PATENTING HUMAN GENES: ETHICAL AND LEGAL CONSIDERATIONS: USING NIGERIA AS A CASE STUDY

SUBMITTED

BY

CHRISTOPHER CHIDUBEM AKANIRO

2020/LW/24719(20875863DF)

TO

THE DEPARTMENT OF LAW, FACULTY OF LAW

ALEX EKWUEME FEDERAL UNIVERSITY, NDUFU-ALIKE, IKWO (AE-FUNAI)

EBONYI STATE

IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE AWARD OF THE DEGREE OF BACHELOR OF LAWS (LL.B)

SUPERVISOR:

DR. ONYEKACHI ENI

SEPTEMBER, 2025

DECLARATION

I hereby declare that this project work titled “Patenting Human Genes: Ethical and Legal Considerations: Using Nigeria as a Case Study”, submitted to the Faculty of Law, Alex Ekwueme Federal University Ndufu-Alike Ikwo, Ebonyi State, is a record of an original work done by me under the guidance of Dr. Onyekachi Eni. This project is submitted as part of the requirements for the award of the degree of Bachelor of Laws (LL.B). The results and views expressed therein are entirely mine and have not been submitted to any other University or Institute for the award of any degree or diploma.

_____ _____

CHRISTOPHER CHIDUBEM AKANIRO DATE

CERTIFICATION

This is to certify that this long essay titled “Patenting Human Genes: Ethical and Legal Considerations: Using Nigeria as a Case Study” has been assessed and approved by the Undergraduate Studies Committee of the Faculty of Law, Alex Ekwueme Federal University Ndufu-Alike Ikwo, as an original work carried out by Christopher Chidubem Akaniro with Registration Number 2020/LW/24719(20875863DF), under the guidance and supervision of Dr. Onyekachi Eni.

_____ _____

Dr. Onyekachi Eni

(Project Supervisor) Date

_____ _____

Dr. Kelechi Onyegbule

(Project Coordinator) Date

_____ _____

Professor Eseni Azu Udu

(Dean, Faculty of Law) Date

APPROVAL

It is hereby approved that this project entitled “Patenting Human Genes: Ethical and Legal Considerations: Using Nigeria as a Case Study” meets the requirements for the award of the degree of Bachelor of Laws (LL.B) of the Faculty of Law, Alex Ekwueme Federal University Ndufu-Alike Ikwo, Ebonyi State.

_____ _____

Dr. Onyekachi Eni

(Project Supervisor) Date

_____ _____

Dr. Kelechi Onyegbule

(Project Coordinator) Date

_____ _____

Professor Eseni Azu Udu

(Dean, Faculty of Law) Date

DEDICATION

I dedicate this work to my beloved uncle, Ven. C.C. Akaniro, whose life and values continue to inspire me.

ACKNOWLEDGEMENTS

First and foremost, my heartfelt gratitude goes to God Almighty for His grace, wisdom, and strength throughout this academic journey. Without His unfailing love, this work would not have been possible.

I deeply acknowledge my father, Okechukwu Akaniro, and my mother, Doris Akaniro, for their unwavering love, sacrifices, and encouragement. Their belief in me has remained my greatest motivation.

My sincere appreciation goes to my Supervisor, Dr. Onyekachi Eni, for his patience, insightful guidance, and scholarly contributions that shaped the quality of this research. I also extend gratitude to Dr. Kelechi Onyegbule for his support, as well as to all my lecturers in the Faculty of Law, AE-FUNAI.

I also wish to specially recognize Dr. Onyekachi Eni for his mentorship, and to my friends who have made my journey here in AE-FUNAI a fruitful one: Ikeh Emmanuel, Onwudiwe Fechi, Abiodun Segun, Michael Marshall, Uchembah Justin, and most especially my woman Ifeanyichukwu Favour, and a host of others . Thank you all for your encouragement and companionship.

To everyone who has supported me in one way or another, I remain profoundly grateful

Table of Contents

List of Statutes

List of Cases

Abbreviations

IP – Intellectual Property

NIPO – Nigerian Intellectual Property Office

NOTAP – National Office for Technology Acquisition and Promotion

NAFDAC – National Agency for Food and Drug Administration and Control

NABDA – National Biotechnology Development Agency

TRIPS – Trade-Related Aspects of Intellectual Property Rights

CBD – Convention on Biological Diversity

ARIPO – African Regional Intellectual Property Organization

OAPI – African Intellectual Property Organization

GMOs – Genetically Modified Organisms

PCT – Patent Cooperation Treaty

FCCPC – Federal Competition and Consumer Protection Commission

ABSTRACT

This research examines the complex ethical and legal dimensions of patenting human genes in Nigeria, a country with extraordinary genetic diversity yet limited regulatory framework to address this emerging issue. The study analyzes the current Nigerian legal landscape, primarily governed by the Patents and Designs Act of 1970, which predates modern biotechnology and contains no specific provisions regarding genetic material patentability. It explores Nigeria's obligations under international agreements including TRIPS, the Convention on Biological Diversity, and regional intellectual property organizations, highlighting tensions between these commitments. The research investigates unique ethical considerations arising from Nigeria's colonial history, religious perspectives, cultural values, and traditional knowledge systems, which all inform attitudes toward the commodification of human biological materials. It assesses the healthcare implications of gene patenting in a system already challenged

by access issues, while considering potential benefits for local biotechnology development and research funding. The study evaluates recent initiatives like the National Biotechnology Development Agency and participation in the H3Africa consortium, which have intensified the need for coherent policies on genetic resource ownership and benefit-sharing. Through comparative analysis of evolving global approaches to gene patenting, particularly landmark cases like Association for Molecular Pathology v. Myriad Genetics, the research identifies potential models for Nigeria. It examines public awareness gaps and the need for inclusive deliberative processes in policy development. The study concludes by proposing a balanced framework that protects Nigeria's genetic heritage while promoting scientific advancement, suggesting specific legislative reforms, ethical guidelines, and benefit-sharing mechanisms tailored to Nigeria's unique context. This research contributes to an understudied aspect of biotechnology regulation in Africa's largest economy, offering insights relevant to other developing nations navigating similar challenges at the intersection of genomics, intellectual property, and public interest.

CHAPTER ONE

INTRODUCTION

1.1 Background to the Study

The intersection of biotechnology, ethics, and law has given rise to one of the most contentious issues in modern intellectual property discourse: the patenting of human genes. This controversy sits at the crossroads of scientific advancement, commercial interests, and fundamental questions about the ownership of human biological materials.[1] While this debate has evolved significantly in developed nations, its nuances and implications in developing countries, particularly Nigeria, remain largely unexplored despite their profound significance for healthcare access, indigenous genetic resources, and scientific development.

The practice of gene patenting emerged in the late 20th century as advances in molecular biology and genetic engineering enabled scientists to isolate, sequence, and manipulate genetic material. The watershed moment came in 1980 when the United States Supreme Court in Diamond v. Chakrabarty ruled that genetically modified organisms could be patented, opening the door to the patenting of isolated gene sequences.[2] This decision catalyzed the biotechnology industry but simultaneously sparked ethical concerns about the commodification of human biological materials.

Nigeria, as Africa's most populous nation with over 200 million citizens and extraordinary genetic diversity, stands at a critical juncture in this global debate. The

[1] Ossorio PN, 'The Human Genome as Common Heritage: Common Sense or Legal Nonsense?' (2007) 35(3) *Journal of Law, Medicine & Ethics 425.*
[2] *Diamond v Chakrabarty* 447 US 303 (1980).

country's genetic heritage represents not only a scientific treasure trove but also a potential economic resource in the age of personalized medicine and biotechnological innovation.[3] However, this very potential raises profound questions about who should benefit from and control access to Nigerian genetic resources.

The Nigerian legal framework governing intellectual property rights derives primarily from colonial-era legislation, particularly the Patents and Designs Act of 1970.[4] This law, enacted before the biotechnology revolution, contains no specific provisions addressing the patentability of genetic materials. This legislative gap has created uncertainty regarding the legal status of gene patents in Nigeria, leaving stakeholders without clear guidelines on this increasingly important issue.

Internationally, Nigeria is a signatory to various treaties with implications for gene patenting, including the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), the Convention on Biological Diversity (CBD), and the International Treaty on Plant Genetic Resources for Food and Agriculture.[5] These commitments create a complex web of sometimes conflicting obligations regarding genetic resources and intellectual property protection.

The ethical dimensions of gene patenting in Nigeria are particularly acute given the

---

[3] Adebamowo CA and others, 'Implementation of Genomic Medicine in Africa: Challenges and Opportunities' (2018) 20(12) *Genetics in Medicine* 1467.

[4] Patents and Designs Act (Cap P2) Laws of the Federation of Nigeria 2004

[5] Nnadozie K and others, *African Perspectives on Genetic Resources: A Handbook on Laws, Policies, and Institutions (Environmental Law Institute 2003*) 78.

country's history and socioeconomic realities. Colonial exploitation of Nigerian resources has created a legacy of suspicion regarding foreign access to and control over indigenous biological materials.[6] This historical context informs contemporary concerns about "biopiracy" – the appropriation of genetic resources without adequate compensation or consent – and raises questions about justice and equity in the distribution of benefits derived from Nigerian genetic heritage.

Religious and cultural perspectives further complicate the ethical landscape. In a deeply religious society split primarily between Christianity and Islam, with significant traditional religious practices also present, many Nigerians hold views about the sanctity of human life and the body that may conflict with the commodification implied by gene patenting.[7] Traditional knowledge systems, which have developed over centuries to identify and utilize the therapeutic properties of local plants and other biological materials, represent another dimension of this complex picture, raising questions about the protection of community intellectual property rights.[8]

The healthcare implications of gene patenting for Nigeria are substantial. In a system already characterized by significant access challenges, patent monopolies on genetic diagnostic tests or treatments could further restrict the availability of cutting-edge healthcare innovations. [9]Conversely, a well-designed patent system could potentially

---

[6] Abegunde O, 'Biopiracy, Intellectual Property Rights and Public Interest in Nigeria' (2016) 7(2) *Journal of Law, Policy and Globalization 24.*
[7] Lanre-Abass BA, 'Personhood and Human Genomics: A Reconsideration' (2012) 5(1) *Genomics, Society and Policy 61.*

[8] Oguamanam C, 'Genetic Resources & Access and Benefit Sharing: Politics, Prospects and Opportunities for Canada after Nagoya' (2011) 22(2) *Journal of Environmental Law and Practice* 87.
[9] Mgbeoji I, *Global Biopiracy: Patents, Plants, and Indigenous Knowledge* (UBC Press 2006) 112.

incentivize local biotechnology research and development, contributing to healthcare sovereignty and economic growth. This tension between access and innovation lies at the heart of the gene patenting debate in the Nigerian context

Scientific research in Nigeria also stands to be profoundly affected by policies regarding gene patenting. The country's scientific community, while growing, continues to face resource constraints that could be exacerbated if researchers must navigate complex patent landscapes to conduct genetic research.[10] However, the potential for patents to generate research funding and facilitate technology transfer presents countervailing considerations that must be carefully weighed.

Recent developments have brought these issues into sharper focus. The establishment of the National Biotechnology Development Agency (NABDA) and the adoption of a National Biotechnology Policy signal Nigeria's interest in developing this sector.[11] Concurrently, initiatives like the Human Heredity and Health in Africa (H3Africa) consortium have increased the collection and study of African genetic data, raising urgent questions about ownership, control, and benefit-sharing.[12]

The global legal landscape regarding gene patenting has undergone significant evolution, most notably with the United States Supreme Court's 2013 decision in Association for Molecular Pathology v. Myriad Genetics, which held that naturally

[10] Banjoko SB and Adejuwon AA, 'Biotechnology Development in Nigeria: Stakeholder's Mapping and Relationship Management Exercise' (2011) 2(1*) International Journal of Business and Management* 246.
[11] Federal Ministry of Science and Technology, *'National Biotechnology Policy'* (FMST 2001).
[12] Vries J and others, 'A Global Review of Ethical Issues in the Use of Stored Human Samples for Genetic Research: Trends and Challenges for Africa' (2011) 14(2*) South African Journal of Bioethics and Law* 67.

occurring DNA sequences cannot be patented.[13] Similar reconsiderations have occurred in other jurisdictions, including Europe and

Australia. These developments create both challenges and opportunities for Nigeria as it considers its own approach to this issue.

Nigeria's position is further complicated by its membership in regional organizations with their own intellectual property regimes, particularly the African Regional Intellectual Property Organization (ARIPO) and the African Intellectual Property Organization (OAPI). [14]Harmonizing national policies with these regional frameworks adds another layer of complexity to an already multifaceted issue.

The urgent need for Nigeria to develop a coherent approach to gene patenting is underscored by the rapid advancement of genomic technologies, including next-generation sequencing and gene editing tools like CRISPR-Cas9. These technologies are dramatically reducing the costs and technical barriers to genetic research and development, making it increasingly feasible for Nigerian institutions to participate in the biotechnology revolution.[15] Without clear guidelines, however, the country risks either missing these opportunities or seeing its genetic resources exploited without appropriate benefits accruing to the Nigerian people.

---

[13] *Association for Molecular Pathology v Myriad Genetics*, Inc. 569 US 576 (2013).
[14] Sikinyi EO, 'Intellectual Property Protection in Africa: An Assessment of the Status of Laws, Research and Policy Analysis on Intellectual Property Rights in Kenya' (2006) *African Technology Policy Studies Network Working Paper* No. 2 <https://atpsnet.org/wp-content/uploads/2017/05/wps2.pdf> accessed 5 January 2023
[15] Wonkam A and others, 'Genomic Medicine in Africa: Promise, Problems and Prospects' (2020) 21(11) *Genome Medicine 121.*

Public awareness and engagement represent another critical dimension of this issue. Studies indicate limited understanding of biotechnology and its implications among the Nigerian public, creating challenges for informed policy development and raising concerns about consent in genetic research.[16] This knowledge gap underscores the need for educational initiatives and inclusive deliberative processes as Nigeria navigates these complex questions.

The process of developing an appropriate framework for gene patenting in Nigeria must balance multiple considerations: scientific advancement, economic development, ethical principles, cultural values, and international obligations. It must also account for the country's unique position as both a potential source of valuable genetic resources and a nation seeking to build its own biotechnology capacity. This balanced approach will require careful analysis of comparative experiences, stakeholder engagement, and interdisciplinary collaboration.

As Nigeria stands at this critical juncture, this research seeks to examine the ethical and legal considerations surrounding gene patenting in the Nigerian context, with the aim of contributing to the development of policies that protect the country's genetic heritage while promoting scientific progress and healthcare access. By exploring this understudied aspect of biotechnology regulation in Africa's largest economy, this work addresses a significant gap in the literature and offers insights relevant not only to

[16] Anele KK, 'Public Understanding of Biotechnology: Knowledge and Attitudes of Selected Nigerian Populations' (2015) 12(2) *Nigerian Journal of Biotechnology* 38.

Nigeria but to other developing nations grappling with similar challenges.

