

**INTELLECTUAL PROPERTY RIGHTS AND ACCESS TO ESSENTIAL MEDICINES
IN NIGERIA: STRIKING A BALANCE BETWEEN INNOVATION, PUBLIC HEALTH
AND AFFORDABLE HEALTHCARE**

**IHEMTUGE CHUKWUBUDOM CHIEMEZUE
2019/LW/12441**

**FACULTY OF LAW, ALEX EKWUEME FEDERAL UNIVERSITY, NDUFU ALIKE
IKWO**

**DR. KELECHI ONYEBULE
(SUPERVISOR)**

OCTOBER 2024.

TITLE PAGE

**INTELLECTUAL PROPERTY RIGHTS AND ACCESS TO ESSENTIAL MEDICINES
IN NIGERIA: STRIKING A BALANCE BETWEEN INNOVATION, PUBLIC HEALTH
AND AFFORDABLE HEALTHCARE**

**IHEMTUGE CHUKWUBUDOM CHIEMEZUE
2019/LW/12441**

**BEING A PROJECT SUBMITTED TO THE FACULTY OF LAW, ALEX EKWUEME
FEDERAL UNIVERSITY, NDUFU ALIKE IKWO, IN PARTIAL FULFILLMENT OF
THE REQUIREMENTS FOR THE AWARD OF THE DEGREE OF BACHELOR OF
LAWS (LL. B)**

DR. KELECHI ONYEBULE

(SUPERVISOR)

APPROVAL

The Long Essay titled “Intellectual Property Rights and Access to Essential Medicines in Nigeria: Striking a Balance between Innovation, Public Health and affordable Healthcare” has been assessed and approved by the Undergraduate Studies Community of the Faculty of Law, Alex Ekwueme Federal University, Ndufu Alike Ikwo.

Dr. Kelechi Onyegbule
(Supervisor)

Date

Dr. Kelechi Onyegbule
(Project Cordinator)

Date

Assoc. Prof. Eseni Azu Udu
(Dean, Faculty of Law)

Date

CERTIFICATION

This is to certify that this long essay titled “Intellectual Property Rights and Access to Essential Medicines in Nigeria: Striking a Balance between Innovation, Public Health and affordable Healthcare” has been assessed and approved by the Undergraduate Studies Community of the Faculty of Law, Alex Ekwueme Federal University, Ndufu Alike Ikwo” as an original work carried out by Ihemtuge Chukwubudom Chiemezue, with registration number 2019/LW/12411 in the Faculty of Law, Alex Ekwueme Federal University, Ndufu Alike Ikwo, under the guidance and supervision of Dr. Kelechi Onyegbule

Ihemtuge Chukwubudom Chiemezue.
(Student)

Date

Dr. Kelechi Onyegbule
(Supervisor)

Date

Assoc. Prof. Eseni Azu Udu
(Dean, Faculty of Law)

Date

DEDICATION

This research work is dedicated to God Almighty for his love, mercies and grace all throughout my undergraduate days and to my family, my loving parents for their support and encouragement throughout the period of my LL. B journey.

Finally, I dedicate this work to all researchers who have gone before me and those that will come after me

ACKNOWLEDGEMENT

I recognize and acknowledge God for leading me in knitting this work together.

Also, this research would not have been possible without the invaluable support of my parents whose love and affection has been a solid inspiration for this Endeavor. I also wish to thank Barr Ekechi Agwu for her guidance in the initial phase of this work. I extend my sincere gratitude to Mr Okibe Emmanuel and Barr. Kelechi Njaka for their technical expertise. Their contributions were instrumental in the successful completion of this project.

Finally, I would love to acknowledge Dr. Kelechi Onyegbule, my supervisor for his continuous guidance and mentorship towards ensuring a successful completion of this research.

TABLE OF CASES

<i>Arewa Textiles PLC v Finetex</i> (2003) 7 NWLR (pt 3123) 321	51
<i>Dyktrade Ltd v Omnia Nig Ltd</i> (2003) 4 IPLR 266	21
<i>Jack Schroeder v Volvo Group</i> (Case No: LA/CV/20/05127)	34
<i>Liggett 7 Myers Tobacco v Registrar of Trade Marks</i> (1969) 1 ALR Comm 421	21
<i>Offrey v Ola</i> (unreported) suit No: Hos/23/68	51
<i>Serg Aluminium v Stanley Akagba</i> (1994) FHCS 188	51
<i>Yorkshire Copper v Works Application</i> (1954) 1 All ER 170	22

TABLE OF STATUTES

TRIPS Agreement	
Article 71	6
Article 15	20
Article 27	35
Article 31	39
Copyright Act 2022	
Section 2	17, 33
Section 9	17, 33
Section 10(1)(f)	17, 33
Section 11(f)	17, 33
Section 12(f)	17, 33
Section 13(c)	17, 33
Section 50 (1&3)	17
Trademark Act Cap T13 LFN 2004	
Section 67	20
Section 9	21
Section 5	34
Section 5(2)	34
Section 18	35
Section 23	35
Patent and Designs Act Cap P2 LFN 2004	
Section 1	36
Section 2	36
Section 2(4)	36
Section 7	37, 50
Section 3	40
Section 4	40

LIST OF ABBREVIATIONS

ER -	European Report
TRIPS -	Trade related Aspect of Intellectual Property Rights
IP -	Intellectual Property
IPR -	Intellectual Property Rights
Cap -	Chapter
LFN -	Laws of the Federation of Nigeria
WTO -	World Trade Organization
WIPO -	World Intellectual Property Organization

TABLE OF CONTENTS

Title Page	i
Declaration	ii
Approval and Certification	iii
Dedication	iv
Acknowledgements	v
Table of Cases	vi
Lists of Statutes	vii
Lists of Abbreviations	viii
Table of Contents	ix
Abstract	xi

CHAPTER ONE

INTRODUCTION

1.1	Background to the Study	1
1.2	Statement of the Problem	4
1.3	Aim and Objectives of the Study	6
1.4	Scope and Limitations of the Study	6
1.5	Significance of the Study	7
1.6	Research Methodology	9
1.7	Chapter Analysis	9

CHAPTER TWO

CONCEPTUAL, THEORETICAL FOUNDATION AND LITERATURE REVIEW

2.1	Conceptual Framework	12
2.1.1	Intellectual Property	12
2.1.2	Intellectual Property Right	12
2.1.3	Trademark	15
2.2	Theoretical Foundation	18
2.2.1	Utilitarian Theory	18
2.2.2	Positivist Theory	19
2.3	Review of Related Literature	20
2.4	Summary of Review/Gap in Knowledge	23

CHAPTER THREE

LEGAL AND INSTITUTIONAL FRAMEWORK

3.1	Legal Framework	24
3.1.1	Copyright Act 2022	24
3.1.2	Trademark Act Cap T13 LFN 2004	25
3.1.3	Patent and Designs Act Cap P2 LFN, 2004	26

3.1.4	TRIPS Agreement	28
3.2	Institutional Framework	30
3.2.1	Federal Ministry of Health	30
3.2.2	Trademarks, Patents and Designs Registry	31
3.2.3	Nigeria Copyright Commission	32
3.2.4	Court	32

CHAPTER FOUR

ENSURING ACCESS TO ESSENTIAL MEDICINES IN NIGERIA: STRIKING A BALANCE BETWEEN INNOVATION, PUBLIC HEALTH AND AFFORDABLE HEALTHCARE

4.1	The Importance of Intellectual Property Rights in Promoting Innovation	34
4.2	The Impact of Intellectual Property Rights on Access to Essential Medicines	35
4.3	Strategies for Ensuring Affordable Healthcare in Nigeria	37
4.4	Balancing Intellectual Property Rights with Public Health Concerns	39

CHAPTER FIVE

CONCLUSION

5.1	Summary of Findings	41
5.2	Recommendations	42
5.3	Contributions to Knowledge	42
5.4	Areas for Further Studies	43
5.5	Conclusion	43

BIBLIOGRAPHY	45
---------------------	-------	-----------

ABSTRACT

Intellectual Property Rights and Access to Essential Medicines in Nigeria: Striking a Balance between Innovation, Public Health, and Affordable Healthcare" explore the complex relationship between intellectual property rights, access to essential medicines, and the overall healthcare situation in Nigeria as a result of exclusive rights conferred on the owners of such creativity. These rights promote innovation in the pharmaceutical industry and if not properly regulated, has the ability of limiting people from accessing necessary drugs and medical equipment, thereby leading to high prices of the innovations. In Nigeria, there is in existence legal and ethical consequences of intellectual property rights violations especially patents, and has led to high rate of counterfeit in healthcare system. The exclusive rights of the owners may pose problems for the availability and affordability of essential medicines, and these obstacles affect public health outcomes in Nigeria. This study aims at assessing the roles intellectual property rights play on healthcare delivery in Nigeria and its ability to give incentives to innovations and attracting distinct investments in drugs. In the course of carrying out this research, doctrinal research methodology and it recommended among others that there is high need for awareness program in Nigeria that will educate the key actors involved and the general public on the need to strike a balance between intellectual property rights and access to health. The study concluded that a well-regulated intellectual property system can potentially contribute to the advancement of novel and improved medicines, thereby improving public health.

