THE ROLE OF COMPULSORY LICENSING IN COMBATTING COUNTERFEIT DRUGS IN NIGERIA.

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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.

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ABSTRAK

Kewujudan ubat-ubatan tiruan yang membawa implikasi negatif kepada masyarakat umum, pihak kerajaan dan syarikat-syarikat farmaseutikal menggesa campurtangan undang-undang bagi menangani masalah tersebut. Justeru, objektif kajian ini ialah untuk mengenalpasti bagaimana peruntukan lessen wajib menurut peruntukan undang-undang yang berkaitan boleh digunapakai untuk menangani masalah percambahan penghasilan ubat-ubatan tiruan di Nigeria. Bagi menjawab persoalan tersebut, kajian ini menggunapakai kaedah doktrinal undang-undang dengan mengkaji peruntukan undang-undang berkaitan iaitu termasuklah Perjanjian TRIPS sebagai rangka asas perundangan di peringkat antarabangsa, akta-akata berkiatan di Nigeria iaitu *Patent and Design Act, Cap P2, laws of the Federation of Nigeria 2004* dan *the National Agency for Food and Drug Administration and Control Act, CAP N1 Laws of the Federation of Nigeria 2004* serta kes undang-undang yang berkaitan. Kajian ini mendapati bahawa kebenaran lesen wajib kepada pihak ketiga di bawah undang-undang paten mempunyai kesan positif dalam dalam memerangi ubat-ubatan palsu sebagai amalan yang merangsang persaingan sihat di kalangan syarikat-syarikat farmaseutikal yang seterusnya boleh menurunkan harga ubat-ubatan tulen yang dipatenkan dan pada masa yang sama tidak menggalakkan orang ramai daripada membeli ubat-ubatan tiruan. Kajian ini mengesyorkan bahawa pihak berkuasa di Nigeria harus menggalakkan amalan lesen wajib ke atas ubat-ubatan berpaten bagi membantu orang ramai mendapatkan akses kepada ubat-ubatan yang berkualiti serta mampu dibeli.

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.**

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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.

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TABLE OF CONTENTS

LIST OF STATUTES.

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

Constitution of the Federal Republic of Nigeria 1999.

Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous) Act, CAP C34 Laws of the Federation of Nigeria 2004.

Doha Declaration on Trips Agreement and Public Health 2001.

Food and Drugs Act**,** CAP F32 Laws of the Federation of Nigeria 2004.

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

National Agency for Food and Drug Administration and Control Act**,** CAP N1 Laws of the Federation of Nigeria 2004.

National Agency for Food and Drug Administration and Control 2013 Annual Report: xiv.

National Drug Policy 2005.

Nigerian National Policy on HIV/AIDS 2003.

Patent and Design Act, Cap P2, laws of the Federation of Nigeria 2004.

Patent Rules, L.N. 96 of 1971.

Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) 1995.

United Nation's Universal Declaration of Human Right 1948.

LIST OF CASES.

Amadi v. Federal Republic of Nigeria (2010) 5 N.W.L.R. (Pt. 1186) 87.

Fomento v Mentomore 1956 RPC 87.

Federal Republic of Nigeria v Adeyemo Abiodun &2 Ors Suit No: FHC/L/70C/2009.

Imunze v Federal Republic of Nigeria (2014) LPELR – 22254 (SC).

James Oitomen Agbonrofo v Grain Haulage and Transport Ltd (1998) F.H.C 1.236.

Pfizer Specialties Limited V. Chyzob Pharmacy Limited & Ors (2006) LPELR-11780(CA).

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

[1] Olugbenga Ebenezer Olatunji, "The Politics and Pathology of Drug Service Administration in Third World Countries: Lessons of Two Drug Distribution Experiments in Nigeria," *Research on Humanities and Social Sciences* 4 no. 8 (2014):1, http://www.iiste.org/Journals/index.php/RHSS/article/view/12472. (accessed January7, 2015).

[2] Ibid.

[3] "The Universal Declaration of Human Right", http://www.un.org/en/documents/udhr/ (accessed May 6, 2015).

[4] Chapter A9, Laws of the Federation of Nigeria 1990, http://www.nigeria-law.org/African%20Charter%20on%20Human%20and%20Peoples%27%20Rights.htm (accessed January 7, 2015).

imposes an obligation upon the Nigerian government to formulate policies that are geared towards the provision of adequate medical and health facilities to its citizens.[5] The Nigerian National Policy on HIV/AIDS 2003[6] also mandates the Nigerian government to provide people living with HIV/AIDS with Anti-Retroviral drugs. The said policy states that;

> "To provide access to cost effective care and support for those infected, including anti-retroviral drugs."

Furthermore the government also formulated the National Drug Policy 2005[7] in order to further enhance the availability and affordability of Drugs in Nigeria. The National Drug Policy 2005 was enacted to actualize the following objective;

> "The goals of the policy shall be to make available at all times to the Nigerian populace adequate supplies of drugs that are effective, affordable, safe and of good quality; to ensure the rational use of such drugs; and to stimulate increased local production of essential drugs."

Counterfeit drugs[8] still continue to exist in Nigeria notwithstanding the numerous efforts by the National Agency for Food and Drug Administration and Control (NAFDAC) towards eradicating this menace.[9] This could be exemplified by the seizure of consignments of counterfeited drugs by the said that were worth USD100, 000.000.00.[10]

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[5] http://www.scielo.org.za/pdf/ahrlj/v13n2/10.pdf (accessed January 6, 2015).
[6] http://www.chr.up.ac.za/undp/other/docs/policy2.pdf (accessed on January 7, 2015).
[7] apps.who.int/medicinedocs/.../s16450e.pdf (accessed on January 7, 2015).
[8] Counterfeit drug may be defined as;

> *"drugs that are not authentic and have been manufactured using incorrect quantities, or incorrect ingredients, to either reduce the potency, or nullify the potency of drugs altogether,"*

Emmanuel C. Agbaraji, Deborah O. Ochulor and Gloria N. Ezeh, "Food And Drug Counterfeiting in the Developing Nations; the Implications and Way-Out," *Academic Research International* 3 no.2 (September 2012):24, http://paper.researchbib.com/?action=viewList&issn=22239944&vol=3&no=2. (accessed February 8, 2015).
[9] Olike Chinwendu, The fight against fake drugs by NAFDAC in Nigeria (September 2008):3, http://www.medbox.org/pharmacy-technologies/the-fight-against-fake-drugs-by-nafdac-in-nigeria/preview?q= (accessed May 6, 2015).
[10] "Championing the Fight against Fake Drugs," http://www.wipo.int/portal/en/news/2008/article_0012.html (accessed February 22, 2015).

Similarly in 2015 in Anambra State, Nigeria, the agency also destroyed counterfeited drugs which monetary value stood at Nigerian Naira 484,000,000.00[11] which is equivalent to approximately USD 2,438,287.[12]

Furthermore, in 2015 NAFDAC in collaboration with the Kano State government destroyed 10 trailer loads of counterfeited drugs whose monetary value was equivalent to approximately USD3, 022,670 in Kano State.[13]

Furthermore, NAFDAC has also in furtherance of its statutory duty of protecting and safeguarding the quality and safety of drugs in Nigeria taken numerous steps towards ameliorating the availability of counterfeited drugs in Nigeria. The agency has organized campaigns, seminars and adverts in order to sensitize the populace on the adverse effects of counterfeit drugs, strengthened cooperation with other agencies such as the Police, Custom, Standard Organization of Nigeria, legislature and the judiciary, introduced an anti-counterfeiting blueprint, enhanced surveillance at ports of entry into Nigeria,[14]deployed anti- counterfeiting technologies (such as Truscan, Radio Frequency Identification and Mobile Authentication Service).[15]

[11] "NAFDAC Destroys N482.2m Fake Drugs in Awka," *Thisday Live*, February 21, 2015. http://www.thisdaylive.com/articles/nafdac-destroys-n482-2m-fake-drugs-in-awka/202315/ (accessed February 22, 2015).

[12] http://www.cenbank.org/rates/ExchRateByCurrency.asp?CurrencyType=$USD (accessed February 22, 2015).

[13]NAFDAC "Nafdac and Kano State Government Jointly Destroys N600m Fake Drugs," November 30, 2013, http://www.nafdac.gov.ng/component/k2/item/230-nafdac-and-kano-state-government-jointly-destroys-n600m-fake-drugs (accessed February 22, 2015).

[14] D. N. Akunyili, "Consideration of Intellectual Property Rights in Regulation and Control: Activities of the National Agency For Food And Drug Administration And Control (Nafdac)," (May 15 -17,2006): 3-8, Http://Www.Wipo.Int/Edocs/Mdocs/Enforcement/En/Wipo_Ace_3/Wipo_Ace_3_9.Doc. (accessed February 21,2015).

[15] National Agency for Food and Drug Administration and Control 2013 Annual Report: xiv.

In 2001, the World Health Organization (WHO) estimated that counterfeited drugs constituted 70% of the drugs in Nigeria.[16] Furthermore in 2002, the Nigeria Health Officials declared that about 40% of the drugs in Pharmaceutical markets in Nigeria were counterfeit.[17] In 2008, WHO once again stated that the prevalence rate of counterfeited drugs in Nigeria was 70%.[18]

In Nigeria, there are several factors that have contributed to the existence of counterfeited drugs. These include corruption and lack of cooperation among the security agencies that are saddled with the responsibility of fighting counterfeited drugs,[19] the existence of a very vast and porous borders into Nigeria that enables counterfeiters to deal in their activities without being detected, the over dependence by Nigeria on imported drugs as a means of satisfying its drug needs due to the inability of Nigerian pharmaceutical companies to operate within their installed capacity[20] and the prevailing harsh economic condition which has rendered a vast majority of

[16]Leslie W. Kennedy and Edmund F. McGarrell, ed., "Crime and Terrorism Risk: Studies in Criminology and Criminal Justice," https://books.google.com.my/books?id=tHSQAgAAQBAJ&pg=PT377&lpg=PT377&dq=70+percent+of+the+drugs+sold+in+Nigeria+WHO,+2008;+PrimoCarpenter,+2009%29&source=bl&ots=Q8BMf3DFcT&sig=w2nrLdOlgIHA704beBAcNkMIOdA&hl=en&sa=X&ei=R0XaVNvAs6fugSulYEY&ved=0CCMQ6AEwAQ#v=onepage&q&f=false (accessed February 12, 2015).
[17]Ibid.
[18]Roy S. Fenoff and Jeremy M. Wilson, "Africa's Counterfeit Pharmaceutical Epidemic: The Road Ahead," (October 2009):5, http://a-capp.msu.edu/sites/default/files/files/AfricaPharmaPaperFINAL.pdf.(accessed February 12, 2015).
[19] Dora N. Akunyili, "Counterfeit Drugs and Pharmacovigilance," (May 2005):28 - 43, http://www.fug.se/ovrigt/Akunyili.pdf (accessed February 11, 2015).
[20] Hashim Ubale Yusufu, "Challenges in Addressing the Problem of Illicit Production, Distribution and Trafficking Of Fraudulent Medicines – Challenges from a Regulatory Agency," (14 – 15th february,2013):14, http://www.unodc.org/documents/organizedcrime/FM/Yusufu_Ubale.pdf (accessed January 20, 2015).

Nigerians incapable of affording genuine and qualitative drugs which are generally very expensive[21]

Counterfeit drugs have negative effects to patients, government[22] and to the manufacturers of genuine drugs in Nigeria.[23] Counterfeit drugs had resulted in the death, poisoning as well as treatment failure of numerous patients.[24]

The existence of counterfeit drugs in Nigeria had caused the government to loose accruable revenue as counterfeiters of drugs do not pay tax.[25] Furthermore the existence of counterfeited drugs has necessitated pharmaceutical companies to incur additional expenditure in their effort towards protecting their drugs from being copied through registration under the patents law.[26]

Patents is a concept which seeks to encourage inventors to engage in research activities that will culminate into the discovery of new products and processes.[27] The concept

[21]Olusegun Akinyademu, "Counterfeit Drugs in Nigeria: A Threat to Public Health," *African Journal of Pharmacy and Pharmacology* 7 no. 36 (September 2013):2574, www.academicjournals.org/article/article1381822397_Akinyandenu.pdf (accessed February 23, 2015).

[22]Onwubiko N. Dike, Julius O. Onah, and Emmanuel Onwuka,"An Assessment of the Effects of Communication Network in Curbing Unethical Marketing Practices of Drug Firms in Nigeria," *Management and Administrative Sciences Review* Vol 3. Issue 2 (March 2014):3, http://absronline.org/journals/index.php/masr/article/viewFile/175/196.(accessed February 6, 2015).

[23] Dora Akunyili, "Fake and Counterfeit Drugs in the Health Sector: The Role of Medical Doctors," *Annals of Ibadan Postgraduate Medicine* 2 no .2 (December,2004):20, http://www.ajol.info/index.php/aipm/article/viewFile/39094/26216. (accessed February 5, 2015).

[24] Supra Note 21.

[25] Supra Note 22.

[26] Chioma Joy Onwuka, "The Situation of Medicines counterfeiting in Africa,"(2010):20, http://www.whpa.org/background_medicines_counterfeiting_in_aTjhfrica_chioma_jo_onwuka11-2010.pdf.(accessed February 6, 2015).

[27] Nasiru Mukhtar, "Nature and Scope of Intellectual Property Law: An Appraisal of Concepts, Issues and Prospects for Developing Economies," *Journal of Politics and Law* Vol. 6, No. 2 (2013):205, http://ccsenet.org/journal/index.php/jpl/article/view/27872/16825 (accessed May 10, 2015).

rewards inventors through the grant of an exclusionary right by the government in their favour over their invention for a period of twenty years.[28] In other words the grant of a patent precludes the commercial dealing in the subject matter of the patent by a third party without the permission of the patent holder.[29] A patent may be defined as;

> "a document, issued, upon application, by a government office (or a regional office acting for several countries), which describes an invention and creates a legal situation in which the patented invention can normally only be exploited (manufactured, used, sold, imported)with the authorization of the owner of the patent."[30]

However the high cost of patented drugs has been identified as one of the factors contributing to the prevalence of counterfeited drugs[31] as patenting of drugs has empowered pharmaceutical companies with the power to determine the prices of their patented drugs according to their own whims and caprices.[32] In this respect, it is argued that the concept of compulsory licensing maybe used in the fight against counterfeited drugs as it will provide the Nigerian populace with the opportunity to purchase genuine drugs at an affordable price.

In Nigeria, a patent right may be granted when a prospective applicant or his appointed agent apply to the Registrar of Patents and Designs[33] by filling Form 1.[34] The aforementioned application must also be accompanied by the payment of prescribed

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[28] Folarin Shyllon, *Intellectual Property Law in Nigeria*, (Munich:Max Planck Institute for Intellectual Property, Competition and Tax Law, 2003), 139.
[29] Ibid at 149.
[30] "Fields of Intellectual Property Protection," https://www.google.com/webhp?sourceid=chrome-instant&ion=1&espv=2&ie=UTF8#q=a+document%2C+issued%2C+upon+application%2C+by+a+government+office+(or+a+regional+office+acting+for+several+countries)%2C+which+describes+an+invention+and+creates+a+legal+situation+in+which+the+patented+invention+can+normally+only+be+exploited+(manufactured%2C+used%2C+sold%2C+imported)with+the+authorization+of+the+owner+of+the+patent (accessed May 6, 2015).
[31] Supra Note 21.