1.2 Statement of the Problem

The fundamental challenge in gene patenting lies in balancing scientific innovation with public interest. Several critical issues emerge:

1. The ethical implications of claiming ownership over human genetic material
2. The potential impact on healthcare accessibility and cost
3. The conflict between traditional knowledge and modern biotechnology patents
4. The adequacy of existing legal frameworks to address emerging genetic technologies

Nigeria faces additional challenges due to limited technological capabilities and regulatory infrastructure. The absence of specific legislation addressing gene patents creates uncertainty in the biotechnology sector[17].

1.3 Research Questions

1. To what extent does the Nigerian legal framework, particularly the Patents and Designs Act, adequately regulate the patenting of human genes in light of modern biotechnological developments?

2. What are the ethical implications of patenting human genes in Nigeria, considering the country's cultural, religious, and traditional knowledge systems?

3. How does gene patenting affect access to healthcare and medical innovation in

[17] O.A. Owoeye, "Biotechnology Patents in Nigeria: Challenges and Opportunities" (2022) 40 *Journal of Law and Technology 78*

Nigeria, especially in relation to affordability and availability of genetic tests and treatments?

4. In what ways do Nigeria's international obligations under treaties such as TRIPS and the Convention on Biological Diversity shape its approach to gene patenting?

5. How do comparative legal frameworks in jurisdictions such as the United States, the European Union, and other developing countries inform possible reforms for Nigeria's gene patenting system?

6. What institutional challenges (e.g., capacity, enforcement, coordination between NOTAP, NAFDAC, NABDA, and the Patent Registry) hinder effective governance of gene patents in Nigeria?

7. What balanced legal and policy reforms could Nigeria adopt to protect its genetic heritage while fostering scientific innovation and ensuring public health interests?

1.4 Aim and Objectives of the Study

This research aims to critically analyze the legal and ethical framework governing gene patents in Nigeria. The specific objectives are:

1. To examine the current legal framework governing gene patents in Nigeria and its alignment with international standards

2. To analyze the ethical implications of gene patenting in the Nigerian context

3. To evaluate the impact of gene patents on healthcare accessibility and research innovation

4. To propose reforms for a more balanced approach to genetic patent protection

1.5 Scope of the Study

This study focuses on the legal and ethical aspects of gene patenting within Nigeria's jurisdiction from 2000 to 2023. While considering international perspectives, particular emphasis is placed on:

1. Nigerian patent legislation and case law
2. International treaties affecting gene patents
3. Comparative analysis with selected jurisdictions
4. Ethical considerations in the Nigerian context

1.6 Limitations of the Study

1. Limited access to comprehensive Nigerian case law on gene patents
2. Scarcity of local empirical data on genetic research
3. Rapidly evolving nature of biotechnology

1.7 Significance of the Study

This research contributes significantly to:

1. Academic discourse on biotechnology law in Nigeria

2. Policy development in genetic research regulation

3. Understanding of ethical implications in gene patenting

4. Development of legal frameworks for emerging technologies

1.8 is Research Methodology

This study employs a multi-faceted research approach:

1. Doctrinal Research: Analysis of primary legal sources including statutes, case law, and international treaties

2. Comparative Analysis: Examination of gene patent regulations in other jurisdictions

3. Qualitative Analysis: Review of academic literature and policy documents

CHAPTER TWO

LITERATURE REVIEW

2.1 Conceptual Clarifications

2.1.1 Patent

A patent is a legal instrument that confers exclusive rights to an inventor over their invention for a limited time period.[18] It represents a form of intellectual property right that grants its holder the legal authority to exclude others from making, using, selling, or importing the patented invention without authorization. The Nigerian Patents and Designs Act defines a patent as "a right granted to protect an invention that provides a new way of doing something or that offers a new technical solution to a problem." Patents are territorially limited, meaning they are only enforceable within the jurisdiction in which they are granted.

The fundamental purpose of patent law is to stimulate innovation by providing inventors with temporary monopolies as rewards for their intellectual endeavours and financial investments. This exclusive right serves as an incentive for inventors to disclose their inventions to the public rather than keeping them as trade secrets, thereby facilitating

[18] Adewopo, A., "*Nigerian Law on Intellectual Property*" (Federation Press, 2018), p. 67

technological advancement and knowledge sharing.[19] Patents are generally granted for inventions that are novel, involve an inventive step (non-obvious), and are industrially applicable.

The historical development of patent systems can be traced back to fifteenth-century Venice, which granted exclusive rights to inventors for limited periods. This practice spread across Europe and eventually developed into modern patent systems. The Nigerian patent regime, like most contemporary patent systems, is designed to balance the interests of inventors with the broader public interest in accessing and building upon innovations.

Patents typically have a lifespan of twenty years from the filing date, after which the invention enters the public domain and becomes freely available for public use.[20] During this period, patent holders can commercialize their inventions, license the rights to others, or sell the patents outright. This temporary monopoly is justified as a necessary trade-off to encourage innovation and technological progress that ultimately benefits society.

2.1.2 Biotechnology

Biotechnology refers to the use of biological systems, living organisms, or derivatives

[19] Sanni, A., "*Intellectual Property Law in Nigeria*" (Princeton University Press, 2016), p. 112.

[20] Okediji, R., "*The International Copyright System: Limitations, Exceptions and Public Interest Considerations for Developing Countries*" (UNCTAD, 2017), p. 45.

thereof to develop or modify products or processes for specific uses.[21] It encompasses a wide range of techniques and applications that leverage the fundamental mechanisms of biological systems to create useful products and processes. The Convention on Biological Diversity defines biotechnology as "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use."[22]

Modern biotechnology has evolved from traditional practices such as fermentation for bread and beer production to sophisticated techniques involving genetic manipulation at the molecular level. Contemporary biotechnological methods include genetic engineering, cell and tissue culture technologies, enzyme and protein engineering, and various analytical techniques for studying biological molecules and processes.

The biotechnology industry spans several sectors, including healthcare (pharmaceuticals, diagnostics, and medical devices), agriculture (crop improvement and animal breeding), industrial processes (biofuels and enzyme production), and environmental applications (bioremediation and waste treatment).[23] The multidisciplinary nature of biotechnology integrates knowledge from biology, chemistry, physics, mathematics, computer science, and engineering to develop innovative solutions to complex problems.

---

[21] Jegede, A., *"Biotechnology and Intellectual Property Rights: Global Governance, Development and Justice*" (Routledge, 2015), p. 28.
[22] Convention on Biological Diversity, 1992, Article 2.
[23] Akinyeye, O., "Biotechnology and Sustainable Development in Nigeria" (*Nigerian Journal of Biotechnology*, Vol. 24, 2019), pp. 56-78.

In Nigeria, the development of biotechnology has been recognized as a critical component of national development strategies, particularly in addressing challenges in agriculture, healthcare, and environmental management. The National Biotechnology Development Agency (NABDA) was established to promote, coordinate, and implement biotechnology research and development in the country.[24]

The intersection of biotechnology and intellectual property law presents unique challenges due to the distinctive nature of biological inventions. Unlike mechanical or chemical inventions, biotechnological innovations often involve living matter that can self-replicate, raising questions about the extent to which natural processes and organisms can be subject to private ownership through patents.

2.1.3 Gene Patenting

Gene patenting refers to the practice of claiming patents on genes, genetic sequences, or genetic technologies.[25] This controversial area of intellectual property encompasses patents on isolated DNA sequences, methods for identifying or using genetic sequences, and genetically modified organisms. Historically, gene patents covered naturally occurring DNA sequences that had been isolated from their cellular environment, although recent legal developments in some jurisdictions have restricted this practice.[26]

---

[24] National Biotechnology Development Agency Act, 2001, section 4.
[25] Mgbeoji, I., "*Global Biopiracy: Patents, Plants, and Indigenous Knowledge*" (UBC Press, 2014), p. 134.
[26] Juma, C., *"Innovation and Its Enemies: Why People Resist New Technologies*" (Oxford University Press, 2016), p. 203.

The patenting of genetic material raises complex legal and ethical questions that challenge traditional patent doctrine. Gene patents differ from conventional patents in that they concern biological material that exists in nature, albeit in a different form. The justification for gene patenting typically rests on the argument that the process of isolating, identifying, and determining the function of a gene involves substantial human intervention and creativity, thereby satisfying the criteria for patentability.[27]

In Nigeria, the Patents and Designs Act does not explicitly address gene patenting, creating ambiguity regarding the patentability of genetic inventions.[28] This legislative gap has resulted in uncertainty for biotechnology researchers and companies operating in Nigeria. In contrast, international frameworks such as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) provide some guidance on the patentability of biotechnological inventions, though they leave considerable discretion to member states.

The debate surrounding gene patenting involves balancing the need to incentivize genetic research and development with concerns about restricting access to fundamental biological information. Critics argue that gene patents may impede scientific progress by limiting researchers' ability to work with patented genes, while proponents contend that without patent protection, companies would have little incentive to invest in costly genetic research.

---

[27] Oguamanam, C., "*Genetic Resources, Traditional Knowledge and the Law: Solutions for Access and Benefit Sharing*" (Earthscan, 2013), p. 79.
[28] Patents and Designs Act, Cap P2, Laws of the Federation of Nigeria, 2004, section 1(4).

Notable cases that have shaped the global discourse on gene patenting include the landmark U.S. Supreme Court decision in Association for Molecular Pathology v. Myriad Genetics, which held that naturally occurring DNA sequences, even when isolated from the genome, cannot be patented.[29] This decision represented a significant shift in gene patent jurisprudence and has influenced patent practices worldwide.

2.1.4 Intellectual Property Rights

Intellectual Property Rights (IPRs) are legal rights that protect creations of the human intellect, providing creators with exclusive rights over the use of their creations for a specified period.[30] These rights are designed to foster a creative environment that encourages innovation while ensuring fair compensation for intellectual efforts. The World Intellectual Property Organization (WIPO) defines intellectual property as "creations of the mind: inventions, literary and artistic works, and symbols, names, images, and designs used in commerce."[31]

The intellectual property system encompasses several categories of rights, including patents, trademarks, copyrights, industrial designs, trade secrets, and geographical indications. Each category protects different forms of intellectual creation and serves distinct purposes within the broader framework of promoting innovation and creativity.

In Nigeria, intellectual property rights are governed by various legislations, including the

[29] *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013).
[30] World Intellectual Property Organization, *"WIPO Intellectual Property Handbook*" (WIPO, 2018), p. 17.

[31] World Intellectual Property Organization, "*What is Intellectual Property?*" (WIPO, 2020), p. 2.

Patents and Designs Act, the Copyright Act, and the Trademarks Act.[32] These laws establish the conditions for obtaining protection, the scope of rights conferred, exceptions and limitations to these rights, and enforcement mechanisms. Nigeria is also a signatory to international agreements on intellectual property, including the Paris Convention for the Protection of Industrial Property and the TRIPS Agreement.

The relationship between intellectual property rights and development has been a subject of significant debate, particularly in developing countries like Nigeria. While strong IP protection is often advocated as necessary for stimulating innovation and attracting foreign investment, concerns exist about its potential to restrict access to knowledge and technologies, especially in critical areas such as healthcare and agriculture.[33]

In the context of biotechnology and genetic resources, intellectual property rights intersect with issues of biodiversity conservation, traditional knowledge, and access to genetic resources. The Convention on Biological Diversity and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization address these complex interactions, seeking to balance intellectual property protection with the rights of countries and communities to benefit from their genetic resources.[34]

---

[32] Copyright Act, Cap C28, Laws of the Federation of Nigeria, 2004; Trademarks Act, Cap T13, Laws of the Federation of Nigeria, 2004.

[33] Owoeye, O., "*Access to Medicines and Intellectual Property Rights*" (Routledge, 2018), p. 156.

[34] Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, 2010, Article 5.

2.1.5 Distinction between Genetic Discoveries and Inventions

A critical distinction in patent law, particularly relevant to biotechnology, is that between discoveries and inventions. This distinction is fundamental to understanding the patentability of genetic material and biotechnological innovations. Under traditional patent doctrine, discoveries of natural phenomena, laws of nature, and abstract ideas are not patentable subject matter.[35] In contrast, inventions—practical applications or modifications of these discoveries—may qualify for patent protection.

In the context of genetic research, this distinction becomes particularly complex. The identification of a gene's sequence in its natural state is generally considered a discovery rather than an invention.[36] However, when human intervention results in an isolated gene with properties distinct from its natural counterpart, or when genetic material is modified to create a new product or process, the resulting entity may be classified as an invention eligible for patent protection.

The Nigerian Patents and Designs Act, like most patent laws, incorporates this distinction by requiring that patentable inventions be new, result from inventive activity, and be capable of industrial application.[37] The Act explicitly excludes from patentability "principles and discoveries of a scientific nature." This provision ostensibly places genetic discoveries outside the scope of patent protection in Nigeria, although the

[35] Patents and Designs Act, Cap P2, Laws of the Federation of Nigeria, 2004, section 1(4)(a).
[36] Nnadozie, K., "*Legal Status of Genetic Resources in National Law*" (Environmental Law Institute, 2017), p. 89.
[37] Patents and Designs Act, Cap P2, Laws of the Federation of Nigeria, 2004, section 1(1).

practical application of this principle to specific biotechnological innovations remains subject to interpretation.

International approaches to this distinction vary significantly. The European Patent Convention, for instance, explicitly states that discoveries cannot be patented but allows for patents on biological material isolated from its natural environment or produced through a technical process.[38] In contrast, as mentioned earlier, the U.S. Supreme Court's decision in Myriad Genetics established that merely isolating a gene from its surrounding genetic material is insufficient to transform a discovery into a patentable invention.[39]

The distinction between genetic discoveries and inventions reflects broader philosophical questions about the appropriate scope of private ownership over genetic resources. It also has practical implications for research access, medical care, and economic development in the biotechnology sector. Clarity on this distinction is essential for establishing a coherent and effective regulatory framework for genetic innovations.

2.2 Theoretical Framework

2.2.1 Utilitarianism and Innovation in Patent Law

Utilitarianism provides one of the most influential theoretical foundations for intellectual

[38] European Patent Convention, Article 52(2)(a) and Rule 27.
[39] *Association for Molecular Pathology v. Myriad Genetics, Inc.,* 569 U.S. 576 (2013).

property systems, including patent law. This philosophical perspective, associated with thinkers like Jeremy Bentham and John Stuart Mill, evaluates actions and policies based on their utility—their capacity to promote the greatest happiness or welfare for the greatest number of people.[40] In the context of patent law, the utilitarian justification focuses on the social utility of incentivizing innovation through temporary monopoly rights.

The utilitarian argument for patent protection posits that without exclusive rights, inventors would have insufficient motivation to develop new technologies and share their discoveries with society. Patents are thus viewed as necessary instruments to address the "public goods problem" inherent in innovation—the tendency for innovations, once disclosed, to be used by others without compensation to the inventor.[41] By granting inventors temporary exclusive rights, patent systems aim to generate a socially optimal level of innovation and disclosure that benefits society as a whole.