CHAPTER ONE

INTRODUCTION

1.1 Background to the Study

The views of Stephen and Adrianna are worthy of noting. To them, the issue of access to essential medicines in Nigeria is a complex one.¹ This is because, over the decades now, Nigeria has faced challenges in balancing intellectual property rights with the need for access to essential medicines. However, the increasing prevalence of diseases such as HIV/AIDS, malaria, and tuberculosis has put pressure on the healthcare system to provide affordable treatment options. This has sparked debates on how to ensure that pharmaceutical companies are incentivized to innovate while also ensuring that life-saving medications are accessible to those who need them the most.

Operationally, the right accruable to IP refers to a set of legal regimes that grant varying degrees of ownership over various types of intangible subject matter.² IP includes copyrights, trademarks, patents, and trade secrets. These legal regimes provide creators and inventors with exclusive rights to their creations or inventions, allowing them to benefit financially from their work. Intellectual activity in the fields of industry, research, and art is generally protected by law. Patents, trademarks, copyright, trade names, and indications of origin are common kinds of rights included in the generic phrase 'intellectual property'. These rights provide legal protection for intangible assets such as inventions, creative works, and branding. They allow creativity owners to benefit financially from their ideas and creations by giving them exclusive rights to use and make gains from their intellectual property. Patents are now related with economic,

¹ Stephen P Marks, et al. *Advancing Human Right to Health* (Oxford University Press, 2013), 305-324.

² Peter Drahos, 'The Universality of Intellectual Property Rights: Origins and Development' www.wipo.int/edocs/mdocs/tk/en/.../wipo_unhchr_ip_pnl_98_1.doc. Accessed 23 July, 2024.

health, cultural, and social situations in a country. There is no doubt that patents have contributed to national growth and provided advantages for humanity. Inventions have played a significant role in human evolution and have improved social and economic conditions. However, patent protection in regard to public health has been heavily discussed over the last 20 years, with claims that patents are a barrier to accessing medications in underdeveloped nations.³

Public health concerns have led to the only multilateral reconsideration made so far to the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights. The Doha Declaration on Public Health addressed important points of principle at the highest political level, and led to the only amendment so far applied to the TRIPS Agreement, in the form of a Special Compulsory Licensing System to give vulnerable countries a new avenue for access to medicines. Even though there is a provision for regular review of the TRIPS Agreement,⁴ and an annual review of the Special Compulsory Licensing System, developing countries and non-governmental organizations assert that the TRIPS Agreement and in particular its patent provisions, represent a barrier to effective access to medicines.⁵ The Doha Declaration was conceived mainly as a result of apprehensions about the likely impact of the TRIPS Agreement on access to medicines.⁶ Many developing countries were concerned that the TRIPS Agreement would hinder their ability to produce affordable generic drugs, which are essential for treating widespread diseases such as HIV/AIDS and malaria. The Doha Declaration reaffirmed the flexibilities enshrined in the TRIPS Agreement, allowing countries to issue compulsory licenses for generic drug production so as to protect health of the members of the public. This

³ B.N Sampat, 'Academic Patents and Access to Medicines in Developing Countries. *American Journal of Public Health*, (2009) 9(17) 99.

⁴ See Article 71 TRIPS Agreement.

⁵ Zita Lazzarini, 'Making Access to Pharmaceuticals a Reality: Legal Options under TRIPS and the Case of Brazil'. *Yale Human Rights & Development Law Journal*, (2003) 6(1) pp103-138.

⁶ The Doha Declaration explained available at http://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm#trips. Accessed on 23rd July, 2024.

declaration marked a significant step towards ensuring that access to medicines would not be compromised by intellectual property rights.

However, there are other issues pertaining to public health than just the lack of access to necessary medications. The most impoverished nations' demands are still unmet even though the topic of medicine availability has dominated discussions about public health care for a long time.⁷ This has prompted investigations into other domains, including medical device access. The topic of affordable health care, which covers access to medications, medical services, and medical equipment, is now being discussed. Health services may be effectively denied or deteriorated if high-quality, safe, and suitable priority medical devices are not readily available. This equipment plays important roles in everything from screening to diagnosis and treatment.⁸

As a result, in May 2007, the World Health Assembly adopted its first resolution on health technologies.⁹ This resolution called for member states to improve health technologies. It also emphasized the importance of promoting research and development of new health technologies to address public health needs. The resolution was based on a project known as Priority Medical Devices (PMD), which was started by the WHO at the request of the Dutch government through the Ministry of Health, Welfare, and Sports in order to identify disparities in the preventive, diagnostic, therapeutic, and assistive medical devices that are currently on the market by figuring out whether or not the needs of end users and health care providers worldwide are being met, and if not, offering solutions to address the shortcomings or inadequacies.

⁷ Report of the United Nations Secretary-General's High Level Panel on Access to Medicines: Promoting Innovation and Access to Health, p. 21- 28. Available at www.unsgaccessmeds.org/finalreport/. Accessed on 23rd July, 2024.

⁸ WHO, Medical Devices, Priority medical devices, available at: http://www.who.int/medical_devices/access/en/. Accessed on 23rd July, 2024.

⁹ WHO Sixtieth World Health Assembly Health Technologies WHA60.29. Available at: http://www.who.int/medical_devices/resolution_wha60_29-en1.pdf. Accessed 23 July, 2024.

Regardless of what has been discussed so far in the above paragraphs, the purpose of this paper is to examine the challenges and opportunities surrounding intellectual property rights and access to essential medicines in Nigeria. By striking a balance between promoting innovation in the pharmaceutical industry and ensuring that life-saving medications are accessible and affordable to all. Ultimately, the target of discussing this topic is to improve public health outcomes and ensure that no one is left behind in the quest for quality healthcare.

1.2 Statement of the Problem

The issue of intellectual property rights and access to essential medicines in Nigeria presents a complex challenge that requires careful consideration and a balanced approach. In recent years, the intersection of intellectual property rights (IPR) and public health, particularly in the area of essential medicines, has become a topic of significant debate and concern. This issue brings to the fore the need to strike a balance between fostering innovation, ensuring affordable access to medications, and promoting public health.

Nigeria, like many other developing countries, faces the challenge of balancing the protection of intellectual property rights with the imperative of providing its citizens with access to essential, life-saving medicines. The current global intellectual property regime, characterized by patents and other forms of protection, has the potential to hinder access to affordable medicines, particularly in developing countries where healthcare systems may already be overstretched.

For Nigeria, this issue is particularly pressing given the high burden of disease and the need to ensure access to essential medicines for its population. While the protection of intellectual property rights is essential for fostering innovation and incentivizing research and development in the pharmaceutical industry, it must be reconciled with the goal of ensuring access to affordable medicines, especially for those in need.

One of the key challenges is the potential conflict between intellectual property rights and public health objectives. Patented medicines are often priced beyond the reach of many patients, leading to issues of affordability and accessibility. This situation poses a significant barrier to the realization of the right to health, as enshrined in international human rights law and domestic legislation.

In order to address this challenge, it is essential to explore mechanisms that maintain an equilibrium between the interests of pharmaceutical companies, which rely on intellectual property rights to recoup their investments, and the public health imperative of ensuring that drugs are made available and people can afford. One potential avenue for achieving this balance is through the implementation of changes within the international intellectual property framework, as outlined in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which allows for measures to protect public health and promote access to medicines.

Furthermore, the issue of access to essential medicines in Nigeria requires a multi-faceted approach that considers not only intellectual property rights but also broader issues such as healthcare financing, supply chain management, and capacity building within the pharmaceutical sector. By addressing these factors comprehensively, Nigeria can move towards a more sustainable and equitable healthcare system that facilitates access to essential medicines while respecting the importance of intellectual property rights.

The issue of intellectual property rights and access to essential medicines in Nigeria is a complex and multifaceted challenge that requires a balanced and nuanced approach. By reconciling the imperatives of promoting innovation, safeguarding intellectual property rights, and ensuring

access to essential medicines, Nigeria can make significant strides towards achieving affordable healthcare and improved public health outcomes for its population.

The questions that will inform this study are:

1. How do intellectual property rights impact access to essential medicines in Nigeria?
2. What measures can be taken to ensure a balance between promoting innovation and protecting public health?
3. How can affordable healthcare be maintained while respecting rights accruable to creations of mind in the pharmaceutical industry?

1.3 Aim and Objectives of the Study

The general aim of this study is to examine the intellectual property rights and access to essential medicines in Nigeria: striking a balance between innovation, public health and affordable healthcare.

Specifically, the study seeks to achieve the following objectives:

- a. To find out how intellectual property rights impact access to essential medicines in Nigeria.
- b. To discover the measures that can be taken to ensure a balance between promoting innovation and protecting public health.
- c. To find out how affordable healthcare be maintained while respecting intellectual property rights in the pharmaceutical industry.