[32] Okechukwu Timothy Umahi, "Proactive Legal Reforms through Nigerian Universities and Nigerian Bar Association push: A case for Intellectual Property Commission (NIPCOM) Bill," *Journal of Jurisprudence and Contemporary Issues* 6 no.2 (2012); 4.

[33] Section 3 (1) (a) of the Patent and Design Act, Cap P2, laws of the Federation of Nigeria 2004.
[34] Rule 8(1) of the Patent Rules, L.N. 96 of 1971.

fees[35] and in a situation where the application for the grant of patent was made by an agent, a signed power of attorney document authorizing the agent is also required to be submitted to the Registrar.[36] Where the Registrar, upon an examination of the patent application, is satisfied that the applicant has duly complied with the formal requirements, he will grant a patent in favour of the applicant.[37] The applicant will then be issued with a document (Form 4) evidencing the grant of the patent in his favour.[38] The Registrar will thereafter enter the particulars of the patent that has been granted in the Register of Patents and also issue the notice of the grant of the said patent to be published in the Federal Gazette.[39] It is argued that the lengthy process of granting patents caused the increase of price of patented drugs.

The patents law confers exclusive rights to patent owner to exploit his/ her patents. One of the exceptions of this exclusive rights is a compulsory licensing.

Compulsory licensing is a concept which entails the granting of a permission or authority by the government to a third party to perform acts (excluding the grant of further licenses to third parties) in relation to the patented product or process which can only be performed by the patent holder or by a third party with the permission of the patent holder.[40]

The World Trade Organization (WTO) defined compulsory licensing as;

> "Compulsory licensing is when a government allows someone else to produce the patented product or process without the consent of the patent owner."

[35] Section 3(1) (b) (i) of the Patent and Design Act, Cap P2, laws of the Federation of Nigeria 2004.
[36] Section 3(1) (b) (iii) of the Patent and Design Act, Cap P2, laws of the Federation of Nigeria 2004 and Section 11(e) of the Patent Rules, L.N. 96 of 1971.
[37] Rule 14 of the Patent Rules, L.N. 96 of 1971.
[38] Rule 15 of the Patent Rules, L.N. 96 of 1971 and Section 5(1) of the Patent and Design Act, Cap P2, laws of the Federation of Nigeria 2004.
[39] Rule 16(a) - (b) of the Patent Rules, L.N. 96 of 1971.
[40] Supra Note 28 at 153.

In Nigeria, the Federal High Court is the body that is generally vested with the jurisdiction to entertain disputes concerning the provisions of the Patent and Design Act, 2004[41] and therefore the jurisdiction to hear an application for compulsory licensing is also conferred to it.[42]

Compulsory licensing plays an important role in promoting access to affordable drugs because it has the effect of triggering a significant reduction in the prices of patented drugs[43] by creating to the said patented drugs.[44]

1.2 STATEMENT OF PROBLEM

The consumption of counterfeit drugs was reported by WHO as well as other studies to have several negative effects such as health related problems, economic loss and other relevant social impacts as discovered above at 1.1.

In Nigeria for example, the consumption of counterfeit drugs by patients was reported to have caused treatment failure, aggravation of disease condition, organ damage, drug resistance, erosion of public confidence in the effectiveness of a health care system

[41] Cap P2, laws of the Federation of Nigeria 2004.

[42] Section 1 of the First Schedule Patent and Design Act, Cap P2, laws of the Federation of Nigeria 2004.

[43]Jaakko Sulander, " The Role of Compulsory Licensing in Improving Access to Essential Medicines in Developing Countries," (2001/ 2002) :5,https://www.kent.ac.uk/law/ip/resources/ip_dissertations/2001-02/Diss-Sulander.doc (accessed May 8, 2015).

[44] Peter Maybarduk, "Compulsory Licensing and its lessons for the A2M movement," (October 2008):9, https://uaem.org/cms/assets/uploads/2013/03/uaemconference2008-compulsory-licensing.ppt(accessed March 1, 2015).

and in some cases death.[45] In this regard, Dora Akunyili, the former Director General of NAFDAC stated that;

> "Fake drugs have embarrassed our healthcare providers and eroded the confidence of the public on our healthcare delivery system. This development has led to treatment failures, organ dysfunction/damage, worsening of chronic disease conditions and the death of many Nigerians. The situation became so bad that even when patients were treated with genuine antibiotics, they no longer respond positively due to resistance induced by previous intake of fake/counterfeit antibiotics."[46]

From an economic point of view, the availability of counterfeit products is closely linked with job loss, loss of tax by government as well discouraging foreign investment into a country.[47] On the part of the producers of genuine drugs, counterfeit may reduce their profit margins, discouraging them from engaging in research and development that will culminate into the invention of new drugs,[48] as well as subjects them to incur additional cost due to the deployment of anti-counterfeit technology to protect and prevent their drugs against being counterfeited.[49]

Literatures on counterfeit drugs showed that there are several factors contributed to development of this activity in Nigeria. Among the prominent factors include enforcement agencies, inadequacy of the drug laws, false declaration by importers of

[45]Supra Note 19 at 9.
[46]Ibid.
[47]Lawal Bello Dogarawa, "Overview of the Socioeconomic Implications and Management of Product Faking and Adulteration," *Greener Journal of Business and Management Studies* 3 no.3 (April 2013):124, http://www.gjournals.org/GJMBS/PDF/2013/April/Dogarawa.pdf. (accessed February 11, 2015).
[48] Chioma Joy Onwuka, "The Situation of Medicines counterfeiting in Africa," (2010):2, http://www.whpa.org/background_medicines_counterfeiting_in_africa_chioma_jo_onwuka11-2010.pdf. (accessed February 11, 2015).

[49]Eilene Zimmerman, "TruTags Stymie Drug Counterfeiters An innovative micro-tag made nano-porous silica makes it nearly impossible for counterfeiters to duplicate when placed on the surface of pharmaceutical pills.," http://www.inc.com/articles/201106/trutags-stymie-drug-counterfeiters.html (accessed February 20, 2015).

counterfeit drugs,[50] importation of drugs, the existence of porous borders,[51]the high cost of genuine drugs[52] and soon.

In order to address the problem of counterfeit drugs, an effective mechanism should be introduced in the country and this can be done through compulsory licensing of a genuine patented drugs.

A patent is a right given to the owner of an invention (product or process) to prevent others from making, using, importing or selling the invention without consent or permission of the patent holder.[53] Patents rights are granted to inventors in order to stimulate them to engage in research and developmental activities.[54]

The law that governs the grant of a patent eights in Nigeria is the Patent and Designs Act 2004.[55] Under the said Act, the procedure to be followed before a prospective inventor is granted a patent right over his invention are;

1. The prospective applicant or his appointed agent applies to the Registrar of Patents and Designs[56] by filling Form 1.[57]

[50] Joe Chukindi, "Nigeria Cannot Attain Mdgs with Fake Drugs in Circulation – Nafdac," (1st March,2014) http://dailypost.ng/2014/03/01/nigeria-attain-mdgs-fake-drugs-circulation-nafdac/ (accessed February 22, 2015).
[51] Supra Note 20.
[52] Supra Note 21.
[53]Intellectual Property Office of Singapore, "What is a Patent," http://www.ipos.gov.sg/AboutIP/TypesofIPWhatisIntellectualProperty/Whatisapatent.aspx (accessed May 10, 2015).
[54]Supra Note 27.
[55]Laws of the Federation of Nigeria 2004.
[56] Section 3 (1) (a) of the Patent and Design Act, Cap P2, laws of the Federation of Nigeria 2004.
[57] Rule 8(1) of the Patent Rules, L.N. 96 of 1971.

2. The application for the grant of a patent must also be accompanied by the payment of prescribed fees.[58] Where the application for the grant of patent was made by an agent, a signed power of attorney authorizing the agent is also required to be submitted to the Registrar.[59]

3. The invention of the applicant must also be patentable.[60] A patent right can only be granted over the applicant's invention if he can establish the fact that;

   a. The invention is new.
   b. That the invention was product of an inventive activity and
   c. The invention is capable of industrial application.

Where the Registrar is satisfied that the above conditions have duly been complied with, he will grant a patent in favour of the applicant.[61]The complicated procedure in obtaining a patent as shown above has increased the price of genuine patented drugs.

Globally, patent has even been identified to be a barrier to access to affordable drugs because pharmaceutical companies use the privilege associated with the grant of a patent to jerk the prices of their patented drugs.[62] This development has therefore made patented drugs unaffordable to the large proportion of the citizens due to their exorbitant price.[63]

[58] Section 3(1) (b) (i) of the Patent and Design Act, Cap P2, laws of the Federation of Nigeria 2004.
[59] Section 3(1) (b) (iii) of the Patent and Design Act, Cap P2, laws of the Federation of Nigeria 2004 and Section 11(e) of the Patent Rules, L.N. 96 of 1971.
[60] Section 1(1) of the Patent and Design Act, Cap P2, laws of the Federation of Nigeria 2004.
[61] Rule 14 of the Patent Rules, L.N. 96 of 1971.
[62]Okechukwu Timothy Umahi, "Access to Medicines: the Colonial Impacts on Patent law of Nigeria,":17, http://www.nlipw.com/wp-content/uploads/Access-to-Medicines-the-Colonial-Impact-on-Patent-Law-of-Nigeria-by-Timothy-Umahi.pdf . (accessed February 26, 2015).

[63]Ellen F. M.'t Hoen, "TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond,"(2003):42, http://www.who.int/intellectualproperty/topics/ip/tHoen.pdf. (accessed February 27, 2015).

The problem of inaccessibility to patented drugs due to their high price tag is further complicated by the ravaging poverty that has beseeched the majority of Nigerians. Poverty negatively affects the purchasing power of the poor as well deprives them with the opportunity to acquire basic necessities of life such as education, healthcare services and soon.[64]

Also, the problem of high cost of drugs in Nigeria is further worsened by the fact that the cost of purchasing drugs is settled by the patients themselves,[65] majority of whom do not have a health insurance cover [66] that would have assisted them to offset the cost of purchasing the drugs.[67] Consequently, these people are therefore personally left to bear the cost of purchasing their drugs.[68] Hence the high cost of genuine drugs and

[64]Adebayo Oyefunke Olayemi, "Analysis Of Poverty Level Among Urban Households In Irewole Local Government Area Of Osun State," *Global Journal of Arts Humanities and Social Sciences*, 1 No.1(March 2013):13, http://www.eajournals.org/wp-content/uploads/gjahsanalysis-of-poverty-level amongurbanhouseholds.pdf. (accessed February 27, 2015).

[65] Giwa Abdulganiyu and Tayo Fola, "Poverty, Affordability of Anti-Diabetic Drugs and Glycemic Control:An Unholy Alliance in a Developing Economy ?," *International Journal of Pharma Sciences and Research* 5(September 2013):114, http://www.ijpsr.info/docs/IJPSR13-04-09-002.pdf (accessed January 9, 2015).

[66] In Nigeria only 7% of its populace have a health insurance cover. Abiodun Awosusi, " Nigeria on the Move towards Universal Health Coverage," (July 2013),http://www.msh.org/blog/2013/07/22/nigeria-on-the-move-towards-universal-health-coverage. (accessed February 27, 2015).

[67] Saheed O. Olayiwola and Olanrewaju A. Olaniyan, "The Welfare Effects of Health Insurance in Nigeria," https://editorialexpress.com/cgibin/conference/download.cgi?db_name=CSAE2014&paper_id=345.https://editorialexpress.com/cgi-bin/conference/download.cgi?db_name=CSAE2014&paper_id=345(accessed February 27, 2015).

[68] Supra Note 9 at 5.

coupled with the fact that atleast 69.0% of Nigerians live below poverty line[69] has forced alot of people to patronize counterfeit drugs which are very cheap.[70]

In order to mitigate the adverse consequences which the grant of patent may pose in relation to access to the patented product, the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement made provision for the compulsory licensing of the said patented product.[71] The Agreement neither restricts member's state's capacity to issue compulsory licensing to only certain types of product or process or upon the existence of a particular situation nor specify the conditions under which compulsory licensing could be issued over a patented product or process.[72] However the said Agreement specified two conditions which are *sine qua non* to the grant of compulsory licensing.

The said conditions are first, the prospective person or company in whose favour the compulsory licensing will be issued to must have made a futile attempt towards obtaining a voluntary licensing of the patented product from the patent's holder. This requirement is mandatory in cases of national emergency or in extreme urgency.[73] Secondly, the person or company to whom the compulsory licensing has been issued to must compensate the patent holder through the payment of adequate remuneration.[74]

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[69] The Nigerian National Bureau of Statistics (NBS), "The Nigeria Poverty Profile 2010 Report," (February 13, 2105):8, http://reliefweb.int/sites/reliefweb.int/files/resources/b410c26c2921c18a6839baebc9b1428fa98fa36a.pdf(accessed May 10, 2015).

[70] Supra Note 21.

[71] Section 31 of the agreement on Trade-Related Aspects of Intellectual Property Rights. https://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm (accessed February 28, 2015).

[72]"Trips And Health: Frequently Asked Questions Compulsory Licensing of Pharmaceuticals and Trips," https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm (accessed February 28, 2015).

[73] Article 31(b) Agreement on Trade-Related Aspects of Intellectual Property Rights (*TRIPS).*

[74] Ibid.

It is argued that compulsory licensing represents a veritable instrument that the Nigerian government can utilize to promote access to affordable and qualitative drugs. Globally there are plethora of examples where the issuance of compulsory licensing had triggered a significant decrease in the cost of patented drugs. For instance, in Malaysia, the government issued compulsory licensing or government use over three patented Aids Medicines and it consequently began importing them from India.[75] This step translated into a reduction in the expenditure that was incurred by the Malaysian Ministry of Health in treating HIV / AIDS patients from $315 to $ 58 per month.[76] Furthermore, the reduction in the expenditure that was incurred by the Ministry also assisted it to increase the number of patients receiving the said medications from 1,500 to 4,000 patients.[77]

Also, through the issuance of a compulsory licensing in respect of a second line patented antiretroviral drug called kaletra which was produced by Abott, the Thai government achieved a drastic reduction in the price of the said drug from $2,200 to $1000 a year.[78] This reduction in the price of the said drugs also assisted the Thai government to provide about 8,000 people yearly with the said drug.[79]

[75]Chee Yoke Ling, "Malaysia's Experience in Increasing Access to Antiretroviral Drugs: Exercising the 'Government Use' Option,"(2006):14, https://www.citizen.org/documents/MalaysianCLexperienceIPRSeries%20No%209.pdf (accessed May 11, 2015).
[76] Ibid.
[77]Supra Note 44 at 10.
[78]Kaye Phillips, "Compulsory Licensing in Thailand: A Case Study," (October 2008):20 and 25, https://uaem.org/cms/assets/uploads/2013/03/uaemconference2008-compulsory-licensing.ppt.(accessed March 1, 2015).
[79] Ibid at 21.

Based on the above premise, it is argued that compulsory licensing may help the government in addressing the problem of counterfeit drugs, thus, justify the detail examination on this issue in this study.

1.3 RESEARCH QUESTIONS

Based on the problems discussed earlier, the questions arise in this study are;

1. What are the implications of the prevalence and consumption of counterfeit drugs to the public, economy and the patents right holders in Nigeria?
2. How the concept of compulsory licensing as provided for under the relevant laws can be used to address the proliferation of counterfeited drugs in Nigeria?
3. How would compulsory licensing may provide a way for affordable and good quality drugs in Nigeria?