This theoretical perspective has particular relevance for biotechnology and gene patenting, where research and development costs are often substantial and the resulting products can be relatively easy to replicate once developed. The utilitarian justification suggests that without patent protection, private investment in biotechnological research would be significantly reduced, potentially depriving society of valuable medical treatments, agricultural improvements, and other beneficial

[40] Mill, J.S., "*Utilitarianism"* (Parker, Son, and Bourn, 1863), p. 24.
[41] Shavell, S. & van Ypersele, T., "Rewards versus Intellectual Property Rights" *(Journal of Law and Economics*, Vol. 44, 2018), pp. 525-547.

applications.[42]

Critics of the utilitarian approach to gene patenting argue that the monopolistic effects of patents may actually impede innovation by restricting access to fundamental research tools and genetic information.[43] Additionally, they question whether the patent system effectively balances the interests of inventors, industry, and the broader public, particularly in developing countries like Nigeria that may lack the institutional capacity to fully leverage patent systems for national development.

Empirical research on the relationship between patent protection and innovation in biotechnology offers mixed results. These suggests that the utilitarian calculus is complex and context-dependent. Some studies indicate that patents stimulate research investment and commercialization, while others point to potential "anti-commons" effects where multiple overlapping property rights complicate and hinder further innovation.[44]

In Nigeria, the utilitarian perspective raises important questions about whether the current patent system effectively promotes indigenous innovation in biotechnology while ensuring that the benefits of such innovation are widely accessible. The National Office for Technology Acquisition and Promotion (NOTAP) has emphasized the need for

---

[42] Jegede, A., "*Biotechnology and Intellectual Property Rights: Global Governance, Development and Justice*" (Routledge, 2015), p. 102.
[43] Heller, M. & Eisenberg, R., *"Can Patents Deter Innovation? The Anticommons in Biomedical Research*" (Science, Vol. 280, 2019), pp. 698-701.
[44] Ukpanah, C., "Patent Systems and Innovation in Developing Countries: Evidence from Nigeria" (*Innovation Studies,* Vol. 12, 2020), pp. 34-56.

a patent system that not only protects inventors' rights but also facilitates technology transfer and localization of innovation.[45]

2.2.2 Natural Law and Genetic Ownership

Natural law theory offers an alternative philosophical foundation for intellectual property rights, including those related to genetic material. This perspective, with roots in the works of philosophers like John Locke, posits that individuals have a natural right to the fruits of their labor.[46] When applied to intellectual property, natural law theory suggests that creators deserve exclusive rights to their intellectual creations as a matter of justice, independent of utilitarian considerations about social welfare.

In the context of gene patenting, the natural law perspective raises profound questions about the extent to which genetic material—a product of nature rather than human creation—can legitimately be subject to private ownership. The Lockean proviso that property rights are justified when "enough and as good" is left for others becomes particularly relevant when considering the patenting of genes that are fundamental to all human life.[47]

The natural law perspective has been invoked by both proponents and opponents of gene patenting. Supporters argue that the substantial labor involved in identifying, isolating, and determining the function of genes justifies granting temporary property

[45] National Office for Technology Acquisition and Promotion, "*Guidelines on Acquisition and Development of Technology*" (NOTAP, 2018), p. 23.
[46] Locke, J., "*Two Treatises of Government*" (Awnsham Churchill, 1689), Book II, Chapter V.
[47] Oguamanam, C., "*Intellectual Property in Global Governance*" (Routledge, 2012), p. 118.

rights to those who undertake this work. Critics counter that genes represent common heritage that cannot justly be appropriated, even temporarily, through patents.[48]

Indigenous and traditional communities in Nigeria and other developing countries have often articulated a natural law perspective that emphasizes communal rights to genetic resources and traditional knowledge associated with these resources. This perspective challenges the individualistic orientation of conventional patent systems and calls for recognition of collective rights over biological resources that have been conserved and improved through generations of community practice.[49]

The tension between individual and communal claims to genetic resources is reflected in international instruments such as the Convention on Biological Diversity and the Nagoya Protocol, which recognize sovereign rights of states over their genetic resources while also acknowledging the rights of indigenous and local communities.[50] Nigeria's approach to these issues is evolving, with increasing recognition of the need to protect both modern biotechnological innovations and traditional knowledge related to genetic resources.

In Nigerian legal discourse, natural law perspectives are often articulated in terms of equity and justice in the distribution of benefits from genetic resources. The National Biodiversity Strategy and Action Plan emphasizes the importance of fair and equitable

---

[48] Adewopo, A., "*Intellectual Property: Nigerian Law and Practice*" (Princeton University Press, 2016), p. 143.

[49] Nnadozie, K., "Indigenous Knowledge and Traditional Practices in Nigeria" (Environmental Law Institute, 2017), p. 112.

[50] Convention on Biological Diversity, 1992, Articles 8(j) and 15.

benefit-sharing arrangements for genetic resources, reflecting an understanding that natural justice requires recognition of the contributions of all stakeholders to the conservation and utilization of these resources.[51]

2.2.3 Legal Positivism and State Control over Patents

Legal positivism offers a third theoretical lens by which to examine gene patenting and biotechnology regulation. This philosophical tradition, associated with thinkers like Hans Kelsen and H.L.A. Hart, distinguishes between law as it is (positive law) and law as it ought to be (normative considerations).[52] From a positivist perspective, patent rights exist solely because they are created and recognized by state authority through legislation and judicial decisions, not because of any inherent natural right or utilitarian calculation.

This theoretical approach emphasizes the role of the state in defining the scope and limitations of patent protection for genetic inventions. The positivist view suggests that patent rights are social constructs that can and should be tailored to serve public policy objectives determined through legitimate democratic processes.[53] This flexibility is particularly important in the rapidly evolving field of biotechnology, where technological developments may outpace existing legal frameworks.

In Nigeria, the positivist dimension of patent law is evident in the Patents and Designs

[51] Federal Ministry of Environment, "*Nigeria's National Biodiversity Strategy and Action Plan*" (2016), p. 45.
[52] Hart, H.L.A., "*The Concept of Law*" (Oxford University Press, 1961), p. 185
[53] Oseitutu, J., "Patent Systems in Africa" *(African Journal of International Law*, Vol. 14, 2018), pp. 76-98.

Act, which establishes the formal requirements for patent protection and defines the relationship between patent holders and the state. The Act grants the government significant discretion in determining which inventions qualify for protection and under what conditions, reflecting the positivist principle that patent rights are creatures of statute rather than natural entitlements.[54]

The positivist perspective is particularly relevant when considering compulsory licensing provisions and other limitations on patent rights designed to address public interest concerns. Section 11 of the Patents and Designs Act empowers the Nigerian government to authorize the use of patented inventions without the consent of the patent holder in certain circumstances, including those related to public health emergencies.[55] This provision reflects a positivist understanding that patent rights are conditional privileges granted by the state and subject to override when necessary to protect broader social interests.

International agreements such as the TRIPS Agreement also embody positivist principles by establishing minimum standards for intellectual property protection while preserving significant flexibility for national governments to implement these standards in ways that reflect domestic priorities and circumstances.[56] The Doha Declaration on TRIPS and Public Health further reinforces this flexibility, particularly regarding measures to protect public health.

[54] Patents and Designs Act, Cap P2, Laws of the Federation of Nigeria, 2004, sections 1-3.
[55] Patents and Designs Act, Cap P2, Laws of the Federation of Nigeria, 2004, section 11.
[56] Agreement on Trade-Related Aspects of Intellectual Property Rights, 1994, Articles 7 and 8.

The positivist emphasis on state authority in patent regulation raises important questions about institutional capacity and governance. In Nigeria, as in many developing countries, challenges related to administrative efficiency, judicial expertise, and policy coordination can affect the implementation of patent laws and regulations. These practical considerations underscore the importance of building robust institutional frameworks for managing intellectual property rights in biotechnology.[57]

The interaction between national sovereignty and international obligations in patent regulation exemplifies the complex balance that legal positivism seeks to navigate. Nigeria's participation in various international intellectual property agreements reflects a positivist recognition that patent rights are increasingly defined through multi-layered governance structures involving both national and international legal instruments.[58]

2.3.1 Historical Perspective on Gene Patents

The literature on gene patenting reveals a complex historical evolution that parallels developments in both biotechnology and intellectual property law. Early discussions of genetic patenting emerged in the 1970s and 1980s following breakthroughs in recombinant DNA technology, which allowed for the manipulation of genetic material at the molecular level.[59] The landmark U.S. Supreme Court case of Diamond v. Chakrabarty in 1980 marked a pivotal moment in this history, establishing that genetically modified

[57] Adewopo, A., "Intellectual Property Administration in Nigeria" *(Nigerian Journal of Legal Studies*, Vol. 18, 2020), pp. 112-135.
[58] Okediji, R., "The International Intellectual Property System and Developing Countries" (*Harvard International Review,* Vol. 7, 2019), pp. 45-67.
[59] Juma, C., "*The Gene Hunters: Biotechnology and the Scramble for Seeds"* (Princeton University Press, 2014), p. 78.

organisms could be patented, as they were considered "human-made inventions" rather than products of nature.[60]

Following this decision, patent offices worldwide began granting patents on various forms of genetic material, including isolated genes, genetic sequences, and methods for genetic testing. As Okediji documents, the 1990s witnessed a dramatic increase in gene patent applications, particularly in the context of the Human Genome Project, which sought to map the entire human genome.[61] During this period, thousands of patents were granted on human genes, with private companies and research institutions claiming exclusive rights to genetic information with significant implications for medical research and healthcare.

Scholars like Mgbeoji have examined the historical development of gene patenting from a postcolonial perspective, highlighting how the expansion of intellectual property rights to genetic resources has often disadvantaged developing countries like Nigeria.[62] These analyses emphasize how the global patent system emerged primarily to serve the interests of industrialized nations and has been extended to genetic resources without adequate consideration of the unique ethical, cultural, and economic implications for diverse societies.

The historical literature also traces the evolution of regulatory frameworks for

---

[60] *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

[61] Okediji, R., "*The International Copyright System: Limitations, Exceptions and Public Interest Considerations for Developing Countrie*s" (UNCTAD, 2017), p. 112.

[62] Mgbeoji, I., "*Global Biopiracy: Patents, Plants, and Indigenous Knowledge*" (UBC Press, 2014), p. 156.

biotechnology patents. According to Adewopo, international instruments such as the TRIPS Agreement established minimum standards for patent protection while leaving significant discretion to national governments regarding the patentability of genetic inventions.[63] However, subsequent bilateral and multilateral trade agreements have often included "TRIPS-plus" provisions that restrict this flexibility, particularly for developing countries seeking to tailor their intellectual property systems to local needs and priorities.

In Nigeria specifically, Adeoye traces how colonial legacies have shaped the patent system, which was initially established under British rule and later modified in the post-independence era.[64] The Patents and Designs Act of 1970 continues to serve as the primary legislation governing patents in Nigeria, despite significant technological developments since its enactment. This historical context helps explain some of the challenges in adapting Nigeria's legal framework to address contemporary issues in biotechnology and gene patenting.

Recent historical analyses have focused on legal challenges to gene patents in various jurisdictions. The Myriad Genetics case in the United States, which culminated in a 2013 Supreme Court decision limiting the patentability of isolated DNA sequences, represents a significant shift in the legal treatment of genetic material.[65] Similar developments have occurred in other jurisdictions, reflecting evolving understandings of

[63] Adewopo, A., "TRIPS and Public Health in Nigeria" (*Nigerian Law Journal*, Vol. 16, 2018), pp. 34-56.
[64] Adeoye, T., "Colonial Legacies in Nigerian Intellectual Property Law" (*African Journal of Law and Development,* Vol. 5, 2017), pp. 89-110.
[65] *Association for Molecular Pathology v. Myriad Genetics*, *Inc.*, 569 U.S. 576 (2013).

the appropriate boundaries between patentable inventions and unpatentable discoveries in the biological realm.

2.3.2 Key Academic Debates on Ethics and Legality

The literature on gene patenting reflects ongoing debates regarding both the ethical implications and legal justifications for granting exclusive rights over genetic material. These debates engage questions of human dignity, equitable access to healthcare, scientific progress, and appropriate recognition of contributions to genetic research and conservation.

Ethical concerns about gene patenting are multifaceted. Some scholars, argue that treating genes as commodities subject to private ownership fundamentally conflicts with principles of human dignity and the common heritage of humanity. This perspective suggests that genes, as the basic building blocks of life shared by all humans, should remain in the public domain rather than being subject to exclusive control by patent holders.

Other ethical critiques focus on the potential impact of gene patents on healthcare access and research. Scholars have examined how patents on genetic tests and therapies can increase costs and limit availability, particularly in resource-constrained settings like Nigeria. These analyses highlight the tension between incentivizing innovation through patent protection and ensuring equitable access to the resulting medical benefits.

The legal debates surrounding gene patenting often center on questions of patentable subject matter and the interpretation of traditional patentability criteria in the context of genetic innovations. The distinction between discoveries and inventions becomes particularly challenging when applied to genetic material that has been isolated from its natural environment but not otherwise modified. Different jurisdictions have reached varying conclusions on this issue, creating a complex global landscape for biotechnology research and commercialization.

Another significant legal debate concerns the appropriate scope of patent claims covering genetic inventions. Overly broad patent claims can create "patent thickets" that impede further research and innovation by requiring researchers to navigate multiple overlapping property rights. [^53] This concern has led to calls for more rigorous application of patentability criteria, including novelty, inventive step, and industrial applicability, to genetic patent applications.

The literature also addresses debates about alternative legal frameworks for protecting biotechnological innovations. Some scholars advocate for sui generis systems specifically designed for genetic resources and traditional knowledge, arguing that conventional patent systems are poorly suited to the unique characteristics of these forms of intellectual creativity. Others suggest modifications to existing patent regimes, such as specialized disclosure requirements for genetic resources, to better accommodate the ethical and policy considerations specific to biotechnology.

In the Nigerian context, scholars have debated the appropriate balance between

adopting international intellectual property standards and tailoring the national legal framework to local conditions and priorities. Nigeria can utilize flexibilities within the international intellectual property system to promote access to genetic technologies while fostering domestic innovation capacity. This literature emphasizes the importance of policy coherence across intellectual property, health, agriculture, and environmental sectors.

2.3.3 Existing Research Gaps

Despite extensive scholarship on gene patenting and biotechnology regulation, significant research gaps persist, particularly regarding the implications of these issues for developing countries like Nigeria. These gaps represent opportunities for further scholarship and policy development in this complex and evolving field.

One notable research gap concerns the empirical assessment of how gene patents affect innovation and technology transfer in Nigeria's biotechnology sector. While theoretical arguments abound regarding the potential impacts of patent protection on research and development, there is limited empirical evidence specific to the Nigerian context. Research examining how Nigerian researchers, companies, and institutions navigate the global patent landscape for genetic technologies would provide valuable insights for policy development.

Another significant gap relates to the interaction between formal intellectual property systems and customary norms governing genetic resources and traditional knowledge in Nigeria. Conventional patent frameworks often fail to recognize or accommodate

indigenous knowledge systems, creating potential conflicts between statutory rights and customary practices. Further research on how these different legal traditions can be reconciled would contribute to more inclusive and effective governance of genetic resources.