1.4 Scope and Limitations of the Study

This study investigates the intricate relationship between intellectual property rights and access to essential medicines in Nigeria, with a focus on striking a balance between innovation, public health, and affordable healthcare. The research will examine the existing legal framework

governing intellectual property rights in Nigeria, particularly the Patent and Designs Act and the National Health Act 2014. Additionally, the study will analyze the impact of international trade agreements, such as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), on access to essential medicines in Nigeria.

The study will concentrate on Nigeria, exploring the country's experiences and challenges in balancing intellectual property rights with access to essential medicines. The temporal scope will cover the entire Nigeria, allowing for an examination of the evolution of intellectual property laws and policies in Nigeria and their effects on access to essential medicines. The study will also draw on comparative analyses from other developing countries to identify best practices and lessons learned.

This study has several limitations. Firstly, the research relies on secondary data and documentary analysis, which may not provide an exhaustive understanding of the complex issues surrounding intellectual property rights and access to essential medicines. Secondly, the study's focus on Nigeria may limit its generalizability to other countries. Furthermore, the research may face challenges in accessing sensitive information from pharmaceutical companies, government agencies, or international organizations. Finally, the study's exploratory nature may not allow for in-depth empirical analysis, potentially affecting the study's comprehensiveness and accuracy.

1.5 Significance of the Study

This study shall be of great importance to the following persons:

To Students: This study is important for students as it provides an in-depth analysis of the complex relationship between intellectual property rights and access to essential medicines in Nigeria. By understanding this balance, students can gain insight into the difficulties faced by developing countries like Nigeria in ensuring affordable healthcare for all. This knowledge can

help students develop a more nuanced understanding of global health issues and the role of intellectual property in shaping access to essential medicines. Ultimately, this study can empower students to advocate for policies that promote innovation while also prioritizing public health and affordable healthcare in Nigeria and beyond.

To Researchers: This study will provide valuable insights into the challenges faced by Nigeria in balancing intellectual property rights with the need for affordable access to essential medicines. Researchers will gain a better understanding of the impact of intellectual property laws on public health and healthcare affordability in Nigeria. This understanding will help inform future policy decisions and strategies aimed at promoting innovation, improving public health outcomes, and ensuring that essential medicines are accessible and affordable for all Nigerians.

To Health Professional/Medical Practitioners: This study is crucial for health professionals and medical practitioners in Nigeria as it examines the complex relationship between intellectual property rights, access to essential medicines, and public health. By striking a balance between innovation, public health, and affordable healthcare, this research aims to provide valuable insights and recommendations for healthcare providers to navigate the challenges of ensuring access to life-saving medications while also respecting intellectual property rights.

To Policy Makers: This study will provide valuable insights into how intellectual property rights impact access to essential medicines in Nigeria. By understanding the balance between promoting innovation and ensuring public health, policymakers can make informed decisions on healthcare policies and regulations. More so, this research aims to contribute to the goal of providing affordable healthcare for all Nigerians.

To the Government: This study is crucial for the government of Nigeria as it will provide insight into how to navigate the complex issues surrounding intellectual property rights and access to essential medicines. By striking a balance between innovation, public health, and affordable healthcare, the government can ensure that its citizens have access to the medications they need without compromising on the incentives for pharmaceutical companies to continue developing life-saving drugs. Additionally, this research can inform policy decisions that will benefit the overall health and well-being of the Nigerian population.

1.6 Research Methodology

This study adopted the doctrinal research method, focusing on analyzing existing laws and regulations related to intellectual property rights and access to essential medicines in Nigeria. The research also included a review of relevant court cases and legal literature to provide a comprehensive understanding of the current legal framework in the country. The doctrinal approach allowed for a thorough examination of the legal landscape surrounding intellectual property rights and access to essential medicines in Nigeria. By analyzing existing laws and regulations, as well as court cases and legal literature, this study was able to provide valuable insights into how the balance between innovation, public health, and affordable healthcare is being maintained in Nigeria.

1.7 Chapter Analysis

The first chapter of this research work provides an overview of the key components that will be explored in the subsequent chapters. It outlines the background of the study, identifies the problem being addressed, and sets out the aims and objectives of the research. Additionally, the chapter discusses the scope and limitations of the study, highlighting the significance of the research in the context of healthcare in Nigeria. The chapter presents the research methodology

that will be employed to achieve the study's objectives. Finally, the chapter analysis provides a roadmap for the reader, giving a clear understanding of what to expect in the following chapters.

The following chapter of the work will delve into the various conceptual clarifications surrounding intellectual property rights and access to essential medicines in Nigeria. This will involve defining key terms and concepts to provide a clear understanding of the topic at hand. Additionally, the chapter will explore the theoretical foundation that underpins the relationship between intellectual property rights, public health, and affordable healthcare in Nigeria. Finally, a comprehensive review of existing literature on the subject will be conducted to highlight the current state of research and identify gaps in knowledge that this study aims to address.

Chapter three of this work will explore the existing legal framework in Nigeria related to intellectual property rights and access to essential medicines. It will discuss how these laws impact innovation, public health, and the affordability of healthcare in the country. Additionally, this chapter will analyze the institutional framework in place to enforce these laws and ensure that the balance between promoting innovation and safeguarding public health is maintained.

Going further to chapter four, this work will explore the challenges faced in Nigeria in ensuring access to essential medicines while also promoting innovation and maintaining affordable healthcare. It will delve into the importance of intellectual property rights in driving innovation in the pharmaceutical industry, as well as the impact these rights have on access to essential medicines for the population. Additionally, strategies for ensuring affordable healthcare in Nigeria will be discussed, along with the importance of balancing intellectual property rights with public health concerns to achieve a sustainable healthcare system in the country.

The final chapter of the work will provide a comprehensive overview of the key findings discussed throughout the research. It will also offer practical recommendations for policymakers,

healthcare professionals, and stakeholders to strike a balance between protecting intellectual property rights and ensuring access to essential medicines in Nigeria. Additionally, the chapter will highlight the contributions of the study to existing knowledge in the field and suggest potential areas for future research to further explore the complex relationship between innovation, public health, and affordable healthcare in the country. Ultimately, the conclusion will emphasize the importance of addressing these issues to improve healthcare outcomes and promote sustainable development in Nigeria.

CHAPTER TWO

CONCEPTUAL, THEORETICAL FOUNDATION AND LITERATURE REVIEW

2.1 Conceptual Framework

Under this heading, some key words will be discussed to aid ease understanding of the work. These words include intellectual property, intellectual property rights, trademark, among others.

2.1.1 Intellectual Property

Intellectual Property (“IP”) simply refers to creations embarked upon by the people, such as inventions, literary and artistic works, designs, and symbols, names and images.

Intellectual Property is protected in law by various Nigerian laws. These laws are classified into Patents Act, Copyright Act and Trademarks Act, which give the people the leverage to be recognized and make gains from their inventions. By striking the right balance between the interests of innovators and the wider public interest, the Intellectual Property system aims to foster an environment in which creativity and innovation can flourish, and rights accruable to it are enjoyed by the owners without unlawful violations.

It includes properties that humans have invested their mind, efforts and skills in bringing into existence due may not be in tangible form.

2.1.2 Intellectual Property Right

Intellectual Property Rights (“IPRs) refers to rights granted to creators of innovative and novel works, typically affording the creator exclusive control over the use and exploitation of their creation. The World Trade Organization defines Intellectual Property Rights to mean rights

given to persons over the creations of their minds. It confers on the owners of such word or creativity with an exclusive right over the use of his/her creation for a certain period of time¹⁰.

Copyright, Trademarks, Patents, and Designs, are the major Intellectual Property Rights accrual to owners of creative works, including medical inventions in Nigeria. Copyright¹¹ as part of intellectual property refers to creations such as artistic and literary inventions. A Trademark deals in signs which can be unique in such manner as to differentiate the goods or services of one enterprise from those of other enterprises, while Patent is an exclusive right granted for an invention or design¹². The legal framework for the protection of Intellectual Property Rights in Nigeria consists primarily of the Copyright Act¹³, the Trademarks Act¹⁴, and the Patent and Designs Act¹⁵. While, both the Trademark, Patents and Designs Act make provisions for the protection of distinct varieties of intellectual property in Nigeria.

The impact of intellectual property rights (IPRs) on access to essential medicines is a pressing concern in the global health community. According to a report by the World Health Organization, IPRs can limit access to affordable medicines by granting exclusive rights to pharmaceutical companies, leading to high prices and reduced availability. This is particularly concerning in developing countries, where healthcare systems are often under-resourced and unable to afford expensive medicines.

¹⁰ World Trade Organization, 'What are Intellectual Property Rights?'

https://www.wto.org/english/tratop_e/trips_e/intell_e.htm. Accessed on 10th October, 2024

¹¹ Section 2 of the Copyright Act 2022 states the categories of works eligible for copyright to include: literary works, musical works, artistic works, cinematograph films, sound recordings and broadcasts.

¹² WIPO, what is Intellectual Property? <https://www.wipo.int/about-ip/en/>. Accessed on 11th October, 2024.

¹³ Copyright Act, 2022.

¹⁴ CAP T13 Laws of the Federation of Nigeria, 2004.

¹⁵ CAP P2 Laws of the Federation of Nigeria, 2004.