1.4 RESEARCH OBJECTIVES

The objectives of this study are:

1. To examine the implications of the prevalence and consumption of counterfeited drugs to public, economy and the patent right holders in Nigeria.
2. To identify how the relevant laws (the TRIPS Agreement, Doha Declaration and the Nigerian Patent and Design Act 2004) on compulsory licensing can be used to address the proliferation of counterfeit drugs in Nigeria.
3. To analyse the role of compulsory licensing in assisting the public to get of affordable and quality drugs in Nigeria.

1.5 SIGNIFICANCE OF THE STUDY

Taking into account the negative effects of counterfeit drugs, this research attempts to examine how the concept of Compulsory Licensing can be utilized towards promoting affordable good quality of genuine to the drugs to the majority of Nigerians living below the poverty line. Hence the research will assist the National Assembly, government, NAFDAC as well as non – governmental organizations in the enactingand formulating the laws, policies and programmes that are directed towards the promotion of accessibility and affordability of genuine drugs in Nigeria.

1.6 SCOPE

The scope of this study is limited to the relevant international laws, Nigerian laws and few selected jurisdictions emphasizing on the concept of compulsory licensing in patent law to combat counterfeit drugs.

1.7 LIMITATION

The limitation of this study include the paucity of indigenous materials or publications on the issue of compulsory licensing of drugs in Nigeria and the dearth of decided cases by Nigerian courts on the issue of compulsory licensing of drugs in Nigeria.

However, these limitations will be surmounted by making recourse to foreign materials that have dealt with compulsory licensing of drugs in countries such as the United Kingdom, Malaysia, Thailand and South Africa.

1.8 RESEARCH METHODOLOGY

This research adopted the doctrinal method[80] which is also known as library based research. The sources of data to be used are both primary and secondary sources. The primary data to be used in this research are relevant decided Nigerian cases, relevant legislations such as the Nigerian National Agency for Food and Drug Administration and Control Act[81], Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous) Act [82], Food and Drugs and Related Products (Registration Etc) Act[83], Food And Drugs Act[84] and the TRIPS Agreement.

The secondary sources to be used in this research are journal articles, books, newspapers and government reports from the Nigerian National Agency for Food and Drug Administration and Control Act as well as reports from international bodies such as the World Health Organization.

The research attempts to examine the provisions of aforementioned laws with a view towards ascertaining deficiencies in the said laws in relation to the provision of affordable, accessible and safe drugs in Nigeria. Hence the doctrinal method was chosen as the research seeks to examine the strength and weaknesses of the existing laws dealing with this issue.

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83 In Anwarul Yaqin, *Legal Research and Writing*, (Malaysia: International Islamic University Dolphin Press,2007) pg.10, a doctrinal research was defined as; *"Doctrinal research (also referred to as theoretical, pure legal, academic, traditional, conventional, armchair research) is essentially a library-based study, which means that the materials needed by a researcher may be available in libraries, archives and other databases."*

[81] CAP N1 Laws of the Federation of Nigeria 2004.

[82] CAP C34 Laws of the Federation of Nigeria 2004.

[83]CAP F33 Laws of the Federation of Nigeria 2004

[84] CAP F32 Laws of the Federation of Nigeria 2004

The content analysis will be used in analyzing the data collected in this research.

1.9 LITERATURE REVIEW.

Counterfeit and pirated products have now inundated almost each and every sector of the Nigerian economy.[85] This development has however brought about a negative reparcaution to the Nigerian economy as well as the consumers[86] and the intellectual property right holders.[87]

One of the sectors that has adversely being affected by the prevalence of counterfeited products is the drug sector in Nigeria. In Amadi v. Federal Republic of Nigeria[88] the Court defined a counterfeit drug as;

> "any drug or drug product which is not what it purports to be, or which is coloured, coated, powdered, polished that the damage is concealed or which is made to appear to be of better or of greater therapeutic value than it really is, or which the label or container or anything accompanying the drug bears any statement, design or device which makes a false claim for the drug or which is false or misleading. It also includes drug or drug product whose label does not contain adequate directions for use or indicating warning of dangers if used by children, unsafe usage methods, or duration of use, or unregistered drug or drug products."

[85] Solomon Ojo ɑnd Adeyemi Oluwakemi OJO, "Prevalence of Counterfeiting in Nigeria: Evaluating Consumers' Experience in South Eastern and South-Western Nigeria," *Global Journal of Human Social Science Sociology, Economics & Political Science* Vol.12 Iss. 12 (2012):87, https://globaljournals.org/GJHSS_Volume12/7-Prevalence-of-Counterfeiting-in-Nigeria.pdf (accessed May 11, 2015).

[86] Bassey Udo, "40 per cent of goods in Nigeria are substandard, counterfeit – SON," Premium Times, August 11, 2014, http://www.premiumtimesng.com/opinion/166460-interview-40-per-cent-of-goods-in-nigeria-are-substandard-counterfeit-son.html (accessed May 11, 2015).

[87] K.M Waziri, "Intellectual Property Piracy and Counterfeiting in Nigeria: The Impending Economic and Social Conundrum," *Journal of Politics and Law* Vol. 4, No. 2. (September 2011):196, http://ccsenet.org/journal/index.php/jpl/article/viewFile/12011/8435. (accessed on January 11,2015).

[88] (2010) 5 N.W.L.R. (Pt. 1186) 87.

As a result of the prevalence of counterfeited drugs in Nigeria, some West African countries prohibited sale of drugs that have been manufactured in Nigeria in their respective countries.[89] In 2012, the WHO stated that Nigeria and Congo accounts for over 40% of the death caused by Malaria globally.[90] Furthermore, Malaria disease accounts for 60% of hospital visits in Nigeria. [91] 64% of the malarial drugs in Nigeria are counterfeited and this development has further compounded the Malaria pandemic in the country.[92]

Several commentators in this field are of the opinion that the factors that have brought about the existence of counterfeited drugs in Nigeria. In the 2005, NAFDAC classified the factors that have brought about the existence of counterfeited drugs in Nigeria into 4. These factors are;[93]

1. The existence of a chaotic and unmonitored drug distribution system: Drugs are sold in unregistered market places by wholesalers and importers.[94] The said wholesalers and importers of drugs have in their quest to make more profit capitalize on the deficiency in the monitoring and regulation of the drug business to inundate the open markets with counterfeited drugs.[95]

[89] Supra Note 9 at 8.
[90]Who global malaria programme World malaria report 2012:xiii. file:///C:/Users/Musa/Downloads/who%20and%20malaria.pdf (accessed January 8, 2015).
[91] Emma Chukwuemeka and Christian Okafor, "Obstacles to Malaria Control Policy in Nigeria: an Assessment of the Impact of Counterfeit Drugs and Regulatory Policies," *Kuwait Chapter of Arabian Journal of Business and Management Review* 1 no. 1 (September 2011):121. http://omicsonline.com/open-access/2224-8358/2224-8358-1-108.pdf?aid=17060 (Accessed on January 7, 2015).
[92]Tanimola Makanjuola Akande, "Population with Ill-Health Burden; Faced With A Sick Health System," (2014):24, https://www.unilorin.edu.ng/UIL/142.pdf (accessed January 8, 2015).
[93] Supra Note 19.
[94] Supra Note 9 at 17.
[95]Supra Note 9 at 17.

2. Inadequate cooperation among government agencies that are saddled with the responsibility of detecting,seizing and also prosecuting people who engage in the business of fake and counterfeited drugs.[96]

3. False declaration by importers of counterfeited and fake drugs as to the nature of the products in their containers in order to evade inspection and possible seizure by the relevant authorities.[97] The failure of the authorities to detect and intercept the said consignments has also contributed to the presence of fake and counterfeited drugs in Nigeria.[98]

4. Inadequate legislation: The failure of the regulatory authorities to fully implement the provisions of the drug laws in Nigeria has also contributed to the availability of counterfeited drugs in Nigeria.[99] Furthermore, the existing conflict in the provision of the numerous drug laws as well as the imposition of very light sentences against convicted drug counterfeiters have also inflamed the menace of counterfeit drugs in Nigeria.[100] Thus Olusegun contended that;

> The penalties for drug offenders are not commensurate with the severity of the crime. Currently, the maximum punishment for contravening the decree on fake drugs in Nigeria is N500,000 (US $ 3,000) or 3 months to 5 years jail term upon conviction (Akunyili, 2007). Stiffer penalties would help sharpen the attitudes of fake drug dealers (Ratanawijitrasin and Wondemagegnehu, 2002). It would make the practice harder and less lucrative for drug counterfeiters[101]

[96] Supra Note 21 at 2575.
[97] Supra Note 9 at 19.
[98] Supra Note 9 at 19.
[99] Supra Note 21.
[100] Supra Note 21.
[101] Supra Note 21.

Additionally, the other factors that have brought about the existence of counterfeited drugs in Nigeria are

a. Exorbitant price of genuine drugs: Counterfeiters of drugs take advantage of the high demand for cheap drugs which is attributable to the prevailing poverty in Nigeria to inundate the market with counterfeited drugs.[102] Thus these counterfeit drugs provides the impoverished patient with the alternative to genuine drugs whose prices are beyond the reach of the poor.[103]
b. The practice of self medication by patients in Nigeria which entails patients buying their drugs the moment they feel sick without any doctor's prescription has also brought about the availability of counterfeited drugs in Nigeria.[104]
c. The existence of a vast and porous borders in Nigeria: Nigeria's border is about 924,000 KM (Kilometre) and also about 1100 illegal routes[105].This routes are being used by some importers to bring into the country counterfeit and fake drugs.[106]

The availability and consumption of counterfeited drugs in Nigeria has a lot of negative consequences on the patients, economy as well as on the pharmaceutical companies. The consumption of counterfeit drugs by patients in Nigeria was reported to have caused treatment failure, aggravation of disease condition, organ damage, drug resistance, erosion of public confidence in the effectiveness of a health care system

[102] Nicholas S. Iwokwagh, "Assessment of New Media use in the Fight against Counterfeit Medicines in Nigeria," (May, 2013): 20, http://www.cmdconf.net/2013/makale/PDF/5.pdf (accessed January 8, 2015).
[103] Ibid.
[104] Ibid.
[105] Chioma Umeha, "Our porous borders are entry points for fake, spurious products,"(March 6, 2014) http://www.mydailynewswatchng.com/porous-borders-entry-points-fake-spurious-products-obi/ (accessed Janaury 12, 2015).
[106] Ibid.

and in some cases death.[107] Dr Paul Orhii that is the present Director General of NAFDAC attributed the failure of the Nigerian government to achieve the United Nations Millennium Development Goals (MDGs) 4, 5 and 6 which canvasses for the reduction in infant mortality, improvement in maternal health and combating HIV/AIDS, malaria and other diseases on the existence of counterfeit drugs.[108]

From an economic point of view, the availability of counterfeit products is closely linked with job loss, loss of tax by government as well discouraging Foreign Direct investment into a country.[109] The negative effect of counterfeiting of drugs to the producers of genuine drugs are that it reduces their profit margins, discourages them from engaging in research and development that will culminate into the invention of new drugs,[110] as well as subjects them to incur additional cost due to the deployment of anti-counterfeit technology to protect and prevent their drugs against being counterfeited.[111]

Pharmaceutical companies invest colossal sum of money, time and expertise to invent drugs that are required for the prevention and treatment of different types of

[107]Supra Note 19 at 9.

[108]NAN, "Sub-Standard Drugs Threat To MDG's Goals, Says NAFDAC," *Leadership Nigeria*, February 28, 2014, *http://leadership.ng/news/350472/sub-standard-drugs-threat-mdgs-goals-says-nafdac* (accessed February 12, 2015).

[109]Supra Note 47.

[110] Supra Note 48.

[111]Supra Note 49.file://C:\Users\Musa\Desktop\MY PROJECT\Eilene Zimmerman, "TruTags Stymie Drug Counterfeiters An innovative micro-tag made nano-porous silica makes it nearly impossible for counterfeiters to duplicate when placed on the surface of pharmaceutical pills.," http:\www.inc.com\articles\201106\trutags-stymie-drug-counterfeiters.html (accessed February 20, 2015).

diseases.[112] For instance a pharmaceutical company spends about $1.2 Billion[113] to $1.9 Billion[114] and also about 10 to 15 years to invent a new drug.[115] Thus in order to stimulate pharmaceutical companies to engage in research and developmental activities that will ultimately culminate into the discovery of new drugs to tackle emerging diseases, governments grants the pharmaceutical companies patent right over these drugs.[116] Furthermore, before pharmaceutical companies are granted patents over their inventions, they must satisfy the following conditions;[117]

a. The invention is new.
b. That the invention was product of an inventive activity and
c. The invention is capable of industrial application.

Based on the above therefore, it can be discerned that the procedure for the grant of a patent in favour of a pharmaceutical company is tedious, time consuming and very expensive.

Compulsory licensing seeks to enhance access to affordable drugs by mitigating the misuse of the monopoly conferred upon the patent right holders on drugs to escalate

[112]Kolawole, Abimbola Omolara Dahunsi,"Patent Rights And Essential Medicines in Developing Countries: Is Access Compromised for Innovation in Nigeria?," *Journal of Medicine and Medical Sciences* 3 no.3 (March 2012):132, http://www.interesjournals.org/JMMS (accessed February 9, 2015).

[113] PHRMA, "2013 profile Biopharmaceutical Research Industry," (July 2013): 32, http://www.phrma.org/sites/default/files/pdf/PhRMA%20Profile%202013.pdf (accessed February 9, 2015).

[114]Office of Health Economics, "OHE Study on Pharmaceutical R&D Costs Released," (December 3, 2012), https://www.ohe.org/news/ohe-study-pharmaceutical-rd costs-released (accessed February 9, 2015).

[115]Supra Note 113.

[116] Supra Note 112 at 131.

[117] Section 1(1) of the Patent and Design Act, Cap P2, laws of the Federation of Nigeria 2004 and Article 27(1) of the Trade Related Aspects of Intellectual Property Rights (TRIPS), https://www.wto.org/english/docs_e/legal_e/27-trips.pdf (accessed May 12, 2015).

the prices of their drugs beyond the reach of the vast majority of the poor populace.[118] Compulsory licensing engenders a reduction in the price of patented drugs through the authorization given to a third party to either produce or import a generic version of the said patented drugs from the other countries without the necessity of obtaining the consent of the patent holder.[119]

The greatest strength of the provisions of the TRIPS Agreement[120], Doha declaration on Trade Related Aspects of Intellectual Property Rights and Public Health[121] and the Nigerian Patent and Designs Act 2004[122] in relation to use of compulsory licensing in the fight against counterfeited drugs is that it serves as a means of checkmating the abuse of the exclusionary right granted to a patent holders to arbitrarily charge exorbitant prices for their patented drugs. This will consequently engender greater accessibility and affordability to patented drugs[123] and also discourage the poor populace who have been forced by poverty and high cost of patented drugs from their continuous patronage of counterfeit drugs.