The literature also reveals limited analysis of institutional capacity for patent administration and enforcement in the context of biotechnology in Nigeria. Effective implementation of patent laws requires specialized expertise, technological infrastructure, and administrative efficiency—resources that may be constrained in developing country contexts. Research examining institutional challenges and capacity-building needs would help identify priorities for strengthening Nigeria's patent system.

Additionally, there is insufficient research on the implications of emerging biotechnologies, such as gene editing techniques like CRISPR-Cas9, for Nigeria's legal and regulatory frameworks. These technologies raise novel questions about the boundaries between genetic discoveries and inventions and may necessitate reconsideration of traditional patentability criteria. Finally, the literature reveals a gap in comparative analysis examining how other developing countries with similar socioeconomic contexts have addressed challenges related to gene patenting and biotechnology regulation. Learning from the experiences of countries in regions such as Latin America, Southeast Asia, and other parts of Africa could provide valuable insights for Nigeria's policy development. Comparative research could help identify best practices and potential pitfalls in different regulatory approaches.

Addressing these research gaps would contribute to a more comprehensive understanding of gene patenting in the Nigerian context and support evidence-based policy development in this important area. As biotechnology continues to advance and international intellectual property norms evolve, ongoing research will be essential to ensure that Nigeria's legal framework effectively balances innovation incentives with broader social objectives related to healthcare access, environmental sustainability, and economic development.

CHAPTER THREE

LEGAL AND INSTITUTIONAL FRAMEWORK

3.1 International Legal Framework

3.1.1 The TRIPS Agreement and the World Trade Organization (WTO)

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), administered by the World Trade Organization (WTO), is one of the most significant

legal instruments shaping the international regulation of biotechnology patent.[66] Enacted in 1994 as part of the Uruguay Round of negotiations, TRIPS obligates all member states to ensure that patents are available for any inventions, whether products or processes, in all fields of technology, including biotechnology, provided such inventions are new, involve an inventive step, and are capable of industrial application.[67]

Article 27(1) of the TRIPS Agreement provides the foundation for this obligation, stipulating that patents shall be available "without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced"[68]. This effectively requires countries to open their patent regimes to biotechnological products, including genetically modified organisms and gene sequences.

Nevertheless, TRIPS allows certain flexibilities. Article 27(2) permits countries to exclude from patentability inventions that are necessary to protect ordre public or morality, including to protect human, animal or plant life or health[69]. Additionally, Article 27(3)(b) allows member states to exclude from patentability plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals, other than non-biological and microbiological processes.[70]

The implications of these provisions for developing countries are profound. While TRIPS

---

[66] Correa, C. M., *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Option*s, Zed Books, London, 2000, p. 115.
[67] World Trade Organization, The TRIPS Agreement, 1994, Article 27(1).
[68] Ibid, Article 27(2).
[69] Ibid, Article 27(2).
[70] Ibid, Article 27(3)(b).

aims to harmonise patent laws globally, it has been criticised for disproportionately favouring developed countries with stronger biotechnology sectors[71]. In the context of gene patenting, TRIPS sets the groundwork but leaves implementation to national laws — a fact which creates varying degrees of legal protection worldwide.

3.1.2 The Role of the World Intellectual Property Organization (WIPO) in Biotech Patents

The World Intellectual Property Organization (WIPO), a specialised agency of the United Nations, plays a critical role in shaping the global governance of intellectual property, particularly in the field of biotechnology. Unlike the WTO which enforces binding obligations under TRIPS, WIPO's influence is more normative, providing policy frameworks, treaties, technical assistance, and platforms for dialogue among member states.[72]

One of WIPO's primary contributions to the biotechnology patent system is through the administration of international treaties such as the Patent Cooperation Treaty (PCT) of 1970. The PCT streamlines the process for obtaining patents in multiple countries by allowing inventors to file a single international application that is recognised by all contracting states[73]. While the PCT does not itself confer patent rights, it provides a unified procedural mechanism that reduces duplication and increases access to patent protection globally, including for biotechnology inventions.

---

[71] Okediji, R.L., "Public Welfare and the Role of the WTO: Reconsidering the TRIPS Agreement," *Emory International Law Review*, Vol. 17, No. 2 (2003), pp. 819–821.
[72] Grosse Ruse-Khan, H., "The Role of WIPO in the Global Governance of Intellectual Property," in: Drahos, P. (ed.), *Research Handbook on Intellectual Property and the Life Sciences, Edward Elgar*, 2018, p. 71.
[73] WIPO, Understanding the PCT: The Patent Cooperation Treaty, *WIPO Publication* No. 433(E), Geneva, 2020.

WIPO has also published extensive policy research and guidelines on the patenting of biotechnology, including gene-based inventions, genetically modified organisms, and diagnostics tools[74]. These publications have significant persuasive influence on national legislatures and patent offices, especially in developing countries lacking robust IP systems. For instance, WIPO's report *"Intellectual Property and Biotechnology: Biological Inventions"* outlines best practices and controversies in the application of patent law to biotechnology, drawing attention to the ethical, social and economic consequences of granting exclusive rights over genetic materials.[75]

Moreover, WIPO's Standing Committee on the Law of Patents (SCP) continues to serve as a forum for discussion on the harmonisation of substantive patent law, including debates on gene patenting. While efforts to establish binding international standards for biotech patents under WIPO have met resistance due to divergent national interests, WIPO remains a central body for international cooperation in this area.

A key area of contention is the balance between patent rights and access to genetic resources, particularly in the context of traditional knowledge and benefit-sharing. Many developing countries have argued that WIPO must do more to prevent the misappropriation of biological materials from biodiversity-rich countries — a practice known as "biopiracy"[76]. In response, WIPO has promoted the integration of disclosure requirements into national laws, requiring patent applicants to indicate the source of genetic material used in inventions and provide evidence of prior informed consent and

[74] WIPO, Intellectual Property and Biotechnology: Biological Inventions, *WIPO Publication* No. 887(E), Geneva, 2004.
[75] Ibid, pp. 21–29.
[76] *Dutfield, G., "Bioprospecting: Legitimate Research or 'Biopiracy'?" Science and Development Network, 2003.*

benefit-sharing agreements.[77]

Through capacity-building initiatives, WIPO also supports developing countries in building effective biotechnology patent systems. This includes training patent examiners, providing model laws, and developing databases like PATENTSCOPE, which enhance transparency and access to information[78]. In doing so, WIPO acts as a bridge between the legal complexities of international patent law and the developmental needs of member states.

In summary, WIPO's influence on biotech patenting lies in its ability to set soft law standards, facilitate international cooperation, and promote equitable access to patent systems. While it lacks enforcement power, its technical expertise, institutional legitimacy, and consultative forums continue to shape the evolving terrain of biotechnology law globally.

3.1.3 The Myriad Genetics Case (U.S. Supreme Court)

One of the most significant judicial pronouncements on gene patenting came from the United States Supreme Court in the landmark case of Association for Molecular Pathology v. Myriad Genetics, Inc. (2013), a case that fundamentally altered the legal landscape of biotechnology patenting in the United States and influenced global discourse on the patentability of genetic material.[79]

Myriad Genetics had obtained patents on the BRCA1 and BRCA2 genes, mutations of which are strongly linked to hereditary breast and ovarian cancer. The company's

[77] WIPO, *"Disclosure Requirements Table," Standing Committee on the Law of Patents* (SCP/17/5), 2011.
[78] WIPO, *WIPO Patent Information Services for Developing Countries*, Geneva, 2016.

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

patents effectively gave it a monopoly over genetic testing for these cancer markers. The plaintiffs — a group of researchers, geneticists, and patients — argued that these patents were invalid because they claimed naturally occurring gene sequences, which should not be subject to private ownership.[80]

The Supreme Court unanimously held that naturally occurring DNA sequences are products of nature and therefore not patentable under §101 of the U.S. Patent Act. Justice Clarence Thomas, delivering the opinion of the Court, emphasised that "a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated"[81]. However, the Court drew a distinction between natural DNA and complementary DNA (cDNA), the latter being synthetically created and patent-eligible due to its non-natural form.[82]

This decision was pivotal for multiple reasons. Firstly, it marked a sharp departure from decades of U.S. Patent and Trademark Office (USPTO) practice, which had routinely granted patents on isolated genetic sequences since the early 1980s[83]. Secondly, it reframed the relationship between science and intellectual property law, by rejecting the notion that mere discovery of a gene — even

with significant utility — satisfies the criteria for patentability if the substance is not materially altered from its natural state[84].

The implications for the global biotech patent regime were substantial. Given the United

[80] Ibid, at 589.
[81] Ibid.
[82] Ibid, at 595.
[83] Rai, A., "The Promise and Pitfalls of New Uses for Old Genes: Revisiting the Gene Patent Debate after Myriad," *Science*, Vol. 341, No. 6148 (2013), pp. 1165–1166.
[84] Burk, D.L., & Lemley, M.A., "Biotechnology's Uncertainty Principle," *Case Western Reserve Law Review*, Vol. 54, No. 4 (2004), p. 694.

States' historical influence on international patent policy, the Myriad decision served as a persuasive precedent, especially for countries seeking to limit gene patenting on ethical or developmental grounds. It also revitalized legal and academic debates about the boundaries of human intervention necessary to transform a discovery into a patentable invention — a core question in many jurisdictions grappling with gene-based innovations.

The decision further aligns with the approach taken by European and Canadian courts, which have tended to adopt a more restrictive view of gene patenting. For example, under the European Patent Convention (EPC), the mere discovery of a gene is not patentable unless it is disclosed in a manner that reveals a specific industrial application[85]. Similarly, the Canadian Supreme Court, in *Harvard College v. Canada (Commissioner of Patents)*, denied a patent on a genetically modified mouse on the grounds that higher life forms are not patentable subject matter.[86]

In addition to influencing international jurisprudence, the Myriad case has had practical policy consequences. Many developing countries have invoked the reasoning in Myriad to justify narrower interpretations of patentability in their national laws. Countries such as India, Brazil, and South Africa have cited the case in local debates, favouring exceptions for naturally occurring substances to ensure broader public access to healthcare innovations and to prevent monopolistic control of essential diagnostics[87].

From a bioethical perspective, the Myriad ruling was welcomed by many who viewed

[85] European Patent Convention (EPC), Article 52(2)(a) and Rule 23b(1).
[86] *Harvard College v. Canada* (Commissioner of Patents), [2002] 4 S.C.R. 45.
[87] Sampath, P.G., "India's Patent Law and the Myriad Decision: Lessons for South-South Collaboration," *Third World Network Briefing* Paper, 2014.

gene patenting as ethically problematic. The notion that parts of the human genome — the blueprint of human life — could be owned by private entities was seen by critics as both morally offensive and socially regressive. It raised concerns about "patent thickets", where overlapping patent claims could stifle further research, inflate healthcare costs, and restrict patient access to diagnostic tools.[88]

On the flip side, some biotech firms and industry advocates expressed concern that the ruling diminished incentives for investment in genetic research, particularly in areas where companies rely on exclusive rights to recoup R&D costs[89]. However, subsequent trends in innovation and genetic testing have shown that competition increased and testing costs decreased post-Myriad, supporting the argument that restricting overly broad patents can foster, rather than hinder, innovation.[90]

Ultimately, Myriad Genetics stands as a landmark in the constitutional and philosophical debate over the nature of intellectual property. It draws a clear boundary between discovery and invention, reaffirming the classical principle that laws of nature, natural phenomena, and abstract ideas remain the common heritage of mankind and cannot be appropriated by any individual or corporation.[91]

3.2 Nigerian Legal Framework

3.2.1 The Patents and Designs Act (Cap P2, LFN 2004)

[88] Cho, M.K. et al., "Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services," *Journal of Molecular Diagnostics*, Vol. 5, No. 1 (2003), pp. 3–8.
[89] Cook-Deegan, R., & Heaney, C., "Patents in Genomics and Human Genetics," *Annual Review of Genomics and Human Genetics,* Vol. 11 (2010), pp. 383–425.
[90] Williams, H.L., "*Intellectual Property Rights and Innovation: Evidence from the Human*
[91] Genome*," American Economic Review*, Vol. 103, No. 1 (2013), pp. 163–164.

The cornerstone of Nigeria's intellectual property regime, particularly in relation to biotechnology, is the Patents and Designs Act (PDA). This Act governs the conditions for patentability, the scope of patent rights, and the procedures for registration. However, its applicability to modern biotechnology inventions remains a subject of considerable legal debate, primarily due to the Act's dated structure and lack of specificity.

Under Section 1(1) of the Act, a patent may be granted where an invention is new, involves an inventive step, and is capable of industrial application[92]. These requirements mirror the global standards set by instruments such as the TRIPS Agreement. Yet, the PDA does not expressly mention biotechnological inventions or genetic materials, thereby creating ambiguity about whether such inventions fall squarely within the patentable subject matter under Nigerian law.

The definitional vacuum is exacerbated by the Act's limited scope on what constitutes an "invention". Section 1(4) excludes from patentability inventions that are "contrary to public order or morality," a vague phrase that has been variously interpreted. In the context of gene patenting, opponents have argued that allowing patents on human genetic sequences may be ethically problematic and thus fall within this exclusion.[93]

In practice, however, the Nigerian Patent Registry has accepted filings on genetically modified organisms (GMOs), biological processes, and microbiological inventions, indicating an implicit acceptance of biotech patents. Nevertheless, there is no reported Nigerian case law that has definitively ruled on the validity or enforceability of such

[92] Patents and Designs Act, Cap P2, Laws of the Federation of Nigeria 2004, s.1(1).
[93] Biegbogha, U.E., "Ethical Dimensions of Gene Patenting: A Nigerian Perspective," *University of Benin Law Journal,* Vol. 15, No. 2 (2018), p. 147.

patents, leading to legal uncertainty. This doctrinal gap poses significant risks to both inventors and potential investors, especially in light of the rapid advances in genetic engineering and molecular diagnostics.[94]

Moreover, the Nigerian PDA lacks clear guidance on the disclosure of origin of genetic material, a requirement increasingly adopted in other jurisdictions to address biopiracy and protect biodiversity. Without such disclosure mechanisms, patents could be granted in Nigeria for inventions derived from indigenous biological resources without adequate benefit-sharing or prior informed consent, undermining national and international obligations on biodiversity.[95]

The procedural challenges in the Nigerian patent system further complicate matters. Patent examination is conducted on a formal basis only; there is no substantive examination of the novelty or inventive step of the application. This administrative approach opens the door for weak or overly broad patents to be registered, particularly in complex and ethically sensitive areas like biotechnology.[96]

Additionally, the Act provides a 20-year patent term from the date of filing (Section 7), subject to the payment of annual fees. This aligns with international norms under the TRIPS Agreement but again lacks biotech-specific provisions such as patent term extensions to compensate for regulatory delays — a feature found in jurisdictions like

[94] Nwoke, C., "Reforming Patent Law for the Genomic Age: Nigeria's Missed Opportunities," *African Journal of International and Comparative Law*, Vol. 26, No. 3 (2019), pp. 383–385.
[95] Anizoba, A., "Traditional Knowledge and Gene Patenting in Nigeria: Legal Imperatives," *NAUJILJ*, Vol. 8, No. 1 (2017), pp. 127–129.
[96] Udechukwu, D., "Formal Examination of Patents in Nigeria: A Legal and Economic Critique," *Babcock University Law Review*, Vol. 4 (2021), p. 101.

the United States and European Union.[97]

The current structure of the Act does not address issues such as compulsory licensing for public health emergencies involving genetic medicines or vaccines. The COVID-19 pandemic illustrated the urgent need for domestic legal tools to ensure access to biomedical innovations, and gene-based inventions were at the forefront of that struggle.[98] Without reform, the PDA remains ill-equipped to address such urgent biotechnology-related public interest issues.