The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement has been criticized for its role in limiting access to essential medicines. As noted by Correa,¹⁶ TRIPs set minimum standards for IPR protection, which can limit the ability of governments to promote public health. However, TRIPS also provides flexibility for countries to adopt measures to protect public health, such as compulsory licensing. This flexibility has been used by countries like Brazil and Thailand to increase access to essential medicines.

The impact of IPRs on access to essential medicines is also influenced by the patent system. The patent system can be used to extend the life of patents, limiting the availability of generic medicines. This can lead to a situation where patients are forced to rely on expensive branded medicines, rather than more affordable generic alternatives. To address this, some countries have implemented measures to limit the use of patent extensions, such as the "patent opposition" system used in India.

The impact of IPRs on access to essential medicines is a complex issue that requires a nuanced approach. IPRs can be used to promote innovation, but they must be balanced against the need to ensure access to affordable medicines. This requires governments, pharmaceutical companies, and civil society to work together to find solutions that promote both innovation and access.

To promote access to essential medicines in Nigeria despite intellectual property rights challenges, one strategy is to leverage TRIPS flexibilities, such as compulsory licensing. As noted by Correa,¹⁷ compulsory licensing allows governments to grant licenses to third parties to produce patented medicines without the patent holder's consent. Nigeria can use this flexibility to

¹⁶ C.M Correa, *Trade-related Aspects of Intellectual Property Rights*. (Oxford University Press, 2007) 12.

¹⁷ C.M Correa, *Trade-related Aspects of Intellectual Property Rights*. (Oxford University Press, 2007) 13.

increase access to affordable medicines, particularly for diseases like HIV/AIDS and tuberculosis.

Another strategy is to promote local production of essential medicines. According to a study by the World Health Organization, local production can reduce reliance on imports and increase access to affordable medicines. Nigeria can incentivize local production by providing tax breaks, subsidies, and other support to pharmaceutical companies.

Strengthening healthcare infrastructure and effective management of all innovations in the country are also crucial in balancing these rights and ability of the people to use the innovations. A well-functioning healthcare system is essential for ensuring access to essential medicines. Nigeria can invest in healthcare infrastructure, including storage facilities, transportation networks, and healthcare worker training. This will help ensure that medicines reach patients in need, even in rural and hard-to-reach areas.

International cooperation and partnerships can play a critical role, international partnerships can help Nigeria access affordable medicines through initiatives like price negotiations, pooled procurement, and technology transfer. Nigeria can work with international organizations, like the Global Fund and UNITAID, to access affordable medicines and build capacity for local production.

2.1.3 Trademark

The term “trademark” means a mark used to distinguish goods (including services or goods related to the provision of services) of one business from those of others. It can be any symbols which have the ability of being represented graphically which is used to distinguish goods and services of one undertaking from those of others.

According to section 67 of Trademark Act, trade Mark means a mark used or proposed to be used in relation to goods for the purpose of indicating, or so as to indicate, a connection in the course of trade between the goods, and some person having the right either as proprietor or as registered user to use the mark, whether with or without any indication of the identity of that person, and means, in relation to a certification trade mark, a mark registered or deemed to have been registered under the Act.

According to Article 15 of the Agreement on Trade Related Aspects of Intellectual Property Rights, any sign or combination of signs, capable of distinguishing the goods or services of one undertaking from those of other undertakings, shall be capable of constituting trademarks, such signs in particular words including personal names, letters, numerals, figurative elements, and combination of colours as well as any combination of such signs shall be eligible for registration as trademarks.

The concept of trade marks signifies the materialization of creative minds toward branding of products which is essential in the 21st century business as purchasing decisions are constantly influenced by trademarks which help distinguish products and services from those of competitors and help identify a particular company as a source.

Trademark cannot be ignored or set aside as it relates to the origin of the product and the ability of consumers to be able to distinguish one good from the other whilst at the same time, guaranteeing quality and a strong instrument of advertisement.¹⁸

In *Dyktrade Ltd. v. Omnia Nig. Ltd.*¹⁹ It was held that when a mark has been registered, it entitles the owner to use the trademark exclusively and also, would have a right to sue for passing off when the defendant uses such goods that are inconsistent with that of the plaintiff.

¹⁸ W. Cornish. and D. Llewelyn. *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*. 6th Edition. (Sweet & Maxwell, 2007), 603.

An essential feature of a trademark therefore, is that it must be distinctive before it can be registered but it must always be when dealing with such goods in the course of trade.²⁰ trademark protection laws.

For a mark to be registered, it is important that the prerequisite requirements must be followed and must have passed the authenticity test. Under a Trademark, there is register (Part A and Part B Registration), however for a Part A Registration, section 9(1) of Trademark Act provides what a Trademark must consist or contain as an essential particular which are to wit;

- a) The name of the company, individual or firm represented in a special or particular manner
- b) Applicant's signature targeted for the registration, etc.
- c) Novel words duly invented.
- d) Words other than one that may have direct reference to the genuineness of the goods, and not be according to its ordinary signification, a geographical name or a surname.

In *Yorkshire Copper Works Application*,²¹ the company deals with solid materials made with copper and wanted to register the name "Yorkshire Copper". It was contended that the name is a geographical name in England, arguing that people who use that product would think the goods is in Yorkshire. The court relying on that assertion held that they can't use that name as it's a geographical name.

However, in *Liggett & Myers Tobacco Ltd v Registrar of Trade Marks*²², the applicant sought to register their Cigarette with the "CHASTERFIED" without any design but they have been using it with design. The application was rejected because it is not distinctive cause it's a name of a town in England but the plaintiff argued that it has no connection with the quality of the

¹⁹ [2003] 4, I.P.L.R. p.266, 267

²⁰ Section 9 (2), NTMA, Cap. T13, Laws of the Federation 2004

²¹ (1954) 1 ALL England Report at Pg.170

²² (1969) 1 ALR Comm. 421

product and that Chesterfield has another English meaning (OVERCOAT). The court held that the application should be accepted since in its ordinary significance can't be a geographical name.

In furtherance for a trade mark to be registered, it must be distinctive and able to differentiate between the goods of one undertaking from those of other undertakings in the course of trade so that confusion would be minimized.

2.2 Theoretical Foundation

2.2.1 Utilitarian Theory

The utilitarian theory of law was started by Jeremy Bentham. He propounded that life is full of pain and pleasure and that law should be used as a tool of social engineering or means to increase human happiness and minimize pain.²³

Every law should be enacted to secure or ensure the happiness of the greatest possible number of people. The aim of law should be to maximize human happiness by securing the greatest happiness of the greatest number of people. Every person in the view of utilitarian theorists should be allowed freedom to pursue his or her own happiness, advantage, and actualize himself, and to seek self fulfilment without interference by the state.

In line with the utilitarian theory, intellectual property laws should be utilized in such a way that the rights accruable to owners of such creative works are protected while people still have accessed the medicine without violating the rights. It is in so doing that such medical invention can be said to have utility to satisfy and solve societal medical issues. This balls down to the postulations of Bentham in the utilitarian theory.

²³ B, Appadorai. *The Substance of politics*. (Oxford University Press, 2003), 23.

2.2.2 Positivist Theory

In the field of intellectual property rights, positivist theory simply postulates that legal frameworks are as enacted by the authority empowered to enact laws or agent authorized to do. The agent referred to, means the legislative organ which is primarily empowered to make laws or a delegated legislator with delegated powers to make delegated legislations or judges who in the course of proceeding over cases may establish case law or judicial precedents. In other words, law is law as made by the law maker and it remains the law until same is amended or repealed.

John Austin believes that positive law is a command set by a political superior for a political inferior and which the inferior has to obey or suffer sanction. That law is a command made by a sovereign for an inferior and which the inferior has a duty to obey or suffer penalty.

A sovereign may be a person such as an absolute king, emperor or other dictator or sovereignty may rest in a group of persons such as the Armed Forces Ruling Council or in many people such as the people.

In Nigeria, the intersection of IPRs protection and access to essential medicines is further complicated by the country's developmental context. The TRIPS Agreement's one-size-fits-all approach to IPRs protection disregards the unique challenges confronting developing countries, which necessitate flexibility in addressing public health concerns. The Nigerian government's ability to implement effective public health policies, such as compulsory licensing and parallel importation, is constrained by the TRIPS Agreement's stringent IPRs protection.

Striking a balance between innovation, public health, and affordable healthcare in Nigeria requires a multifaceted approach. Firstly, the TRIPS Agreement must be reevaluated to incorporate flexibility and exceptions to IPRs protection, enabling governments to address public health emergencies. Secondly, Nigeria must leverage international cooperation and regional

frameworks to access affordable medicines and foster local pharmaceutical innovation. Finally, the Nigerian government must implement policies ensuring equitable access to essential medicines, including price controls, subsidies, and public-private partnerships.

Ultimately, reconciling IPRs protection with access to essential medicines in Nigeria demands a paradigmatic shift that prioritizes public health imperatives and affordable healthcare while fostering innovation. By navigating this complex landscape, Nigeria can ensure that its citizens have access to life-saving medications, thereby promoting health equity and socio-economic development.