The most important weakness of the provisions of the aforementioned Laws in relation to the use of compulsory licensing as a weapon in the fight against counterfeit drugs

[118]Raadhika Gupta, "Compulsory Licensing under Trips: How far it Addresses Public Health Concerns in Developing Nations," *Journal of Intellectual Property Rights* Vol. 15 (September 2010):358, nopr.niscair.res.in/bitstream/123456789/.../JIPR%2015(5)%20357-363.pdf (accessed May 12, 2015).
[119]Charitini Stavropoulou and Tommaso Valletti, "Compulsory licensing and access to drugs," Eur J Health Econ(Decemeber2013):2, http://www.cresse.info/uploadfiles/Compulsory%20licensing%20and%20access%20to%20drugs.pdf.(accessed May 12, 2015).
[120] Article 31 of the Trade Related Aspects of Intellectual Property Rights (Trips).
[121] Paragraph 5(b) of the Doha declaration on Trade Related Aspects of Intellectual Property Rights and Public Health and section 11.
[122]First schedule of the Patent and Designs Act 2004, Cap P2, Laws of the Federation of Nigeria 2004.
[123] Supra Note 44 at 9.

is their failure to take into consideration of the fact that pharmaceutical companies are primarily established with the objective of maximizing profit[124] and are such the continuous or recurrent grant of compulsory licensing as a means of reducing the prices of patented drugs will negatively affect the willingness of the said companies to engage in future research and development and are such pharmaceutical innovation is stultified.[125]

From the available literatures which the researcher have reviewed, the thrust of this research has not been extensively dealt with by any author in the past. Hence this research will attempt to carry out an indepth analysis on how the concept of compulsory licensing of drugs could be used in ameliorating the availability of counterfeit and fake drugs in Nigeria.

1.10 CHAPTERIZATION.

After this introductory chapter, the discussion of this study will be based on the objectives as discussed earlier and will be arranged in the following chapters.

Chapter Two – The causes and effects of counterfeit drugs in Nigeria.

[124]Lawrence Perkins, "Commentary Pharmaceutical companies must make decisions based on profit," *West J Med* 175 (December 2001):422, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1275981/ (accessed May 9, 2015).
[125]Shuchi Midha and Aditi Midha, "Compulsory license: Its impact on innovation in Pharmaceutical Sector," *International Journal of Application or Innovation in Engineering & Management* Vol. 2, Issue 6 (June 2013):223, www.ijaiem.org/Volume2Issue6/IJAIEM-2013-06-20-056.pdf (accessed May 9, 2015).

This chapter examines the factors that have brought about the existence of counterfeited drugs in Nigeria as well the adverse effects their existence have caused to Nigeria. The chapter also proffers solutions towards addressing the menace of counterfeit drugs in Nigeria.

Chapter Three - In this chapter, the research examines the relevant international law; TRIPS Agreement, Doha declaration on TRIPS Agreement and Public Health 2001 and the Nigerian Patent and Design Act 2004 dealing with compulsory licensing of drugs. This chapter will also examine how the concept of compulsory licensing can be utilized to lower the price of genuine drugs to the level affordable for the public.

Chapter Four - The Legal / regulatory framework for drug administration in Nigeria. This chapter examines the several drug laws that have been enacted in Nigeria to fight the counterfeit drugs. The discussion will also covers the legal or administrative bodies against counterfeit drugs in Nigeria.

Chapter Five- Conclusion, Findings and Recommendations.

CHAPTER TWO

CAUSES AND EFFECTS OF COUNTERFEIT DRUGS IN NIGERIA.

This chapter attempts to unravel the reasons behind the prevalence of counterfeited drugs in Nigeria, negative effects counterfeit drugs may cause on the patients, public health, government and pharmaceutical companies.

2.1 Definition of Counterfeit Drugs in Nigeria.

Good quality drugs are amongst the important factors that determine the effectiveness of different types of drugs in the prevention and treatment of wide range of ailments.[126] However counterfeit drugs may defeat this purpose.[127] Thus the existence of counterfeit drugs is considered as a major public health problem due to the adverse consequences its causes to the public.[128]

WHO defined Counterfeit drugs as;

> "A medicine, which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging. "[129]

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[126]Sauwakon Ratanawijitrasin and Eshetu Wondemagegnehu, "Effective drug regulation A multicountry study," (2002):7, www.who.int/medicinedocs/pdf/s2300e/s2300e.pdf (accessed February 4,2015).

[127] Onwubiko N. Dike and Julius O. Onah, "Evaluating Consumer's Protective Measures Against Unethical Marketing of Medical Drugs in Nigeria," *Internal Journal of Business and Management Invention* 3 no.1(January 2014):14, http://www.ijbmi.org/papers/Vol(3)1/Version-2/B0312014021.pdf (accessed February 4,2015).

[128] Supra Note 102 at 18.

[129] Alex Dodoo, "Patient Safety Problems Related to Drug Counterfeiting," pg 6, https://www.google.com.my/search?q=Alex+Dodoo%2C+%E2%80%9CPatient+Safety+Problems+Related+to+Drug+Counterfeiting%2C%E2%80%9D&oq=Alex+Dodoo%2C+%E2%80%9CPatient+Sa

In Nigeria, section 12 of the Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Ac[130] defined a counterfeit drug as;

> (a) any drug or drug product which is not what it purports to be; or
> (b) any drug or drug product which is so coloured, coated, powdered or polished that the damage is concealed or which is made to appear to be better or of greater therapeutic value than it really is, which is not labelled in the prescribed manner or which label or container or anything accompanying the drug bears any statement, design or device which makes a false claim for the drug or which is false or misleading; or
> (c) any drug or drug product the container of which is so made, formed or filled as to be misleading; or
> (d) any drug or drug product the label of which does not bear adequate directionsfor use and such adequate warning against use in those pathological conditions or by children where its use may be dangerous to health or against unsafe dosage or methods or duration of use; or
> (e) any drug or drug product which is not registered by the Agency in accordance with the provisions of the Food, Drugs and Relaled Products (Registration, etc.) Act;

From these definitions, a counterfeit drug refers to a drug that has been fraudulently or deceitfully labelled, packaged or a drug that is devoid of the required ingredients or a drug that has not been registered with the relevant authority and which does not have any therapeutic value in relation to the treatment and prevention of diseases.

NAFDAC being the regulatory body that is vested with task of monitoring the safety and quality of regulated products (drugs inclusive) in Nigeria has unravel several modes that counterfeiters deploy to perpetuate their heinous crime. Example of these mode include;[131]

fety+Problems+Related+to+Drug+Counterfeiting%2C%E2%80%9D&aqs=chrome..69i57.433j0j4&sourceid=chrome&es_sm=93&ie=UTF-8 (accessed February 5, 2015).

[130] CAP C32 Laws of the federation of Nigeria 2004.

[131] Supra Note 23 at 19.

a. Drugs with no active ingredients. For instance capsules or tablets containing chalk or olive oil.
b. Drugs with insufficient ingredient for example a drug containing less than the required ingredient such as a drug containing 41mg of Chloroquine as against the required 200 mg.
c. Disparity between the active ingredients contained in the drug and the ingredients specified in the package. For instance were Loratadine tablet is been packaged as Paracetamol.
d. Cloning of genuine drug. For instance were the counterfeiters produce a replica of the same genuine drug with the same active ingredients encapsulated in it.
e. Drugs that do not contain the name and address of the producer of the said drug.
f. Herbal preparations that are harmful to the health.
g. Expired drugs or re-packaging of expired drugs in order to deceive the public as to the shelf - life of such a drug.
h. Drugs that have not been registered with NAFDAC.

2.2 Causes of Counterfeit Drugs in Nigeria.

There are several factors that have been identified in contributing to the prevalence of counterfeited drugs in Nigeria. These factors are;

1. The existence of a chaotic drug distribution network: Open markets[132] constitutes a major source for the procurement of prescription and non- prescription drugs in Nigeria[133]. These open markets are usually unregulated, unregistered and very difficult to supervise their activities by the regulatory authorities.[134] Hence suppliers of counterfeited drugs in their quest to maximize profit leverage on this administrative laxity to inundate the said market with counterfeited drugs.[135] Ebenezer while lamenting on the disorganized nature of the drug distribution network in Nigeria opined that;

> "The drug and pharmaceuticals distribution system in Nigeria is so poorly organized that it permits very high prices, fake, adulterated, substandard, expired drugs and other forms of unprofessional practices."[136]

2. Lack of cooperation among the government agencies: The absence of cooperation among the relevant stakeholders had adversely impaired upon the capacity of the NAFDAC to frontally address the existence of counterfeit drugs due to the fact that the said agency cannot single handily prosecute this task without the support and

[132] An open market may be defined as;

> "An open market is characterized by the absence of tariffs, taxes, licensing requirements, subsidies, unionization and any other regulations or practices that interfere with the natural functioning of the free market. Anyone can participate in an open market. There may be competitive barriers to entry, but there are no regulatory barriers to entry."

"Open Market", http://www.investopedia.com/terms/o/open-market.asp (accessed March 4, 2015).

[133]Habibat A Garuba, Jillian C Kohler and Anna M Huisman, "Transparency in Nigeria's public pharmaceutical sector: perceptions from policy makers," *Globalization and Health* 5 *(*2009):9, http://www.globalizationandhealth.com/content/5/1/14 (accessed March 4, 2015).

[134] Ndjamawe Bah-Traore,"Quality Assurance and Safety issue of Pharmaceutical Products marketed in Developing countries," (2012):49, http://hss.ulb.uni-bonn.de/2012/3056/3056.pdf (accessed March 4, 2015).

[135] Ibid.

[136]Ebenezer Olatunji Olugbenga "The Politics of Pharmaceutical Regulation in Nigeria: Policy Options for Third World Countries," *Public Policy and Administration Research* Vol.3, No.8 (2013):92, http://www.iiste.org/Journals/index.php/PPAR/article/view/7105/7338(accessed March 4, 2015).

cooperation of other stakeholders such as the Police, Customs Services, Judiciary,[137]Standard Organization of Nigeria and the Nigerian Port Authority.[138]

Hence perpetrators of drug counterfeiting have taken advantage of this lack of synergy and cooperation among government agencies that are saddled with the responsibility of detecting, seizing and also prosecuting people who engage in the business of counterfeiting of drugs to continue committing their illicit business.[139]

Furthermore, the pervasive corruption that has infested the security agencies that are empowered to tackle counterfeiting of drugs has also negatively affected their willingness to decisively deal with this menace.[140] This development has therefore brought the failure to arrest, prosecute and eventually prosecute the perpetrators of this heinous crime of counterfeiting of drugs.[141]

3. Non - imposition of stiff punishment against persons convicted of committing the offence of counterfeiting of drugs: The anti- counterfeiting Laws in Nigeria do not provide for the imposition of very severe punishment against persons who engage in the business of counterfeiting of drugs. The punishment imposed is too lenient that it does not deter potential counterfeiters from engaging in the unlawful act.

[137]Drug Counterfeit – A Global Menace and its Remedial Measures, http://www.pharmainfo.net/reviews/drug-counterfeit-global-menace-and-its-remedial-measures (accessed March 5, 2015).
[138]D. N. Akunyili, "Is the Time Ripe for an International Anticounterfeiting Commission?,":17, http://projects.msh.org/seam/conference2005/pdf/Day1/37_Tr03_Akunyili_speech.pdf (accessed March 5, 2015).
[139]Supra Note 19 at 43.
[140]Supra Note 102.
[141] Supra Note 102.

Nnamdi Obi (the President of Association of Pharmaceutical Importers in Nigeria) while drawing a comparison between the punishment meted out to counterfeiters of drugs in China and Nigeria stated that;

> ….. the requisite laws to deter people are not there. I give an example, somebody imported fake products from China, a brand of one of the big pharmaceuticals in Nigeria. I am not going to mention the brand. In concert with stakeholders – Association of pharmaceutical importers which I am the President and Nafdac played a very vital role, the guy was apprehended. The exporters of that product from China, five of them have been executed by the Chinese government for the export of spurious pharmaceutical product, but the guy in Nigeria has been taken to court by NAFDAC and has been released on bail and is walking the streets of the country freely, so what are we talking about. What the law says is that a fake importer or manufacturer in Nigeria on conviction is liable to a fine of N500,000 only or three months imprisonment. Most of them freely pay those fines and say; 'in worst case scenario, get me convicted.' Can you quantify the worth of life?[142]

4. The expensive nature of genuine drugs: WHO placed Nigeria among the countries that have very prohibitive cost of drugs.[143] This development portends a very grave danger to Nigeria because a vast majority of Nigerians cannot afford to purchase genuine drugs due to the abject poverty that has plagued the Country.[144]

The high cost of genuine drugs also gave rise to the existence of counterfeit drugs in Nigeria as well necessitated people to patronize them because they are relatively cheaper and affordable than their genuine counterparts.[145]Olike on this issue opined that;

> There are higher chances for fake drug proliferation when medicine prices are high; counterfeiters take the advantage to supply cheap fake drug products to consumers especially those who cannot afford the high priced good quality version in the legal sector. A survey conducted by World Health Organization (WHO) and Health Action International

[142] Supra 105.

[143] Chuba Keshi ,"In-Licensing as a Business Strategy for Pharmaceutical Companies: A Framework for the Nigerian Industry," (May 2012):3, http://c807089.r89.cf2.rackcdn.com/KESHI-Chuba-Doctoral-Proposal-Final.pdf. (accessed March 5, 2015).

[144] Supra Note 134 at 52.

[145] Supra Note 134 at 52.

(HAI) in Nigeria 2004 to determine the prices people pay for their medicines showed a high rise in the prices for example people pay between 2 to 64 times international reference prices for medicines in various health facilities.[146]

5. False Declaration by importers of fake drugs: About 60% of the drugs in Nigeria are imported[147]and are such Nigeria has to rely on importation of drugs to augment it's drug needs. In view of Nigeria's dependence on imports as a major of satisfying its drug needs, some unscrupulous importers of counterfeit drugs have devised several means of concealing the identity of the content of their illicit consignments in order to evade inspection and possible seizure by the relevant authorities.[148]

For instance in 2009, NAFDAC at Apapa Port, Lagos State, Nigeria confiscated a container that was falsely declared by its importer as containing Cellotape. But however, the said container was loaded with 960 and 196 cartons of counterfeit Maloxine and Amalar anti – malaria drugs respectively.[149]

6. The participation of non – pharmacists in the sale of drugs: The opportunity accorded to non- pharmacists who are interested in the sale of drugs to do so upon obtaining a patent and propriety medicine vendors right has also assisted in the existence of counterfeit drugs in Nigeria.[150] These category of drug sellers[151]

[146] Supra Note 9 at 20.
[147] Supra Note 20.
[148] Supra Note 19 at 32.
[149]Hassan Zaggi, "The Need to Support Death Sentence for Fake Drug Dealers," http://www.gamji.com/article8000/NEWS8815.htm (accessed March 6, 2015).

[150] Supra Note 9 at 16.
[151] A patent medicines vendor (PMV) may be defined as;
" a person without formal pharmacy (and/or health care) training, selling orthodox pharmaceutical products on a retail basis for profit."
Patricia Nonye Aniebue, Emmanuel Nwabueze Aguwa and Emmanuel Ikechukwu Obi, "Universal Precautions: Awareness and Practice of Patent Medicines Vendors in Enugu Metropolis, South East

represents a major source for the supply of drugs in Nigeria due to their presence in the nooks and crannies of the country.[152]

The minimum educational qualification which a prospective holder of patent and proprietary medicine vendor's license must possess is a primary school certificate.[153] Hence since the aforementioned license holders do not possess any formal education in pharmacy and are such they lack the capacity to distinguish between genuine and counterfeit versions of the drugs they sell to their clients.