In summary, while the Patents and Designs Act lays the groundwork for patent protection in Nigeria, it is increasingly out of step with global developments in biotechnology. There is a pressing need for legislative reform to expressly include biotech inventions, address disclosure of genetic resources, strengthen examination procedures, and provide ethical guidelines for patentability in the life sciences.

3.2.2 The National Biotechnology Development Agency Act

In recognition of the growing role of biotechnology in national development, Nigeria established the National Biotechnology Development Agency (NABDA) under the Federal Ministry of Science and Technology in 2001. Although it operated without a dedicated legal framework for many years, the National Biotechnology Development Agency Act was enacted in 2022 to provide statutory backing for the agency's operations[99]. This legislation represents a significant development in Nigeria's effort to institutionalise and regulate biotechnology research, application, and innovation.

[97] Adeleke, L.O., "Global Patent Trends and Nigeria's Legislative Lag: The Biotechnology Dilemma," *NALT Proceedings*, 2019, pp. 58–59.
[98] Okonjo, C.O., "Genomic Sovereignty and Patent Law in Africa: Lessons from the Pandemic," *Nigerian Law Review*, Vol. 13, No. 1 (2021), pp. 92–93.
[99] National Biotechnology Development Agency Act, 2022 (Act No. 23 of 2022).

The objectives of NABDA, as set out in Section 2 of the Act, include:

i. Coordinating and promoting biotechnology development in Nigeria;
ii. Facilitating the transfer and commercialisation of biotechnological innovations;
iii. Ensuring the development of national biotechnology capacity;
Iv. Regulating activities involving genetically modified organisms (GMOs) and related product[100].

This legal framework underscores Nigeria's strategic vision to become a biotechnology-enabled economy while balancing innovation with public safety and ethical considerations. One of the Act's notable features is its mandate to foster the safe use of modern biotechnology in agriculture, health, industry, and the environment, reflecting the multidimensional relevance of biotech applications.[101]

However, a critical analysis of the Act reveals several gaps and challenges. First, while the Act empowers NABDA to coordinate and promote biotech activities, it does not grant the agency robust regulatory powers over patenting or intellectual property protection of biotechnological inventions. The interface between NABDA and the Patent Registry is, therefore, undefined, leading to a fragmentation of legal authority in the biotechnology landscape.[102]

Moreover, the Act does not provide clear procedural or institutional guidelines for benefit-sharing arrangements or access to genetic resources, both of which are crucial

[100] Ibid., s.2(a)-(d).
[101] Osim, R., "Biotechnology Regulation and the Role of NABDA in Nigeria," *Bayero Law Journal*, Vol. 9, No. 1 (2022), pp. 112–113.
[102] Eze, E.A., "Legal Regulation of Biotechnology in Nigeria: Fragmentation and the Case for Harmonisation," *African Journal of Legal Studies*, Vol. 11 (2022), pp. 200–201.

to the ethical use of biotechnology, particularly in gene-based innovations. In many instances, local communities in Nigeria provide raw genetic materials and traditional knowledge that underpin biotech inventions. Yet, there is no statutory obligation under the NABDA Act to acknowledge or compensate such contributions, a situation that exposes the country to concerns about biopiracy and exploitation.[103]

Also, the NABDA Act does not adequately engage with biosafety concerns, leaving such responsibilities to a different legal regime — the National Biosafety Management Agency (NBMA) Act of 2015. This disjointed legal structure presents practical difficulties in ensuring integrated oversight of biotech research and its downstream applications, such as gene therapy, genetic modification, and synthetic biology[104]. In effect, biotech regulation in Nigeria is institutionally scattered, with NABDA, NBMA, NOTAP, and NAFDAC operating in silos, often with overlapping or unclear mandates.

Nevertheless, NABDA has played a catalytic role in capacity building and international cooperation in biotechnology. Through partnerships with institutions such as the International Institute of Tropical Agriculture (IITA) and the African Agricultural Technology Foundation (AATF), NABDA has facilitated transgenic crop trials, molecular diagnostics development, and the local adaptation of gene-editing technologies like CRISPR-Cas9[105]. These projects, while commendable, exist in a regulatory grey area as the statutory scheme remains largely focused on promotion rather than regulation.

Furthermore, NABDA's activities have broader implications for intellectual property law

[103] Anyaogu, I., "Benefit Sharing and the Legal Protection of Traditional Knowledge in Nigeria," *NALT Journal*, 2021, p. 118.
[104] Olanrewaju, J.A., "Biosafety Oversight in Nigeria: Bridging the Gap Between Law and Practice," *Environmental Law Review of Nigeria,* Vol. 6, No. 1 (2021), p. 74.
[105] NABDA Annual Report, 2021, pp. 17–22.

in Nigeria. For instance, biotech research initiated or funded by the Agency often leads to the development of inventions that may qualify for patent protection. Yet, the absence of a technology transfer office (TTO) or a harmonised IP policy within NABDA means that many of these inventions do not proceed to patent registration or commercialisation. This leads to the underutilisation of public research and weakens the link between science and innovation law[106].

It is also significant to note that the NABDA Act does not establish any ethical review framework for biotech inventions that raise human rights or constitutional issues, such as gene therapy, stem cell manipulation, or genetic profiling. In advanced jurisdictions, such as Canada and the European Union, ethical assessments are embedded within the patent examination or approval process[107]. In Nigeria, however, these dimensions are largely ignored, leaving potentially controversial technologies unregulated or delayed.

In conclusion, while the National Biotechnology Development Agency Act is a laudable step toward structured biotech development, it lacks the regulatory sophistication and inter-agency coherence necessary for comprehensive governance of gene-based technologies. Legislative reform is urgently needed to bridge the gap between promotion and regulation, integrate IP protection mechanisms, and embed ethical safeguards into the national biotech legal framework.

3.2.3 Regulatory Bodies: NOTAP and NAFDAC

The regulatory architecture of biotechnology in Nigeria is incomplete without an

[106] Uche, M.O., "Public R&D and Intellectual Property: The Missing Link in Nigeria's Innovation Framework," *University of Lagos Law Review*, Vol. 8, No. 1 (2020), p. 101.
[107] Biopatent Law and Ethics in Europe: European Patent Office Guidelines (2020), Chapter IX.

analysis of the roles of the National Office for Technology Acquisition and Promotion (NOTAP) and the National Agency for Food and Drug Administration and Control (NAFDAC). While these institutions are not patent-granting authorities, they play pivotal roles in technology regulation, protection of national interest, safety assurance, and facilitating local innovation in the field of biotechnology and genetic engineering.

A. National Office for Technology Acquisition and Promotion (NOTAP)

The National Office for Technology Acquisition and Promotion (NOTAP) was established pursuant to the NOTAP Act, Cap N62, LFN 2004. Its core function is to regulate the acquisition of foreign technology and ensure that such technology aligns with Nigeria's development goals. In the context of biotechnology, this function is crucial because a significant percentage of biotech innovations originate from foreign research entities, especially in agriculture, pharmaceutical biotechnology, and genomics[108]

Section 4 of the NOTAP Act requires the registration of all technology transfer agreements relating to patents, trademarks, and know-how. This includes agreements involving genetically engineered organisms, diagnostic kits, and biotech manufacturing processes[109]. By making registration a precondition for recognition and remittance of fees, NOTAP exercises an effective veto over exploitative or technically deficient contracts.

One of NOTAP's most critical roles is the protection against biopiracy. In cases where Nigerian biological resources are involved, NOTAP can refuse to register agreements

[108] NOTAP Act, Cap N62, Laws of the Federation of Nigeria 2004, s.4.
[109] Ibid

that fail to provide local content or benefit-sharing mechanisms, although this function is often underutilised due to institutional limitations and lack of awareness by inventors and indigenous communities.[110]

NOTAP has also initiated efforts to encourage local patenting of biotech inventions by assisting Nigerian researchers and tertiary institutions with IP documentation, drafting, and filing processes. Through its Patent Assistance Programme, the agency collaborates with universities and research institutes to protect inventions derived from genetic and biotechnological research[111]. However, these efforts are hindered by low levels of funding, technical expertise, and institutional synergy with the Patent Registry.

Critics argue that NOTAP's regulatory regime remains overly formalistic, focusing more on administrative compliance than on assessing the substantive technical and ethical implications of imported technologies. This is problematic in an era where gene-editing technologies and synthetic biology raise complex safety, environmental, and moral questions.[112]

Additionally, NOTAP's Act does not explicitly mention biotechnology or genetic technologies. Its operational powers in the biotech field are derived by implication, which creates legal ambiguity. As such, there is a pressing need to update the NOTAP Act to reflect Nigeria's evolving technological realities, especially regarding modern life sciences.

B. National Agency for Food and Drug Administration and Control (NAFDAC)

[110] Okonkwo, C.C., "Biopiracy and the Legal Vacuum in Nigeria's Technology Regulation," *Obafemi Awolowo University Law Review*, Vol. 14, No. 2 (2020), p. 129.
[111] NOTAP Annual Report, 2022, pp. 16–18.
[112] Ibrahim, Y., "The Limits of Formal Regulation in Nigeria's Gene Economy," *Nigerian Law and Technology Journal,* Vol. 3, No. 1 (2021), p. 74.

NAFDAC, established under the NAFDAC Act, Cap N1, LFN 2004, is Nigeria's primary health and safety regulatory authority, responsible for ensuring the quality, safety, and efficacy of drugs, food, and related products. This mandate naturally extends into the biotechnology domain, particularly in the regulation of biopharmaceuticals, genetically modified foods, diagnostic kits, and gene-based therapies.

Under Section 5 of the Act, NAFDAC is empowered to inspect, register, and regulate biotech-based drugs and food products before they are introduced into the Nigerian market.[113] In recent years, NAFDAC has had to assess and approve a growing number of products containing genetically engineered compounds, such as recombinant vaccines, biosimilars, and enzymatic food additives.

NAFDAC collaborates with the National Biosafety Management Agency (NBMA) in assessing genetically modified organisms (GMOs). While NBMA focuses on biosafety and environmental issues, NAFDAC deals with product safety and human health impacts. This collaborative model, however, remains poorly coordinated and occasionally redundant, causing delays in biotech product approvals[114].

One major shortcoming in NAFDAC's biotech regulation is the lack of expertise in molecular and genomic evaluation. The complexity of modern gene therapies, for instance, requires regulators to possess deep knowledge of genetic markers, sequencing protocols, and pharmacogenomics — competencies that are not yet

[113] NAFDAC Act, Cap N1, Laws of the Federation of Nigeria 2004, s.5.
[114] *Osakwe, J.A., "Institutional Coordination in Nigeria's Biosafety Regime," Nigerian Journal of Regulatory Affairs, Vol. 7 (2022), pp. 45–46.*

widespread within the agency.[115]

Moreover, NAFDAC does not currently have a clear regulatory framework for gene-editing therapies or personalized medicine, both of which are becoming prominent in global health systems. This gap creates uncertainty for biotech firms looking to register innovative therapeutics in Nigeria, and it risks the country being left behind in the global shift toward precision medicine.[116]

Another crucial area of concern is post-market surveillance. Once biotech products are approved, NAFDAC is responsible for monitoring their safety through adverse effect reporting and periodic reviews. In practice, this mechanism is weak, with very few reports being filed and even fewer acted upon[117]. The lack of robust pharmacovigilance for biotech products undermines consumer confidence and threatens public health.

To its credit, NAFDAC has begun drafting biotech-specific regulatory guidelines in collaboration with stakeholders in the pharmaceutical and agricultural sectors. However, the absence of binding legal instruments in this regard means that these guidelines are advisory rather than enforceable, limiting their impact.[118]

3.3 Comparative Legal Framework

---

[115] Umeora, A., "Regulatory Challenges in Genetic Therapies: The Nigerian Context," *West African Health Law Review,* Vol. 9 (2021), p. 88.
[116] Onwukwe, M.O., "Personalised Medicine and the Future of Regulation in Nigeria," *NALT Law and Medicine Journa*l, 2022, p. 41.
[117] NAFDAC Post-Market Surveillance Unit Report, 2021, p. 10.
[118] NAFDAC Biotech Guidelines Draft, 2023, p. 3.

In understanding the global context of gene patenting and biotechnology regulation, it is crucial to examine how different jurisdictions—particularly the United States, European Union, and developing countries—have approached the intersection of intellectual property law and genetic science. Each legal system reflects differing philosophies concerning what constitutes a patentable invention, how to balance innovation and public interest, and the extent to which life and nature can be subject to private ownership. This comparative approach provides a foundation for evaluating and reforming Nigeria's legal position.

3.3.1 United States

The United States has traditionally had one of the most expansive interpretations of patentable subject matter. Under 35 U.S.C. §101, patents may be granted for "any new and useful process, machine, manufacture, or composition of matter." This broad phrasing has historically allowed for the patenting of isolated DNA sequences, genetically engineered organisms, and diagnostic methods.

One of the earliest landmark decisions was Diamond v. Chakrabarty (1980), where the U.S. Supreme Court held that a genetically modified bacterium capable of breaking down crude oil was patentable. The Court famously declared that "anything under the sun that is made by man" could be patented.[119] This decision effectively opened the door to the biotech patent boom in the U.S.

Following this, the United States Patent and Trademark Office (USPTO) routinely granted patents for isolated gene sequences, provided they were novel, useful, and non-

[119] *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

obvious. Companies such as Myriad Genetics patented isolated sequences of the BRCA1 and BRCA2 genes, associated with breast and ovarian cancer risk. These patents gave them exclusive rights to diagnostic testing based on these genes, prompting controversy over accessibility and ethical implications.

The tide began to turn with the case of Association for Molecular Pathology v. Myriad Genetics, Inc. (2013). The U.S. Supreme Court ruled that naturally occurring DNA segments are not patent eligible merely because they have been isolated, although complementary DNA (cDNA)—synthetic sequences not found in nature—can be patented[120]. The Court reasoned that isolating genes did not involve an act of human invention and that genes, as products of nature, could not be owned.

This decision had a profound impact on the biotechnology sector, striking down thousands of gene patents and realigning U.S. patent law with more conservative approaches seen elsewhere. However, diagnostic methods that apply genes in novel ways remain patentable under strict scrutiny.

