The copyright © of this thesis belongs to its rightful author and/or other copyright owner. Copies can be accessed and downloaded for non-commercial or learning purposes without any charge and permission. The thesis cannot be reproduced or quoted as a whole without the permission from its rightful owner. No alteration or changes in format is allowed without permission from its rightful owner.
THE ROLE OF COMPULSORY LICENSING IN COMBATTING COUNTERFEIT DRUGS IN NIGERIA.

MUSA IBRAHIM UMAR (816503)

A Project Paper Submitted to Ghazali Shafie Graduate School of Government, Universiti Utara Malaysia in fulfilment of the requirements for the Master of Commercial Law.
PERMISSION TO USE

In presenting this project paper in partial fulfilment of the requirements for LLM Master of Commercial Law from Universiti Utara Malaysia, I agree that Universiti Library may make it freely available for inspection. I further agree that thr permission for copying of this project paper in any manner either in whole or in part, for scholarly purpose may be granted by my supervisor or in his absence, by the Dean, Ghazali Shafie Graduate School of Government, College of Law, Government and International Studies (COLGIS). It is understood that any copying or publication or use of this project paper or parts thereof for financial gain shall be given to me and to Universiti Utara Malaysia for any scholarly use which may be made of any material from this project paper.

Request for permission to copy or to make use of material in this project paper in whole or in part, should be addressed to:

Dean (Ghazali Shafie Graduate School of Government)
UUM College of Law, Government and International Studies (COLGIS).
Universiti Utara Malaysia
06010 UUM Sintok
Kedah Darul Aman.
ABSTRAK


Kata kunci: lessen wajib, ubat-ubatan tiruan, paten, ubat-ubatan berkualiti.
ABSTRACT

The negative implication of the existence of counterfeit drugs to the public, government and pharmaceutical companies urge legal interruption to curb the problem.

The objective of this study is to identify how the relevant laws on compulsory licensing can be used to address the proliferation of counterfeit drugs in Nigeria.

In answering the question, this study employed doctrinal legal method by examining the relevant legal provisions dealing with counterfeit drugs that include TRIPS Agreement as the basis of international framework and the Patent and Design Act, Cap P2, laws of the Federation of Nigeria 2004 and the National Agency for Food and Drug Administration and Control Act, CAP N1 Laws of the Federation of Nigeria 2004. The content analysis is used in analyzing the data collected in this research.

The study found out that the concept of compulsory licensing practised under the patents law has the positive effect in enhancing access to affordable drugs through the authorization given 3rd party which subsequently stimulate to a healthy competition among pharmaceutical companies.

The study thus recommended that the authority in Nigeria should encourage the practise of compulsory licensing over patented drugs in order to assist the public to get access to a good quality and affordable drugs.

Keyword: compulsory licensing, counterfeit drugs, quality and affordable drugs and patenting of drugs.
ACKNOWLEDGEMENT

I wish to extend my gratitude and appreciation to Allah the Al-mighty for giving me the health and wisdom to finish this project paper.

I also wish to express my gratitude to my supervisor Dr Khadijah Binti Mohamed for the comments, painstaking guidance and tremendous support I have received from her. I will forever remain indebted to her.
My gratitude also goes to my beloved parents Hon. Justice Ibrahim Umar and Hajia Fatima Shehu Azare, my caring and supporting wife; Dr Fatima Bala Shehu and my Mother – in-law; Hajia Magajia Bala and the rest of my family members for the assistance you have rendered to me financially, academically, emotionally and socially.
I owe a huge amount of gratitude to the Kano State Judiciary for providing me with the opportunity to advance my studies abroad as well as to Hon. Justice Abdu Aboki J.C.A, Hon. Justice Lawal Shuaibu J.C.A and Mallam Dahiru Jafaru Usman of Faculty of Law, Bayero University Kano.
Finally, I thank all my friends and associates that contributed in one way or the other toward the success of this study.
DEDICATION

This project paper is dedicated to my Uncle and Father – in – Law; Alhaji Bala Shehu Muhammad. May Allah (SWT) continue to grant you eternal rest and may Jannatul Firdaus be your final place of abode. Ameen.
DECLARATION

I, MUSA IBRAHIM UMAR, solemnly declare that this project paper is the product of my own endeavour and that all sources have been adequately and duly acknowledged and that all the inadequacies in this project paper are the product of my own shortcoming. And that this project paper has not been submitted in this faculty or elsewhere.

MUSA IBRAHIM UMAR (816503)

Ghazali Shafie Graduate School of Government
UUM College of Law, Government and International Studies (COLGIS).
Universiti Utara Malaysia
06010 UUM Sintok
Kedah Darul Aman.
TABLE OF CONTENTS

CERTIFICATION ........................................................................................................... ii

PERMISSION TO USE ................................................................................................ iii

ABSTRAK......................................................................................................................... iv

ABSTRACT ....................................................................................................................... v

ACKNOWLEDGEMENT ................................................................................................. vi

DEDICATION .................................................................................................................. vii

DECLARATION .............................................................................................................. viii

TABLE OF CONTENTS

CHAPTER ONE: OVERVIEW OF THE STUDY

1.1 Introduction ........................................................................................................... 1- 8.