Furthermore, the open markets represents the main source where the said license holders acquire their drugs from and the said open market is more often than not synonymous with counterfeited drugs.[154] Hence this therefore further them to the possibility of purchasing and subsequently selling counterfeited drugs to their customers.[155]

7. The existence of illegal entry points into Nigeria: Nigeria is a country that has about 90 legal entry points and also about 1,497 illegal routes.[156] The porous nature of the Nigerian borders[157] as well as the existence of illegal entry routes provides a fertile

Nigeria," *Nigerian Medical Journal* (2010):30, .nigeriamedj.com/temp/NigerMedJ51130-7587251_210432.pdf (accessed March 7, 2015).

[152] Ibid.

[153]Asa Auta, Simeon Omale, Nwamaka C. Anukam and Kennedy I. Amagon, "Patent Medicine Vendors' Clients: Medicine Use Behaviour," journalmanagers.org/files/journals/1/articles/23/.../23-69-1-RV.docx (accessed March 7, 2015).

[154] Ibid.

[155] Ibid.

[156]Abdulrahman Dambazau, "Overcoming Nigeria's Security Challenges,":10, http://www.iuokada.edu.ng/Files/Convocation/Overcoming%20Nigerias%20Security%20Challenges.pdf. (accessed March 7, 2015).

[157]Supra Note 20.

ground for the importation of counterfeited drugs into Nigeria by unscrupulous businessmen. Nnamdi while commenting on the negative implication of the porous nature of Nigerian borders stated that;

> "Of course, there's no gainsaying about that. We just have to accept that the porous nature of our borders is responsible for the proliferation of fake drugs. I have said it repeatedly that it is not easy getting fake drugs through Apapa ports. It is not easy getting fake products through Murtala Muhammed International Airport. But it is very easy for people to get these products through the porous borders."[158]

8. Advancement in technology: The advancement in technology has improved the quality and quantity of counterfeited drugs.[159] Counterfeiters of drugs have through the use of these sophisticated printing technologies (which are relatively cheap and easily available[160]) produced drugs that are almost similar or identical with the genuine version of the counterfeited drugs and are such the innocent purchaser can hardly distinguish between the counterfeited drug and its genuine version.[161]

In Nigeria these advancement in printing technology has therefore made it practically impossible for the innocent purchaser to detect a counterfeited drug with the aid of the naked eyes.[162]

[158]Nnamdi Obi, "War against fake drugs is like fighting Boko Haram," http://sunnewsonline.com/new/?p=61224 (accessed March 7, 2015).
[159]Supra Note 18 at 5.
[160]JDSU, "Pharmaceutical Counterfeiting, Tampering, and Diversion: Solutions for Addressing a Growing Threat,":4, http://www.jdsu.com/ProductLiterature/Pharmaceutical_White_Paper.pdf. (accessed March 11, 2015).
[161] "A Serious Threat to Patient Safety Counterfeit Pharmaceuticals,":8, http://www.pfizer.com/files/products/CounterfeitBrochure.pdf (accessed March 8, 2015).

[162] Supra Note 20 at 12.

2.3 Effects of counterfeit drugs in Nigeria

Counterfeit drugs in Nigeria have several negative effects on patients, public health,[163]government[164] as well as to the manufacturers of genuine drugs.[165]

In Nigeria, the consumption of counterfeit drugs was reported to have caused numerous health problems to the patients who consumed them.[166] The consumption of counterfeit and fake drugs had resulted in the death, poisoning as well as treatment failure of numerous patients.[167] For instance, in 2008, over 80 Nigerian children died as a result of acute renal failure that they suffered sequel to consuming a counterfeited drug called My Pikin Baby Teething.[168]The said cough syrup contained a poisonous substance called diethylene glycol.[169] Similarly in 1990, over 100 children lost their lives after been treated with a fake Paracetamol drug.[170]

[163] The World Health Organization (WHO) defined Public Health as;

> *"Public health refers to all organized measures (whether public or private) to prevent disease, promote health, and prolong life among the population as a whole. Its activities aim to provide conditions in which people can be healthy and focus on entire populations, not on individual patients or diseases."*

http://www.who.int/trade/glossary/story076/en/ (accessed February 6, 2015).

[164]Supra Note 22.

[165] Supra Note 23.

[166] Supra Note 21.

[167] Supra Note 21.

[168] Hye Lynn Choi, David Lee and Jude Nwokike, "Safety of Medicines in Sub-Saharan Africa Assessment of Pharmacovigilance Systems and their Performance," : 23, apps.who.int/medicinedocs/documents/s19152en/s19152en.pdf (accessed February 5,2015).

[169] A. Chika, S.O Bello, A.O Jimoh and M.T Umar, "The Menace of Fake Drugs:Consequences, Causes and Posssible Solutions," *Research Journal of Medical Sciences* 5 (2011):258, http://docsdrive.com/pdfs/medwelljournals/rjmsci/2011/257-261.pdf (accessed March 10, 2015).

[170]Ayobola Abolape Iyanda, "A Study On The Impact Of Fake Paracetamol Syrup On Serum Micronutrient Levels In Female Wistar Rats," *World Journal of Pharmacy and Pharmaceutical Sciences* 3 no. 7(2014):123, http://www.wjpps.com/download/article/1404458960.pdf (accessed February 8, 2015).

From a public health perspective, the proliferation of counterfeit drugs constitutes a major public health threat that is associated with the erosion of the public confidence in the effectiveness of a health care system of the country affected.[171] This negative perception of the public on the effectiveness of the drugs has a negative repercussion on the willingness of patients to subsequently comply with the prescribed dose of medications given to them or to attend health care facilities in order to treat them.[172]

It has also necessitated the public to patronize imported and very expensive brand of drugs which they believe are more potent and effective.[173]

Furthermore, the existence of counterfeit drugs has also given rise to drug resistance[174] by diseases in Nigeria. For instance the prevalence of counterfeit drugs was identified as a major factor that has brought about drug resistance by Tuberculosis disease.[175] The availability of counterfeit and fake drugs was also identified to be amongst the factors that had contributed to antimicrobial resistance[176] in Nigeria.[177] The emergence

[171]Julian Harris, Helmy Haja Mydin, Philips Stevens and Julian Morris, "Keeping it Real Combating Fake Drugs in Malaysia November 2011,":8, http://ideas.org.my/wp-content/uploads/2011/11/Fake-Drugs-Nov-20111.pdf (accessed March 10, 2015).
[172]Ibid.
[173]Supra Note 26.
[174] Drug resistance is defined as;

> ***"The ability of bacteria and other microorganisms to withstand a drug that once stalled them or killed them."***

http://www.medicinenet.com/script/main/art.asp?articlekey=3120 (accessed February 6, 2015).
[175] Supra Note 26 at 22-23.
[176] The World health Organization explained antimicrobial resistance as follows;

> ***"Antimicrobial resistance occurs when microorganisms such as bacteria, viruses, fungi and parasites change in ways that render the medications used to cure the infections they cause ineffective."***

http://www.who.int/features/qa/75/en/ (accessed February 6, 2015).
[177]Charles Nwabuisi, "Antimicrobials and Superbugs: The Survival Game," (November, 2014):28, https://www.unilorin.edu.ng/UIL/154.pdf (accessed February 6, 2015).

of antimicrobial resistance portends a grave danger because it has rendered drugs that were previously used in the effective treatment of different diseases impotent.[178]

The existence of counterfeit drugs in Nigeria had caused the government to incur huge expenditure in the course of tackling this menace and also loss of accruable revenue as counterfeiters of drugs do not pay tax.[179]

The availability of counterfeit drugs also has a negative effect on pharmaceutical companies. It has necessitated pharmaceutical companies to incur additional expenditure in their effort towards protecting their drugs against being counterfeited.[180]Pharmaceutical companies spend colossal sum of money in deploying technologies that will assist them to prevent and also detect the counterfeiting of their drugs.[181]

Furthermore, the menace of counterfeit drugs has also brought about a reduction in the volume of sale of companies that produce genuine pharmaceutical drugs[182]due to the fact that patients tend to patronize or purchase counterfeit drugs because they are relatively cheaper than genuine drugs.[183]For instance in 2001, the producers of Panadol and antimalarial drug called Halofantrine (Halfan) recorded low volume of sale due to the counterfeiting of their products.[184] This in turn adversely affects the willingness of

[178] http://www.who.int/features/qa/75/en/ (accessed February 6, 2015).
[179] Supra Note 22.
[180] Supra Note 26.
[181] Supra Note 26.
[182] Supra Note 26 at 19.
[183] Supra Note 9 at 20.

[184]Supra Note 26 at 19.

pharmaceutical companies to invest in research and development for the purpose of discovering new drugs to treat emerging diseases.[185]

Lawal summarized the negative implication of counterfeited drugs as follows;

> Cofie (2011) argues that counterfeit products results into loss of volume, under-utilisation of capacity, increased cost of production, depressed earnings, debased trade mark, loss of customs and excise duties, loss of corporate and personal income tax for government, high cost of enforcement and judicial proceedings, undermine innovations as well as discourages Foreign Direct Investments (FDI) due to trade structural imbalance. For example, in 2005, firms making products which were prone to counterfeiting suffered combined losses of US$5.2 billion in Los Angeles leading to 106,000 job loss with US$5.1 billion in wages and derived state and local governments tax revenue of at least US$483 million loss. The existence of counterfeits has therefore denied genuine producers the opportunity to sell their goods to consumers (Freeman, Sidhu and Montoya, 2007). More than US$500 million was lost by the East African Community comprising Burundi, Kenya, Rwanda, Uganda and Tanzania as tax collectables as a result of counterfeit goods. In addition, IPR holders lose about US$390 million annually in Kenya to counterfeiting and piracy (Wison and Fenoff, 2011).[186]

2. 4 Concluding Remarks.

This chapter has unraveled several reasons that have brought about the existence of counterfeit drugs in Nigeria. The factors include existence of a chaotic or a disorganized drug distribution network, corruption and lack of cooperation among the security agencies that are saddled with the responsibility of fighting counterfeited drugs, the imposition by the Court of very soft sentences against offenders who have been convicted of committing the offence of counterfeiting of drugs and soon.

[185] Supra Note 26 at 19.
[186] Supra Note 47.

This chapter also discovered that the existence of counterfeit drugs had an adverse implication of on the patients, the government and pharmaceutical companies.

CHAPTER THREE.

INTERNATIONAL LEGISLATIONS ON COMPULSORY LICENSING OF DRUGS.

3.1 Introduction.

This chapter attempts to examine the consequences of the patenting of drugs on access to affordable drugs in Nigeria. The examination of the provisions of the TRIPS Agreement and the Nigerian Patent and Design Act 2004[187] which provides for the patenting of products and processes were conducted. This chapter also examines how the concept of compulsory licensing can be used towards enhancing accesses to affordable drugs in Nigeria.

Patents are exclusionary rights granted in favour of their holders in order to encourage innovators to invent new product and to protect them against the activities of counterfeiters.[188] It is argued that pharmaceutical companies invest colossal sum of money, time and expertise to invent drugs that are required for the prevention and treatment of different types of diseases.[189] Ironically, these genuine drugs are susceptible to being easily imitated.[190] Thus, the granting of patent right to

[187] Chapter P2, Laws of the Federation of Nigeria 2004.
[188]James Bessen and Eric Maskin,"Sequential innovation, patents, and imitation," *Rand Journal of Economics* Vol. 40, No. 4 (Winter 2009):611, scholar.harvard.edu/.../sequential_innovation_patents_and_imitation.pdf (accessed March 25, 2015).
[189]Kolawole Abimbola Omolara Dahunsi,"Patent rights and essential medicines in developing countries: is access compromised for innovation in Nigeria?," *Journal of Medicine and Medical Sciences* 3 no.3 (March 2012):132, http://www.interesjournals.org/JMMS (accessed February 9, 2015).
[190] Bruce Lehman, "The Pharmaceutical Industry and the Patent System,":7, users.wfu.edu/mcfallta/DIR0/pharma_patents.pdf (accessed March 25,2015).

pharmaceutical companies serves as a means of providing assurance to them so they are able to gain profit from their investments.[191]

The grant of a patent's right entitle the pharmaceutical company of an exclusive monopoly over the patented drug for a period of 20 years.[192] This means, the patented product can neither be made, imported, sold[193]nor marketed[194] except with the permission of the said company.[195]

The patenting of pharmaceutical products has negatively affected access to affordable drugs because the exclusive monopoly may lead to pharmaceutical companies to charge exorbitant prices for their patented drugs.[196]

Laurence and Graeme in this respect, contended that the patenting of drugs coupled with the quest of pharmaceutical companies to maximize profit has enticed the said

[191] Holger P. Hestermeyer, "Access to Medicines 2.0: Preferential Trade Agreements as an Impediment to Access,":1, https://www.academia.edu/1194914/Access_to_Medicines_2.0_Preferential_Trade_Agreements_as_an_Impediment_to_Access (accessed February 9,2015).

[192]Amit K Kashyap and Anjani Singh Tomar, "Trips & Public Health: With Special Reference to Doha Declaration & Indian Patents Law" *International Journal of Health Sciences* Vol. 1 No. 1 (December 2013): 2, http://ijhsnet.com/journals/ijhs/Vol_1_No_1_December_2013/1.pdf (accessed February 26, 2015).

[193] Gaius Ezejiofor, "The law of Patents in Nigeria: A Review,":50, http://heinonline.org/HOL/LandingPage?handle=hein.journals/jlpul9&div=5&id=&page= (accessed February 22, 2015).

[194]S. Babafemi Odunsi, "Pharmaceutical Industry, Patenting, Human Rights and Access to Treatment in Developing Countries; Another look at Commercialization of Bio- Medical Research," https://www.google.com.my/search?q=S.+Babafemi+Odunsi%2C+%E2%80%9CPharmaceutical+Industry%2C+Patenting%2CHuman+Rights+and+Access+to+Treatment+in+Developing+Countries%3B+Another+look+at+Commercialization+of+Bio+Medical+Research%2C%E2%80%9D&oq=S.+Babafemi+Odunsi%2C+%E2%80%9CPharmaceutical+Industry%2C+Patenting%2CHuman+Rights+and+Access+to+Treatment+in+Developing+Countries%3B+Another+look+at+Commercialization+of+Bio+Medical+Research%2C%E2%80%9D&aqs=chrome..69i57.1687j0j4&sourceid=chrome&es_sm=93&ie=UTF8#q=S.+Babafemi+Odunsi%2C+Pharmaceutical+Industry%2C+Patenting%2CHuman+Rights+and+Access+to+Treatment+in+Developing+Countries%3B+Another+look+at+Commercialization+of+Bio-+Medical+Research. (accessed February 22, 2015).

[195] Section 6(1) of the Patents and Designs Act, P2, laws of the federation of Nigeria 2004.

[196] Supra Note 32.

companies to channel their research and developmental activities towards the discovery of new drugs for the treatment of diseases that are prevalent in developed countries and thereby neglecting the discovery of new drugs that will be useful in the treatment of diseases plaguing developing countries.[197]

Similarly, according to the report of the United Kingdom Commission on Intellectual Property Rights (CIPR), it concluded that the existence of patent's right over drugs had negatively affected the capacity of patients in developing countries to purchase them.[198]

Thus, in order to mitigate the negative effect which the patenting of drugs has on access to affordable drugs, TRIPS Agreement made provision for the compulsory licensing.[199] The Doha Declaration on Trade Related Aspects of Intellectual Property Rights and Public Health 2001 further acknowledged the use of compulsory licensing in addressing the negative repercussion caused by the patenting of drugs.[200]

In Nigeria, section 11 and the First Schedule of the Patent and Designs Act 2004[201] also give cognizance to use of compulsory licensing.