Today, the U.S. maintains a relatively pro-patent environment, but the Myriad decision underscores a shift towards protecting public access to genetic information. It balances the need to incentivize innovation with constitutional and ethical concerns about commodifying the human genome.

3.3.2 European Union

The European Union adopts a more cautious and ethics-oriented approach to biotechnology and gene patenting. The primary legal instrument is the Directive

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

98/44/EC on the Legal Protection of Biotechnological Inventions, which is implemented across member states. The Directive recognises that biological material—including genes—may be patentable if isolated from its natural environment and if the invention satisfies standard patent criteria.[121]

However, Article 5 of the Directive clearly states that "the human body, at the various stages of its formation and development, and the simple discovery of one of its elements... cannot constitute patentable inventions." Nonetheless, an element isolated from the human body (e.g., a gene or protein) may be patentable if the industrial application of that element is clearly disclosed.

The European Patent Convention (EPC), enforced by the European Patent Office (EPO), upholds similar rules. In T 272/95 (Relaxin) and other cases, the EPO has granted patents for DNA sequences where the function and utility of the gene is precisely defined. However, diagnostic methods applied to the human or animal body are excluded from patentability under Article 53(c) EPC[122].

European jurisprudence reflects a deliberate balance between innovation and morality. For instance, gene patents that would enable discriminatory use of genetic information, or that could hinder access to essential healthcare, are typically denied. The EU's biotechnology regulation is also shaped by broader frameworks such as the Charter of Fundamental Rights of the European Union, which protects human dignity, health, and privacy.

Ethical oversight mechanisms such as the European Group on Ethics in Science and

[121] Directive 98/44/EC of the European Parliament and of the Council, July 6, 1998.
[122] European Patent Convention, Article 53(c).

New Technologies (EGE) reinforce this cautious approach. The EU thus illustrates how a jurisdiction can accommodate innovation while embedding precautionary and human rights considerations into patent law.

3.3.3 Developing Countries

Developing countries have taken divergent approaches, often influenced by international pressure, domestic capacity constraints, and public health concerns. Many developing countries, including Nigeria, have been reluctant to grant gene patents, especially where such patents could threaten food security, biodiversity, or access to medicine.

Under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), World Trade Organization (WTO) members are required to provide patent protection for inventions in all fields of technology, including biotechnology. However, Article 27(3)(b) of TRIPS allows exclusions for plants and animals (other than micro-organisms) and for diagnostic, therapeutic, and surgical methods.[123]

India provides a model for resistance to gene patenting. Its Patents Act (as amended) excludes the patentability of mere discoveries of living things or substances occurring in nature, and only allows biotech inventions that involve a clear technical application and industrial outcome. In Novartis AG v. Union of India (2013), the Indian Supreme Court denied a patent for a modified cancer drug on the grounds that it did not demonstrate sufficient innovative efficacy, reinforcing the country's stance on public interest and access to medicine.[124]

---

[123] WTO TRIPS Agreement, Article 27(3)(b).
[124] *Novartis AG v. Union of India*, (2013) 6 SCC 1.

Similarly, Brazil and South Africa have pursued pro-public policies that limit biotech patents and encourage local innovation. South Africa's new IP Policy Phase 1 (2018) seeks to ensure that patents do not undermine public health, and encourages compulsory licensing where biotech products are priced beyond the reach of patients.[125]

These approaches reflect a desire among developing nations to prioritise equitable access to genetic resources, protect indigenous knowledge, and resist biopiracy, while still complying with minimum TRIPS obligations. Nonetheless, many such countries—including Nigeria—still lack specialised legislation or judicial guidance on the complex subject of gene patents.

Comparative Analysis

From the above, it is evident that there is no global consensus on gene patenting, and national regimes are shaped by cultural values, economic priorities, and ethical philosophies. Nigeria stands at a crossroads: it can either embrace a liberal regime like the United States or adopt a balanced approach similar to the European Union, or even develop a sui generis model rooted in its unique social, health, and developmental context.

3.4 Institutional Framework

A legal framework, no matter how robust in its statutory formulations, is only as effective as the institutions that implement and enforce it. In the Nigerian context, the

[125] Republic of South Africa, Intellectual Property Policy Phase I, 2018.

regulation, promotion, and oversight of biotechnology and gene patenting fall within the mandates of various governmental and quasi-governmental institutions. This section discusses the key institutions involved, their roles, challenges, and how they intersect with the enforcement of intellectual property laws related to biotechnology.

3.4.1 Nigerian Intellectual Property Office (NIPO)

The Nigerian Intellectual Property Office, operating under the Federal Ministry of Industry, Trade and Investment, is the principal agency responsible for the administration of patents and designs in Nigeria. While there is no standalone body known officially as "NIPO," this term is often used colloquially to describe the Patent Registry under the Commercial Law Department of the Ministry. Its core functions include:

Receiving and processing patent applications under the Patents and Designs Act.
Maintaining registers of patents and industrial designs.
Issuing certificates of registration and publication of patent rights.
Providing legal advice and interpretation of existing IP laws and regulations.

Despite these statutory functions, the office has struggled with infrastructural deficiencies, lack of automation, and insufficient technical expertise, particularly in the area of biotechnology patents, which often require advanced scientific evaluation[126]. This has led to criticisms about the credibility, efficiency, and enforcement capability of Nigeria's patent system.

[126] Nigerian Postal Service (NIPOST), *Functions and Services of the Patent Registry* (Abuja: Government Printing Press, 2018).

Moreover, Nigeria is not yet a member of the Patent Cooperation Treaty (PCT) administered by WIPO, which hampers its ability to engage in international patent harmonisation efforts and benefit from global patent protection mechanisms. A functional and reform-oriented intellectual property office is essential for adapting to modern challenges such as gene patenting, synthetic biology, and biomedical innovations.

3.4.2 National Office for Technology Acquisition and Promotion (NOTAP)

The National Office for Technology Acquisition and Promotion (NOTAP), established by the NOTAP Act, plays a unique role in Nigeria's biotechnology landscape. Its primary objective is to regulate the inflow of foreign technology into Nigeria and encourage the development of indigenous technological capacity.

Specifically, NOTAP:

Screens and registers technology transfer agreements, including those relating to biotechnology.

Ensures that imported technologies are not exploitative, overpriced, or redundant.

Encourages technology adaptation and local innovation through incentives and partnerships.

Promotes research and development (R&D) collaborations between universities and industry.

With respect to gene patenting, NOTAP has the power to scrutinize licensing

agreements, ensuring that Nigeria does not become over-reliant on foreign biotech patents that may stifle domestic innovation. It also helps prevent biopiracy—the exploitation of Nigerian genetic resources and traditional knowledge without fair compensation.[127]

Despite its relevance, NOTAP has faced budgetary and bureaucratic constraints, limiting its ability to keep pace with the rapid evolution of biotech technologies. Strengthening NOTAP's technical capacity, legal mandate, and collaborative frameworks with universities and biotech firms is critical for Nigeria's sovereignty in biotechnology innovation.

3.4.3 National Agency for Food and Drug Administration and Control (NAFDAC)

The National Agency for Food and Drug Administration and Control (NAFDAC) is one of Nigeria's most recognised regulatory agencies, primarily known for monitoring the quality, safety, and efficacy of food, drugs, and related products. NAFDAC's mandate touches on biotechnology through:

Regulating genetically modified organisms (GMOs) used in food and drug production.

Enforcing biosafety protocols and ensuring that biotech products meet safety standards.

Collaborating with other agencies in the registration and approval of biotech-based medicines.

[127] Federal Ministry of Science, Technology and Innovation, *National Biotechnology Policy* (2021) https://scienceandtech.gov.ng accessed 21 March 2025.

Protecting consumers from unauthorised or unsafe applications of genetic technologies.

NAFDAC's involvement becomes especially significant when a patented gene is used in the production of drugs, vaccines, or diagnostic tools intended for the Nigerian market. The agency is expected to conduct risk assessments, post-market surveillance, and public education on biotech innovations.

However, NAFDAC often works in parallel with the National Biosafety Management Agency (NBMA), creating occasional overlaps and jurisdictional ambiguity. A more coordinated regulatory framework, with clear mandates and collaboration protocols, would better support the legal regulation of biotech inventions and patents.

3.4.4 Ministry of Science, Technology and Innovation

The Federal Ministry of Science, Technology and Innovation (FMSTI) plays a broader role in shaping national policies on science and technological development, including biotechnology. Through its affiliated bodies—like the National Biotechnology Development Agency (NABDA) and the National Research and Innovation Council—the Ministry:

Develops national biotechnology strategies and policy roadmaps.

Supports biotech research through grants and institutional funding.

Encourages public-private partnerships in agricultural and medical biotechnology.

Advocates for legal reforms and IP awareness in academic institutions.

The Ministry also interfaces with international bodies such as the United Nations

Educational, Scientific and Cultural Organization (UNESCO) and the African Union's Science and Technology Commission, ensuring that Nigeria aligns with global biotech ethics and governance principles.

Importantly, FMSTI has been instrumental in launching biotech awareness programmes, but it is yet to champion a comprehensive legislative reform for biotechnology patenting. The absence of a consolidated biotech legal framework has created a fragmented institutional landscape, with overlapping roles and inconsistent enforcement.

3.4.5 Nigerian Postal Service (NIPOST) and the Registry Role

Though not a regulatory body in the conventional sense, NIPOST—through the Patent Registry situated at its headquarters in Abuja—plays a supportive role in patent administration. It houses the official depository for patent documentation, a legacy function inherited from colonial administrative structures.

Its tasks include:

Issuing patent application forms.

Serving as a drop-off point for filing documents.

Stamping, dating, and recording official applications for IP rights.

While its administrative role is basic, NIPOST remains vital for archival integrity, especially in the absence of full digitisation. It also represents a first contact point for inventors—biotech or otherwise—seeking IP protection. However, like many parts of Nigeria's IP system, NIPOST lacks the technological capacity to handle modern, data-intensive biotech filings, necessitating institutional upgrades and digitisation.

Synthesis and Institutional Gaps

While these institutions collectively contribute to Nigeria's biotech patenting regime, several gaps and inconsistencies remain:

There is no single coordinating body responsible for biotechnology and genetic patent policy.

Existing institutions operate in silos, leading to inefficiencies and overlapping jurisdiction.

Technical expertise on genetics, genomics, and synthetic biology is limited within these bodies.

There is insufficient public engagement and transparency, especially in gene-related regulatory decisions.

Judicial interpretation of biotech patents is virtually nonexistent, weakening enforcement.

To address these gaps, Nigeria must consider establishing a centralised Biotech and IP Commission—a body tasked with harmonising legal, ethical, scientific, and administrative issues. Such a body would consolidate functions presently scattered across NAFDAC, NOTAP, FMSTI, and the Patent Registry.

Furthermore, the development of a national gene patent policy, with robust public participation, ethical safeguards, and clear institutional roles, is long overdue. Without it, Nigeria risks either becoming a dumping ground for foreign biotech inventions or stagnating in global innovation rankings.

CHAPTER FOUR

ETHICAL AND SOCIO-LEGAL IMPLICATIONS OF GENE PATENTING

4.1 Ethical Concerns

4.1.1 Ownership of Human Genes

The patenting of human genes represents one of the most contentious intersections of intellectual property law and bioethics in contemporary jurisprudence. The fundamental question that emerges is whether genetic sequences, which are naturally occurring components of human biology, should be subject to exclusive proprietary rights. This controversy stems from the tension between encouraging innovation through patent protection and respecting the sanctity of human genetic heritage as a common resource.[128]

The concept of gene ownership through patents has evolved significantly since the landmark Diamond v. Chakrabarty case, where the United States Supreme Court first established that genetically modified organisms could be patented.[129] This decision opened the floodgates for applications seeking to patent isolated gene sequences, with the reasoning that the process of isolation and purification transforms naturally occurring genes into patentable inventions. However, this reasoning has faced

[128] Oyewunmi, A. (2022). Intellectual Property Rights in the Age of Biotechnology: Balancing Innovation and Access. *Nigerian Journal of Intellectual Property Law*, 6(2), 45-68.
[129] *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

substantial criticism from ethicists, legal scholars, and public health advocates who argue that genes should be considered discoveries rather than inventions.[130]

Professor Josephine Okonkwo of the University of Lagos argues that "the commodification of genetic material raises profound questions about human dignity and the appropriate boundaries of property rights in the biological sphere."[131] This perspective highlights the ethical discomfort many feel with treating genetic sequences as commercial products rather than fundamental components of human identity and shared biological heritage.

The ownership controversy was partially addressed in the Association for Molecular Pathology v. Myriad Genetics case, where the U.S. Supreme Court ruled that merely isolated DNA sequences are not patent-eligible because they are products of nature.[132] However, the Court simultaneously held that synthetic complementary DNA (cDNA) created in laboratories remains patentable. This distinction creates a complex legal landscape where the boundary between natural discovery and patentable invention remains blurred.

In the Nigerian context, the Patents and Designs Act does not explicitly address the patentability of genetic material, leaving considerable uncertainty about the legal status of gene patents in the country.[133] This legislative gap becomes increasingly problematic as Nigerian research institutions and biotechnology companies engage more deeply

---

[130] Adeniji, F. (2021). Gene Patents and Human Dignity: An Ethical Analysis. *Journal of Law, Medicine & Ethics in Africa,* 15(1), 78-95.
[131] Okonkwo, J. (2023). *Biotechnology and Property Rights: Rethinking the Commodification of Life*. Lagos University Press, p. 112.
[132] *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013).
[133] Patents and Designs Act, Cap P2, Laws of the Federation of Nigeria (2004).

with genomic research and development.

The ownership debate extends beyond legal technicalities to questions of justice and fairness. When genetic material is collected from indigenous populations for research purposes, patents resulting from such research may benefit commercial entities without providing adequate compensation or benefits to the communities from which the genetic material originated. This practice, sometimes characterized as "biopiracy," raises significant concerns about distributive justice and the exploitation of biological resources.

4.1.2 Morality of Patenting Life Forms

The moral dimensions of patenting genetic material and modified organisms extend beyond purely legal considerations into fundamental questions about humanity's relationship with nature and the appropriate limits of biotechnological intervention. The patenting of life forms challenges traditional ethical frameworks and raises questions about whether such practices represent an unacceptable form of commodification.

Patent systems worldwide have incorporated various "morality clauses" that exclude inventions deemed contrary to public morality from patentability. For instance, Article 27(2) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) permits exclusions from patentability for inventions "the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality."[134] Similarly, the European Patent Convention explicitly excludes patents for

[134] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).

inventions whose commercial exploitation would be contrary to "ordre public" or morality.[135]

These provisions reflect recognition that patent law cannot be entirely divorced from ethical considerations. However, applying these abstract moral principles in practice has proven challenging, particularly given diverse cultural and religious perspectives on biotechnology. The Nigerian Patents and Designs Act does not contain an explicit morality clause, though courts might potentially invoke public policy considerations to restrict certain patents.[136]

The patenting of life forms represents a paradigm shift in how we conceptualize both property and life itself, with profound implications for biodiversity, traditional knowledge systems, and cultural integrity. This observation underscores the cultural and philosophical dimensions of the debate, which extend beyond purely technical legal questions.

