced application of patentability criteria, stronger research exemptions, support for open-source biology initiatives, and international agreements that ensure the benefits of microbial and genetic innovation are shared justly across the globe. The law must continue to evolve to ensure it protects inventors without locking away the fundamental tools of biological science.

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Antioxidant and Dietary Fibre Content of Noodles Produced From Wheat and Banana Peel Flour

This study found that adding banana peel flour to wheat flour can improve the nutritional value of noodles, such as increasing dietary fiber and antioxidant content, while reducing glycemic index.

DOI: <https://doi.org/10.54117/ijjnf.v2i2.24>

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Impact of Pre-Sowing Physical Treatments on The Seed Germination Behaviour of Sorghum (*Sorghum bicolor*)

This study found that ultrasound and microwave treatments can improve the germination of sorghum grains by breaking down the seed coat and increasing water diffusion, leading to faster and more effective germination.



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