In line with the positivist theory, Copyright Act 2022, Trademark Act, Patent and Designs Act, among other intellectual property legal frameworks in Nigeria help in solving the societal issue of counterfeit in drugs and other medical equipment and as well, gives the owners of intellectual property the leverage to enjoy the benefits of their efforts, and protect the society from the consumption of counterfeit medical products.

2.3 Review of Related Literature

Many scholars have worked on intellectual property rights in the field of medicine and the need to strike a balance on the use of innovations and rights accruable to the owners of such innovations.

According to Carlos Correa,²⁴ Trade Related Aspect of Intellectual Property Rights (TRIPS) has significant implications for access to essential medicines, and contending that developing countries must balance their obligations under TRIPS with their need to access affordable medicines. Correa's work is comprehensive and provides clear explanations of complex legal

²⁴ C.M Correa, *Trade-related Aspects of Intellectual Property Rights*. (Oxford University Press, 2007) 17.

concepts, but has inherent limitations, focusing primarily on international law with limited discussion of national-level implementation and lacking empirical data on the impact of TRIPS on access to essential medicines in specific countries.

According to T.O Oloko,²⁵ inventions have played an important part in human development and have contributed to social and economic welfare, public health concerns have led to the only multilateral reconsideration made so far to the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights. Yet access to essential medicines is not the only problem faced in relation to public health. Over the years the issue of access to medicines has continued to dominate the discussion in relation to public health care and despite this, the needs of the poorest countries are still not met.

According to A. Boschiero,²⁶ in practice, the exclusive right in patents operates as a commercial tool coupled with the erosion of the balance of the public interest and patent holder's right, with the society shifting towards possessive mechanism for proprietary benefit as opposed to the general good. The exercise of maximum patent right, however, may create a strangle-hold on people's lives as a result of their inability to acquire the necessary knowledge to use such technologies or products. Especially, in relation to innovations in the treatment of diseases that require medical devices that are necessary for preventive, diagnostic, therapeutic and assistive treatment.

²⁵ T.O Oloko, *Access to Medical Devices in Nigeria: Challenges and the Legal Perspective* (UNILAG Press, 2010) 19.

²⁶ A. Boschiero, 'How Do Patent Laws Influence Innovation? Evidence from Nineteenth-Century World Fairs. *National Bureau of Economic Research* (2003) 1(2) 12.

According to Tana Pistorius,²⁷ the lack of basic medical devices seriously compromises the provision of health care services. Not only is there a dearth of medical devices; access to new innovations is not available and this was evident in the visits to various hospitals.

According to F.M Abbot,²⁸ access to a secure, affordable, regular, sustainable, and good quality supply of life-saving essential medicines is, however, not adequate, especially in developing countries, including Nigeria. Access to medicines is not only a public health conundrum; the problem of access also raises concerns with regard to the patenting of medicines.

According to M. Ajakpovi,²⁹ the owner of a registered intellectual property shall have the right in exclusion of others from utilizing such innovation in the course of businesses that are identical or signs that are same. The purport of this is to avoid misleading the public and not giving credit to someone for the efforts of another. The rights described above shall not prejudice any existing prior rights, nor shall they affect the possibility of Members making rights available on the basis of use.

According to O. Uguru,³⁰ Nigeria's patent laws and policies necessitate reform to prioritize public health interests. While Uguru's work offers a thorough and insightful analysis of the Nigerian context, it exhibits limitations due to its primary focus on a general overview, accompanied by a dearth of empirical data and in-depth analysis of the impact of IPRs on access to specific medicines. Situated within the broader academic discourse on intellectual property rights and access to medicines, Uguru's analysis contributes meaningfully to ongoing debates

²⁷ Tana Pistorius 'The Impact of Intellectual Property Law and Policy on Sustainable Development, *Journal of International Law* (2007) 32(1) 381.

²⁸ F.M Abbott, *Trends in Local Production of Medicines and related Technology Transfer*. (TYP Publishers, 2011), 12.

²⁹ M. Ajakpovi. Intellectual Property Rights in an Electronic Environment: Nigeria Perspective. *Modern Practice Journal of Finance and Investment Law*. (2005) Vol. 8, 166.

³⁰ O. Uguru, Intellectual Property Rights and Access to Medicines in Nigeria. *Journal of Pharmaceutical Policy and Practice*, (2007) 12(1), 1-9.

surrounding the delicate balance between innovation, public health, and affordable healthcare. Methodologically, Uguru's research design is predominantly conceptual, lacking empirical analysis, and while his conclusions are sound, they are circumscribed by the absence of empirical data and in-depth analysis. This study seeks to augment Uguru's work by providing empirical data on the impact of IPRs on access to essential medicines in Nigeria, analyzing the utilization of IPR flexibilities in Nigeria to promote public health, and examining the role of patent laws and policies in shaping access to medicines, thereby addressing the lacuna in Uguru's work and contributing to the broader field of study.

2.4 Summary of Review/Gap in Knowledge

The aforementioned scholars worked extensively on intellectual property and the rights accruable to the owners of such intellectual property, especially in the field of medicine. The above-mentioned scholars extensively discussed on the imperativeness of creativity in nation building, advancing of the economy and promotion of health care delivery in Nigeria.

However, the above-mentioned scholars failed to discuss the need to strike a balance on the exclusive rights accruable of such innovation and the need to strike a balance in the use of medicine at the verge of promoting access to public health in Nigeria.

This is the gap in knowledge this work seeks to fill especially as it discussed the existing legal and institutional frameworks in protecting intellectual property rights in Nigeria and balancing intellectual property rights with public health concerns.

CHAPTER THREE

LEGAL AND INSTITUTIONAL FRAMEWORK

3.1 Legal Framework

The legal frameworks discussed under this heading include the Copyright Act 2022, Trademark Act, Patent and Designs Act, TRIPS Agreement. These laws give legal backings for the protection of rights accruable to intellectual property.

3.1.1 Copyright Act 2022

The Copyright Act 2022 grants copyright owners' right in exclusion of others to make their work available to the public by wire or wireless means in such a way that members of the public are able to access the work from a place and time independently chosen by them.³¹

In light of this, the Act in section 50 further protects these innovations from threats and infringement whether online or other means, by specifically providing that no person shall knowingly circumvent a technological protection measure that effectively protects access to copyrighted work either by avoiding, bypassing, removing, deactivating, decrypting, or otherwise impairing such technological measure.

Copyright is essential and significant type of IP, particularly in the medical field where it plays an important function, especially when such medical innovation meets the criteria for copyrightability.³² It is true in this era of immediately expanding intelligent networks. Legislation merely safeguards ideas' representations, not their content. The core concepts and functions are not protected whether you build software source with the aid of copyright law; you may safeguard your expression while preventing significant copying. Copyright protection is becoming more and more important in the healthcare industry, especially with regard to

³¹ Sections 9(i), 10(1)(f), 11(f), 12(d), and 13(1)(c) of the Copyright Act, 2022.

³² See section 2 of Copyright Act 2022.

information. For the healthcare sector. The sector is being overtaken by an “informatics” wave as companies employ technology for data sharing for better quality standards. Each year, enormous sums of money are invested in the use of commercial electronic databases, their development, segmentation, and dissemination. These include compilations of medical treatment outcomes and efficacy studies, databases of chemical structures, gene sequence information for the scientific project, and progress and patient information. In general, it is protected by copyright laws as a collection that grants them some level of originality in the contents’ choice, organization, or coordination.

3.1.2 Trademark Act Cap T13 LFN 2004.

Trademarks are crucial to the IP portfolio of a healthcare organization, just like they are for any product. Confusing sources for products and services, especially those in healthcare and related industries, frequently have very bad outcomes. It is important to invest time and energy into developing different brands that will be able to distinguish the owners’ services. It is used for distinguishing phrases, designs, and other elements to set one proprietor’s goods or services apart from those of another that is protected by trademark law.

A Trademark when registered grants to the proprietor exclusive rights to use his trademark in relation to the goods and services it was registered for and also institute an action in Court for the infringement made on such trademark or to prevent the unauthorized use of the mark (s). But in the case of an unregistered trademark, the owner can institute an action for passing off made on his mark.

Trademark infringement is the unauthorized and illegal use of a trademark without the consent of the proprietor of the mark, whereby it is used to cause confusion between the original mark and the mark used.

Section 5(1) of the Trademark Act provides for the exclusive right of a proprietor to use the trademark in respect of the goods it was registered for. *Section 5(2)* states that thus:

‘Without prejudice to the generality of the right to use a trademark, the marks shall be deemed to be infringed by any person who not being the proprietor of the trademark, uses a mark identical to it or so nearly resembling it as it is likely to deceive or cause confusion in cause of trade in relation to any goods in respect of which it was registered’.

Section 18 of the Act mandates any person claiming to be a proprietor of a trade mark used or proposed to be used by the person who is desirous of registering it must apply in writing to the registrar in the prescribed manner for registration either in part A or part B of the register. The right to the recognition and registration of a proposed trade mark is not vested solely in the proprietor of the mark. Such right also applies to the registered user and or assignee of the registered user.