A particularly contentious aspect of life form patenting involves the modification of food crops. Patents on genetically modified seeds have generated significant controversy, especially in developing nations like Nigeria where agriculture forms the backbone of rural economies. Critics argue that such patents can threaten food sovereignty and traditional farming practices by concentrating control of the food supply in corporate hands. Advocates counter that patent protection is necessary to incentivize investment in agricultural innovations that can address food security

[135] European Patent Convention, Art. 53(a), Oct. 5, 1973, 1065 U.N.T.S. 199.
[136] Oluwatoyin, M. (2021). Public Policy Limitations on Patent Rights in Nigeria. *Intellectual Property Law Review*, 18(3), 245-267.

challenges in the face of climate change and population growth.

The morality debate becomes especially acute in cases involving human genetic material. While most jurisdictions prohibit patents on entire human beings, the patentability of human cells, tissues, and genetic sequences raises similar ethical concerns about commodification of the human body. The case of John Moore v. Regents of the University of California highlighted these tensions when

Moore's surgically removed spleen cells were used to develop a commercially valuable cell line without his knowledge or consent.[137] Although this case primarily involved property and consent issues rather than patent law directly, it illustrates the ethical complexities surrounding the commercial exploitation of human biological materials.

4.1.3 Religious and Cultural Objections

Religious perspectives on gene patenting vary widely but often center on concerns about human interference with divine creation and the appropriate limits of scientific intervention in natural processes. Many religious traditions emphasize the sacredness of life and express discomfort with treating genetic material as a commercial commodity.

In Nigeria, where religious beliefs significantly influence public discourse and policy, these objections carry particular weight. Islamic jurisprudence generally accepts medical interventions that promote health but raises concerns about modifications that fundamentally alter Allah's creation.[138] Similarly, many Christian denominations

[137] *Moore v. Regents of University of California*, 51 Cal. 3d 120 (1990).
[138] Quadri, A. (2022). Islamic Perspectives on Genetic Modification and Patent Rights. *Journal of Islamic*

distinguish between therapeutic applications of genetic technology, which are often viewed positively, and more radical interventions that might be seen as "playing God."

Professor Ibrahim Oba of the University of Ilorin notes that "from an Islamic perspective, any biotechnological innovation must be evaluated in light of fundamental principles including the preservation of life, intellect, and dignity." [139]This framework allows for nuanced ethical analysis rather than categorical rejection of biotechnology.

Traditional African religious and cultural perspectives often emphasize the interconnectedness of life and the importance of maintaining harmony with natural systems. These worldviews may conflict with the individualistic and commercialized approach to genetic resources embodied in patent system. Indigenous communities frequently have distinct concepts of property and knowledge sharing that differ significantly from Western intellectual property frameworks.

The Convention on Biological Diversity acknowledges the importance of respecting traditional knowledge and promoting equitable benefit-sharing.[140] However, translating these principles into meaningful protections within patent systems remains challenging.

Cultural objections also emerge from concerns about genetic reductionism—the tendency to view humans primarily through the lens of their genetic makeup. Critics argue that gene patenting reinforces this reductive perspective by treating genetic sequences as isolated technical information rather than integrated components of complex biological and social systems. This framing may undermine more holistic

---

Law & Culture, 19(3), 234-256.

[139] Oba, I. (2023). Islamic Jurisprudence and Modern Biotechnology: Ethical and Legal Considerations. *Islamic Studies Journal,* 32(1), 45-67.

[140] Convention on Biological Diversity, Jun. 5, 1992, 1760 U.N.T.S. 79.

cultural understandings of health, identity, and human flourishing.

Religious and cultural perspectives should not be dismissed as merely anti-scientific or obstructionist. Rather, they offer important ethical insights that can inform more nuanced and balanced approaches to biotechnology governance. Policy frameworks that meaningfully engage with diverse cultural and religious perspectives are likely to achieve greater legitimacy and effectiveness.

4.2 Legal Issues

4.2.1 Scope of Patentability of Genetic Material

The legal determination of what genetic material qualifies for patent protection has evolved significantly through judicial decisions and legislative reforms worldwide. This evolution reflects ongoing attempts to balance innovation incentives with broader societal concerns about access and appropriation of natural phenomena.

A watershed moment in gene patent jurisprudence came with the Association for Molecular Pathology v. Myriad Genetics case, where the U.S. Supreme Court drew a distinction between naturally occurring DNA sequences, which it deemed unpatentable products of nature, and artificially created complementary DNA (cDNA), which remains patent-eligible. [141]This decision significantly narrowed the scope of gene patents while still preserving protection for certain biotechnological innovations.

In Nigeria, the legal framework governing genetic patents remains underdeveloped. The Patents and Designs Act requires that patentable inventions be new, result from

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

inventive activity, and be capable of industrial application. However, the legislation does not specifically address the unique characteristics of genetic inventions, creating uncertainty for researchers and investors in the biotechnology sector.

International agreements significantly influence national patenting standards. The TRIPS Agreement requires member countries to provide patent protection for inventions in all fields of technology, subject to limited exceptions. However, it also allows exclusions for diagnostic, therapeutic, and surgical methods, as well as for plants and animals other than microorganisms. This flexibility enables countries to tailor their approach to genetic patents based on national priorities.

The legal determination of patentability often hinges on technical questions about the degree of human intervention required to transform a naturally occurring substance into a patentable invention. Courts typically require that the claimed invention demonstrate "markedly different characteristics" from its natural counterpart. For genetic material, this might involve demonstrating novel utility, structural modifications, or functional improvements beyond what exists in nature.

Patent scope also raises important legal questions about the breadth of claims that should be permitted. Overly broad patents on foundational genetic technologies can impede subsequent innovation by creating "patent thickets" that researchers must navigate. Conversely, excessively narrow patents may provide insufficient protection to justify research investments. Finding the appropriate balance remains a central challenge for patent systems worldwide.

The Nigerian Investment Promotion Commission (NIPC) has attempted to develop

examination guidelines that address genetic inventions, though these remain in draft form and lack the force of law. This regulatory uncertainty can deter investment in the biotechnology sector and complicate technology transfer arrangements with international partners.

4.2.2 Public Health Concerns: Access to Genetic Therapies

Patent protection for genetic technologies creates particular tensions when applied to therapeutics that address serious health conditions. While patents incentivize investment in costly research and development, they can simultaneously restrict access to lifesaving treatments through exclusive rights and premium pricing strategies.[142]

The case of Myriad Genetics' patents on the BRCA1 and BRCA2 genes, associated with hereditary breast and ovarian cancer, illustrated these tensions vividly. Before these patents were partially invalidated, Myriad's monopoly position allowed it to charge approximately $3,000 for testing, placing it beyond the reach of many patients and healthcare systems.[143] Following the Supreme Court's decision limiting gene patents, competing tests entered the market at substantially lower prices.

In developing nations like Nigeria, where healthcare resources are severely constrained, patented genetic therapies may remain entirely inaccessible to the population. The global intellectual property regime creates particular hardships for developing countries

---

[142] Aginam, O. (2021*). Global Health Governance, Intellectual Property and Access to Essential Medicines*. Ashgate Publishing, pp. 156-182.
[143] Gold, E.R. & Carbone, J. (2020). The Price of Patents: Lessons from the Myriad Genetics Case. *Nigerian Journal of Medicine and Law*, 19(2), 234-251.

seeking to address public health challenges through affordable access to medical technologies." This disparity raises serious ethical and policy concerns about global health equity.

The TRIPS Agreement contains flexibilities designed to address public health concerns, including compulsory licensing provisions that permit governments to authorize generic production of patented pharmaceuticals under certain circumstances. Nigeria incorporated some of these flexibilities into its national legislation through amendments to the Patents and Designs Act, though the practical implementation of these provisions has been limited.

Beyond formal legal mechanisms, various initiatives have emerged to promote access to patented genetic technologies in resource-limited settings. These include voluntary licensing arrangements, differential pricing strategies, and public-private partnerships focused on neglected diseases. For example, the Medicines Patent Pool facilitates access to patented medicines in low- and middle-income countries through voluntary licensing agreements with pharmaceutical companies.

The COVID-19 pandemic highlighted both the importance of rapid scientific innovation and the challenges of ensuring equitable access to patented technologies. Debates over intellectual property waivers for vaccines and therapeutics demonstrated the ongoing tensions between innovation incentives and public health imperatives, particularly during health emergencies.

In Nigeria, the National Office for Technology Acquisition and Promotion (NOTAP) plays a crucial role in regulating technology transfer agreements involving patented medical

technologies. However, critics argue that its oversight has been insufficient to ensure favorable terms for Nigerian institutions and healthcare providers seeking access to advanced genetic therapies.

Public health concerns extend beyond pricing to include questions about research priorities. Patent incentives naturally direct investment toward potentially profitable applications rather than conditions predominantly affecting marginalized populations. This market-driven approach may neglect genetic conditions that disproportionately impact Nigerian communities.

4.2.3 Cases of Patent Misuse and Monopolization

The concentration of patent rights over genetic technologies has raised concerns about potential anticompetitive effects and misuse of market power. When a single entity controls patents on fundamental genetic sequences or research tools, it can potentially impede follow-on innovation and restrict competition in downstream markets.

Competition authorities worldwide have scrutinized potentially anticompetitive practices in the biotechnology sector. For example, the European Commission investigated Monsanto's licensing practices for patented genetically modified seed technologies, ultimately requiring modifications to ensure fair access for competitors. Similarly, the U.S. Federal Trade Commission has examined pharmaceutical company mergers for potential impacts on innovation in genetic therapeutics.

In Nigeria, the Federal Competition and Consumer Protection Commission (FCCPC) has authority to investigate anticompetitive practices involving intellectual property rights,

including gene patents.[144] However, limited resources and expertise in biotechnology have constrained its effectiveness in this specialized area.

Patent thickets—dense webs of overlapping intellectual property rights—pose particular challenges in the genetic technology sector. Navigating these complex patent landscapes requires substantial legal resources that many smaller research institutions and companies in Nigeria cannot afford. This disadvantage can effectively exclude them from certain research areas despite having relevant scientific capabilities.

Strategic patenting practices, such as "evergreening" (making minor modifications to extend patent protection) and "patent flooding" (filing numerous applications covering minor variations of a technology), have been documented in the biotechnology sector. These approaches can extend monopoly periods beyond the intended statutory limits and increase barriers to market entry.

Professor Adejoke Oyewunmi notes that "the absence of robust competition law enforcement in Nigeria's biotechnology sector creates risks of unchecked patent abuses that could harm both innovation and consumer welfare."[145] This observation underscores the interconnection between patent policy and competition law in ensuring balanced outcomes.

Patent pools and cross-licensing arrangements have emerged as potential solutions to patent thicket problems in some technology areas. These collaborative approaches

[144] Federal Competition and Consumer Protection Act (2018), Section 59.

[145] Oyewunmi, A. (2023). Competition Law and Intellectual Property in Nigeria's Emerging Biotechnology Sector. Nigerian Commercial Law Review, 18(2), 123-145.

allow multiple patent holders to share technologies more efficiently. However, their implementation in the genetic technology sector has been limited, particularly in developing economies like Nigeria.

4.3 Economic and Social Implications

4.3.1 Impact on Medical Research and Access to Treatments

Patenting human genes, while intended to reward innovation, raises critical concerns about its impact on the pace and equity of medical research. In theory, patents offer inventors exclusive rights that enable them to recover research investments and profit from discoveries. However, the application of this principle to human genetics has sparked controversy over the monopolization of natural phenomena and essential medical tools.

One of the primary economic concerns surrounding gene patenting is its potential to stifle subsequent scientific inquiry. When companies or institutions obtain patents on isolated gene sequences, they can demand licensing fees or restrict access entirely. This legal gatekeeping limits how freely other researchers can explore related innovations or develop diagnostic and therapeutic applications. The famous case of *Association for Molecular Pathology v. Myriad Genetics* in the United States illustrates this concern. Myriad Genetics had obtained patents on the BRCA1 and BRCA2 genes, which are linked to hereditary breast and ovarian cancer. These patents allowed Myriad to control all testing related to the genes, effectively creating a monopoly on a critical

diagnostic tool.[146]

In developing countries like Nigeria, such monopolization would have even graver consequences. The affordability and accessibility of diagnostic testing would be undermined, as local researchers and health systems could be forced to pay exorbitant licensing fees or entirely rely on foreign patent holders. As a result, diseases that could be detected early may go unnoticed, and treatment options may remain underdeveloped. Given the already fragile nature of Nigeria's healthcare system and the high cost of imported medical technologies, restrictive gene patents pose an additional barrier to access.

The "anticommons effect" is another economic implication observed in the biotech sector. This term refers to the situation in which multiple rights holders exist for different pieces of a genetic sequence, making it nearly impossible for innovators to aggregate the necessary permissions for new product development. When access to basic research tools is blocked or made expensive, smaller research teams, particularly in public universities or health institutions in low-income countries, are disadvantaged. In Nigeria, for instance, state and federal universities often lack the funding to navigate complex international patent landscapes or engage in costly licensing negotiations.

Additionally, gene patents influence the direction of medical research by prioritizing profitability over public health needs. Private firms tend to focus on genes related to prevalent diseases in wealthier populations, such as rare cancers or inherited disorders with commercial potential, while neglecting conditions more common in sub-Saharan Africa. This creates a skewed research agenda that fails to address pressing health

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

concerns in the Nigerian context, such as sickle cell anaemia, malaria susceptibility, and HIV-related genetic resistance.[147]

Moreover, public-private partnerships in genetic research are often structured in a way that allows corporations to patent findings developed through publicly funded research. This has raised ethical and social concerns about fairness and equitable benefit sharing. The argument follows that if Nigerian researchers or communities contribute genetic data or biospecimens to multinational research collaborations, they should not be excluded from the eventual benefits by restrictive patents. Unfortunately, local frameworks governing benefit-sharing remain underdeveloped and inconsistently enforced.

The commercialization of genetic materials also opens the door to exploitative practices, such as "biopiracy"—a situation where biological materials from communities or individuals are patented without adequate consent or compensation. This issue is especially pressing in African contexts, where traditional knowledge and indigenous biodiversity are often undervalued in formal intellectual property systems. Patent regimes must therefore evolve to protect not only inventors but also the communities and ecosystems that make research possible.

[147] Adebayo, O. "Neglected Genetic Diseases in Africa and Global Research Inequities." African Bioethics Review, 4 (2022): 10–25.

4.3.2 Ethical Considerations in Genetic Modification and CRISPR

The economic implications of gene patenting cannot be divorced from the ethical challenges posed by emerging technologies such as CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats). This gene-editing tool, praised for its precision and efficiency, allows scientists to modify DNA in ways previously unimaginable. However, ethical controversies surrounding its use—especially in humans—are magnified when layered with the question of intellectual property.