[197] Laurence R. Helfer and Graeme W. Austin, *Human Rights and Intellectual Property Mapping the Global Interface* (United States of America: Cambridge University Press), 140.
[198]Duncan Matthews, "WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the Trips Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?," Journal of International Economic Law 7(1) (march 2004):2.

[199]Supra Note 192 at 4.
[200]Supra Note 119 at 1.
[201] Cap P2, Laws of the Federation of Nigeria 2004.

Compulsory licensing has the effect of ameliorating the negative impact of patenting of drugs through the lowering of drug prices and thereby enhancing access to drugs.[202]

3.2 Patent Law

The term patent is derived from the Latin word "Patene" which means "to open".[203] A patent may be defined as;

> "A patent is a document, issued, upon application, by a government office (or a regional office acting for several countries), which describes an invention and creates a legal situation in which the patented invention can normally only be exploited (manufactured, used, sold, imported) with the authorization of the owner of the patent."[204]

TRIPS represents the international Agreement for intellectual property protection among member countries of the World Trade Organization.[205] Nigeria being a member of the World Trade Organization(WTO) is bound by its provisions.[206]

The most significant impact of this Agreement in granting patents right is the basic requirements of an invention.

Article 27 of this Agreement provides;

> "Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology,

[202] Colleen Chien, "Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation," *Berkeley Technology Law Journal* Volume 18 Issue 3 (June 2003): 855, www.btlj.org/data/articles/vol18/Chien.web.pdf (accessed March 26, 2015).
[203] K. Uma Devi, G. Indira Priya Darsini and V. Sowbhagya Rani, *The Law of Intellectual Property Rights Various Dimensions* (New Delhi: Regal Publications), 94.
[204] Wipo Intellectual Property Handbook (2008):17, www.wipo.int/edocs/pubdocs/en/intproperty/489/wipo_pub_489.pdf (accessed March 23, 2015).
[205]Richard Elliott And Marie-Hélène Bonin, "Patents, International Trade Law and Access to Essential Medicines,":3, http://www.umich.edu/~spp638/Coursepack/ipr-msf.pdf. (accessed March 19, 2015).
[206]Nwachukwu Sunny Nnabuihe, Nwachukwu Tobechukwu Odunze and Nwosu Ezekwesiri Okebugwu, "World Trade Organization and the Developing World Nigerian Economy: A Case Study," *European Scientific Journal* 1(September 2014): 395, http://eujournal.org/index.php/esj/article/download/4109/3942. (accessed March 19, 2015).

> provided that they are new, involve an inventive step and are capable of industrial application."

In the Nigerian context, the Patent and Design Act 2004,[207] is the main legislation dealing with the patenting of inventions in Nigeria. Section 1(1) of Act provides the conditions that must be satisfied before an invention could be granted a patent. The section provides;

> "1. Patentable inventions
>
> (1) Subject to this section an invention is patentable –
> (a) If it is new, results from inventive activity and is capable of industrial application; or
> (b) If it constitutes an improvement upon a patented invention and also is new, results from inventive activity and is capable of industrial application. "

A patented invention is said to be new if the subject matter of the invention is not known to the public prior to the filing of the patent application.[208] In Fomento v Mentomore[209] a patent right was refused to be granted over the design of a ball point pens based upon the fact that the above design was known to the public prior to the filing the patent application as a result of the publication of the design by the inventor.

An invention is said to have resulted from an inventive step if the invention represents a sufficient advancement in a particular field and it is not apparent that any skilled person in that field could make such an advancement as at the time of filing the application for the grant of a patent.[210] In James Oitomen Agbonrofo v Grain Haulage and Transport Ltd,[211] the plaintiff made a significant improvement to a heating device and he was consequently granted a patent right over it.

[207] Chapter P2, Laws of the Federation of Nigeria 2004.
[208] Section 1(3) of the Patent and Designs Act, Chapter P2, Laws of the Federation of Nigeria 2004.
[209] Fomento v Mentomore 1956 RPC 87.
[210] Module V Patents:3, https://www.wto.org/english/tratop_e/trips_e/ta_docs_e/modules5_e.pdf (accessed June 1, 2015).
[211] (1998) F.H.C 1.236.

An invention is capable of industrial application if it can be put into use in any kind of industry[212] or being put into any meaningful use.[213]

Where the inventor has satisfied the aforementioned conditions for patentability and his application for the patenting of the said invention is successful, the Registrar of patents issues the applicant with a Letter of Patent upon the payment by the applicant of a prescribed fee.[214]

The implication of the grant of a patent is that it precludes a third party from making, importing, selling, using stocking the product or process that has been patented without the consent of the patent holder.[215]Hence the patentee is conferred with an exclusive monopoly over the subject matter of the patent for a period of 20 years from the date of filing.[216]

According to the proponents of the grant of patent over inventions, they contended that patenting is desirous and necessary because;

1. An inventor is equivalent to an owner of any other property and are such the inventor should through the instrumentality of patent be granted an exclusive right over the said invention.[217] The grant of exclusivity over the invention is an acknowledgement by the society of the right of the patentee in the said invention.[218]

[212] Supra Note 210 at 4.
[213]HV Sandhya, "General Principles Of Patent Law" (2014):58, shodhganga.inflibnet.ac.in/bitstream/10603/21666/4/chapter-iii.pdf (accessed June 1, 2015).
[214]K.M Waziri,"The Legal Regime Of Patents And Designs Law And its Effects On National Development,":5, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1875725 (accessed March 23, 2015).
[215] Section 6 of the Patents and Designs Act, Chapter P2, Laws of the Federation 2004.
[216] Section 7 of the Patents and Designs Act, Chapter P2, Laws of the Federation 2004.
[217]Fritz Machlup and Edith Penrose, "The Patent Controversy in the Nineteenth Century," *The Journal of Economic History* Vol. 10 No.1 (May 1950):10 and 13, http://c4sif.org/wp-content/uploads/2010/09/Machlup-Penrose-The-Patent-Controversy-in-the-Nineteenth-Century-1950-b.pdf. (accessed March 24, 2015).
[218]Ibid at 10.

2. The grant of a patent serves as a means for the society to express their appreciation and thus consequently reward the inventor for the invention which he has created.[219]

3. Patenting stimulates inventions: The grant of a patent serves as source of galvanizing innovators to invent new inventions that will spur industrialization.[220]

Pharmaceutical companies also invest huge sum of capital, time and expertise to invent new drugs that are required for the prevention and treatment of different types of diseases.[221]

For instance a pharmaceutical company spends about $1.2 Billion[222] to $1.9 Billion[223] and also about 10 to 15 years to invent a new drug.[224]

Thus in order to stimulate pharmaceutical companies to continue evolving new drugs that will be beneficial in tackling different diseases, the government usually grants a patent in favor of the said drug sequel to an application by the interested company. The implication of granting a patent are two fold in that it provides the pharmaceutical company with an incentive to engage in future research and development works that will culminate in the invention of new drugs and it also provides pharmaceutical companies with a buffer against the activities of free riders such as counterfeiters and imitators from copying the patented product.[225]

[219] Ibid at 17.
[220] Supra Note 217 at 21.
[221]Supra Note 189.
[221] Supra Note 190.
[222]Supra Note 113.
[223] Supra Note 114.

[224] Ibid.
[225]Daniel Benoliel and Timothy John Chirwa,"The Impact of Pharmaceutical Patents on Health Expenditures in Least-Developed Countries,":3, http://weblaw.haifa.ac.il/he/Faculty/BenOliel/Publications/BenolielChirwa.pdf. (accessed March 19, 2015).

Grabowski while buttressing the importance of the grant of patent to pharmaceutical companies stated that;

> Patents have been found to be critically important to pharmaceutical firms in appropriating the benefits from drug innovation. The reason for this follows directly from the characteristics of the pharmaceutical innovation process. As discussed above, it takes several hundred million dollars to discover, develop, and gain regulatory approval for a new medicine. Absent patent protection, or some equivalent market barrier, imitators could free-ride on the innovator's FDA approval and duplicate the compound for a small fraction of the originator's costs. In essence, imitation costs in pharmaceuticals are extremely low relative to the innovator's costs of discovering and developing a new compound. Some form of market exclusivity or market barrier to easy imitation has been essential in this industry to allow pioneers to appropriate enough of the benefits from new drug innovation to cover their large R&D costs and earn a risk-adjusted return on their overall portfolio of R&D programs.[226]

4. Patent provides the society with a platform to garner a cesspool of technological knowledge.[227] Patent is borne out of a bargain between the patentee and the society whereby the patentee agrees to make full disclosure about his invention while in return the society grants him an exclusive monopoly over the said invention for a specified period of time.[228]

3.3 Compulsory Licensing of Drugs.

One of the negative implication of the patenting of drugs is that it has resulted in the escalation in the prices of patented drugs.[229] For instance, 150Mg of the HIV drug flucanozole costs to USD697, USD703 and USD817 in Malaysia, Indonesia and

[226]Henry Grabowski, "Increasing R&D Incentives for Neglected Diseases: Lessons from the Orphan Drug Act,": 462, https://fds.duke.edu/db/attachment/326 (accessed March 19, 2015).
[227] Supra Note 217 at 25.
[228] Supra Note 217 at 26.
[229]Alan O. Sykes, "TRIPs, Pharmaceuticals, Developing Countries and the Doha Solution,": 2, http://papers.ssrn.com/abstract=300834 (accessed March 26, 2015).

Philippines respectively where the said drug is patented while concomitantly the same drug cost USD55 in India, where the drug does not have a patent protection.[230]

The patenting of drugs has therefore given rise to the problem of inaccessibility to affordable drugs in developing countries.[231]

The grant of a patent over a particular drug in favour of a pharmaceutical company confers upon the said company with a monopoly over the sell, making or the importation of the patented drug and this will consequently bestow upon the company with the power to determine the quantity of the patented drug to be produced, the market to be supplied and the price of the patented drug without any fear of competition from any third party.[232]Hence pharmaceutical companies capitalize on the absence of competitors due to the existence of monopoly resulting from the grant of a patent over a particular drug as well as due to the desire to maximize profit which is the primary objective behind the establishment of a pharmaceutical company to charge exorbitant prices for their patented drugs. [233]

[230]C. Nwobike, "Pharmaceutical Corporations and Access to Drugs in developing Countries: the Way Forward," *International Journal On Human Rights* Number 4(2006):127, www.surjournal.org/eng/conteudos/artigos4/ing/artigo_nwobike.htm (accessed March 26, 2015).
[231]Supra Note 32 at 3.
[232]Burton Ong, "Compulsory Licences of Pharmaceutical Patents to Remedy Anti-Competitive Practices Under Article 31(k) of the TRIPS Agreement: Can Competition Law Facilitate Access to Essential Medicines?," :236, http://bookzz.org/book/2473945/c288dd (accessed March 26, 2015).
[233]Brook K. Baker, "Patents, Pricing, and Access to Essential Medicines in Developing Countries," American Medical Association Journal of Ethics Volume 11, Number 7 (July 2009):528, http://journalofethics.ama-assn.org/2009/07/pfor1-0907.html (accessed March 26, 2015).

Thus compulsory licensing of patented drugs serves as means of addressing the negative consequences associated with the grant of a patent over drugs in relation to access to affordable patented drugs.[234] WTO defined compulsory licensing as;

> "…when a government allows someone else to produce the patented product or process without the consent of the patent owner." [235]

Compulsory licensing may also be defined as the authorization or permission given by the government to a company, government agency or a third party[236] to produce, use or sell a patented invention without prior consent of the patent owner[237] and in return the person in whose favour the compulsory licensing has been issued to pays the patent holder a remuneration or a royalty.[238]

From the definitions of compulsory licensing above, the following salient features could be discerned;

1. Compulsory licensing is issued by the government to a third party.

2. The issuance of compulsory licensing legally authorizes the third party to make, use or sell the patent invention without any liability.

3. The person in whose favour the compulsory licensing has been issued to is required to pay the patent holder of the subject matter of the compulsory licensing a royalty.

4. The issuance of compulsory licensing does not terminate the right of the patent holder over the patented invention. In other words, the patent holder still

[234]Kenneth Shadlen, "Patents and Pills, Power and Procedure: The North-South Politics of Public Health in the WTO," No. 03-42 (2003):20**,** www.lse.ac.uk/internationalDevelopment/pdf/WP/WP42.pdf (accessed March 27, 2015).
[235] Supra Note 72.
[236] Supra 43 at 4.
[237] Supra Note 855.
[238] Supra 43 at 4.

has the right to restrict the unauthorized usage or sell of the patented product by any unlicensed third party.[239]

Internationally, Article 31 of the Trade-Related Aspects of Intellectual Property Rights (Trips) and Paragraph 6 of the Doha Declaration on the Trips Agreement and Public Health all recognise the right of the member nations to use compulsory licensing in addressing public health problems.[240]

In Nigeria, section 11 and the first schedule of the Patent and Designs Act 2004 also recognized the use of compulsory licensing.

Compulsory licensing is generally issued over a patented product or process in a situation where there is either;

i. Insufficient working of the patented product or process.

ii. Anti – competitive practices.

iii. Emergency or under any public interest ground.[241]

i. Insufficient working of the patented product or process: A patent is usually granted under the supposition that the patent holder will locally manufacture the patented product and are such in a situation where the holder becomes incapable of manufacturing the said patented product locally that will constitute a valid ground for

[239]Carlos Correa, "Integrating Public Health Concerns into Patent Litigation in Developing Countries,": 93, www.who.int/medicinedocs/pdf/h2963e/h2963e.pdf (accessed March 28, 2015).
[240]Christopher Gibson, "A Look at the Compulsory License in Investment Arbitration: The Case of Indirect Expropriation," *American University International Law Review* Vol. 25 Issue 3 (2010):362, digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1072 (accessed March 28, 2015).

[241]Supra Note 239 at 94.

the issuance of a compulsory licensing over the said patented invention.[242] For instance where the patented invention is been importing and not locally manufactured.

ii. Anti – competitive practices: Compulsory licensing in this respect has the effect of countering the abuse of the monopoly conferred upon the patent holder.[243] This may occur in a situation where for instance a patent holder refuses to grant a third party a voluntary licensing over his patented product which the third party needs in order to invent a new product[244] or were the patent holder refuses to grant a voluntary licensing upon a reasonable commercial terms.

iii. Public interest ground: Compulsory licensing may be granted in order to preserve public interest. For instance in order to lower the price of a patented medicine[245] or were the government issued the license in order to address an emergency situation such as war.[246]

In relation to patented drugs, the issuance of compulsory licensing has the effect of increasing access to affordable drugs through a reduction in the prices of patented drugs.[247] This achievement in the reduction in the prices of patented drugs is made

[242]Cynthia M. Ho, "Compulsory Licenses Under Trips: An Introduction,": 130- 131, http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1922803 (accessed April 4, 2015).

[243]"Compulsory Licensing and the Anti-Competitive Effects of Patents for Pharmaceutical Products: from a Developing Countries' Perspective,"(October 2009):1, http://www.cuts-citee.org/pdf/Compulsory_Licenses_and_anti-competitive_effects_of_patents.pdf,(accessed April 4, 2015).

[244]Anders Karlsson, "Green technology patents. - TRIPS, compulsory licensing and global health," (2014):10, www.diva-portal.org/smash/get/diva2:764784/fulltext01.pdf (accessed April 4, 2015).