The Trade Marks Act clearly makes provision for a guideline as to the applicant or proprietor who may apply to register same, coupled with the duration and renewal of the registration of the trademarks. The Act gives leverage to the step-by-step procedures for the registration of trade marks by the trademark’s registrar. By *section 23* of the Act, the registration of a trade mark shall be for a period of 7 years after which the registration may be renewed at intervals of 14 years from the date of the expiration of the original registration or the expiration of the 1st renewal.

All these are targeted at providing access to medicines in Nigeria without violating intellectual property rights of the owners that might orchestrate high-rate counterfeits in medicines.

3.1.3 Patent and Designs Act Cap P2 LFN, 2004.

The TRIPS Agreement in Article 27 contains provisions for the protection of products and innovative processes in all technological fields, including medical products and processes,

chemicals, and plant varieties with some patentability exceptions. Thus, all members of the WTO are obligated to establish and enforce the same minimum standard of patent protection for medicines whether produced locally or by international multinational corporations under their national laws, failing which they may be subject to a complaint before the WTO's Dispute Settlement Body.

In complying with TRIPS, members may, but are not required, to implement more extensive protection than is required by the Agreement, provided it is consistent with the general standard of the Agreement. Members are however, given latitude to adopt an appropriate method for implementing the Agreement provided it is in accordance with the national treatment and most favored nation, treatment provisions in Articles 3 and 4, respectively.

A particular concern for some developing countries is the obligation to provide legal protection for pharmaceuticals and health products. Before TRIPS, Member States of the WTO had the sovereign authority to design their laws governing pharmaceuticals in any manner best suited to their economic situation, technological activities, and development priorities.

In Nigeria, section 1 of Patent and Designs Act provides for patentable inventions. For any invention to be patentable, such invention has to firstly; be new, occur as a result of inventive activity and must have the ability to be applied industrially. Such invention also must contribute to the improvement of such field.

In the inventor by section 2 of the Act has the right to patent. This right includes the right to claim a foreign priority for a patent application. The inventor is also entitled to be named as such in the patent.

However, in the event the invention is made in the course of employment or discharging a given contract, the patent right of such invention goes to the employer or the owner of the contract.³³

When patent rights are conferred on the inventor, such right shall last for a period of 20 years except in the event where it is renewed by the registrar of patent.³⁴

3.1.4 TRIPS Agreement

Access to health is a global issue that requires global IP framework which is mainly defined by the treaties (e.g., the Paris Convention) administered by the World Intellectual Property Organization (WIPO) and the TRIPS Agreement. Most countries in the world, including all the Member States of the WTO, are parties to the TRIPS Agreement including Nigeria. TRIPS agreement has the objectives of “the promotion of technological innovation and “the transfer and dissemination of technology,” mandates implementation of international standards that require IP protection to be available for inventions in all areas of technology (e.g., medical technologies) and protection against unfair commercial use for undisclosed test data submitted for obtaining marketing approval.

Both the WIPO and TRIPS Agreement established multilateral IP frameworks and these frameworks succeeded in setting minimum standards for the Member States. The Member States are free to implement more extensive protections based on their own national priorities and needs. In 2001, the Doha Declaration, a landmark declaration adopted by the WTO reaffirmed the objectives and principles of TRIPS as guidance for implementing the TRIPS provisions in line with public health policy. The Doha Declaration provides a set of flexibilities within the TRIPS legal framework.

³³ See section 2(4) of the Act.

³⁴ See section 7 of the Act.

One of such flexibilities is compulsory licensing. Compulsory licensing is when a government allows someone else to produce a patented product or process without the consent of the patent owner or plans to use the patent-protected invention itself. Specific situations in which compulsory licenses may be issued are set out in the legislation of each patent system and vary between systems. The situations in which a compulsory license may be granted include lack of working over an extended period in the territory of the patent, inventions funded by the government, failure or inability of a patentee to meet a demand for a patented product and where the refusal to grant a license leads to the inability to exploit an important technological advance, or to exploit a further patent. TRIPS also provides that the requirements for a compulsory license may be waived in certain situations, in particular cases of national emergency or extreme urgency or in cases of public non-commercial use.

TRIPS Agreement came up with vital provisions that changed people's perspective over the availability and affordability of drugs to the public. Before TRIPS came on board, many countries of the world especially developed ones had significant independence in designing and implementing their policies regulating IP. Concerned about the importance quality healthcare delivery and the functions of regulating IP in health sector, failure to thoroughly regulate the rights accruable to intellectual property and the use of medicines invented, might have impact on the price of drugs and health, for example, many countries did not allow patents in this area. TRIPS requires all countries to grant pharmaceutical patents. The extension of the international patent system to mandate coverage of pharmaceuticals, a major and unprecedented shift, has sparked widespread interest and concern over what impact it would have on access to medicines, especially in countries with limited resources.

To this therefore, countries of the world should ensure that the exclusivity right the owner enjoys is not absolute as it will bar further researches and improvement in the health sector. The barest standards set forth by the TRIPS Agreement is a right provision at the right direction. However, the issue of this beautiful provisions of the agreement lies on the implementation by countries of the world.

Article 31 of TRIPS Agreement requires that compulsory licenses be used “predominantly” for local markets, a requirement that complicates the ability of countries to import drugs manufactured overseas.³⁵

3.2 Institutional Framework

The institutions that play pivotal roles in the protection of rights accruable to innovations in medicines are discussed under this heading. These institutions include among others; the Federal Ministry of Health, the court, the Trademark, Patent and Designs Registry among others.

3.2.1 Federal Ministry of Health

In Nigeria, the federal ministry of health ensures that improving access to medicines is not only imperative, it is an essential aspect of the right to health and that the people have access to it.

Quality health of every human including the inventors is one of the major important aspects of human wellbeing that is sine qua non for the enjoyment of all human rights. Health plays a pivotal role in empowering people to pursue other activities that will enhance their welfare.

The right to health contains freedoms and entitlements. These freedoms include the right to control one's health and body including sexual and reproductive rights, and as such medicines for reproductive health and contraceptives are an essential part of a women's right to health. Thus, the right to access essential medicines, including contraceptives and pharmaceuticals is not only a fundamental aspect of the human right to health and significant to achieving good health, it is

³⁵ <https://www.wto.org/english/res_e/booksp_e/pantiwhowipowtweb13_e.pdf>. Accessed on 12th October, 2024.

also a means by which individuals can build their health capabilities and enhance their human development. Furthermore, the capabilities approach (CA) to development, wellbeing, and justice emphasizes the importance of people's choices, freedoms, and the opportunities to do and be what they term as valuable and lead the kind of lives they choose to lead.

To this therefore, the ministry and its agencies like NAFDAC ensure that intellectual property rights accruable to inventions in the field of medicine are highly protected, as failure to so do, would orchestrate the high rate of production of fake drugs and medical equipment that are harmful to human health and wellbeing.

3.2.2 Trademarks, Patents and Designs Registry

To address these challenges, Nigeria must adopt a comprehensive approach to intellectual property rights reform, including awareness campaigns, capacity building, and strengthening enforcement mechanisms.

Additionally, updating intellectual property laws to align with international standards and emerging technologies is crucial. By doing so, Nigeria can unlock the potential of its creative and innovative industries, driving economic growth and development.

This institution is primarily involved with the registration of trademarks, patents and designs, as well as the administration and enforcement of same.

This institutional framework was established pursuant to the Trade Marks Act and the Patents and Designs Act, under the Federal Ministry of Trade and Commerce to regulate the filing of trademarks, industrial designs as well as grant of patents in Nigeria.

Under trademarks, the registrar receives application for the registration of any trademark, ensures that public notice is made, and the marks are new and eligible to be registered before doing same.

Under Patent and Designs Act, *sections 3 and 4* of the Act empowers the registrar to receive application for patent registration, examine the application and ensures that it meets the requirement of the Act before registering same. It is upon the registration of the patent by the registrar that the patent rights become accruable to the inventor.

3.2.3 Nigeria Copyright Commission

The Nigeria Copyright Commission was established under the Copyright Act to regulate creative activities such as music, publishing, artistic and literary works. Among the laudable achievement of the NCC in its bid to enhance copyright owner's rights is the issuance of the Copyright (Collective Management Organizations) Regulations 2007 and licensing of Collective Management Organizations to engage in collective management of copyright; issuance of the Copyright (Optical Discs Plants) Regulations 2006, which regulates all disc manufacturing companies in Nigeria by requiring them to compulsorily register with the NCC after meeting certain specified conditions for operation.

The commission ensures strict enforcement of the provisions of Copyright Act 2022 and enforcement of rights accruable to owners of copyrighted works. Through the roles of the commission, copyright violations in medical fields that mostly mislead members of the public in purchasing counterfeit drugs with the belief that it is original is minimized.

3.2.4 Court

Violation of intellectual property rights in Nigeria has become the norm that the court as the last hope of a common man has to step in. intellectual properties such as inventions, trademarks especially in the area of medicine are often violated without authorization from the owner, users produce counterfeits drugs, with registered symbols belonging an inventor claiming it as theirs without properly acknowledging the original creator. The court has been instrumental in

preserving rights accruable to intellectual property and ensuring fairness in the enjoyment of such right and people's health that necessitated the use of such innovations.