1.2 Statement of Problem .......................................................................................... 8 – 15.

1.3 Research Questions ............................................................................................. 15.

1.4 Research Objectives ............................................................................................ 16.

1.5 Significance of the Study .................................................................................... 16.

1.6 Scope ..................................................................................................................... 16.

1.7 Limitation .............................................................................................................. 16.
CHAPTER TWO: CAUSES AND EFFECTS OF COUNTERFEIT DRUGS IN NIGERIA.

2.1 Definition of Counterfeit Drugs in Nigeria .................................................. 27 – 29.
2.2 Causes of Counterfeit Drugs in Nigeria ......................................................... 29 – 35.
2.3 Effects of Counterfeit Drugs in Nigeria ......................................................... 36 – 39.
2.4 Concluding Remarks .......................................................... 39 – 40.

CHAPTER THREE: INTERNATIONAL LEGISLATIONS ON COMPULSORY LICENSING OF DRUGS.

3.1 Introduction ................................................................................. 41 – 44.
3.3 Compulsory Licensing of Drugs .................................................... 48 – 53.
3.4 Conditions Precedent for the Issuance of Compulsory Licensing .... 53 – 56.
3.5 Concluding Remarks ............................................................... 56.

CHAPTER FOUR: THE LEGAL / REGULATORY FRAMEWORK FOR DRUG ADMINISTRATION IN NIGERIA.

4.1 Introduction ................................................................................. 57.
4.2 National Agency for Foods and Drugs Administration and Control (NAFDAC).. 57 - 62.
4.3 Nigerian Relevant Legislations ........................................ 63 – 67.

4.4 Concluding Remarks ......................................................... 67.

CHAPTER FIVE.

5.1 Conclusion and Recommendations .................................... 68 – 73.

List of References .............................................................. 74 – 91.
List of Statutes ................................................................. xii.
List of Cases ................................................................. xiii.
List of Abbreviation ........................................................... xiv.
LIST OF STATUTES.

African Charter on Human and Peoples’ Right (Ratification and Enforcement) Act 1990,
Chapter A9, Laws of the Federation of Nigeria 1990.


Food and Drugs and Related Products (Registration Etc) Act, CAP F33 Laws of the Federation of Nigeria 2004.


United Nation’s Universal Declaration of Human Right 1948.
LIST OF CASES.


Fomento v Mentomore 1956 RPC 87.


LIST OF ABBREVIATION

CIPR - Commission on Intellectual Property Rights
FDAC - Food and Drugs Administration and Control
MDGs - Millennium Development Goals
NAFDAC - National Agency for Food and Drug Administration and Control
HIV / AIDS - Acquired Immune Deficiency Syndrome / Human Immunodeficiency Virus
TRIPS agreement - Trade Related Aspects of Intellectual Property Rights
WHO - World Health Organization
CHAPTER ONE:

OVERVIEW OF THE STUDY

1.1. INTRODUCTION

The importance of drugs in the medical parlance cannot be overemphasized as they play a prominent role in the diagnosis, treatment and prevention of different types of diseases as well as in the restoration of the health of the patients who consumed them.\(^1\) Furthermore, the provision of affordable, accessible and safe drugs constitutes one of the determinants used in ascertaining the effectiveness of a health care system.\(^2\)

Globally, Article 25 of the United Nation’s Universal Declaration of Human Right 1948 confers upon every human being with the right to be provided access to medical care.\(^3\) Regionally, Article 16 of the African Charter on Human and Peoples’ Right (Ratification and Enforcement) Act 1990\(^4\) also confers upon every person with the right to have his physical and mental wellbeing protected.

In Nigeria, several statutory provisions imposed a duty on the government to evolve policies that are tilted towards the enhancement of the citizen’s health status. For instance section 17(3) (d) of the 1999 Constitution of the Federal Republic of Nigeria

---


\(^{2}\) Ibid.


The contents of the thesis is for internal user only
LIST OF REFERENCES.


“Fields of Intellectual Property Protection,” https://www.google.com/webhp?sourceid=chrome-instant&ion=1&espv=2&ie=UTF8&q=a+document%2C+upon+application%2C+which+describes+an+invention+and+creates+a+legal+situation+in+which+the+patented+invention+can+normally+only+be+exploited+(manufactured%2C+sold%2C+imported)+with+the+authorization+of+the+owner+of+the+patent (accessed May 6, 2015).


Gustafsson-Wright Emily And Onno Schellekens,” Achieving Universal Health Coverage In Nigeria One State At a Time,” (june 2013):8, http://www.brookings.edu/-/media/research/files/papers/2013/06/achieving-


BOOKS.


Yaqin Anwarul, Legal Research and Writing, (Malaysia: International Islamic University Dolphin Press, 2007).