[245]Supra Note 242 at 133.

[246] Section 20(a – f) of the First Schedule, Part II of the Patent and Design Act, Chapter P2, Laws of the Federation of Nigeria 2004.

[247]Supra Note 44 at 9.

possible through the authorization given to other producers to manufacture the said patented drugs and this will in turn spur competition.[248]

3.4 Conditions Precedent for the issuance of Compulsory Licensing.

Article 31 of TRIPS[249] lays down certain important prerequisite that must be fulfilled prior to the issuance of compulsory licensing over a patented invention. These conditions are;

1. The 3rd party in whose favour a compulsory licensing has been issued to over a patented invention must made futile effort towards obtaining a license from the patent holder on a fair economic term but it has proved abortive. The above requirement need not to be complied in cases of either national emergency, extreme urgency or for public non- commercial use.[250]

2. There must be the payment of adequate remuneration to the patent right holder.

3. The issuance of the compulsory licensing must be geared primarily towards the satisfaction of the supply needs of the Member State that has issued the said license.

[248]John M. Wechkin, "Drug Price Regulation And Compulsory Licensing for Pharmaceutical Patents: The New Zealand Connection,"(1995):239, digital.law.washington.edu/dspace-law/...1/.../5PacRimLPolyJ237.pdf? (accessed March 28, 2015).

[249] Article 31 of the Trade-Related Aspects of Intellectual Property Rights (TRIPS).
[250] Ibid.

It is also noteworthy to emphasize at this point that the issuance of compulsory licensing is also subject to the impositions of certain restrictions against the 3rd party in whose favour the said license was issued to as provided for by Article 31(b) of the TRIPS Agreement. The said restrictions are;

a. The authorization given to a 3rd party through compulsory licensing are non- assignable and non-exclusive.

b. Where the condition which necessitated the issuance of compulsory licensing ceases to exist and there is no likelihood of the reoccurrence of the said condition, then the said license must instantly be terminated.

c. The scope and duration of the usage of compulsory licensing must strictly be adhered to.

Similarly, in Nigeria, the Nigerian Patent and Design Act 2004 also provides for the satisfaction of certain conditions before the court issues a compulsory licensing in favour of a 3rd party. The conditions are;

1. The 3rd party must have exerted futile effort towards a obtaining a contractual license from the patent holder on a reasonable time and terms and

2. The 3rd party must make an undertaking to the court that the issuance of the compulsory license over the patented drug has the capacity of ameliorating

the ills associated with patented invention which is the subject matter of the compulsory.[251] The negative ills associated with the patented invention may range from non- working of the patented invention in Nigeria for example as a result of its importation into Nigeria, inability of the patent holder to satisfy the demand for the patented invention in Nigeria and that that the refusal of the patent holder to grant a contractual license over the patented invention is adversely affecting commercial and industrial activities in Nigeria.[252]

Furthermore the issuance of a compulsory license by the court in Nigeria is subject to the following restrictions to wit[253];

a. The 3rd party in whose favour the compulsory licensing has been issued to is restricted from importing the patented invention into Nigeria.

b. The 3rd party cannot grant a further license over the subject matter of the compulsory license to another party.

c. The 3rd party has a non – exclusive right over the subject matter of the compulsory license.

[251] Section 5 of the First Schedule of the Patent and Design Act, Chapter P2, Laws of the Federation of Nigeria 2004.
[252] Section 1 of the First Schedule of the Patent and Design Act, Chapter P2, Laws of the Federation of Nigeria2004.
[253] Section 5 of the First Schedule of the Patent and Design Act, Chapter P2, Laws of the Federation of Nigeria 2004.

d. The issuance of compulsory licensing may also be subject to additional restrictions as may be imposed by the Court against both the 3rd party and the patentee.

3.5 Concluding Remarks.

This chapter has discovered the fact that the grant of a patent to pharmaceutical companies serves as a means of motivating them towards engaging in future research and developmental activities in to diseases that are plaguing the populace.

Furthermore, it also serves as a means of protecting pharmaceutical companies against the imitation or copying of their products. The chapter has also uncovered that the grant of a patent to pharmaceutical companies has also bought about an escalation in the prices of patented drugs and this has made them to be unaffordable to a vast majority of the populace in Nigeria.

The chapter has also discovered that the concept of compulsory licensing constitutes an instrument that may be used towards enhancing access to affordable patented drugs in Nigeria.

CHAPTER FOUR.

THE LEGAL AND REGULATORY FRAMEWORK FOR DRUG ADMINISTRATION IN NIGERIA.

4.1 Introduction.

This chapter attempts to examine the effectiveness of NAFDAC that is the government institution is conferred with the authority of monitoring the quality of drugs in Nigeria as well as the provisions of the of the Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous) Act [254], Food and Drugs and Related Products (Registration Etc) Act[255] and the Food And Drugs Act[256] in relation to tackling the menace of counterfeited drugs will also be made.

4.2 National Agency for Foods and Drugs Administration and Control (NAFDAC).

The Nigerian government had in its effort towards nipping the problem of the proliferation of counterfeited drugs in the country established NAFDAC.[257] NAFDAC was established to regulate the safety and quality of drugs, medical devices, food, cosmetics and other regulated products in Nigeria.[258]

[254] CAP C34 Laws of the Federation of Nigeria 2004.
[255]CAP F33 Laws of the Federation of Nigeria 2004
[256] CAP F32 Laws of the feration of Nigeria 2004
[257] CAP N1 Laws of the Federation of Nigeria 2004.
[258] Olatunji , E. Olugbenga, "Impact of Administrative Law on the Functioning of Regulatory Agencies: Cases and Materials from a Third World Country," *International Research Journal of Law* 1 no. 1 (March 2014):7, http://acascipub.com/Journals.php (accessed February 24, 2015).

Similarly several legislations were also enacted in Nigeria in order to tackle the problem of counterfeit drugs. These include the Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous) Act [259], Food and Drugs and Related Products (Registration Etc) Act[260] and the Food And Drugs Act[261]. These legislations prohibits and criminalizes the production, sell and importation of counterfeited drugs, dealing in unregistered drugs and also adulterated drugs respectively.

For example, a Federal and States taskforce were respectively established[262] which are given the powers and responsibility of detecting and seizing any counterfeit, adulterated or banned drugs.[263]

The existence of drugs also constitute an important benchmark that is used in evaluating the efficiency of a health care system.[264] Habibat while adumbrating on the importance of safe and qualitative drugs stated that;

> Pharmaceuticals are critical for the health and well-being of populations. Their access and consumption can be likened to a double-edged sword: on one hand, they alleviate the manifestation of disease but on the other hand, if they are inappropriately used, or worse, counterfeit or substandard, they may be ineffective and even toxic to the individuals who take them [3-5]. As such, it is necessary for countries to adhere to the highest standards of quality in the manufacture, regulation, and distribution of drugs.[265]

[259] CAP C34 Laws of the Federation of Nigeria 2004.
[260]CAP F33 Laws of the Federation of Nigeria 2004
[261] CAP F32 Laws of the feration of Nigeria 2004
[262]sections 5 and 7 of the Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Act, CAP C32 Laws of the federation of Nigeria 2004.
[263] Sections 6 (1) (c – g) and 8 (1) (a – e) of the Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Act, CAP C32 Laws of the federation of Nigeria 2004.
[264]Supra Note 1.
[265] Supra Note 133 at 2.

It was in recognition of the important position that provision of safe and qualitative drugs has in the lives of the citizens that various countries have established institutions that are saddled with responsibility of regulating the standard and quality of drugs in their respective countries.

In Nigeria, the responsibility of regulating and ensuring the safety of drugs and food was initially vested to the Department of Food and Drugs Administration and Control (FDAC), Federal Ministry of Health.[266] As a result of administrative bottlenecks that enmeshed the activities of the said department, it could not effectively carryout its statutory mandate.[267] It was against this background that the Nigerian government through Decree No. 15, 1993 established NAFDAC[268] inorder to effectively carryout the responsibility of regulating the quality and safety regulated products.[269]

[266] Muhammed Tawfiq Ladan, "The Limits of Legal and Enforcement/Regulatory Frameworks in Consumer Protection Against Counterfeit and Pirated Products: - The Nigerian Experience," *Review of Nigerian Law and Practice* 2 no.1(2008):25, http://www.unisza.edu.my/library/images/IDC/counterfeit.pdf (accessed January 21, 2015).

[267] National Agency for Foods and Drugs Administration and Control Information Brochure (Ilupeju:Integrated Press Ltd),2-3.

[268] Ugwuishiwu while commenting on the duties of the National Agency for Food and NAFDAC stated that;

> ***"National Agency for Food and Drug administration and Control (NAFDAC) is the government agency in Nigeria that is fully empowered to regulate and control the importation, exportation, manufacture, advertisement, distribution, sales and use of drugs, food, cosmetics, medical devices, bottled water and chemicals."[268]***

Ugwuishiwu C.H., Inyiama H.C. and Ezema M.E, "A Model of NAFDAC Real-Time Crime Information System," *International Journal of Soft Computing and Engineering* 2 no.5 (November 2012):1, http://www.ijsce.org/attachments/File/v2i5/E0967092512.pdf. (accessed January 22,2015).

[269] Supra Note 267 at 4 and Section 31 of the National Agency for Foods and Drugs Administration and Control Act, CAP N1 Laws of the Federation of Nigeria 2004 defined regulated products as;

> "***food, drugs, cosmetics, medical devices, detergents bottled water and chemicals."***

Section 5 of the NAFDAC Act[270] confers upon the said agency with the responsibility of regulating the quality and safety of drugs and other regulated products. The section provides;

5. Functions of the Agency.
(1) The Agency shall have the following functions, that is, to -
(a) regulate and control the importation, exportation, manufacture, advertisement, distribution, sale and use of food, drugs, cosmetics, medical devices, bottled water and chemicals.
(b) conduct appropriate tests and ensure compliance with standard specifications designated and approved by the Council for the effective control of the quality of food, drugs, cosmetics, medical devices, bottled water and chemicals and their raw materials as well as their production processes in factories and other establishments;
(c) undertaken appropriate investigations into the production premises and raw materials for food, drugs, cosmetics, medical devices, bottled water and chemical and establish relevant quality assurance systems, including certificate of the production sites and of the regulation products;
(d) undertake inspection of imported food, drugs, cosmetics, medical devices, bottled water and chemicals and establish relevant quality assurance systems, including certification of the production sites ancd of the regulated products
(e) compile standard specifications and guidelines for the production, importation, exportation, sale and distribution of food, drug, cosmetics, medical devices, bottled water and chemicals;
(f) undertake the registration of food, drugs, cosmetics, medical devices, bottled water and chemicals;

(g) control the exportation and issue quality certification of food, drugs, cosmetics, medical devices, bottled water and chemicals intended for export;
(h) establish and maintain relevant laboratories or other institutions in strategic areas of Nigeria as may be necessary for the performance of its functions under this Act;
(i) pronounce on the quality and safety of food, drugs, cosmetics, medical devices, bottled water and chemicals after appropriate analysis;
(j) undertake measures to ensure that the use of narcotic drugs and psychotropic substances are limited to medical and scientific purposes;
(k) grant authorisation for the import and export of narcotic drugs and psychotropic substances as well as other controlled substances,
(l) collaborate with the National Drug Law Enforcement Agency in measures to eradicate drug abuse in Nigeria;
(m) advise Federal, State and Local Governments, the private sector and other interested bodies regarding the quality, safety, and regulatory provisions on food, drugs, cosmetics, medical devices, bottled water and chemicals;;
(n) undertake and co-ordinate research programmes on the storage, adulteration, distribution and rational use of food, drugs, cosmetics, medical devices, bottled water and chemicals;
(o) issue guidelines on, approve and monitor the advertisement of food, drugs, cosmetics, medical devices, bottled water and chemicals;
(p) compile and publish relevant data resulting from the performance of the functions of the Agency under this Act or from other sources;
(q) sponsor such national and international conferences as it may consider appropriate;
(r) liase with relevant establishments within and outside Nigeria in pursuance of the functions of the Agency;

[270] CAP N1 Laws of the Federation of Nigeria 2004

(s) determine the suitability or otherwise of medicines, drugs, food products,cosmetics, medical devices or chemicals for human and animal use; and

(t) carry out such activities as are necessary or expedient for the performance of its functions under this Act.

NAFDAC has in the course of discharging its statutory mandate of safeguarding the quality and safety of drugs in Nigeria evolved numerous policies that are directed towards the detection, elimination and seizure of counterfeited drugs in Nigeria. These policies include;[271]

a. Organizing sensitization campaigns in order to enlighten the members of the public on the dangers posed by counterfeited drugs in Nigeria. The agency has sponsored numerous seminars, produced leaflets, sponsored jingles in the media and also established NAFDAC Consumer Safety Clubs in Schools in Nigeria in order to sensitize and encourage the populace on the benefits of purchasing and consuming genuine products.

b. Collaboration with the relevant stakeholder: The agency has also built a synergy with other relevant stakeholders such as the Police, Customs, the Ports Authority, the National Drug Law Enforcement Agency, the Standards Organization of Nigeria, the legislature, judiciary and the Nigerian Bar Association in order to decisively tackle the problem of counterfeit drugs in Nigeria. These aforementioned institutions all have an important role to play in the detection, prevention, prosecution, conviction and sentencing of persons who engage in the heinous act of counterfeiting of drugs in Nigeria.

[271] Supra Note 14.

c. Adoption of an anti – counterfeiting blue print. The blue print encapsulated numerous strategies that are to be deployed by the agency towards tackling the problem of counterfeit drugs in Nigeria. The blue print seeks to leverage on consumer enlightenment, strengthening of collaboration between manufacturers, importers of drugs with the National Agency for Food and Drug Administration and Control and the prosecution of alleged counterfeiters as the tools to be utilized in nipping the problem of counterfeit drugs in Nigeria.

d. Reorientation of the staffs of the National Agency for Food and Drug Administration and Control so as to enhance their productivity and commitment towards the eradication of the menace of counterfeit drugs in Nigeria.

e. Introduction of stringent administrative guidelines that will ensure or safeguard the quality and safety of drugs in Nigeria.

f. Strengthening of surveillance at all ports of entry in Nigeria so as to ensure proper monitoring and detection of counterfeit drugs. Airlines are now required to obtain National Agency for Food and Drug Administration and Control's permit before conveying consignments of drugs into Nigeria.

4.3 Nigerian Relevant Legislations

In Nigeria, there are several legislations that have been enacted in order to regulate and monitor the quality and safety of drugs. Example of these legislations are;

a. The Food and Drugs and Related Products (Registration Etc) Act 2014.[272]
b. The Food and Drugs Act 2004[273]
c. The Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous) Act 2004. [274]

(a) The Food and Drugs and Related Products (Registration Etc) Act 2014.[275]

Section 1(1) of the Food and Drugs and Related Products (Registration Etc) Act 2014[276] prohibits dealing in unregistered drugs, foods and soon. The section provides;

> " 1 (1) No processed food, drug, drug product, cosmetic, medical device or water shall be manufactured, imported, exported, advertised, sold or distributed in Nigeria unless it has been registered in accordance with the provisions of this Act or regulations made under it."