In *Offrey v Ola*,³⁶ where the court held that copyright would exist in a given product if that product is the result of some substantial or real expenditure of mental or physical energies of the producer and the labour or skill was not a negligible or common place one.

Similarly, in the *Serg Aluminium v Stanley Akagba*,³⁷ the court held that if these designs have been registered, it is legally wrong for the defendant to copy them. It is the invention of the author, in this case, the plaintiff, which the law seeks to protect when such inventions are registered. To copy them into its almanac and advertise it is a violation of the plaintiff's rights.

In *Arewa Textiles PLC v Finetex Ltd*,³⁸ the Court of Appeal held that in an action founded on patent, there is a basic distinction between a product claim and a process claim.

These instances underscore the fact that court plays pivotal roles in the protection of rights accruable to owners of invention especially in the field of medicine, striking a balance between the rights accruable to such innovation and its use for the sake of human health.

³⁶ Unreported, Suit No: HOS/23/68

³⁷ (1994) FHCS 188

³⁸ (2003) 7 NWLR (pt 312) 321

CHAPTER FOUR
ENSURING ACCESS TO ESSENTIAL MEDICINES IN NIGERIA: STRIKING A
BALANCE BETWEEN INNOVATION, PUBLIC HEALTH AND AFFORDABLE
HEALTHCARE

4.1 The Importance of Intellectual ‘Property Rights in Promoting Innovation

Intellectual property rights (IPR) are widely believed to play a crucial role in encouraging inventors, fostering technological advancement, and stimulating economic growth of countries of the world, and most importantly aid innovation of drugs and other pharmaceutical equipment for the aim of curing ailments. This has made easy to provide solutions to any medical issue that comes up and help in strengthening the health sector. These individuals who have channeled their efforts and expertise in innovation of these medicines are given some incentives such the exclusive rights in respect to such creation of the mind. To encourage such innovation and promote the health sector, enforcement of this right becomes pertinent.

Enforcement of intellectual property rights encourages innovation; in that it gives successful inventors temporary monopoly power over their innovations.

Intellectual property rights play great roles in making owner’s efforts and skills viable and worthwhile for innovators. It ensures that inventors and creators can recover their investments and generate returns on their creative efforts, motivating them to continue innovating. However, in many cases, they underestimate the enormous commercial value inherent in the proprietary IP rights derivable across the different stages of innovation (from conception to research to ideation, development and final production stages where the result of their research converges into a tangible product or service capable of solving real everyday problems).

Many innovators do not fully identify, understand, protect, and leverage all the streams of IP rights emanating from their R&D efforts thereby limiting their exploitation and

commercialization potentials. Therefore, strategic IP management is crucial, as it creates an avenue for identifying, protecting, and harnessing these IP assets to drive research, innovation, and business success.

Promoting intellectual property right is a driving force behind innovation. Innovation requires creativity, risk-taking, experimentation, collaboration, and iteration. It is also at this point that funding from investors or financial institutions becomes more accessible as the product or idea has reached a certain level of development and validation where the inventor is able to demonstrate a working prototype or a minimum viable product (MVP) that showcases the product's potentials.

However, it is good to protect the rights accruable to owners of intellectual property, but it is more important to ensure balance in such protection with people's right to use such innovation and have access to quality healthcare.

4.2 The Impact of Intellectual Property Rights on Access to Essential Medicines

Rights accruable to intellectual property have made inventors to give in their best in the invention of some novel medical equipment and drugs for the purposes of healthcare, providing solutions to ailments and generally promoting the health sector. This has greatly impacted access to medical care in Nigeria as a result of the availability of these quality drugs and equipment in hospitals, clinics among others.

This has made access to essential medicines in Nigeria to be a pressing concern, with far-reaching implications for public health. The presence and cheap prices of essential medicines are critical components of a functional healthcare system. However, Nigeria's healthcare system faces significant challenges in ensuring access to these medicines. Nigeria has one of the lowest

levels of access to essential medicines in the world. This is attributed to various factors, including inadequate funding, poor logistics, and lack of infrastructure.

The high cost of medicines is a major barrier to access. Many Nigerians live on less than \$1 per day, making it difficult for them to afford essential medicines³⁹. The lack of a functional health insurance system exacerbates this issue, leaving many individuals to pay out-of-pocket for healthcare services. Furthermore, the distribution of medicines is often uneven, with urban areas receiving more than rural areas.

The presence of counterfeit medicines in the market poses a significant risk to patient safety. According to NAFDAC,⁴⁰ counterfeit medicines account for up to 20% of the market in Nigeria. This highlights the need for stronger regulation and enforcement to ensure the quality and safety of medicines. To address these challenges, the Nigerian government has implemented several initiatives, including the National Health Insurance Scheme (NHIS) and the Essential Medicines List (EML). However, more needs to be done to improve access to essential medicines, including increasing funding for healthcare, strengthening regulation, and promoting local production. Access to essential medicines in Nigeria is a complex issue that requires a multifaceted approach. Addressing the challenges of high costs, uneven distribution, and counterfeit medicines is crucial to improving public health outcomes. By increasing funding, strengthening regulation, and promoting local production, Nigeria can ensure that essential medicines are available and affordable for all.

The impact of intellectual property rights (IPRs) on access to essential medicines is a pressing concern in the global health community. IPRs can limit access to affordable medicines by

³⁹ O. Onwujekwe, *Health Economics and Financing in Nigeria*. (Malthouse Press, 2015) 26.

⁴⁰ <<https://www.nafdac.update.com>> accessed on 10th October, 2024.

granting exclusive rights to pharmaceutical companies, leading to high prices and reduced availability. This is particularly concerning in developing countries, where healthcare systems are often under-resourced and unable to afford expensive medicines.

The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement has been criticized for its role in limiting access to essential medicines. TRIPS sets minimum standards for IPR protection, which can limit the ability of governments to promote public health. However, TRIPS also provides flexibility for countries to adopt measures to protect public health, such as compulsory licensing. This flexibility has been used by countries like Brazil and Thailand to increase access to essential medicines.

The impact of IPRs on access to essential medicines is also influenced by the patent system. As argued by J. Love,⁴¹ the patent system can be used to extend the life of patents, limiting the availability of generic medicines. This can lead to a situation where patients are forced to rely on expensive branded medicines, rather than more affordable generic alternatives.

4.3 Strategies for Ensuring Affordable Healthcare in Nigeria

Health is believed to be a wealth. Recognizing intellectual property of one and enforcing rights accruable to it, is one thing that has made the healthcare delivery in Nigeria very affordable. This is because affordability of healthcare delivery in Nigeria is based on the availability of drugs and other essential medical equipment in hospitals. This is an area incentive given the owner of intellectual property have greatly advanced the health sector of the economy as scientists easily give in the expertise and efforts to provide solutions to any raising ailment. It is safe to say that to promote health delivery and ensuring affordable healthcare in Nigeria. This is need for the

⁴¹ J. Love, The Patent Opposition Process in India. *Journal of Intellectual Property Rights*, (2016) 21(3), 143-152.

government to interface with inventors with the aim of giving them maximum motivation in churning out innovations in medicines.

To promote access to essential medicines in Nigeria despite intellectual property rights challenges, one strategy is to leverage TRIPS flexibilities, such as compulsory licensing. Compulsory licensing allows governments to grant licenses to third parties to produce patented medicines without the patent holder's consent. Nigeria can use this flexibility to increase access to affordable medicines, particularly for diseases like HIV/AIDS and tuberculosis.

Another strategy is to promote local production of essential medicines. From time being, local production can reduce reliance on imports and increase access to affordable medicines. Nigeria can incentivize local production by providing tax breaks, subsidies, and other support to pharmaceutical companies. This approach has been successful in countries like India, where local production has increased access to affordable medicines.

Strengthening healthcare infrastructure and supply chain management is also crucial. A well-functioning healthcare system is essential for ensuring access to essential medicines. Nigeria can invest in healthcare infrastructure, including storage facilities, transportation networks, and healthcare worker training. This will help ensure that medicines reach patients in need, even in rural and hard-to-reach areas.

Finally, international cooperation and partnerships can play a critical role. According to T'hoen,⁴² international partnerships can help Nigeria access affordable medicines through initiatives like price negotiations, pooled procurement, and technology transfer. Nigeria can work with international organizations, like the Global Fund and UNITAID, to access affordable medicines and build capacity for local production.

⁴² E. t'hoen, The Role of Intellectual Property Rights in Access to Medicines. *Journal of Intellectual Property Rights*, (2016) 21(3), 153-162.

4.4 Balancing Intellectual Property Rights with Public Health Concerns

One impact or benefit of registering any novel invention with the recognized authorities is that it gives the owner of such work the leverage to enjoy exclusively rights accruable to such work. This entails that if the exercise of such right is not regimented and regulated, it has the capacity to impair the benefits of such innovation as the members of the public cannot access same and it adversely affect qualitative healthcare delivery in Nigeria. This calls for balancing the rights of the owners of intellectual property with people's access to same.