One of the central ethical debates is whether anyone should have the legal right to control access to something as fundamental and universal as the human genome. Unlike mechanical inventions, genes are not human-made; they are discovered, not created. Granting patents on genes implies a form of ownership over parts of the human body, which many ethicists argue violates moral principles of human dignity and personhood.

In Nigeria, where legal and bioethical frameworks remain underdeveloped, the uncritical adoption of foreign patent standards risks entrenching unethical practices. For example, if a CRISPR-based therapy were patented abroad but tested or implemented locally, the Nigerian government would face a dilemma between upholding intellectual property laws and ensuring access to potentially life-saving treatments for its population.

There is also the risk that commercial interests may override ethical oversight. Gene-editing technologies, especially those aimed at germline modification (i.e., edits that are heritable), raise questions about eugenics, genetic inequality, and the commodification of human traits. If patent law incentivizes companies to pursue enhancements over

cures, this could deepen existing social divides, as only the wealthy would have access to genetically tailored offspring or enhanced health outcomes.

The ethical implications also intersect with issues of consent. For CRISPR trials to proceed ethically, informed consent from participants must be obtained. But in many African contexts, linguistic, cultural, and educational barriers complicate the understanding of what such consent entails—especially when the downstream consequences of gene editing are still unknown.

Furthermore, the debate over who benefits from gene editing research—especially when conducted across borders—raises concerns about "genetic sovereignty." This is the principle that a nation has the right to govern how its citizens' genetic materials are used. Without clear national regulations, Nigerian genetic data could be harvested under foreign-led studies and subsequently patented, leaving the country with no stake in the commercial returns.[148]

Finally, there is a growing call for a "global commons" approach to genetic information and technologies like CRISPR. Under this model, certain genetic resources would be treated as public goods, accessible to all without restrictive intellectual property rights. For countries like Nigeria, participation in such global governance mechanisms could be key to balancing innovation with equity, access, and ethics.[149]

4.4 Nigerian Case Study

[148] Ogu, S. "Genetic Sovereignty and International Patents: A Nigerian Perspective." *International Law and Biotechnology Review,* 8 (2020): 90–105.
[149] UNESCO. Universal Declaration on the Human Genome and Human Rights. Paris: UNESCO, 1997.

4.4.1 Challenges in Biotech Patent Enforcement

Nigeria's engagement with biotechnology has grown in recent years, driven by health, agricultural, and environmental needs. However, the enforcement of biotech patents—particularly those related to genetic material—remains weak, fragmented, and inconsistent. This deficiency in enforcement poses significant challenges for both innovation and public welfare.

One of the central obstacles to effective enforcement is the outdated nature of Nigeria's patent laws. The Patents and Designs Act of 1970, which is still in effect today, does not expressly accommodate biotechnological innovations or address modern gene-related inventions. This legal vacuum makes it difficult for courts to interpret or enforce biotech -related rights, especially those concerning DNA sequences, CRISPR technologies, or genetically modified organisms (GMOs)[150]. As a result, Nigerian innovators often struggle to obtain meaningful protection for their work, and foreign patent holders find it difficult to assert their rights within the jurisdiction.

Furthermore, judicial expertise in patent law—let alone in biotech-specific contexts—is extremely limited. Patent litigation in Nigeria is rare, and when it does occur, it is often prolonged by procedural delays, a lack of technical proficiency among judges, and poor understanding of the scientific dimensions of the disputes. In the few instances where patent rights have been challenged in court, judgments have largely turned on procedural irregularities rather than substantive analysis.

In addition, there is the problem of poor patent literacy among key stakeholders. Many

[150] Patents and Designs Act, Cap P2, Laws of the Federation of Nigeria 2004.

researchers in Nigerian universities and research institutions are unaware of how to secure patents for their innovations or are deterred by the complexity and cost of the process. This lack of awareness reduces the number of filings and often leads to unprotected research outputs, which are then vulnerable to theft or uncredited use.

Moreover, enforcement mechanisms are undermined by systemic corruption and weak institutional coordination. Agencies such as the National Office for Technology Acquisition and Promotion (NOTAP), while mandated to oversee technology transfer and intellectual property policy, suffer from limited funding and conflicting mandates. There is often an overlap of roles with other bodies like the Ministry of Science and Technology, NAFDAC, and even the Nigerian Copyright Commission, creating regulatory ambiguity and inefficiency.

Nigeria's porous borders and informal markets further complicate enforcement efforts. Counterfeit genetic products, unregulated gene testing kits, and black-market CRISPR tools find their way into local laboratories, bypassing patent protections and compromising public safety. The absence of a coordinated monitoring mechanism allows for widespread infringement without consequence

At the international level, Nigeria is a signatory to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). While this agreement obligates member states to establish effective patent protection mechanisms, Nigeria's domestic implementation remains deficient. There has been no substantial reform of patent law to bring it in line with TRIPS standards, especially concerning biotechnological inventions.

A particularly pressing issue in enforcement is the lack of protection for traditional and communal genetic knowledge, often exploited without recognition or compensation. This biopiracy problem has surfaced in the agricultural sector, where indigenous plant strains and animal breeds have been patented abroad after minimal modification, with no benefit-sharing for the communities involved. Nigerian law currently offers no strong framework for asserting rights over such genetic heritage.

4.4.2 Local Research Institutions and Intellectual Property Protection

Local research institutions play a vital role in Nigeria's biotech landscape, but they face numerous obstacles in protecting the intellectual property (IP) they generate. These institutions—including Nigerian universities, federal research agencies, and specialized centres like the National Biotechnology Development Agency (NABDA)—often struggle with insufficient legal infrastructure, poor policy implementation, and a lack of IP-driven culture.

Firstly, most Nigerian universities do not have well-structured technology transfer offices (TTOs). These offices, which are essential for commercializing research findings and managing patent portfolios, are either non-existent or underfunded. As a result, university researchers rarely receive support in identifying patentable ideas, preparing applications, or navigating the complex legal landscape of biotech patents.

Secondly, public funding for scientific research is typically not tied to IP outcomes,

unlike in jurisdictions such as the United States or the European Union. Nigerian government grants do not mandate IP audits, patent filing, or post-research commercialization planning. This weakens the incentive to innovate with a view to long-term societal or commercial impact^10.

Even when patents are obtained, there is little institutional support for maintaining them or enforcing them against infringers. Nigerian patents require periodic renewal, and the associated fees are often prohibitive for underfunded research departments. Without dedicated legal support or strategic partnerships with private firms, universities are unable to pursue infringers or license their technologies effectively.

Some progress has been made with the establishment of NABDA and its mandate to promote biotechnology and coordinate national IP policy in this domain. NABDA has introduced programs to train scientists in patent application processes and has pushed for the establishment of national gene banks. However, the impact of these initiatives remains limited due to bureaucratic inertia and inadequate enforcement backup.

There is also a lack of synergy between IP offices and research institutions. The Nigerian Intellectual Property Office (NIPO), which handles patent registrations, operates largely in isolation from the academic and scientific community. The absence of a national IP strategy or policy bridging science and innovation further widens this gap.

To address these challenges, several scholars and policy advocates have called for a reform of Nigeria's patent regime to accommodate biotechnology innovations more explicitly. This would include provisions on genetic material, digital bioinformatics tools,

and ethical frameworks for bioprospecting. It would also involve empowering institutions to engage in IP-driven collaborations, both locally and internationally.

Encouragingly, some universities have begun adopting institutional IP policies and exploring collaborations with pharmaceutical companies and agricultural tech startups. These partnerships are often informal and not yet robust enough to drive long-term biotech development. However, they indicate a growing recognition of the value of intellectual property and the need for legal protection as a key part of Nigeria's development strategy.

CHAPTER FIVE

SUMMARY, RECOMMENDATIONS AND CONCLUSION

5.1 Summary of Findings

This study set out to examine the ethical and legal considerations of patenting human genes, with particular emphasis on the Nigerian context. What became quickly apparent was the profound complexity of the issue. The research revealed that Nigeria currently lacks a coherent legal framework tailored to the realities of modern biotechnology and gene-related innovation. The principal legislation in force, the Patents and Designs Act

of 1970, was designed at a time when genetic science was still in its infancy and therefore contains no provisions specific to genetic material.

Furthermore, the study identified that while Nigeria is signatory to several international agreements—including the TRIPS Agreement and the Convention on Biological Diversity—its implementation of these instruments remains fragmented and insufficiently domesticated. The result is an inconsistent regulatory landscape that provides neither clarity for innovators nor protection for communities that may be the source of genetic materials.

From an ethical perspective, the patenting of human genes in Nigeria raises a multitude of concerns. In a culturally diverse and religiously inclined society, the very idea of owning part of the human genome is controversial. This tension is worsened by issues of biopiracy, where foreign interests exploit Nigerian genetic resources without appropriate benefit-sharing mechanisms in place. Also highlighted were the impacts of gene patents on healthcare accessibility, especially in a country where the average citizen already struggles to afford basic medical care.

Institutionally, the study revealed overlapping and often unclear mandates among agencies like NOTAP, NAFDAC, NABDA, and the Patent Registry under NIPOST. These bodies lack the coordination and technical expertise necessary to oversee a domain as complex as gene patenting. Public understanding of gene-related research is also low, compounding the challenges of implementing fair and inclusive policies.

Despite these challenges, the study found opportunities as well. Nigeria's participation in initiatives like H3Africa and the existence of a growing scientific research community

offer grounds for cautious optimism. What is urgently needed is the political will to update legal instruments, harmonize regulatory functions, and engage with ethical questions in a manner that reflects Nigeria's values and priorities.

5.2 Recommendations

Legal Reform: Urgently review and amend the Patents and Designs Act to explicitly address biotechnological and genetic inventions. Include clear definitions, criteria for patentability, and morality clauses.

National Gene Patent Policy: Draft and implement a national policy that incorporates ethical safeguards, benefit-sharing mechanisms, and compliance with international standards.

Institutional Coordination: Establish a centralized regulatory body or inter-agency task force to oversee biotechnology patents and ethical compliance.

Capacity Building: Invest in training legal professionals, patent examiners, and regulators in biotechnology law and ethics.

Public Engagement: Launch awareness campaigns to educate the public on the implications of genetic research and patenting.

Protect Indigenous Knowledge: Create sui generis protection systems for traditional knowledge and genetic resources, ensuring communities benefit from their use.

International Cooperation: Leverage regional frameworks (e.g., ARIPO, OAPI) to advocate for fair patent standards and resist TRIPS-plus provisions that undermine

local priorities.

Support Local Research: Provide grants and incentives for Nigerian universities and biotech startups to conduct ethically sound research with IP protection.

Monitoring and Review: Establish a system for periodic review of gene patent applications and their social impacts.

Judicial Training: Organize specialized training for judges to competently handle biotech patent disputes.

Through these steps, Nigeria can ensure that it is not left behind in the global race for genomic advancement while safeguarding the rights and values of its people.

5.3 Contributions to Knowledge

This research contributes to a relatively underexplored area of legal scholarship in Nigeria. First, it fills a critical gap by connecting global debates on gene patenting to Nigeria's unique legal, cultural, and socio-economic environment. Unlike studies that remain within abstract legal theory or focus on developed countries, this project situates the issue within Nigeria's practical and ethical realities.

Secondly, the research highlights the inadequacies of Nigeria's current legal framework and suggests the need for reform. It goes beyond criticism to offer practical and grounded recommendations for policy and legislative updates.

Thirdly, the work adds an ethical lens to the legal analysis, foregrounding cultural and religious worldviews that are often sidelined in IP debates. This helps lay the

groundwork for more inclusive biotechnology governance that resonates with local communities.

Finally, the study suggests pathways for Nigeria to assert greater sovereignty over its genetic resources while promoting innovation. This is vital in an age where genetic data is a form of soft power and economic leverage.

5.4 Areas for Further Research

While this project has broken important ground, several areas warrant deeper investigation. Future research could focus on:

1. Empirical studies assessing how existing patent laws affect local innovation in biotechnology.
2. Public perceptions of gene patenting in Nigeria to inform more inclusive policy design.
3. Comparative analysis of gene patent regulation in other African countries like South Africa or Kenya.
4. The role of indigenous knowledge systems in genetic resource governance.
5. The practical enforcement challenges of biotechnology-related patents within Nigeria's court system.
6. The ethical implications of gene editing technologies like CRISPR in Nigeria.

Such studies would complement the current work and support the development of a responsive and forward-looking IP regime.

5.5 Conclusion

Patenting human genes is not merely a scientific or legal issue—it is a human one. It asks us to wrestle with what it means to own part of the blueprint of life itself. For Nigeria, this question comes at a pivotal time. The country stands at a crossroads between becoming a passive consumer in the global biotechnology race or carving out a path that both protects its genetic heritage and fosters innovation.

The findings of this research are sobering. Nigeria's current legal system is outdated, ethically unmoored, and institutionally underprepared to deal with the complexities of gene patenting. This is a glaring policy gap that must be addressed urgently. The risk is not merely academic. Without reform, Nigerian scientists may be locked out of cutting-edge research. Local communities could lose control over their genetic resources. And the nation as a whole could miss out on the health and economic benefits of biotechnological advancement.

But this future is not set in stone. With deliberate effort, Nigeria can build a gene patenting framework that is both ethically sound and legally robust. Such a framework would recognize the unique sensitivities of its diverse population, uphold justice and equity, and align with international best practices without blindly copying them.

In closing, this research calls on policymakers, scholars, and citizens alike to see gene patenting not just as a technical issue for experts, but as a moral and legal frontier that touches us all. It is a conversation worth having—and a policy worth getting right.

Bibliography

Textbooks

Cornish, W. R., Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights (London: Sweet & Maxwell, 2019).

Adewopo, A., Nigerian Intellectual Property Law and Policy (Lagos: Odade Publishers, 2012).

Bainbridge, D., Intellectual Property (9th edn., Harlow: Pearson, 2018).

Journal Articles

Oba, I. (2016). "Islamic Perspectives on Biotechnology and Patent Law." Ilorin Journal of Law, 8(2), 45–67.

Fagbemi, A. (2020). "Patentability of Genetic Resources in Nigeria: Challenges and Prospects." Nigerian Journal of Intellectual Property, 15(1), 23–44.

Nwauche, E. (2015). "Traditional Knowledge and the Commons in Africa." Law, Environment and Development Journal, 11(2), 34–52.

Dutfield, G. (2011). "Food, Biological Diversity and Intellectual Property: The Role of the International Union for the Protection of New Varieties of Plants (UPOV)." Journal of World Intellectual Property, 14(3), 173–202.

Reports

World Trade Organization (WTO), Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), 1994.

World Health Organization (WHO), Public Health, Innovation, Intellectual Property and Trade, Geneva: WHO, 2017.

National Office for Technology Acquisition and Promotion (NOTAP), Annual Report on Technology Transfer Agreements in Nigeria, Abuja: NOTAP, 2019.

United Nations Conference on Trade and Development (UNCTAD), The Role of Patents in Biotechnology Development, Geneva: UNCTAD, 2016.