In Pfizer Specialties Limited v. Chyzob Pharmacy Limited & Ors.[277], Per Garba JCA in the course of interpreting the provision of section 1(1) of the Food and Drug and Related Products(Registration Etc) Decree 1993[now Food and Drugs and Related Products (Registration Etc) Act 2014][278] had this to say;

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[272]CAP F33 Laws of the Federation of Nigeria 2004
[273] CAP F32 Laws of the feration of Nigeria 2004
[274] CAP C34 Laws of the Federation of Nigeria 2004.
[275]CAP F33 Laws of the Federation of Nigeria 2004
[276]CAP F33 Laws of the Federation of Nigeria 2004

[277] (2006) LPELR-11780(CA)

[278]Jane Omojokun, "Regulation and Enforcement of Legislation on Food Safety in Nigeria," (2013):254. http://www.intechopen.com/download/pdf/44083. (accessed January 25, 2015).

> These provisions of the Decree are very clear, straight forward an unambiguous. Given their ordinary meaning, they are meant to prohibit, outlaw, make illegal, unlawful, and, an offence; the importation, manufacture, advertisement, sale or distribution of any drug, etc not registered under the Decree in Nigeria. It cannot be disputed that compliance with the provisions of the Decree by the registration of such drug etc as stipulated, draws and confers on the Registrant, the benefit and right to sell, manufacture import, etc, the registered drug in Nigeria. While being the only holder of the registration in respect of the particular named, branded or specified drug, the Registrant would or better out, shall be entitled to the sole or exclusive benefit and right to sell, distribute, etc, the said drug in Nigeria. I should not be misunderstood here to be talking about entitlement and right to a trade mark in respect of the drug which is not what is involved in the Appellant's action. The essence of the provisions of Section 1(1) above is to limit, restrict, confine and control the sale, distribution etc of drugs in Nigeria strictly to the ones registered in accordance with the provisions of the 1993 Decree. Put in other words, the sale, distribution etc of drugs in Nigeria is made strictly subject to the registration of such drug as provided by the 1993 Decree. That is why the Decree in Section 6 (1) makes it illegal, unlawful and therefore an offence for any drugs not registered to be sold, distributed etc in Nigeria. Accordingly, the provisions of Section 10 of the 1991 Decree are therefore circumscribed by the provisions of the 1993 Decree which are later in time. No person natural or artificial including the Respondents has a right to sell, distribute etc, any drug in Nigeria not registered as required by the 1993 Decree.

Thus transactions involving the aforementioned regulated products can only be lawfully carried out if the said products have duly been registered with NAFDAC.

Furthermore, criminal liability is imposed against any erring individual or corporation that violates the provisions of the said Act. Section 6-7 of the Act provides;

> 6. Offences
> (1) A person who contravenes a provision of this Act or a regulation made under it is guilty of an offence and liable on conviction-
> (a) in the case of an individual, to a fine not exceeding N50,000 or to imprisonment for a term not exceeding two years or to both such fine and imprisonment; and
> (b) in the case of a body corporate, to a fine not exceeding N 1 00,000.
> 7. Offences by bodies corporate, etc.
> Where an offence under this Act is committed by a body corporate or firm or other association of individuals-
> (a) every director, manager, secretary or other similar officer of the body corporate; or
> (b) every partner or officer of the firm; or
> (c) every trustee of the body concerned; or
> (d) every person concerned in the management of the affairs of the association; or

(e) every person who was purporting to act in a capacity referred to in paragraphs (a) to (d) of this section, is severally guilty of that offence and liable to be proceeded against and punished for that offence in the same manner as if he had himself committed the offence unless he proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

(b) The Food and Drugs Act 2004.[279]

Sections 8 – 9 of the Food and Drugs Act 2004[280] also prohibits the selling of adulterated drugs, or drugs that have been manufactured under an unhygienic condition as well as engaging in any act that is calculated to deceive members of the public as to the quality or safety of a particular drug.

(c) The Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous) Act 2004. [281]

Section 1 of the Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Act,[282] prohibits and penalizes the production, importation, distribution, sell, display or being in possession of any counterfeit drug as well as aiding or abetting the commission of any of the aforementioned illegal offences.

In Imunze v Federal Republic of Nigeria,[283] the Supreme Court dismissed an appeal that was filled by the appellant. The appellant was arraigned before a Court on a two counts charge bordering on the manufacture and being in possession of counterfeit Barbicillin Ampicilin (Syrup Powder) and Rampicillin Ramsey Syrup (Powder) contrary to the provisions of section 1 of the Counterfeit and Fake Drugs and

[279] CAP F32 Laws of the feration of Nigeria 2004
[280] CAP F32 Laws of the federation of Nigeria 2004.
[281] CAP C34 Laws of the Federation of Nigeria 2004.
[282] CAP C32 Laws of the federation of Nigeria 2004.
[283] (2014) LPELR – 22254 (SC).

Unwholesome Processed Foods (Miscellaneous Provisions) Act.[284]The appellant pleaded guilty to the two charges and the lower court accordingly sentenced him to five years imprisonment with an option of #500,000.00 fine on each count.

Also, in order to effectively tackle the availability of counterfeit drugs in Nigeria, sections 5 and 7 of the Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Act,[285] provides for the establishment Federal taskforce and state taskforce respectively. The federal taskforce is conferred with the responsibility of monitoring and supervising the activities of the state taskforce.[286] Furthermore both the Federal and State taskforce are also saddled with the responsibility of detecting and seizing any counterfeit, adulterated or banned drugs.[287]

The provision of section 1(18)(a)(i) and (ii) of the Miscellaneous Offences Act[288] also penalizes the adulteration or engaging in the selling or offering to sell any petroleum product, drink, drugs, medicinal preparation or any manufactured product that has been adulterated[289]. In Federal Republic of Nigeria v Adeyemo Abiodun &2 Ors[290],the accused persons were arraigned before the Federal High Court of Nigeria on a six count charge bordering on the manufacture, distribution and selling of an adulterated drug called my Pikin Baby Teething Mixture contrary to the provisions of sections

[284] CAP C32 Laws of the federation of Nigeria 2004.
[285] CAP C32 Laws of the federation of Nigeria 2004.
[286] Section 6(1) (a) of the Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Act, CAP C32 Laws of the federation of Nigeria 2004.
[287] Sections 6 (1) (c – g) and 8 (1) (a – e) of the Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Act 2004.
[288] CAP M17 Laws of the federation of Nigeria 2004.
[289] According to Black's Law Free Online Legal Dictionary 2nd Ed. adulteration is defined as;
> "The act of corrupting or debasing. The term is generally applied to the act of mixing up with food or drink intended to be sold other matters of an inferior quality, and usually of a more or less deleterious quality."

[http://thelawdictionary.org/adulteration/.(accessed Janaury28, 2015)].
[290] Suit No: FHC/L/70C/2009.

1(a) and 1(18)(a)(i) of the Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Act 2004 and the Miscellaneous Offences Act 2004. At the conclusion of the trial, the court sentenced the accused persons to seven years imprisonment and the 3rd accused person's company was ordered to be wound up and its assets forfeited to the Federal government of Nigeria.

4.4 Concluding Remarks

This chapter has discovered that the Nigerian government in its efforts towards ameliorating the problem of counterfeit drugs in Nigeria established NAFDAC in order to regulate the quality and safety of drugs in Nigeria as well as the enacted various anti - counterfeiting legislations.

However, the existence of counterfeit drugs still continue to constitute a public health problem in Nigeria as counterfeiters target drugs whose demands are very high. Example of these drugs that are being counterfeited include anti -malarials, antibiotics, antihypertensives, antidiabetic agents, life style drugs[291],anticancer[292] and other lifesaving drugs.[293] Thus, this chapter reiterate that the concept of compulsory licensing is important in reducing the dessimination of counterfeit drugs by providing competitive and affordable price for genuine drugs to the public.

[291] Supra Note 20 at 7.

[292]A. Chika ,S.O. Bello,A.O. Jimoh and M.T. Umar**, "**The Menace of Fake Drugs: Consequences, Causes and Possible Solutions," *Research Journal of Medical Sciences* 5 no. 5(2011):257, http://www.medwelljournals.com/abstract/?doi=rjmsci.2011.257.261(accessed February 2, 2015).

[293]Dora Akunyili, "Lessons from Nigeria: the fight against counterfeit drugs in Africa,": 2, http://apps.who.int/medicinedocs/documents/s18404en/s18404en.pdf. (accessed January 30, 2015).

CHAPTER FIVE.

5.1 CONCLUSION AND RECOMMENDATIONS.

The discussion in this chapter is done according to the research questions and research objectives.

In answering research question one, chapter two and four examined the factors that have brought about the existence of counterfeit drugs in Nigeria, the negative implications of counterfeit drugs on the patients, public health, government and pharmaceutical companies and the legal framework that has been put in place to address these problem.

In chapter two, several factors were identified as the reason behind the prevalence of counterfeit drugs in Nigeria. These include corruption and lack of cooperation among the security agencies that are saddled with the responsibility of fighting counterfeited drugs, the existence of a very vast and porous borders into Nigeria that enables counterfeiters to deal in their activities without being detected, the over dependence by Nigeria on imported drugs as a means of satisfying its drug needs due to the inability of Nigerian pharmaceutical companies to operate within their installed capacity[294] and the prevailing harsh economic condition which has rendered a vast majority of Nigerians incapable of affording genuine and qualitative drugs which are generally very expensive.[295]

[294] Supra Note 20.
[295] Supra Note 21.

Based on the discussion in the above chapters, the high cost of drugs was identified as a factor that has compelled the public to patronize counterfeit drugs in Nigeria.

The huge expenditure incurred by pharmaceutical companies in the course of embarking on research and development in order to invent a drug has being identified as a major factor that has brought about the high cost of drugs.[296] The consequences of the high cost of drugs in Nigeria is further complicated by the fact that atleast two third of Nigerians live below the poverty line[297] and only 7% of its populace have a health insurance cover.[298]The juxtaposition of the high cost of drugs, ravaging poverty and the absence of a health insurance cover has therefore left a vast majority of the Nigerian populace incapable of affording genuine patented drugs.

NAFDAC in collaboration with the Bank of Industry established the Pharmaceutical Development Fund in order to provide financial support to pharmaceutical companies in Nigeria at a low interest rate.[299] The government can make recourse to the said Pharmaceutical Development Fund so as to provide a non – interest yielding loan to pharmaceutical companies to engage in research and development activities. This will reduce the expenditure pharmaceutical companies incur in the course of embarking on

[296]Sola Ogundipe,"Nigerians pay for cancer treatment with their lives," (September 22, 2013), http://www.vanguardngr.com/2013/09/nigerians-pay-for-cancer-treatment-with-their-lives/ (accessed April 8, 2015).
[297] Emily Gustafsson-Wright 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-universal-health-coverage-nigeria-gustafsson-wright/achieving-universal-health-coverage-in-nigeria.pdf. (accessed April 27, 2015).

[298] Supra Note 66.
[299]Shaba Mohammed, "Practical Tools and Approaches for SPOCS - Nigerian Experience," (January 2015):18, http://www.nifds.go.kr/apec/files/tp201501/(30)%20Shaba%20-%20SPOCs%20Nigeria%20-%2029jan2015.pdf. (accessed April 8, 2015).

research and development and this will consequently translate into a reduction in the prices of drugs in Nigeria.

In chapter two, it was also discovered that the consumption of counterfeit drugs had resulted in the death, poisoning as well as treatment failure of numerous patients, erosion of the public confidence in the effectiveness of a health care system, caused the Nigerian government to incur huge expenditure in the course of tackling this menace, loss of accruable revenue as counterfeiters of drugs do not pay tax as well as necessitated pharmaceutical companies to incur additional expenditure in their effort towards protecting their drugs against being copied.

Chapter four chronicled the legal framework that have been put in place to address the existence of counterfeit drugs in Nigeria through an examination of the anti – counterfeit legislations such as the Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous) Act, [300] Food and Drugs and Related Products (Registration Etc) Act[301] and the Food and Drugs Act[302] and the National Agency for Foods and Drugs Administration and Control Act.[303]

The chapter discovered that the punishment provided under these legislations needs to be reviewed and very stringent punishment should be provided for against counterfeiters of drugs. The Nigerian government should consider the adoption of death penalty against counterfeiters of drugs as this will deter potential counterfeiters from engaging in the said act.[304]

[300] CAP C34 Laws of the Federation of Nigeria 2004.
[301]CAP F33 Laws of the Federation of Nigeria 2004
[302] CAP F32 Laws of the feration of Nigeria 2004
[303] CAP N1 Laws of the Federation of Nigeria 2004.

[304]Supra Note 149.

In answering research questions two and three, chapter three examined the provisions of the TRIPS Agreement, Doha declaration on Trade Related Aspects of Intellectual Property Rights and Public Health and section 11 of the Nigerian Patent and Designs Act 2004. The chapter discovered that these relevant provisions legalised and recognised the patenting of drugs.

In the said chapter it was also discovered that these relevant legislations have also recognized the use of certain safeguards inorder to mitigate the adverse consequences the grant of a patent may have on access to affordable drugs. These safeguards are cumulatively called Trips flexibilities.[305] Example of these safeguards are compulsory licensing, parallel importation and provision for early working (bolar provision).[306]

It was also discovered that the issuance of compulsory licensing has the effect of increasing access to affordable drugs through a reduction in the prices of patented drugs.[307] This achievement in the reduction in the prices of patented drugs is made possible through the authorization given to other producers to manufacture the said patented drugs and this will in turn spur competition.

Notwithstanding the capacity that compulsory licensing has to trigger a reduction in the prices of patented drugs, certain factors militates Nigeria from utilizing this concept. These factors;

1. Inadequate Manufacturing capacity: One of the conditions attached to the issuance of the compulsory licensing is that the said license must be utilized towards the

[305]Supra Note 192 at 4.
[306] Supra Note 192 at 4.
[307] Supra Note 44.

satisfaction of the domestic needs of the country that issued it. Article 31(f) of the TRIPS Agreement provides;

> "any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;"

The implication of this aforementioned provision is that were a Member state of the World Trade Organisation issues a compulsory licensing over a particular drug, then the said license must be used to produce drugs that will be used primarily to satisfy the demand for the said drug at the domestic Market. This provision serves as a clog to developing nations because a vast majority of them do not have the manufacturing capacity to produce the patented drugs in their country.

Similarly, it has also foreclose developing countries from importing the patented drug that a compulsory licensing has been issued over it. In relation to Nigeria, the country has a low production capacity in the manufacturing of drugs.[308] This therefore portends a serious threat to Nigeria because Nigeria cannot effectively utilize the concept of compulsory licensing to produce the patented drugs because of the inadequate production capacity.

3. Political pressure from developed Countries: Developed countries in consonance with major pharmaceutical companies have continued to exert intense pressure on developing countries against the use of compulsory licensing over their patented drugs.[309] A case in point is the pressure and threat that the European Union Commissioner for external trade, the United

[308] Supra Note 20.
[309] T.G "Trips Agreement and Public Health: The Post Doha Crisis," *Journal of Intellectual Property Rights* Vol 18(May 2013):289, nopr.niscair.res.in/bitstream/123456789/.../JIPR%2018(3)%20287-293.pdf (accessed April 6, 2015).

States of America as well as Abbot Laboratories (a pharmaceutical company) exerted on Thailand when it attempted to issue a compulsory licensing in respect of antiretroviral drug called Kaletra in 2007.[310]

The areas i will recommend for future research include;

a. Incapacity of Nigerian pharmaceutical companies to invent new drugs despite the existence of a Patent law in Nigeria.

b. The role government sponsorship of research and development into drugs in the reduction in the prices of patented drugs in Nigeria.

[310] Ibid.

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