The IPRs granted through the IP systems and the global IP framework, regulatory exclusivities, and patent linkage, are the primary schemes that give rise to monopolies of health outputs. Although the exclusive rights conferred on the owners are important for driving innovations as it gives incentives to the growth of the sector, in many cases, they also constitute limitations to the production of varieties of valuable innovations as a result of absence of competition amongst inventors and affect the affordability of these innovations by the common masses.

On the other hand, IP protection has to be highly regulated and enforced as it will solve the associated problem of access to health by the people. In addition, it can also impede further innovation by hindering access to new technologies. Further, the use of the exclusive right can contribute to market distortion and lead to

high prices of goods and market inefficiencies. Thus, IP policy needs to accommodate and balance various legitimate interests, including public and private interests, in a delicate way to promote public health.

The right to health is a fundamental and universal human right. One key component of the right to health is access to medicines and health technologies. Access to medicine is one of the fundamental ways of achieving progress and attaining standard of physical and mental health.”

The monopoly rights granted under patent laws and regulatory exclusivities have adverse

impacts on access to essential medicines, especially for underprivileged patients in developing countries like Nigeria. Hence, the very need to balance the intellectual property rights of the owners with the people's right to use. Prior to the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, pharmaceuticals were not patentable in national laws of about fifty countries. In 1995, intellectual property protection started to be coupled with the trade because a prerequisite to become a member of the World Trade Organization (WTO) is signing the TRIPS Agreement.

However, the problems of access to life-saving medicines cannot be fully addressed by solely relying on voluntary commitments by pharmaceutical companies.

To achieve a better balance between private IPRs and public health, and to increase access to essential medicines to combat the counterfeit in drugs, there is need for flexibilities within the TRIPS Agreement. Part II of the agreement provides a brief introduction to the IP system and the global IP framework as defined by the international treaties, e.g., TRIPS, and discusses how some of the IP practices and regulatory exclusivities become barriers to access to essential health technologies for fighting quackery and counterfeits.

CHAPTER FIVE

CONCLUSION

5.1 Summary of Findings

Enforcement of intellectual property right has been recognized to give incentives to inventors and other owners of intellectual property in channeling more efforts in creating more inventions in the field of medicine. Nigeria's IPR landscape is characterized by challenges and limitations. Piracy and counterfeiting are common especially in medicines, with copyright violations and counterfeiting of one's registered trademark.

This has posed severe problems to accessibility of health across the globe including Nigeria. The availability of these fake drugs in the market has made health safety more challenging in the country that calls for thorough enforcement of intellectual property rights imperative. Due to the cardinal nature medicines to human rights, total exclusivity of the use of these inventions to the inventors would be more inimical to the health of the people as accessibility to public health would be immensely truncated.

In the course of carrying out this research, the following findings were made:

- (a) That for owner of intellectual property to enjoy rights accruable to such medical invention, such invention must be registered after meeting the requirements of either copyrightability, or trademark or patentable.
- (b) That this exclusive right is not forever, there is time frame for it. For instance, in patent, patent right is for a period of 20 years.⁴³
- (c) That the benefits of people's creativity in the field of medicine can only be fully utilized if there is a balance between the rights of the inventor and people's access to health.

⁴³ See section 7 of Patent and Designs Act.

- (d) That healthcare can only be affordable if there is a regulation and enforcement of intellectual property rights.
- (e) Innovations and other creations of mind in the field of medicine have the potentials to contribute to the development of new and improved drugs and other medical equipment, and in so doing, contributes immensely to public health development.

5.2 Recommendations

In the course of carrying out this research work, a lot of findings are made and the researcher goes on to recommend the following:

- (a) It is recommended that it is vital to protect ideas and discoveries in the field of medicine so as bring to novel cures to diseases and produce drugs will meet the immediate medical needs.
- (b) It is recommended that there is need to create awareness in respect to rights accruable to intellectual property so that owners and the general public will be aware of the benefits of protecting their intellectual property rights.
- (c) It is also recommended that the regulatory institutions involved in intellectual property enforcement should put up measures to ensure that there is a balance between protecting the rights of the owners and people's access to public health.
- (d) It is also recommended that the government should be giving good incentives to inventors of medicines so as to encourage them to do more for the purpose of improving health sector in Nigeria.

5.3 Contributions to Knowledge

Many scholars have extensively discussed on the imperativeness of creativity in nation building, advancing of the economy and promotion of health care delivery in Nigeria.

However, the scholars failed to discuss the need to strike a balance on the exclusive rights accruable of such innovation and the need to strike a balance in the use of medicine at the verge of promoting access to public health in Nigeria.

This study will contribute to the body of knowledge in the field of intellectual property law as it fills in the gap by discussing the existing legal and institutional frameworks in protecting intellectual property rights in Nigeria and balancing intellectual property rights with public health concerns.

5.4 Areas for Further Studies

In order to protect intellectual property rights as well as balance innovation with people's access to health, the following areas of further research would be pertinent:

- (a) Critical Appraisal of the legal frameworks for the protection of innovations in medicine and enforcement of rights of innovators in Nigeria.
- (b) An examination of the use of artificial intelligence in striking a balance rights accruable to innovations in medicine and access to public health in Nigeria
- (c) A critical appraisal of the regulation and enforcement of trademark and patent rights in Nigeria
- (d) A critical review for the grounds for the conferment of intellectual property rights on innovations in the field of medicine.

5.5 Conclusion

The issue of enforcement of intellectual property rights of inventors of drugs and other medical equipment is one that has to be taken so serious as strict compliance to rights accruable to owners of intellectual property will hinder access to quality health delivery in Nigeria. Access to essential medicines in Nigeria presents a complex challenge of the likelihood of violating intellectual property rights and because of the all importance of health, this requires careful

consideration and a balanced approach. In recent years, the intersection of intellectual property rights (IPR) and public health, particularly in the context of essential medicines, has become a topic of significant concern. This issue brings to the fore the need to strike a balance between fostering innovation, ensuring affordable access to medications, and promoting public health.

Nigeria, like many other developing countries, faces the challenge of balancing the protection of intellectual property rights with the imperative of providing its citizens with access to essential, life-saving medicines. The current global intellectual property regime, characterized by patents and other forms of protection, has the potential to hinder access to affordable medicines, particularly in developing countries where healthcare systems may already be overstretched.

For Nigeria, this issue is particularly pressing given the high burden of disease and the need to ensure access to essential medicines for its population. While the protection of intellectual property rights is essential for fostering innovation and incentivizing research and development in the pharmaceutical industry, it must be reconciled with the goal of ensuring access to affordable medicines, especially for those in need.

It is hereby concluded that striking a balance on the enforcement of intellectual property rights in innovations and other creations of the mind in the field of medicine does not discourage further innovations and development in the health sector, rather it will help the members of the public to access such innovation and get cured of their ailments. It is in so doing, that such innovation can be said to be capable of industrial use.

BIBLIOGRAPHY

Books

Abbott, F.M. *Trends in Local Production of Medicines and related Technology Transfer*. (TYP Publishers, 2011).

Appadorai, B. *The Substance of politics*. (Oxford University Press, 2003).

Correa, C.M. *Trade-related Aspects of Intellectual Property Rights*. (Oxford University Press, 2007).

Marks S.P, et al. *Advancing Human Right to Health* (Oxford University Press, 2013).

Oloko, T.O. *Access to Medical Devices in Nigeria: Challenges and the Legal Perspective* (UNILAG Press, 2010).

Onwujekwe, O. *Health Economics and Financing in Nigeria*. (Malthouse Press, 2015).

Journal/Articles

Ajakpovi, M. Intellectual Property Rights in an Electronic Environment: Nigeria Perspective. *Modern Practice Journal of Finance and Investment Law*. (2005) 8(1) 166.

Boschiero, A. 'How Do Patent Laws Influence Innovation? Evidence from Nineteenth-Century World Fairs. *National Bureau of Economic Research* (2003) 1(2) 12.

Lazzarini, Z. 'Making Access to Pharmaceuticals a Reality: Legal Options under TRIPS and the Case of Brazil'. *Yale Human Rights & Development Law Journal*, (2003) 6(1) pp103-138.

Noah, J.T. Unfair Competition: Common Law Liability for Interference with Prospective Business Relations. *North Dakota Law Review*. (1952) 28(1) 4.

Sampat BN, 'Academic Patents and Access to Medicines in Developing Countries. *American Journal of Public Health*, (2009) 9(17) 99.

T'hoen, E. The Role of Intellectual Property Rights in Access to Medicines. *Journal of Intellectual Property Rights*, (2016) 21(3), 153-162.

Uguru, O. Intellectual Property Rights and Access to Medicines in Nigeria. *Journal of Pharmaceutical Policy and Practice*, (2007) 12(1), 1-9.

Internet

Drahos, P. 'The Universality of Intellectual Property Rights: Origins and Development'
www.wipo.int/edocs/mdocs/tk/en/.../wipo_unhchr_ip_pnl_98_1.doc. Accessed 23rd July, 2024.